

DESIGN CONSIDERATIONS AND GUIDANCE FOR THE SAFE USE OF MEDICAL GAS VIPR

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Prepared by Medical Gases Council Ad Hoc Group M-8

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Amendments from 183/13

Section	Change
	Rewrite to reflect current practices

1 Introduction

EIGA Member Companies have been successfully using valves with an integrated pressure regulator (VIPR) for many years in medical gases applications. The VIPR represents a major improvement compared to the former practice when separate customer owned and maintained pressure regulators were used, see EIGA Doc 104, *Safety Principles for Pressure Regulators for Medical Oxygen Cylinders* [1].

VIPR come under the scope of two European regulations, the Transportable Pressure Equipment Directive [2] (TPED) and the Medical Devices Directive, (MDD,) [3].

There have been incidents involving medical gas cylinder packages, (primarily oxygen) using VIPRs. These incidents are well known within the gases industry as well as to the medical gas regulatory authorities.

Since the first publication of this document a decrease of the severity of oxygen ignition incidents involving VIPRs has been observed, even though the numbers in service has been increasing. This publication has been revised to include additional information on VIPR design and operation.

2 Scope and purpose

2.1 Scope

This publication covers medical gas cylinders fitted with VIPRs, designed in accordance with EN ISO 10524-3, *Pressure regulators for use with medical gases. Pressure regulators integrated with cylinder valves -- Part 3*, [4].

2.2 Purpose

The purpose of this publication is to:

- Provide recommendations for those responsible for specifying, designing, manufacturing, cylinder filling and maintaining such devices as well as for end-users and authorities. These recommendations are based on a review of the known incidents involving medical gas cylinders fitted with VIPRs designed and filled up to 300 bar;
- Describes the life time of medical VIPRs; and
- Provides guidance both to gas companies and to healthcare providers as how to treat VIPR-equipped cylinders along the supply chain, in the filling, handling, transportation, storage and maintenance processes.

3 Definitions

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

3.1 Publication terminology

3.1.1 Shall

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

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional

3.1.4 Will

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

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Valve with Integrated Pressure Regulator (VIPR)

Combination of a pressure regulator and cylinder valve intended to be fitted to a medical gas cylinder, EN ISO 10524-3 [4])

4 Feedback from incident reports and investigations

EIGA member companies have reported incidents with VIPRs from different valve manufacturers.

Recommendations are based on individual incidents review and resulting expertise. The incidents have occurred at both customer premises and gas company filling facilities.

The investigations showed that the VIPR incidents could be broken down into the following types:

- Type 1: Failure without ignition
 - o failure of gauges;
 - o wrong flow / no flow;
 - o leakages; and
 - o failure leading to the activation of the pressure relief device.
- Type 2: Failure with internal ignition
 - o on the high-pressure side (shut off mechanism, residual pressure unit or filling port); and
 - o on low pressure side (pressure regulation seat and regulator).

Where the causes for both types of the incidents were identified, they included:

- improper design;
- inappropriate materials;
- improper spare parts
- improper manufacture
- improper operation, and
- internal contamination, for example external debris ingress.

Following incident reviews, the resulting actions have included:

- withdrawal of the VIPR from service via a product recall;
- improvements to the user instructions and training;
- improvement of the cylinder filling procedures (including pre and post fill check) and personnel training;
- improvement in the maintenance procedures and personnel training;
- redesign of the VIPR; and
- improvement of the VIPR manufacturing process and procedures.

5 Design considerations

The minimum design requirements for VIPR are defined in EN ISO 10524-3 [4]. Additional recommendations are outlined below. EIGA Safety Information 21 *Cylinder Valves - Design Considerations* provides information for safe valve design [5].

The design of VIPR should minimise the need for testing and maintenance over its service life.

5.1 Usability and Ergonomics

The usability, defined as the characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction, shall be considered by the VIPR manufacturer as it can have a direct impact on safety.

VIPRs are used routinely in healthcare facilities by professional users, for example nurses, and at patient homes by non-professional users including the patient or family members.

They are also used in applications such as intensive care units, helicopters, ambulances and in emergency situations, when the caregiver is already busy managing a stressful activity. Therefore, the usability shall take into account the user specified applications.

The usability shall also take into account the combination of the VIPR and valve guard.

The points of particular attention for the VIPR are:

- sequence of operations which are required to supply a flow of gas, usually from opening the valve to selection of the flow;
- identification of the status open/close of the valve;
- selection of the flow settings: unambiguity, such as “.5” can be confused with “5” or “6” can be confused with “9”, when the cylinder is upside down, ease of selection including grip, force to be applied, self-capability;
- protection against inadvertent change of settings;
- resistance to excessive force applied by the user on the controls and mobile parts;
- legibility of the flow settings, indicators and markings;

- ease of connection of the various accessories such as flexible hoses, tubing, humidifiers or filling connectors; and
- ability to use the VIPR with the cylinder in various positions including standing and laying on the ground in various orientations.

The points of particular attention for the valve guard are:

- ease of carrying the cylinder, including with gloves;
- visibility access to the settings and indicators; and
- handling of the moving parts such as bed hangers or protections and plugs.

5.2 Materials

Selection of materials is critical to the development of a safe VIPR. All components in the VIPR shall be reviewed for gas compatibility and fit for purpose. In addition, the operating conditions should be reviewed for materials selection including:

- pressure;
- flowrate;
- temperature;
- component exposure to gas, in normal or fault condition; and
- flow path, whether impingement or not impingement area.

Guidance of material selection criteria can be found in EN ISO 15001 *Anaesthetic and respiratory equipment -- Compatibility with oxygen* and EIGA Doc 13, *Oxygen pipeline and piping system* [6,7].

VIPRs and their associated filling connectors shall be tested to validate the material selection, see 5.7. This validation shall be in the form of a test for resistance to ignition of the VIPR and its associated filling connector as described in EN ISO 10524-3. [4]

An accelerated life cycle endurance test and environmental testing on the VIPR shall also be undertaken as part of the validation of the design as required in EN ISO 10524-3 [4].

Non-metallic components are the most susceptible to ignition and therefore their use in the gas wetted areas of the VIPR shall be minimised. Typical examples of uses of non-metallic components include, but are not restricted to valve seats, O-rings, diaphragms and lubricants.

The material selection of non-metallic components shall consider not only the compatibility with the intended gas, for example, oxygen but also the consequence of ignition

There are restrictions in medical applications on the use of polymers that can give off a toxic gas during combustion, such as halogenated polymers, see EN ISO 15001 and EIGA Doc 73, *Design Considerations to Mitigate the Potential Risks of Toxicity when using Non-Metallic Materials in High Pressure Oxygen Breathing Gas Systems* [6,8].

Design should be as such that non-metallic components are protected against direct stream of the gas. Non-metallic surfaces in contact with gas should be minimized.

Lubricants and oils for the low-pressure sections are preferred to be of a grade suitable for high pressure to prevent risk due to migration in high pressure section.