

MEDICAL OXYGEN SYSTEMS FOR HOMECARE SUPPLY

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Amendments to 89/16

Section	Change
1	Inclusion of Hygienic and infection risks into the scope and other parts of the document
6.3	Risk analysis for Home Care Personnel – incorporate elements of Doc 198 – Security of Home Care Personnel, in order to archive EIGA Doc 198
Other sections	Alignment with other documents, denomination alignments, text simplifications
Annexes	Included content of former Doc 198 into the check lists and risk analysis list
	Included comments received from MGC

1 Introduction

Medical oxygen is used to supply additional oxygen to patients with respiratory disorders to compensate for the reduced functionality of the lungs. It is the responsibility of the homecare service provider to ensure that the medical oxygen systems they supply to patients, provides a safe supply of oxygen for therapy to the patient, as prescribed by their doctor.

This publication provides advice to the Homecare Service Provider (HSP) on the installation, instructions for use and maintenance of the equipment used for oxygen therapy. It specifies the need to provide adequate training to the patient or carer to ensure safe usage of the equipment for oxygen therapy.

The publication also provides a number of practical guides for the homecare service provider supporting the management of oxygen therapy in a safe and effective manner. It also provides practical guides to handle safety issues surrounding home oxygen therapy, including risks that be present in terms of hygienic challenges in the patient's environment, or potential behavioural risks.

Oxygen therapy is always prescribed by a doctor.

The equipment used with oxygen therapy shall be CE marked, which indicates that it complies with the European regulation on medical devices.

When prescribing oxygen therapy to their patients, the doctor may consider the method of oxygen source to the patient. It is the homecare service provider's responsibility to ensure that the specific prescription conditions are followed in full, and changes to the prescription are only authorised by the patient's doctor.

2 Scope and Purpose

2.1 Scope

This publication applies to the supply of homecare oxygen therapy supplied by homecare service providers using:

- compressed oxygen gas cylinders;
- transportable liquid oxygen system (TLOS);
- (portable) oxygen concentrators, and
- oxygen cylinder filling system (self-fill system)

The advice covers both the supply to healthcare facilities and to patient's homes and applies not only to the oxygen therapy but also to the ancillary equipment.

2.2 Purpose

This publication describes the recommended precautions and safety procedures to be followed when home oxygen therapy systems are used in healthcare facilities and in the patient's home. The publication endeavours to provide the best operating practices for the supply of home oxygen therapy but does not cover all of the relevant applicable national regulations that could apply in some countries.

This publication provides guidance to the homecare service provider about the:

- Hazards associated with the supply of medical oxygen;
- Minimum operational characteristics of the home oxygen therapy equipment;
- Environment risk assessment by the HSP at the patient's home and surroundings;

- Precautions to be observed whilst using the home oxygen therapy equipment, and
- Safe use of home oxygen therapy and the associated equipment.

The publication includes in the Appendices patient user instruction cards that provide basic advice on how to safely use the different types of home oxygen therapy equipment.

The instruction cards for each modality of home oxygen therapy are in two formats:

- A patient user training card to be used as a guide by the homecare service provider when training the patient/carer on how to use the home oxygen therapy and providing information on the safe use of the product.
- A patient user instruction card to be used by the patient/carer as a quick reference guide on the safe use and operation of the equipment.

It is intended that both the card will be left with the patient/carer for future reference and shall be adapted to reflect the specific therapy equipment that is supplied.

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 and need not

Indicate 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)

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

3.2.2 Healthcare facility

Organisation providing the medical oxygen therapy to the patient on their premises, where they are responsible for the care of the patient.

3.2.3 Home Oxygen

Oxygen provided to patient from either medical liquid oxygen systems, medical gas cylinders or oxygen concentrators.

4 Description of gaseous and liquid oxygen

The basic characteristics of gaseous and liquid oxygen are:

- Oxygen is essential to sustain life and is normally supplied from the earth's atmosphere, which is made up of approximately 20.9% oxygen.
- Gaseous oxygen is a colourless, odourless, tasteless gas with a specific density of 1.1 relative to air.
- Liquid oxygen is a light blue liquid that flows like water. It has a boiling point of -183.0 °C at atmospheric pressure and has a specific density of 1.14 relative to water.
- One volume of liquid oxygen will generate 860 volumes of gaseous oxygen at atmospheric pressure and temperature.
- Oxygen, in gaseous or liquid form, is a non-flammable, non-toxic powerful oxidiser. It is considered hazardous as it intensifies combustion (see point 5).

5 General hazards and safety precautions with oxygen therapy supply systems

There are precautions that shall be observed with medical oxygen irrespective of the therapy modality. When making the installation of home oxygen therapy, advice shall be given to the patient/carer or healthcare facility to explain the general hazards of using home oxygen therapy and shall include the following information:

- Materials that burn in air will burn much more vigorously at a higher temperature in an oxygen-enriched atmosphere.
- Most serious incidents involving the use of home oxygen therapy are caused by smoking or fire (fireplace, candles,...)
- Instructions shall be given to the patient/carer/healthcare facility staff to:
- Never smoke or be exposed to open flames whilst using home oxygen therapy;
- Never allow any other person to smoke in the vicinity of the patient using home oxygen therapy;
- Keep sources of ignition away from areas where home oxygen therapy is used or stored;
- Avoid ignition sources, including lighted cigarettes, gas cookers, electrical toys and equipment or open fires when in potentially high oxygen-enriched atmospheres.
- Oils and grease burn in an oxygen-enriched environment with explosive violence. Ignitions can occur with oxygen equipment if it has been contaminated with oil or grease. This can also be caused by handling equipment with hands that have been contaminated with petroleum jelly or hand/face creams containing petroleum-based ingredients or using tools contaminated with oil or grease.

Instructions shall be given to:

- Only handle or operate home oxygen therapy equipment with clean hands and tools.

- Keep the oxygen equipment clean and free from any oils or grease.
- Where the patient requires to use a moisturiser or cream, for example to prevent their nostrils from drying out, only use approved products that are suitable for use with oxygen.
- Take into consideration that absorbent materials, such as clothing or bedding, when saturated with oxygen, will readily ignite and that these materials can remain oxygen-enriched for some time after removal from the oxygen source.

Instructions shall be given to the patient/carer/healthcare facility staff to:

- Ventilate any clothing or bedding, where it is suspected that it has become saturated with oxygen, to ensure that any oxygen enrichment is cleared. It can take at least 15 minutes to adequately ventilate clothing or 30 minutes to ventilate bedding before it is safe to approach with a source of ignition.
- Never cover any oxygen equipment with any material or store it adjacent to curtains as they could become oxygen enriched.
- Never use the ambulatory unit under clothing.
- Where an ambulatory unit is carried in a bag or holder, select a bag specifically designed for the home care oxygen therapy container, made from appropriate material, provided with adequate ventilation and designed to allow any oxygen that leaks out of the container.
- Prevent any unnecessary oxygen-enrichment of the air by turning off the oxygen system when not in use.
- Only allow trained persons to operate the home oxygen therapy equipment.
- Ensure that children and pets are not allowed to tamper with the equipment.
- Keep the total length of flexible tubing, from supply source to the connection to the nasal cannula or mask to a minimum, but in any case no more than 15 metres.
- Prevent the kinking of the tube to avoid flow's restrictions.

5.1 Hazards with compressed oxygen

There are specific hazards with the supply of medical oxygen in gas cylinders. These hazards relate to the fact that oxygen is stored at high pressure and supplied in cylinders that are relatively heavy and require to be handled correctly. The hazards relate to high pressure cylinders supplied by the homecare service provider or cylinders filled using a self-fill oxygen concentrator.

Instructions concerning the handling and use of compressed oxygen systems shall include:

- Compressed oxygen supplied in cylinders is filled to a high pressure and care is needed to ensure that cylinder valves are kept closed when not in use to prevent leakage. It is important that cylinders' storage areas are kept well ventilated to prevent any build-up of oxygen concentration if a leak occurs.
- The stored energy in an oxygen cylinder under pressure is very high and care is needed to store cylinders correctly. As the pressure in a cylinder increases as the cylinder gets hotter (with corresponding increase in stored energy) it is important that cylinders are stored away from sources of heat.
- As the compressed oxygen is at a high pressure in the cylinder, care is needed to ensure that the regulator, where required, is fitted correctly and set at zero / minimum flow before opening the cylinder valve.

- Instructions shall always be given to open the cylinder valve slowly, to prevent adiabatic compression of the oxygen, which could lead to an ignition. When opening the cylinder valve the patient/carer should be at the side of cylinder valve and not in front or at the back of the cylinder valve



- Care is needed when storing or using compressed oxygen cylinders to ensure that they are suitably restrained to prevent them from falling so as to avoid the cylinder, cylinder valve or regulator being damaged.
- Due to the potential of a high-pressure gas release and because of the relatively high risk of an ignition and contamination, transferring compressed oxygen from one cylinder to another cylinder is dangerous and forbidden.

5.2 Hazards with liquid oxygen

The specific hazards relating to treating patients with medical oxygen in liquid form relate to the extremely low temperature of the liquid and the need to ensure that appropriate precautions are taken concerning cold temperatures when handling the equipment.

Instructions concerning handling and use of liquid oxygen systems shall include (see also appendix 3):

- Care shall be taken as liquid oxygen is extremely cold and stored at approximate -183°C .
- Touching spills of liquid oxygen or cold surfaces on liquid oxygen systems, such as the valves, pipes or couplings, can cause severe cryogenic burns or frostbite. When handling liquid oxygen systems do not allow liquid oxygen or frosted pipework to contact the skin or non-protective clothing.
- Moisture can accumulate on exposed surfaces of equipment containing liquid oxygen forming ice, causing components such as valves or filling couplings to freeze open or shut. If moisture is permitted to enter liquid oxygen lines or systems, it will freeze and can prevent components such as pressure relief devices or control valves from correctly functioning which could result in a potentially unsafe condition.
- One volume of liquid oxygen at standard atmospheric pressure when vaporised will produce approximately 860 volumes of gaseous oxygen at ambient temperatures. The large volume of gaseous oxygen resulting from the vaporisation of liquid oxygen has the potential, if trapped in a closed circuit not adequately protected by pressure relief devices, to generate gas pressures high enough to cause explosive rupture of containers, transfer hoses, piping or other system components. Care shall be taken to avoid blockage of the outlets of vent lines, ports and safety relief devices, for instance by dirt or ice.
- Due to the extremely cold temperature of liquid oxygen, it will constantly absorb heat through the container walls which will result in it vaporising to produce gaseous oxygen. Any gaseous oxygen produced in excess of the patient's requirements will be automatically vented which is normal. It is important to keep liquid oxygen containers in a well-ventilated area to avoid the generation of oxygen-enriched atmospheres and to keep them away from combustible

materials and protected from exposure to heat sources, which can accelerate the venting of oxygen from the container.

- Due to the density of the low temperature gas vented from a liquid container, it is heavier than air and will accumulate in low lying areas if not adequately ventilated.

Hazard with transfilling liquid oxygen

The main risk for transfilling liquid oxygen is associated with cryogenic temperatures. Provided that the equipment is specifically designed for transfilling and designed to protect the patient or user from these cold conditions, it is safe for liquid oxygen to be transfilled.

It is important that the homecare service provider supplies the patient/carer/healthcare facility with approved filling procedures prepared by or based on the equipment manufacturer's instructions.

These instructions shall provide the patient or user with sufficient information to ensure that when transfilling liquid oxygen:

- The container being filled is suitable for filling;
- The container is filled safely;
- During transfilling liquid oxygen spillages of oxygen are avoided, and
- When transfilling liquid oxygen into the mobile unit, care is taken to ensure that all connections are dry, clean and that leaks do not occur.

5.3 Hazards with stationary oxygen concentrators

As the stationary oxygen concentrator is supplying oxygen to the patient at relatively low flowrates and at low pressure, care is still required to ensure that the general precautions associated with the use of medical oxygen are still to be followed.

There are specific precautions concerning the electrical supplies to the concentrator that shall be followed and instructions concerning the handling and use of medical oxygen concentrator systems shall include the following (see also appendix 4):

- When operating oxygen concentrators, care is needed to connect the equipment to a suitable electrical supply and to avoid any possibility of electrical shock.
- Always switch off the machine and isolate it from the mains electrical supply when maintaining the medical oxygen concentrator or refilling the humidifier.
- Never operate the concentrator in a bathroom.

5.4. Hazards with portable oxygen concentrators

Portable concentrators, on top of the above risks, have some specific hazards that need to be taken into account, namely:

- Be aware of the autonomy of batteries, and battery deterioration over time. Damaged batteries shall not be used any longer and the Home Care Service Provider needs to be contacted for replacement
- Be aware of difference between settings and liter per minute equivalence
- Portable concentrators are not designed to be used continuously

- As portable concentrators are more fragile and mobile, they are exposed to various environmental conditions (dirt, moisture,...) and require adequate care by the patient
- Refer to the manufacturer's manual for specific instructions for use.

5.5 Hazards with self-fill systems

It is important that the homecare service provider supplies the patient / carer / healthcare facility staff with approved filling procedures prepared by or based on the equipment manufacturer's instructions.

These instructions shall provide the patient or user with sufficient information to ensure that:

- The self-fill concentrator/compressor system is correctly assembled and stable;
- The self-fill concentrator/compressor system should not be installed in a kitchen or garage, where there is a higher risk of contaminating connections with oil and/or grease;
- No leaks occur during the filling process;
- The cylinder being filled is suitable for filling. Only cylinders supplied by the medical oxygen homecare service provider should be filled;
- The self-fill concentrator/compressor system and cylinder are used in accordance with the user instructions and only for the use for which it is intended;
- The use of the system is dedicated to the patient and the cylinder can not be used to supply anyone else;
- The handling and the filling of the cylinder is carried out with care to avoid the cylinder being dropped, and
- The self-fill concentrator/compressor system is not moved whilst filling the cylinder.

The recommendations in 5.1, concerning high pressure cylinders and 5.3, concerning stationary oxygen concentrators should also be followed.

5.6 Hazards linked to contaminated devices, containers and cylinders

It is important for the safety of health care facility staff, caregivers and homecare service personnel to identify and treat any potentially externally contaminated equipment with care, as described in the following documents from EIGA See references [8 and 9].

6 Installation of the oxygen therapy supply system

The homecare service provider is responsible for:

- Providing a safe and reliable source of home oxygen therapy in accordance with the prescription;
- Ensuring that equipment is correctly installed at the patient's home, or place of residence. In case of delivery to a health care facility, instruct the staff on how to correctly set-up the equipment.
- Instructing the patient, carer or health care staff on how to use the equipment correctly at the flowrate prescribed by their doctor, and

- In case oxygen is prescribed for use with another medical device, for example ventilator, sleep apnoea device, ensure these devices are suitable for use with oxygen and if this is the case then the manufacturers' instructions for use should be consulted.

The homecare service provider shall have a formal system to review the initial set up of the oxygen systems to ensure that:

- The installation has been carried out correctly, and
- The appropriate training, literature and advice have been provided and understood.

This review shall be recorded and signed.

A system of periodically auditing the quality and effectiveness of this initial set-up shall be carried out by the homecare service provider and the appropriate corrective actions put in place to address any short falls.

6.1 Initial setting up of patients at home for home care oxygen therapy

When the initial installation is made at the patient's home, it is very important that the appropriate information is given to the patient or carer to ensure that they are not put at risk by their own actions. Only fully trained and suitably assessed competent personnel shall be used for the initial training of the patient/ carer.

Irrespective of the method of supply, it is essential that the homecare service provider has carried out the following actions to ensure that:

- A user instruction manual has been provided to the patient/carer, which provides a detailed procedure on how to use the equipment both effectively and safely. Where appropriate, instructions shall also be provided in pictorial format for ease of understanding. The instructions shall cover the use of the equipment to provide the oxygen supply safely and routine responsibilities for the patient/carer to keep the equipment in an appropriate condition.
- The patient/carer has been adequately trained by the homecare service provider so he or she knows how to use their equipment effectively and safely.
- A formal assessment program has been followed to ensure that the patient/carer understands the principle actions they shall take both in the safe operation of the equipment and in the event of an emergency.
- The patient/carer has been requested to sign an acknowledgement sheet to indicate that they have understood their training and the safety requirements for the use of their oxygen equipment, recognise the importance of not smoking or letting anyone else smoke in the vicinity whilst the oxygen equipment is being used and know what to do in the event of an emergency.
- Advice has been given on the best location for the storage and use of the home care oxygen therapy to minimise any risks.
- The total length of flexible tubing, from supply source to the connection to the nasal cannula or mask shall be kept to a minimum, but in any case no more than 15 metres. Care is needed to prevent the kinking of the tube to prevent restrictions in the flow.
- Consideration shall be given to possible country requirements for providing the patient/carer with a draft letter which they could send to their own insurance company informing them of the presence of home care oxygen therapy in their home and their car. Where appropriate, this draft letter may also be sent to the local fire brigade to inform them of the presence of oxygen in the home.

- A contact number has been given that the patient/carer can use at any time (365 days per annum / 24 hours per day). The patient/carer shall be instructed to use this number only to contact the homecare service provider in case of problems with the equipment.
- A list has been given to the patient/carer of all the equipment provided at the initial supply and any ancillary therapy equipment that may need replacing. The user instruction manual shall also cover the use of this ancillary therapy equipment.

6.2 Initial setting up of healthcare facilities providing medical oxygen therapy

When the initial installation is made at the healthcare facility, it is very important that for the initial installation (as described under 6.1.), adequate information and training is given to the relevant healthcare facility staff to ensure safe supply to all of their patients.

It is the responsibility of the healthcare facility to ensure that they have sufficient trained and competency assessed personnel to ensure that the provided operating procedures are followed and to ensure that they continue to keep sufficient adequately trained staff to operate the equipment. It may be appropriate for the homecare service provider to assist the healthcare facility in the preparation of suitable protocols to ensure that the oxygen is delivered correctly and that their patients are not put at risk.

Irrespective of the method of supply of home care oxygen therapy to the healthcare facility, it is essential that the homecare service provider, on top of the elements under 6.1. has carried out the following actions:

- Adequate training, as well as suitable training material, has been provided by an approved trainer to a suitable number of healthcare facility representatives. The training shall be followed by an assessment to ensure that the healthcare facility staff have an understanding of both the safe use of the equipment and the actions to be taken in the event of an emergency.
- The healthcare facility representative has been requested to sign an acknowledgement sheet to indicate that they have understood their training and safety requirements and know what to do in the event of an emergency.
- Specific instructions are given on the possible best locations in the health care facility for storage and use to minimise any risks.

6.3 Homecare environment risk assessment

Risk analysis shall take in consideration also the environment surrounding the delivery and installation address, like vicinity, neighbourhood, isolated location, or potentially unsafe areas, and so it is not limited to the patients' residence alone.

In order to ensure that equipment is installed in a safe manner at the patient's home, the homecare service provider shall carry out a risk assessment at the patient's home, and the provider should acknowledge this risk assessment. In case of apparent risks, the technician starts the process of dealing with the risks found. Appendix 10 shows an example of a typical risk assessment checklist, with some of the most common potential risks.

The checklist can be used by the homecare service provider technician to assist in determining whether there are any significant risks. It also allows the technician and his supervisor to document the appropriate actions taken to address any of these identified risks.

Homecare environments can be emotionally charged and potentially unstable places which can present a unique set of security challenges. In unsafe locations, field homecare personnel can be at risk (injury, assault, hygiene situation...). Potential violence to field homecare personnel can result from patients and occasionally from hostile family members and/or others present in the home who feel stressed, disturbed, frustrated, vulnerable, or out of control.

The content of the onsite risk assessment should be reviewed at regular intervals to ensure that it remains actual, and any new information is adequately incorporated in day to day operations.

This can be done for example by the regular five-step approach (incorporating elements of risk management) such as the one presented below (example see appendix X).

Step 1: Identifying hazards and those at risk: Looking for those things at work that have the potential to cause harm, and identifying workers who could be exposed to the hazards.

Step 2: Evaluating and prioritising risks: Estimating the existing risks (the severity and probability of possible harm) and prioritising them in order of importance.

Step 3: Deciding on preventive actions: Identifying the appropriate measures to eliminate or control the risks.

Step 4: Taking action and putting in place the preventive and protective measures through a prioritisation plan.

Step 5: Monitoring and reviewing.

Suspicious incidents and/or behaviours, people, safety and or security concerns should be immediately reported to the management for inclusion in the review process of the risk assessment;

There are a number of factors which have to be taken into account in determining risk, including:

- known past safety and security incidents at the patients home, or at nearby locations or locations identified as unsafe by the authorities;
- Possible threat or hazards from interaction with people that live there and/or patients.

The employer must ensure that proper health and safety information, instruction, and training for work activities are provided to the employees.

Appendix 9 shows a completed Failure Mode and Effects Analysis (FMEA) study, which was used to develop a typical risk assessment checklist. It covers all aspects of the homecare installation which could have an impact on the safe and correct handling and use of the equipment in the patient's home. Such FMEA study identifies the specific risks associated with each of the modes of supply.

Such FMEA study may be used as training material to assist the technician in understanding how to determine where potential risks can occur with the installation of oxygen therapy systems in the patient's home.

7 Home oxygen incidents

Following installation of the home oxygen supply system it is important that the patient/carer or healthcare facility representative is informed of the actions that should be taken in the event of an incident with their oxygen supply. The type of incident can include the loss of supply, malfunction of the oxygen supply system, adverse reaction by the patient to the oxygen or the involvement of the equipment in a fire whether caused by the equipment or not.

Provided that the equipment is installed correctly and the user is adequately trained and warned about the potential hazards of using home oxygen, the likelihood of an incident is considered remote. Where incidents do occur, they are often caused by external events that impact on the medical oxygen supply system. The patient/carer/healthcare facility staff shall be instructed to contact their homecare service provider immediately if they have any doubt about the safety of any situation.

Most serious incidents involving the use of home oxygen are caused by the patient smoking.

Where the home oxygen supply system is involved in a fire, the patient/carer/healthcare facility shall be instructed to:

- contact the fire brigade, ensuring they are informed that oxygen is in use.
- If there is any doubt about the safety of the situation, not to touch the equipment and to leave the property immediately
- Isolate the oxygen supply system only when it is safe to do so, before following any other instructions.

Where there is a major leak of oxygen either from a home oxygen cylinder caused by the cylinder falling over and the attached pressure regulator sheering off or a large leak developing between the cylinder valve and the regulator or where a liquid oxygen containers develops a major gas or liquid leak the patient /carer /healthcare facility shall be instructed to:

- Close the cylinder or liquid container valve only if it is safe to do so;
- Ensure that external windows and doors are opened to ventilate the area, and
- Inform the homecare service provider immediately to obtain advice.

In the event of a cylinder or liquid container falling over, where there is no other apparent damage, the homecare service provider should still be notified immediately to obtain advice as to the appropriate actions to be taken.

If there is any evidence of a home oxygen concentrators running hotter than usual, the patient/carer/healthcare facility shall be advised to isolate the equipment from the mains supply and inform the homecare service provider immediately. Where applicable, the patient should be instructed to use their back-up cylinder supply.

In all cases the patient/carer/healthcare facility shall be advised to contact the homecare service provider whenever they are concerned that any unusual event may have occurred that they believe could lead to a failure of the home oxygen supply.

8 Maintenance of medical oxygen therapy equipment

8.1 General maintenance requirements

Prior to installing any equipment in the patients' home or healthcare facility, it is the responsibility of the homecare service provider to ensure that the equipment is functioning correctly and that there is no chance of contamination between patients:

- Components that can influence the cleanliness of the supply of the medical oxygen, such as bacterial filters, nasal cannula, and distribution tubing, shall be renewed before the equipment is installed at a new patient location, according to the manufacturers' instructions.
- Should any part of the home oxygen system fail to operate correctly it is important that the patient/carer/healthcare facility contacts the homecare service provider immediately so that an authorised, competent person can diagnose the fault and implement the appropriate corrective action.
- Under no circumstances shall any piece of equipment be disassembled by the patient/carer or healthcare facility staff other than the specified routine maintenance or the changing of consumable items from the breathing circuit detailed in the user manual.
- Repairs shall only be carried out by authorised and competent persons or organisations.

- The patient/carer/healthcare facility shall be informed that they are responsible for the routine hygiene maintenance of the equipment, including the humidifier, nasal cannulas, face masks, dust filters and the external surfaces of the devices. These responsibilities shall be defined in the user manual.
- Advice should be given to the patient/carer/healthcare facility about suitable non-abrasive cleaning agent or disinfectant that may be used for cleaning any home oxygen equipment.

When carrying out routine inspection and cleaning at the patient's or healthcare facilities premises, procedures based on the manufacturer's instructions shall be followed and include:

- Only use a dampened cloth using an approved, non-abrasive cleaning agent or disinfectant to wipe down the equipment, cylinder or container before use.
- When cleaning equipment with cleaning agents or disinfectants, ensure that no residues are left after cleaning that could come in contact with the oxygen.
- Do not allow free water to come into contact with any of the controls or fill connectors on a liquid oxygen container as this will lead to the malfunction of the equipment caused by ice freezing on the components.
- Do not allow free water to come into contact with oxygen concentrators/self-fill systems due to the risk of an electrical fault or short circuit.
- Never lubricate any part of any equipment with oil or grease.
- Always switch off the concentrator/self-fill systems and remove the power lead when the external surfaces are being wiped down or when changing the filter.

If any of the equipment fails to operate correctly or the controls become stiff to operate, the patient/carer/healthcare facility shall be instructed to contact their homecare service provider immediately.

8.2 Ancillary therapy equipment

- The accessories, such as humidifiers, cannulas, tubes and face masks used with home oxygen therapy equipment must comply with the essential requirements of the medical device regulation [1].
- If the patient has any specific requirements with respect to material allergies or irritations, the homecare service provider shall either provide a fitting alternative or be instructed of the specific needs by the patient's doctor.
- Only connectors, tubes, nasal cannulas, probes or masks designed for use with home oxygen therapy systems shall be used.
- It is important that only accessories supplied by the homecare service provider are used by the patient.
- Most ancillary items are designed for a single patient use and as such shall be disposed by the patient in accordance with national or local regulations.

Where the patient/carer/healthcare facility staff are cleaning humidifiers and face masks, they shall:

- Always follow the manufacturer's instructions when using or maintaining any ancillary equipment;
- Make sure that nasal cannulas are free from grease and dirt especially inside the nasal prongs, and

- When the humidifier is refilled, ensure that it is cleaned and refilled as per the manufacturer's instruction and the lid replaced so that oxygen leaks do not occur.

Where it is appropriate that the patient should change their ancillary equipment, sufficient supplies shall be provided and appropriate advice given when to change the equipment. They shall be advised to isolate the oxygen supply when any ancillary equipment is being changed.

The homecare service provider shall check regularly the cleanliness and condition of the ancillary equipment supplied to the patient to administer the home oxygen.

8.3 Therapy equipment spare parts

Only approved replacement spare parts, including filters, meeting the operating parameters of the supply equipment shall be used to maintain the medical oxygen therapy device.

Where the homecare service provider decides to use a replacement spare part not specified as original equipment of the medical device, it is their responsibility to obtain validation that the part is suitable for use for the specific model.

8.3.1 Therapy equipment replacement batteries

It is recommended that replacement batteries are sourced from the original equipment supplier. This is because of concerns that non original equipment replacement batteries do not fully meet the specification of the original batteries and could malfunction. Exception here is to be made for devices where the manual of the manufacturers allows use of generic batteries (eg. LOX).

8.4 Patient/carer/healthcare facility maintenance responsibilities

Apart from changing filters or ancillary equipment, home oxygen gas supply systems and their associated regulating equipment do not require to be maintained by the patient/carer/ healthcare facility staff.

Only authorised and competent persons shall carry out any maintenance on any of the equipment in accordance with the manufacturer's instructions. This includes the changing of 'O' rings and sealing washers on regulators and flowmeters.

The patient/carer/healthcare facility staff are responsible for keeping the cylinder, container, or concentrator externally clean, which may be carried out by wiping the surface with a clean cloth.

When cleaning the equipment always ensure that the home oxygen supply is turned off and for concentrators or self-fill system, always disconnect the unit from the mains before cleaning. Never use solvents or other flammable or abrasive products to clean the equipment.

9 Oxygen cylinder therapy supply

Medical oxygen cylinders can either be fitted with a standard cylinder valve that requires the use of an additional regulator to reduce the pressure to a useable level, or with an integrated cylinder valve (VIPR) [5,6] that has the pressure regulator built into it. Where patients require mobility, ambulatory medical oxygen cylinders can be prescribed.

It is the responsibility of the homecare service provider to ensure that the equipment supplied is suitable to provide the home oxygen to the patient at the prescribed flowrate.

When installing an oxygen cylinder system at a new patient, the entire home oxygen circuit, including the oxygen therapy nasal cannulas or masks and distribution tubing, shall be new.

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