Designation: G175 – 13

Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Pressure Regulators Used for Medical and Emergency Applications[1]

This standard is issued under the fixed designation G175; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 For the purpose of this standard, a pressure regulator, also called a pressure-reducing valve, is a device intended for medical or emergency purposes that is used to convert a medical or emergency gas pressure from a high, variable pressure to a lower, more constant working pressure [21 CFR 868.2700 (a)]. Some of these oxygen pressure regulators are a combination of a pressure regulator and cylinder valve. These devices are often referred to as valve integrated pressure regulators, or VIPRs.

1.2 This standard provides an evaluation tool for determining the ignition sensitivity and fault tolerance of oxygen pressure regulators and VIPRs used for medical and emergency applications. An ignition-sensitive pressure regulator or VIPR is defined as having a high probability of ignition as evaluated by rapid pressurization testing (Phase 1). A fault-tolerant pressure regulator or VIPR is defined as having a low consequence of ignition as evaluated by forced ignition testing (Phase 2).

NOTE 1—It is essential that a risk assessment be carried out on breathing gas systems, especially concerning toxic product formation due to ignition or decomposition of nonmetallic materials as weighed against the risk of flammability (refer to Guide G63 and ISO 15001.2). See Appendix X1 and Appendix X2 for details.

1.3 This standard applies only to:

1.3.1 Oxygen pressure regulators used for medical and emergency applications that are designed and fitted with CGA 540 inlet connections, CGA 870 pin-index adapters (CGA V-1), or EN ISO 407 pin-index adapters.

1.3.2 Oxygen VIPRs used for medical and emergency applications that are designed to be permanently fitted to a medical gas cylinder.

1.4 This standard is a test standard not a design standard; *This test standard is not intended as a substitute for traditional design requirements for oxygen cylinder valves, pressure regulators and VIPRs. A well-designed pressure regulator or VIPR should consider the practices and materials in standards such as Guides G63, G88, G94, and G128, Practice G93, CGA E-18, CGA E-7, ISO 15001, ISO 10524-1 and ISO 10524-3.*

NOTE 2—Medical applications include, but are not limited to, oxygen gas delivery in hospitals and home healthcare, and emergency applications including, but not limited to, oxygen gas delivery by emergency personnel.

1.5 This standard is also intended to aid those responsible for purchasing or using oxygen pressure regulators and VIPRs used for medical and emergency applications by ensuring that selected pressure regulators are tolerant of the ignition mechanisms that are normally active in oxygen systems.

1.6 This standard does not purport to address the ignition sensitivity and fault tolerance of an oxygen regulator or VIPR caused by contamination during field maintenance or use. Pressure regulator and VIPR designers and manufacturers should provide design safeguards to minimize the potential for contamination or its consequences (see Guide G88).

NOTE 3—Experience has shown that the use of bi-direction flow filters in components can lead to accumulation and re-release of contaminants (refer to Guide G88-05 Section 7.5.3.8 and EIGA Info 21/08).

1.7 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

[1] This test method is under the jurisdiction of ASTM Committee G04 on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres and is the direct responsibility of Subcommittee G04.01 on Test Methods.

Current edition approved Oct. 1, 2013. Published November 2013. Originally published as PS 127 – 00. Last published in 2011 as G175 – 03(2011). DOI: 10.1520/G0175-13.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

G63 Guide for Evaluating Nonmetallic Materials for Oxygen Service
G88 Guide for Designing Systems for Oxygen Service
G93 Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments
G94 Guide for Evaluating Metals for Oxygen Service
G128 Guide for Control of Hazards and Risks in Oxygen Enriched Systems
D618 Practice for Conditioning Plastics for Testing
D4066 Classification System for Nylon Injection and Extrusion Materials (PA)
D6779 Classification System for and Basis of Specification for Polyamide Molding and Extrusion Materials (PA)

2.2 *Other ASTM Documents:*[2]
Manual 36 Safe Use of Oxygen and Oxygen Systems
Smith, S. R., and Stoltzfus, J. M., "Preliminary Results of ASTM G175 Interlaboratory Studies," *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres: Tenth Volume, ASTM STP* 1454, T. A. Steinberg, H. D. Beeson, and B. E. Newton, Eds., ASTM International, West Conshohocken, PA, 2003.
Smith, S. R., and Stoltzfus, J. M., "ASTM G175 Interlaboratory Study on Forced Ignition Testing," *Journal of ASTM International*, Vol. 3, No. 7, Paper ID JAI13542, pp. 314-318.

2.3 *Compressed Gas Association (CGA) Standards:*[3]
CGA E-4 Standard for Gas Pressure Regulators
CGA E-7 Standard for Medical Pressure Regulators
CGA E-18 Medical Gas Valve Integrated Pressure Regulators
CGA G-4 Oxygen
CGA G-4.1 Cleaning Equipment for Oxygen Service
CGA V-1 American National/Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections
CGA V-14 Performance Standard for Sealing Gaskets Used on CGA 870 Connections for Medical Oxygen Service

2.4 *United States Pharmacopeial Convention Standard:*[4]
USP 24 – NF 19 Oxygen monograph

2.5 *Federal Regulation:*[5]
21 CFR 868.2700 (a) Pressure regulator

2.6 *ISO Standards:*[6]
ISO 10524-1 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices
ISO 10524-3 Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves
ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen

2.7 *European Industrial Gas Association Documents:*[7]
EIGA Info 21/08 Cylinder Valves—Design Considerations

3. Summary of Test Method

3.1 This test method comprises two phases. A pressure regulator or VIPR must pass both phases in order to be considered ignition-resistant and fault-tolerant.

3.2 *Phase 1: Oxygen Pressure Shock Test*—In this test phase, the ignition sensitivity of the pressure regulator design is evaluated by subjecting the pressure regulator or VIPR to heat from oxygen pressure shocks. The test is performed according to ISO 10524–1 Section 6.6 for oxygen regulators, which is similar to CGA E-7 and ISO 10524–3 Section 6.6 for oxygen VIPRs.

3.3 *Phase 2: Promoted Ignition Test*—The Phase 1 component test system is used for Phase 2 to pressure shock a pressure regulator or VIPR so that an ignition pill is kindled to initiate combustion within the pressure regulator or VIPR. The ignition source is representative of severe, but realistic, service conditions.

3.3.1 *Oxygen Pressure Regulator*—In this test phase, and for this component type, fault tolerance is evaluated by subjecting the pressure regulator to the forced application of a positive ignition source at the pressure regulator inlet to simulate cylinder valve seat ignition and particle impact events.

3.3.2 *Oxygen VIPR*—In this test phase and for this component type, fault tolerance is evaluated by subjecting the VIPR to the forced application of a positive ignition source at the cylinder connection port to simulate a shut-off valve seat ignition and particle impact events in the use (not cylinder filling mode) configuration.

4. Significance and Use

4.1 This test method comprises two phases and is used to evaluate the ignition sensitivity and fault tolerance of oxygen pressure regulators used for medical and emergency applications.

4.2 *Phase 1: Oxygen Pressure Shock Test*—The objective of this test phase is to determine whether the heat or temperature from oxygen pressure shocks will result in burnout or visible heat damage to the internal parts of the pressure regulator.

4.2.1 The criteria for a valid test are specified in ISO 10524–1, Section 6.6 for oxygen pressure regulators and ISO 10524–3, Section 6.6 for oxygen VIPRs.

4.2.2 The pass/fail criteria for a pressure regulator are specified in ISO 10524–1, Section 6.6 for oxygen pressure regulators and ISO 10524–3, Section 6.6 for oxygen VIPRs.

4.3 *Phase 2: Promoted Ignition Test*—

4.3.1 *Oxygen Pressure Regulator*—The objective of this test phase is to determine if an ignition event upstream of the

[3] Available from Compressed Gas Association (CGA), 4221 Walney Rd., 5th Floor, Chantilly, VA 20151-2923, http://www.cganet.com.

[4] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852.

[5] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[6] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

[7] Available from European Industrial Gas Association (EIGA), AISBL Avenue des Arts, 3-5-b-1210 Brussels, Belgium, https://www.eiga.eu/.

pressure regulator inlet filter will result in sustained combustion and burnout of the pressure regulator.

4.3.1.1 The criterion for a valid test is either, (*1*) failure of the pressure regulator, as defined in 4.3.1.2, or (*2*) if the pressure regulator does not fail, consumption of at least 90 % of the ignition pill as determined by visual inspection or mass determination.

4.3.1.2 Failure of the pressure regulator is defined as the breach of the pressurized regulator component (burnout), which may include the CGA 870 seal ring, and ejection of molten or burning metal or any parts, including the gauge, from the pressure regulator. See Appendix X6 Testing Pressure Regulators and VIPRs with Gauges. However, momentary (less than 1 s) ejection of flame through normal vent paths, with sparks that look similar to those from metal applied to a grinding wheel, is acceptable and does not constitute a failure.

4.3.2 *Oxygen VIPR*—The objective of this test is to determine if an ignition event upstream of the shut-off valve or within the shut-off valve will result in sustained combustion and burnout of the VIPR, while the VIPR is flowing oxygen in the patient-use direction.

4.3.2.1 The criterion for a valid test is either, *(1)* failure of the VIPR as defined in 4.3.2.2, or *(2)* if the VIPR does not fail, consumption of at least 90 % of the ignition pill as determined by visual inspection or mass determination. Although the intent and desired result is to provide sufficient energy to ignite the shut-off valve seat, ignition of the shut-off valve seat is not required for a valid test. See Rationale in Appendix X7.

4.3.2.2 Failure of the VIPR is defined as the breach of the pressurized VIPR component (burnout) and ejection of molten or burning metal or any parts, including the gauge, from the VIPR. See Appendix X6 Testing Pressure Regulators and VIPRs with Gauges. However, momentary (less than 1 s) ejection of flame through normal vent paths, with sparks that look similar to those from metal applied to a grinding wheel, is acceptable and does not constitute a failure.

4.3.3 There is no requirement that the oxygen pressure regulator or oxygen VIPR be functional after being subjected to the promoted ignition test.

NOTE 4—The criterion for both the pressure regulator and VIPR Phase 2 tests does not include evaluation of external hardware (such as plastic guards and bags) that could be subjected to a momentary ejection of flame through normal vent paths.

5. Apparatus

5.1 Both phases of this test shall be performed in a test system as specified by ISO 10524-1 and ISO 10524-3.

5.2 Fig. 1 depicts a schematic representation of a typical pneumatic impact test system that complies with ISO 10524-1 and ISO 10524-3.

5.3 The ambient temperature surrounding the pressure regulator or VIPR must be 70 ± 9°F (21 ± 5°C) for both phases of this test. For Phase 2 testing, the initial test gas temperature shall be 140 ± 5.4°F (60 ± 3°C).

6. Materials

6.1 For both phases of testing, the pressure regulator or VIPR shall be functional and in its normal delivery condition and shall be tested as supplied by the manufacturer. For further information, see Section 8.2.2.1 for pressure regulators and Section 8.2.3.1 for VIPRs. If a prototype or nonproduction unit is used to qualify the design, it shall be manufactured using design tolerances, materials, and processes consistent with a production unit. A possible total of eight pressure regulators or VIPRs will be tested: three in Phase 1 and five in Phase 2. If the test articles from Phase 1 are undamaged, they may be reassembled and used for Phase 2.

6.2 *Ignition Pill Manufacture and Assembly*—Follow these steps to manufacture and assemble the ignition pill used for Phase 2 testing. Use the materials listed in Table 1 to manufacture the ignition pills. The total required energy for the

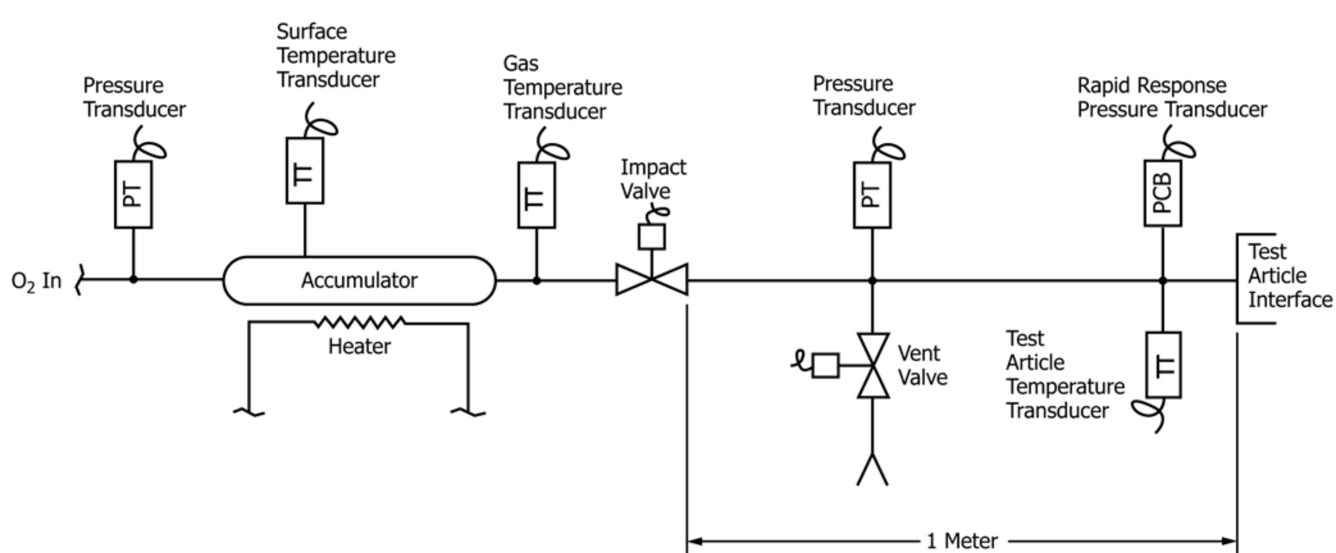

FIG. 1 Typical Test System Configuration