

DESIGN AND OPERATION OF VEHICLES USED IN MEDICAL OXYGEN HOMECARE DELIVERIES

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Amendments to 128/21

Section	Change
5.2.7	Add certification, e.g. ref to EN standard (see also new Ref [13]) and reference to wooden floor and carpeting was removed.

1 Introduction

The delivery of medical oxygen with the associated therapy equipment is made by field personnel using purpose designed delivery vehicles. These guidelines also apply to vehicles operated by subcontractors on behalf of the Homecare Service Providers (HSP). This document describes the basic design principles for the vehicles and safe operation used for the delivery of medical oxygen and associated therapy equipment.

2 Scope and purpose

2.1 Scope

The scope of this document covers

- the design of the vehicles used for the delivery of medical oxygen and related equipment's to the patient, including safety design specifications for the interior
- The operation of the vehicles used for the patient delivery of medical oxygen and related equipment
- The operation of filling of the tank installed inside the vehicle; and
- The operation of filling of the base units at the patient's home.

It specifically does not cover:

- the make, model and size of the vehicle;
- the logistics of the deliveries;
- the carriage of other medical gases with the medical oxygen supplies for homecare use. Where medical gases other than medical oxygen are transported, a risk assessment shall be carried out to consider any additional risks associated with the other medical gases;
- the homecare service provider's operations inside the patient's home or the healthcare facility;
- vehicles used by the patient;
- Transport of Dangerous Goods Regulation 'ADR' [1] requirements, where quantities carried are above the ADR exemption limits for small loads;
- design and operational requirements for the transportable cryogenic tanks, which are covered in EN 1251 [2]; and
- the Good Manufacturing Practice (GMP) [3] requirements for filling and testing the mother tank or for the filling of the base units at either the Homecare Service Provider's premises or at the patient's home.

2.2 Purpose

The purpose of this document is to give guidance on minimum vehicle design and operational safety requirements for the homecare service provider.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

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

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

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

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions**3.2.1 Homecare Service Provider (HSP)**

An organisation / company that provides the medical oxygen and medical devices for treating patients either in their home or supplied direct to the Healthcare Facility treating the patient.

3.2.2 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.

3.2.3 Transportable Liquid Oxygen System (TLOS)

The base unit and the portable unit that can be filled from the base unit.

3.2.4 Base Unit

A vacuum insulated cryogenic vessels, fitted with an integral vaporiser that can supply medical oxygen to a patient who requires additional oxygen. Unless otherwise designed, the base unit is used to supply the patient with their medical oxygen whilst in the home and holds the principal supply of liquid oxygen for the patient.

3.2.5 Portable Unit

A vacuum insulated cryogenic vessels, fitted with an integral vaporiser that can supply medical oxygen to a patient for ambulatory use. The portable unit can be filled from the base unit by the patient and, unless otherwise designed, used to only supply medical oxygen for ambulatory use.

3.2.6 Transfer Hose

A transfer hose is a flexible hose suitable for cryogenic liquids fitted with medical oxygen specific couplings to connect the base unit to the mother tank or the mother tank with the storage tank for filling purposes only.

3.2.7 Operation

For homecare vehicles refer to the practice of transporting, filling, transfilling and handling the different medical oxygen packages on the road.

3.2.8 Closed maintenance facility

A building used for carrying out maintenance on the vehicle operated by the company or 3rd party owned, with minimal ventilation and standard electrical equipment.

3.2.9 Hot work

Any work requiring brazing, welding, cutting or grinding.

3.2.10 Maintenance of vehicles

Any hot or cold repair to the vehicle's cab or cargo compartment or any automotive maintenance.

3.2.11 Purpose-built Vehicle

Any type of vehicle that has undergone modifications to ensure, as a minimum, efficient ventilation and load security.

3.2.12 Service

The action of installation or removal and replacement, preventative maintenance, repair, technical verification of equipment.

3.2.13 Transfilling

The operation of transferring a cryogenic liquid from a larger tank into a smaller tank via differential pressure.

3.2.14 Mother tank

A transportable cryogenic vessel constructed as a minimum to ADR requirements and with a typical water capacity of between 180 litres and 2000 litres.

3.2.15 Segregation

The separation of cylinders and base units carried on the vehicle to be able to determine its status. The method used to achieve segregation will depend on the nature, extent and complexity of the operation. Marked out floor areas, partitions, barriers and signs could be use.

4 General requirements

Any vehicle and any distribution and transfilling service shall meet all applicable:

- European, national and local regulations,
- ADR Regulations (where they are applicable), and
- the requirements of this document.

The most stringent requirements shall be applicable.

5 Design principles for purpose-built vehicles

The vehicles used by the Homecare Service Provider should be modified to meet the requirements of this document and are referred to hereafter as purpose-built vehicles. The design and operation of these purpose build vehicles shall follow all relevant transport legislation. In addition, there is also specific legislation for the equipment transported; the lifts used for lifting loads and personnel protection and local labour rules.

The scope of this document does not include specifications or considerations on the type of propulsion system or power system (for example CNG, LNG or electric powered vehicles). Any choice on

propulsion system considered should be based on a risk analysis and be compliant with actual ADR regulations.

Following these design principles prevent incidents involving oxygen fires, shown in the images below. The design principles also allow risk minimisation on consequences of collisions and road accidents.





5.1 General specifications

The basic requirements for the design of vehicles used by the Homecare Service Provider are:

- compressed and liquid oxygen shall only be carried in a vehicle with adequate ventilation to avoid a build-up of oxygen;
- the load shall be secured at all times;
- oxygen vessels shall be physically segregated from combustible material;
- full and empty vessels shall be segregated and identified to prevent an empty vessel being supplied for patient use;
- dirty and suspected contaminated vessels shall be also identified and segregated to prevent cross contamination;
- there shall be physical separation between the driver cab and the load carrying compartment;
- the cladding of the Cargo compartment shall use non-combustible materials;
- the vehicle design and material selection for the Cargo compartments shall ensure that the vehicle can be maintained in a clean condition to ensure the hygiene requirements of the equipment being carried, and
- the vehicle design shall ensure that the manual handling aspects of loading and unloading of the vehicle can be carried out safely.

Where the design of the vehicle does not follow the basic principles specified in this document, the alternative design shall be risk assessed to demonstrate that an equivalent degree of safety is obtained.

5.2 Specific requirements

5.2.1 Driver's cab

There shall be a physical separation between the driver's cab and the Cargo compartment to protect the driver from any material projection in the case of emergency braking or road traffic accident.

The physical separation between the driver's cab and the Cargo compartment can be achieved by:

- a bulkhead between the driver's cab and the rear compartment. Fixed windows are permitted in the bulkhead; the bulkhead shall be sealed in case of transportation of medical liquid oxygen;
- an independent rear compartment mounted on a cab chassis; or
- a trailer designed for the purpose.

The bulkhead between the driver's cab and the cargo area shall also be designed to withstand the forces of any loose container or item in the vehicle (identified by risk assessment) moving forward in the event of heavy braking.

Where the cargo is fixed to the bulkhead, it shall withstand forces identified in 5.2.4.

5.2.2 Cargo compartments

Where two or more cargo compartments are used, all of the following requirements shall apply to each of the compartments.

5.2.3 Ventilation

The ventilation of the cargo compartment shall be designed to ensure that any oxygen enrichment of the atmosphere in the compartment is dispersed quickly to keep the oxygen content of the air below 23.5% in normal operation; see EIGA Doc 04 [4].

Cargo compartment containing cylinders or cryogenic liquid vessels shall be equipped with effective ventilation. The setup should ensure a continued ventilation, even when the van is not in use.

Where only compressed gas cylinders are carried, each cargo compartment shall have a minimum of two vents, one at the front near the top of the compartment and one at the rear near the floor. The total free area of the vents shall be at least 600 cm².

Where liquid oxygen is carried in the vehicle, each cargo compartment shall have a minimum of three vents, two at the front near the top of the compartment and one at the rear near the floor. The total free area of the vents shall be at least 900 cm² per compartment carrying oxygen; see CGA Document P-2.6 [5].

Vents shall be of the fixed open type, such as grills, or roof mills.

It shall not be possible to close off these vents and the cargo being carried on the vehicle shall not be allowed to block off the ventilation openings.



Figure 1 Typical ventilation grill at the bottom of the rear door on delivery vehicle

5.2.4 Load security

The HSP should provide the driver with adequate information concerning the safe loading of the vehicle. This information may include details of the maximum number of cylinders or liquid oxygen vessels that may be carried at one time and the distribution of these items within the cargo compartment.

The vehicle manufacturer or vehicle body manufacturer shall be consulted on the requirements for the weight distribution in the vehicle. The maximum loads for the vehicle shall be respected. The loading requirements of the vehicle design can be controlled by restricting the number of storage locations to limit the maximum load on the vehicle.

All loads shall be secured so that the cylinders, liquid vessels or equipment being carried cannot move during normal driving conditions or under harsh braking.

Any modifications to the vehicle shall be designed so that the vehicle can withstand the forces required to secure the maximum intended load in the vehicle under all conditions.

Any securing / anchor points for retaining the load and the associated structure shall be designed to, withstand the forces generated during acceleration or braking in accordance to ADR requirements. If the bulkhead between the driver's cab and the cargo area is used to secure the cargo, it shall be capable of withstanding the same forces.

The bulkhead shall also be designed to withstand the horizontal forces of any loose container or item in the vehicle (identified by risk assessment) moving forward in the event of heavy braking. Gas cylinders or base units may be secured singularly or as a group with a single security system. However, cylinders and base units shall not be secured together. Where more than one container is secured, the system shall be capable of withstanding the forces exerted by the maximum number of containers for which the system is designed.

The method of securing the load under normal driving conditions shall not damage any part of the container or equipment being carried.

Consideration should be given to use straps with protection between the locking fastener and the container walls.

Where cylinders are carried on the vehicle, depending upon their size, they shall be either:

- secured by straps,
- placed in baskets or racks attached to the vehicle, or
- placed in portable racks, secured in the vehicle to prevent them from moving or falling over

If cylinders are transported horizontally, they shall not be able to move inside the compartment during transportation. An example of a cylinder rack is given in Fig. 2.



Figure 2 Typical cylinder storage rack on delivery vehicle

Where base units are carried on the vehicle they shall be secured by straps or by removable locking bars, to ensure that the units remain stable and cannot move.

It is advisable to arrange the base units in a single row when secured in the cargo compartment to avoid any damage to the outer vessels by excessive contact pressure when tightening the straps.

Where straps are used to secure any part of the load, the safe limits under dynamic conditions for the fastened mass takes into consideration the document EIGA 52 – Load securing of class 2 receptacles.

Where trolleys are used for moving cylinders, base units or equipment on the vehicle, they shall be secured in the vehicle.

All other equipment, disposable items and spare parts for the equipment shall be securely stored to prevent them moving and damage during transport.



Figure 3 Typical liquid cylinder storage and security systems on delivery vehicle

5.2.5 Load segregation

When transporting medical oxygen cylinders together with liquid oxygen vessels, either in a bulk tank or in filled base units, the cylinders shall be located or protected so that any spillage of liquid oxygen will not affect the integrity of the medical oxygen cylinders.

Where devices or containers are collected from the patient, there shall be sufficient space or segregation to ensure that the new equipment is supplied in a clean condition and avoid cross contamination.

It is important to ensure that full and empty containers are identified on the vehicle to prevent an empty container being supplied to the patient.

The spare wheel / tyre should not be carried in the cargo area unless it is in a separate compartment or in a box in the cargo area.

In case of transporting other materials not referred here verify the compatibility with oxygen and follow the ADR rules.



Figure 4 Typical segregation of base units with full and empty cylinders secured separately

5.2.6 Cargo compartment access

At each external door there shall be a secure grab handle and a low-level step to provide safe access to the vehicle load area.

To avoid being locked from the inside each cargo compartment door shall have means to be opened from the inside of the vehicle.

Risk Assessment shall be used to determine whether some form of lifting equipment or ramp to handle liquid oxygen vessels, compressed gas cylinders and any heavy medical equipment in and out of the vehicle is required.

Where a hydraulic lift is used, with its driving system inside the vehicle, it shall be shielded from possible oxygen vapours and maintained in a clean condition. Any spillage of hydraulic oil shall be cleaned up immediately to mitigate fire hazards.

The layout of the vehicle, with the specific areas for storing containers and equipment shall allow safe access during any activity, even when the vehicle is fully loaded.

The layout shall also take into account the manual handling aspects of moving the load on and off of the vehicle in a full and empty condition.



Figure 5 Examples of homecare delivery vehicle used for supplying full for empty

5.2.7 Selection of materials

The materials used in the construction of homecare delivery vehicles for the cargo compartment(s) shall either be of metal, certified (e.g. to EN 13501-1 [13]) or of a non-flammable material. These materials should be as light as possible in order to keep the overall vehicle weight low.

Absorbent combustible materials shall not be used for the cladding of internal surfaces of the cargo compartment.

The flooring shall be made of striated metal or certified non-flammable material, over the entire surface of the cargo compartment. Where a wooden floor or wooden bulkhead is used in the construction of the cargo area it shall be completely covered by a sealed metal plate (stainless steel or aluminium).

5.2.8 Fire extinguishers

In compliance with ADR requirements the vehicle transporting oxygen shall carry fire extinguishing materials:

- The driver's cab shall be fitted with a fire extinguisher in compliance with ADR. It is recommended to also have one fire extinguisher in the cargo compartment.
- In the cargo compartment the extinguisher shall be located just inside the cargo hold adjacent to the access door as this allows access even when the vehicle is on its side.
- The fire extinguisher in the driver's cab shall be fixed accessible either from within or outside the vehicle, so that it is available to be used for an engine fire.

5.2.9 Signs and markings

The vehicle shall be marked with the signs as required by national / European legislation. Where the carrying capacity of the vehicle is above the threshold of subsection 1.1.3.6 of the ADR regulations, the placards and plates shall be in accordance with the ADR Regulations.

In the driver's cab a 'No Smoking' sign shall be displayed, visible to both the driver and the passenger. It is recommended to remove the cigarette lighter and ashtray from the driver's cab.

Inside the cargo compartment, the following signs shall be displayed:

- “No Smoking”
- Use of appropriate Personal Protective Equipment (PPE).

Consideration shall be given to display the following signs outside the vehicle when oxygen is being carried:

- “Oxygen”
- Compressed Gas and Oxidising Hazard diamonds, where required.

The emergency / safety instructions shall be available to the field personnel.

A contact number of the HSP is recommended to be displayed outside the vehicle.

If the transport is above 1000 ADR points, additional regulations apply, for which we refer to the ADR.

5.2.10 Safety equipment

All vehicles shall carry a minimum level of safety equipment for use in an emergency. This equipment shall be in addition to that PPE equipment used for the operation of the vehicle.

The safety equipment carried on the vehicle shall comply with the ADR Regulations and the national Highway Code regulations and shall include:

- First-aid kit,
- Reflective warning triangle,
- Torch light,
- “No smoking” sign,
- Two safety cones,
- Reflective jacket(s).

If the transport is above 1000 ADR points, additional regulations apply, for which we refer to the ADR.

5.2.11 Lighting

Each vehicle cargo compartment shall be equipped with a light of at least 300 lux focused on the work area. The lighting shall be operated from each access door into the load area.

If the transfilling of base units is done outside the vehicle, there shall be sufficient lighting to provide at least 300 lux, focused on the work area. Standard lighting and associated wiring is permitted in vehicles used for transfilling liquid medical oxygen (no ATEX – atmosphere explosive - required).

5.2.12 Reversing Indicators

Where the vehicle has a cargo compartment that obscures the rearward vision of the driver, a reversing indicator, flashing light or warning bleeper should be fitted to the vehicle to warn the public when the vehicle is being reversed (unless national or local regulations control their use).

5.3 Purpose-built vehicles used for transfilling medical liquid oxygen

The following specifications are in addition to those specified in 5.2.

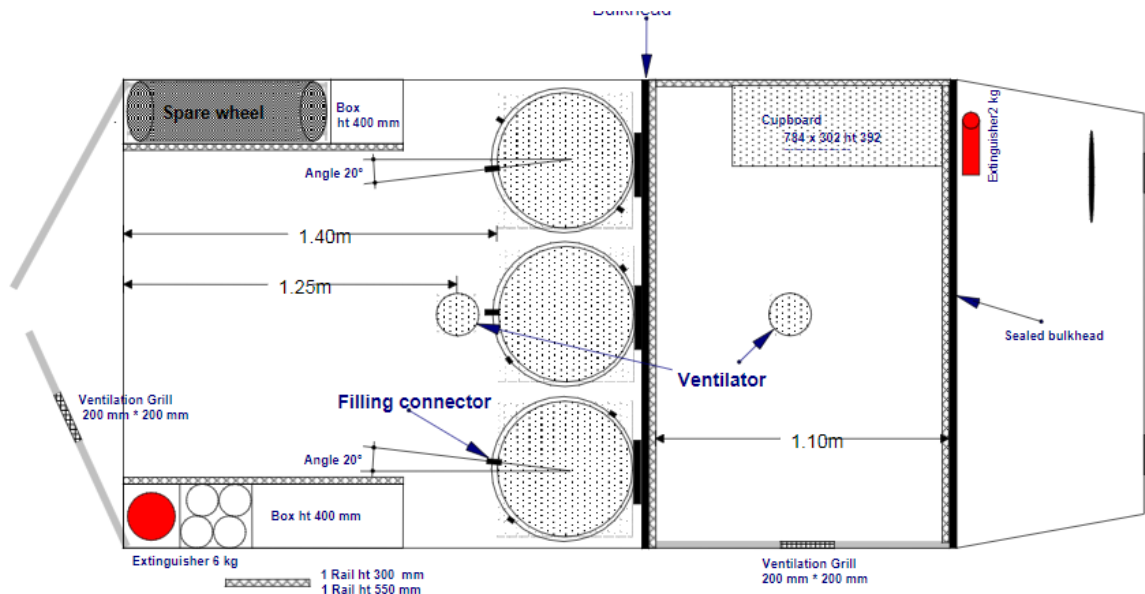


Figure 6 Examples of layout of vehicle used for transfilling

The mother tank shall be fixed into the vehicle and the anchor points shall be designed so that they meet the specifications in 5.2.4.

All mother tanks in the vehicle shall have their:

- vent lines, main pressure relief valves and bursting discs and vent-relief regulators (where fitted) piped leading outside the vehicle;
- if the mother tank is equipped with bursting disc(s) these shall be piped outside the vehicle separately from the other vent lines, to prevent it from damaging them; and
- thermal relief devices are permitted to relieve inside the vehicle compartment.

The vent and relief valve discharge pipework shall be sized correctly to ensure that the pressure within the mother tanks is maintained at a safe limit. These vent lines shall be designed and installed to prevent blockage due to weather conditions, pipework damage or other obstructions.

The vent discharge outlet shall be oriented slightly downwards to prevent blockage caused by freezing water in the vent line.

These vents shall be designed so that the discharge minimises impact on:

- vehicle exhaust system,
- vehicle tyres,
- vehicle fuel tank connection,
- road surfaces, and
- public adjacent to the vehicle.

During transport to prevent damage any equipment used in the transfilling of base units, e.g. pressure gauge, flow meter, shall be secured and the transfer hose(s) to be stowed securely (also to prevent contamination).

6 Minimum safety requirements for the operation of deliveries

6.1 General requirements

Distribution, transportation and transfilling shall be performed by trained, qualified personnel in accordance with written procedures. For further information refer to EIGA Doc 158 [6].

The inspection, examination and maintenance of any vehicle and mother tank shall meet all applicable European, national and local regulations, manufacturer's requirements and the requirements of this document. The most stringent requirements shall be applicable.

Inspection, examination and maintenance of the vehicle and the mother tank shall be performed by trained, qualified personnel. The work shall be carried out in accordance with written procedures.

If a vehicle is fitted with a mother tanks of less than 1000 litre capacity, the mother tank is defined by ADR as 'Closed Cryogenic Receptacles' and the vehicle is not considered as a 'tank vehicle'. For the periodic inspection and test of these receptacles, subsection 6.2.3.5.2 of ADR and Packing Instructions P203 are applicable.

Where the capacity of the mother tank is greater than 1000 litres, the mother tank is defined as a 'tank vehicle' and requires all relevant approvals as such. For the periodic inspection and test of these tanks, subsection 6.8.3.4. of ADR is applicable.

6.2 Driver training requirements

All drivers shall be fully trained in the operation of their vehicle and their competency assessed.

All drivers shall attend training in the transport of dangerous goods.

6.2.1 Vehicle operation training requirements

All drivers shall be trained in safe parking of vehicles and transfilling operations, see also Appendix 1.

All drivers shall be trained in the general driving and handling aspects of their job including:

- The correct category of driving license for the vehicle, including ADR certification if required
- Good Distribution Practices (GDP) [7] requirements, including pharmaceutical awareness,
- homecare therapy awareness with specific attention for patients requiring 24/7 therapy supply
- defensive driving,
- vehicle safety
- personal protective equipment requirements,
- manual handling requirements,
- oxygen enrichment hazards,
- high pressure gas hazards,
- liquid oxygen and cryogenic hazards,
- transfilling hazards and requirements for both the mother tank and the base unit, (where applicable),
- slips, trips and falls,
- cleanliness requirements with oxygen,
- hygiene requirements for homecare activities, and
- emergency response and the use of fire extinguishers.

The Homecare Service Provider shall have a quality management system to fulfil his obligation in terms of maintaining field personnel trained, by reassessing and retraining based on a defined training plan.

Where the amount of units carried exceeds 1000 ADR points (in case of oxidizing and asphyxiating gases the sum of the water volume in litre for gaseous products and the mass in kilogram for refrigerated liquefied products), subsection 8.2. of ADR on training of drivers applies. In this case drivers shall hold an ADR training certificate according to 8.2.1.1.

6.3 Minimum requirements for homecare delivery operations

6.3.1 Driver personal protective equipment (PPE)

The driver shall always wear safety shoes when handling cylinders, liquid oxygen vessels or heavy equipment.

When transfilling the driver shall wear cryogenic gloves and safety glasses or face shield.

The driver shall always wear appropriate protective clothing to protect the body, arms and legs. The protective clothing should be chosen to minimise oxygen retention and to be flame retardant.

The vehicle should carry products to allow the driver to disinfect their hands.

All PPEs shall be kept in good conditions to remain efficient.

Additional guidance can be found in EIGA Doc 136 [8].

6.3.2 Transport restrictions – road tunnels, ferries etc.

The HSP should plan the route in advance taking into consideration tunnels, ferries and other potential local restrictions.

6.3.3 No smoking

Smoking is not allowed inside and in the proximity of the vehicle. Further information EIGA SI32 [9]

When smoking away from the vehicle, the driver shall wait at least 15 minutes after transfilling before smoking, to allow any accumulation of oxygen in his clothing to disperse.

6.3.4 Transfilling Locations

When parking the vehicle to transfill medical liquid oxygen the driver shall select a safe location due to the properties of the delivered product. The areas listed below shall be avoided (non-exhaustive list):

- underground areas,
- drains / gullies / low lying areas,
- petrol stations,
- LPG storage tanks areas,
- bus stops, and
- near combustible material,
- blocking roadways or close to road junctions.

Transfilling is only permitted when an appropriate safety zone, for example 3 metres from the base unit vent valve outlet can be ensured for the following areas:

- heavily used pedestrian areas,
- busy shopping areas,

- close to pedestrian crossings.

6.3.5 Parking

A safe location shall always be selected for parking the vehicle unattended to ensure that there are no environmental risks to the products stored on the vehicle or the public in the vicinity of the vehicle.

The driver should consider the requirements to park away from open flames, heaters and air conditioning outlets.

The vehicle shall be locked at all times whilst parked unattended in areas where the public have unrestricted access.

The preferred location for overnight parking of the vehicle is at the Homecare Service Provider's premises. Where this is not possible, a risk assessment shall be carried out of the environment to establish a safe parking environment for the vehicle.

Appendix 1 details the preferred areas for overnight parking and details the areas to avoid where possible.

Where vehicles are parked overnight on the public road or where public have un-restricted access to the vehicle, all oxygen cylinders and tanks shall be positioned so that they cannot be seen from the outside of the vehicle.

If the oxygen cylinders and liquid oxygen vessels are removed from the vehicle they shall be stored securely in an authorized facility.

Vehicles carrying oxygen should not be parked in underground vehicle parking areas.

Where vehicles are fitted with a mother tank that does not have a vent regulator, the tank shall be vented to reduce the pressure to 2 bar(g) below the relief valve setting before parking, to prevent the relief valves from venting overnight.

6.3.6 Weight distribution

The weight distribution of the products carried on the vehicle shall be made to ensure that individual maximum permissible axle loads are not exceeded. Heavy loads shall be equally distributed and stored on the vehicle or in the front of the cargo compartment to ensure that the vehicle can be driven and stopped safely.

The maximum load of all products and equipment carried shall not exceed the vehicle manufacturers specified maximum load capacity.

All loads shall only be transported in the cargo compartment of the vehicle. Under no circumstances shall cylinders or liquid oxygen vessels be carried in the driver's cab, even when empty.

6.3.7 Fixtures and fittings

Large, non-permanent fixtures and fittings, such as pressure regulators and humidifiers shall be removed from cylinders and base units prior to transport to reduce the risk of leakage or damage to the equipment or injury to personnel.

Where the cylinder is designed to have a valve cap fitted, it shall be fitted prior to loading on the vehicle.

6.3.8 Housekeeping and hygiene

As the vehicle is being used for carrying medical devices and medical gas containers, it is essential that the interior of the vehicle be kept in a clean condition. The HSP shall determine the standards of hygiene

and cleanliness. It could be necessary to disinfect the interior of the vehicle following the collection of very dirty or suspected contaminated equipment, cylinders or vessels

6.3.9 Segregation of vehicle load

The driver shall segregate the used and unused cylinder, vessels and equipment on the vehicle in the appropriate designated or labelled areas.

HSP personnel shall use the appropriate PPE, possibly covering the container with a plastic bag, and adding a warning label. For further information refer to EIGA Doc 222 [10].

6.3.10 Manual handling

The requirement to use trolleys shall be identified by a risk assessment and should be in accordance with local manual handling regulations.

The use of a purpose-built trolley is recommended when carrying any weights of more than 25 kg (men) or 20 kg (women). For further information on ergonomic handling and carrying, see ISO-11228 [11]

Electrically driven trolleys are recommended when moving loads up or down stairs.

Cryogenic vessels can only be carried inside elevators when they are not venting.



Figure 7 Example of a lift for loading and unloading a base unit of the vehicle

6.3.11 Driver's Checks

The driver shall carry out a check on his vehicle before starting the deliveries, that includes:

- load is secure,
- tyres are in good condition
- safety equipment is available,
- no obvious defects,
- braking system is working properly.
- correct documentation is available:
 - correct transport documentation and product safety data sheets,
 - vehicle and driver documents,

- relevant work instructions.
- Where applicable the check shall include that:
 - all liquid and gas off take valves and pressure build up valves on vessels are firmly closed;
 - there are no gas leaks;
 - the pressure of mother tank(s) is at least 1 bar below the relief valve pressure;
 - the cryogenic vessels do not have excessive ice on the outer wall indicating a possible bad vacuum;
 - all valve caps (if required) are in place, and
 - where used, the weight scale used for filling the base units shall be calibrated to national standards.

Any vehicle or equipment damage or fault shall be reported as soon as it is identified and notified to the Supervisor.

If the vehicle pipework has a gas leak, the vehicle shall not be used until the Supervisor has been informed and the appropriate instructions have been given.

The vehicle engine shall be switched off and parking brake applied during loading, unloading and transfilling.

To reduce the risk of oxygen atmosphere enrichment in the van the following precautions are recommended: If the vehicle has been parked for a long period (such as a lunch break or overnight) with an oxygen load in the cargo compartment, before starting the engine, the driver shall open all the doors of the compartment in order to ensure ventilation. Also, the driver's cabin shall be ventilated. Some experiences indicate that opening doors for 3 minutes reduces substantially the enriched oxygen atmosphere.

6.4 Vehicles used for transfilling oxygen

Mother tanks shall not be vented during driving (venting through the vent regulator is allowed). Venting is only allowed when and where it can be done safely.

Vented liquid or gas shall be kept away from combustible materials and the vehicle's fuel tank connection, vehicle tyres and from areas where the public has unrestricted access.

Similar to EIGA BN18 [12] the activity of transfilling by the driver is exempted under ADR.

6.4.1 Transfilling the mother tank

The transfilling procedures for refilling the mother tank shall take into account any specific requirements specified by the tank manufacturer.

The transfilling hose shall always be purged prior to transfilling.

Whenever possible it is recommended that the mother tank should not be filled more than 72 hours before the vehicle is scheduled to make deliveries.

Any operator who is responsible for filling the mother tank shall be suitably trained and qualified.

The operator filling the mother tank shall remain in attendance and supervise the filling throughout the transfilling process.

During the filling process, the operator in attendance shall check for leaks on the pipework and the connection between the filling point and the transfilling hose.

To rectify the leak, the hose / pipework shall first be depressurised and the joint remade. If the leak cannot be rectified:

- replace the filling hose and label the faulty hose to prevent reuse / identify for repair if the hose is leaking, and
- immediately bring to the attention of the Supervisor if the leak occurs on the fixed pipework on the mother tank.

When transfilling is carried out inside the vehicle, the vehicle shall remain stationary with the engine turned off during the transfilling process. A system shall be in place to manage the control of the vehicle such that it is not driven away or moved whilst the transfilling hose is connected such as wheel chocks, procedure to hand over the engine keys, interlock between the engine/braking system and the cargo compartment external access door(s).

All cargo compartment doors shall be opened during the transfilling process. At the end of the transfilling procedure, after the transfilling hose has been disconnected, vapours from the filling process shall be allowed to disperse for at least 3 minutes before starting the vehicle's engine.

Transfilling of medical liquid oxygen shall not be carried out on asphalt or any other combustible material.

The transfilling area shall be adequately lit.

The operator shall stay away from the vent outlet during the transfilling process.

The operator shall check that all liquid and gas off take valves and pressure raising valve on the tank are firmly closed, that no ice formation on the outer wall of the mother tank(s) has developed and that valves, piping and fittings are free from leaks.

If the transfilling hose(s) are kept in the vehicle, they shall be kept clean and stored safely to protect them from damage during transport.

6.4.2 Transfilling base units

Base units may either be filled in a filling depot and transported full to the patients, or they can be filled from the mother tank at or near the patients' home, according to national regulations.

The procedure for transfilling the base unit shall take into consideration specific requirements by the base unit manufacturer. All operators driving the vehicle and transfilling the base units shall be trained in the various operations required and informed of the risks associated with transfilling medical oxygen at the patient's premises.

During the transfilling process:

- the transfilling hose shall always be purged prior to transfilling;
- the connector of the base unit shall be dried with a dry tissue;
- the operator filling the base unit shall remain in attendance throughout the transfilling process to control it;
- the operator shall avoid standing in oxygen vents to avoid oxygen enrichment of clothing, and
- the vehicle shall remain stationary with the engine turned off.

At the end of the filling process, oxygen vented during the filling process shall be allowed to disperse for 3 minutes before starting the vehicle's engine.

When base units are filled inside the vehicle cargo compartment, the rear doors shall be fully opened (90 degrees) to ensure adequate ventilation. Unauthorised persons shall be kept outside the controlled

area of at an appropriate distance (for example at least 1.5 metres) from the transfilling point by signalling properly (for example with cones). The base unit vent valve outlet shall be directed out of the vehicle. Where side operated sliding doors are used, they shall be kept fully open.

When base units are filled outside the vehicle, a controlled area of at least 1.5 metres from the transfilling position is to be restricted by reflective cones or equivalent and the operator shall not allow unauthorised persons in this area. If this condition cannot be maintained throughout the transfilling process, the filling shall be completed inside the vehicle or carried out at another safe location.

When filling is carried out outside the vehicle on asphalt or similar combustible materials, a stainless steel or aluminium catchment plate, of minimum 600mm x 600mm shall be used, which is designed to prevent saturation of the low-lying ground.

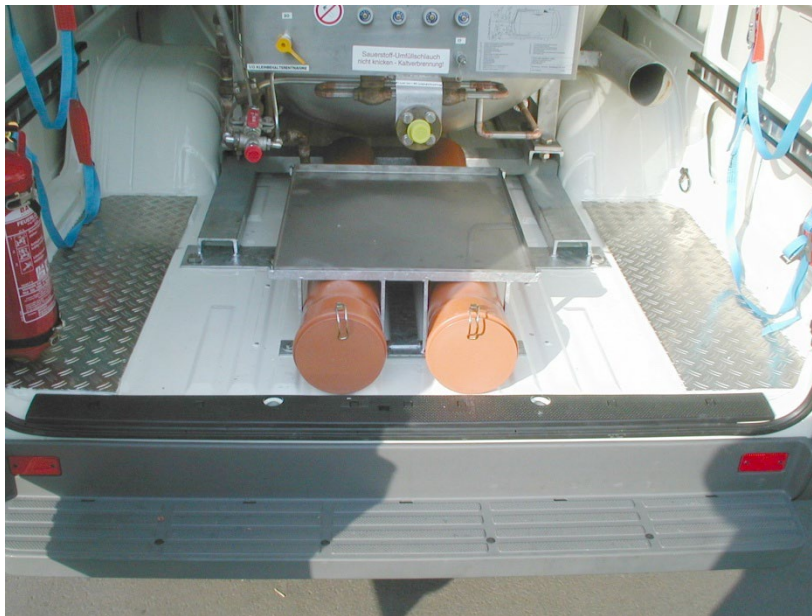


Figure 8 Typical storage arrangements on transfilling vehicle with stowage for cryogenic hoses and plate used for filling vessels outside vehicle

The operator shall stay outside the vapour cloud.

After the transfilling process is complete, the operator shall check that all liquid and gas off take valves and pressure raising valve on the tank are firmly closed, that no ice formation on the outer walls has developed and that valves, piping and fittings are free from leaks.

The transfilling hose(s) inside the vehicle shall be kept clean and stored safely to protect them from damage during transport. After venting the transfilling hose the vent valve shall be closed to prevent the ingress of moisture / formation of ice on the inside of the hose.

7 Actions in case of vehicle emergency

The HSP establishes procedures to cover emergencies such as fire or any other hazardous events that can occur.

Emergencies to be considered include:

- cryogenic liquid spillages;
- relief valve lifting or bursting disc rupture (for example in the public street);
- ice blockages of vent lines or valves;

- cryogenic burns, and
- problems with inhalation.

In case of an incident the driver shall be instructed that cylinders and base units should only be removed from the vehicle when it is safe. If the driver considers it is not safe to do so he should warn the public to stay well clear of the vehicle. As soon as the police or fire brigade are in attendance, he should hand over responsibility to the appropriate authority.

In case of a fire, the cylinders and cryogenic tank(s) shall be kept cool by spraying with water, but not directly on the safety relief system if this can be avoided. When the fire brigade are notified of an incident with a vehicle, they shall be notified about the nature of the vehicle load and specifically warned of the presence of high-pressure cylinders on the vehicle.

The company emergency procedures shall be followed in case of accidents, such as road accidents. All drivers shall receive appropriate training in the procedures to be followed in the event of an incident with the vehicle or the load being carried.

Persons who have been exposed to an oxygen-enriched atmosphere shall be instructed not to smoke or go near naked flames, sources of ignition or sparks until they have ventilated their clothes in an area where there is no oxygen enrichment. A ventilation period of at least 15 minutes is needed, with movement of the arms and legs and with coats unbuttoned.

Where a large liquid oxygen spillage occurs inside the vehicle, the spillage should only be isolated when it can be done safely without endangering the operator. The vehicle shall be left with the engine turned off and well ventilated by opening all cargo doors. Any materials which can become easily enriched with oxygen, shall be allowed to ventilate in a normal atmosphere for several hours. Vapours shall be prevented entering sewers, pits and trenches.





Figure 9 Rollover incident

The public shall not be allowed to enter the area where there has been an oxygen spillage until it has been determined that all of the gas has been dispersed.

8 Inspections, maintenance and examination of vehicles

8.1 General requirements

8.1.1 Trained personnel

Trained, qualified personnel shall perform any inspections, examinations or maintenance carried out on the vehicle. They shall be familiar with the precautions necessary to be taken when working near compressed gas cylinders and cryogenic vessels.

8.1.2 Work instructions and records

Work shall be carried out in accordance with approved written procedures.

Records of inspections and maintenance shall be kept during the time the vehicle and/or equipment is in use.

8.1.3 Vehicle maintenance when carrying oxygen

The preferred safe practice for the maintenance and repair of a homecare oxygen vehicle is to remove all of the cylinders and vessels from the vehicle and to empty and make safe any fixed installed vessel on the vehicle.

Where it is impracticable to remove all of the product from the vehicle, any hot or cold maintenance work shall be carried out in the open air to avoid the possibility of an oxygen enriched atmosphere in the garage / workshop.

Where this is not possible, the loaded vehicle can only be maintained in the garage / workshop under very strict controlled conditions, as described in 8.5.

The requirements detailed in 8.3 and 8.4 are valid for all maintenance conditions.

Maintenance activities on homecare oxygen vehicles have specific additional risks due to the nature of the presence of oxygen.

1. Hot and cold works

Hot work is a process that can be a source of ignition when flammable material is present or can be a fire hazard regardless of the presence of flammable material. Oxygen enriched atmosphere dramatically increases these risks.

Common hot work processes include welding, soldering, cutting, brazing burning and the use of powder-actuated tools or similar fire producing operations.

Grinding and drilling may be classified as cold works, but however possess the same risks as hot works when in oxygen enriched atmosphere.

Any work that applies heat or causes sparks can create risks when undertaken in oxygen enriched atmosphere.

2. Risk of spillage

When a mother tank is installed, the risk of liquid oxygen spillage should be considered.

This is particularly:

- when there is a defect of the mother tank itself, its piping is present or instrumentation;
- in case of any works in the cargo compartment, by accidentally damaging the tank or its piping; or
- in case of unauthorized manipulation by people unfamiliar to cryogenic vessels.

3. Activities using flammable products

When using flammable products during the maintenance works, the risks of an oxygen enriched atmosphere shall be considered.

This includes adding or replacing engine oil, applying grease or flammable cleaning products (e.g. alcohol-based cleaners).

4. Work environment

It shall be considered that additional risks occur when the maintenance activities are done in a non-controlled environment (e.g. external garage where staff isn't familiar with the specific risks of oxygen).

8.2 Approval of maintenance facilities

Any garage or workshop used to maintain a purpose-built vehicle designed for the carriage of medical oxygen for homecare use, shall be approved by the HSP.

Approval shall only be given on the basis that the garage or workshop has:

- a copy of the relevant product safety data sheets;
- appropriate control and precaution procedures to work on a vehicle fitted with a storage vessel;
- an appropriate permit to work scheme;
- emergency action plan in place to implement the requirements of this document;
- clear instructions for action in case of product leaks and fires, and
- met the conditions listed in 8.4 and, where applicable, those in 8.5.

8.3 General conditions for vehicle maintenance

8.3.1 Pre-work inspection

All equipment shall be made safe and approved by a trained and qualified employee of the HSP (or subcontractor) before any hot or cold work is carried out on the vehicle in accordance with the permit to work system. If any defects with the mother tank are suspected, such as cold spots or continual ice formation on the vessel or pipework, then it shall be emptied and inerted prior to release for maintenance work.

8.3.2 Preparation of the mother tank

Ideally, the mother tank is emptied as much as possible before the maintenance work. Should it be not feasible, all valves on the mother tank shall be closed whilst in the maintenance facility. The only exception is where a valve is fitted on the backpressure vent regulator circuit. This valve shall be left open as this provides an early warning of pressure increase, when the vessel can be safely controlled by manual venting.

8.3.3 Vehicle / vessel signs – mother tank inerting

During transit, to or from the maintenance facility, vehicles shall display the appropriate product labelling (for example empty or not, inert gas). Where the vessel has been purged with an inert gas, the

conversion process shall be controlled by a Permit to Work procedure and the vehicle and/or vessel(s) signs shall reflect the change of service.

Where the vessel has been purged with an inert gas, the relevant refilling procedure shall be followed to ensure that the tank is refilled with liquid oxygen and certified before the mother tank is used for filling base units.

8.3.4 Maintenance completion

When the maintenance work has been completed, the vehicle or equipment shall be inspected to ensure that:

- the planned repair or inspection has been completed;
- mechanical condition of the vehicle is suitable for use against a planned checklist;
- any permit to work procedures have been formally completed (and any oxygen monitor used removed);
- The maintenance facility supervisor should sign the checklists to demonstrate that the inspections have been completed to handover the vehicle to the driver.

8.4 Maintenance facility conditions

The maintenance facility supervisor shall be responsible for ensuring that:

- smoking is prohibited in the maintenance facility ;
- flammable liquids, such as solvents, oils and grease are kept away from the vehicle. Only amounts required for servicing and maintaining the vehicle shall be allowed in the vicinity of the vehicle.

8.5 Indoor maintenance of vehicle with liquid oxygen present

8.5.1 Maintenance facility training

Where vehicles are required to be maintained in the workshop with liquid oxygen in the mother tank, the maintenance facility shall be provided with sufficient information to ensure that all personnel involved with the vehicle maintenance are aware of the special hazards associated with the product.

8.5.2 Ventilation

The maintenance facility shall have adequate ventilation of the area where the work is being carried out to ensure that there is no build-up of oxygen if a release of gas occurs.

A recommended solution is to have the garage doors open for the period that the vehicle is in the workshop. If this is not possible, due to ambient conditions, then an air circulation fan to ensure good mixing within the workshop is acceptable.

Whilst the vehicle is in the maintenance facility, the door of the oxygen compartment(s) shall be opened to allow the interior to be ventilated.

8.5.3 Hazard warning sign

A hazard warning sign, identifying the hazards of liquid oxygen, shall be displayed whilst the vehicle is in the maintenance facility. This sign shall include a 24-hour emergency telephone number for contacting the medical Healthcare Service Provider.

8.5.4 Precautions during hot work

Where hot work close to the mother tank, pipe work or pipe supports is necessary, it shall be controlled by a permit to work procedure. The mother tank and pipe work shall be emptied and purged typically with nitrogen and the ends of the pipework blanked prior to starting work.

8.6 Preventative and corrective vehicle maintenance

8.6.1 Automotive maintenance

The type and frequency of maintenance of the vehicle and tyres shall follow the vehicle manufacturer's recommended procedures and the maintenance procedures of the HSP.

8.6.2 Vehicle and cargo compartment checks

It is recommended that every 6 months, the homecare service provider or their nominee completes the following maintenance checks and record the results:

- the structure of the cargo compartments and specifically the floor as well as any shelving is in good condition;
- the vehicle ventilation system is working and free from obstruction;
- the load security system is in good condition, including the condition of any straps;
- the fixings for the mother tank to the vehicle are not damaged or corroded;
- all the doors are opening and closing correctly;
- where installed, the lift is functioning correctly, and there are no leaks in case of a hydraulic system;
- electrics such as lighting or lift controls are clean and not damaged;
- labelling of the mother tank and the interior and exterior of the vehicle are conform to specification and legislation;
- all valves, gauges and piping, not belonging to the mother tank, but part of the cryogenic transfilling system and the cryogenic transfer hoses with their thermal relief valves, where fitted, shall be visually externally inspected;
- the mother tank, associated pipe work, relief valves (including thermal relief valves), bursting disc, vent valve and vent regulator (where fitted) shall be inspected for external visual damage, leaks or blockage, and
- the safety equipment carried in the vehicle shall be checked to ensure that it is in good condition and where applicable within its test or expiry date.

The homecare service provider or their nominee shall, by regular and recorded audits, ensure that vehicles are:

- in a safe operating condition,
- maintained to a standard that meets both the legal and company requirements.

The frequency of these checks shall be defined within the company procedures.

9 Inspections, maintenance and examination of mother tanks

9.1 ADR periodic inspections

The statutory periodic inspections of the mother tanks shall be carried out under the supervision of a notified body in accordance with the requirements of the ADR regulations. Additional inspections according to ADR shall be done after repairs if required.

Suitable records shall be retained for the lifetime of the equipment.

9.2 Non-ADR periodic inspection

On top of daily routine checks, it is recommended to check the mother tank every 12 months

- on the correct functioning of all valves and gauges;
- by external inspection that the thermal pressure relief valves are not damaged, corroded or blocked and their pressure setting correct, and
- the date plate and other markings and labelling for correct content and for signs of damage and legibility.

The results shall be recorded and the records retained for the lifetime of the equipment.

10 Repairs to the mother tank

Mother tanks shall only be repaired by approved maintenance facilities.

Any repairs to the mother tank shall be recorded and the report retained with the test certificates for the vessel.

Repairs shall be in accordance with the manufacturer's instructions.

Any maintenance on a mother tank containing oxygen should be performed in a well-ventilated setting. This activity shall only be carried out under the control of a permit to work.

Water may be used to defrost any isolating valves on the mother tank. Water shall not be used to defrost relief valves.

The mother tank contents gauge and the pressure gauge need to be verified regularly but do not require to be calibrated to national standards because they are for indication only and not for invoicing.

After repair, an assessment shall be made to determine whether it is necessary to reclean the vessel or pipework to meet the oxygen cleanliness standards.

11 Repair work to the cryogenic transfer hoses

Cryogenic transfer hoses and couplings shall be visually externally inspected for excessive wear or damage prior every transfilling operation. Worn or damaged parts, such as seals shall be renewed as necessary.

If leaks are identified during the filling process that cannot be rectified, they shall be removed from service, labelled and reported to the supervisor.

12 References

- [1] European Agreement on the Carriage of Dangerous Goods https://www.unece.org/trans/danger/publi/adr/adr_e.html
- [2] EN 1251 *Cryogenic Vessels – Transportable Vacuum Insulated Vessels of not more than 1000 litres volume* www.cen.eu
- [3] *Guide to Good Manufacturing Practice*. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
- [4] EIGA Doc 04 *Fire Hazards of oxygen and Oxygen Enrichment Atmospheres* www.eiga.eu
- [5] CGA: SB-9 Recommended Practice for the Outfitting and operation of Vehicles used in the Transportation and Transfilling of Liquid Oxygen used for Respiration. www.cga.com
- [6] EIGA Doc 158 *Good Homecare Practice* www.eiga.eu
- [7] Guidelines on Good Distribution Practice of medicinal products for human use, 94/C 63/03 https://ec.europa.eu/health/human-use/good_manufacturing_distribution_practices_en

- [8] EIGA Doc 136 *Selection of personal protective equipment* www.eiga.eu
- [9] EIGA SI 32 *Restricted Use of Electronic Cigarettes with Oxygen Therapy* www.eiga.eu
- [10] EIGA Doc 222 *Guidelines for Cleaning Externally Contaminated Medical Gas Containers* www.eiga.eu
- [11] ISO-11228 *Ergonomics- Manual handling- Part 1: Lifting and carrying.* www.iso.org
- [12] EIGA BN18 *Connecting Packages to Customer Processes by Vehicle Crew Members* www.eiga.eu
- [13] EN 13501 *Standard for fire classification of construction materials: Overview of performance classes & criteria.* www.cencenelec.eu

13 Additional references

- [1] EIGA Doc 99/Part 1 *Good Manufacturing Practice Guide Part I for Medical Gases*
- [2] EIGA Doc 98 *Safe Supply of Transportable Medical Liquid Oxygen Systems by Homecare Service Providers*

Appendix 1 - Overnight / long term parking of homecare vehicles containing supplies of medical oxygen

Best areas for parking

Locations in descending order of preference for parking.

- Secure private parking area with no public access (Fenced area with controlled access such as company's own facility)
- Private parking with no public access (Not fenced with controlled access such as driver's home)
- Unsecured parking area with no public access (Non fenced area with public access denied such as hotel car parks)
- Secure public parking with barriers (such as closed public parking)
- Unsecured public parking with no restriction to public access (such as public parking areas at supermarket)
- Roadside parking on major road in an approved parking area (in a lay by on major road)
- Roadside parking in rural area (in a country area / low population)
- Roadside parking in urban area (in a town area with housing)
- Roadside parking in town centre area (in a town centre area with shops etc.)

Locations to avoid and to limit third party consequences of incidents

Locations in descending order of risk.

- Underground parking
- Hospitals
- Campsites and caravan parks
- Cinemas and theatre type areas
- Petrol stations
- LPG storage tank(s) areas
- Stadiums
- Festival / park areas
- Shopping precincts
- Schools
- Refuse disposal areas