



Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Pressure Regulators Used for Medical and Emergency Applications¹

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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.

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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.