

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

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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: