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**MEDICAL GAS VALVE
INTEGRATED PRESSURE
REGULATORS**

SECOND EDITION

CGA

Compressed Gas Association

The Standard For Safety Since 1913

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NOTE—Technical changes from the previous edition are underlined.

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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Definitions.....	1
4 Materials.....	3
5 Cleanliness.....	4
6 Design features	4
6.1 Connections.....	4
6.2 Pressure relief devices	5
6.3 Filtration.....	6
6.4 Fill connection.....	6
6.5 Optional shutoff valve	6
6.6 Pressure adjusting mechanism	6
6.7 Flow-control mechanism.....	6
6.8 Handles/shrouds.....	7
7 General test requirements.....	7
7.1 Leakage.....	7
7.2 Temperature	7
7.3 Excess pressure testing	7
7.4 Ignition testing	8
7.5 Endurance	8
7.6 Mechanical strength	8
7.7 Flow accuracy.....	8
8 Test procedures	9
8.1 General.....	9
8.2 VIPR qualification testing and documentation	9
8.3 Leakage tests	10
8.4 Temperature tests	10
8.5 Excess pressure tests	11
8.6 Ignition test	12
8.7 Endurance	13
8.8 Mechanical strength	15
9 Performance characteristics.....	16
9.1 Performance characteristics.....	16
9.2 Performance tests	19
10 Final assembly testing.....	21
11 Marking.....	21
12 Packaging.....	21
12.1 General.....	21
12.2 Product information	21
12.3 Performance information	22
13 Hazards	22
14 In-service inspection and testing	22
15 References	23

Tables

Table 1—VIPR qualification test sequence 9
Table 2—Pressure regulator performance characteristics 16

Figures

Figure 1—VIPR ignition test logic flow diagram 17
Figure 1—VIPR ignition test logic flow diagram 13
Figure 2—Pressure regulation curve 17
Figure 3—Flow regulation curve at inlet pressure, P_3 18
Figure 4—Typical regulator test setup 20

1 Introduction

This publication 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. 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.

2 Scope

This publication applies to medical gas VIPRs used 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.

Devices described in this publication are 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), and the Health Canada requirements described in the *Medical Devices Regulations* [1, 2].¹ Persons intending to manufacture, distribute, import, or sell medical devices as described by FDA and Health Canada shall adhere to all regulations.

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. Shall 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

Indicate 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.

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