



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

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 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 (Guide G128).

NOTE 1—It is essential that a risk assessment be carried out on breathing gas systems, especially concerning oxygen compatibility (refer to Guides G63 and G94) 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 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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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 (Guide G88).

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

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

2.2 ASTM Manual:

Manual 36 Safe Use of Oxygen and Oxygen Systems²

2.3 Compressed Gas Association (CGA) Standards:

CGA E-4 Standard for Gas Pressure Regulators³

CGA G-4 Oxygen³

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.

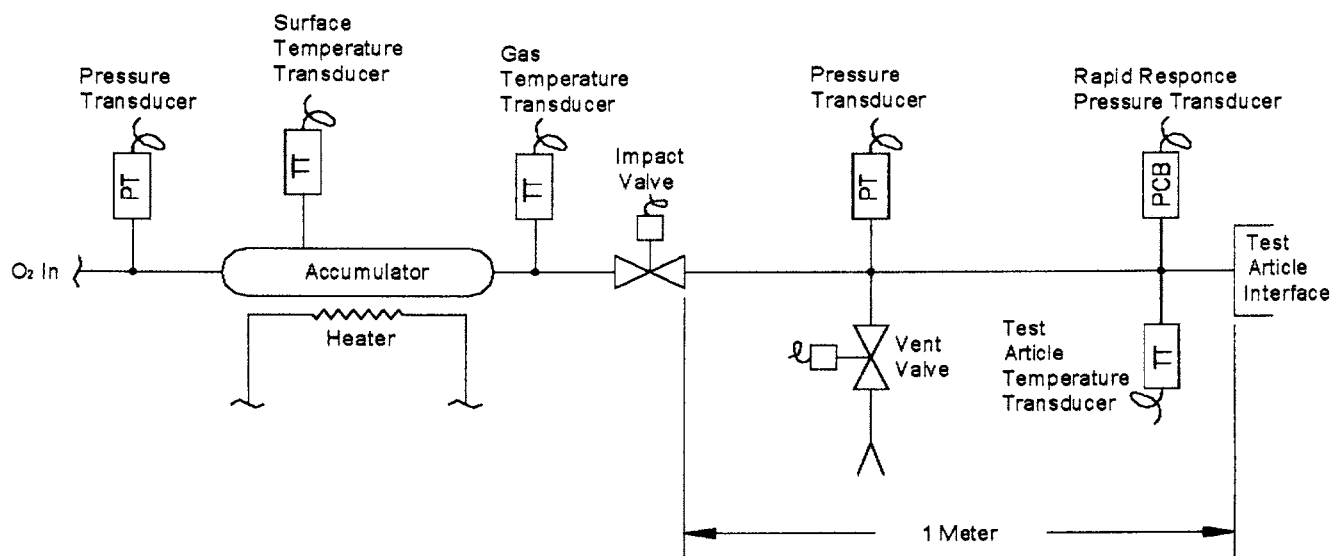


FIG. 1 Typical Test System Configuration

CGA G-4.1 Cleaning Equipment for Oxygen Service³

CGA V-1 American National/Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections³

2.4 *United States Pharmacopeial Convention Standard: USP 24 – NF 19* Oxygen monograph⁴

2.5 *Federal Regulation:*

21 CFR 868.2700 (a) Pressure regulator⁵

2.6 *ISO Standards:*

ISO 10524 Pressure regulators and pressure regulators with flow-metering devices for medical gas systems⁶

ISO 15001 Anaesthetic and respiratory equipment – Compatibility with oxygen⁶

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.

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>.

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**.

5.3 The ambient temperature surrounding the regulator must be $70 \pm 9^{\circ}\text{F}$ ($21 \pm 5^{\circ}\text{C}$) 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 $\frac{3}{16}$ 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**.

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	500 ± 50 cal
Polyamide sheet (2 mil)	Cylinder valve stem lubricant	
Aluminum powder (325 mesh)	Contaminant from bottle	
Iron powder (325 mesh)	Contaminant from bottle	

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.

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.

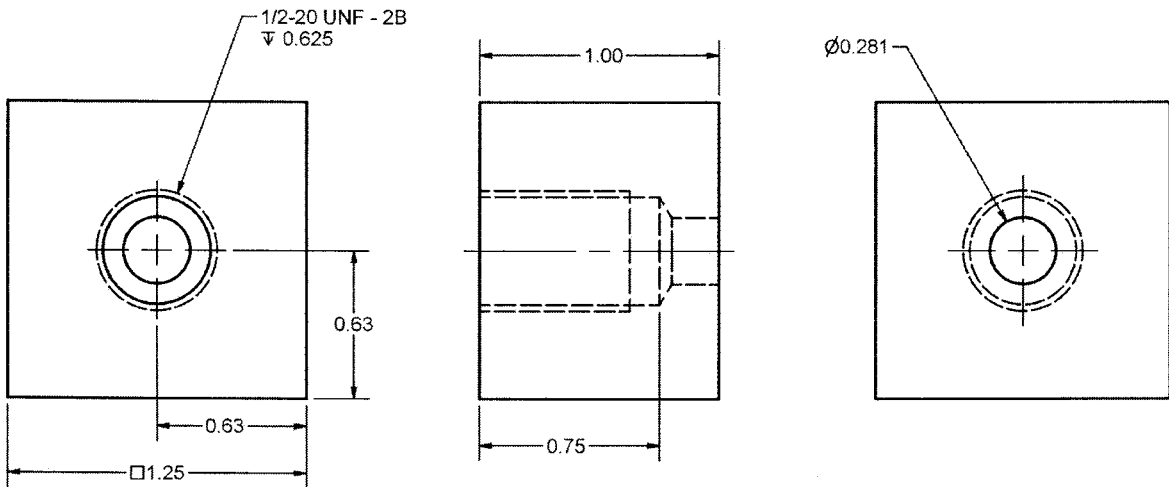
NOTE 12—If the top of the cup is not situated in the sealing fixture just slightly below the surface, the heat of the soldering iron could deform the top of the cup.

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



Notes:

1. Material: Yellow Brass
2. 1 inch = 25.4 mm

UNLESS OTHERWISE SPECIFIED			
DIMENSIONS ARE IN INCHES			
.X	.XX	.XXX	ANGLE
$\pm .1$	$\pm .010$	$\pm .005$	$\pm 1/2^\circ$
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FIG. 2 Brass Sealing Fixture

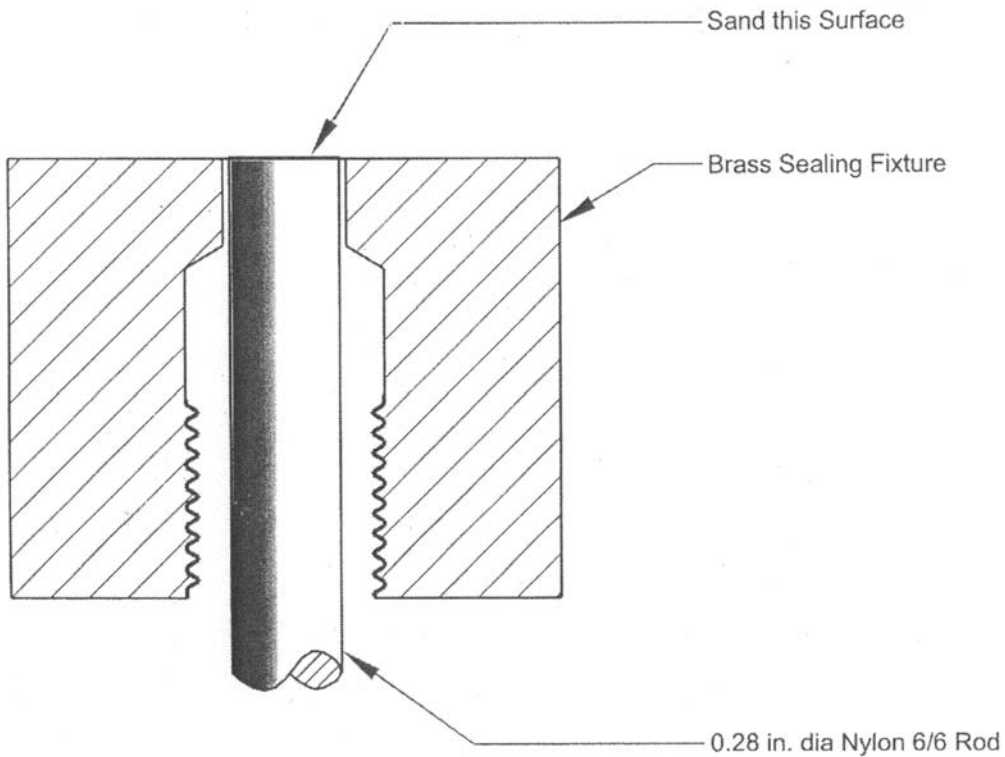
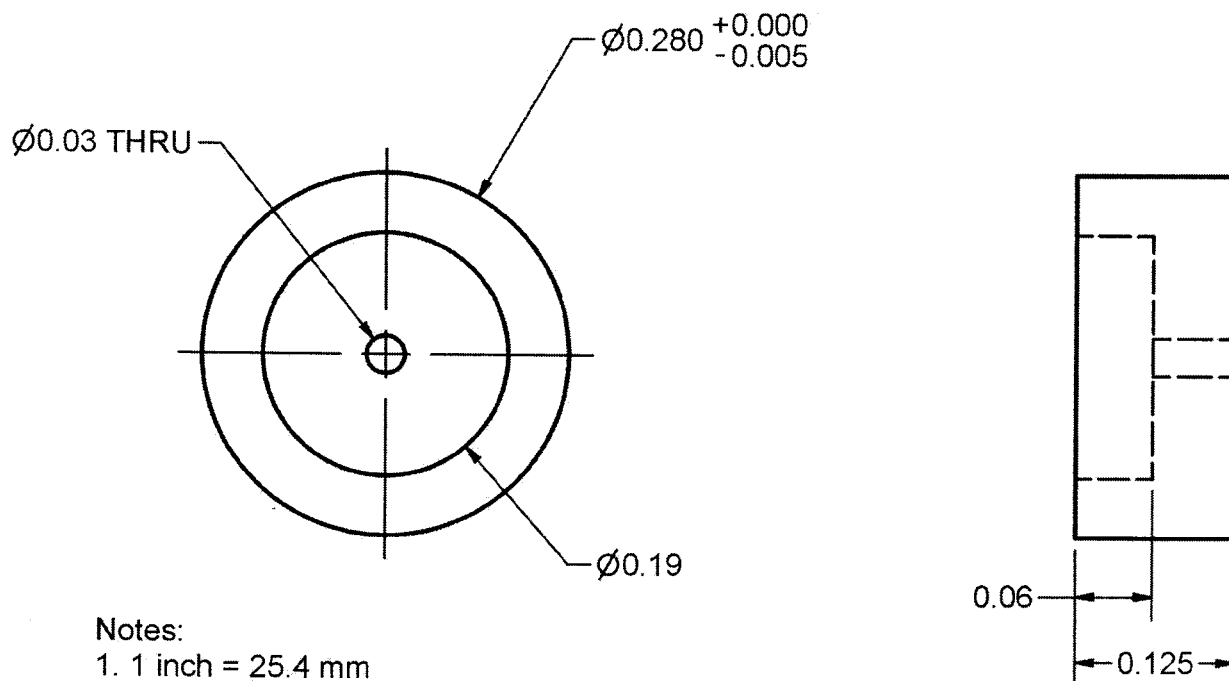


FIG. 3 Nylon Rod in Sealing Fixture

the cup cool for ~1 min before removing the remaining



Notes:

1. 1 inch = 25.4 mm

UNLESS OTHERWISE SPECIFIED			
DIMENSIONS ARE IN INCHES			
.X	.XX	.XXX	ANGLE
$\pm .1$	$\pm .010$	$\pm .005$	$\pm 1/2^\circ$
DIMENSIONING & TOLERANCING PER ANSI Y14.5M-1994			

FIG. 4 Pill Base

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 will be sealed to it and the remainder of the sheet will easily pull off. It is especially critical to ensure the first layer of polyamide sheet is completely sealed to the top of the cup, or else the pill contents will leak out and render the pill unusable.

6.2.4.5 Once the pill is properly sealed and cooled, remove it from the brass sealing fixture. Place the pill upside down in the sealing fixture so that the pill bottom is exposed.

NOTE 15—Take care to ensure that the pill is properly squared in the fixture so that it can be properly sanded. If the pill is not squared in the sealing fixture, the cup bottom can be sanded open, thus exposing the metallic powder and ruining the pill.

6.2.4.6 Using a belt or palm sander, sand the pill until a final weight of 67 ± 1 mg is achieved. Use the push tool to remove the pill from the sealing fixture.

6.3 *Adapter Block and Pill Holder Manufacture*—Adapter blocks and pill holders for regulators with CGA 540 inlet connections shall be made according to the drawings shown in Figs. 10 and 11. Adapter blocks and pill holders for regulators

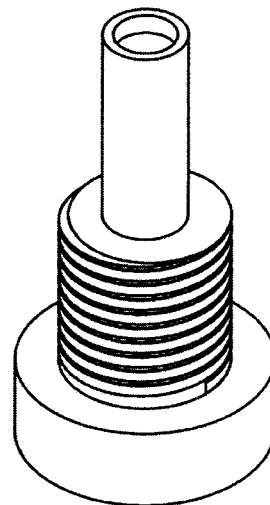
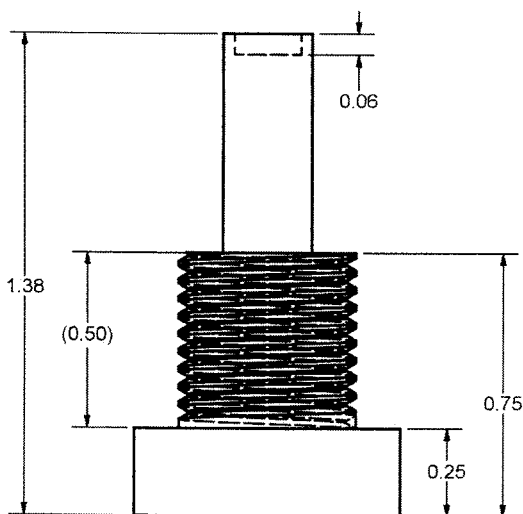
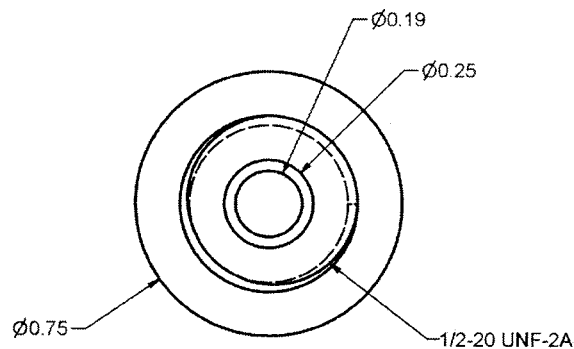
with CGA 870 pin-index adapters shall be made according to the drawings shown in Figs. 12 and 13.

6.4 For Phase 1 testing, the minimum oxygen concentration shall be of 99.5 % purity and shall not contain more than 10 ppm hydrocarbons. For Phase 2 testing, the minimum oxygen concentration shall conform to USP 24-NF 19, Type 1, or shall be of 99.0 % purity. Oxygen of higher purity may be used, if desired.

7. Safety Precautions

7.1 This test can be hazardous. The test cell shall be constructed of fire- and shrapnel-resistant materials in a manner that shall provide protection from the effects of test system component rupture or fire that could result from regulator reaction or failure of a test system component. Normal safety precautions applicable to the operation and maintenance of high-pressure gas systems must be followed when working with the test system.

7.1.1 Complete isolation of personnel from the test system is required whenever the test cell contains a regulator and is pressurized above atmospheric pressure with oxygen. Violent



Notes:

1. Material: Nylon 6/6
2. 1 inch = 25.4 mm

UNLESS OTHERWISE SPECIFIED			
DIMENSIONS ARE IN INCHES			
.X	.XX	.XXX	ANGLE
±.1	±.010	±.005	± 1/2°
DIMENSIONING & TOLERANCING PER ANSI Y14.5M-1994			

FIG. 5 Nylon Push Tool

reactions between regulators and high-pressure oxygen must be expected at all times. Test cell component failure caused by violent regulator reaction has produced shrapnel, flying ejecta, dense smoke, and high-pressure gas jets and flames inside the test cell. Test cell design and layout, test procedures, personnel access controls, and emergency shutdown procedures must be designed with this type of failure expected at any time the test system contains oxygen.

7.1.2 Complete isolation can be assured by locating the test apparatus in an enclosure and behind a barricade. The operator should be stationed in a control room opposite the barricade from the test cell. Visual observation of the test cell shall be accomplished by an indirect means such as a periscope, mirrors, or closed-circuit television.

7.1.3 Equipment used in a high-pressure oxygen system must be properly designed and rated for oxygen service. Proper design of high-pressure oxygen systems includes designing for minimum internal volumes, thereby limiting the magnitude of catastrophic reactions that may occur while testing a regulator. Components used in the test system, such as valves, regulators, gages, filters, and the like shall be fabricated from materials that have a proven record of suitability for high-pressure

oxygen service. Examples of such materials are Monel 400, nickel, and selected stainless steels.

7.1.3.1 High-pressure oxygen systems require the utmost cleanliness (Practice G93). Therefore, test system components should be designed to facilitate disassembly, thorough cleaning, and reassembly without compromise of cleanliness level. Screening tests performed on nonmetallic materials have shown that the impact sensitivity of these materials can vary from batch to batch. Because nonmetallic materials are usually the most easily ignited components in a high-pressure oxygen system, nonmetallic items to be used in this test apparatus such as seats, seals, and gaskets should be chosen from the best (that is, least sensitive) available batch of material. Preferably, two valves shall be provided between the high-pressure oxygen source and the regulator interface. These valves shall be closed, and the test cell and the volume between the two valves shall be continuously vented to atmospheric pressure, before personnel perform work on the regulator.

7.2 When testing is to be performed at elevated temperature, normal safety precautions applicable to the operation and maintenance of electrical systems must be followed.

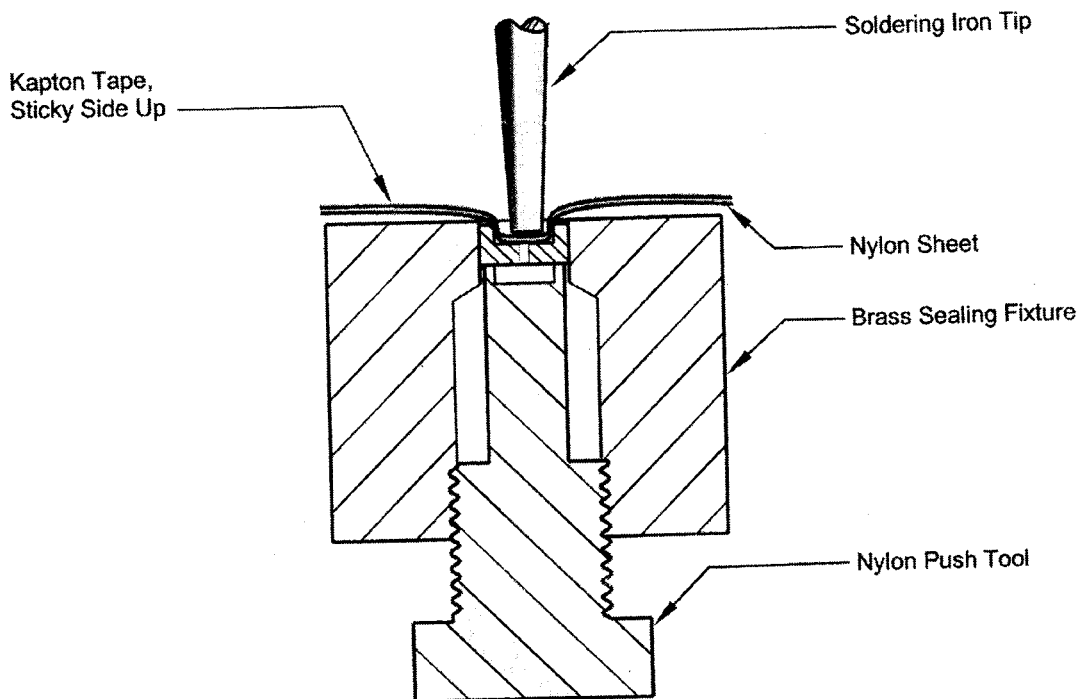


FIG. 6 Sealing the Bottom of the Cup

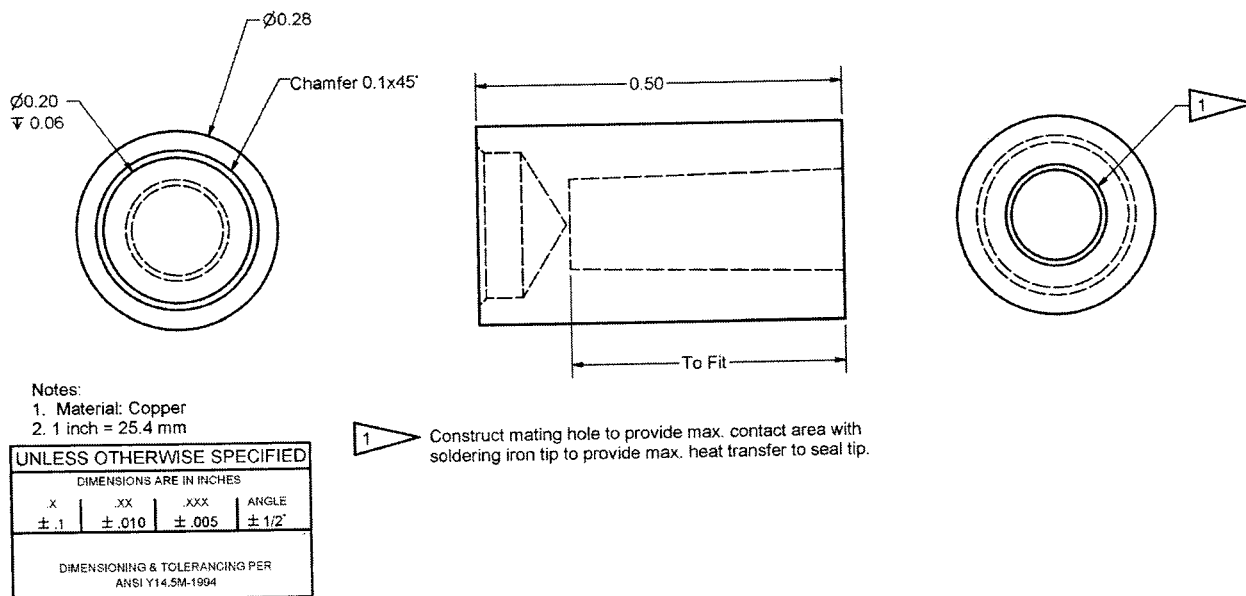


FIG. 7 Copper Seal Tip

7.3 Caution: Approved eye protection shall be worn in the test area at all times. Other protective equipment such as gloves and ear protection shall be required if the system vent is adjacent to the test system or if the audible levels are expected to be greater than OSHA limits.

7.4 No personnel shall be permitted in the test cell when remotely controlled valves are operated or when testing is in progress.

7.5 The test area shall be maintained safe and clean.

7.6 Warning: Oxygen vigorously accelerates combustion. Keep oil and grease away. Do not use oil or grease on regulators, gages, or control equipment. Use only equipment conditioned for oxygen service by carefully cleaning to remove oil, grease, and other combustibles. Keep combustibles away from oxygen and eliminate ignition sources. Keep surfaces clean to prevent ignition or explosion, or both, on contact with oxygen. Always use a pressure regulator to reduce the pressure where possible. Fully reduce the regulator before opening

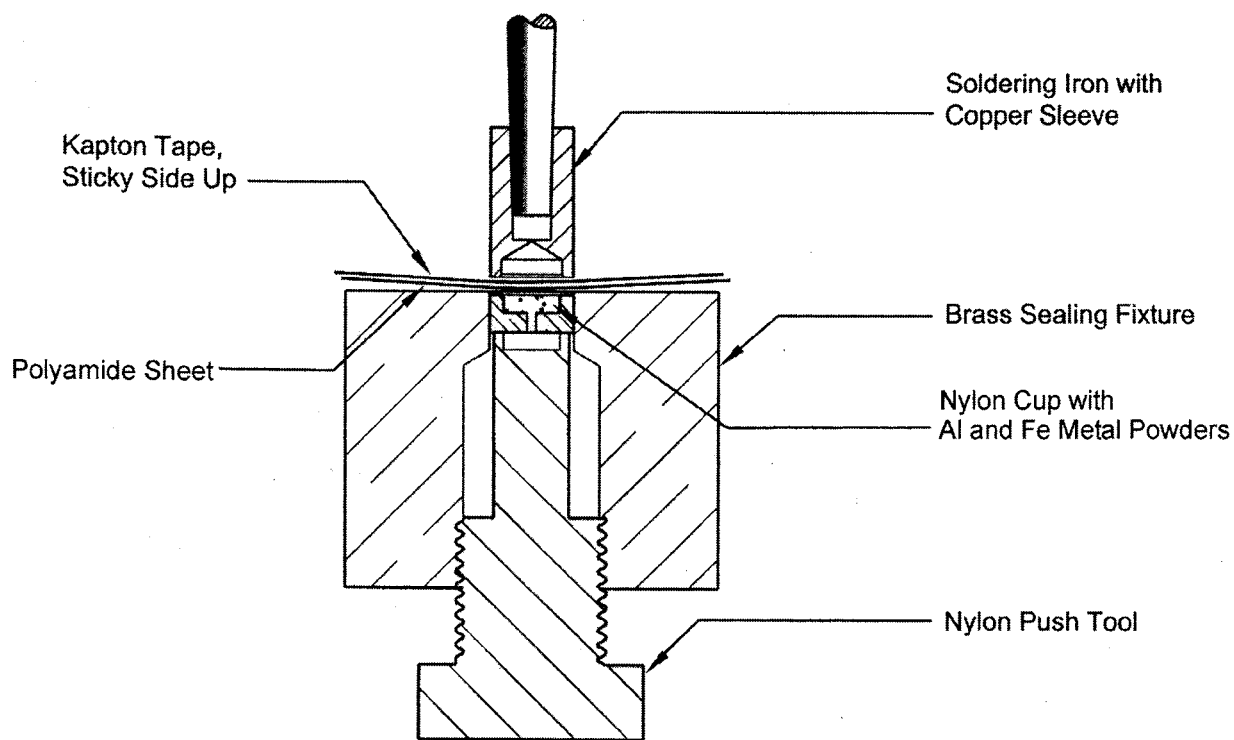


FIG. 8 Sealing the Top of the Pill

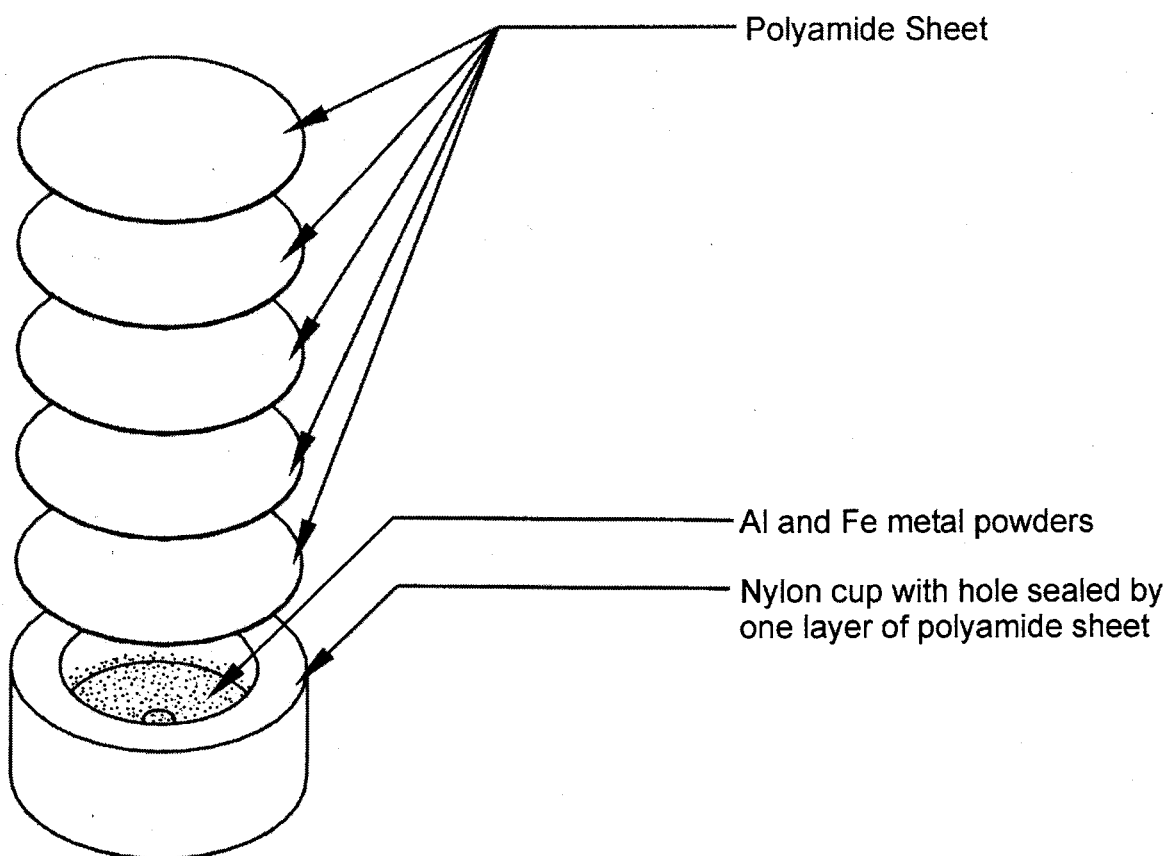


FIG. 9 Five Layers of Polyamide Used to Seal Pill

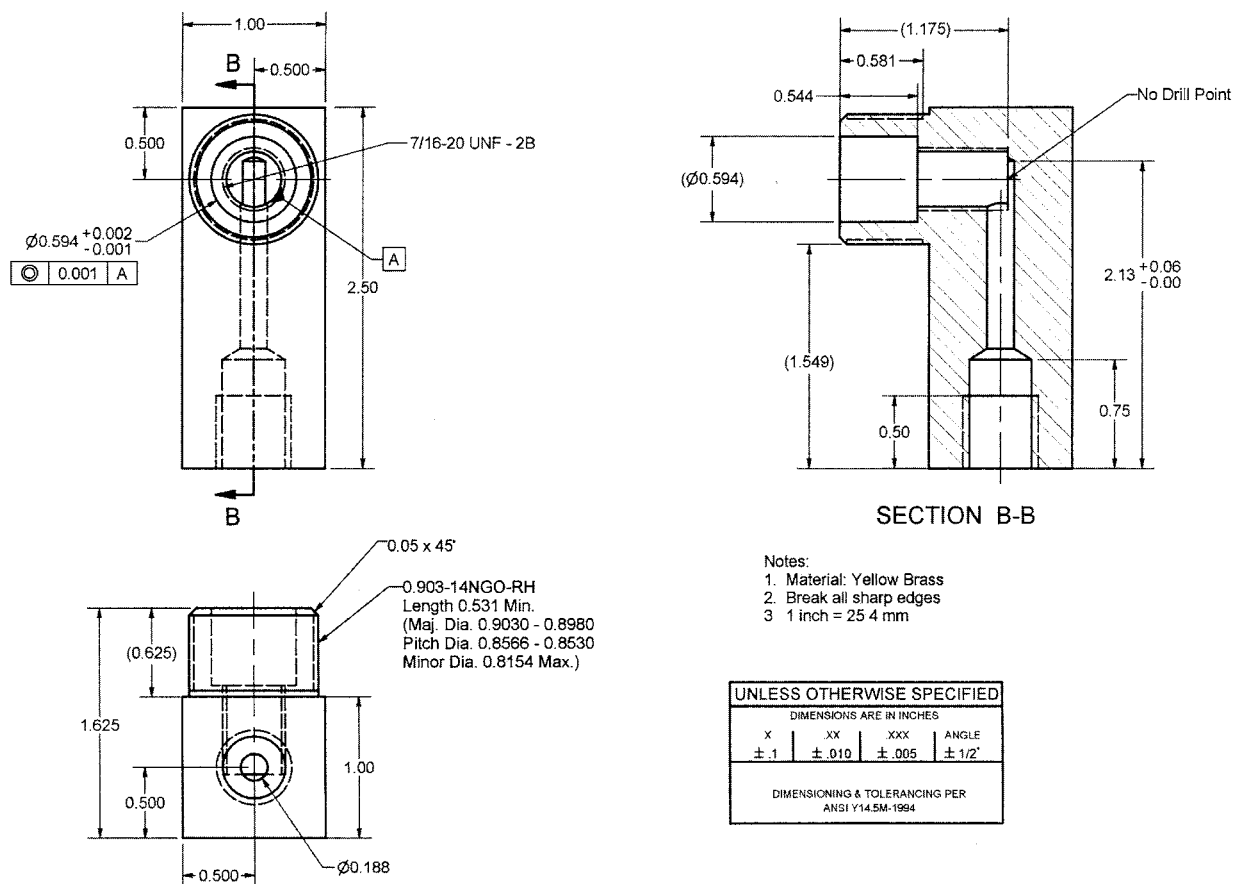


FIG. 10 CGA 540 Adapter Block

upstream cylinder valve. All equipment and containers used shall be suitable and recommended for oxygen service. Never attempt to transfer oxygen from a cylinder in which it is received to any other cylinder. Do not mix gases in cylinders. Do not drop cylinder. Make sure cylinder is secured and positioned upright at all times. Keep cylinder valve closed when not in use. Stand away from valve outlet when opening cylinder valve. Keep cylinder out of sun and away from heat. Keep cylinder away from corrosive environment. Do not use an unlabeled, dented, or damaged cylinder.

7.7 See Guides G63, G88, Practice G93, Guides G94, G128 and Compressed Gas Association publications G-4 and G-4.1 for additional information regarding safe practice in the use of oxygen.

8. Procedure

8.1 *Phase 1: Oxygen Pressure Shock Test*—Phase 1 is performed according to ISO 10524, Section 11.8.1.

8.2 *Phase 2: Regulator Inlet Promoted Ignition Test*—Phase 2 tests five functional regulators in normal delivery condition at a minimum pressure of 2200 ± 50 psi (15.2 ± 0.34 MPa). All five regulators must pass for the regulator to be considered fault tolerant.

8.2.1 *Installing the Pill*—Use gloves and clean handling techniques when handling the pill, adapter block, pill holder, and regulator. Using the copper seal tip (Fig. 7), press the

ignition pill, polyamide sheet-side up, into the threaded end of the pill holder. Ensure the pill fits snugly in the pill holder, or it may not ignite. Install the pill holder into the adapter blocks (Fig. 14 and Fig. 15).

8.2.2 *Installing the Seal*—For those regulators possessing a CGA 870 connection, carefully inspect both mating surfaces for the seal ring. If any possibility of leakage exists, repair the surfaces. Place the seal around the inlet fitting.

8.2.3 *Installing the Regulator*—Test the regulator in the condition supplied by the manufacturer. Set the regulator flow or pressure setting, if applicable, to mid-range. Carefully mate the regulator to the CGA 870 or 540 adapter block. Using a torque wrench, apply sufficient mating pressure to the sealing surfaces to ensure that there is no leakage at the seal and that the regulator will stay bound to the adapter fitting during pneumatic impact. Install the adapter block and regulator into the test system (Figs. 14 and 15).

NOTE 16—A torque specification for mating the adapter block to the regulator is not available. Labs that have performed this test have torqued this connection in the range of 15 to 60 in.-lb. The intention of this instruction is to ensure that there is no leakage between the adapter block and the regulator seal ring. Leakage across the seal ring could lead to burn-out of the seal ring and therefore invalidate the test.

NOTE 17—Leakage between the regulator and CGA 870 or 540 adapter block may prevent the apparatus from providing the proper heat of compression for pill ignition and therefore invalidate the test.

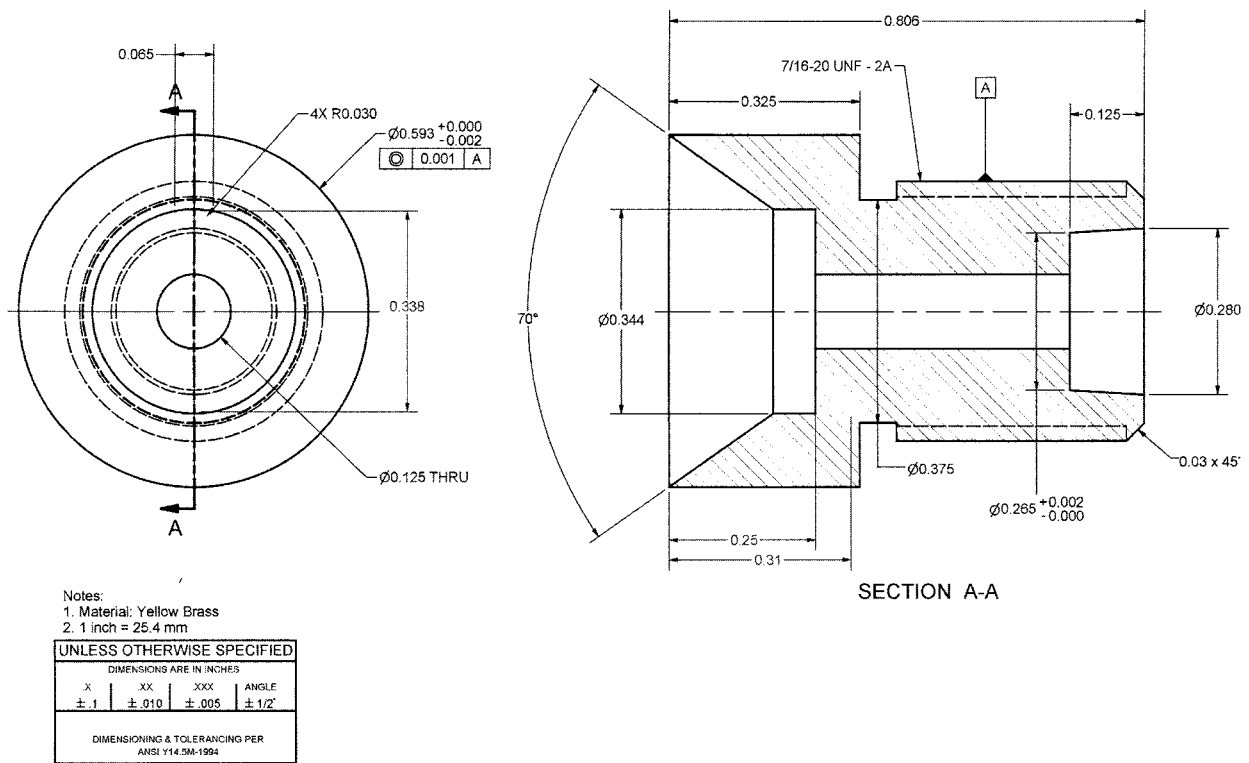


FIG. 11 CGA 540 Adapter Pill Holder

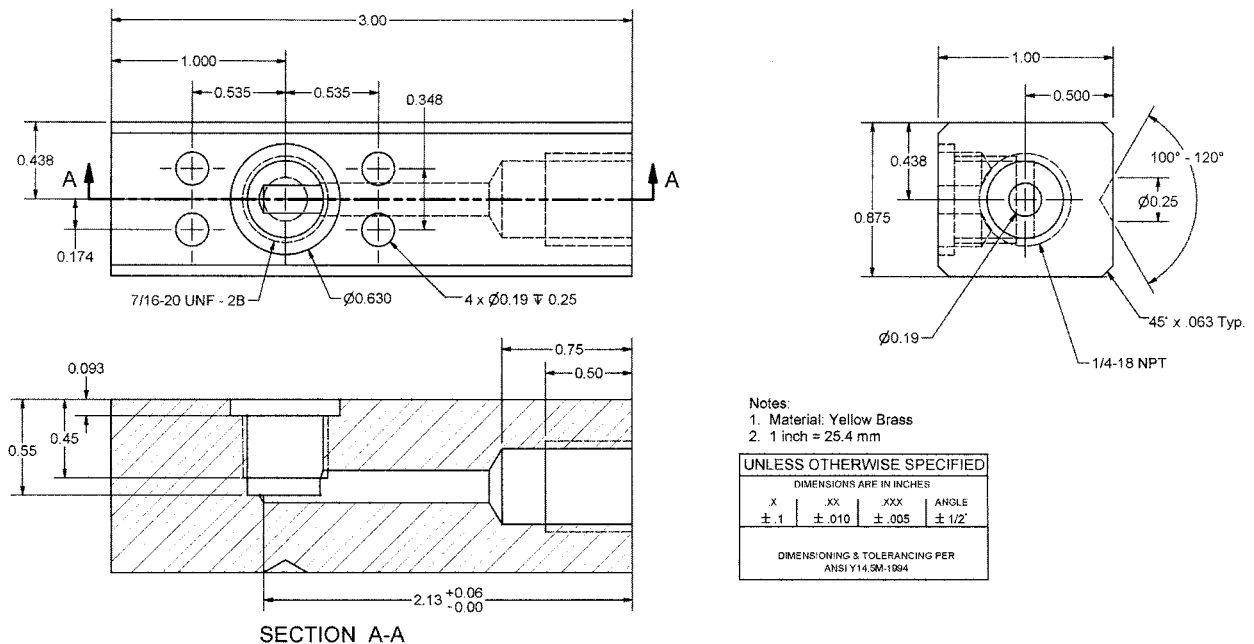


FIG. 12 CGA 870 Adapter Block

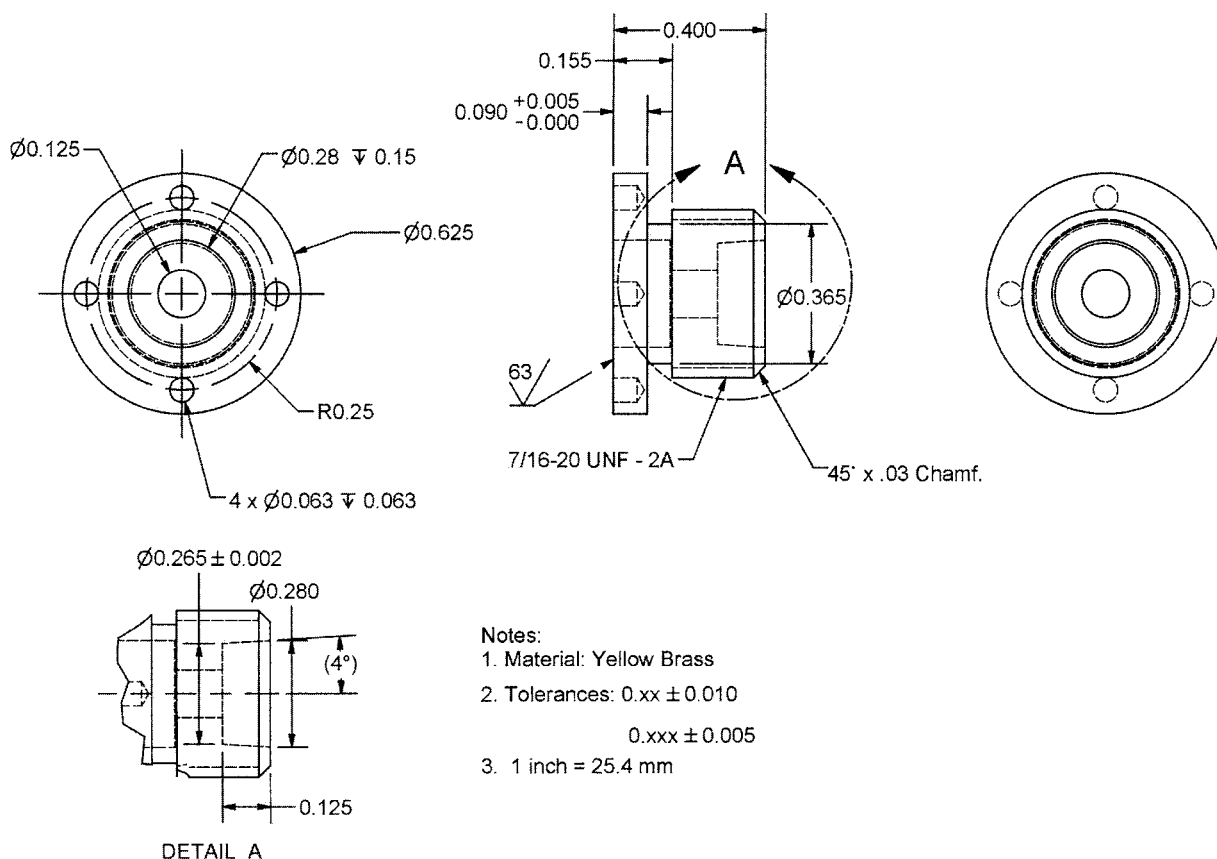


FIG. 13 CGA 870 Adapter Pill Holder

8.2.4 *System Purge*—Before testing, purge the test system by slowly pressurizing the test article with gaseous oxygen (approximately 200 psig [1.38 MPa]), then vent to ambient to empty the accumulator.

8.2.5 *Securing the Piping System*—At a minimum, securely fasten the supply system as close as possible to the regulator.

NOTE 18—Because burnout of the regulator is possible, special precautions must be taken to ensure the safety of personnel and equipment. When part of the regulator body is burned away, much more jet force is possible than would normally be expected from an intact device. The direction and magnitude of the force generated is unpredictable. Also, precaution against flying debris should be implemented because whole regulators can be ejected. The “cutting torch” action of these fires is another hazard that weakens normally sufficient anchorages.

8.2.6 *Videotaping*—A videotape record should be made of the regulator during testing.

NOTE 19—A30 frame-per-second camera is sufficient to capture an ejection event that may be missed by the naked eye. Usually one view is sufficient to capture ejection events from any angle. Some events are visible for only $\frac{1}{30}$ th of a second; therefore, tape records should be scrutinized carefully. Also, a monochrome camera is capable of capturing ejection events.

8.2.7 *Testing*—Impact the ignition pill by fully pressurizing in 20 +0/-5 ms and vent the regulator to ambient pressure using an upstream vent valve.

8.2.8 *Observe External Evidence*—Review the test video and examine the posttest results to determine the following:

8.2.8.1 Were any internal parts ejected from the regulator?
8.2.8.2 Was any molten or burning material ejected from the regulator?

8.2.8.3 Did a breach of the pressurized regulator component occur?

8.2.8.4 Was flame ejected through the normal vent ports for >1 s?

8.2.8.5 If a “yes” answer is given to any of these questions, the regulator is not considered fault tolerant. When the regulator has sufficiently cooled, remove it from the test system and document its condition per 9.3.4.

8.2.8.6 If “no” answers are given to all the questions in 8.2.8.1-8.2.8.4, remove the regulator from the test system and proceed to 8.2.9.

8.2.9 *Disassembly and Inspection*—Disassemble and examine the posttest regulator.

8.2.9.1 *Verify Pill Ignition*—If the ignition pill did not ignite, remove it, install a new pill, and repeat the test until ignition occurs. If the ignition pill ignited, verify the degree of its consumption per 8.2.9.2.

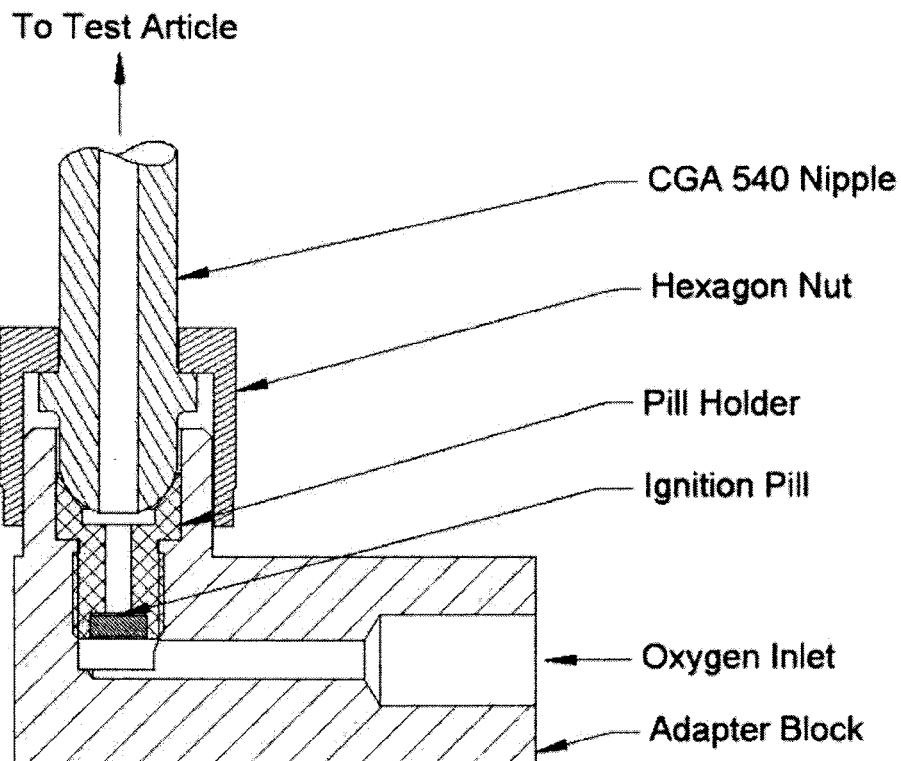


FIG. 14 Typical Ignition Pill Installed in CGA 540 Adapter Block

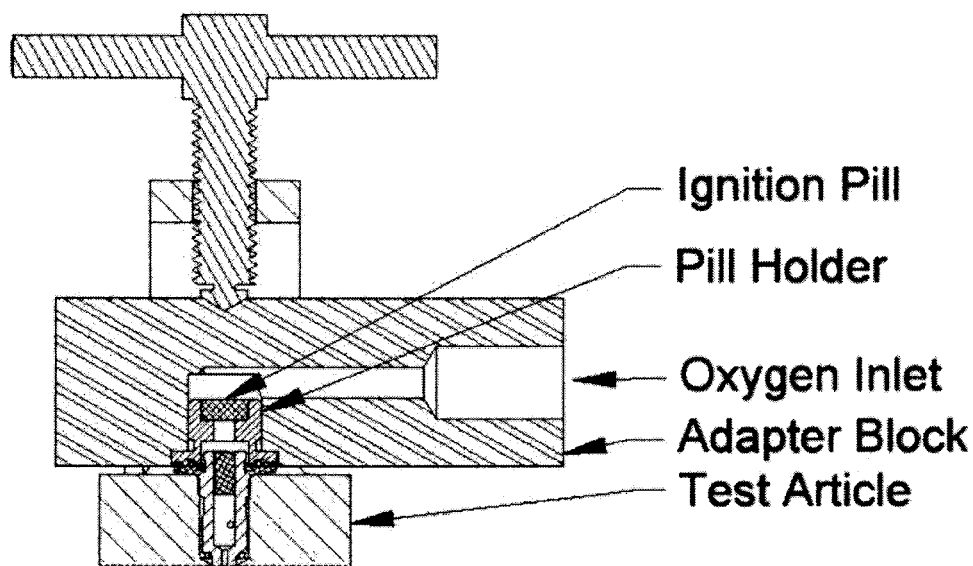


FIG. 15 Typical Ignition Pill Installed in CGA 870 Adapter Block

8.2.9.2 *Verify Appropriate Ignition Pill Consumption*—If pill remnant is found, verify by visual inspection or by mass determination that greater than 90 % of the ignition pill was consumed.

(1) If less than 90 % of the pill was consumed, repeat the test with the same test article if it has not been damaged or with a new test article if necessary.

(2) If greater than or equal to 90 % of the pill was consumed, and “no” answers were given to all the questions in 8.2.8.1-8.2.8.4, the regulator is considered fault tolerant.

9. Report

9.1 The following information regarding the regulator evaluation shall be included.



9.2 Phase 1: Oxygen Pressure Shock Test

9.2.1 Regulator manufacturer, model and serial numbers, regulator type, and a description of the seat, body, and trim materials,

9.2.2 Test media, including oxygen purity and specification,

9.2.3 Test conditions, including impact pressurization rates and test media temperature and pressure,

9.2.4 Pneumatic impact test results, including external evidence of ignition and combustion,

9.2.5 Posttest functional test results, and

9.2.6 Disassembly and inspection results, including a description of evidence of burning or charring and ignition/propagation.

9.3 Phase 2: Regulator Inlet Promoted Ignition Test

9.3.1 Regulator manufacturer, model and serial numbers, regulator type, and a description of the seat, body, and trim materials,

9.3.2 Test media, including oxygen purity and specification,

9.3.3 Test conditions, including impact pressurization rates and test media temperature and pressure,

9.3.4 Test results, including a written description of external evidence of pill ignition and sustained combustion and burnout of the regulator if it occurred. Record whether or not a valid ignition occurred. If valid ignition did not occur, repeat test. If

a valid ignition occurred, determine whether regulator is considered fault tolerant by answering 9.3.4.1-9.3.4.4. “No” answers to all four indicate fault tolerance:

9.3.4.1 Indicate yes/no whether internal parts were ejected from the regulator.

9.3.4.2 Indicate yes/no whether molten or burning material were ejected from the regulator.

9.3.4.3 Indicate yes/ no whether a breach of the pressurized regulator component occurred.

9.3.4.4 Indicate yes/no whether flame was ejected through the normal vent ports for more than 1 s.

9.3.5 Posttest inspection, including verification that ignition pill burned to >90 % consumption. Attach photo of posttest pill remains, and

9.3.6 Video record and/or still photographs (if taken).

10. Precision and Bias

10.1 Precision and bias of this method have not been determined at this time.

11. Keywords

11.1 fault tolerance; forced ignition; ignition; ignition sensitivity; impact test; medical oxygen regulator; oxygen pressure shock test; oxygen regulator; promoted ignition

APPENDIXES

(Nonmandatory Information)

X1. OXYGEN COMPATIBILITY

X1.1 Oxygen regulator manufacturers and designers must address the issue of the hazards associated with the ignition and combustion of materials used in oxygen service. Experience indicates that ignition mechanisms are present under most service conditions. A hazards analysis process as described in Guides G63 and G94 and ASTM Manual 36 is recommended to assess materials compatibility and flammability. The aim of

these standards is to minimize the risk of ignition under reasonably foreseeable service conditions and to reduce the consequence of combustion. These standards recognize that good design and materials selection, along with proper operation, are essential in reducing the risk of fires in oxygen systems.

X2. TOXICITY

X2.1 In addition to the issue of flammability of materials used in medical gas systems, the risk of generating toxic combustion/decomposition products of such materials must be evaluated. It is essential that a risk analysis according to the requirements and methods of ISO 15001 be carried out on medical gas systems.

X2.2 Nonmetallic materials may ignite as a result of local heating by several common ignition sources, such as adiabatic compression and mechanical impact. Therefore, designers tend to choose materials with the highest possible autoignition temperature (AIT). However, several materials (including lubricants) with a comparatively high AIT contain high propor-

tions of fluorine or chlorine, such as polytetrafluoroethylene and polychlorotrifluoroethylene. All combustion and decomposition gases containing fluorine and chlorine are toxic; some are extremely toxic. Other widely used nonmetallic materials that contain nitrogen (polyamide, polyurethane) or sulfur (polyphenylene sulfide PPS) may also produce toxic combustion products, but these are generally less toxic than the gases that contain fluorine and chlorine. The gases released depend on the chemical composition and the conditions of combustion and decomposition, particularly temperature, pressure, and oxygen concentration.

X3. TEST PRESSURE RATIONALE

X3.1 It was determined that the minimum test pressure for this standard would be 2200 psi (15 MPa) rather than the 3481 psi (24 MPa) specified in **ISO 10524** because of the relative flammability of typical materials of construction for these devices. Based on data from promoted combustion testing of 0.125 in. dia rods (ASTM G124), Al supports burning at ~25 psi, stainless steel at ~500 psi, and Zn at ~800 psi. On the other hand, 0.125 in. dia rods of brass, Cu, Monel K-500, Monel 400, and bronze will not support burning at pressures up to 10,000 psi (69 MPa). It is clear that Al, stainless steel, and Zn castings are flammable at either 2200 psi (15 MPa) or 3481 psi (24

MPa) and that brass, Cu, Monel, and bronze will not be flammable at either pressure. Therefore, a test run at either pressure will be effective to determine if the device is resistant to burnout, which is the test objective.

X3.2 It is recognized that the pill will burn slightly faster at the higher test pressure than at the lower test pressure, but the total energy released will be the same.

X3.3 Based on these considerations, 2200 psi (15 MPa) was selected as the required minimum test pressure for this standard.

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