



DESIGN AND OPERATION OF VEHICLES USED IN MEDICAL OXYGEN HOMECARE DELIVERIES

MGC Doc 128/12/E

Revision of MGC Doc 128/10

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Amendments to 128/10

Section	Change
5.3.12	More detailed requirements for drivers checks to reduce risk of build-up of oxygen in the vehicle
11	References moved to new section to align with EIGA Style manual

Note: Technical changes from the previous edition are underlined

1 Introduction

The provision of oxygen therapy in the home for patients requiring supplementary oxygen in Europe is growing every year.

Patients are prescribed medical oxygen by their doctor or clinician for use at home and this therapeutic gas, with the related medical devices, is provided to the patient's home. The delivery of the medical oxygen with the associated therapy equipment is made using purpose designed delivery vehicles by drivers either employed by the homecare service providers or by independent contractors on behalf of the homecare companies.

This document describes the basic design principles for the vehicles used for the delivery of medical oxygen and associated therapy equipment. It covers the design and safe operation of vehicles used for delivering all modes of supply of medical oxygen.

The quality system management requirements concerning these kinds of vehicles can be found in the Good Homecare Practice, MGC Doc 158[1]

2 Scope and purpose

2.1 Scope

The scope of this document covers the design and operation of the vehicles used to:

- deliver medical oxygen supplies and medical devices directly to the patient at home or in the healthcare facility.

The scope also includes:

- the minimum safety design specifications for the outfitting of the vehicles, including the anchorage of a medical liquid oxygen tank inside a vehicle;
- the filling of the tank installed inside the vehicle; and
- the 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 healthcare service provider's operations inside the patient's home or the healthcare facility;
- those vehicles used for homecare service where only occasionally oxygen cylinders or base units are transported;
- standard vehicles used by the homecare patient;
- Transport of Dangerous Goods Regulation 'ADR' [2] 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 "Cryogenic Vessels – Transportable Vacuum Insulated Vessels of not more than 1000 litres volume"[3];
- the Good Manufacturing Practice (GMP) 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 medical healthcare service provider.

This guidance covers the:

- design of the outfitting of the load compartment and the cabin of the vehicles;
- operation of delivering gaseous and liquid oxygen, and
- transport of medical devices and medical oxygen supplies.

In most cases these vehicles carry quantities of medical oxygen below the level defined in the ADR regulations.

This document is applicable to purpose built homecare oxygen therapy vehicles, irrespective of whether they are covered by the requirements of ADR.

2.3 Definitions

Medical Healthcare Service Provider(MHSP)	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.
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.
Transportable Liquid Oxygen System (TLOS)	The base unit and the portable unit that can be filled from the base unit.
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.
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.
Transfer Hose	A transfer hose is a flexible cryogenic hose 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.
Operation:	For homecare vehicles refer to the practice of transporting, filling, transfilling and handling the different medical oxygen packages on the road.

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.
Hot work:	Any work requiring brazing, welding, cutting or grinding.
Maintenance of vehicles:	Any hot or cold repair to the vehicle's cab or cargo compartment or any automotive maintenance.
Purpose Built Vehicle:	Any type of vehicle that has undergone modifications to ensure, as a minimum, efficient ventilation and load security.
Service:	The action of installation or removal and replacement, preventative maintenance, repair, technical verification of equipment.
Transfilling:	The operation of pressure transferring a cryogenic liquid from a larger tank into a smaller tank.
Mother tank:	A transportable cryogenic vessel constructed as a minimum to ADR requirements and with a typical capacity of between 180 litres and 2000 litres, water capacity.
GMP	Good Manufacturing Practice of Medicinal Gases [4]
GDP	Good Distribution Practice of Medicinal Products [5]
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 but marked out floor areas, partitions, barriers and signs could be used

3 Types of Healthcare Delivery Operations

The operations of the Medical Healthcare Service Providers are diverse.

Besides the services for oxygen therapy there are many other patient related therapies, such as sleep, ventilation and nutrition therapies, that can be supplied by the Medical Healthcare Service Provider, sometimes using the same vehicle. This means that, although the transport of oxygen in gaseous and liquid form is the main objective of this document, the transport safety requirements for the other therapies are also taken into consideration.

The vehicles used by the Homecare Service Provider can be designed for the:

- supply of medical oxygen cylinders;
- supply of medical liquid oxygen containers on a 'full for empty' basis. (These units are filled at the Healthcare Service Provider facility.);
- supply of oxygen concentrators and other medical devices;
- transfilling of medical liquid oxygen from the delivery vehicle at the patient's home. (The base units can be filled, either inside the vehicle or outside in the public street.);
- delivery of accessories for medical devices and disposable items;

- limited maintenance and/or cleaning of medical equipment;
- combinations of the above.

The design of the vehicles used by the Medical Healthcare Service Provider are normally based on standard vehicles, but modified to meet the requirements of this document and referred to 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 operator protection and local labour rules.

4 Design principles for purpose built vehicles

4.1 General specifications

The basic requirements for the design of vehicles used by the Medical Healthcare 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 packages shall be physically segregated from combustible material, such as fuel;
- full and empty equipment shall be segregated and identified to prevent an empty container being supplied for patient use;
- dirty and suspected contaminated equipment 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 load compartment shall use non-combustible materials;
- the vehicle design and material selection for the load 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.

This document specifies the minimum requirements for the design of the vehicle as defined in the scope.

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. This shall include any temporary or hired vehicle used for the delivery of medical oxygen supplies for homecare use.

The requirements in this document specifically relate to the carriage of all types of medical oxygen supplies used for homecare use. There could be additional requirements necessary where the vehicle is used to carry other medical gas supplies. In this case the risk assessment shall consider the requirements for the safe transport and delivery of the different medical gases.

The EN ISO 14971 "Medical Devices – Application of Risk Management to Medical Devices" can be used as the basis for this risk assessment.[6]

4.2 Specific requirements

4.2.1 Driver's cab

There shall be a physical separation between the driver's cab and the load compartment to prevent the accumulation of oxygen in the driver's cab in the event of an oxygen enriched atmosphere in the cargo compartment.

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

- a sealed bulkhead between the driver's cab and the rear compartment. Fixed windows are permitted in the bulkhead;
- 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 4.2.4,.

4.2.2 Cargo compartments

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

4.2.3 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.

Cargo compartment containing cylinders or cryogenic liquid vessels shall be equipped with effective natural ventilation.

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 SB-9 [7].

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.



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

4.2.4 Load security

The vehicle manufacturer or vehicle body manufacturer shall be consulted on the requirements for the weight distribution in the vehicle and the maximum loads suitable for the vehicle. 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 of at least 2 g downwards and horizontally and 1 g upwards. 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 liquid containers may be secured singularly or as a group with a single security system. Medical oxygen 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. Where required, the securing points shall be located at 1 or 2 levels (dependent on the size of the containers being transported) and typically should be between 300 and 900 mm above the floor level.

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 wide straps with protection between the locking fastener and the container walls;
- application of rubber/plastic strips on the fastening rails.

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, themselves with equipment 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.



Fig 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 load 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 is calculated as $\frac{1}{3}$ of the braking load of the straps. For example, if the braking load of the straps used is 1.200 kg, the fasten load will have a weight of 400 kg.

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

Fragile medical devices, such as sleep apnoea (CPAP) machines, shall be protected against damage during transport on the vehicle.

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



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

4.2.5 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 so that any spillage of liquid oxygen will not affect the medical oxygen cylinders.

This could be achieved by locating the liquid vessels in separate compartments, behind a shield, with the cylinder in a closed compartment / rack or by maintaining adequate distance between the medical oxygen cylinders and the liquid oxygen vessels.

Where medical devices are carried in the same vehicle as medical oxygen cylinders and / or liquid medical oxygen containers, they shall be protected to ensure that they are supplied to the patient in a clean condition. Where devices or containers are collected from the patient and there is a risk of cross contamination with replacement items due to items having gross contamination or being very dirty, there shall be sufficient space or segregation to ensure that the new equipment is supplied in a clean condition. See also 5.3.10,.

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 tamper evident seal identifies full cylinders. The contents indicator can identify the full or empty base units.

In case absorbent combustible equipment (such as mattresses) is transported with either liquid or compressed oxygen, it shall either be located in the vehicle away from the oxygen source or protected so that it does not become enriched with oxygen in the event of an oxygen leak. Consideration shall be given to transporting this type of equipment in a separate compartment.

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. Under no circumstances shall any of the load areas be used for carrying spare fuel in containers or oils and grease.



Fig 4 Typical segregation of liquid cylinders with full and empty cylinders secured separately

4.2.6 Load 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. Each cargo compartment door shall have the means to be opened from the inside of the vehicle.

Risk Management 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. This will be dependent upon the height of the floor in the load area and the weight of the containers or equipment being handled and the handling frequency. The lift can be mounted at the side, underneath or inside the vehicle or at the back of the vehicle and can also be used as the rear door.

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.

Where it is required for the driver to enter the load area of the vehicle or to handle full and empty containers and cylinders or to carry out equipment maintenance activities, the vehicle shall be designed to ensure that there is sufficient height for the operator to stand upright.

Where medical equipment is required to be maintained and cleaned / disinfected on the vehicle, it shall have sufficient space assigned to this activity to ensure that it can be carried out effectively, safely and without contaminating any other items carried on the vehicle. Because most disinfecting products are flammable, they shall be kept away from oxygen package and preferable be stored outside the oxygen vehicle compartments.

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.

The load area should be designed so that access to high-pressure cylinders carried is as close as possible to the doors.

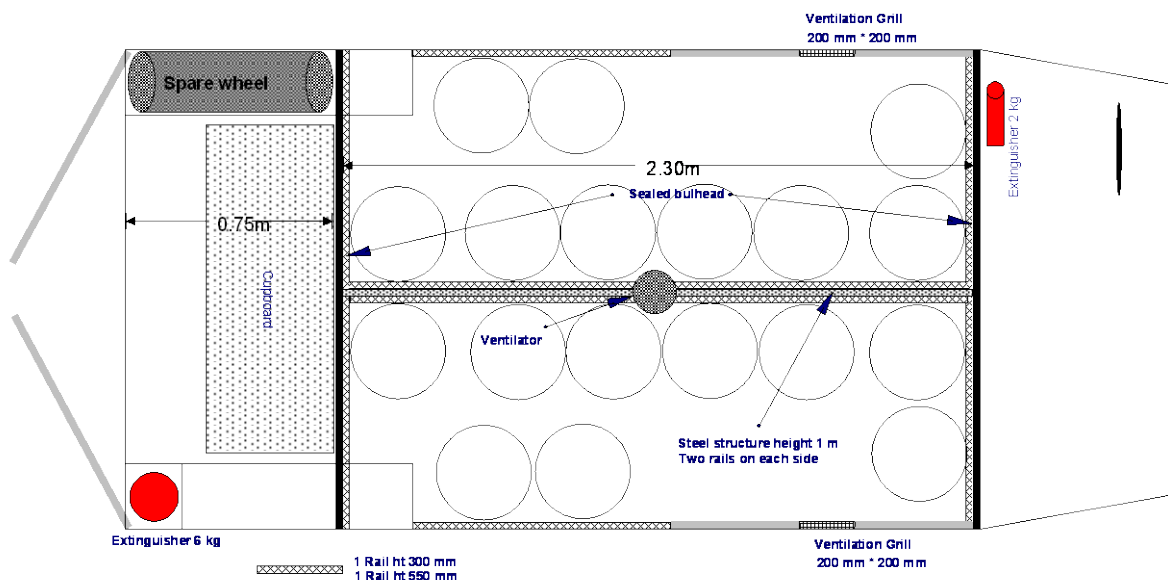


Fig 5 Typical layout for a homecare delivery vehicle used for supplying full for empty

4.2.7 Selection of materials

The materials used in the construction of homecare delivery vehicles for the cargo compartment(s) and the frames of cupboards shall either be of metal or of a non-flammable construction. The shelves of cupboards and racking system for small cylinders may be made of light materials in order to keep the overall vehicle weight as low as possible.

Absorbent combustible materials, such as wood and carpeting, shall not be used for the cladding of internal surfaces of the cargo compartment.

The flooring shall be made of metal 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 (typically striated or smooth aluminium).

In areas in the cargo compartment, where the operator has access, the floor shall have an anti-slip surface.

4.2.8 Fire extinguishers

The vehicle transporting oxygen shall carry at least two fire extinguishers:

The load area shall be fitted with at least one 6 kg powder type fire extinguisher. The extinguisher shall be located just inside the load area adjacent to the rear door as this allows access even when the vehicle is on its side.

The driver's cab shall be fitted with at least one 2 kg powder type fire extinguisher, fixed accessible either from within or outside the vehicle, so that it is available to be used for an engine fire.

All extinguishers shall be regularly inspected and carry a label to indicate when they are next due for inspection.

4.2.9 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 signs 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 may be appropriate to remove the cigarette lighter and ashtray from the driver's cab.

Inside the load carrying section of the vehicle, the following signs shall be displayed:

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

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

- No Smoking
- Oxygen
- Compressed Gas and Oxidising Hazard diamonds, where allowed

Where required, the emergency / safety instructions shall be available and may be displayed in the load area.

It is left to the Medical Healthcare Service Provider to display a label detailing the gases being transported for the benefit of the emergency services in case the vehicle is involved in a fire or accident.

It is recommended that an emergency telephone number is displayed.

4.2.10 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
- No smoking sign, for use when transfilling medical liquid oxygen
- Safety cones or warning ribbon to mark out a safety zone in case of e.g. a traffic accident.
- Reflective jacket(s)
- Two reflective cones or similar when transfilling base units outside the vehicle
- Stainless steel or aluminium plate of 600 x 600 mm to allow for possible spillage of liquid to evaporate quickly (for use when base units are filled outside the vehicle on asphalt)

This equipment shall be stored and secured safely.

A separate box may be provided for carrying specific tools required to carry out any routine operations. These tools shall be kept separate from the cargo.

4.2.11 Lighting

Each vehicle 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.

4.2.12 Reversing Indicators

Where the vehicle has a load 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).

4.3 Purpose built vehicles used for transfilling medical liquid oxygen

The following specifications are in addition to those specified in 4.2.

Where the vehicle is used for transfilling base units in or outside the vehicle, providing the vehicle is appropriately designed, it may also carry:

- Base and portable liquid oxygen units
- High pressure cylinders
- Medical devices and disposable items.

The vehicle used for transfilling liquid oxygen base units may be designed so that, either the mother tank is permanently fixed on the vehicle or removable and filled out of the vehicle prior to loading.

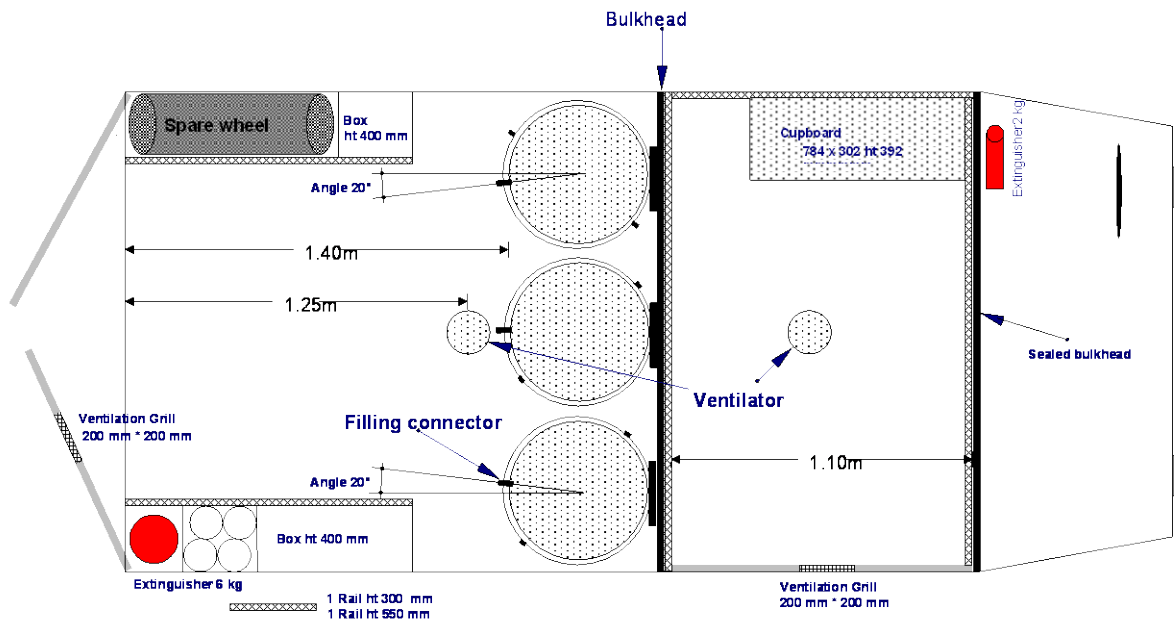


Fig 6 Typical layout of vehicle used for transfilling

Where the mother tank is filled outside the vehicle, specific attention shall be given when strapping or fixing the mother tank(s) into the vehicle to ensure that the security system meets the g forces specified in 4.2.4.

Where the mother tank is permanently fixed into the vehicle, the anchor points shall be designed so that they meet the g-forces specified in 4.2.4.

All mother tanks either permanently mounted or temporarily fitted in the vehicle shall have their:

- vent lines piped outside the vehicle
- main pressure relief valves and bursting discs permanently piped outside the vehicle.
- vent-relief regulator (where fitted) permanently piped outside the vehicle
- bursting disc(s) piped outside the vehicle separately from the other vent lines, to prevent it from damaging.

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 water in the vent line freezing.

These vents shall be designed so that the discharge does not impinge on:

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

There shall be means to allow the transfer hose(s) to be stowed securely during transport to prevent damage and contamination.

Any equipment used in the transfilling of base units, e.g. pressure gauge, flow meter, shall be secured to prevent damage during transit.

5 Minimum safety requirements for the operation of deliveries

5.1 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.

Distribution, transportation and transfilling shall be performed by trained, qualified personnel in accordance with written procedures.

The inspection, examination and maintenance of any vehicle and mother tank shall meet all applicable European, national and local regulations 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, it is defined by ADR and EIGA as 'Closed Cryogenic Receptacles' and not considered as a 'tank vehicle'. For the periodic inspection and test of these receptacles, subsection 6.2.6.1 of ADR and Packing Instructions P203 are applicable.

Where the capacity of the mother tank is greater than 1000 litres is defined as a 'tank vehicle'. For the periodic inspection and test of these receptacles, subsection 6.8.3.4.6 of ADR is applicable.

5.2 Driver training requirements

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

5.2.1 Vehicle operation training requirements

All drivers shall be trained in risk assessment for the safe parking of vehicles, specifically in the selection of parking locations where transfilling occurs. Where contract drivers are used, the Medical Healthcare Provider shall require the contractor to demonstrate that all drivers are appropriately trained to satisfy the requirements of this document. Appendix 1, Overnight / Long Term Parking of Homecare Vehicles containing supplies of medical oxygen can be used by the driver as a training aid to assess safe parking overnight.

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

- GDP [5] 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.

Where the driver is transfilling medical liquid oxygen on the vehicle it may be appropriate to train the driver in the principles of GMP [4].

The driver's job responsibilities shall be defined with respect to both the delivery of the product and the supply to the patient.

The Medical Healthcare Service Provider shall have a system to fulfil his obligation in terms of maintaining a trained workforce by retraining or reassessing drivers based to a defined training plan. Where a non conformance has been identified with the driver, it may be necessary to retrain a driver before formal training is due to ensure no reoccurrence.

The driver shall be trained to select the most appropriate area to carry out any transfilling operations.

5.2.2 ADR driver training requirements

All drivers shall be fully trained in accordance with the requirements in Chapter 8.2 of ADR.

Where more than 1000 units (where the units relate to units of oxidant and inert gases and liquids, where 1000 equals the sum of the water capacity in litres of the gaseous cylinders plus the weight in kilograms of the cryogenic liquid) are carried, subsection 8.2.1.1 applies. The driver shall hold an ADR training certificate.

5.3 General minimum requirements for homecare delivery operations

5.3.1 Driver personal protective equipment (PPE)

The driver shall always wear safety shoes (metatarsal protection is optional) when handling cylinders, liquid oxygen vessels or heavy equipment.

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

The driver shall always wear appropriate protective clothing to protect the body, arms and legs. The protective clothing should be specified to reduce the electrostatic loading and oxygen retention of the clothing.

The protective clothing shall always be kept clean in accordance with the manufacturer's instructions.

The vehicle shall carry products to disinfect the driver's hands and/or equipment. Note that most of these products are flammable and shall therefore be stored and used away from oxygen packages and equipment.

Additional guidance can be found in EIGA Doc 136, Selection of personal protective equipment [8]

5.3.2 Transport restrictions – road tunnels, ferries etc.

Generally vehicles carrying less than 1000 units of liquid or gaseous oxygen may use tunnels and ferries, but some tunnel and ferry operators forbid their carriage.

It is the responsibility of the company employing the driver to check the planned route for such issues and to comply with whatever restriction the authorities or operators impose.

The driver shall comply with the legislative requirements for the country including for speed restriction and tachometer requirements.

5.3.3 No smoking

Smoking is only allowed during defined breaks away from the vehicle.

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.

5.3.4 Transfilling Locations

When parking the vehicle to transfill medical liquid oxygen the driver shall select a safe location. The areas listed below shall be avoided:

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

Transfilling is only permitted when a safety zone of 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.

5.3.5 Overnight parking

The preferred location for overnight parking of the vehicle shall be at the Medical Healthcare 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 highway or where public have un-restricted access to the vehicle, all oxygen cylinders and tanks shall be positioned so that they can not be seen from the outside of the vehicle.

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

Alternatively, all oxygen cylinders and liquid oxygen vessels shall be removed from the vehicle and stored securely.

When vehicles carrying oxygen are parked inside closed garages or workshops, an assessment shall be carried out to determine whether, in the event of an oxygen leak:

- there is adequate ventilation in the garage or workshop to prevent an accumulation of oxygen;
- the vehicle is located a safe distance from oils, greases and other combustible materials.

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 below 2 bar(g), under the relief valve setting, to prevent the relief valves from venting overnight.

5.3.6 Unattended parking

Periods of non-attendance shall be avoided, especially when parking in areas of unrestricted public access. The vehicle shall always be locked during any period of unattended parking.

Appendix 1, Overnight / long term parking of homecare vehicles containing supplies of medical oxygen can be used by the driver to assess the safety of the parking location. If the risk assessment considers that the parking location is unsafe, alternative methods of supplying medical oxygen to the patient should be considered by the Medical Healthcare Service Provider.

Alternative methods of supply could include:

- the use of two drivers;
- the use of concentrators to supply the patient.

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 risk assessment should include the requirements to park away from open flames, heaters and air conditioning outlets.

5.3.7 Weight distribution

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

The weight distribution of the products carried on the vehicle shall be made to ensure that individual axle loadings 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 carried of all products and equipment 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 containers be carried in the driver's cab, even when empty.

5.3.8 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.

5.3.9 Housekeeping and hygiene

A high standard of housekeeping inside the driver's cab and the cargo compartment is mandatory to ensure a safe transport and use of medical products and equipment.

The cargo compartments shall be kept clean to ensure the hygiene requirements of the equipment being carried are maintained.

5.3.10 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.

In the rare occurrence, when very dirty or suspected contaminated equipment is collected from the patient, it shall be stored and carried in a segregated area on the vehicle. Consideration shall be given to cover the item with a plastic bag to limit the spread of the contamination and to reduce the chance of the person handling the item from being contaminated. Specific care is needed with the covering the base unit and gas cylinders if there is a potential that oxygen could leak / vent within the plastic bag. Where the base unit or cylinder could leak / vent, the bag shall not be sealed. The bag will only be used to protect the operator from the contaminated surfaces. Alternatively, where a contaminated base unit, which contains product, has to be collected, the pressure in the vessel could be reduced before the plastic bag is fitted. The risks involved with oxygen accumulation within the bag and possible problems associated with static electricity shall be considered before placing any item in a plastic bag.

Where the clinician or person responsible for the patient notifies the Medical Healthcare Service Provider that the patient could have a contagious disease, they shall consider if special precautions have to be taken when handling that equipment. The Medical Healthcare Service Provider shall consult the clinician or person responsible for the patient to provide advice on how to handle this equipment safely. This equipment shall be clearly identified when collected from that patient.

5.3.11 Manual handling

The use of a purpose built trolley is recommended when carrying weights of more than 25 kg or weights of less than 25 kg in total for more than 20 operations per shift.

The requirement to use of trolleys shall be identified by risk assessment and should be in accordance with local manual handling regulations. Electric driven trolleys are recommended when moving loads up or down stairs.

When cryogenic vessels are carried inside elevators, the driver may accompany them only if they are in a safe condition and not continuously venting.

Where a lift is fitted to the vehicle, it shall be used to lift or lower loads in and out of the vehicle.



Fig 7 Typical lift used for loading full and empty cylinders in and out of the vehicle

5.3.12 Driver's Checks

The driver shall carry out a check on his vehicle before starting the deliveries.

These checks shall include that the:

- load is secure;
- tyres are in good condition;
- safety equipment is available;
- no obvious defects;
- braking system is functioning adequately by testing it at 30 km/h;
- the correct documentation shall be available including:
 - correct transport documentation and product safety data sheets;
 - legal vehicle and driver documents;
 - relevant work instructions.

Where applicable the check shall include that:

- all liquid and gas off take valves and pressure raising valves on vessels are firmly closed;
- there are no gas leaks;
- the tank pressure of mother tank(s) is at least 1 bar under 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 fitted) are in place, and
- where used for invoicing the gas supplied, 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 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 compartment shall be ventilated. Some experiences indicate that opening doors for 3 minutes reduces substantially the enriched oxygen atmosphere.

5.4 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.

5.4.1 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 person who is responsible for transfilling the mother tank shall be suitably trained and certified.

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

During the filling process, the person 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 can not 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 chock, 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 adequately be lit.

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

The filler 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.

5.4.2 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.

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 operator filling the base unit shall remain in attendance throughout the transfilling process to control the process;
- 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.



Fig 8 Typical filling of a base unit inside the vehicle with the doors open

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 least 1.5 metres from the transfilling point. 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 combustibile 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.

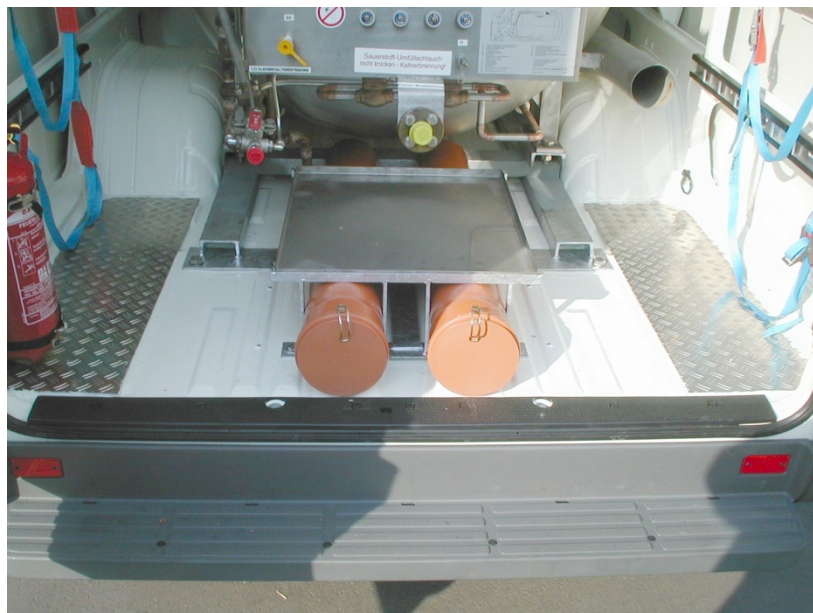


Fig 9 Typical storage arrangements on transfilling vehicle with stowage for cryogenic hoses and plate used for filling vessels outside vehicle

The filler shall stay outside the vapour cloud.

After the transfilling process is complete, the filler 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.

6 Actions in case of vehicle emergency

The Medical Healthcare Service Provider shall establish procedures to cover emergencies such as fire or any other hazardous events that can occur.

Emergencies should include:

- cryogenic liquid spillages;
- relief valve lifting or bursting disc rupture in the public street;
- ice blockages of vent lines or valves;
- cryogenic burns, and
- problems with inhalation.

The driver shall be instructed that cylinders should only be removed from a vehicle after an incident when it is safe to do so. If the driver considers it is not safe to move cylinders involved in an incident, 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. 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. It may be appropriate to provide the driver with a checklist to assist in deciding the correct actions to be taken.

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, such as paper disposables and mattresses, shall be allowed to ventilate in a normal atmosphere for several hours. Vapours shall be prevented entering sewers, pits and trenches.

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.

7 Inspections, maintenance and examination of vehicles

7.1 General requirements

7.1.1 Trained staff

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.

7.1.2 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.

7.1.3 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 7.5.

The requirements detailed in 7.3 and 7.4 are valid for all maintenance conditions.

7.2 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 Medical Healthcare Service Provider.

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 7.4 and, where applicable, those in 7.5.

7.3 General conditions for vehicle maintenance

7.3.1 Pre-work inspection

All equipment shall be made safe & approved by a trained and qualified employee of the Medical Healthcare Service Provider (or their nominated deputy) 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.

7.3.2 Maintenance periods

If the maintenance period requires the vehicle to be held by the maintenance facility for more than 48 hrs then the mother tank shall be fully emptied of liquid and depressurised.

Alternatively, if the maintenance facility has a facility or safe area for venting any released oxygen, it may be acceptable to allow the vehicle to be held in the maintenance facility for longer periods.

The vehicle shall be taken out of the maintenance facility as soon as possible once the work is completed.

7.3.3 Vehicle handover

Prior to handover to the garage staff the mother tank shall be vented to atmospheric pressure outside the maintenance facility as close to handover time as reasonably practical.

7.3.4 Preparation of the mother tank

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.

7.3.5 Base units and portable units

As the base units and portable units are designed to vent through their relief valves as a normal function, they shall always be removed from the vehicle when the vehicle is being maintained in the maintenance facility.

7.3.6 Cylinders

All compressed gas cylinders should be removed from the vehicle before it is taken into the maintenance facility. Where it is not practicable to remove cylinders from the vehicle, they shall be checked to ensure that all valves are closed and that there is no evidence of any leaks.

Leaking cylinders shall be removed from the vehicle.

7.3.7 Vehicle / vessel signs

During transit, to or from the maintenance facility, vehicles shall display the appropriate product signs. 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.

7.3.8 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.

7.4 Maintenance facility conditions

The maintenance facility supervisor shall be responsible for ensuring that:

- smoking is prohibited within 3 metres of the vehicle or mother tank;
- 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.

7.5 Indoor maintenance of vehicle with liquid oxygen present

7.5.1 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.

The maintenance facility personnel shall be given training in the use of the oxygen monitor.

7.5.2 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.

7.5.3 Fire extinguisher

The maintenance facility shall have a fire extinguisher available in the vicinity of the vehicle.

7.5.4 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.

7.5.5 Oxygen monitoring

A calibrated oxygen monitor with an alarm, to monitor oxygen enrichment or oxygen depletion in air around the vehicle shall be used continuously whenever the vehicle is inside the maintenance facility.

Whether hot or cold work is being carried out on the vehicle, the oxygen monitor shall be positioned according to the work being carried out under the following conditions if working:

- on the outside of the vehicle. The monitor shall be positioned at the tank vent outlet;
- inside of the vehicle. The monitor shall be positioned inside the vehicle close to the work area, at low level.
- on the vehicle over a pit. The monitor shall be positioned at low level inside the pit.

7.5.6 Restricted activities

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 vessel and pipe work shall be emptied and purged with nitrogen and the ends of the pipework blanked prior to starting work.

7.6 Preventative and corrective vehicle maintenance

7.6.1 Vehicle cleanliness

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 Medical Healthcare Service Provider 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.

The exterior of both the vehicle and the mother tank(s) shall be cleaned as frequent as necessary, determined by the Medical Healthcare Service Provider to keep it in a clean condition.

7.6.2 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 Healthcare Service Provider.

7.6.3 Cargo compartment maintenance

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

- the structure of the load compartments and specifically 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.

7.6.4 Fire extinguisher maintenance

A competent authorised person shall inspect the fire extinguishers at least every 12 months for possible refilling or replacing with a new or refurbished unit.

The inspection date shall be marked on the extinguisher.

7.7 Vehicle audits

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, and
- are visually appropriate for the companies' image.

The frequency of audit and its content shall be defined within the company procedures.

8 Inspections, maintenance and examination of mother tanks

8.1 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.

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

8.2 Non ADR periodic inspection

It is recommended to check every 12 month the mother tank:

- 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.

9 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 shall be completed in the open air. 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.

10 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.

10.1 Periodic testing

Cryogenic hoses do not need to be periodically pressure tested, unless this is required by national legislation. Due to the high frequent use of these hoses with cryogenic liquids, the material embrittlement is the main cause for repair or renewal.

Repair of cryogenic hoses is allowable only by companies approved by the medical healthcare service provider.

Cryogenic hoses should be replaced at the following recommended frequency;

- after 3 years of service for hoses used to fill base units
- after 5 years of service for hoses used to fill the mother tank.

11 Reference documents

[1] Good Homecare Practice, MGC Doc. 158.

[2] European Agreement on the Carriage of Dangerous Goods

[3] EN 1251, Cryogenic Vessels – Transportable Vacuum Insulated Vessels of not more than 1000 litres volume.

- [4] The Directive for Good Manufacturing of Medical Products, 91/356/EC amended by 2003/94/EC
- [5] Guidelines on Good Distribution Practice of medicinal products for human use, 94/C 63/03
- [6] EN ISO 14971, Medical Devices – Application of Risk Management of Medical Devices
- [7] CGA: SB-9 'Recommended Practice for the Outfitting and operation of Vehicles used in the Transportation and Transfilling of Liquid Oxygen used for Respiration
- [8] EIGA Doc 136 Selection of personal protective equipment

Note EIGA Doc 98, 'Safe Supply of Transportable Medical Liquid Oxygen Systems, and EIGA Doc 99 'Good Manufacturing Practice Guide for Medicinal Gases' contain additional background information.

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