CGA E-7—2013

MEDICAL GAS PRESSURE REGULATORS, FLOWMETERS, AND ORIFICE FLOW SELECTORS

FOURTH EDITION

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Work Item 08-014
Medical Equipment Committee

NOTE—Technical changes from the previous edition are underlined.

FOURTH EDITION: 2013
THIRD EDITION: 2006
REAFFIRMED 1998
SECOND EDITION: 1992

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1 Introduction

This publication establishes minimum performance and safety requirements for medical gas pressure-regulating and flow-metering 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 flow-metering 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/province, and national regulations and laws.

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/flowgauge 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.

Devices described in this document shall be compliant with the U.S. Food and Drug Administration (FDA) requirements described in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) [1].[1] Persons intending to manufacture, distribute, assemble, import, or sell medical devices as described by FDA shall adhere to all required regulations.

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

3.3 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.

3.4 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.

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