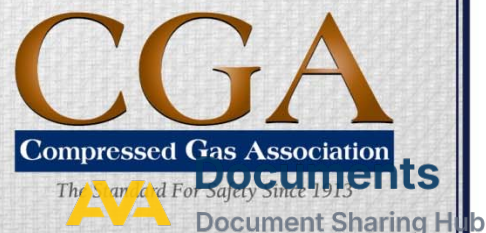


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**CGA E-18—2019**

**STANDARD FOR MEDICAL GAS  
VALVE INTEGRATED  
PRESSURE REGULATORS**

**THIRD EDITION**



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NOTE—Technical changes from the previous edition are underlined.

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## 1 Introduction

This standard establishes minimum performance and safety requirements for medical gas valve integrated pressure regulators (VIPRs). These requirements are based on existing technology and represent the state-of-the-art at the time of publication. There is no intent to discourage or impede future innovation of VIPRs.

## 2 Scope

This standard applies to medical gas VIPRs that are mounted on refillable cylinders use in the administration of medical gases for the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or other animals. VIPRs covered by this standard are pressure preset and provided with a pressure outlet and/ or preset flow outlets.

Devices described in this standard shall comply with the U.S. Food and Drug Administration (FDA) requirements described in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR), and the Health Canada requirements described in the *Medical Devices Regulations* [1, 2].<sup>1</sup> Persons intending to design, manufacture, distribute, import, or sell medical devices as described by FDA and Health Canada shall comply to all regulations. This publication does not address any personnel safety or health concerns, nor does it address any environmental requirements, which may be involved in the testing or manufacture of these devices.

## 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 Creep

Continuing rise above set pressure after downstream flow is shut off due to an internal leak.

NOTE—Creep is also called crawl.

#### 3.2.2 Demand style pressure-metered outlet connection

Outlet connection that allows regulated low pressure gas to flow only after the connection is made.

#### 3.2.3 Fill connection

Portion of the device that is attached to a pressure source for transfilling of the VIPR system.

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

**3.2.4 Fill flow path**

Path from the fill connection to the inlet connection through which gas flows when charging or evacuating a cylinder.

**3.2.5 Flow-metered outlet connection**

Outlet connection that allows a calibrated gas flow at pressures near ambient.

**3.2.6 Inlet connection**

Portion of the device that connects to a compressed gas cylinder.

**3.2.7 Intended media**

Gas type for which the VIPR is designed to operate.

**3.2.8 Low pressure**

Pressure less than or equal to 200 psi (1380 kPa).<sup>2</sup>

**3.2.9 Maximum service pressure**

Maximum pressure at which the VIPR is designed to operate.

NOTE—Maximum service pressure is determined by the pressure rating of the fill connection unless otherwise specified by the manufacturer.

**3.2.10 Orifice flow selector**

Device that uses one or more orifices to deliver the indicated flow of a specific gas or gas mixture when provided with a specified pressure.

**3.2.11 Outlet connection**

Portion of the device that provides regulated low pressure gas.

**3.2.12 Oxygen-enriched gas**

Gas mixtures having an oxygen content that exceeds 23.5% by volume at sea level or gas mixtures when the partial pressure of oxygen exceeds 175 torr (mm Hg).

NOTE—See CGA P-45, *Fire Hazards of Oxygen and Oxygen-Enriched Atmospheres*, for additional information [4].

**3.2.13 Pressure-metered outlet connection**

Outlet connection that provides regulated low pressure gas.

**3.2.14 Pressure regulator**

Gas pressure-reducing and -controlling device designed to provide a controlled delivery (downstream) pressure over a range of variable inlet (cylinder) pressures and/or flow rates.

NOTE—A pressure regulator can have one or more stages of pressure reduction.

**3.2.15 Pressure relief device (PRD)**

Device designed to relieve pressure at a preset value.

**3.2.16 Transfilling**

Transfer of cryogenic liquid, compressed gas, or both from one container to another.

**3.2.17 Valve cap or guard**

Device attached directly to a cylinder that covers the VIPR during handling, transportation, and storage.

**3.2.18 Valve handle or shroud**

Device attached directly to the VIPR that covers it during handling, transportation, storage, and use.

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<sup>2</sup> kPa shall indicate gauge pressure unless otherwise noted as (kPa, abs) for absolute pressure or (kPa, differential) for differential pressure. All kPa values are rounded off per CGA P-11, *Guideline for Metric Practice in the Compressed Gas Industry* [3].

### 3.2.19 Valve integrated pressure regulator (VIPR)

Device comprised of both a shutoff system and a pressure reduction system that can be directly connected to the threaded gas cylinder.

NOTE—VIPR can have flow metered through a set of fixed orifices or a flow control valve.

### 3.2.20 VIPR system

Combination of the VIPR and a compressed gas cylinder.

## 4 Materials

The materials of construction including sealing materials and lubricants shall be selected to fulfill the mechanical, chemical, and physical requirements of the intended application, and shall be compatible with the gas or gas mixture controlled under the operating conditions stated by the manufacturer.

The manufacturer should consider and if necessary, conduct a risk analysis in regards to choice of materials for meeting biocompatibility requirements, see CGA M-19, *Standard for Biocompatibility of Materials for Medical Gas Equipment* [5].

Materials of construction shall be selected such that VIPRs pass ignition testing per 7.4.

NOTE—Materials can be ignited by friction at a valve seat or by adiabatic compression when a gas at high pressure is introduced to a pressure regulator cavity that is at low pressure.

Use caution any time oxygen-enriched gases are used. In any application, pressure, flow rates, cleanliness, and particle generation shall be considered in the design and selection of materials. In general, the higher the pressure and the higher the flow, the greater the chance of ignition.

Plating of springs and other moving parts in contact with the flow of gas should be avoided as plating can cause problems if particles are shed into the gas flow stream.

Gas-wetted elastomers and/or plastics shall be selected to ensure suitability for the application. Selection should consider physical effects on the elastomers and/or plastics such as leaching, blistering, cracking, swelling, and tearing from either rapid decompression, aging, compatibility, ignition due to adiabatic heating, or any other cause. Consideration should be given to materials of VIPR components not in contact with gas for suitability with the product (e.g., gaskets, O-rings).

Nonmetallic materials used in medical gas valves shall be selected in accordance with the guidelines established in CGA V-9, *Compressed Gas Association Standard for Compressed Gas Cylinder Valves*, and CGA G-4.10, *Use of Nonmetallic Materials in High Pressure Oxygen Breathing Gas Applications* [6, 7].

VIPRs intended for use in magnetic resonance (MR) environment shall be investigated for MR conditionality as well as operation as intended in a MR environment. The following publications can be useful in the selection of such materials:

- ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* [8]; and
- ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* [9].

## 5 Cleanliness

All surfaces in contact with a medical gas shall be cleaned in accordance with CGA G-4.1, *Cleaning of Equipment for Oxygen Service* [10]. This cleaning requirement applies to production, repair, and replacement components. Only use cleaning agents that are approved by the VIPR manufacturer and that are compatible with the gas service, materials, and application. Hydrocarbon contamination in excess of limits specified in CGA G-4.1 increases the risk of fire or explosion [10]. Foreign particles can cause loss of pressure control, which can cause seat leakage or creep. This condition can release energy on impact, starting a fire. Gases can be contaminated

by an inadequately cleaned VIPR. Cleaning requirements also apply to production, repair, and replacement components when in use, when not in use, and during shipping and handling.

The manufacturer shall ensure the VIPR is protected from contamination during manufacturing, storage, and shipping.

## 6 Design features

### 6.1 Connections

#### 6.1.1 Inlet connections

VIPRs are usually connected to a cylinder by means of a threaded connection. VIPR inlet connections have either tapered or straight threads. The threads shall be in accordance with FED-STD-H28, *Screw Thread Standards for Federal Services*, or other standards [11].

Design considerations for inlet connections include:

- Modified National Gas Taper (NGT) threads such as those with special thread root and crest forms are acceptable where enhanced sealing, extended VIPR life, or extended cylinder life can be achieved;
- To accommodate VIPR or cylinder tapered thread wear due to repeated removals and insertions, an oversized inlet thread can be used (i.e., 4 thread oversized);
- Undersized threads are permitted where tinning or other metallurgically bonded coatings are applied to the inlet threads. Tinning or coating of threads to satisfy specification tolerances due to manufacturing errors is not permitted;
- To provide increased thread engagement, undersized tapered threads are permitted. However, care shall be taken to ensure VIPR inlet-to-cylinder thread engagement and leak tightness is achieved when installed; and
- VIPR inlet bore diameter and length shall be in accordance with the requirements of CGA V-1, *Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections*, or other applicable standards [12].

#### 6.1.2 Fill connections

A means shall be provided to isolate the fill connection from the cylinder inlet pressure source. VIPRs shall have either gas-specific fill connections that conform to the dimensions in CGA V-1 or the manufacturer's own proprietary noninterchangeable, gas-specific connection [12].

Undersized threads are permitted if metallurgically bonded coatings are applied to the fill connection threads. Other types of coatings are also permitted on fill connection threads.

These threads that do not meet specifications due to manufacturing errors cannot be tinned or coated to achieve specification tolerances.

The minimum torque needed to remove the fill connection from a VIPR body shall be 25 ft-lb (34 Nm).

Fill connections shall have, at a minimum, a dust cap to prevent contamination.

Flow passages modified to incorporate filters, flow restrictors, flow limiting devices, check valves, or other features are allowed if the integrity of the joint and noninterchangeability are maintained.

Torque guides for sealing CGA outlet connections are found in CGA V-21, *Torque Guidelines for Sealing CGA Valve Outlet Connections* [13].

#### 6.1.3 Flow-metered outlet connections

The torque required to remove a gas-specific threaded outlet connection or other threaded outlet fittings from the VIPR body shall be  $\geq 15$  ft-lb (20 Nm).

When a gas-specific threaded outlet connection is provided, it shall be in accordance with CGA V-5, *Standard for Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)*, other recognized industry standards for medical gases, or be the manufacturer's own proprietary, noninterchangeable gas-specific connection [14].

For applications involving the transmission of medical gas at near ambient pressure, the use of nonthreaded outlet connections, for example, hose barbs, is acceptable provided all other requirements regarding gas specificity are met.

#### **6.1.4 Pressure-metered outlet connections**

The torque required to remove a gas-specific threaded outlet connection or other threaded outlet fittings from the VIPR body shall be  $\geq 15$  ft-lb (20 Nm).

When a gas-specific threaded outlet connection is provided, it shall be in accordance with CGA V-5, or other recognized industry standard for medical gases, or be the manufacturer's own proprietary, noninterchangeable gas-specific connection [14].

#### **6.1.5 Demand style pressure-metered outlet connections**

The torque required to remove a gas-specific threaded outlet connection or other threaded outlet fittings from the VIPR body shall be  $\geq 15$  ft-lb (20 Nm).

When a gas-specific threaded outlet connection is provided, it shall be in accordance with CGA V-5, other recognized industry standard for medical gases, or be the manufacturer's own proprietary, noninterchangeable gas-specific connection [14].

Demand style pressure-metered outlet connections shall be equipped with a device that prevents inadvertent release of the low pressure regulated gas.

### **6.2 Pressure relief devices**

#### **6.2.1 Cylinder pressure relief device**

PRDs, as required, shall be in accordance with CGA S-1.1, *Pressure Relief Device Standards—Part 1—Cylinders for Compressed Gases* [15]. The gas service for which the valve is used, not the design of the valve, dictates the type of device needed.

Where required, PRDs shall be incorporated in the valve in accordance with CGA S-1.1. Where not specifically required but where permitted as an option, PRDs can be incorporated in the valve in accordance with CGA S-1.1 [15].

PRDs for gas mixtures shall be in accordance with CGA S-7, *Standard Method for Selecting Pressure Relief Devices for Compressed Gas Mixtures in Cylinders*, and pertinent sections of CGA S-1.1 [16, 15].

#### **6.2.2 Regulator pressure relief devices**

The use of PRDs is optional based on the pressure regulator design and application.

PRDs are only intended to protect a VIPR and shall be located to minimize the danger of discharged gas to the user. Characteristics of operation of the relief device shall be available from the device manufacturer.

Since pressure regulator PRDs are not intended to protect downstream equipment, additional PRDs could be needed.

A PRD shall be either preset or adjusted only with the use of a special tool. Field adjustments are not recommended except by direction of the manufacturer.