



SAFETY PRINCIPLES FOR PRESSURE REGULATORS FOR MEDICAL OXYGEN CYLINDERS

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Amendments to 104/16

Section	Change
	No changes, just a re-affirmation of this document

1. Introduction

The pressure regulators that are mounted on transportable gas cylinders for medical use, and particularly those for oxygen, constitute a critical interface in the area of safety in the use of gases.

Their use is very diverse including for example hospital services, ambulances and home care patients.

The design, manufacture, operation and maintenance of these pressure regulators shall only be carried out by suitably qualified persons with expertise and knowledge in the areas concerned. These aspects shall comply with the applicable regulations and standards. Regulators placed on the market and into service within the European Union shall comply with the Medical Devices Regulations¹.^[1]

Regulators shall take account of factors such as:

- The pressure in the cylinder, possibly up to 300 bar;
- Many common materials that are considered not to be combustible will burn in oxygen; and
- The conditions of use, that can sometimes be harsh such as impacts and environmental conditions.

The pressure regulators shall be operated in accordance with the manufacturers operating instructions and the users shall be trained.

2. Scope and purpose

2.1 Scope

Pressure regulators intended for use with medical oxygen or medical breathing gas mixtures with an oxygen partial pressure above 30 bar.

2.2 Purpose

This publication provides guidance and safety information for the selection, use, and maintenance of pressure regulators for oxygen cylinders in medical service.

It is intended for those who specify, operate, manage and use medical pressure regulators

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.

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

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

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

3.1.5 Can

Indicates a possibility or ability.

4. Recommendations for the selection and use

The principles for the selection and use of pressure regulators are covered in the following sections.

4.1 Risks

The main risks with pressure regulators are:

- Failure to provide the desired flow and/or pressure of medical gases;
- Failure to indicate the correct remaining contents of the cylinder;
- Ignition, that can be caused by adiabatic compression, materials incompatible with oxygen and contaminants such as grease;
- Release of toxic products in the case of internal combustion; and
- Uncontrolled release of high pressure and/or ejection of parts.

4.2 Selection

The following points need to be taken into account when selecting a medical oxygen regulator.

- Given the possibility of violent combustion of aluminium alloys in oxygen, their use shall be limited and preferably should be avoided. Suitable alternative materials shall be used such as copper alloys.
- All parts in contact with oxygen shall be compatible with oxygen.
- In order to ensure correct operation of the pressure regulator, it should be equipped with an inlet filter made from material compatible for use in oxygen, such as bronze.
- The use of non-metallic materials in the manufacture of the pressure regulator shall be minimised and chosen taking into consideration the recommendations provided in EIGA Doc 73, *Non-metallic materials in high pressure breathing gas applications*. [2]
- The pressure regulator shall be fitted with a pressure relief device,
- The pressure gauge, if supplied, shall include a flow restriction device,
- The level of cleanliness shall be in accordance to ISO 15001 *Anaesthetic and respiratory equipment -- Compatibility with oxygen*, [3].

NOTE Recommendations for cleaning for oxygen service are given EIGA Doc 33, *Cleaning of equipment for oxygen service* [4].

- In the case where lubricants are used, the quantities of these shall be minimised, and they shall be compatible for use with oxygen.
- The regulator shall pass the adiabatic compression test as specified in ISO 10524-1, *Pressure regulators with or without flow-meter for medical gas systems* [5].

A regulator complying with ISO 10524-1 [5] and CE marked meets the above criteria.

5. Implementation and use

The users, whether they are hospital professionals or home care patients, shall be familiar with the correct use and potential risks before first use. This information shall be provided by the operating instructions supplied with the pressure regulator or by training provided by a competent person.

The precautions for use shall include the following:

- Never use oxygen in the vicinity of a potential point of ignition;
- Do not use flammable organic materials such as oils, greases, creams;
- Do not operate the pressure regulator with dirty or greasy hands;
- Keep the cylinder valve/pressure regulator interfaces clean and free of greasy materials;

Prior to connecting the pressure regulator to the cylinder:

- Check that the pressure regulator has a rated pressure, (see marking on the pressure regulator), above or equal to the working pressure of the oxygen cylinder;
- Check that the pressure regulator is appropriate for the gas service and application. In particular, never use a medical gas regulator with an industrial gas cylinder;
- Check the general condition of the pressure regulator. In the event of signs of damage, impact or fall, remove the equipment from service and have it checked and repaired by an authorised specialist;
- Check the integrity of the cylinder valve/pressure regulator connection, for example;
 - Cleanliness and good mechanical condition of the mating surfaces; and
 - Presence, good condition and appropriate positioning of any gaskets.

Prior to opening the valve:

- Ensure that the person operating the valve is behind the valve, opposite the pressure regulator;
- Check that the flow selector is on zero and nothing is connected downstream of the pressure outlet.

Opening the valve:

- Open the cylinder valve gradually and in case of adjustable regulators, ensure that the regulator screw is in the zero position before opening the cylinder valve. Both will avoid dangerous adiabatic pressure impact;
- In the event of a leak in the high-pressure side, close the cylinder valve. Never try to re-tighten a defective connection under pressure;

- In the event of a persistent leak, remove the equipment from service and have it repaired by an authorised specialist.

Disconnecting the pressure regulator from the cylinder valve:

- Make sure that the cylinder valve is closed and that the upstream pressure of the pressure regulator has dropped to atmospheric pressure; and
- Store the pressure regulator in a clean and safe place.

6. Routine maintenance

Routine maintenance is usually performed by the user.

Routine maintenance instructions shall be available to the user and this shall include the list of materials required for the routine maintenance, such as gaskets.

If it is necessary to replace the gasket make sure that the new gasket is the one recommended by the manufacturer (material / dimension). Any spare gaskets shall be stored in a closed plastic bag to avoid contamination with dust, dirt, grease, etc. It is imperative to use the correct gasket as failure to do this is a common cause of ignition.

7. Maintenance

Only technicians who have been suitably qualified and trained shall undertake maintenance of the pressure regulators. Maintenance by users shall be limited to the routine maintenance only and in no case dismantling of the pressure regulator.

It is essential to:

- Ensure that maintenance is carried out at the periods specified by the manufacturer;
NOTE Adverse service conditions can require a reduced maintenance period.
- Comply with the servicing recommendations of the manufacturer;
- Systematically check the performances of the pressure regulator:
 - Accuracy of the flow delivered at the flow outlet over the full range of settings; and
 - Range of the pressure at the pressure outlet.
- Use only the spare parts recommended by the manufacturer;
- Use only cleaning and disinfection products recommended by the manufacturer of the pressure regulator and according to the instructions for use of these products.
- Prevent ingress of cleaning or disinfection products into the pressure regulator, and always check that there no remaining products in the internal passages of the regulator prior to placing back into service.

8. References

Unless otherwise stated the latest edition shall apply.

[1] *Medical Device Regulations*, (under revision) www.ec.europa.eu

[2] EIGA Doc 73, *Non-metallic materials in high pressure breathing gas applications* www.eiga.eu

- [3] ISO 15001: Anaesthesia and respiratory equipment - compatibility with oxygen www.iso.org
- [4] EIGA Doc. 33 *Cleaning of equipment for oxygen service* www.eiga.eu
- [5] ISO 10524-1 *Pressure regulators with or without flow-meter for medical gas systems* www.iso.org