MEDICAL GASES

SAFE SUPPLY OF TRANSPORTABLE MEDICAL LIQUID OXYGEN SYSTEMS BY HOMECARE SERVICE PROVIDERS

Doc 98/24

Revision of Doc 98/17

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Amendments from 98/17

Section	Change
	Editorial to align style with EIGA Style Manual
Whole Doc	Review aligning content with doc 89
Section 14	Include specific notions of top fill versus side fill Liquid portables
Section 15	Simplified section on travelling to align and refer directly to Doc 141

Note: Technical changes from the previous edition are underlined

1 Introduction

Medical liquid oxygen is a well-established method of supplying patients with supplementary oxygen either in their homes or in healthcare facilities, where permitted, according to the national regulations. Liquid oxygen for medical oxygen therapy is supplied in a transportable liquid oxygen System (TLOS), which comprises a base unit and its associated portable unit.

The equipment used with medical oxygen therapy shall be CE marked to indicate that they comply with the requirements of Medical Device Regulation 2017/745 (MDR) [1] [1]. In addition, this equipment is required to comply with the European Agreement on the Transport of Dangerous Goods, ADR regulations [2], and shall be 'π' marked to show compliance with the Transportable Pressure Equipment Directive, (TPED) 2010/35/EC [3].

It is the responsibility of the doctor to prescribe the correct flowrate for the patient and the responsibility of the Homecare Service Provider HSP to supply a set of devices that ensures that the patient receives the prescribed flowrate and mobility needs. As a part of this responsibility, the homecare service provider shall also instruct the patient on how to use the equipment correctly and how to select the prescribed flowrate.

In addition, this publication provides a guide for the HSP to give information to the patient, carer or healthcare facility staff to emphasise the safe use and storage requirements for medical liquid oxygen supplies, both in the home and in healthcare facilities.

2 Scope and Purpose

2.1 Scope

This publication covers the use and maintenance of TLOS, used to supply medical liquid oxygen to patients at home or in healthcare facilities.

It includes the operational specification of the TLOS to provide the patient with the prescribed flowrate but excludes its basic design requirements.

This publication does not cover:

- Filling of the TLOS base unit by the medical oxygen Homecare Service Provider (HSP).
- Traceability of medical equipment, which is covered by the MDR [1].

The general requirements for the supply and safe use of medical oxygen are given in EIGA Doc 89, *Medical Oxygen Systems for Homecare Supply* [4].

2.2 Purpose

This publication gives guidance on:

- The specific safety issues related to the handling and use of medical liquid oxygen;
- Safety precautions recommended for the homecare service provider for installing, handling and maintaining the TLOS; and
- Safety precautions recommended to be given to the patient / carer when using and handling the TLOS and transfilling the portable unit.

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

3 Definitions

For the purposes of this publication, the following definitions apply:

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation

3.1.1 Should

Indicates that a procedure is recommended

3.1.2 May

Indicates that the procedure is optional.

3.1.3 Will

Used only to indicate the future, not a degree of requirement.

3.1.4 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Base unit

Mobile device that is vacuum insulated intended to store oxygen and maintain it in the liquid state for the purpose of refilling portable units and that includes an internal vaporiser and a flow control valve for the direct supply of gaseous oxygen to the patient.

3.2.2 Healthcare facility

Organisation providing the medical oxygen therapy to the patient in their premises, where they are responsible for the care of the patient, for example, hospital or care-home.

3.2.3 Homecare service provider

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

3.2.4 Portable unit

Portable device including a vacuum insulated cryogenic vessel to maintain liquid oxygen at cryogenic temperatures, an internal vaporiser and a flow control to provide gaseous oxygen to the patient. The portable unit can be filled from the base unit by the patient.

3.2.5 Transportable liquid oxygen system (TLOS)

Comprising of the base unit and the portable unit.

4 Characteristics of oxygen

The basic characteristics of gaseous and liquid oxygen are:

- Oxygen is essential to sustain life and is normally supplied from the Earth's atmosphere, which is made up of approximately 20.9% oxygen.

- Gaseous oxygen is a colourless, odourless, tasteless gas with a specific density of 1.1 relative to air.

- Liquid oxygen is a light blue liquid that flows like water. It has a boiling point of -183.0 °C at atmospheric pressure and has a specific density of 1.14 relative to water.

- One volume of liquid oxygen will generate 860 volumes of gaseous oxygen at atmospheric pressure and temperature.

- Oxygen, in gaseous or liquid form, is a non-flammable, non-toxic powerful oxidiser. It is considered hazardous as it intensifies combustion (see point 5).

5 Hazards when handling liquid oxygen

When making the initial supply of medical liquid oxygen, advice shall be given to the patient / carer or healthcare facility representative to explain the general hazards when using medical liquid oxygen in a TLOS and shall include the following information:

- Liquid oxygen is extremely cold and boils at -183.0°C at atmospheric pressure. Touching any cold surfaces on the TLOS, such as the valves, pipes or couplings, can cause serious cryogenic burns or frostbite. When handling the TLOS, do not allow spills of liquid oxygen or frosted pipework to come in contact with the skin or non-protective clothing.

- Moisture can accumulate on exposed surfaces of equipment containing liquid oxygen forming ice, causing components such as valves or filling couplings to freeze open or shut. If moisture is permitted to enter liquid oxygen lines or systems, it will freeze and can prevent components such as pressure relief devices or control valves from functioning properly, leading to 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 produce gaseous oxygen. Any gaseous oxygen produced in excess of the patient's requirements will be automatically vented, generating an oxygen-enriched atmosphere. It is important to keep the TLOS in a well-ventilated area to avoid the generation of oxygen-enriched atmospheres and to keep it away from combustible materials and protected from exposure to heat sources, which can accelerate the venting of oxygen from the vessel.

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

- 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.

- 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.

- Absorbent materials, such as clothing or bedding, when saturated with oxygen, can readily ignite. These materials remain oxygen-enriched for some time after removal from the oxygen source.

6 Precautions when handling liquid oxygen

To ensure the safe operation of TLOS, the following instructions shall be provided to the patient / carer / healthcare facility representative in the form of operating instructions. A typical patient user instruction card that shall be supplied to the patient and / or carer, when the equipment is initially installed at the patient's home or healthcare facility, is given in Appendix 4. Appendix 5 gives a typical patient user training card that can be used by the HSP to instruct the patient or carer. It covers the correct operation of the unit and the safety precautions that shall be followed. It may be appropriate for both cards to be left with the patient or carer to provide additional information.
In addition, the TLOS User Manual shall also be provided to the patient / carer. If the user manual specifies a different way of using, handling or transfilling the TLOS, the information provided to the patient should be adapted to ensure that there is no contradiction between the information supplied and the manufacturer's instructions.

The precautions to be given to the patient / carer / healthcare facility representative shall cover the following information (see also Appendix 5 for training card to patient):

- 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, including lighted cigarettes, e-cigarettes, gas cookers, electrical toys and equipment or open fires away from areas where medical oxygen is used or stored.

- It is advisable that 'No Smoking' symbols and instructions shall be displayed on TLOS.

- When handling the TLOS never touch any frosted parts or allow liquid oxygen or frosted pipe work to come in contact with the skin or non-protective clothing. If suffering from a cold burn, the affected part should immediately be immersed in tepid water and a doctor contacted immediately for further advice.

- Never use oils and grease on any oxygen equipment because these materials can burn in an oxygen-enriched environment with explosive violence for example petroleum jelly or hand and face creams containing petroleum-based ingredients. Where the patient requires to use a moisturiser or cream to prevent their nostrils from drying out to only use an acceptable oil-free product that is suitable for use with medical oxygen.

- Oxygen equipment shall only be handled or operated with clean hands and tools and the equipment shall be kept clean, taking specific care to keep the filling couplings clean. Where available, the filling coupling cover should be fitted when not in use.

- 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 sources of ignition.

- Never use the portable unit under clothing. Where ambulatory portable unit is carried in a bag or holder, it shall be specifically designed for the unit 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 should 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.

- In order to ensure that the medical oxygen flow rate remains satisfactory, the total length of the 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. If tubing is fixed to the walls to provide outlets in different rooms, this shall be with no constrictions at corners.

- The TLOS shall never be covered with material or stored adjacent to curtains as they may become oxygen enriched.

- The TLOS shall be kept in a well-ventilated area to avoid the generation of oxygen-enriched atmospheres. They shall also be kept away from combustible materials and protected from exposure to heat sources, which may accelerate the venting of gaseous oxygen from the vessel.

- Care shall be taken to avoid blockage of vent lines, ports and safety relief devices.

- TLOS shall be handled with care and should never be knocked violently, dropped or allowed to fall over.

7 Medical Liquid Oxygen incidents

The homecare service provider shall provide the patient / carer or healthcare facility representatives with the following advice:

7.1 Immediate actions

- If a sustained release of liquid oxygen occurs, if it is possible and safe to do so, close the valve of the TLOS to stop the oxygen flow. Stay out of the vapour cloud and the immediate surrounding area, open all external doors and windows and evacuate all persons from the area and contact the homecare service provider immediately.

- If clothing ignites in an oxygen enriched atmosphere, use a flood of water to extinguish the flame, as just smothering the flame from oxygen enriched materials will not extinguish the fire.

- If a fire occurs, where the TLOS is present, immediately evacuate the area and call the fire brigade. It is important to advise the fire brigade that oxygen is in the premises, even though it may not be involved in the fire.

7.2 After the incident

- If clothing, bedding or furniture has been exposed to a high concentration of oxygen, avoid any sources of ignition until they have been either:

- removed; or

- thoroughly aired to remove any excess oxygen for at least 15 minutes and at least 30 minutes for bedding / furniture; or

- drenched with water.

8 General description of equipment

The TLOS consists of two units:

- Base unit that holds the principal supply of liquid oxygen and is filled by the home care service provider; and

- Portable unit, usually intended for ambulatory use that can be filled by the patient or carer from the base unit.

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

It is a normal function of the TLOS, when it is not in continuous use, to eventually start to vent oxygen gas to atmosphere.

The base unit is fitted with a liquid oxygen transfer connector to allow the transfilling of the portable unit by the patient or carer.

There are 2 different concepts of portable units: Top fill (trans filling via connection at the top of the base unit) and Side fill (trans filling via connection at the side of the base unit).

The portable unit is designed to be filled to a specific type of transfilling connector on the base unit. The HSP shall only supply the patient a portable unit that is compatible with the base unit.

9 Steps to set up the therapy

The patient or carer should be instructed to only use the portable with the base unit that has been provided by the same HSP. In general it is not allowed for safety reasons to use the portable with a base unit from another HSP, as compatibility of the connector is not guaranteed. In case patient has its own Portable Unit, HCP will evaluate compatibility of the supplied Base Unit with the Portable unit. Initial installation of the transportable liquid oxygen systems

9.1 Initial assessment

When planning the installation and storage arrangements for TLOS, whether used in healthcare facilities or by domiciliary patients at home, an assessment of the property shall be carried out in accordance with the document EIGA Doc 89 [4].

Excessive stocks of full TLOS will increase the potential of any incident that can occur. The HSP shall determine the size and number of the base units to suit the patient's requirements at the prescribed flowrate and delivery frequency.

9.2 Equipment preparation

Prior to installing any equipment in the patient’s home or healthcare facility, it is the responsibility of the HSP to verify that the equipment is functioning correctly, including that the:

- TLOS are within their periodic statutory test date;

- Exterior condition of the TLOS is clean, and not damaged to an extent that impairs the correct functioning of the unit;

- Transfilling connector is clean, not leaking and has no visible sign of damage;

- Receiver for collecting condensation on the base unit is both empty and clean;

- Patient outlet is clean and in good condition;

- Flow control valve is mechanically functioning correctly;
- Level indicator, including battery where fitted, is operational;
- TLOS is labelled correctly;
- Portable units vent valve is easy to operate; and
- Portable unit will connect satisfactorily to the base unit.

Where the TLOS is found to not conform to any of the above checks, the HSP shall follow the appropriate procedures to either rectify or replace the faulty unit.

The specific manufacturer's instructions shall be followed when transferring any reusable accessories used with TLOS to another patient.

9.3 Initial Installation

Before use, the patient / carer or the healthcare facility representative shall be given adequate training in the operation, handling and cleaning of the TLOS. In addition, they shall also receive instructions about the potential hazards and recommended safety precautions for handling the TLOS. If the patient and carer are considered to be incapable of operating the TLOS safely, the HSP shall inform the patient's prescriber that an alternative method of supplying medical oxygen is required.

For healthcare facilities, it is the responsibility of their appointed representative of the healthcare facility to ensure that all patients using TLOS and healthcare facility staff are trained in all of the appropriate procedures for handling the TLOS and refilling the portable unit.

Documents and information (user manual, product data safety information, etc.), including instructions on filling of the portable unit shall be provided through any appropriate communication channel to the patient/carer by the HSP. The procedures shall include any other safety information required to be followed when using the equipment. The HSP shall ensure that the patient/carer has read and understood the approved written procedures for using their equipment. As part of the training the HSP shall ensure that the portable unit is filled correctly by the patient or carer.

The HSP shall agree with the patient / carer on a safe location for the base unit and the area where the portable unit will be transfilled. The base unit should not obstruct doorways, corridors and hallways, to avoid any risk of falling over.

The HSP shall take care and explain that all liquid oxygen containers shall be kept at least 1.5 metres[2] away from:

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

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

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

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

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

In order to ensure that the medical oxygen flow rate remains satisfactory, the total length of the 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. If tubing is fixed to the walls to provide outlets in different rooms, this shall be with no constrictions at corners.

Where the transfilling is carried out on an adsorbent surface, such as a carpet, the patient / carer shall be informed to ensure that the area is well ventilated to prevent the surface becoming enriched with oxygen in the unlikely event of a spillage. If transfilling is done in the open, it shall never be carried out on an asphalt surface.
The HSP shall instruct the patient / carer / healthcare facility representative to:

- Not place any form of cover over the equipment, as this will restrict ventilation. Specifically, do not drape clothing or any other material over the vessel nor store the base unit near curtains, as they could become oxygen enriched and burn vigorously if ignited. For the same reason, the portable unit shall never be carried or used under any clothing;

- Not to block the outlets of the relief valves;

- Not apply any labels or markings to the TLOS; and

- Not repair or modify any part of the TLOS.

When the installation is complete and the training satisfactorily completed, the patient / carer should be requested to sign the equipment checklist and acknowledgement form (see typical example in Appendix 3).

9.4 High flowrate requirements

In the majority of circumstances, a single TLOS will be able to supply an adequate flowrate for the patient. Where the patient requires higher flowrates, it is preferable to use a single unit with a higher output as long as it does not lead to icing up of the base unit.

Where the prescribed flow exceeds the flowrate capabilities of a single base unit or leads to icing up of the unit, two units can exceptionally be connected to provide the patient's requirements. As this type of patient normally requires high flowrates at all times they can be supplied with a specifically designed high flowrate portable unit (or any other alternative high flowrate system) for exceptional ambulatory use. Two portable units shall not be connected for safety reasons.

If a humidifier is required, it shall be installed downstream of the additional flow regulating device.

Ensure that the oxygen tubing is appropriate to deliver the required flowrate.

If additional oxygen is being stored in the patient's home, it is important to consider the storage and ventilation requirements when carrying out the assessment.

10 Storage of the transportable liquid oxygen systems

10.1 Storage of the TLOS at the patient's home

The TLOS shall always be stored in a covered area and preferably indoors, but in any case in a secure place away from the public.
The most suitable locations for installing the TLOS at the patient’s home will normally be either in a living room or bedroom. When agreeing the storage arrangements in the patient's home, the patient / carer shall be advised to consider the following requirements:

- As the TLOS will periodically release small amounts of oxygen gas, keep the units in a well-ventilated area. Allow air to circulate around the unit at all times to prevent any significant oxygen enrichment in the vicinity. Never store the TLOS in small and closed areas such as cupboards.

- Never store the TLOS within the immediate vicinity of sources of ignition because the atmosphere around the TLOS may become oxygen enriched by the venting of the vessel.
- Wherever possible keep the TLOS at least 1.5 metres away from:
- Electrical appliances such as televisions, air conditioning fans or hair dryers; and
- Heating sources or stoves (where there are no open flames).
- Wherever possible keep the TLOS at least 3 metres away from:
- Open fires and any open flames; and
- Heating sources or stoves with open flames.
- When selecting a storage place at the patient's home, avoid placing the TLOS:
- Obstructing corridors and hallways or near doorways;
- Where they could impede patient's or carer's movement; and
- Where they may be bumped into or tipped over.

10.2 Storage of the TLOS at the healthcare facility

Healthcare facilities storing TLOS shall be advised that the storage area has to comply with the following:

- Storage is covered, 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;
- Designed to have a floor constructed / covered with a non-flammable material;
- Large enough to allow for segregation of full and empty TLOS, with the different storage areas being identified;
- Separation from any non-medical gas storage areas;
- Located to have good access for the delivery vehicle to enable vessels to be off loaded safely;
- Located away from any sources of heat or ignition and combustible materials;
- Designed to prevent unauthorised entry;
- Provided with warning notices prohibiting smoking and open flames within the vicinity of the store.

11 Homecare service provider checks for the TLOS

11.1 Checks for the base unit

Each time that the base unit is supplied to the patient or to the healthcare facility, the HSP shall check:

- Exterior condition of the base unit is clean and not damaged;
- Transfilling connector is clean and in good condition;

- Transfilling connector is not leaking;
- Condensate water collector is both empty and clean;
- Patient outlet is clean and in good condition;
- Flow control valve is functioning correctly;
- Level indicator, included battery where fitted, is operational;
- Base units have no cold spots indicated by frosting;
- TLOS is not leaking (other than from the relief valve, which is a normal function for a serviceable unit);
- Pressure relief devices have been maintained according to the manufacturer's instructions and any legal requirements; and
- Base unit is labelled correctly.

Where the base unit is found to not conform to any of the above checks, the HSP shall follow the appropriate procedures to either rectify or replace the unit.

11.2 Checks for the portable unit

Each time the homecare service provider supplies the patient it is recommended to check that the portable unit:

- Is clean and in good condition;
- Will connect satisfactorily to the base unit without leaking; and
- Vent valve is easy to operate.

Where the portable unit is found to not conform to any of the above checks, the HSP shall follow the appropriate procedures to either rectify or replace the unit.
The HSP is recommended to periodically ensure that the patient / carer is still competent to refill the portable unit safely and effectively. It is advisable to observe the patient / carer filling the portable unit.

11.3 Checks for the disposable accessories

Each time the HSP supplies the patient they shall check the cleanliness and condition of:

- Disposable accessories; and
- The humidifier, specifically the connection of the water container to the humidifier cover.

Where the cleanliness of the accessories is considered to be inadequate, the patient should be instructed how to clean / exchange the equipment, as specified by the manufacturer or the HSP.
When new or replacement accessories are delivered, the HSP shall control the packaging and labelling of the new accessories, and if needed, instruct the patient how to use, clean and exchange.

12 Handling of the TLOS

In addition to the precautions in Section 6 and appendix 5, the patient shall be advised that the TLOS shall be handled with care and should never be knocked violently, dropped or allowed to fall over.

- Where the base unit is required to be mobile, a roller base should be used and only used on level surfaces to prevent it from tipping over.

- The base unit shall always be kept upright at all times.

When moving the base unit up and down stairs, the unit should only be moved by the HSP in an appropriately designed trolley.
Where a lift is available, it may only be used provided that:

- The unit is in a safe condition and not venting gas; and

- There are no other occupants in the lift whilst the base unit is being moved.

The patient shall be instructed that the portable unit shall only be:

- Carried in the holder fitted to the portable unit or in an approved bag or trolley; and

- Kept upright at all times unless the unit is designed to be used in other specific orientations.

13 Operation and use of the TLOS

The patient / carer shall be instructed to follow the manufacturer's instructions when using the TLOS, and specifically to:

- Never place anything on top of the base unit or push down on the fill connector, as it could lead to the fill connector being operated and cause liquid oxygen to be vented;

- Not to put anything inside the shroud;

- Not put anything hot on the plastic shroud;

- Turn off the oxygen supply when not in use to prevent enrichment of the air, even for short periods of time;

- Ensure that the oxygen tubing and accessories are attached correctly and the humidifier assembled correctly in order to avoid leaks;

- Ensure that the oxygen tubing is placed correctly to prevent it becoming kinked or blocked;

- Check that the oxygen flows out of the nasal cannula. If in doubt or in case of troubleshooting put the prongs of the nasal cannula under the surface of water in a glass: flow will be indicated by bubbles. This method is not applicable when oxygen conserving devices are used;

    - Keep the TLOS clean, taking specific care to keep the connectors both clean and dry; only select the flowrate prescribed by the patient's doctor.

    - The patient should not consume oxygen from the portable unit whilst left connected to the base unit.

14 Transfilling of the portable unit

As the portable unit only contains a relatively small volume, the heat in-leak into the vessel can lead to the product evaporating prior to it being required for use. The patient shall be instructed that they should only fill the portable unit just before it is needed, to avoid any unnecessary evaporation losses.

The portable unit should only be used when the unit is required for ambulatory use or when it is impracticable to use the base unit.

Transfilling of the portable unit requires the patient / carer to take care as it can lead to the spillage of liquid oxygen and shall always be carried out in a well-ventilated area. Where the transfilling is carried out on an adsorbent surface, such as a carpet, the patient / carer shall be informed to take extra care to ensure the area is well ventilated to prevent the surface becoming enriched with oxygen.

The portable unit shall never be left unattended during the transfilling process.

The manufacturer's transfilling instructions shall always be followed and specific attention shall be given to ensure that:

- The portable unit is clean and the moisture adsorbing pad, where fitted, is clean and dry;
- The level indicator, included battery where fitted, is operational;
    - The transfilling connectors are checked on both vessels to ensure that they are clean (clean it with a lint free cloth) and dry prior to refilling to avoid malfunction due to freezing;
- The portable unit is correctly aligned with the transfilling connector on the base without leaking and the portable unit's vent valve is easy to operate;
- Any vented gas is directed away from the person filling the unit and away from any combustible materials, such as curtains. The patient or carer should be warned of the possibility that some liquid can escape from the vent valve of the portable unit at the end of the filling if the instructions provided by the HSP are not followed;
- During the refilling operation, the person filling the portable unit shall be instructed to briefly close and open the portable unit vent valve during the filling process to dislodge any ice that may have formed in the outlet;
    - An evaluation of the specific circumstances determines if side fill is advisable. Dedicated instructions in case of a side filling portable unit shall be given, highlighting the need to stay present during the whole filling process to avoid risk of spillage. Information on the risk of leaks around the manipulation area when disconnecting the filled portable unit shall be provided.
- If a minor liquid oxygen leak occurs after the portable unit is disengaged from the base unit, it shall be refitted immediately to the base unit. This procedure can help to dislodge any ice or other obstruction in the transfilling connector. When the portable unit is subsequently disconnected the leak should have disappeared.
- If the portable unit will not separate easily from the base unit, never use undue force to separate the portable unit, as the units can be frozen together. Never use a hair dryer to melt the ice. Leave the units connected for a short period with the portable unit vent valve closed to allow the transfill connector to warm and the ice to melt, which will generally allow the units to separate easily.
    - The patient / carer shall be instructed to always adhere to safety guidelines when transfilling the portable unit.

Should a major liquid oxygen leak occur on either unit, the patient / carer shall be instructed in accordance with Section 6.

15 Travelling with TLOS

The transport of liquid oxygen systems by the HSP is covered by the conditions of the ADR regulations. These regulations do not affect the transport of liquid oxygen systems by the patient. However, national legislation may affect the carriage of liquid oxygen in privately owned vehicles.

EIGA Doc 141 *Planning Oxygen Supplies for Respiratory Patients when Travelling* [5] gives all information including safety cards for using oxygen whilst travelling. This document shall be used to make preparations for travelling with Oxygen.

16 Maintenance and cleaning of the TLOS

The patient / carer / healthcare facility representative shall not be permitted to carry out any maintenance to the TLOS, other than any routine operations defined in the user's manual. Only authorised and trained persons shall be permitted to carry out maintenance on the TLOS.

Where batteries are used for the level indication, the patient / carer shall be responsible for changing them only where they are instructed to do it by HSP.

The patient or carer is only responsible for the routine hygiene maintenance of the equipment, including the humidifier, nasal cannulas, face masks, water condensate collectors and the external surfaces of the TLOS. These actions should be defined in the manufacturer's user manual.

The patient / carer shall be instructed that if any part of the TLOS fails to operate correctly, they should contact the HSP immediately so that an authorised person can diagnose the fault and implement the appropriate corrective action. Appendix 2 gives typical questions asked by the patient and provides the appropriate corrective actions to be taken by the patient.

The patient / carer shall be instructed to never lubricate any part of the equipment with oil or grease and to ensure that hands are clean and free from oils and creams when handling the oxygen equipment.

When cleaning the equipment, the patient or carer shall be instructed to always turn off the oxygen supply and to never use any solvents or other flammable products to clean the equipment.

When carrying out routine cleaning of the equipment, the patient / carer shall be instructed to note the following issues:

- Only use a clean dampened cloth using an approved type of non-abrasive cleaning agent to wipe down the TLOS before use. Abrasive substances or sharp objects shall never be used for cleaning;
- When cleaning equipment, ensure that no residues are left after cleaning that could come in contact with the medical oxygen;
- Do not allow water to come into contact with the filling connector on the TLOS.

Condensate water collector, should be regularly emptied and cleaned in accordance with the manufacturer's instructions. The portable unit is fitted with a moisture adsorbing pad and where applicable, this should be changed and dried to prevent moisture accumulating on the equipment.

The HSP shall carry out the periodic maintenance requirements as specified in the manufacturer's user's manual. A typical troubleshooting guide for the HSP is given in Appendix 1.

17 References

Unless otherwise specified the latest edition shall apply.

[1] Medical Device Regulation 2017/475 www.europa.eu

[2] European Agreement on the Transport of Dangerous Goods, ADR www.unece.org

[3] Transportable Pressure Equipment Directive, (TPED) 2010/35/EC www.eur-lex.europa.eu

[4] EIGA Doc 89 *Medical Oxygen Systems for Homecare Supply* www.eiga.eu .

[5] EIGA Doc 141 *Planning Oxygen Supplies for Respiratory Patients when Travelling* www.eiga.eu

18 Additional references

EN ISO 18777 *Transportable liquid oxygen systems for medical use – Particular requirements* www.cen.eu

CGA P-2.7 *Guide for the Safe storage, Handling and Use of Small Portable Liquid Oxygen Systems in Health Care Facilities* www.cganet.com

Appendix 1 TLOS Troubleshooting Guide - Service Provider at the Patient's Home

Typical Troubleshooting Guide for Transportable Liquid Oxygen Systems For the HSP at the Patient's Home			
No	**Abnormal Operational Condition**	**Possible Cause**	**Corrective Action Service Provider**
1	Pressure too low.	Liquid too cold and not at the required saturated pressure (defined by the manufacturer).	Check the pressure in the unit. If unit pressure is very low, replace unit at the patient's home with correctly filled unit. If pressure is only slightly low, leave unit standing until the natural evaporation rate increases the pressure to its minimum operating level.
		Unit empty.	Refill the unit or replace with a full unit.
		Vent valve left open too long after filling.	Leave unit standing until the natural evaporation rate increases pressure to its minimum operating level.
		Leaks from the unit.	Replace unit.
		Other malfunctions.	Replace unit.
2	No flow from the unit.	Flow regulating valve set at zero.	Set the flow to the prescribed level. Check flow from outlet by placing tubing in water and check for bubbles. If conserving device is fitted, remove device or switch to continuous flow and check for flow.
		Unit empty.	Refill the unit or replace with a full unit.
		Components not fitted correctly.	Check correct fitting of the humidifier lid Check fitting of the tubes to humidifier. Check that the tube is not kinked. Check that humidifier is not blocked. Check by removing humidifier and see if flow continues.
		Blockage of components.	Replace faulty unit.
3	Flow appears to be too low.	Base unit pressure too low.	Refer to the Section 1
		Flow controller set too low.	Check setting of flow controller to prescribed flowrate. Follow instructions in Section 2.
		Blockage of internal components.	Replace faulty unit.
		Blockage of ancillary equipment.	Remove any obstructions or replace faulty ancillary equipment.
		Leaks from the humidifier or tubing.	Refit humidifier and tubing connectors.
		If confirmed that flow rate and oxygen outlet percentage is correct, but patient senses too low flow rate and/or desaturates	Refer to the physician to review therapy needs
4		No charge in battery (where used).	Replace battery or replace unit where not practicable to replace on site.

	Wrong indication of the liquid level.	Failure of liquid level gauge system.	Replace faulty unit.

No	Abnormal Operational Condition	Possible Cause	Corrective Action Service Provider
5	Gaseous oxygen temperature appears too cold.	Flow setting too high.	Reset flow setting to the prescribed flowrate.
		Flow setting correct.	Explain to patient that this is the normal operation of the unit
6	Perception of bad odour.	Water in humidifier dirty.	Demonstrate to patient when to clean humidifier and how to refit it, including regular refilling with clean water
		Cannula dirty.	Instruct patient how and when to replace cannula.
		Felt on the portable unit dirty.	Instruct patient how and when to replace felt pad on portable unit.
		Other components dirty.	Demonstrate to the patient how to clean the external surface of the unit. Replace dirty components or replace unit as necessary.
7	Problems connecting the portable unit to the base unit.	Base cover on portable unit still in place (where fitted).	Demonstrate to the patient how to remove base cover on portable unit.
		Cover on the base unit fill connector still in place (where fitted).	Demonstrate to the patient how to remove cover on fill connector.
		Incompatible materials (for example Side fill portable unit and topfill base unit)	Exchange the unit with a compatible unit.
8	Leaks when connecting portable unit to base unit.	Dirt on the connecting faces or worn / damaged connector on portable or base unit.	Demonstrate to the patient how to disconnect the unit and clean the connecting faces with a clean cloth. If leaks persist, replace the unit.
9	Problems disconnecting the portable unit from the base unit.	Ice on the connecting faces.	Demonstrate to patient how to check that vent valve is closed and how long to leave unit to allow ice to melt. Ensure that excessive force is not used to remove portable unit. Demonstrate to patient how to clean and dry connecting faces with a clean cloth before and after unit is fitted. Repeat the training on correct portable filling
10	Hissing noise from either unit.	Safety valve venting.	Explain to the patient that this is normal operation and that no action is required.
11	Portable unit fills too slowly.	The base unit is empty.	Replace / refill base unit.
		The base unit pressure is too low.	Instruct the patient to leave the base unit for a period, (typically up to one hour) and retry filling the unit. If the portable unit still fills too slowly, replace the base unit.

		The portable unit vent valve is closed or only partially open.	Instruct the patient on how to open the vent valve fully when filling the portable unit.

No	Abnormal Operational Condition	Possible Cause	Corrective Action Service Provider
12	Portable unit leaking after disconnection.	Ice in the fill valve or worn / damaged connector.	For major leaks, if safe, refit portable unit and remove the units from inside patient's home and allow unit to empty in a safe place by opening vent valve. Open windows to ventilate the home. For minor leaks, instruct the patient on the following points: 1. reconnect the portable unit to the base unit with vent valve closed; 2. wait two minutes; 3. disconnect the portable unit and check if leak stops; 4. if leak stops, re-emphasise to the patient how to clean and dry connecting faces with a clean cloth before and after portable unit is fitted; 5. if leak continues, replace portable unit.
13	Leak of water from portable unit.	Water condensate adsorbing pad on the portable unit is saturated from condensation.	Instruct the patient on how and when to replace the water condensate adsorbing pad with a dry unit.
14	Leak of water from the base unit.	Condensate receiver full.	Instruct the patient on how and when to remove and empty condensate receiver and to clean before replacing.
15	Duration of use from the portable unit shorter than usual.	Portable unit not filled correctly.	Instruct the patient on how to refill the portable unit correctly and to check the portable unit level indicator indicates 'Full'.
		Leak on portable unit.	Replace the portable unit.
		Flow setting is too high.	Check flowrate and if required reset flowrate to the prescribed flowrate.
16	Base unit empties too quickly.	The base unit vacuum is inadequate.	Replace the base unit.
		Leaks on the external pipe work**.**	Replace base unit.
		Flow setting is too high.	Check flowrate and if required reset flowrate to the prescribed flowrate.

Appendix 2 Typical Patient Questions concerning TLOS

Typical Patient Questions concerning Transportable Liquid Oxygen Systems			
No	**Typical Question**	**Possible Cause**	**Corrective Action to be taken by Patient**
1	No flow from the unit.	Flow regulating valve set at zero.	Set the flow to the correct setting. Check the flow from the outlet by immersing in water and checking for bubbles. If conserving device is fitted, remove device or switch to continuous flow and check for flow.
		Base unit empty.	Check contents gauge. If empty call service provider to refill the base unit.
		Components not fitted correctly.	Check the fitting of the tubes to the humidifier. Check that the tube is not kinked. Check that the humidifier is not blocked / check by removing the humidifier and see if the flow continues.
		Blockage of components.	Check that the tube is not kinked. Inform service provider.
2	Flow appears to be too low.	Leaks from the humidifier or tubing.	Refit humidifier and tubing connectors.
		Flow controller set too low.	Check setting of flow controller to prescribed flowrate. Follow instructions in Appendix 1.
3	Wrong indication of the liquid level.	No charge in battery (where used).	Replace battery or arrange for HSP to change.
		Failure of the liquid level gauge system.	Inform HSP.
4	Gaseous oxygen temperature appears too cold.	Flow setting too high.	Reset flow setting to the prescribed flowrate.
		Flow setting correct.	Normal operation of the unit, though HSP should be consulted.
5	Perception of bad odour	Smell from newly unpacked canula	Provide some time for the odour to disappear. If problem persist, check the points below.
		Water in humidifier dirty.	Clean the humidifier and replace with clean and demineralised water.
		Cannula dirty.	Replace the cannula if dirty.
		Water condensate adsorbing pad on the portable unit dirty.	Replace pad on portable unit.
		Other components dirty.	Inform HSP.
6	Problems connecting portable unit to base unit.	Base cover on portable unit still in place (where fitted).	Remove base cover from portable unit.
		Cover on the base unit fill connector still in place (where fitted).	Remove cover from base unit.

7	Hissing noise from either unit.	Safety valve venting.	Normal operation - no action.

No	Typical Question	Possible Cause	Corrective Action to be taken by Patient
8	Leaks when connecting the portable unit to the base unit.	Dirt on the connecting faces or worn / damaged connector on portable or base unit.	Disconnect the portable unit and clean the connecting faces with a clean and dry cloth and then refit unit. If leaks persists, contact the HSP.
9	Problems disconnecting the portable unit from the base unit.	Ice on the connecting faces.	Ensure the vent valve is closed and leave unit to allow ice to melt naturally. Do not use: • force to remove portable unit; • a hair dryer to melt the ice. • Tepid or hot water Clean and dry connecting faces with a clean and dry cloth after the unit is removed.
10	Portable unit leaking after disconnection.	Ice in the fill valve or worn / damaged connector.	For major leaks: • stay away from the unit; • open windows to ventilate room; • immediately inform the HSP. For minor leaks: • reconnect portable unit to the base unit with vent valve closed; • wait two minutes; • disconnect portable unit; • check if leak stops. If leak stops: • clean and dry connecting faces with a clean and dry cloth after unit is removed. If leak continues: • reconnect portable unit with the vent valve closed and inform HSP.
11	Leak of water from the portable unit.	Felt pad on the portable unit is saturated from condensation.	Replace the felt pad with a dry pad.
12	Leak of water from the base unit.	Condensate receiver full.	Remove and empty condensate receiver. Clean the receiver before replacing.
13	Duration of use from the portable unit shorter than usual.	Portable unit not filled correctly.	Refill portable unit correctly Check the portable unit level indicator that the gauge indicates 'Full'.
		Flowrate too high.	Check flowrate is the prescribed flowrate.
		Leak on portable unit.	Inform HSP.
14	Any other problems.		Inform HSP.

Appendix 3 Typical Patient Equipment Checklist and Acknowledgement Form

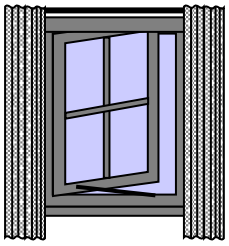
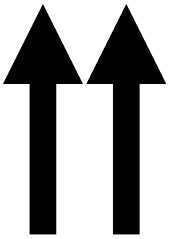
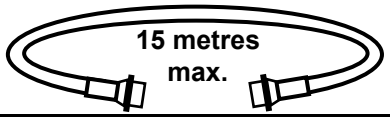
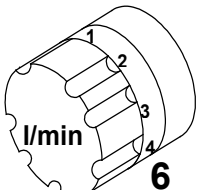
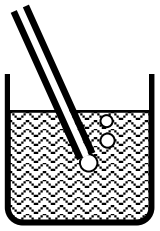
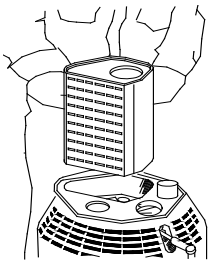
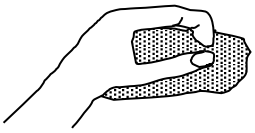
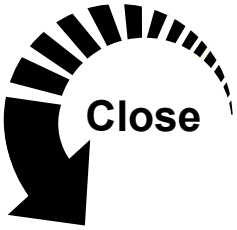
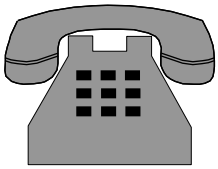
PATIENT EQUIPMENT CHECKLIST AND ACKNOWLEDGEMENT FORM

GENERAL	**Tick**
Patient and / or carer present who will need to operate equipment.	☐
Provide relevant patient information including details about the delivery service.	☐
Explain the prescription to the patient and need to **only** use the correct flowrate.	☐
Instruct that no one shall attempt to repair or adjust equipment.	☐
SAFETY INFORMATION	
Explain oxygen is non-flammable but will assist all sorts of materials to burn vigorously.	☐
Explain about fire hazards and describe ignition sources such as **smoking**, fires, cookers, etc.	☐
Explain **never to smoke,** or allow anyone else to smoke, in the presence of oxygen.	☐
Explain never to use grease or oil on any oxygen equipment and only to use approved creams.	☐
Explain the need for adequate ventilation and to **not** cover the units or use under clothing.	☐
Explain the effects of cold liquid on skin and eyes.	☐
Explain the procedure to travel with oxygen, if required.	
BASE UNIT OPERATION	
Agree safe location of base unit for storage and use.	☐
Explain correct operation of base unit.	☐
Advise that slow escape of oxygen from relief valve is normal, evident by hissing noise.	☐
Confirm that the patient / carer has operated the base unit correctly.	☐
PORTABLE UNIT OPERATION	
Explain correct operation of portable unit and duration of use at the prescribed flowrate.	☐
Explain **never** to carry or use portable unit under clothing.	☐
Confirm that the patient / carer has successfully filled the portable unit.	☐
DISPOSABLE ACCESSORIES	
Provide nasal cannula or mask, humidifier, and show how to use ancillary equipment correctly.	☐
Demonstrate how to clean, dry and when to replace ancillary equipment.	☐
OXYGEN DELIVERY AND incidents	
Explain normal delivery procedures for supplies of oxygen and provide telephone number.	☐
Explain incident / breakdown procedures and provide telephone number (if different).	☐
Explain when to use the out of office hours service.	☐
PATIENT / CARER CONFIRMATION	
Patient Information Pack and telephone numbers supplied to Patient / Carer.	☐
Confirmation that the HSP have gone through all the points mentioned above.	☐
I have understood all the instructions given to me by the HSP including that smoking is prohibited in the vicinity of either unit.	☐

Patient Signature: _____ **Date** _____

Homecare Service Provider Signature _____ **Date** _____

Appendix 4 Patient User Instruction Card

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 
7 Connect oxygen tubing 	**8** Open flow control 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

1

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

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

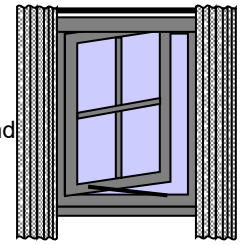
2

Materials burn much more vigorously in oxygen than air.

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

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

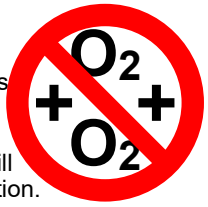
3



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

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

4



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

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

Never use or carry the portable oxygen container under any

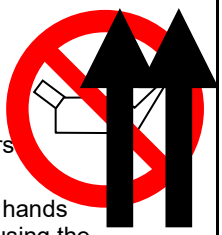
5

Follow the advice your service provider has given you about where to safely store and use your liquid oxygen container.

Use and store your liquid oxygen base unit ***upright***.

Use the portable unit only as shown in the Instruction Manual.

6



Do not use oils or grease with your liquid oxygen containers or equipment.

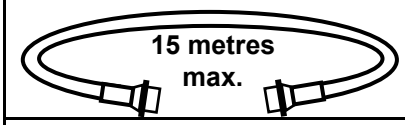
Ensure that your hands are ***clean*** when using the containers.

Only use authorised creams and moisturisers when using your

7

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

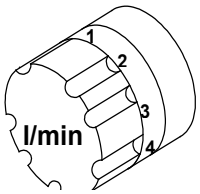
Ensure that the length of the tubing does not exceed 15 metres



8

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

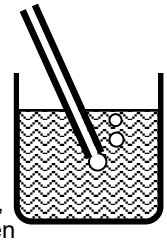
9



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

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

10

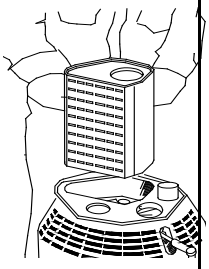


Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.

If no bubbles appear, check a flow has been selected and there are no leaks.

If a flow is still not evident, contact your HSP.

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.

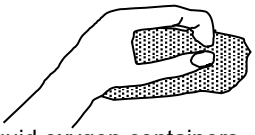
12

Never touch any cold parts on either containe or allow liquid oxygen to come into contact with your skin.

This could cause a serious burn.

Immerse affected parts in tepid water if you receive a cold burn.

13

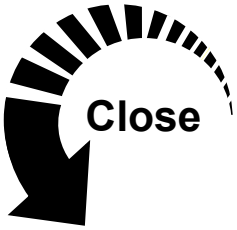


Use only a clean damp cloth to clean your liquid oxygen containers or any associated equipment.

Only use mild non-abrasive cleaning materials.

Allow the liquid oxygen containers to dry after wiping down.

14



Select zero on the oxygen flow control valve after use.

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

15

If either liquid oxygen containe fails for any reason call your service provider immediately.

Never try and repair any fault unless specifically instructed by your HSP