Designation: G 175 – 03

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

This standard is issued under the fixed designation G 175; 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 This standard describes a test method for evaluating the ignition sensitivity and fault tolerance of oxygen regulators used for medical and emergency applications.

1.2 For the purpose of this standard, a pressure regulator is a device, also called a pressure-reducing valve, that is intended for medical or emergency purposes and 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)].

1.3 This standard applies only to oxygen regulators used for medical and emergency applications that are designed and fitted with CGA 540 inlet connections or CGA 870 pin-index adapters (CGA V-1).

1.4 This standard provides an evaluation tool for determining the fault tolerance of oxygen regulators used for medical and emergency applications. A fault tolerant regulator is defined as (*1*) having a low probability of ignition as evaluated by rapid pressurization testing, and (*2*) having a low consequence of ignition as evaluated by forced ignition testing.

1.5 This standard is not a design standard; however, it can be used to aid designers in designing and evaluating the safe performance and fault tolerance capability of oxygen regulators used for medical and emergency applications (G 128).

NOTE 1—It is essential that a risk assessment be carried out on breathing gas systems, especially concerning oxygen compatibility (refer to ASTM G 63 and G 94) and toxic product formation due to ignition or decomposition of nonmetallic materials as weighed against the risk of flammability (refer to ISO 15001.2). See Appendix X1 and X2.1 for details.

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

1.7 This standard does not purport to address the ignition sensitivity and fault tolerance of an oxygen regulator caused by contamination during field maintenance or use. Regulator designers and manufacturers should provide design safeguards to minimize the potential for contamination or its consequences (G 88).

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:*

G 63 Guide for Evaluating Nonmetallic Materials for Oxygen Service[2]

G 88 Guide for Designing Systems for Oxygen Service[2]

G 93 Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments[2]

G 94 Guide for Evaluating Metals for Oxygen Service[2]

G 128 Guide for Control of Hazards and Risks in Oxygen Enriched Systems[2]

2.2 *ASTM Adjuncts:*

Manual 36, Safe Use of Oxygen and Oxygen Systems[3]

2.3 *Compressed Gas Association (CGA) Standards:*

CGA E-4, Standard for Gas Pressure Regulators[4]

CGA G-4, Oxygen[4]

CGA G-4.1, Cleaning Equipment for Oxygen Service[4]

CGA V-1, American National/Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections[4]

2.4 *United States Pharmacopeial Convention Standard:*

[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.

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[2] *Annual Book of ASTM Standards*, Vol 14.04.

[3] Available from American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428–2959.

[4] Available from Compressed Gas Association (CGA), 1725 Jefferson Davis Hwy., Suite 1004, Arlington, VA 22202-4102.

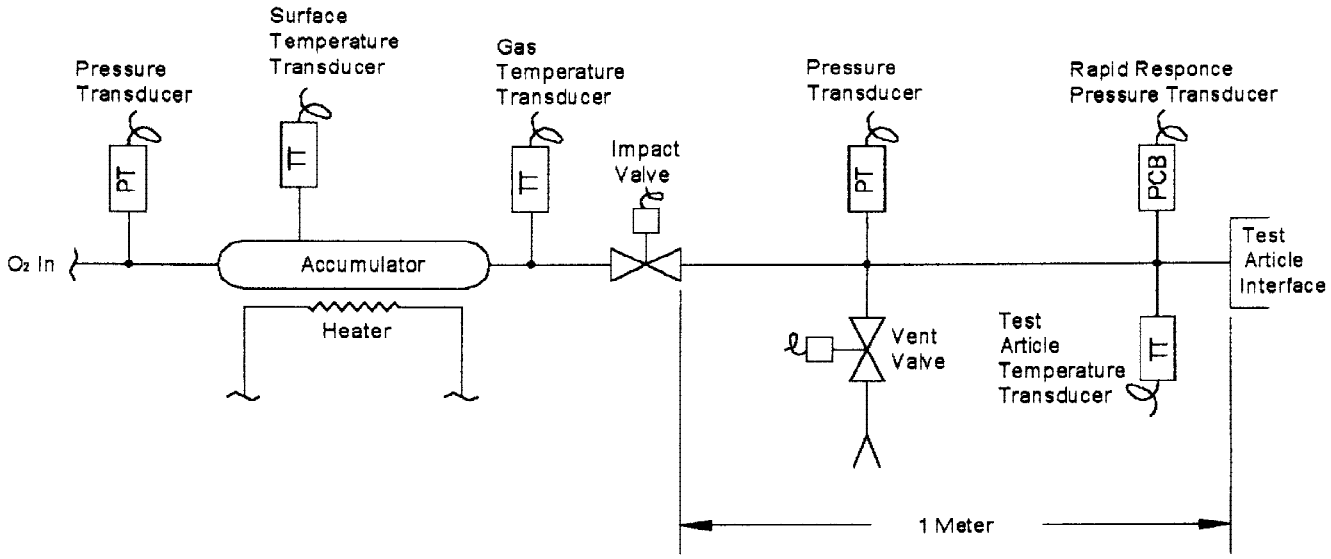

FIG. 1 Typical Test System Configuration

USP 24 – NF 19, Oxygen monograph[5]

2.5 *Federal Regulation:*

21 CFR 868.2700 (a), Pressure regulator[6]

2.6 *ISO Standards:*

ISO 10524 Pressure regulators and pressure regulators with flow-metering devices for medical gas systems[7]

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen[7]

3. Summary of Test Method

3.1 This test method comprises two phases. A regulator 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, fault tolerance is evaluated by testing the ignition resistance of the regulator design by subjecting the regulator to heat from oxygen pressure shocks. The test is performed according to ISO 10524, Section 11.8.1, which is similar to CGA E-4.

3.3 *Phase 2: Regulator Inlet Promoted Ignition Test*—In this test phase, fault tolerance is evaluated by subjecting the regulator to the forced application of a positive ignition source at the regulator inlet to simulate cylinder valve seat ignition and particle impact events. The ignition source is representative of severe, but realistic, service conditions. The Phase 1 component test system is used for Phase 2 to pressure shock a regulator upstream of its inlet so that an ignition pill is kindled to initiate combustion within the regulator.

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 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 from oxygen pressure shocks will result in burnout or visible heat damage to the internal parts of the regulator. Phase 1 is performed according to ISO 10524, Section 11.8.1.

4.2.1 The criteria for an acceptable test are specified in ISO 10524, Section 11.8.1.

4.2.2 The pass/fail criteria for a regulator are specified in ISO 10524, Section 11.8.1.

4.3 *Phase 2: Regulator Inlet Promoted Ignition Test*—The objective of this test phase is to determine if an ignition event upstream of the regulator inlet filter will result in sustained combustion and burnout of the regulator.

4.3.1 The criterion for an acceptable test is either, (*1*) failure of the regulator, which is defined as the breach of the pressurized regulator component (burnout) and ejection of molten or burning metal or any internal parts from the regulator, or (*2*) if the regulator does not fail, consumption of at least 90 % of the ignition pill as determined by visual inspection or mass determination. Failure of the regulator at the seal ring does not constitute an acceptable test.

4.3.2 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.

5. Apparatus

5.1 Both phases of this test will be performed in a test system as specified by ISO 10524.

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

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

[6] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

[7] Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

5.3 The ambient temperature surrounding the regulator must be 70 ± 9 °F (21 ± 5 °C) for both phases of this test. For Phase 2 testing, the test gas temperature can range from 50 to 140 °F (10 to 60 °C).

6. Materials

6.1 For both phases of testing, the regulator must be functional and in its normal delivery condition and must be tested as supplied by the manufacturer. If a regulator is supplied with a filter, perform the test with the filter installed. If a prototype or nonproduction unit is used to qualify the design, it must be manufactured using design tolerances, materials, and processes consistent with a production unit. A possible total of eight regulators will be tested; three in Phase 1 and five in Phase 2. If the regulators 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. Total required energy for the ignition pill is 500 ± 50 cal.

NOTE 2—The ignition pill was developed to simulate both particle impact events and cylinder valve seat ignition. Particle impact events are simulated by iron/aluminum powder within the ignition pill. Nonmetallic promoters within the ignition pill simulate cylinder valve seat ignition. The nonmetallic promoters are also used to bind and kindle ignition of the metallic powder.

6.2.1 *Forming the Cup*:

6.2.1.1 Turn the nylon rod down to 0.28 +0/-0.0025 in. OD (7.11 +0/-0.064 mm) OD.

6.2.1.2 Place the rod in the brass sealing fixture (Fig. 2), sand the rod face flat, and remove any noticeable burrs.

NOTE 3—Fig. 3 shows the nylon rod held in the sealing fixture for sanding.

6.2.1.3 Use a 3⁄16 in. (4.76 mm) dia end mill to bore an ~0.06 in. (1.52 mm) deep cavity in the rod to form a cup.

6.2.1.4 Cut the cup from the rod.

NOTE 4—The cup should be slightly taller than 0.13 in. (3.30 mm). This is an initial pill height; the final pill height is achieved after sanding and is based on the required final pill weight.

6.2.1.5 Using a #69 drill, drill a hole completely through the center of the bottom of the cup. If necessary, square the bottom of the cup with a file to ensure it sits flat and will not tip over.

NOTE 5—The pill base and dimensions are shown in Fig. 4.

6.2.2 *Sealing the Bottom of the Cup*:

6.2.2.1 Put the cup and nylon push tool (Fig. 5) into the brass sealing fixture and adjust the push tool so that the top of the cup is just slightly below the surface of the sealing fixture.

TABLE 1 Ignition Pill Materials and Characteristics

Materials for Phase 2 Ignition Pill	Possible Source	Total Required Energy
Nylon 6/6 rod stock	Cylinder valve seat	
Polyamide sheet (2 mil)	Cylinder valve stem lubricant	
Aluminum powder (325 mesh)	Contaminant from bottle	500 ± 50 cal
Iron powder (325 mesh)	Contaminant from bottle	

NOTE 6—If the top of the cup is not situated in the sealing fixture just slightly below the surface, the heat of the soldering iron could deform the top of the cup.

6.2.2.2 Place one layer of polyamide sheet in the bottom of the cup and cover it with Kapton tape, with the adhesive side facing away from the pill.

NOTE 7—The Kapton tape is used as a mold release and does not remain attached to the final pill. If the adhesive side faces the pill, it will add an undesired residue to the pill.

6.2.2.3 Seal the polyamide to the bottom of the cup using a soldering iron tip (Fig. 6). Ensure that heat is applied evenly around the perimeter of the inside cup bottom so as to melt the polyamide sheet to the bottom of the cup.

NOTE 8—The soldering iron temperature should be approximately 450 °F (232 °C).

6.2.2.4 Remove the Kapton tape and the remaining polyamide sheet.

NOTE 9—The polyamide sheet should easily tear away from the bottom of the cup, leaving a disc of polyamide sealed to the bottom of the cup. If it does not, the ignition pill has not been sealed properly, and the procedure should be repeated.

6.2.3 *Filling the Cup*:

6.2.3.1 Place the cup on a scale capable of a resolution to 0.1 mg and zero the scale.

6.2.3.2 Add 10 ± 1 mg aluminum powder and 3 ± 1 mg iron powder to the cup. Put the aluminum powder in the cup first, then the iron.

NOTE 10—If too much iron is added to the pill, a magnetic spatula may be used to remove iron from the cup.

6.2.3.3 After filling the cup, push any metallic powder on the top surface of the cup into the cup.

NOTE 11—A small paintbrush can be used for this purpose. This is a critical step in making the pill, and it is important to ensure that no material remains on the surface to inhibit a proper heat seal.

6.2.4 *Sealing the Cup*:

6.2.4.1 Put the cup and the nylon push tool into the brass sealing fixture and adjust the push tool so that the top of the cup is just slightly below the surface of the sealing fixture.

NOTE 12—If the top of the cup is not situated in the sealing fixture just slightly below the surface, the heat of the soldering iron could deform the top of the cup.

6.2.4.2 Place one layer of polyamide sheet over the top of the cup, then cover the polyamide sheet with Kapton tape.

6.2.4.3 Place a copper seal tip (Fig. 7) onto the tip of the soldering iron.

NOTE 13—The copper seal tip temperature should be approximately 450 °F (232 °C).

6.2.4.4 Hold the soldering iron perpendicular to the top of the cup, rotate the soldering iron slightly, and apply heat until the polyamide sheet is sealed to the top of the cup (Fig. 8). Let the cup cool for ~1 min before removing the remaining polyamide sheet and Kapton tape. Repeat this process until the cup is capped with five layers of polyamide sheet (Fig. 9).

NOTE 14—If the cup is sealed properly, a disc of the polyamide sheet