MEDICAL OXYGEN SYSTEMS FOR HOMECARE SUPPLY

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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 Medical Oxygen Healthcare 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 Medical 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 Medical Oxygen Healthcare 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 marked, which indicates that it complies with the requirements of the Medical Device Directive 93/42/EEC (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 the gas to the patient. It is the Medical Oxygen Healthcare 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 is used and that the correct advice is given to the patient.

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

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

2 Scope

The scope of this document applies to the supply of medical oxygen supplied by Medical Oxygen Healthcare Service Providers in the form of:

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

3 Purpose

The purpose of this document is to describe how the Medical Oxygen Healthcare 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 document endeavours to provide the best operating practices for the supply of medical oxygen but may not cover all of the relevant applicable national regulations that may apply in some member states.

This document provides advice to the Medical Oxygen Healthcare 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 document 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 Medical Oxygen Healthcare 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 customer 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 customer 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 individual Medical Oxygen Healthcare Service Providers.

4 Definitions

For the purposes of this document, the following terms are defined as:

Medical Oxygen Healthcare Service Provider	An organisation / company 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.
Healthcare Facility	An organisation / company providing the medical oxygen therapy to the patient on their premises, where they are responsible for the care of the patient.

5 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

6 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 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 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 may 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 medical oxygen equipment with any material or store it adjacent to curtains as they may become oxygen enriched.
- Never use the ambulatory unit under clothing. Where an ambulatory unit is carried in a bag or holder, it must 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 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. Special 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.

6.1 Hazards with compressed oxygen

There are a number of specific hazards with the supply of medical oxygen in compressed 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 Medical Oxygen Healthcare 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 a compressed 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.
- 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.

6.2 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 standard 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 may prevent components such as pressure relief devices or control valves from functioning properly, 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 vessel 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 vessels 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 may accelerate the venting of oxygen from the vessel.

- 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.

6.3 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.
However, there are specific precautions concerning the electrical supplies to the concentrator that need to 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.

6.4 Hazards with self-fill systems

It is important that the Medical Oxygen Healthcare Service Provider (HSP) supplies the patient / user 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 HSP should be filled;
- the self-fill concentrator/compressor system and cylinder are used 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 section 6.1, concerning high pressure cylinders and section 6.3, concerning oxygen concentrators should also be followed.

6.5 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 specifically designed for transfilling and suitably 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 Medical Oxygen Healthcare Service Provider supplies the patient / user 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.

7 Initial set up of the oxygen therapy supply system

The Medical Oxygen Healthcare 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.

The Medical Oxygen Healthcare Service Provider needs to 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.

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 Medical Oxygen Healthcare Service Provider and the appropriate corrective actions put in place to address any short falls.

7.1 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.

Irrespective of the method of supply, it is essential that the Medical Oxygen Healthcare Service Provider has carried out the following actions to ensure that:

- A user instruction manual has been given to the patient, 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 or carer to maintain the equipment in an appropriate condition shall be covered by these instructions.
- The patient or care has been adequately trained by the Medical Oxygen Healthcare 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 or 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 or 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 supplies 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 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 or carer may use at any time (365 days per annum / 24 hours per day). The patient or carer shall be instructed to use this number only to contact the Medical Oxygen Healthcare Service Provider to inform of any problems with the equipment.
- A list has been given to the patient or care of all the equipment provided at the initial supply and any ‘consumable’ equipment that may need replacing. The user nstruction manual shall also cover the use of these consumable items.

7.2 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 fully 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 Medical Oxygen Healthcare 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 Medical Oxygen Healthcare 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 own staff and their patients.
- Adequate training, as well as suitable training material, has been provided by an approved trainer to a suitable number of healthcare facility representatives. It is important to provide sufficient training to the healthcare facility so that they always have sufficient suitably trained personnel available who know how to use the gas and the equipment effectively and safely. The training shall be followed by an assessment to ensure that the healthcare facility representatives 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 annum / 24 hours per day) to inform the Medical Oxygen Healthcare Service Provider of the need to re-supply medical oxygen or of any problems with the equipment.

7.3 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 Medical Oxygen Healthcare Service Provider shall carry out a risk assessment (RA) at the patient's home prior to the initial installation of the equipment. Appendix 7 shows a typical risk assessment checklist, which lists the most of the common potential risks the Medical Oxygen Healthcare Service Provider, should check for prior to making the initial installation.

The Checklist should be used by the Medical Oxygen Healthcare 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 vessels will be stored.

The risk assessment checklist should be completed by the Medical Oxygen Healthcare 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 Medical Oxygen Healthcare Service Provider.

Appendix 8 shows a completed FMEA study (Failure Mode and Effects Analysis), 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.

8 Medical oxygen incidents

Following installation of the medical oxygen supply system it is important that the patient 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 unit, 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 / user shall be instructed to contact their Medical Oxygen Healthcare 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 / user 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 only when it is safe to do so, before following any other instructions.

Where there is a major leak of gas 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 vessels develops a major gas or liquid leak the patient / user shall be instructed to:

- close the cylinder or liquid vessel valve only if it is safe to do so;
- ensure that external windows and doors are opened to ventilate the area, and
- inform the Medical Oxygen Healthcare Service Provider immediately to obtain advice.
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In the event of a cylinder or liquid vessel falling over, where there is no other apparent damage, the Medical Oxygen Healthcare 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 / user shall be advised to isolate the equipment at the mains supply and inform the Medical Oxygen Healthcare 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 / user shall be advised to contact the Medical Oxygen Healthcare 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.

9 Maintenance of medical oxygen therapy equipment

9.1 General maintenance requirements

Prior to installing any equipment in the patients' home or healthcare facility, it is the responsibility of the Medical Oxygen Healthcare 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 contacts the Medical Oxygen Healthcare 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 or carer 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 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 about suitable non-abrasive cleaning agent or disinfectant that may be used for cleaning any medical oxygen equipment.

When carrying out routine inspection and routine hygiene maintenance of the equipment, following the manufacturer's instructions, at the user's premises, the following procedures shall be followed:

- Only use a dampened cloth using an approved, non-abrasive cleaning agent or disinfectant to wipe down the equipment, cylinder or vessel 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 vessel 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 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 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 / user shall be instructed to contact their Medical Oxygen Healthcare Service Provider immediately.

9.2 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 93/42/EEC. These accessories must be made from biocompatible materials, compatible with oxygen and free of any allergenic substances. If the patient has any special requirements with respect to material compatibility, the Medical Oxygen Healthcare Service Provider needs to 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 Medical Oxygen Healthcare 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.

Where the patient is cleaning their own 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 Medical Oxygen Healthcare Service Provider shall check regularly the cleanliness and condition of the ancillary equipment supplied to the patient to administer the medical oxygen.

9.3 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 Medical Oxygen Healthcare Service Provider elects 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.

9.4 Patient / user's 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 or healthcare staff. Only authorised and competent persons may 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 / user is only responsible for keeping the cylinder, vessel or concentrator externally clean, which may be done 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, always unplug the unit from the mains before cleaning. Never use solvents or other flammable or abrasive products to clean the equipment.

10 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 gas in the cylinder.

It is the responsibility of the Medical Oxygen Healthcare 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 and distribution tubing, must be new.

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

10.1 Storage of medical oxygen cylinders

When planning the storage arrangements for medical gas cylinders, whether used in clinics and hospitals 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 Medical Oxygen Healthcare 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 may 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. However, the general principles for safe cylinder storage shall be applied to the storage facilities in the patient's home.

Where liquid oxygen vessels 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.

10.1.1 Storage of medical oxygen cylinders at the healthcare facility

Advice shall be given to ensure that purpose built medical cylinders stores in clinics and hospitals 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 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.

10.1.2 Storage of Medical Oxygen Cylinders at the Patient's Home

Advice shall be given to ensure that medical 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 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.

10.2 Handling of medical oxygen cylinders

When handling and moving medical oxygen cylinders, the patient / user 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 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 medical 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 may cause the valve to be knocked open accidentally
- Never handle cylinders with handwheel valves by the valve as they may 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

10.3 Use of medical oxygen cylinders

10.3.1 Selecting cylinders for use

When selecting medical 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 Medical Oxygen Healthcare 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 Medical Oxygen Healthcare Service Provider immediately.

10.3.2 Connecting pressure regulators

For cylinders not fitted with integral cylinder valves, the patient / user 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 / user shall be advised to not use the equipment.
- Ensure that the pressure regulator is attached to the cylinder valve using only moderate force.
- Not to open the valve until the pressure regulator and downstream equipment has been fitted.

Cylinders with integral valves do not require an additional regulator to be fitted prior to use.

10.3.3 Setting up medical oxygen delivery equipment

For all types of cylinders, to set up the medical oxygen delivery equipment the patient / user 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 opposite to the regulator outlet 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 may 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 Section 10.4, Checking for Leaks.
- Ensure that the oxygen tubing is attached correctly to the nasal cannula or humidifier.
- Set the flowrate on the equipment to the prescribed flowrate defined by the doctor.

10.3.4 After use

The patient / user shall be advised to not empty the cylinders below the 'residual' pressure level, as indicated on the cylinder contents gauge. It is the Medical Oxygen Healthcare 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 / user 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 Medical Oxygen Healthcare Service Provider

10.4 Checking for leaks when using medical oxygen cylinders

When medical oxygen equipment is in use, leaks may occur between the cylinder valve and the patient's equipment. 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 Medical Oxygen Healthcare Service Provider informed.

For cylinders not fitted with integral valves, if a leak occurs between the cylinder valve and the equipment, the patient / user shall be instructed not to rectify whilst the equipment is still under pressure.

When a leak has been identified, the patient / user 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 equipment 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 Medical Oxygen Healthcare 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 Medical Oxygen Healthcare Service Provider, keeping the cylinder segregated from other cylinders on site.
- Where the equipment shows signs of damage, ensure that the equipment is returned to the Medical Oxygen Healthcare Service Provider.

10.5 Use of medical oxygen cylinders in vehicles

The transport of oxygen cylinders by the Medical Oxygen Healthcare Service Provider is covered by the conditions of the ADR regulations. 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 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 can not 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.

11 Medical liquid oxygen vessels 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 vessel 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 vessels 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 Medical Oxygen Healthcare 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 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 vessel can lead to the product evaporating prior to it being required for use. The patient 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 vessel, 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 vessel to rise to the primary relief valve pressure setting, at which point the excess gas will vent to atmosphere, making a slight venting noise.

11.1 Installation and storage of medical liquid oxygen vessels

When planning the installation and storage arrangements for liquid oxygen vessels, 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 or healthcare worker are not subjected to undue risk in the event of any incident with a liquid oxygen vessel that is in use or being stored. For domiciliary patients, the person 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 vessels increase the potential of any incident that may occur on site. The Medical Oxygen Healthcare 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 / user shall be advised to store the liquid oxygen vessels indoors.

When storing liquid oxygen vessels at the patients home, the patient / carer 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 vessels because the atmosphere may become oxygen enriched by venting of the containers.

The patient / user shall be advised to keep all liquid oxygen vessels at least 1.5 metres[1] 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 vessels at least 3 metres[2] away from:

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

The patient / user shall also be advised to:

- Keep all liquid oxygen vessels 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 vessels 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.
- Never place any form of cover over the equipment, as this will restrict ventilation.
- Never drape clothing or any other material over the liquid oxygen vessel, 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 vessel storage in a healthcare facility, in addition to the above they shall be advised to:

- design the store to prevent unauthorised entry
- provide warning notices prohibiting smoking and naked flames within the vicinity of the store.

11.2 Handling of Medical Liquid Oxygen Vessels

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 / user 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.

1 This distance is based on the advice stated in CGA P-2.7

2 This distance is based on the advice stated in EN 1251-3

11.2.1 Domiciliary use

It is the responsibility of the Medical Oxygen Healthcare 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 vessel shall be provided to the patient / carer by the Medical Oxygen Healthcare Service Provider. The procedures shall include any other safety information required to be followed when using the equipment. The Medical Oxygen Healthcare Service Provider shall ensure that the patient / carer has read and understood the approved written procedures for using their equipment and filling the portable vessel 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 shall also be advised to only carry the portable unit using the built in carrying handle or in an approved carrying bag or trolley.

11.2.2 Healthcare facility use

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

- all relevant personnel (employees and patients) 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 systems, advice shall be given to the Healthcare Facility to ensure that:

- Medical liquid oxygen vessels 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 vessels.
- 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 vessels 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 vessel is evacuated and the area ventilated by opening doors and windows. Instructions shall be given to inform the Medical Oxygen Healthcare Service Provider immediately to obtain advice as to the appropriate actions to be taken.

11.3 Operation and use of medical liquid oxygen vessels

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 is closed valve 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 vessel is available for reference by the patient / carer when the unit is being used.
- The labels and pictograms applied to the liquid oxygen vessel by the manufacturer are explained to the patient / carer during training.

Where the patient requires a flowrate that exceeds the output from a single base unit, the Medical Oxygen 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. Additional care is needed when operating multiple units to provide higher flowrates to prevent the back feeding of water from the humidifier from one unit to the other.

11.4 Use of medical liquid oxygen vessels in vehicles

The transport of liquid oxygen vessels by the Medical Oxygen Healthcare Service Provider is covered by the transport regulations, such as for road, the European Agreement on the Transport of Dangerous Goods, (ADR regulations). These regulations do not affect the transport of liquid oxygen vessels by the patient in their own vehicle. However, national legislation may affect the carriage of liquid oxygen in privately owned vehicles.

There are potential risks involved with the transport and use of liquid oxygen vessels in motor vehicles. Where a medical liquid oxygen vessel is used in a motor vehicle, the patient 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 vessel 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 tank 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 vessels in the passenger compartment of the car when they are not in use.
- Keep the outlet valve shut when the liquid oxygen vessel is not in use.
- Avoid using the medical liquid oxygen vessel 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.
- 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 vessels 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 vessels on public transport such as buses, trains, ships and planes.

12 Oxygen concentrators therapy supply

Oxygen concentrators produce a continuous flow of oxygen enriched air for patient use by separating the oxygen and nitrogen in 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.

Oxygen concentrators are suitable for those patients at home requiring oxygen for long periods of time and where there is only a limited requirement for medical oxygen for ambulatory use.

The performance of the concentrator is quoted at 21 °C and 1013 mbar and may 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.

The method of supplying medical 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. As a consequence, the Medical Oxygen Healthcare 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.

12.1 Installation of oxygen concentrators

When planning the medical 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 or healthcare worker are not subjected to undue risk in the event of any oxygen incident. For domiciliary patients, the person installing the concentrator 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 / user 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 place 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 install the concentrator in a kitchen or garage where there is likely to be oils and greases used and stored.
- Not to install the concentrator so that the air intake or the concentrator exhaust is obstructed.
- Keep and use in the upright position.
- 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 Section 10.1.2.

12.2 Use of oxygen concentrators

The Medical Oxygen Healthcare Service Provider is responsible for ensuring that the patient 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 Medical Oxygen Healthcare Service Provider shall leave a copy of the manufacturer's user's manual for the specific concentrator with the patient / carer. When training the patient / carer, the labels and pictograms applied to the concentrator by the manufacturer shall also be explained to the patient / carer.

The patient / carer 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.

Where the patient requires a flowrate that exceeds the output from one medical oxygen concentrator, the Medical Oxygen 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.

13 Oxygen self-fill systems

Self-fill oxygen concentrators are used for both supplying medical oxygen to the patient and allowing the patient/carer 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 is 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.

13.1 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 Section 12.1 (Installation of oxygen concentrators), about where to install the concentrator, should be followed. The information provided in Section 10. (Medical oxygen cylinder therapy supply) should also be used to advise the patient /carer 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.

13.2 Oxygen self-fill system risk assessment

The risk assessment carried out by the HSP shall be used to evaluate whether:

- the patient/carer is competent to operate the oxygen self-fill system;
- the patient/carer understands the risks associated with filling of medical oxygen cylinders, and
- the 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 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 Section 12.1 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.

13.3 Oxygen self-fill system set up

The Medical Oxygen Healthcare Service Provider (HSP) is responsible for ensuring that the patient 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 HSP 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 HSP shall provide the patient/carer 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 sited in a location where there is no risk of oxygen enrichment in the event of a leak, and
- the manufacturer's instructions are followed when connecting and disconnecting the cylinder from the compressor, making sure that:
    - no tools are used when disconnecting the cylinder
    - two hands are used when handling cylinders
    - only a damp lint free cloth is used to clean the surfaces of the self-fill oxygen system and cylinder
    - the filling connector is covered when cleaning the concentrator to protect against ingress of moisture or contaminants.
- the patient/carer understands how to move the oxygen self-fill system, and this includes that the oxygen self-fill system shall:
    - never be transported with a cylinder connected
    - never be moved whilst a cylinder is being filled
    - only be moved by lifting it using the handles provided or where wheels are fitted by pushing/pulling.
- the correct flow is selected, in line with patient's prescription and the manufacturer's User Instructions

13.4 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 may compromise the safe use of the equipment.

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

- the cylinder is within its test date (marked on the shoulder of the cylinder);
- the cylinder and equipment shows no signs of damage;
- the electrical lead and the plug are not damaged, and
- the 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, the patient/carer should be instructed to notify the Homecare Service Provider

Prior to connecting the cylinder to the cylinder filling concentrator, the patient/career 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 shall be instructed to notify the Homecare Service Provider

Having completed the pre-filling checks, the patient/career shall be instructed to:

- correctly position the cylinder on the compresso,r
- 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/career should check:

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

If problem is not resolved, the patient/carer shall be instructed to notify the Homecare Service Provider.

After the cylinder has been filled, the patient/career 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.

13.5 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 specified in Section 9.1, General maintenance requirements.

The patient/career shall be instructed not to modify the cylinder filling equipment in anyway, including replacement of seals and tightening of connections. The patient/career 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, 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.

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 Vessels in the Home

Appendix 4 Patient User Instruction Card – Liquid Systems
Patient User Instruction Card
Use of Medical Liquid Oxygen Vessels in the Home

Appendix 5 Patient User Training Card – Concentrators
Patient User Training Card
Use of Medical Oxygen Concentrators in the Home

Appendix 6 Patient User Instruction Card – Concentrators
Patient User Instruction Card
Use of Medical Oxygen Concentrators in the Home

Appendix 7 Patient User Training Card – Self-fill Systems
Patient User Training Card
Use of Medical Oxygen Self-fill Systems at Home

Appendix 8 Patient User Instruction Card – Self-fill Systems
Patient User Instruction Card
Use of Medical Oxygen Self-fill Systems at Home

Appendix 9 Risk Assessment Checklist
Homecare Installation Risk Assessment Checklist

Appendix 10 FMEA Analysis
Failure Mode and Effects Analysis for “Homecare Patient Environment Risk Assessment – Oxygen Therapy”

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

1

Read the ***User Instruction Manual*** carefully before operating your medical oxygen cylinder and equipment.

Pay special attention to information where the hazard symbol is shown.

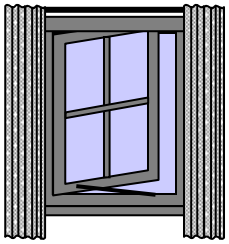
2

Materials burn much more vigorously in Oxygen than air.

Never smoke (or let someone else smoke near you) whilst using your oxygen equipment.

Do not use your oxygen cylinders near open fires or naked flames..

3



Only use your medical oxygen cylinder and equipment in a ***well ventilated area.***

Keep internal doors open whilst your oxygen cylinder is in use.

4

Never place your oxygen cylinders near curtains or cover them with clothing as this will restrict air circulation.

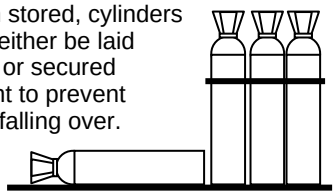
Materials become ***oxygen enriched*** if any leak occurs with no ventilation.

Never use or carry the portable oxygen vessel under any clothing.

5

Follow the advice your supplier has given you where to safely store and use your cylinders.

When stored, cylinders must either be laid down or secured upright to prevent them falling over.



6

Do not use oils or grease with your oxygen cylinders or equipment.

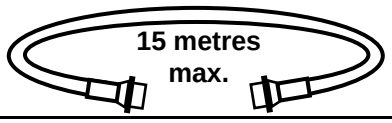
Ensure that your hands are ***clean*** when using the cylinder.

Only use authorised creams and moisturisers when using your Medical Oxygen.

7

Attach the Oxygen tubing to the outlet connector on the valve or regulator.

Ensure that the length of the tubing does not exceed 15 metres



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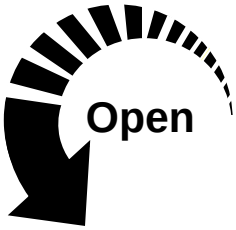
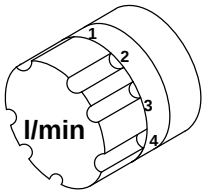


Ensure the flowmeter is set to zero before the valve is opened.

Open the cylinder valve ***slowly.***

Open the valve fully by turning the handwheel anti-clockwise.

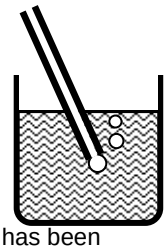
9



Set the flow control valve to the flowrate ***prescribed by your Doctor***

Check for any leaks on the tubing connection after opening the cylinder valve.

10

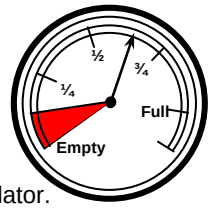


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

If bubbles do not appear, check a flow has been selected and there are no leaks.

If a flow is still not evident, contact your Service Provider.

11



Check how much Oxygen is available for use by checking the gauge on the valve or the regulator.

Never fully empty the cylinder.

Always change over your cylinders so that you leave some gas in the them after use.

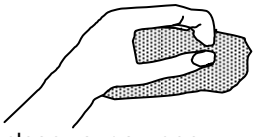
12

If a regulator is used with your Oxygen cylinder, ensure that it is only connected hand tight .

Never use excessive force.

Never use spanners unless specifically instructed by your Service Provider.

13

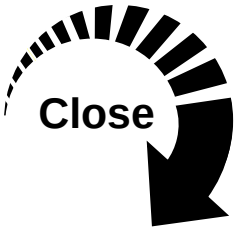


Only use a clean damp cloth if it is necessary to clean your oxygen cylinder or any associated equipment.

Only use mild non-abrasive cleaning materials.

Allow the cylinder to dry after wiping down.

14



Close the valve when the cylinder is not in use.

Close the valve by turning the handwheel clockwise.

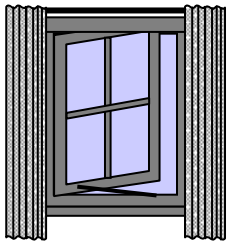
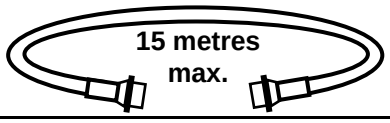
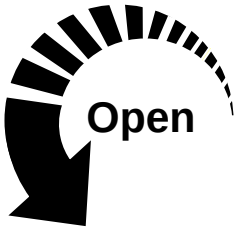
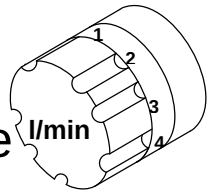
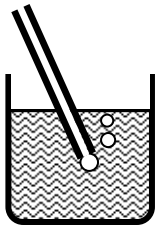
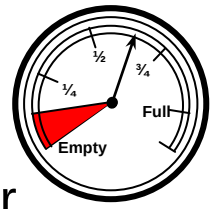
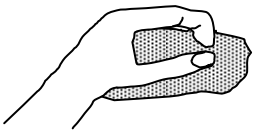
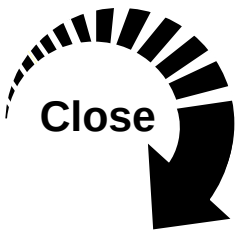
Never use excessive force.

15

If your cylinder or regulator fails for any reason call your Service Provider immediately.

Never try and repair any fault unless specifically instructed by your Service Provider

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

1 Always Read Instructions 	**2** No Smoking No Naked Flames 	**3** Use in a Ventilated Area 
4 Avoid Oxygen Enrichment 	**5** Secure Cylinders Upright or Lay Down 	**6** Never Use Oil or Grease  6
7 Connect Oxygen Tubing 	**8** Open Valve Slowly 	**9** Adjust Flowrate as Prescribed 
10 Check For Flow 	**11** Check Cylinder Contents 	**12** Do Not Use Excessive Force 
13 Only Clean With a Damp Cloth 	**14** Close Valve After Use 	**15** Phone For Assistance If Required 

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

1

Read the ***User Instruction Manual*** carefully before operating your liquid oxygen vessels and equipment.

Pay special attention to information where the hazard symbol is shown.

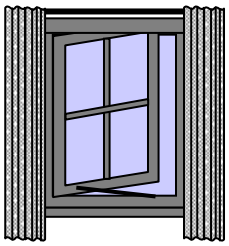
2

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 vessels near open fires or naked flames.

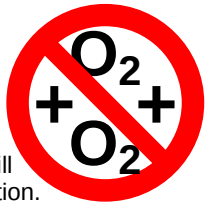
3



Only use your liquid oxygen vessels and equipment in a ***well ventilated area.***

Keep internal doors open whilst your oxygen vessels are in use.

4

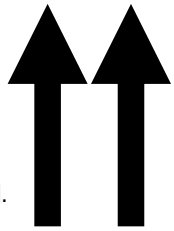


Never place your oxygen vessels near curtains or cover them with clothing as this will restrict air circulation.

Materials become ***oxygen enriched*** if any leak occurs with no ventilation.

Never use or carry the portable oxygen vessel under any clothing.

5



Follow the advice Your Service Provider has given you where to safely store and use your liquid oxygen vessel.

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 vessels or equipment.

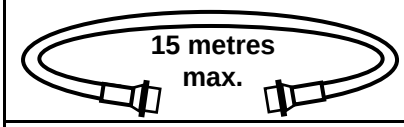
Ensure that your hands are ***clean*** when using the vessels.

Only use authorised creams and moisturisers when using your medical oxygen.

7

Attach the oxygen tubing to the outlet connector on the liquid oxygen vessel.

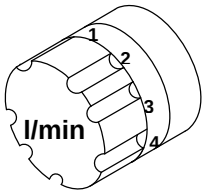
Ensure that the length of the tubing does not exceed 15 metres



8

To turn on your liquid oxygen vessel, turn the oxygen flow control valve anticlockwise**.**

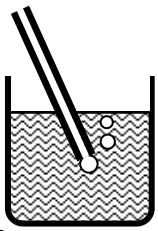
9



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

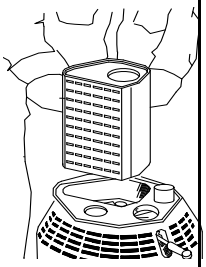


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

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.

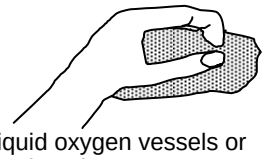
12

Never touch any cold parts on either vessel 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

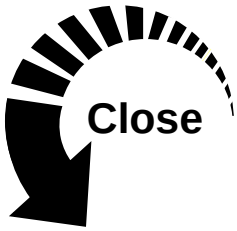


Use only a clean damp cloth to clean your liquid oxygen vessels or any associated equipment.

Only use mild non-abrasive cleaning materials.

Allow the liquid oxygen vessels to dry after wiping down.

14



Select zero on the oxygen flow control valve after use.

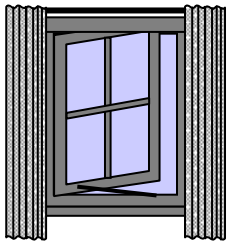
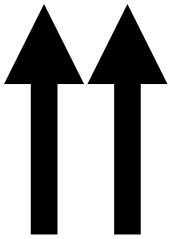
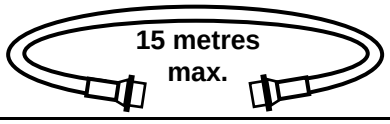
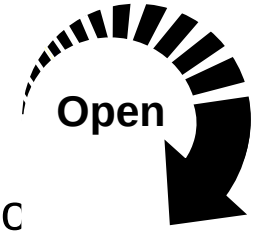
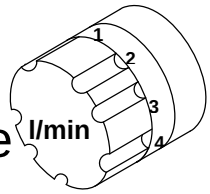
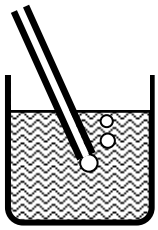
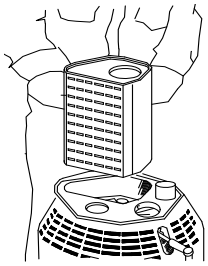
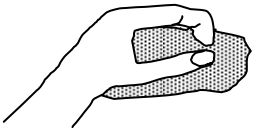
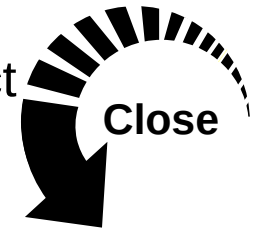
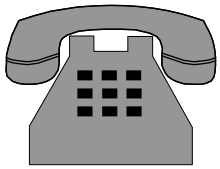
Keep closed when the liquid oxygen vessel is not in use.

15

If either liquid oxygen vessel 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 VESSELS IN THE HOME

1 Always Read Instructions 	**2** No Smoking No Naked Flames 	**3** Use In A Ventilated Area 
4 Avoid Oxygen Enrichment 	**5** Keep Upright 	**6** Never Use Oil or Grease  6
7 Connect Oxygen Tubing 	**8** Open Flow Contrc Valve 	**9** Adjust Flowrate as Prescribed 
10 Check For Flow 	**11** Stay whilst Transfilling 	**12** Do Not Touch Cold Parts 
13 Only Clean With a Damp Cloth 	**14** Select Zero Flow After Use 	**15** Phone For Assistance If Required 

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

1

Read the ***User Instruction Manual*** carefully before operating your oxygen concentrator and equipment.

Pay special attention to Information where the hazard symbol is shown.

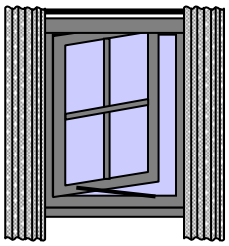
2

Materials burn much more vigorously in oxygen than air.

Never smoke (or let someone else smoke near you) whilst using your oxygen concentrator.

Do not use your concentrator near open fires or naked flames.

3



Only use your oxygen concentrator and equipment in a ***well ventilated area***.

Keep internal doors open whilst your oxygen concentrator is in use.

4

Never place your oxygen concentrator near curtains or cover it with clothing as this will restrict air circulation.

Materials become ***oxygen enriched*** if any leak occurs with no ventilation.

5

Follow the advice your Service Provider has given you where to safely position your oxygen concentrator when it is being used.

Your concentrator must be used upright as detailed in the Instruction Manual.

6

Do not use oils or grease with your oxygen concentrator .

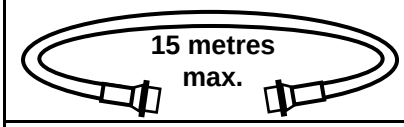
Ensure your hands are ***clean*** when handling your oxygen equipment.

Only use authorised face creams and moisturisers when using your Medical Oxygen.

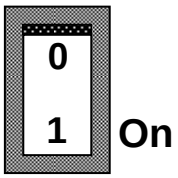
7

Attach the oxygen tubing to the outlet connector on the oxygen concentrator.

Ensure that the length of the tubing does not exceed 15 metres



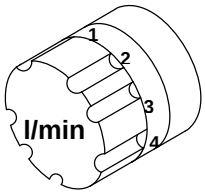
8



Connect your oxygen concentrator to the electrical supply and switch on.

Never use extension leads to connect your concentrator unless instructed by your Service Provider.

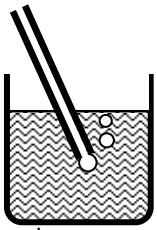
9



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

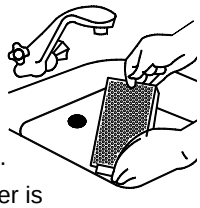


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

If 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.

11

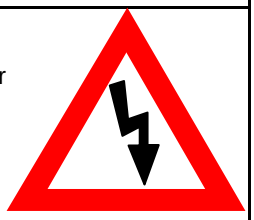


Regularly clean the air inlet filter as instructed in the User Instruction Manual.

Ensure that the filter is ***dried*** before replacement.

Switch off and isolate your medical oxygen concentrator from the mains supply when replacing the filter.

12

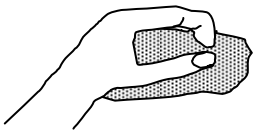


Never open or remove the concentrator cover at any time.

Do not use extension cables unless instructed.

Only authorised personnel should carry out any repairs on your oxygen concentrator.

13

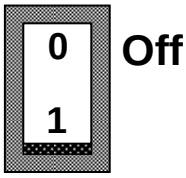


Use only a clean damp cloth to clean your oxygen concentrator or any associated equipment.

Only use mild non-abrasive cleaning materials.

Allow the oxygen concentrator to dry after wiping down before using.

14



Switch off your medical oxygen concentrator after use.

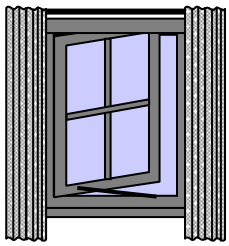
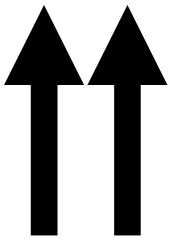
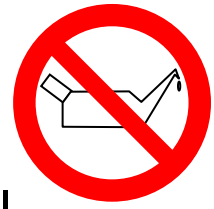
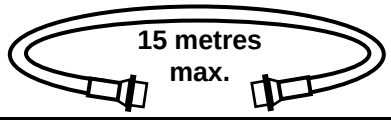
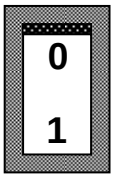
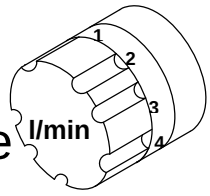
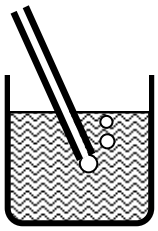
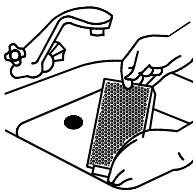
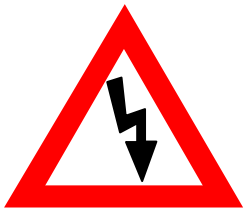
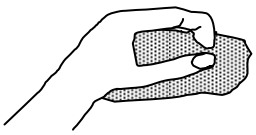
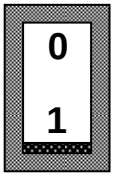
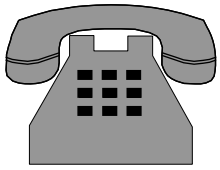
Never leave you medical oxygen concentrator running when it is not in use.

15

If your oxygen concentrator fails for any reason call your Service Provider immediately.

Never try and repair any fault unless specifically instructed by your Service Provider

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

1 Always Read Instructions 	**2** No Smoking No Naked Flames 	**3** Use In A Ventilated Area 
4 Avoid Oxygen Enrichment 	**5** Keep Upright 	**6** Never Use Oil or Grease  **6**
7 Connect Oxygen Tubing 	**8** Turn On to Obtain Oxygen  **On**	**9** Adjust Flowrate as Prescribed 
10 Check For Flow 	**11** Keep Filter Clean 	**12** Do Not Open Concentrator 
13 Only Clean With a Damp Cloth 	**14** Always Turn Off After Use  **Off**	**15** Phone For Assistance If Required 

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

1

Read the ***User Instruction Manual*** carefully before operating your oxygen concentrator and equipment.

Pay special attention to Information where the hazard symbol is shown

2

Only fill cylinders provided with your self-fill system

Never fill any other cylinder on the system

Keep the cylinder filling connector covered when not in use.

Check the test date on the cylinder to ensure it is suitable for filling.

3

Materials burn much more vigorously in oxygen than air.

Never smoke (or let someone else smoke near you) whilst using your oxygen concentrator or cylinder.

Do not use or keep your concentrator or cylinder within 3 metres of open fires or naked

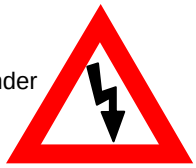
4

Do not use oils or grease with your self-fill system or cylinder.

Ensure your hands are ***clean*** when handling your oxygen equipment.

Do ***not*** use aerosols near your equipment. Only use authorised face creams and moisturisers.

5



Keep your oxygen concentrator / cylinder at least 1.5 metres from electrical equipment such as TVs and electrical heaters

Only use your oxygen concentrator and cylinder in ***well ventilated area***. Keep doors ***open*** whilst in use.

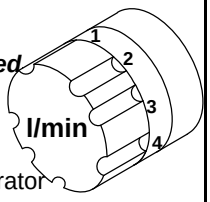
6

Never place your oxygen self-fill system or cylinder near curtains or cover them with clothing. This will restrict air circulation and allow oxygen enrichment.

Materials become ***oxygen enriched*** if any leak occurs with no

7

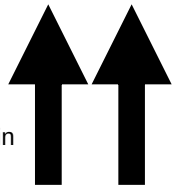
Set the flow to the flowrate ***prescribed by your Doctor.***



Check User Instructions when using the concentrator whilst filling cylinders.

Check for leaks on the tubing connection after selecting the correct flowrate

8

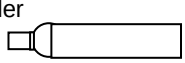


Install the self-fill system on level ground, in an upright position, as detailed in the User Instruction.

Never move concentrator with a cylinder connected.

Use two hands when moving the self-fill system

9



Ensure the cylinder valve is closed when connecting cylinder to the self-fill system.

Make sure the cylinder is secured firmly before starting filling.

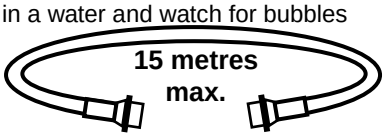
Ensure the correct flowrate is selected when filling cylinders as detailed in the User Instruction

10

Attach the oxygen tubing to the outlet connector on the oxygen concentrator. ***Check*** for leaks.

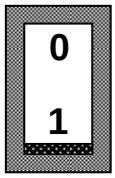
Ensure that the length of the tubing does not exceed 15 metres

Check for flow by immersing tubing in a water and watch for bubbles



11

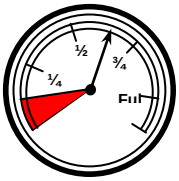
Connect your self-fill system to the electrical supply and switch on.



Off

Never use extension leads to connect your concentrator unless instructed by your Service Provider.

12



Before filling check connections are ***clean***.

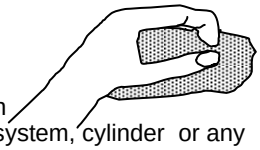
Open the cylinder valve slowly.

If leaks occur, stop the filling and refit the cylinder. If leaks continue contact the HSP.

Do not remove cylinder when filling.

Check gauge at end of fill to ensure cylinder is full. ***Close*** valve slowly

13

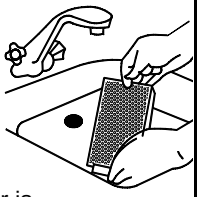


Use only a clean damp cloth to clean your self-fill system, cylinder or any associated equipment.

Replace fill port cover when cleaning.

Only use mild non-abrasive cleaning materials. Allow to dry after wiping down before using.

14



Regularly clean the air inlet filter as instructed in the User Instruction Manual.

Ensure that the filter is ***dried*** before replacement.

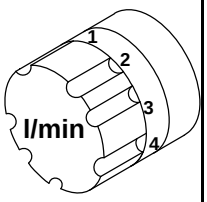
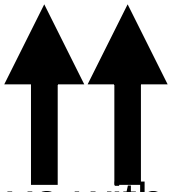
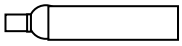
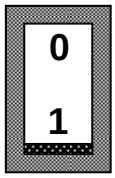
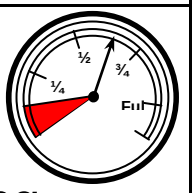
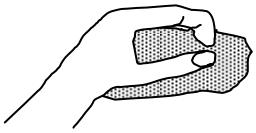
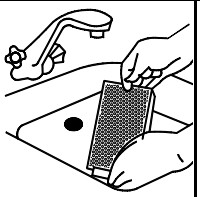
Switch off and isolate your medical oxygen self-fill system from the mains supply when replacing filter.

15

If your oxygen concentrator fails for any reason call your Service Provider immediately.

Never try and repair any fault unless specifically instructed by your Service Provider

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

1 Always Read Instructions 	**2** Only use cylinders provided with self-fill system 	**3** No Smoking No Naked Flames 
4 Never Use Oil or Grease 	**5** Keep away from electrical equipment 	**6** Avoid Oxygen Enrichment 
7 Adjust Flowrate as Prescribed 	**8** Keep upright. Do not move with cylinder attached 	**9** Connect cylinder securely Open valve slowly 
10 Connect tubing. Check for leaks 	**11** Turn On to Obtain Oxygen 	**12** Check for leaks when filling Open and close valve slowly 
13 Only Clean With a Damp Cloth 	**14** Keep filter Clean 	**15** Phone For Assistance If Required 

Appendix 9 – RISK ASSESSMENT CHECKLIST

HOMECARE INSTALLATION RISK ASSESSMENT CHECKLIST							
Patient's Address							
Patient's Name				**Installation Date**			
Installation Type	**Concentrator** ☐	**Liquid Cylinders** ☐		**Gas Cylinders** ☐		**Ambulatory Cylinders** ☐	
	Backup Cylinders ☐	**Multiple Units** ☐		**Pipeline** ☐		**Self fill system** ☐	
Potential Risks						**Observations / Recommendations**	
Property Access Profile			**Yes**	**No**			
No suitable vehicle parking / Poor access/ surface condition to property / Tarmac							
Steep / Narrow / Spiral / Limited use Stairs to property / No guard rail							
Access to property using lift							
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 meters of oils & grease / LPG / Paints / flammable materials							
Stored within 1.5 meters of open flame							
Installer's Comments / Other Concerns or Potential Risks							
Installer's Name / Signature					**Date**		
Company internal Comments / Actions							
Company internal Name / Signature					**Date**		

Appendix 10 – FMEA ANALYSIS

Homecare Patient Environment Risk Assessment

SEVERITY SCORE Patient's Home Environment		
Score	Impact on Patient Safety	Impact on Equipment Safety & Functioning
1	Incorrect position of equipment with no impact	Incorrect position of equipment with no impact
2	Incorrect position of equipment with impact on reduced comfort of patient	Incorrect position of equipment with impact on reduced cleanliness
3	Incorrect position of equipment with impact on slip, trip and fall hazards, e.g. installed in corridor	Incorrect position of equipment with impact ultimately leading to incorrect functioning of equipment, e.g. heating up
4	Incorrect position of equipment leading to oxygen enrichment	Incorrect position of equipment leading to break down of equipment.
5	Incorrect position of equipment leading to house fire or explosion	Incorrect position of equipment leading to equipment fire, short circuit, catastrophic failure or blockages of safety features.

Occurrence		
Score		
1	Very unlikely	< 1 : 100,000
2	Unlikely	< 1 : 20,000
3	Seldom	< 1 : 500
4	Common Occurrence	< 1 : 100
5	Every time	< 1 : 2

Detection	
Score	
1	100% Detection (Automatically)
2	Detection Likely
3	Detectable by Chance
4	Detection Unlikely
5	No Detection by System, Procedure, Inspection

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

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	**Potential Effect of Risk**	**Severity**	**Potential Outcome**	**Occurrence**	**Current Protection**	**Detection**	**RPN**	**Recommended Actions**	**Concentrators**	**Self-fill System**	**Gaseous Oxygen**	**Liquid Oxygen**
Patient with low physical capacity and children/ babies.	Unable to handle equipment safely. Unable to operate in an emergency	4	Patient creates unsafe situation with equipment. Inability to open/close the cylinder valve and change the pressure regulator onto another cylinder.	3	• Carer to assist with equipment. • Change mode of supply. • Oxygen source should be accommodated to the profile of the patient (e.g. small patients require lower LOX stationary). • Provide integrated cylinder valve packages.	1	12		✓	✓	✓	✓
Patients with language / communication problems	Unable to understand the instructions for use and unable to communicate back	3	Operate equipment incorrectly or explain problems	3	Carer to assist with equipment Use of sign languages / manuals in picture format	2	18		✓	✓	✓	✓
Poor housekeeping standards / cleanliness in house	Contamination of equipment Blockage of filters etc	2	Cross contamination to engineer Failure of equipment	3	Training for cleanliness Carer to assist	2	12		✓	✓	✓	✓
Bed or chair ridden patients	Unable to move around house with oxygen supply	2	Oxygen enrichment of bedding / clothing Potential fire risk	4	Training. Conserving device where possible. Carer to assist with equipment.	2	16		✓	✓	✓	✓
Smoker	Smoking with oxygen	5	Fire Burning around the mouth / nose area	4	Training on safety issues Inform doctor/ insurance, if no change of patient attitude.	2	40	In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	**Potential Effect of Risk**	**Severity**	**Potential Outcome**	**Occurrence**	**Current Protection**	**Detection**	**RPN**	**Recommended Actions**	**Concentrators**	**Self-fill System**	**Gaseous Oxygen**	**Liquid Oxygen**
Hygiene standard	Infection for patient, carer, installer & workshop technician from equipment surface contamination	2	Patient is not taking care of the continuous cleanliness of the equipment	2	Training and reminding of the patient & carer (i.e. Specific, clear instructions). Technician has gloves and cleaning agent available and mark the unit to allow the workshop technician to take appropriate measures.	4	16	In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	✓	✓	✓	✓
Behaviour of patient	Aggressive	1	Harassment to Installer	2	Involve carer/ neighbour Assistance in the installation	1	2		✓	✓	✓	✓
Patient has other illnesses	Has contagious disease, which is most often not told to the Installer or unknown to him	2	Infection of installer and carer Contamination of equipment	2	Installer consults the responsible prescriber Consideration to vaccinate installer	4	16		✓	✓	✓	✓
Patient is also using other therapy equipment , e.g. CPAP, ventilator	Oxygen used together with electric powered equipment	3	Oxygen compatibility risk and risk of ignition	2	Train and strictly follow the procedure/manual. Use the original adaptors.	2	12	Keep oxygen source 1.5 m from electric appliances.	✓	✓	✓	✓
Other Occupants / Animals												
Children	Interference / damage of the equipment – interruption of supply etc	3	Malfunction of equipment – leading to leaks, fire etc.	2	Clear instructions to parents / patient / carer	1	6		✓	✓	✓	✓
Other smokers	Smoking with oxygen	4	Fire Damage to property	4	Training on safety issues	2	32		✓	✓	✓	✓
Animals	Interference / damage of the equipment – interruption of supply etc Problems to the installer.	2	Malfunction of equipment – leading to leaks, fire etc. Lack of correct hygiene of the equipment	2	Clear instructions to parents / patient. Special advice to installer	1	4		✓	✓	✓	✓

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Carers (with responsibility for patient)												
Elderly people	Don't understand or cannot remember the instructions	2	Slow reaction in case of emergency Incorrect handling Incorrect adherence to prescription	3	Try to get other carers/neighbours involved Provide other means of handling, e.g. trolley Provide tele-surveillance & emergency tel.	1	6		✓	✓	✓	✓
Physical disabled Low mobility	Possibly cannot move the equipment	3	Cannot change out the container Incorrect adherence to prescription Cannot react adequately in case of emergency	2	Try to get other carers/neighbours involved Provide other means of handling, e.g. trolley Provide tele-surveillance & emergency tel.	1	6		✓	✓	✓	✓
With low mental capabilities	Cannot apply the therapy safely/adequately	3	Incorrect adherence to prescription Cannot react adequately in case of emergency	2	The service provider is not going to install the therapy	1	6	Consultation with the person responsible for prescription, recommending to find another carer or social assistant. Contact a 'patient association' when available. Develop a list of recommended conditions for appointment as Carer.	✓	✓	✓	✓
With language / communication problems	Don't understand the instructions	3	Slow reaction in case of emergency Incorrect handling Incorrect adherence to prescription	2	Try to get other carers/neighbours involved Provide tele-surveillance & emergency tel.	2	12	Develop instructions based on pictograms/symbols, photos, video recommending to find another carer or social assistant. Contact a 'patient association' when available.	✓	✓	✓	✓

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"Do-it-yourself" carers	Modifications done to the installation and/or equipment	3	Malfunctioning of equipment. Injury. Damage.	2	Stress to these carers that no changes are allowed prior approval of the service provider. No technical changes are allowed at all.	3	18		✓	✓	✓	✓
Storage Facilities (for units not in use)												
Product stored outside	Potential for vandalism / theft. Stored against flammable material. Animals present.	2	Theft of equipment Interference leading to damage, leaks or fire	2	Advice to store securely	1	4		✓	✓	✓	✓
Product stored inside building	Potential hazard if containers leak	5	Fire leading to explosion	2	Advise patient of how / where to store safely Limit stocks of containers. Review storage arrangements	1	10		✓	✓	✓	✓
Storage in Garage	Oils grease and solvents coming into contact. Presence of oxy-acetylene kit. Damage when parking vehicles	4	Self ignition leading to explosion Damage. Stability of container / fall over.	3	Review storage areas / advise not to store with oils and grease etc.	1	12		✓	✓	✓	✓
Storage in Workshop	Dust / chemicals / solvents etc coming in contact with the containers. Presence of oxy-acetylene kit.	4	Self ignition leading to explosion Damage. Stability of container / fall over.	3	Review storage areas / advise not to store with Dust / chemicals / solvents etc.	1	12		✓	✓	✓	✓

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Storage in cupboards	Poor ventilation leading to oxygen enrichment if leaks occur Storage of other materials such as solvents	4	Oxygen enrichment Potential fire Potential cooling affect from LOX container	3	Review storage areas with sufficient ventilation	1	12		✓	✓	✓	✓
Storage in kitchens	Contaminatio n with cooking oils etc. Presence of a naked flame / hot surfaces with cooker	4	Increased risk in case of fire	3	Review storage areas / advise not to store in the vicinity of cooking area	1	12		✓	✓	✓	✓
Difficult access to container storage area	Tendency to store too many container in home and associated risks	2	Congestion / container falling etc Large volume of oxygen stored.	3	Assign different storage location More frequent delivery Different mode of supply	1	6	To recommend a max. number of containers to be kept in stock: **JS**	✓	✓	✓	✓
Storage under stairs	Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit	2	Oxygen enrichment Increased risk in case of fire Trip, slips & falls	2	Review storage areas with sufficient ventilation	1	4		✓	✓	✓	✓
Storage in basements	Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit	2	Oxygen enrichment Increased risk in case of fire Trip, slips & falls. Dropping of containers.	2	Review storage areas with sufficient ventilation	1	4		✓	✓	✓	✓
Poor access to storage areas	Difficult to handle the equipment/ containers	2	Slips and trips etc Risk to empty the container due to not in time change-out Dropping of containers	3	Review alternative storage areas or install smaller units	1	6		✓	✓	✓	✓

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Limited room in storage area	Difficult to access	2	Slips and trips etc Risk to empty the container due to not in time change-out Dropping of containers	3	Review alternative storage areas or install smaller units	1	6		✓	✓	✓	✓
Other Products Stored Near Therapy Equipment / Containers												
Other gases e.g. LPG, Propane	Leaks from these gas containers	4	Increased risk in case of fire	2	Have these gas containers in a separate compartment.	1	8	To recommend a min. distance between these gases and oxygen equipment Be extra careful with LOX installation due to its normal function of venting periodically.	✓	✓	✓	✓
Tins of oils & greases, oil based paints, varnish Flammable products e.g. solvents.	Oils grease and solvents coming into contact with pure oxygen	4	Self ignition leading to explosion	2	Review storage areas / advise not to store with oils and grease etc.	1	8		✓	✓	✓	✓
Open fire, candles or stove or electric heater	Heating of the oxygen source	5	Increased risk in case of fire	2	Recommended distance of 3m to open fires and 1.5 m to closed fires.	1	10		✓	✓	✓	✓
Absorbent furniture in the vicinity	Oxygen enrichment	4	Increased risk in case of fire	3	Currently no specific instructions given	1	12	To recommend a min. distance	✓	✓	✓	✓
Curtains in the vicinity	Oxygen enrichment	4	Increased risk in case of fire	3	Currently no specific instructions given	1	12	To recommend a min. distance	✓	✓	✓	✓
Water tanks or water reservoirs in the vicinity	Damage to the electric parts of the equipment Electrocution	3	Short circuit No functioning of the equipment	3	Instructions to avoid liquids in the vicinity	1	9		✓	✓	✓	✓

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Types of Room where Therapy Equipment Used												
Garage, workshop	Oils grease and solvents coming into contact. Presence of oxy-acetylene kit. Potential presence of sparks Much dust, debris Damage when parking vehicles	5	Ignition leading to explosion Damage. Stability of container / fall over. Unsafe path for the tubing.	2	Review storage areas / advise not to store with oils and grease etc.	1	10	To recommend to not use oxygen therapy when welding and grinding	✓	✓	✓	✓
Kitchen	Oils, grease coming into contact. Presence of propane, electric appliances, open fire	5	Ignition leading to explosion Damage. Stability of container / fall over. Unsafe path for the tubing.	3	Best practice is not to install the oxygen therapy equipment in the kitchen	2	30	To recommend the same distance between container or concentrator as for open and closed fires (this distance does not apply to the nasal cannula)	✓	✓	✓	✓
Living room Bedroom	Furniture, open fires, etc.	3	Oxygen enrichment Dropping of room temperature when using LOX	4	Combination of most precautions given in this table	1	12		✓	✓	✓	✓
Bathroom	Water splash	3	Short circuit No functioning of the equipment	2	Best practice is not to install the oxygen therapy equipment in the bathroom	2	12		✓	✓	✓	✓
Upstairs, downstairs	Kinking of tubing	2	Not correct flow Water condensation Slips and trips over the tubing Unsafe path for the tubing. Disconnection of tubing.	3	Install purpose build tubing on the wall Fit humidifier & flow meter close to patient Use anti-collapse tubing	1	6		✓	✓	✓	✓

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Balcony	Kinking of tubing Rain, birds, animals, vandalism	2	No or incorrect functioning of the equipment Damage. Disconnection of tubing.	2	Take precautions against Kinking of tubing Rain, birds, animals, vandalism	1	4		✓	✓	✓	✓
Apartment or fully attached house	Presence of many people	2	As result of a fire, adjacent buildings may catch fire. Interference of other people to the equipment	4	Currently no specific instructions given	1	8	To recommend to never install oxygen equipment in common areas	✓	✓	✓	✓
Hygiene situation of the room	Infection for patient, carer, installer & workshop technician from equipment surface contamination	2	Patient is not taking care of the continuous cleanliness of the equipment	4	Training and reminding of the patient & carer (i.e. Specific, clear instructions). Technician has gloves and cleaning agent available In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	2	16		✓	✓	✓	✓
Area where the equipment is installed is far away from the user	Kinking of tubing	3	Not correct flow Water condensation Slips and trips over the tubing	3	Install purpose build tubing on the wall Fit humidifier & flow meter close to patient Use anti-collapse tubing	1	9		✓	✓	✓	✓
Room Flooring												
Level of floor Steps	Unlevelled, steps	3	Slips, trips & falls Stability of container Difficult/dangerous handling conditions. Disconnection.	3	Provide trolley or other handling tools Provide smaller/lighter oxygen source equipment Train/warn patients	1	9		✓	✓	✓	✓

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Carpet, Cork Wooden floor Linoleum and similar	Porosity Softness of the underground	4	Spillage Damage Oxygen enrichment	4	Ensure for sufficient ventilation Precautions/means (e.g. the rolling base) to prevent that the floor is damaged by the container's weight.	2	32		✓	✓	✓	✓
Tiles and similar	Finish of the surface	2	Damage e.g. cracks	4	Precautions/means (e.g. the rolling base) to prevent that the floor is damaged by the container's weight.	1	8		✓	✓	✓	✓
Supply Method and Requirements												
Static installation of the oxygen source	Cleanliness of the equipment Source equipment or containers take up space	2	Accumulation of dust/dirt Access and handling problems	3	Patient training on hygiene Provide trolleys/roller base	2	12		✓	✓	✓	✓
Need to move the supply system	Restricted space for movement	3	Slips, trips & falls. Dropping of equipment/ container	3	Patient training Provide trolleys/roller base	2	18		✓	✓	✓	✓
Need for multiple outlet points Need for multiple units connected together	Disconnected tubing Leakages Ensure positive closure of unused outlets Oxygen compatibility of all installation components	2	Incorrect or stop of flow Oxygen enrichment from the leak	3	Use wall-outlet with quick connector or shut-off valve All installation components to meet medical devices directive	1	6	To recommend to Technician to verify leak tightness of tubing installation	✓	✓	✓	✓
Location of multiple outlet points	Vicinity to combustibles Leakages	4	Oxygen enrichment	2	Follow instructions for installer	1	8	To recommend to Technician to verify leak tightness of tubing installation	✓	✓	✓	✓

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Electric supply needed	Condition of the electric socket	4	Electrocution	2	Warn the patient of the risk Use the power cord delivered with the equipment	1	8		✓	✓	✓	✓

Note: 'container' indicates high pressure gas cylinder for stationary and portable use or portable liquid container
Note: some stationary units may have telemetry or heated humidifier, i.e. with electric power