

CGA E-7—2018

**STANDARD FOR MEDICAL GAS
PRESSURE REGULATORS,
FLOWMETERS, AND ORIFICE
FLOW SELECTORS**

FIFTH EDITION

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1 Introduction

This publication establishes minimum performance and safety requirements for medical gas pressure-regulating and flowmetering devices. 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 pressure-regulating and flowmetering devices.

This publication does not address any personnel safety or health concerns, nor does it address any environmental requirements, which can be involved in the testing or making of these devices. Each manufacturer shall address these matters relative to their operations and comply with local, state/provincial, and national regulations and laws.

Persons intending to manufacture, distribute, assemble, import, or sell medical devices in the United States shall adhere to all U.S. Food and Drug Administration (FDA) required regulations as described in Title 21 of the U.S. Code of Federal Regulations (21 CFR) [1].¹ In Canada, these firms shall adhere to Health Canada's *Medical Device Regulations* (SOR 98-282) [2].

2 Scope

This publication applies to cylinder gas-pressure regulators; pressure regulators with integrated flowmeter devices; medical gas flowmetering devices (flowmeters); pressure regulator/flowmeter and pressure regulator/flow-gauge combinations; and orifice flow selectors used in the administration of medical gases for treatment, management, diagnostic evaluation, and care of patients. A pressure regulator and flowmeter used in combination shall meet the minimum requirements for each device.

This publication does not apply to pressure regulators or flowmeters used as a permanent part of a piped medical gas distribution system; pressure regulators or flowmeters used as an integral part of medical equipment, vacuum regulators, demand valves or gas mixers; cylinder valve-integrated pressure regulators; or electrical or electronic regulators or flowmeters.

For the purpose of this publication, the use of the term device(s) includes pressure regulators, flowmeters, and orifice flow selectors.

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.

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

3.2 Technical definitions

3.2.1 Backpressure-compensated device

Device designed so any variation in the pressure downstream of the device does not affect the accuracy of its indicated flow.

NOTE—Changes in downstream flow resistance can cause the indicated flow rate to change. However, the device will remain accurate at the new indicated flow rate provided the calibration temperature, inlet pressure, and flowmeter specific gas are correct.

3.2.2 Flow coefficient

Experimentally derived number (C_v) that defines the flow capacity of an orifice or valve.

3.2.3 Flow regulation

Change in set or delivery pressure caused by a change in flow.

NOTE—Pressure change is measured downstream from the pressure regulator outlet.

3.2.4 Flowgauge

Gauge calibrated in units of flow rate that measures pressure differential.

NOTE—The flowgauge does not measure flow. It indicates flow by measuring the pressure upstream of a restriction.

3.2.5 Flowmeter

Thorpe tube (ball and tube) style device that measures and indicates the rate of flow, e.g., liters per minute, of a specific gas or a gas mixture.

NOTE—A flowmeter may or may not incorporate flow adjustment.

3.2.6 Gas specific

Having characteristics that prevent interchangeability, allowing assignment to a specific gas or gas mixture service only.

3.2.7 Leakage

3.2.7.1 External leakage

Unintentional escape of gas from a pressurized device to the atmosphere.

3.2.7.2 Internal leakage

Unintentional escape of gas from a pressurized device in a closed system.

NOTE—Internal leakages normally occur across operating valves seats and cause a rise in internal pressure.

3.2.8 Medical gas

Any gas or mixture of gases used for the diagnosis, treatment, or mitigation of a disease, disorder, abnormal physical state, or the symptoms thereof in man or animal; or used to restore, correct, or modify organic functions in man or animal.

3.2.9 Orifice flow selector

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

3.2.10 Oxygen-enriched atmosphere

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 [3].

3.2.11 Pressure

Force per unit area exerted by a gas on the walls of the gas container.

NOTE—In the International System of Units (SI), pressure is expressed as bar. 14.5 lb/in² (1 psi) = 6.895 kPa, which is 1/100 of a bar.²

3.2.12 High pressure

Pressure greater than 200 psi (1380 kPa).

3.2.13 Low pressure

Pressure less than or equal to 200 psi (1380 kPa).

3.2.14 Pressure gauge

Gauge that indicates the pressure relative to atmospheric pressure.

3.2.15 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.

3.2.16 Adjustable pressure regulator

Pressure regulator fitted with a means of adjusting the delivery pressure without the use of tools.

3.2.17 Flowgauge pressure regulator

Adjustable pressure regulator that incorporates a flowgauge and a restriction downstream of the flowgauge.

NOTE—The flowgauge is calibrated in units of flow corresponding to the pressure required to attain the indicated flow. This device is not pressure compensated.

3.2.18 Flowmeter pressure regulator

Preset pressure regulator that incorporates a permanently attached flowmeter.

NOTE—Flow is controlled by adjusting the attached flowmeter.

3.2.19 Preset pressure regulator

Pressure regulator having the outlet pressure fixed at a prescribed pressure by the manufacturer.

3.2.20 Orifice flow-control pressure regulator

Pressure regulator that incorporates one or more orifices to control flow rate.

3.2.21 Pressure regulation

Change in outlet pressure corresponding to a change in inlet pressure.

3.2.22 Pressure relief device (PRD)

Device designed to relieve pressure at a preset value.

3.2.23 Static increment

Increase in set pressure resulting from a reduction in flow from a relatively small flow to no flow.

NOTE—Static increment is sometimes referred to as lock up.

4 Materials of construction

The materials of construction of the devices 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 within the operating conditions stated by the manufacturer. Considerations and

² 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, Metric Practice Guide for the Compressed Gas Industry](#) [4].

if necessary, risk analyses, shall be conducted with regards to choice of materials of construction. See [CGA G-4.10](#), *Use of Nonmetallic Materials in High Pressure Oxygen Breathing Gas Applications* and [CGA M-19](#), *Standard for Biocompatibility of Materials for Medical Gas Equipment* [5, 6].

Many 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 at low pressure.

The use of aluminum, aluminum alloys, or other materials when used in oxygen service shall be evaluated for potential ignition characteristics.

Plating of springs and other moving parts in contact with the flow of gas shall be evaluated for particulate matter and ignition sensitivity. For example, plating can separate from the components and enter the gas flow stream.

For devices intended to be used in a magnetic environment, e.g., magnetic resonance imaging (MRI), the device compatibility shall be researched. The following publications can be useful in evaluating device compatibility, [ASTM F2052](#), *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* and [ASTM F2213](#), *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* [7, 8]. If required, the device shall be properly labelled as specified in [ASTM F2503](#), *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* [9]. The devices functionality should also be evaluated in a magnetic environment.

5 Cleanliness

Hydrocarbon contamination causes a high risk of fire or explosion. Foreign particles can cause loss of pressure control, which causes seat leakage or crawl. This condition can release energy on impact, starting a fire. In addition, gases can be contaminated by inadequately cleaned components. External surfaces of the pressure regulator should be clean and protected from contamination.

All surfaces in contact with the medical gas or gases being controlled shall be cleaned for oxygen service. See [CGA G-4.1](#), *Cleaning of Equipment for Oxygen Service* [10]. This requirement applies equally to production, repair, and replacement components. Maintaining oxygen cleanliness applies to components during shipping, handling, storage, and use.

6 Pressure regulators

6.1 Connections

Pressure regulators shall have gas-specific inlet connections. Connections shall:

- conform to [CGA V-1](#), *Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections*;
- be the manufacturer's own proprietary, noninterchangeable, gas-specific connection; or
- conform to internationally recognized designs, such as ISO [11].

The torque required to remove the inlet fitting from the pressure regulator body shall be equal to or greater than 25 ft-lb (34 Nm).

The torque required to remove a gas-specific threaded outlet connection or other threaded outlet fittings from the pressure regulator body shall be equal to or greater than 15 ft-lb (20 Nm).

When a gas-specific threaded outlet connection is provided, it shall conform to [CGA V-5](#), *Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)* or an internationally recognized design, such as ISO [12].

For applications involving the transmission of nonpressurized medical gas, the use of nonthreaded outlet connections, e.g., hose barbs, is acceptable provided all other requirements regarding gas specificity have been met.