

Oxygen (Compressed Gas) Cylinder Hazard Summary

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Scope of this Summary

- ✚ This Summary addresses portable medical grade oxygen cylinders (also called tanks or bottles)
- ✚ This Summary is a SUPPLEMENT; It DOES NOT replace existing guidelines and directives for proper handling, storage, and operation of medical oxygen (e.g., JCAHO guidance on storage of “E” cylinders)

Audience

- ✚ Patient and occupational safety personnel (e.g., patient safety managers, industrial hygienists)
- ✚ Respiratory technicians
- ✚ Nurses and technicians who handle oxygen (especially in high use areas like OR & Urgent Care)
- ✚ Physicians who direct the usage of oxygen and other gases (interventional radiologists)
- ✚ Biomedical Engineers, physical plant personnel, and medical system maintenance personnel

Background/Rationale

- ✚ Close calls and adverse events have occurred at VA facilities and private hospitals
- ✚ Human factors engineering design problems have been identified by NCPS through RCAs and the SPOT data base
- ✚ Case studies and “alerts” involving adverse events with oxygen cylinders have been issued from:
 - Center for Devices and Radiology Health (CDRH) at FDA
 - ECRI <http://www.mdsr.ecri.org/>
 - Compressed Gas Association (CGA) <http://www.cganet.com/>

Vulnerabilities

- Fire*
- Materials that are slow to ignite or that will not burn in air will ignite and burn in an oxygen rich environment. This environment is created by oxygen flowing during treatment and the inadvertent releases. 100% O₂ saturates into surgical drapes, bed sheets, clothing, etc. Ignition sources could include electro-surgical instruments (e.g., ESU devices - Bovie or cautery pencil), defibrillators, cigarette lighter, matches, outdoor grills, or any other spark or heat-producing appliance. Recent fires have included a patient on O₂ who's hair and clothing started on fire while grilling (Hibachi) in his back yard; a patient in the OR who was burned when surgical drapes ignited due to oxygen and use of an ESU.
 - Rapidly opening a valve on a compressed gas cylinder can cause particle impact ignition resulting in a fire (this is why aluminum regulators are not permitted – aluminum is a combustible metal). See http://vaww.ceosh.med.va.gov/Hazards/Product_Recall/VA_Alerts/Allied_Oxy_Regulator_Alert.htm
- Mix- ups*
- CO₂ and O₂: A grayish green cylinder was confused for a greenish gray cylinder that resulted in a patient inhaling CO₂ during transport instead of oxygen. The use of universal adaptors (universal adaptors override the pin indexing system on the cylinder) contributed to this event.
 - CO₂/O₂ and CO₂: Insufflation of the body cavity for arthroscopy is done with CO₂ as the gas will not sustain combustion and is easily absorbed by the body. A gray and green CO₂/O₂ cylinder was confused with the gray CO₂ cylinder that resulted in an internal body cavity fire when a surgical laser was used. The CO₂/O₂ gas will support combustion.
- Oxygen not Available*
- It isn't always apparent whether an oxygen cylinder is full, partially full, or empty. In cases where the cylinder valve is closed and the regulator valve is open (see photograph), no pressure will register on the pressure gauge. Staff in a hurry has assumed the cylinder is empty when in fact it is full.
 - In some cases the O₂ cylinder is believed to be empty when trapped pressure in regulator is bled off by opening the flow meter/regulator valve when the cylinder valve is in the closed position.
 - You can't always tell by just looking at the valve if it's open or closed. Valves controlling the oxygen flow are not indicating type valves. What's an indicating valve? See: *A Brief History of Indicating Valves for Fire Protection*, <http://vaww.ncps.med.va.gov/O2ContValve.html> for further information on this topic.
- Cylinder goes ballistic*
- Ferromagnetic O₂ cylinders introduced into the MRI environment can inadvertently be turned into missiles when they are drawn into the magnet. For more information on projectile hazards in and around MRIs see: <http://vaww.ncps.med.va.gov/alerts/MRI.doc>.
 - A second way a cylinder can be turned into a missile is to fracture the cylinder. Escaping gas will propel the cylinder with enough force to penetrate cinder block walls.

Case Studies (From FDA Manufacturer and User Facility Device Experience Database (MAUDE), ECRI, and VA databases)

- ✚ An “E” cylinder containing CO₂ was mistaken for O₂ and was used during patient transport - he died. The modified O₂ regulator had been modified to fit “grayish” O₂ cylinder that really contained CO₂. This event emphasizes the point that cylinder color alone cannot be used to confirm the content of the cylinder.
- ✚ A gray “E” cylinder (usually indicating CO₂) was used for insufflating a uterus for endoscopic laser surgery. Instead, it contained a 20% CO₂ - 80% O₂ mixture normally used by anesthesiologists to induce breathing. Use of the laser resulted in an internal fire. This event again emphasizes the point that cylinder color may not be used as the primary indicator for the type of gas the cylinder contains.
- ✚ Misunderstanding of the dangers of using O₂ near ignition sources have resulted in minor fires and burns while: a) patient using a Hibachi grill on home O₂ therapy; b) hospital team used a defibrillator during cardioversion; and c) operating room team used electrosurgery.
- ✚ Empty O₂ cylinders have been inadvertently stored in code (crash) carts. During ACLS, the empty cylinder either contributed to difficulties in resuscitation, or caused undue commotion and diversion.

Root Causes/Contributing Factors and Suggested Action

- ✚ The most obvious cue for staff on the contents of a gas cylinder is the cylinder color, however, the color may be misleading or misunderstood. **The cylinder label is the primary means of identifying the cylinder content.** Follow directions and labels first – not color or other cues (e.g., storage location)... To be truly effective, CGA/ECRI recommends that the label be overwhelming in size
- ✚ If there is a mismatch between the color of the cylinder and the cylinder content, for example a gray cylinder that contains oxygen or a green cylinder that contains nitrogen, this is a guarantee that future problems will occur. For more information on color mismatch confusion and how humans cannot ignore conflicting inputs see the “Stroop Effect” exercises at <http://faculty.washington.edu/chudler/words.html> Provide as many cues that a cylinder does not contain 100% O₂ as possible for mixed and non-O₂ gas cylinders (e.g., store separately, transport in “odd-shaped” wheel cart)
- ✚ Text labels on cylinder can be damaged or for some reason may be illegible; if the label cannot be reliably read the cylinder should not be used.
- ✚ Cylinder tags (Full/In-use/Empty) are often misused and misunderstood and are a relic from systems used for compressed gases found in industry (welding torches, etc). Relying upon the pressure gauge reading is the most effective method of determining how much gas is left in the cylinder
- ✚ Improved cues are needed to signify to non-experts when cylinders are “empty” (like the empty cylinder warning light on your dashboard). For example, caution labels stating which valves need to be open.
- ✚ The regulator pressure gauge appears to be direct measure of gas available in the cylinder – however it can be isolated from the cylinder by closing the cylinder valve. If this occurs the gauge is only reading pressure trapped between the cylinder valve and the flow meter/regulator valve.
- ✚ Compressed gas pin indexing systems should not be overridden or defeated under any circumstances.

✚ To prevent ballistic missile type injury all cylinders, even empty ones, should be handled as if they are pressurized (all guns are “loaded”)

Next Steps

✚ Color-coding may be misleading and is not ideal for use in identifying medical gases., NCPS will work with CGA and FDA to determine optimal labeling without use of color for coding on cylinders.

References and Websites

FDA. “Avoiding The Hazards Of Medical Gases” July/August 2000 *FDA Consumer Magazine*
www.fda.gov/fdac/features/2000/400_gas.html

FDA Med watch Alert March 2001 – on mix-up of oxygen and other gases

CGA/USP/AGA/ISO. “Standard color marking of compressed gas containers intended for medical use” 1988, reaffirmed Sept 1993. Compressed Gas Association, Inc. 1235 Jefferson Davis Highway, Arlington, VA 22202.

Summary available at: <http://vaww.ncps.med.va.gov/CompGasSummary.doc>

CEOSH CEOSH Aluminum Oxygen Regulator Recall/Alert:

http://vaww.ceosh.med.va.gov/Hazards/Product_Recall/VA_Alerts/Allied_Oxy_Regulator_Alert.htm

APPENDIX A. Case Studies from FDA CDRH databases

FDA's MAUDE Database -- Case study from searching on "CO2 Cylinder"

REPORT DATE: 07/20/1999 MDR TEXT KEY: 783215 Patient Sequence Number: 1

AT APPROX 12:30PM ON JULY 12, 1999, A VASCULAR SHUNT WAS PLACED IN A PT FOR THE PURPOSES OF DIALYSIS. THE PROCEDURE WAS SUCCESSFUL AND THE PT WAS PREPARED TO RETURN TO THE NURSING UNIT. THE OXYGEN CONNECTION WAS REMOVED FROM THE WALL OXYGEN SOURCE AND ATTACHED TO A PORTABLE CYLINDER. THE OXYGEN CANNULA WAS THEN ATTACHED TO THE PT'S EXISTING TRACHEOSTOMY. THE PT WAS THEN TRANSPORTED BY BED TO THE INTENSIVE CARE UNIT. THE TRANSPORT WAS COMPLETED WITHIN A FEW MINUTES. ON ARRIVAL TO THE INTENSIVE CARE UNIT, THE PT WAS NOTED TO BE IN VENTRICULAR FIBRILLATION. THE PT THEN BECAME APNEIC AND SUSTAINED A CARDIAC ARREST. CARDIO-PULMONARY RESUSCITATION WAS IMPLEMENTED INCLUDING MEDICATIONS (CALCIUM AND SODIUM BICARBONATE) AND INTRAVENOUS FLUIDS. THE PT FAILED TO RESPOND AND WAS PRONOUNCED DEAD AFTER APPROX TEN MINS. AT THIS TIME, IT WAS DISCOVERED THAT THE PORTABLE CYLINDER USED TO TRANSPORT THE PT WAS A CARBON DIOXIDE CYLINDER. THE PHYSICIAN INVOLVED IN THE CASE CONCLUDED THAT THE CO2 HAD PROBABLY CONTRIBUTED TO THE PT'S CARDIOPULMONARY ARREST. ON EXAMINATION, IT WAS NOTED THAT THE ORIGINAL TANK USED FOR TRANSPORT WAS ALUMINUM O2 TANK WITH GREEN PAINT NEAR THE TOP AND THE CO2 TANK WAS A STEEL CONTAINER THAT WAS SIMILAR IN COLOR TO THE O2 TANK THAT WAS ORIGINALLY USED FOR TRANSPORT TO THE OPERATING ROOM. THE GUNMETAL GRAY COLOR OF THE CO2 TANK WAS SIGNIFICANTLY DISTORTED BY RUST. IN ADDITION, THE CO2 TANK CONTAINED A STANDARDIZED (DEPT OF TRANSPORTATION) GREEN LABEL THAT READS "NON-FLAMMABLE". THIS STANDARD GREEN LABEL WAS LOCATED NEAR THE TOP OF THE TANK WHERE THE GREEN PAINT WAS LOCATED ON THE ORIGINAL ALUMINUM OXYGEN CYLINDER. IN ADDITION, THE CO2 TANK WAS EQUIPPED WITH A FLOWMETER AND A GREEN NIPPLE ADAPTER THAT WAS SIMILAR IN APPEARANCE TO THE FLOWMETER NORMALLY USED FOR OXYGEN. THE REGULATORS ON THE TWO CANISTERS LOOKED IDENTICAL WITH THE EXCEPTION OF THE WORDS "CARBON DIOXIDE" WRITTEN IN SMALL PRINT ON THE FLOWMETER PORTION. IN ESSENCE, THE PIN INDEXING SYSTEM THAT WAS DESIGNED TO CONSTRAIN THIS TYPE OF EVENT WAS OVER-RIDDEN BY A LOOK-ALIKE PRODUCT. FURTHER REVIEW REVEALED THAT THE COLOR AND TYPE OF OXYGEN TANKS LOCATED IN THE FACILITY WERE INCONSISTENT. TANKS CAN BE STEEL PAINTED IN LIGHT OR DARK GREEN. THEY MAY ALSO BE ALUMINUM (GRAY) IN COLOR WITH A GREEN PAINTED BAND AT THE TOP. THE CO2 TANKS HAD A GREENISH HAZE WITH RUST MARKS AND SCRATCHES ON THEM. BOTH HAVE DEPT OF TRANSPORTATION LABELS, WHICH HAVE A GREEN BACKGROUND. THE VENDOR WAS NOTIFIED.

FDA's MAUDE Database -- Case study from searching on "CO2 Tank"

REPORT DATE: 01/30/2001 MDR TEXT KEY: 1084430

THE CO PRODUCT'S POLYBAG INSTRUCTS THE USER FOR OXYGEN CONNECTION LOCATION. SECTION H.3: DEVICE EVAL SUMMARY....THE MEDWATCH REPORT FILED BY THE USER FACILITY, DATED 12/2000, INDICATED THAT A HOSP STAFF MEMBER ACCIDENTALLY OBTAINED A CO2 TANK INSTEAD OF AN O2 TANK AND CONNECTED THE TUBING TO THE CO2 FLOWMETER CONNECTOR ON THE TANK REGULATOR. THE REPORT ALSO INDICATED THAT AS A RESULT OF THIS, THE PT HAD A CARDIAC ARREST. CPR WAS ADMINISTERED, THE PT WAS RECONNECTED TO O2, AND THE PT HAD A GOOD RECOVERY. THE STAFF MEMBER LATER RECOGNIZED THE ERROR. ALTHOUGH THE ACCOUNT DID NOT REPORT THE FINISHED PRODUCT CODE NUMBER AND LOT NUMBER, THEY DID PROVIDE A COMPONENT PART NUMBER. NO SAMPLE WAS RETURNED TO VSI FOR INVESTIGATION. A DOCUMENT INVESTIGATION REVEALED THAT THE CO SHIPPED TWO ORDERS OF A CODE BLUE II RESUSCITATOR, 7552K, LOT NUMBER A042, TO THIS ACCOUNT. BASED ON THIS THE CO BELIEVES THAT THIS MAY BE THE PRODUCT CODE AND LOT NUMBER INVOLVED IN THIS INCIDENT. THE CO DOCUMENT INVESTIGATION REVEALED THAT THE TUBING USED IN THIS LOT NUMBER HAD A GREEN CONNECTOR ON THE END OF THE TUBING. THE GREEN COLOR IS USED TO ALERT THE END USER THAT THE TUBING IS USED FOR OXYGEN SUPPLY. BASED ON THIS INVESTIGATION, THE CO BELIEVES THAT THIS INCIDENT IS THE RESULT OF USER ERROR, NOT PRODUCT MALFUNCTION OR PERFORMANCE.

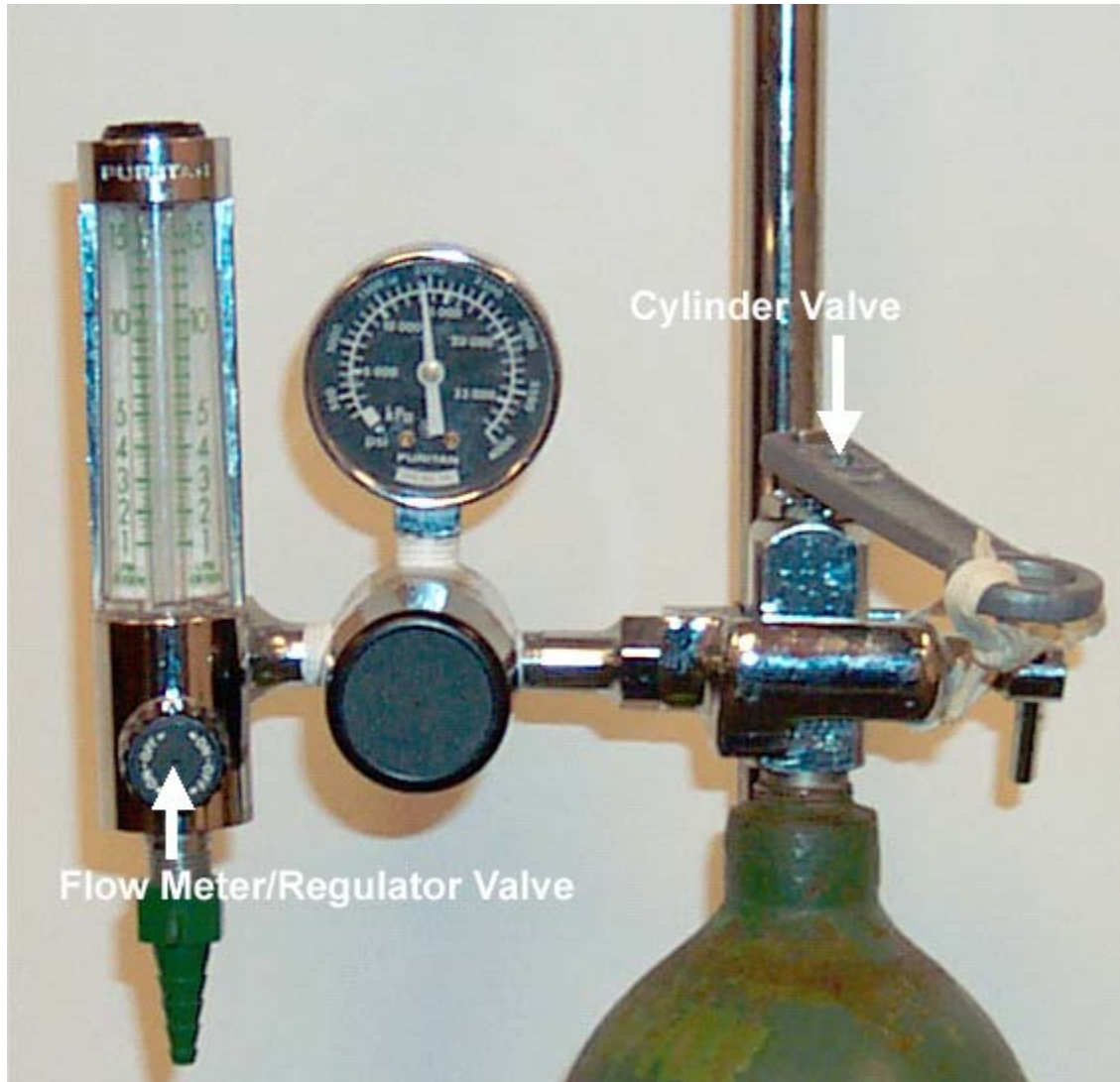
FDA's MDR database -- Case study from searching on "O2 and CO2"

Access Number: M331912

Date Received: 11/20/92

Product Description: LAPAROFLATOR

Event Description: ALTHOUGH THIS UNIT IS SPECIFIED TO BE USED WITH **CO2** ONLY, HOSP HOOKED THE LAPAROFLATOR UP WITH A **CO2/O2** MIXED GAS BY MISTAKE (14% **CO2** AND 86% **O2**). WHILE THE LAPAROSCOPIC CHOLECYSTECTOMY PROCEDURE WAS ABOUT 95% COMPLETED, AN EXPLOSION OCCURRED INSIDE THE PT. DR OPENED THE PT TO VERIFY ANY DAMAGE AND FOUND NO INJURY TO PT.



O₂ cylinder appears empty, after initially being full (main valve open, inter-valve area pressurized, gauge now reading full, then main valve re-closed).