

SurgeX

Surge Suppressing Post Valve

***The Solution to Safe Handling
of Oxygen Systems***

FIRE PREVENTION STARTS RIGHT HERE

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THE SURGEX SOLUTION

A. INTRODUCTION

Oxygen Regulators (Figure 1 on page 4) are mounted on the post valves of compressed oxygen tanks. The post valves are simple on/off valves. When they are opened, oxygen at 2200 psi (or less as the tank is emptied) enters the oxygen regulator where its pressure is reduced to 50 psi before being delivered via plastic tubing to a patient.

During the period from 1995 to 2001, there have been 40 fires reported to the FDA associated with oxygen regulators (See Attachment A): 14 have taken place in the emergency environment, 12 in hospitals, 13 in home care treatment and 1 in a dental office.

While these fires are rare, they can and do result in severe bodily injury and property damage. (See Figure 2 on page 5.)

B. CAUSES OF OXYGEN REGULATOR FIRES

Oxygen regulator fires take place when there is a combustible contaminant (e.g., motor oil, gasoline, hand lotion, cleaning agent, etc.) in the flow channel of the oxygen regulator and when the post valve is opened very rapidly. In such situations, the oxygen, on being released from the tank through the post valve, undergoes a rapid expansion and drop in pressure. Upon entering the constricted channels of the oxygen regulator, the gas is recompressed, causing a rapid rise in temperature. If there are combustible contaminants (e.g., motor oil, etc.) in the flow channels of the oxygen regulator during this rapid rise in temperature, they can and do catch fire in an environment of relatively high pressure oxygen at high flow rates. The oxygen markedly increases the likelihood and severity of the fire, resulting in serious risk to patients and healthcare workers.

One other agent can play a role in this process. Minute shavings of aluminum can and do collect in aluminum oxygen tanks. They can become entrapped in the released gas and can create friction sparks as they hit the oxygen regulator flow channel walls. Such sparking on its own can cause contaminants to burn in the presence of pressurized oxygen at high rates of flow.

C. ALUMINUM OXYGEN REGULATORS

Historically, oxygen regulators have been offered in brass and aluminum. Aluminum was the material of choice where light weight was called for. Aluminum and brass oxygen regulators placed on the market have been tested to meet the C.G.A.'s (Compressed Gas Association) E-4 Test which subjects all designs to a simulation of a rapidly opened post valve. Unfortunately, such testing is done on clean or contaminant-free regulators. Under such conditions, fires do not take place in a properly designed aluminum or brass oxygen regulator. Because of this, it did not become apparent to either manufacturers or government and industry regulatory bodies that when such contaminant fires do occur with high pressure oxygen present, aluminum itself catches fire. In other words, the body of the oxygen regulator itself becomes fuel for the fire.

OXYGEN REGULATOR MOUNTED ON A POST VALVE

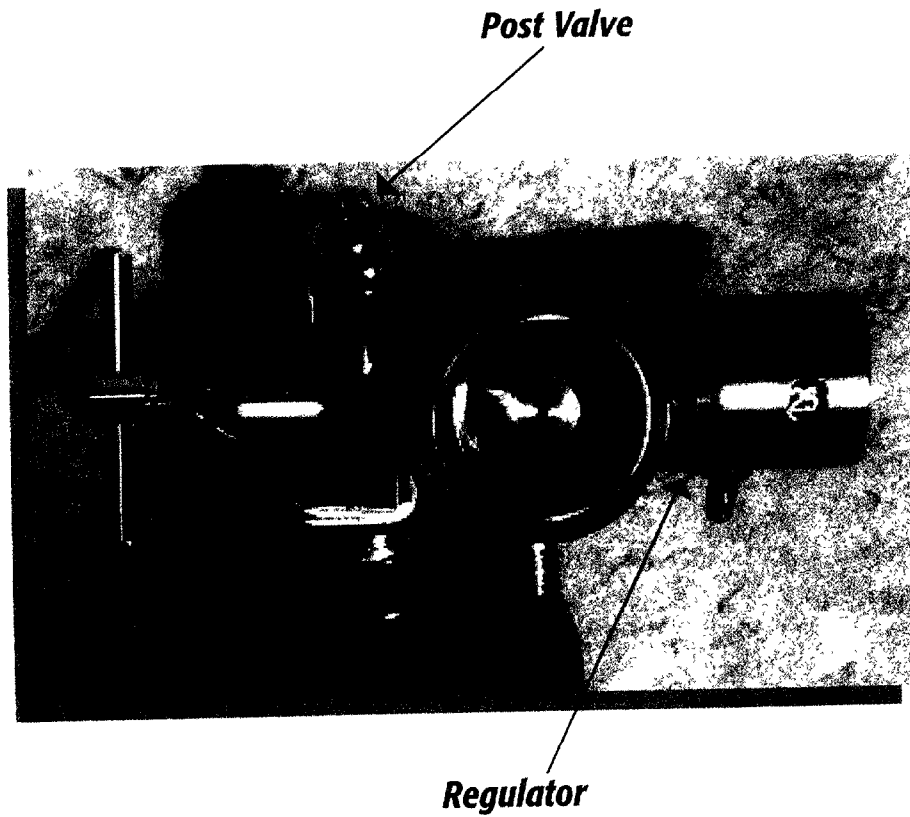


Figure 1

AFTERMATH OF AN OXYGEN REGULATOR FIRE

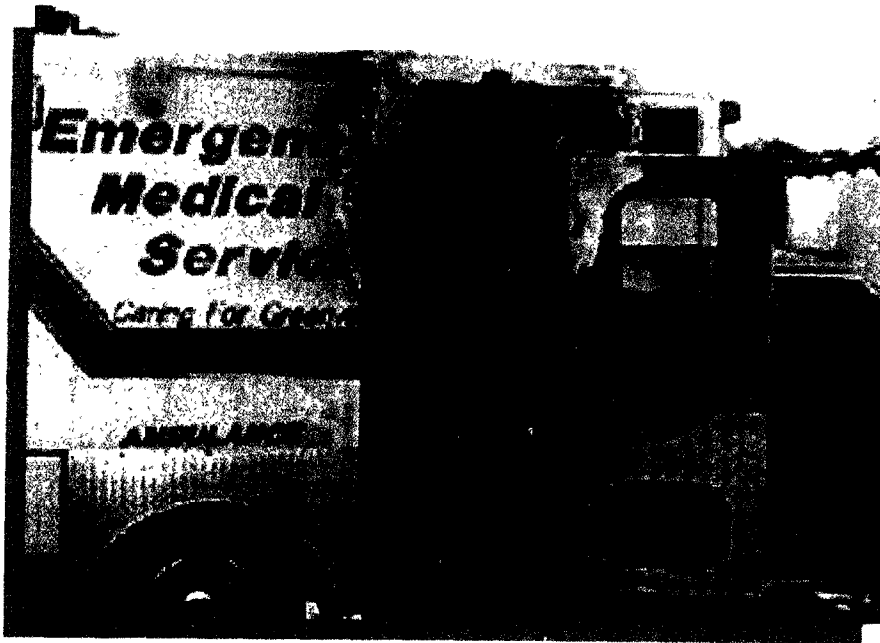


Figure 2

D. REGULATORY AGENCY REACTION

In February, 1999, after a rash of fires in the emergency market, the FDA and NIOSH (National Institute for Occupational Safety and Health) issued a public health advisory entitled "Explosions and Fires in Aluminum Oxygen Regulators" (see Attachment B). In this advisory, the FDA recommended that aluminum regulators be replaced with brass regulators.

The FDA also tasked the "Committee G4 on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres" (commonly called the G4 Committee) of ASTM (American Society for Testing and Materials) to develop a testing method which would subject oxygen regulators to a realistic but severe test environment to determine which ones would produce "burn-out". In other words, the G4 Committee was tasked with developing a test which each regulator on the market would be required to pass. The ASTM developed that test protocol, publishing it in November 2000 as PS 127-00 (see Attachment C) entitled "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications."

E. WHERE WE ARE NOW

The actions taken to date have been targeted at minimizing the effects of oxygen regulator fires. By utilizing brass regulators, emergency agencies, hospitals, and home care dealers insure that the body of the regulator will not become fuel for the fire and thereby limiting the fire's duration and severity. The brass body may, however, under certain conditions melt. But given current post valve technology, the danger of a rapid opening of the valve and a resulting rapid increase in gas temperature still exists, and aluminum filings from the cylinder can still be caught up in the gas flow with resulting sparks. Therefore, if any contaminants have worked themselves into the flow channels of the oxygen regulator, a fire can start. That fire, even if it is in a brass regulator, can and will project out from the regulator itself.

These realities are reflected in the criteria in PS 127-00 (see Attachment C) for determining whether or not a given brass oxygen regulator is fit to be on the market. PS 127-00 is a forced ignition test. No one foresaw the possibility of preventing the temperature rise associated with gas recompression from reaching levels that would ignite contaminants. Therefore, in the PS 127-00 protocol a "pill" containing a realistic mix of contaminants is placed in the port of the oxygen regulator being tested. The current technology post valve is opened rapidly (in .020 seconds) and because of the heat of recompression a fire is ignited. A regulator passes the test and is considered "fault tolerant" if, when the inevitable fire takes place, the "ejection of flame through normal vent paths lasts less than one second with sparks that look similar to those from metal applied to a grinding wheel." (See 4.3.2 of PS 127-00 in Attachment C.)

Thus, while an oxygen regulator that passes the forced ignition test in PS 127-00 is measurably safer than the old aluminum regulators that actually provide fuel for the fire, they are by no means safe. One second of flame can cause a great deal of damage, injury and human suffering.

It is only by attacking the root cause of the problem — the heat of recompression — that one can virtually eliminate the danger of fire when contaminants, as they inevitably will, work their way into oxygen regulators.

F. THE SURGEX SOLUTION

Allied's engineers found that the best place to control the heat of recompression was at the post valve. They designed a new post valve that suppresses the surge of oxygen no matter how rapidly one opens the valve. We call this new post valve "SurgeX", and it is pictured in Figure 3 on page 9.

The pressure versus time graph in Figure 4 on page 10 shows what happens when one opens a conventional post valve rapidly and what happens when one opens a SurgeX rapidly. A conventional post valve's flow channel can be opened in .020 seconds if one really cranks it as fast as is humanly possible. The dotted line in Figure 4 shows the gas pressure level through time at the exit of the post valve (and entrance to the oxygen regulator) when the flow channel of the conventional post valve is opened in .020 seconds. The gas pressure rises to 2200 psi virtually instantaneously. This rapid rise or recompression results in a rapid rise in temperature, which in turn can and does lead to fire if contaminants with suitably low auto ignition temperatures are present.

The solid line on Figure 4 displays the pattern of pressure increase associated with the SurgeX post valve when the handle is opened in .020 seconds. Mechanisms within the valve cause the valve flow channel to open more slowly so that it takes about .848 seconds for the pressure exerted by and on the gas to reach 2000 psi. The greater amount of time allows heat to dissipate, resulting in less temperature increase within the system. Because of these smaller temperature increases, contaminants do not catch fire.¹

Allied's engineers conducted the tests described in detail in Attachment D to demonstrate that the SurgeX, with its surge suppression capability, did in fact prevent heat of recompression fires in oxygen regulators.

In these tests, highly volatile contaminant packages were placed at the entrance to a brass regulator. The brass regulator was in turn connected first to a conventional or CGA 870 post valve, and in subsequent tests to the SurgeX post valve. In each test, the post valve being tested was opened mechanically at an angular velocity which represents the fastest that a person can open a post valve.

¹ In actual tests with SurgeX valves, maximum pressure (2000 psi) was reached between .750 seconds and 1.2 seconds. Effective heat dissipation was achieved throughout this range.

As summarized on Table 1 below, we conducted 50 such tests on conventional post valves and saw 2 recompression fires. We conducted 100 such tests on SurgeX valves and saw no such fires. Surge suppression works, virtually eliminating the heat of recompression as a source of fires in oxygen regulators. While the incidence of fires with conventional valves even with highly volatile contaminants is low, they do take place replicating experience in the field. Oxygen regulator fires with conventional valves are rare, but dangerous.

Table 1

<u>Conventional Post Valve</u>			<u>SurgeX</u>		
<u># of Trials</u>	<u># of Fires</u>	<u>% of Trials w/Fires</u>	<u># of Trials</u>	<u># of Fires</u>	<u>% of Trials w/Fires</u>
50	2	4%	100	0	0%

As noted earlier, a second and related source of fires is frictional heat caused by aluminum filings. We have placed a 50 micron filter in the flow channel of SurgeX which prevents aluminum filings from being entrapped in the gas flow, thereby eliminating that source of ignition.

In conclusion, the SurgeX represents a solution to a relatively rare but very real and nasty safety problem, and we believe all oxygen tanks in the medical and dental industry should be fitted with it.

FIRE PREVENTION STARTS RIGHT HERE



**SURGEX VALVE SHOWN MOUNTED
TO A CUT-AWAY ALUMINUM OXYGEN TANK**

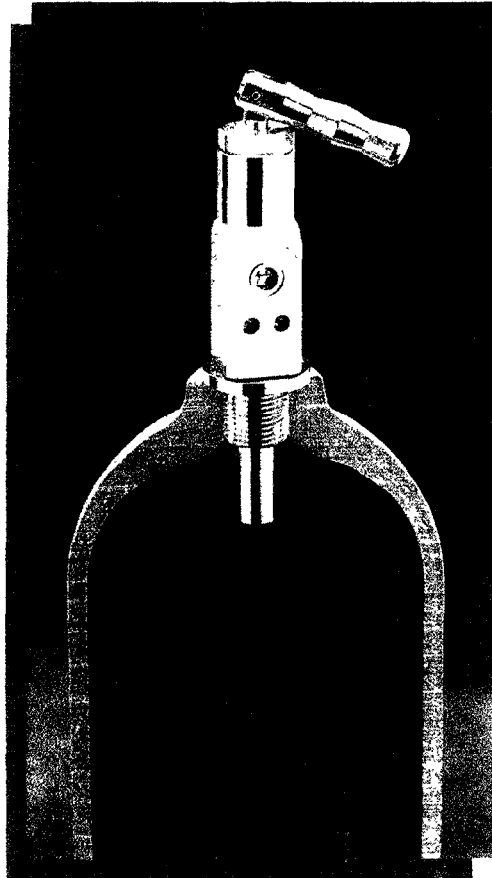


Figure 3

POST VALVE ACTUATION TIMES

.848 SECONDS - SURGEX
.020 SECONDS - CONVENTIONAL POST VALVE

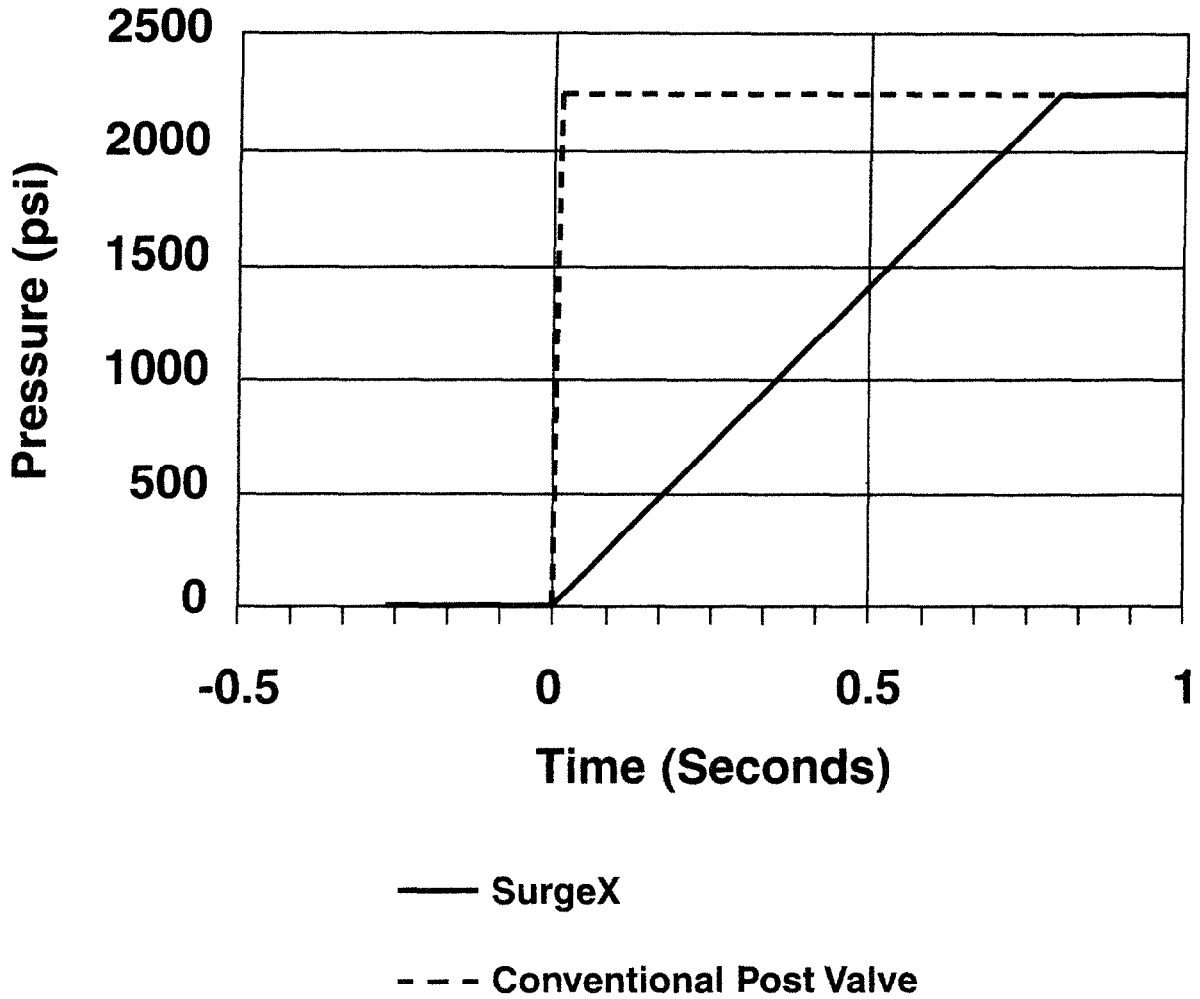


Figure 4

HISTORY OF OXYGEN REGULATOR FIRES REPORTED TO FDA FROM 1995-2001

<u>Company</u>	<u>Report #</u>	<u>Date</u>	<u>Event</u>	<u>Outcome</u>	<u>Market</u>
Veriflo	29145	12/29/95	Fire & rescue squad responded to emergency. After turning oxygen to 6 lpm, in 1 minute, the tank exploded.	Hospitalized	EMS
Victor Equip.	34079	5/22/96	Regulator involved in house fire. Cig left burning unattended. Claim alleges regulator/cylinder was leaking oxygen.	Other	Home Care
Allied	33429	6/18/96	O2 cylinder exploded upon opening & gauge flew off. Regulator body burned through around gauge with a nickel size hole found.	Life Threat	EMS
Allied	33428	6/18/96	Flash fire from D oxygen cylinder when valve opened on oxygen cylinder to administer oxygen to patient. Flash fire immediately.	Hospitalized	EMS
Allied	34993	8/5/96	During treatment oxygen cylinder valve was turned on by firefighter. Flash fire occurred with severe damage to regulator body, D size cylinder.	Hospitalized	EMS
Contemporary Products	2024040-1996-00004	10/28/96	When tank turned on, a piece from regulator flew across room. Regulator had 2 washers; patient did not follow directions.	Other	Home Care
Western Enterprises	1526809-1996-90001	11/25/96	Regulator burn out.	Other	Hospital
Unknown	67287	2/7/97	Fire in patient's home. Patient on respirator.	Death	Home Care
Allied	1924066-1997-00002	4/7/97	EMT checking equipment. He turned toggle of oxygen cylinder to "On" position to check pressure, pressure gauge. Was hissing sound/ignite.	Life Threat	EMS
Chad Therapeutics	2024040-1997-00002	4/25/97	Cig fell on pouch, caught fire.	Other	Home Care
Allied	1924066-1997-00003	5/13/97	Respiratory therapist opened cylinder. There was a ball of fire. E size cylinder was being used.	Life Threat	Hospital
Allied	1924066-1998-00008	7/30/98	Firefighter checking pressure in cylinder; there was a flash & a fire occurred.	Hospitalized	EMS
BOC Gases	1022618-1998-00001	9/30/98	Valve ejected from E size oxygen cylinder & contents ignited during equipment check.	Hospitalized	Hospital

HISTORY OF OXYGEN REGULATOR FIRES REPORTED TO FDA FROM 1995-2001 (continued)

<u>Company</u>	<u>Report #</u>	<u>Date</u>	<u>Event</u>	<u>Outcome</u>	<u>Market</u>
Chad Therapeutics	2024040-1998-00002	11/5/98	Heard a burst, saw flames shooting out of top of cylinder where the regulator connected.	Other	Home Care
Chad Therapeutics	2024040-1998-00003	12/22/98	Patient complained of terrible smell like cleaning fluid & it made him choke.	Hospitalized	Home Care
Flotec, Inc.	207262	1/22/99	Patient being transported into ambulance when threaded insert popped out.	No Injury	EMS
Contemporary Products	1223412-1999-00001	2/8/99	Heard a pop & swoosh noise, ran out of doctor's office on fire.	Death	Home Care
Chad Therapeutics	209294	2/10/99	Portable oxygen bottle ignited. Origin of fire is area adjacent to top of oxygen cylinder and regulator mount at top of oxygen bottle.	Death	Home Care
Allied	1924066-1999-00001	2/16/99	Firefighter checking equipment turned cylinder on & there was a flash of fire & fire occurred.	Hospitalized	EMS
Allied	1924066-1999-00002	2/16/99	Firefighter checking equipment turned cylinder on & there was a flash of fire & fire occurred.	Hospitalized	EMS
Precision Medical	2523148-1999-00001	3/9/99	Operator opened cylinder valve switching dial regulator. The end cap assembly blew out of regulator.	Hospitalized	Hospital
Chad Therapeutics	2024040-1999-00003	5/28/99	Oxygen tank in back seat of car caught on fire and burned seat.	Other	Home Care
Contemporary Products	1223412-1999-00003	7/30/99	Patient transferring regulator to a new cylinder opened valve & piece of regulator flew off & hit him on hand.	Other	Home Care
Allied	1924066-1999-00017	8/30/99	Firefighter attempted to turn an oxygen regulator on that was attached to a D size cylinder.	Other	EMS
Allied	1924066-1999-00018	9/9/99	Regulator Model 370 - Check valve wasn't producing necessary flow to power the demand valve.	Other	Home Care
Veriflo	2921585-1999-00001	9/30/99	Cylinder gas produced a fire when operator attempted to release oxygen. When crack open cylinder, valve made loud pop & flames from cap vent holes.	Other	Dental

HISTORY OF OXYGEN REGULATOR FIRES REPORTED TO FDA FROM 1995-2001 (continued)

<u>Company</u>	<u>Report #</u>	<u>Date</u>	<u>Event</u>	<u>Outcome</u>	<u>Market</u>
Precision Medical	2523148-1999-00007	12/30/99	Nurse opened oxygen tank cylinder valve. There was a flash with loud noise. Endcap of regulator & some internal parts propelled.	Hospitalized	Hospital
Precision Medical	260217	1/6/00	Cannula transf to E cylinder oxygen canister. EMT opened O2 regulator valve, combustion occurred & a brief flash occurred.	Other	Hospital
Chad Therapeutics	2024040-2000-00001	1/20/00	Patient's oxygen system caught fire.	Hospitalized Home Care	
Precision Medical	2523148-2000-00001	1/27/00	Loud noise, flash of flame as valve of cylinder was opened. Black substance through cannula attached to patient.	Hospitalized	Hospital
Contemporary Products	1223412-2000-00001	2/15/00	Incident included a Chad conserving device & CPI regulator. Patient's oxygen system caught fire.	Other	Hcme Care
Nellcor PB	2024500-2000-00042	3/24/00	Oxygen regulator exploded when installed on high-pressure oxygen cylinder.	Other	Hospital
Precision Medical	276811	5/8/00	Oxygen regulator attached to E cylinder ignited when hit floor causing sparks & smoke. No actual fire.	Life Threat/Other	Hospital
Precision Medical	277749	5/11/00	Oxygen regulator caught on fire/ exploded. Patient on O2 using this regulator & E cylinder on cart heard loud hiss & loud boom/explosion.	Life Threat	Hospital
PB/Cryo Equip.	1825511-2000-00011	5/17/00	While attaching regulator to a new oxygen cylinder, regulator suddenly exploded when 1 cylinder valve was opened by knocking opener with mallet.	Required Intervention	Hospital
Allied	1924066-2000-00002	5/18/00	Firefighter changed empty D cylinder with a full cylinder with regulator assembled to full tank. Valve was opened, then a pop sound, then flame.	N/A	EMS
Precision Medical	2526148-2000-00003	5/31/00	Oxygen cylinder rolled off bed, struck floor. Brass oxygen regulator attached to cylinder ignited, burned briefly, then self extinguished.	Required Intervention	Hospital
Allied	1924066-2001-00001	2/2/01	Explosion in ambulance.	Life Threat/Other	EMS
Allied	317591	2/26/01	Patient placed on gurney. EMT opened cylinder valve & fire was seen.	Hospitalized	EMS
Allied	1924066-2001-00002	2/28/01	Paramedic laid a D size cylinder between patient's legs. When cylinder was opened, a fire occurred.	Hospitalized	EMS

EXPLOSIONS AND FIRES IN ALUMINUM OXYGEN REGULATORS

FDA and NIOSH Public Health Advisory:
Explosions and Fires in Aluminum Oxygen Regulators
February 1999

To: Fire Departments, Safety Directors, Biomedical Engineers, Nursing Homes, Emergency Transportation Services, Rescue Squads, State EMS Systems, Hospital Administrators, Home Health Care Agencies, and Risk Managers

This notice is to advise you of hazards with oxygen regulators made of aluminum and to provide recommendations regarding these devices.

THE PROBLEM

Over the past 5 years, FDA has received 16 reports of aluminum regulators used with oxygen cylinders burning or exploding. These incidents caused severe burns to 11 health care workers and patients. Many of the incidents occurred during emergency medical use or during routine equipment checkout. FDA and The National Institute for Occupational Safety and Health (NIOSH) believe that the aluminum in these regulators was a major factor in both the ignition and severity of the fires, although there are likely other contributing factors. Most of the reports received by FDA were for the Model L270 series of aluminum regulators manufactured by Life Support Products Inc. and Allied Healthcare Products Inc. (Earlier models were known as "270" regulators.)

Allied Healthcare Products currently has 60% of the market share of oxygen regulators for emergency use. The manufacturer has plans to cease the distribution of all regulators containing aluminum and solely manufacture brass regulators. In an effort to avoid potential product shortages, Allied is instituting an interim measure wherein they will replace internal high-pressure aluminum components with brass components in all models manufactured.

Because aluminum is lighter in weight than steel, it is also used in oxygen cylinders. FDA and NIOSH believe that aluminum cylinders can be used safely with brass regulators, but that the combination of both oxygen regulators and cylinders made from aluminum poses an increased fire hazard. Contamination of the oxygen supply with particulate matter can also increase the risk of fire.

BACKGROUND

Most oxygen regulators are made of brass or aluminum. Aluminum and its alloys are more likely to ignite than brass. In standard tests, aluminum can burn vigorously at pressures as low as 25 pounds per square inch (psi), while brass does not burn at pressures below 10,000 psi.

BACKGROUND (continued)

Although there are rare instances of fires in brass oxygen regulators, they have a long history of safe use and are believed to be safer than aluminum oxygen regulators for use with high pressure compressed oxygen. FDA has no reports of fire or explosion with aluminum oxygen regulators used in low pressure systems (e.g., piped distribution to wall mounted supply taps at <50 psi).

RECOMMENDATIONS

FDA is pursuing plans to work with manufacturers to improve the safety of oxygen regulators and restrict the use of aluminum exposed to high-pressure oxygen in regulators. In the meantime, FDA and NIOSH advise that the following precautions be taken to avoid explosions and fires from oxygen regulators containing aluminum:

- If you are presently using high pressure oxygen regulators which contain any aluminum exposed to high-pressure oxygen, replace them with regulators made of brass. Consult the manufacturer if you don't know what material is used in your regulators.
- If non-aluminum oxygen regulators are not available, it is recommended that you follow the precautions as described in the addendum to this advisory to minimize the risk of fires until brass replacement regulators become available.

REPORTING ADVERSE EVENTS TO FDA

The Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices. Questions about mandatory reporting can be answered by the Division of Surveillance Systems, Reporting Systems Branch by phone on (301) 594-2735 or FAX, (301) 827-0038 or write to FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Written reports will go into FDA's MDR data base. Submit voluntary reports directly to the FDA's voluntary reporting program, MedWatch; by telephone at (800) FDA-1088, by FAX at (800) FDA-0178, or by mail to: MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, MD 20857-9787.

GETTING MORE INFORMATION

Send questions about this Public Health Advisory to the Issues Management Staff, Office of Surveillance and Biometrics, HFZ-510, 1350 Piccard Drive, Rockville, Maryland, 20850, FAX (301) 594-2968, or e-mail ssm@cdrh.fda.gov or aag@cdrh.fda.gov. You may photocopy or print this notice from the CDRH homepage at www.fda.gov/cdrh/safety.html.

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Sincerely yours,

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Director, Division of Safety Research,
CDC, NIOSH

SAFE PRACTICES FOR HANDLING AND OPERATING OXYGEN EQUIPMENT

Oxygen used in the medical profession can be very hazardous. Although oxygen does not burn, it does support combustion. A material which will not burn in air may burn in high pressure pure oxygen - such as the metal in oxygen regulators or cylinders. Comprehensive guidelines and training on safe practices for handling oxygen are available from several sources listed at the end of this section. Some general guidelines for minimizing the chance of fire are provided below:

STORAGE, MAINTENANCE AND HANDLING

- Do not allow smoking around oxygen.
- Store oxygen in clean, dry locations away from direct sunlight.
- Do not allow post valves, regulators, gauges, and fittings to come into contact with oils, greases, organic lubricants, rubber or any other combustible substance.
- Make sure that any cleaning, repair or transfilling of oxygen equipment is performed by qualified, properly trained staff.
- Do not work on oxygen equipment with ordinary tools. Designate special tools, clean them and store them For Use With Oxygen Equipment Only.
- Ensure that any components added to the regulator, e.g., gauge guards, are installed so that they do not block the regulator vent holes.
- Use plugs, caps and plastic bags to protect "off duty" equipment from dust and dirt.
- Particulate migration from the cylinder can be minimized by the installation of a standoff tube (bayonette) at the inlet of the post valve.

USE

- Make sure that staff using oxygen equipment are adequately trained in its operation and in oxygen safety and have knowledge of manufacturer's instructions for using the equipment.
- Visually inspect the post valve gasket and regulator inlet prior to installation. If they are not visually clean, they should not be used.
- Momentarily open and close ("Crack") the post valve to blow out debris prior to installing a regulator.
- Ensure that the regulator is set with the flow knob in the off position before attaching it to the cylinder.
- Position the equipment so that valve is pointed away from the user and any other persons.
- Open the cylinder valve slowly and completely to minimize the heat produced and achieve the desired flow conditions within the equipment.
- Do not look at the regulator pressure gauge until the cylinder valve is fully opened.

Additional information, guidance and training regarding oxygen and fire safety can be obtained from a number of sources, including the following organizations:

- Compressed Gas Association, 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102 (www.cganet.com)
- National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269-9101 (www.nfpa.org)
- American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 (www.astm.org)
- Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, Division of Safety Research. ***Oxygen Regulator Flash Severely Burns One Fire Fighter - Florida***, Report Number 98-F23. This report is available on the NIOSH homepage at: (www.cdc.gov/niosh/firehome.html).

(Updated February 4, 1999)



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

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This standard is issued under the fixed designation PS 127; 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.

INTRODUCTION

Investigation of recent medical oxygen regulator fires indicates that promoted ignition of vulnerable regulators has occurred, with increasing frequency, resulting in catastrophic burnout and injury to equipment operators. In February 1999, the National Institute for Occupational Safety and Health and the Food and Drug Administration issued a joint public health advisory regarding explosions and fires in oxygen regulators used in medical and emergency applications. In response, several oxygen equipment manufacturers have participated in the preparation of this provisional standard, which is intended to evaluate regulators for use in these applications.

The test method described in this standard is under evaluation and validation but can be used by regulator manufacturers who need a tool to evaluate their designs.

The intent of this provisional standard is to develop a test method that will fairly evaluate the ignition sensitivity and fault tolerance of oxygen regulators used in medical and emergency applications.

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 870 pin-index adapters and CGA 540 inlet connections (CGA V-1).

Note 1—Although this standard applies only to oxygen regulators used for medical or emergency applications, it may also apply to other types of oxygen regulators outside of this scope at the discretion of the authority having jurisdiction.

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 conse-

quence 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 2—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. 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.

¹ This provisional standard is under the jurisdiction of ASTM Committee G4 on Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres. Current edition approved Nov. 10, 2000. Published December 2000.

2. Referenced Documents

2.1 ASTM Standards:

G 63 Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service²

G 88 Standard Guide for Designing Systems for Oxygen Service²

G 93 Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments²

G 94 Standard Guide for Evaluating Metals for Oxygen Service²

G 128 Standard Guide for Control of Hazards and Risks in Oxygen Enriched Systems²

2.2 ASTM Adjuncts:

Manual 36. Safe Use of Oxygen and Oxygen Systems³

2.3 Compressed Gas Association (CGA) Standards:

CGA E-4. Standard for Gas Pressure Regulators⁴

CGA G-4. Oxygen⁴

CGA G-4.1. Cleaning Equipment for Oxygen Service⁴

CGA V-1. American National/Compressed Gas Association Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections⁴

2.4 United States Pharmacopeial Convention Standard:

USP 24 – NF 19. Oxygen monograph⁵

2.5 Federal Regulation:

CFR 868.2700 (a). Pressure regulator⁶

2.6 ISO Standards:

ISO 10524 Pressure regulators and pressure regulators with flow-metering devices for medical gas systems⁷

ISO 15001.2 Anaesthetic and respiratory equipment – Compatibility with oxygen⁷

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.* This test phase is performed to evaluate the ignition resistance of the regulator design. The resistance to ignition by the heat from oxygen pressure shocks is evaluated. 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.* This test phase is performed to evaluate the fault tolerance of the regulator design. Fault tolerance is evaluated by forced application of a positive ignition source upstream of the inlet filter, at the regulator inlet, to simulate cylinder valve seat ignition and particle impact events. The ignition sources are 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 filter so that a positive ignition promoter, such as 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 consumption of at least 90 % of the ignition pill as determined by visual inspection or mass determination.

4.3.2 A regulator is considered fault tolerant when consumption of the ignition pill has occurred without external breach of any pressurized regulator component or ejection of molten or burning metal or ejection of any internal parts from the regulator. Momentary (less than 1 second) 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.

5.3 The ambient temperature surrounding the regulator must be 21 ± 5 °C for both phases of this test.

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 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 six regulators will be tested; three in each phase of the test. If the regulators from Phase 1 are undamaged, they may be reassembled and used for Phase 2.

6.2 *Phase 2: Regulator Inlet Promoted Ignition Test.* The Phase 2 ignition pill materials, possible sources of these materials, and the total required energy of an ignition pill are listed in Table 1 (see also Fig. 2). The ignition pill shall, at a minimum, be comprised of a combination of metallic and nonmetallic materials listed in Table 1 which replicate contaminants that may be found in actual applications and that promote a kindling chain to ignite the metal component of the ignition pill.

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, 1725 Jefferson Davis Highway, Arlington, VA 22202

⁵ Available from U. S. Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852

⁶ Available from U. S. Government Printing Office, Washington, D.C. 20401

⁷ Available from International Organization for Standardization, Case Postale 56, CH-1211 Geneva 20, Switzerland

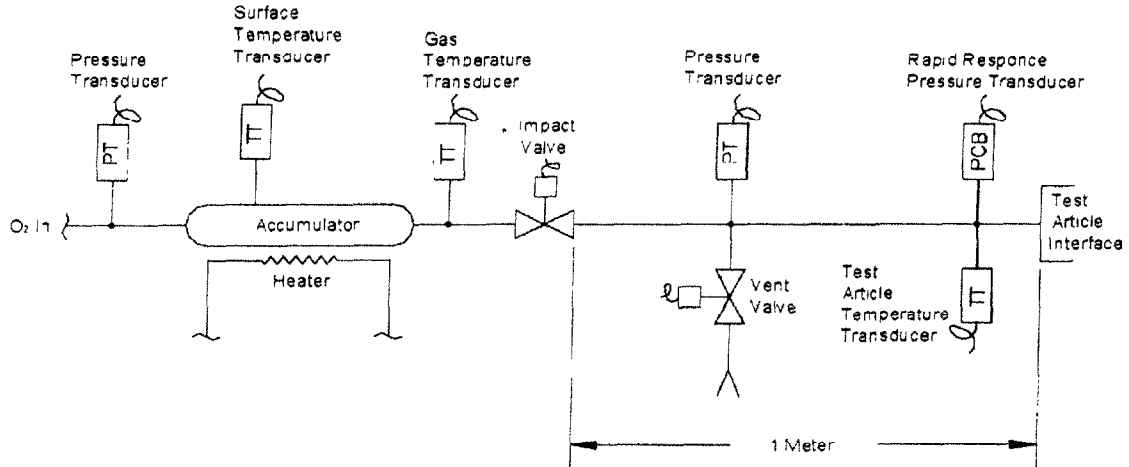


FIG. 1 Typical Test System Configuration

TABLE 1 Ignition Pill Characteristics

Possible Materials for Phase 2 Ignition Pill	Possible Source	Total Required Energy
Nylon	Cylinder valve seat	500 ± 50 cal
Teflon	Cylinder valve stem lubricant	
Aluminum	Contaminant from bottle	500 ± 50 cal
Iron	Contaminant from bottle	
Hydrocarbon-based Contaminant	Contaminant from user and/or gage	

6.3 The ignition pill may vary in size and geometry based on the regulator being tested. However, the energy content must be held constant for all sizes and geometries. A typical Phase 2 ignition pill is comprised of a nylon case (40 to 50 mg) that contains a predetermined mixture of iron powder (3 to 5 mg) and aluminum powder (10 to 12 mg). A thin layer (0.5 to 1 mg) of Elmer's^a rubber cement consisting of rubber, isopropanol, and heptane is applied to the pill to simulate hydrocarbon contamination and to promote ignition.

NOTE 3—The Phase 2 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.

6.4 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

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 of personnel is assured by locating the test apparatus in an enclosure and behind a barricade. The operator is 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.

NOTE 4—Where not otherwise indicated, stainless steel shall be of the AISI 300 series.

7.1.3.1 High-pressure oxygen systems require the utmost cleanliness (G 93). 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

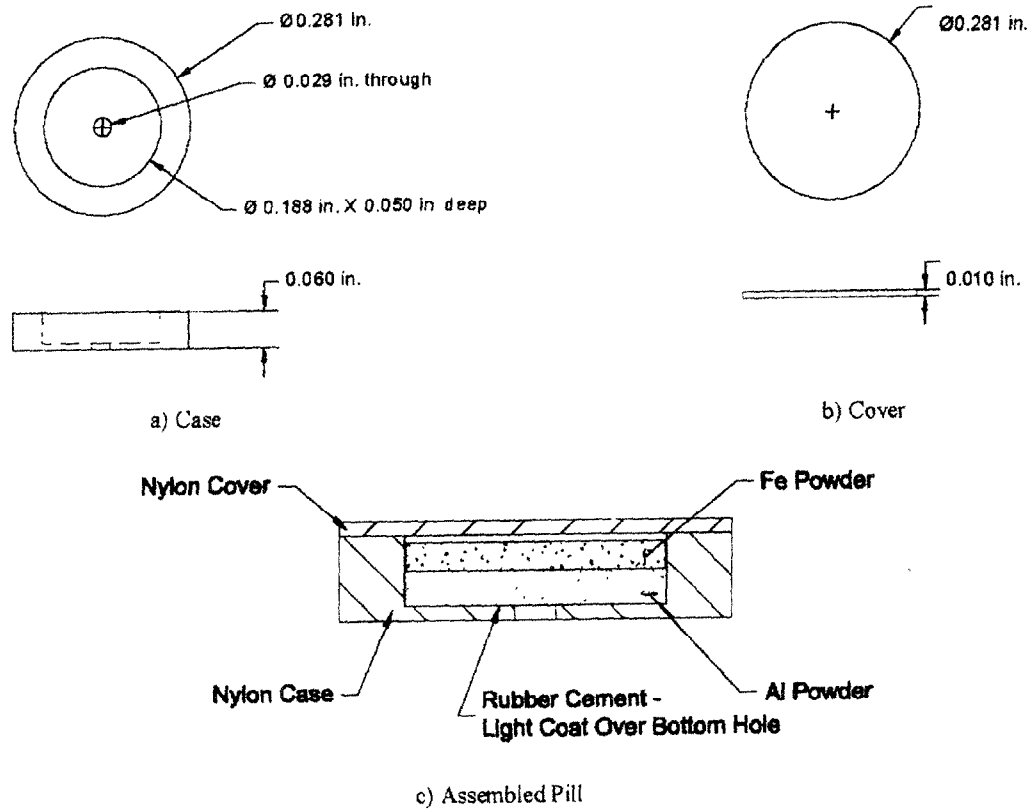


FIG. 2 Example Phase 2 Ignition Pill

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.

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 housekeeping and maintenance characteristics of the test area shall be considered for both safety and cleanliness aspects.

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. Release regulator tension before opening the 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 outlet when opening cylinder valve. Keep cylinder out of sun and away from heat. Keep cylinder away from corrosive environment. Do not use unlabeled, dented, or damaged cylinders.

7.7 See ASTM G 63, G 88, G 93, G 94, G 128 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 testing consists of three functional regulators in normal delivery condition evaluated at a pressure that is consistent with their maximum end-use application. Regulators for Phase 2 testing must be supplied with filters installed.

8.2.1 *Installing the Pill.* Use gloves and clean handling techniques when handling the pill and regulator. Press the ignition pill into the top of the CGA 540 or CGA 870 adapter fitting as shown in Fig. 3 or Fig. 4, respectively. Orient the pill so that the hole in the pill faces the regulator. Ensure that the pill fits snugly so that it forms nearly a complete blockage and so that the pill will not move during regulator installation.

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.

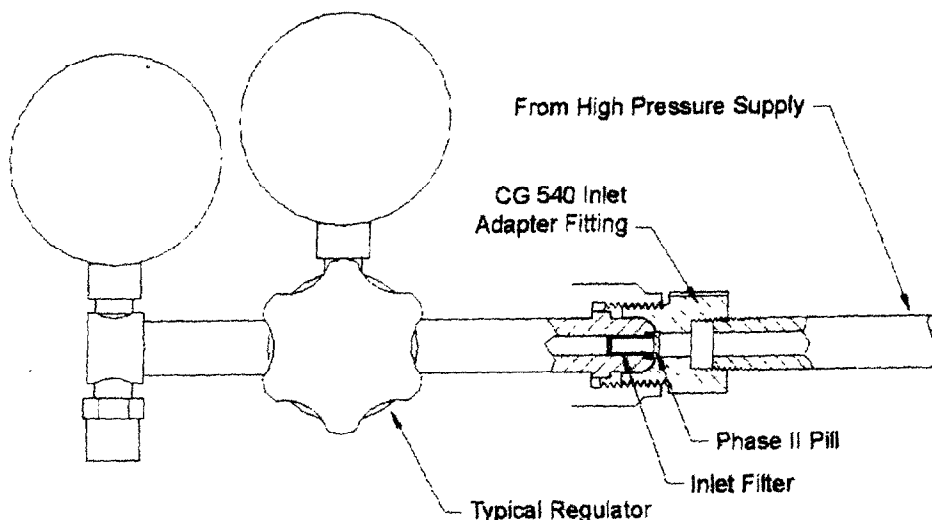


FIG. 3 Typical Phase 2 Ignition Pill Installed in Regulator with CGA 540 Adapter Fitting

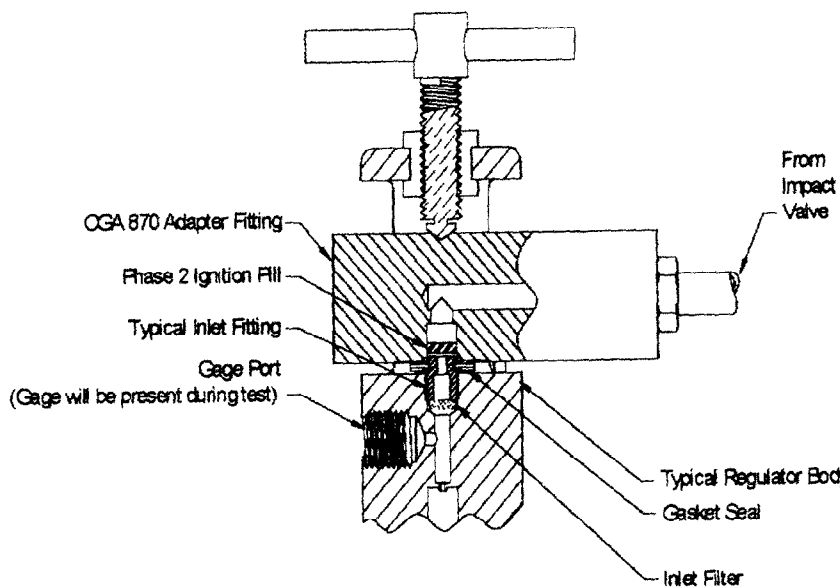


FIG. 4 Typical Phase 2 Ignition Pill Installed in Regulator with CGA 870 Adapter Fitting

NOTE 5—Leakage at this juncture may stop the apparatus from providing the proper heat of compression for pill ignition and therefore invalidate the test.

8.2.3 *Installing the Regulator.* Install the regulator as supplied by the manufacturer. Set the regulator flow or pressure setting, if applicable, to mid-range. Carefully mate the regulator to the piping system adapter without any jarring that could dislodge the pill from the filter top. 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. Use the manufacturer's torque specifications.

NOTE 6—The mid-range position is chosen as an initial assumption regarding what setting is most severe. A final requirement will be established for the full consensus standard.

8.2.4 *Pretest Leak Check Test.* Before test, leak check the regulator to its maximum allowable working pressure, then

purge all oxygen-wetted surfaces with low pressure (200 psig or lower) gaseous oxygen.

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

NOTE 7—Because blowout 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 8—A 30 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 1/80th of a second; therefore, tape records should be scrutinized carefully. Also, a monochrome camera is capable of capturing ejection events.

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

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 Ignition pill, including materials, quantities, weights, and dimensions

9.3.5 Test results, including a description of external evidence of pill ignition and sustained combustion and burnout of the regulator.

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 ASTM G 63 and G 94 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 system.

X2. TOXICITY

X2.1 In addition to the issue of flammability of materials used in breathing 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 breathing gas systems.

itions 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.

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-

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CONVENTIONAL POST VALVE AND SURGEX IGNITION SENSITIVITY TESTING

I. INTRODUCTION

When current technology post valves in bottled oxygen systems are opened rapidly, fires can and do occur downstream in oxygen regulators if combustible contaminants (oil, grease, etc) are present in the flow channels of the oxygen regulator.

The incidence of such oxygen regulator fires is low. When they do occur, they occur because a conventional post valve has been opened in the presence of combustible and volatile contaminants. When a conventional post valve is opened rapidly, the highly compressed oxygen from the oxygen cylinder first expands and then is recompressed rapidly as the surge of gas enters the oxygen regulator. The recompression process creates a rapid rise of temperature within the flow channel of the oxygen regulator. If contaminants are present, they can and do catch fire in the presence of high-pressure oxygen as a result of this temperature rise from the recompression process. The incidence of such fires is increased if minute filings of aluminum from the oxygen tank become entrapped in the rapid oxygen gas flow. These aluminum filings either catch fire themselves or cause sparks as they strike the walls of the oxygen regulator.

In this test, Allied's SurgeX post valve and conventional CGA 870 post valves were connected upstream to oxygen tanks and downstream to brass oxygen regulators containing an ignition pill with volatile contaminants, to determine whether opening the post valves rapidly would cause the ignition pill to ignite.

II. PURPOSE

We know that oxygen regulator fires do not occur every day or even every month. But we also know that when highly volatile contaminants are present and conventional post valves are opened rapidly, very dangerous fires do occur. The SurgeX post valve, by greatly reducing the heat of recompression, virtually eliminates the potential for such fires.

The purpose of this test is to demonstrate that the SurgeX valve, when opened rapidly in the presence of very volatile contaminants, prevents ignition in a downstream oxygen regulator, and that under the very same conditions with the very same contaminants, and with rapid opening, conventional post valves can cause fires to ignite in these same downstream oxygen regulators.

The reader may well ask after reviewing this test whether contaminants with the volatility we utilize in this test are likely to be found in normal field conditions. The answer is no. But, in a small number of cases each year, a very unlikely combination of very rapid post valve openings and

contaminant conditions are in fact present and both caregivers and patients are severely injured. In short, the incidence of this danger is infrequent but real, and testing under these extreme conditions is thus very valid.

III. THE SURGEX TECHNOLOGY

A. Current Technology

To understand how the SurgeX works, we will first look at what happens when a conventional post valve is opened. There is one style of post valve that is used on most portable oxygen cylinders and that style is commonly referred to as the 870 post valve. A number of manufacturers produce this type of valve but the operation of each is identical. The conventional 870 post valve has been designed such that the valve can be fully opened very quickly. When this valve is opened rapidly, the pressure in the regulator can go from atmospheric to full pressure in as little as .020 seconds. The heat generated by the recompression of the gas produces high temperatures in the oxygen regulator. This production of high temperatures in an oxygen regulator is inherent in the design of all conventional 870 type post valves.

B. SurgeX Technology

The SurgeX offers new patent pending technology for a post valve. The SurgeX is designed such that a controlled flow slowly pressurizes the oxygen regulator. This slow pressurization time (.750 seconds to 1.20 seconds) allows heat to be dissipated and therefore does not allow high temperatures to be reached, thus virtually eliminating the possibility of fires.

IV. TEST METHOD

The test method described in this section is an overview of the actual test procedure and describes the key steps. The detailed test procedure is described in Section V of this document.

A. Test Equipment

- High pressure oxygen source at 2000 to 2200 psi
- Piping system with control valves for safely operating the test stand
- Conventional CGA 870 and SurgeX post valves
- Mechanical valve-opening fixture
- Test articles consisting of a test regulator and an ignition pill

A large high pressure oxygen cylinder provided pressure for the test. The high pressure oxygen cylinder was connected to a piping system to deliver the gas to post valves being tested. This piping system was designed with remotely-operated valves for safety. Used in conjunction with the piping system was a remotely-operated mechanical valve-opening system. The CGA 870 post valve test articles consisted of conventional and new SurgeX style post valves.

We connected test articles to the outlet of the post valve. Each test article consisted of a test regulator and an ignition pill. The test regulator was a brass B&F oxygen regulator modified as described in Section D. The ignition pill was placed in the inlet of the regulator and consisted of nylon 6/6, aluminum foil, aluminum powder and polyethylene. These contaminants are highly volatile and sensitive to heat generated by the recompression of the oxygen gas. While this ignition pill would not be found in the actual use of oxygen regulators, it does simulate the highly volatile condition where contaminants can and do ignite in such oxygen regulators.

B. Test System Set-Up

For safety reasons it was necessary to create a piping system that could be remotely operated and that would enable us to stop the flow of oxygen should a fire occur. A manifold was constructed of brass pipe. This manifold contained 3 remotely-operated valves. Valves 1 and 2 were used to stop the flow of oxygen. Valve 3 was a purge valve that allowed us to release the gas in the manifold. This allowed us to bring the manifold back down to atmospheric pressure between test trials.

C. Valve Opening Time Verification

To determine the time in which a conventional valve could be opened, we had individuals open the conventional post valve as fast as they could and recorded the time it took for the pressure to go from atmospheric to full pressure (which we defined as 2000 psi) in the regulator. This testing revealed, when using a conventional post valve, that the pressure in the regulator could increase from atmospheric pressure to full pressure in as little as .020 seconds.

A mechanical test fixture was developed to duplicate this opening time.

D. Test Articles

The test articles used consisted of an oxygen regulator and an ignition pill. The test oxygen regulator used was a brass B&F CGA 870 oxygen regulator that was modified as follows: The low pressure end of the regulator was removed to enable us to observe the results of the testing. We were able to do this and still have a valid test because ignition from the recompression of gas originates in the high pressure end of the regulator, not the low pressure end. Because the low pressure end of the regulator had been removed, we had to find a way to simulate an oxygen

regulator in the off position. To accomplish this, we removed the inlet filter and replaced it with a brass washer, nylon disk and nylon washer.

The ignition pill was placed inside the inlet stem. This test article configuration is shown in Figure 1. The test regulator components are identified on the left side of the figure, while the ignition pill components are identified on the right.

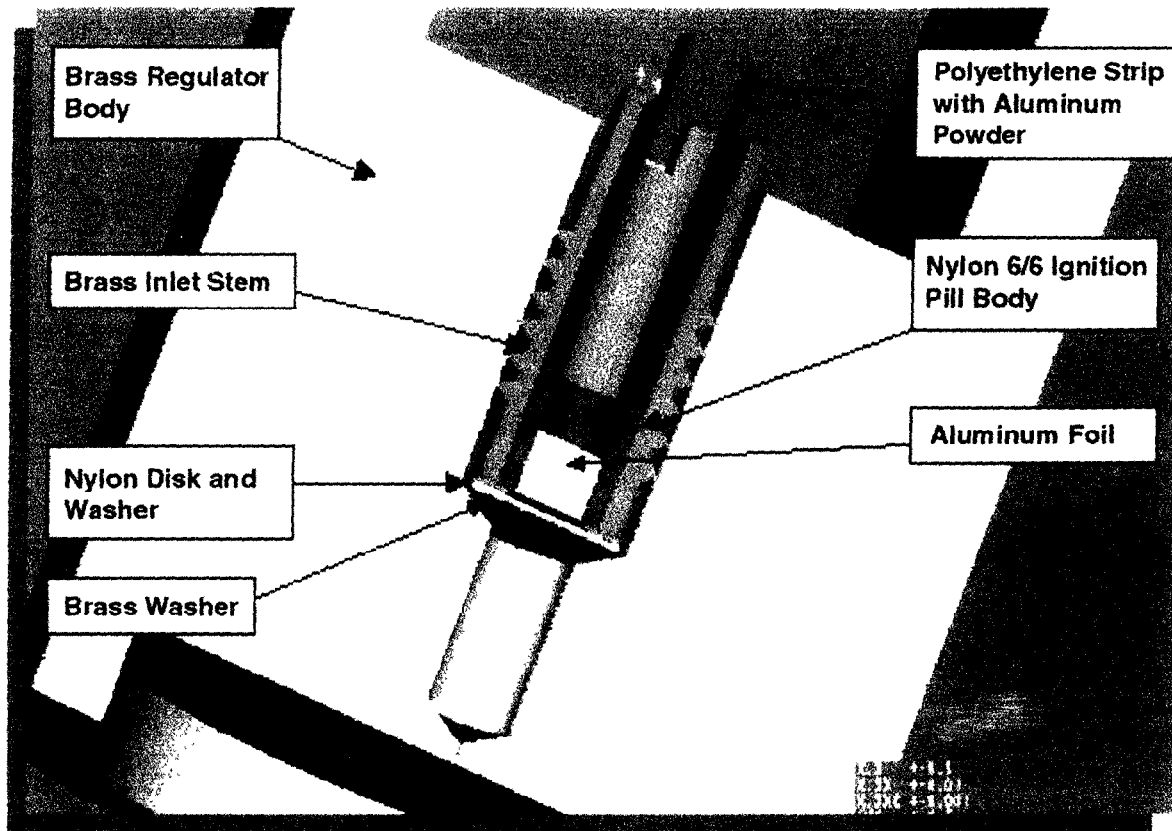


Figure 1: Test Article Design

E. Ignition Testing

Tests were conducted by installing the post valve to be tested in the mechanical valve-opening fixture. The test article was installed on the outlet of the post valve. The piping system was then purged to remove any air from the system. The piping system pressure was increased to the test pressure of between 2000 to 2200 psi. The post valves were then opened with the mechanical valve-opening fixture. We recorded by video tape whether an ignition did or did not occur.

Our tests used 50 conventional and 50 SurgeX post valves. Each conventional valve was tested once (50 tests), while each SurgeX post valve was tested twice (100 tests). A new test article was used for each test (150 total).

F. Test Results Summary

As indicated below in Table 1, with 100 trials the SurgeX valve had no ignitions. The conventional 870 valve ignited in 2 of the 50 trials, for a 4% failure rate.

Table 1

<u>SurgeX Post Valve</u>			<u>Conventional Post Valve</u>		
<u># of Trials</u>	<u># of Fires</u>	<u>% of Trials w/Fires</u>	<u># of Trials</u>	<u># of Fires</u>	<u>% of Trials w/Fires</u>
100	0	0%	50	2	4%

The detailed test procedure is contained in the following pages of this report.

V. DETAILED TEST PROCEDURE

A. Fixture Opening Time Verification

During this procedure we first established the time it took an individual to open a conventional post valve. We then verified that our mechanical valve-opening fixture replicated this time.

The valve opening time is defined as the time it takes the pressure to go from atmospheric to full pressure (which we have defined as 2000 psi) in an attached oxygen regulator. To accurately measure this time we installed a pressure transducer in the gauge port of an oxygen regulator and used an oscilloscope to measure the time it took for the pressure to increase to full pressure.

To conduct this portion of the test we connected a conventional post valve to a pressure source and instructed 11 people to open the valve as quickly as they could. Each individual performed 3 trials, for a total of 33 trials. These times, with an average of .02323 seconds, are recorded in Table 1 on page 31.

The mechanical valve-opening fixture was then connected to the same post valve with the same pressure source and activated to verify that it produced results equivalent to the 11 individuals opening the post valve by hand. The opening fixture produced an average time of .02475 seconds in 6 trials, as seen in Table 2 on page 31.

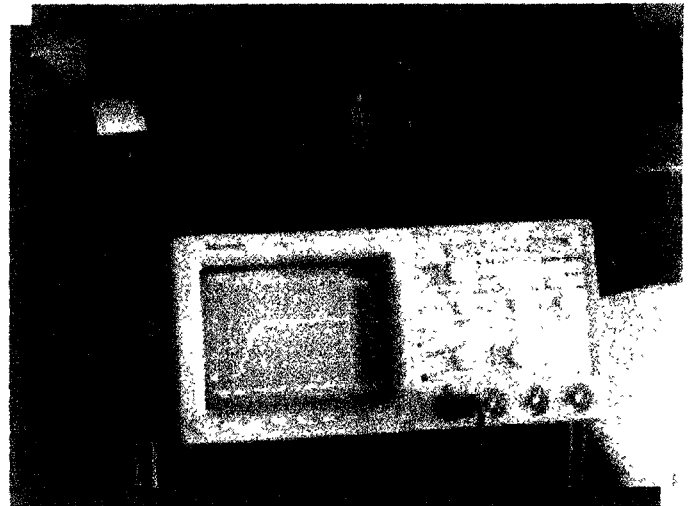


Figure 2: Test Set-Up For Measuring Opening Times

Fixture opening time verification required the following equipment to be calibrated:

- Supply line pressure gauge - Allied Tool Number 3500
- Oscilloscope - Allied Tool Number 3501

The pressure transducer did not require calibration but had, by manufacturer's specification, a response time of 1 millisecond.

FIXTURE OPENING TIME VERIFICATION TEST RESULTS

Table 1: Manual Opening Times

Opened By	Trial 1 Seconds	Trial 2 Seconds	Trial 3 Seconds	Average Seconds
Wayne	.0245	.0280	.0230	.02517
Seig	.0230	.0215	.0210	.02183
Matt	.0205	.0215	.0235	.02183
Tim	.0240	.0200	.0200	.02133
Tana	.0210	.0210	.0250	.02233
Kevin	.0225	.0215	.0215	.02183
Bill	.0225	.0205	.0260	.02300
Mark	.0220	.0265	.0265	.02500
Dan	.0215	.0215	.0215	.02150
Gary	.0250	.0250	.0250	.02500
Dan C.	.0265	.0265	.0270	.02667

Average by Hand = .02323 Seconds
Maximum by Hand = .0280 Seconds
Minimum by Hand = .0200 Seconds

Table 2: Mechanical Valve Opening Fixture Times

Opened By	Trial 1 Seconds	Trial 2 Seconds	Trial 3 Seconds	Average Seconds
Fixture Test 1	.0265	.0265	.0265	.02650
Fixture Test 2	.0230	.0230	.0230	.02300

Average by Fixture = .02475 Seconds
Maximum by Fixture = .0265 Seconds
Minimum by Fixture = .0230 Seconds

B. IGNITION PILL DEFINITION

The ignition pill was composed of polyethylene, aluminum powder, aluminum foil, and nylon 6/6. The following details how this pill was constructed.

The components of the pill were manufactured to the following specifications: The body of the pill is a cylinder machined from a nylon 6/6 rod. The body measured .200" long with an outside diameter of .178" and an inside diameter of .125". Aluminum foil measuring .001" thick was punched into a .875" diameter disk. Polyethylene measuring .002" in thickness was cut into strips 5" long and .160" wide. This polyethylene was then stretched to a length of 20". This stretching process reduced the thickness of the polyethylene to .0005" or less. The aluminum powder used had a trade name of "Alex" powder from Argonide Corporation.

To assemble the ignition pill the stretched polyethylene strip was placed over the top of the pill body and then pushed down inside the pill body. The disk of aluminum foil was formed into a ball and pushed down inside the pill body and smashed into place using a .07" diameter rod to retain the polyethylene strip. The polyethylene strips were then cut so they extended .3" past the top of the ignition pill body. The aluminum powder was brushed onto the polyethylene strips using a foam-tipped swab just prior to testing. Figure 3 shown below provides a drawing of the ignition pill cut in half.

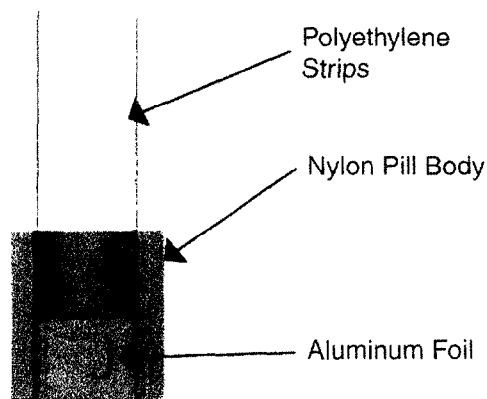


Figure 3: Ignition Pill

C. VALVE TESTING PROCEDURE

Cleaned parts were assembled into test regulators and placed in closed containers to insure that the test regulator was kept free of contaminants. Ignition pills were made in batches. Each batch was marked for identification.

C. VALVE TESTING PROCEDURE (continued)

50 SurgeX valves and 50 conventional post valves were tested. Each SurgeX valve was tested with 2 different test articles. Testing was conducted alternately between the SurgeX and conventional CGA 870 post valves.

Step 1. The post valve was installed into the test fixture. The valves were tightened to prevent leaks between the fixture and the post valve. The test fixture was checked for leaks during pressurization of the fixture. The outlet of the valve was positioned down and to the front of the test fixture.

Step 2. Aluminum powder was brushed onto the polyethylene strands of the ignition pill.

Step 3. The ignition pill was installed into a test regulator to create a test article. The ignition pill batch number was recorded on the test data sheet.

Step 4. The piping system was purged to remove any air in the piping system.

Step 5. The test article was installed on the post valve. The T-handle was tightened to prevent leaks between the regulator and the post valve.

Step 6. The switch on the motor of the mechanical valve-opening fixture was then turned on so the valve-opening fixture was ready for use.

Step 7. The high pressure oxygen supply was slowly opened to pressurize the test fixture. The piping system was checked for leaks. The oxygen supply pressure was checked and recorded on the test data sheet. The oxygen pressure was maintained between 2000 and 2200 psi.

Step 8. The temperature of the room near the test stand was checked and recorded.

Step 9. The temperature of the high pressure oxygen piping system was checked and recorded on the test data sheet. This temperature was maintained between 50°C and 60°C (122°F and 140°F).

Step 10. The test building was evacuated and the doors closed.

Step 11. The video equipment was checked for proper alignment and focus, then set to record the test.

Step 12. The mechanical valve-opening fixture was then actuated by its remote control switch to open the post valve and provide an oxygen surge. The test article was observed on the video equipment for an ignition.

C. VALVE TESTING PROCEDURE (continued)

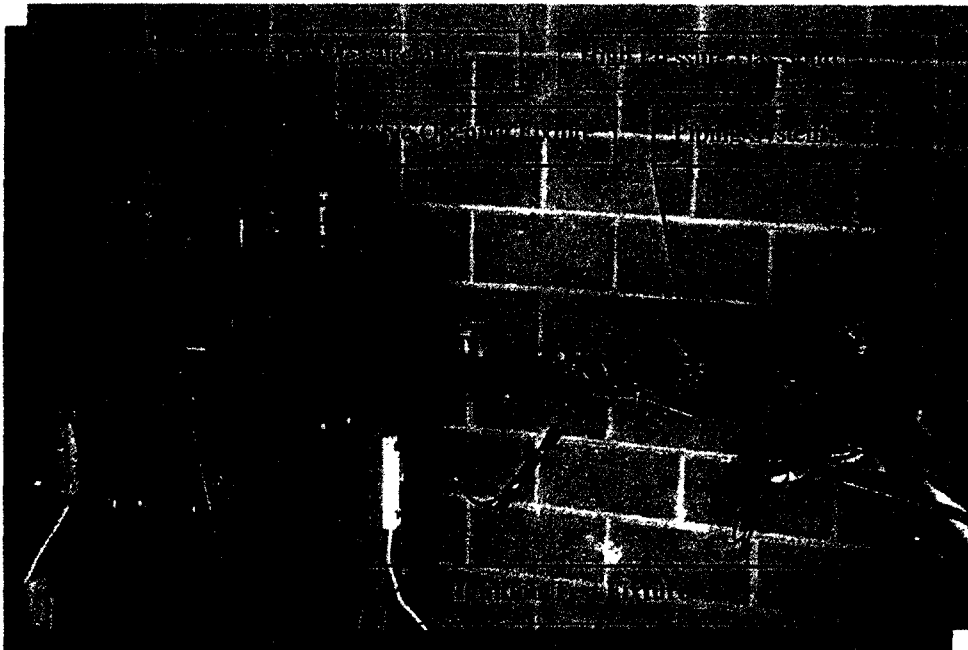
Step 13. Each test article was observed for 5 seconds after the fixture was actuated. After this the 2 gas supply valves were turned off. In the case of an ignition the gas supply valves were turned off immediately. The purge valve was then opened to bring the piping system pressure back down to atmospheric pressure.

Step 14. The valve on the high pressure oxygen cylinder and the switch on the motor of the mechanical valve-opening fixture were turned off immediately after test personnel entered the test building.

Step 15. The test samples were inspected and results recorded on the test data sheet.

The post valve testing required the following equipment to be calibrated:

- Supply line pressure gauge - Allied Tool Number 3500
- Thermocouple - Allied Tool Number 671



D. TEST DATA

Data from this testing was recorded on the test data sheets. These test data sheets are contained on the following 3 pages. The first test data sheet on page 35 contains data from the testing of the conventional CGA 870 post valve. The remaining 2 data sheets on pages 36 and 37 contain data from the testing of the SurgeX post valve.

**Test for Ignition Sensitivity
Conventional CGA 870 Post Valve**

DATE	TEST # (VALVE #)	TEST ARTICLE # / PILL BATCH#	SYSTEM PRESSURE PSI	GAS MANIFOLD TEMP °C	AMBIENT TEMP °C	RESULT
4/12/02	1 (169)	1 / 1	2200	58.1	23.5	NONE
4/12/02	2 (150)	1 / 1	2200	55.5	24.3	NONE
4/12/02	3 (117)	1 / 1	2200	56.4	25.2	NONE
4/12/02	4 (119)	1 / 1	2200	55.0	25.4	NONE
4/12/02	5 (171)	1 / 1	2200	57.3	25.9	NONE
4/12/02	6 (166)	1 / 1	2200	59.6	25.6	NONE
4/12/02	7 (133)	1 / 1	2200	55.7	25.7	NONE
4/12/02	8 (104)	1 / 1	2200	58.9	26.1	NONE
4/12/02	9 (136)	1 / 1	2180	59.9	26.3	NONE
4/12/02	10 (126)	1 / 1	2180	58.5	26.5	IGNITION
4/12/02	11 (107)	1 / 1	2180	57.8	26.7	NONE
4/12/02	12 (154)	1 / 1	2180	56.9	27.0	NONE
4/12/02	13 (140)	1 / 1	2160	56.5	27.1	NONE
4/12/02	14 (121)	1 / 1	2160	56.7	27.1	NONE
4/12/02	15 (151)	1 / 1	2160	59.9	26.5	NONE
4/12/02	16 (124)	1 / 1	2150	59.9	27.1	NONE
4/12/02	17 (142)	1 / 1	2150	60.0	27.3	NONE
4/12/02	18 (139)	1 / 1	2140	59.9	27.2	NONE
4/12/02	19 (149)	1 / 1	2140	59.7	27.4	NONE
4/16/02	20 (129)	1 / 1	2200	58.2	28.9	NONE
4/16/02	21 (125)	1 / 1	2200	56.2	28.7	NONE
4/16/02	22 (145)	1 / 2	2200	56	29.0	NONE
4/16/02	23 (105)	1 / 2	2200	54.5	30.2	NONE
4/16/02	24 (137)	1 / 2	2190	56.9	31.4	NONE
4/16/02	25 (155)	1 / 2	2190	58.3	31.8	NONE
4/17/02	26 (156)	1 / 2	2200	60.0	25.0	NONE
4/17/02	27 (157)	1 / 2	2200	59.3	25.4	NONE
4/17/02	28 (134)	1 / 2	2200	60.0	26.8	NONE
4/17/02	29 (175)	1 / 2	2190	56.5	27.2	NONE
4/17/02	30 (168)	1 / 2	2190	58.5	27.5	NONE
4/17/02	31 (122)	1 / 2	2190	57.6	27.4	NONE
4/17/02	32 (174)	1 / 2	2190	57.5	27.4	NONE
4/17/02	33 (112)	1 / 2	2180	54.8	27.5	NONE
4/17/02	34 (148)	1 / 2	2180	56.6	28.0	NONE
4/17/02	35 (123)	1 / 2	2180	55.4	28.2	IGNITION
4/17/02	36 (111)	1 / 2	2180	53.3	28.4	NONE
4/17/02	37 (131)	1 / 2	2180	57.1	28.8	NONE
4/17/02	38 (161)	1 / 2	2180	54.7	28.5	NONE
4/17/02	39 (162)	1 / 2	2170	57.0	28.8	NONE
4/17/02	40 (176)	1 / 2	2170	58.1	31.8	NONE
4/17/02	41 (172)	1 / 2	2170	57.5	31.6	NONE
4/17/02	42 (177)	1 / 2	2170	59.2	31.8	NONE
5/3/02	43 (1)	1 / 3	2170	58.7	20.4	NONE
5/3/02	44 (2)	1 / 3	2160	56.4	20.3	NONE
5/3/02	45 (3)	1 / 3	2140	57.3	20.4	NONE
5/3/02	46 (4)	1 / 3	2160	57.8	20.3	NONE
5/3/02	47 (5)	1 / 3	2140	59.0	20.4	NONE
5/3/02	48 (6)	1 / 3	2020	55.8	24.3	NONE
5/3/02	49 (7)	1 / 3	2020	59.8	24.3	NONE
5/3/02	50 (8)	1 / 3	2020	56.1	24.6	NONE

Test for Ignition Sensitivity SurgeX Post Valve

DATE	TEST # (VALVE #)	TEST ARTICLE # / PILL BATCH#	SYSTEM PRESSURE PSI	GAS MANIFOLD TEMP °C	AMBIENT TEMP °C	RESULT
4/12/02	1 (153)	1 / 1	2200	55.0	23.8	NONE
		2 / 1	2200	55.0	24.1	NONE
4/12/02	2 (86)	1 / 1	2200	57.8	24.6	NONE
		2 / 1	2200	59.1	24.7	NONE
4/12/02	3 (160)	1 / 1	2120	59.8	27.3	NONE
		2 / 1	2120	59.9	27.5	NONE
4/12/02	4 (88)	1 / 1	2120	58.9	27.5	NONE
		2 / 1	2120	59.8	27.5	NONE
4/12/02	5 (77)	1 / 1	2120	59.5	27.6	NONE
		2 / 1	2100	58.6	27.5	NONE
4/12/02	6 (80)	1 / 1	2100	60.0	27.7	NONE
		2 / 1	2100	59.9	27.7	NONE
4/12/02	7 (83)	1 / 1	2100	57.8	27.7	NONE
		2 / 1	2100	58.3	27.6	NONE
4/12/02	8 (90)	1 / 1	2100	60.0	27.5	NONE
		2 / 1	2100	59.4	27.5	NONE
4/12/02	9 (93)	1 / 1	2080	57.2	27.7	NONE
		2 / 1	2080	57.0	27.7	NONE
4/12/02	10 (159)	1 / 1	2080	59.6	27.7	NONE
		2 / 1	2080	59.8	27.7	NONE
4/12/02	11 (92)	1 / 1	2080	59.1	27.6	NONE
		2 / 1	2060	56.8	27.8	NONE
4/12/02	12 (87)	1 / 1	2060	55.2	27.7	NONE
		2 / 1	2060	55.5	27.7	NONE
4/12/02	13 (91)	1 / 1	2060	60.0	27.8	NONE
		2 / 1	2040	60.0	27.7	NONE
4/12/02	14 (94)	1 / 1	2040	58.0	27.8	NONE
		2 / 1	2040	56.4	27.7	NONE
4/12/02	15 (111)	1 / 1	2040	57.3	27.7	NONE
		2 / 1	2040	58.3	27.7	NONE
4/12/02	16 (84)	1 / 1	2020	59.5	27.7	NONE
		2 / 1	2020	57.1	27.8	NONE
4/12/02	17 (81)	1 / 1	2020	55.4	27.7	NONE
		2 / 1	2020	55.0	27.9	NONE
4/12/02	18 (82)	1 / 1	2000	56.4	27.8	NONE
		2 / 1	2000	58.7	27.7	NONE
4/12/02	19 (55)	1 / 1	2000	56.4	27.7	NONE
		2 / 1	2000	58.5	27.7	NONE
4/16/02	20 (103)	1 / 2	2200	56.0	27.8	NONE
		2 / 2	2200	57.3	28.3	NONE
4/16/02	21 (56)	1 / 2	2200	57.5	29.5	NONE
		2 / 2	2200	56.9	30.4	NONE
4/16/02	22 (51)	1 / 2	2190	55.3	30.9	NONE
		2 / 2	2190	55.1	30.9	NONE
4/16/02	23 (78)	1 / 2	2190	55.3	30.8	NONE
		2 / 2	2190	56.0	31.0	NONE
4/17/02	24 (76)	1 / 2	2200	59.8	25.6	NONE
		2 / 2	2200	60.0	25.9	NONE
4/17/02	25 (26)	1 / 2	2200	59.2	26.8	NONE
		2 / 2	2200	60.0	27.0	NONE

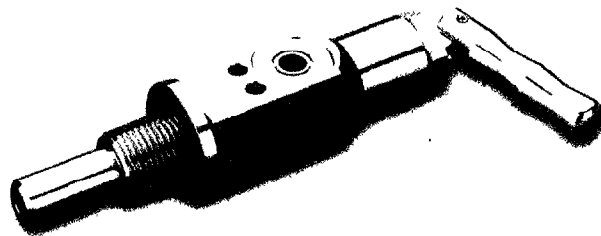
Attachment D

**Test for Ignition Sensitivity
SurgeX Post Valve (continued)**

DATE	TEST # (VALVE #)	TEST ARTICLE # / PILL BATCH#	SYSTEM PRESSURE PSI	GAS MANIFOLD TEMP °C	AMBIENT TEMP °C	RESULT
4/17/02	26 (102)	1	2200	58.3	29.8	NONE
		2	2200	57.6	29.8	NONE
4/17/02	27 (54)	1	2170	58.4	32.3	NONE
		2	2170	59.0	32.3	NONE
4/17/02	28 (85)	1	2170	60.0	32.3	NONE
		2	2170	59.5	33.0	NONE
4/17/02	29 (89)	1	2170	60.0	31.2	NONE
		2	2170	60.0	31.2	NONE
4/17/02	30 (99)	1	2160	60.0	31.2	NONE
		2	2160	60.0	31.2	NONE
5/3/02	31 (10?)	1	2060	58.9	19.4	NONE
		2	2060	58.7	19.3	NONE
5/3/02	32 (114)	1	2040	60.0	20.0	NONE
		2	2040	60.0	19.8	NONE
5/3/02	33 (86)	1	2040	60.0	19.7	NONE
		2	2040	59.7	19.8	NONE
5/3/02	34 (113)	1	2020	59.9	19.8	NONE
		2	2200	50.2	19.8	NONE
5/3/02	35 (122)	1	2200	52.4	20.0	NONE
		2	2200	53.0	20.1	NONE
5/3/02	36 (140)	1	2190	59.7	20.4	NONE
		2	2190	60.0	20.4	NONE
5/3/02	37 (131)	1	2180	60.0	20.3	NONE
		2	2180	58.7	20.4	NONE
5/3/02	38 (107)	1	2180	57.2	20.4	NONE
		2	2180	57.6	20.4	NONE
5/3/02	39 (141)	1	2160	57.8	20.3	NONE
		2	2160	58.3	20.4	NONE
5/3/02	40 (133)	1	2160	59.2	20.4	NONE
		2	2160	58.7	20.3	NONE
5/3/02	41 (139)	1	2160	50.3	25.3	NONE
		2	2140	50.8	25.2	NONE
5/3/02	42 (156)	1	2140	51.3	25.1	NONE
		2	2140	52.6	24.9	NONE
5/3/02	43 (146)	1	2120	53.7	23.8	NONE
		2	2120	52.0	23.8	NONE
5/3/02	44 (135)	1	2120	51.1	23.6	NONE
		2	2110	52.3	23.7	NONE
5/3/02	45 (151)	1	2110	55.1	23.7	NONE
		2	2100	53.8	23.7	NONE
5/3/02	46 (157)	1	2100	56.9	23.6	NONE
		2	2100	56.8	23.7	NONE
5/3/02	47 (137)	1	2100	59.1	23.5	NONE
		2	2080	55.5	23.7	NONE
5/3/02	48 (149)	1	2080	59.1	23.7	NONE
		2	2060	59.4	23.7	NONE
5/3/02	49 (147)	1	2060	57.7	24.0	NONE
		2	2060	58.6	24.1	NONE
5/3/02	50 (154)	1	2040	59.8	24.1	NONE
		2	2020	57.1	24.2	NONE

SurgeX

Surge Suppressing Post Valve



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