



## Frequently Asked Questions

### I. Regulatory Questions

#### Who Should Buy oxyQuik?

- Commercial Customers/Public Venues: oxyQuik should be purchased by any venue, such as:
  - a. Schools
  - b. Airports
  - c. Offices & Factories
  - d. Retail Stores/Malls
  - e. Hotels
  - f. Etc.

#### Does an institution, or a representative of the institution, need a doctor's prescription to buy an oxyQuik?

- No, the oxyQuik unit is exempted for emergency use by properly trained personnel under provisions of the FDA's definition of an "emergency oxygen device." Training can be obtained through the American Red Cross, American Heart Association, or other EMT training programs. Training materials provided by "MEDIC First Aid International" are also shipped with each unit.
- \*\* Requirements may vary from state to state. The State Board of Pharmacy is the authority regarding dispensing of Drugs. Oxygen is considered a drug by the FDA. Check your state regulations for definitions regarding emergency oxygen.

#### Does a distributor need a license or permit to sell a filled Emergency Oxygen Unit?

- Requirements may vary from state to state. The State Board of Pharmacy is the governing authority regarding dispensing of Drugs. Oxygen is considered a drug by the FDA. Check your state regulations for definitions regarding emergency oxygen.

#### What is the FDA definition of an emergency of Oxygen Device?

- Emergency Oxygen Equipment must deliver a minimum flow rate of 6 liters of oxygen per minute for a minimum of 15 minutes. Labeling for emergency oxygen may not contain references to heart attacks, strokes, shock or any other medical condition amenable to diagnosis or treatment only by a licensed practitioner.

### What is the FDA Emergency Oxygen Label?

- This text is required on all Oxygen cylinders.

#### FDA Emergency Oxygen Compliance Regulation

"For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only. Caution: Federal law prohibits dispensing without prescription."

- The label is located on the plastic shroud (on the back of the unit) and on the cylinder.

### What Emergency Oxygen Training does a customer need?

- As required by the FDA Emergency Oxygen Label, an individual must have received proper training within the past twenty-four months or other interval in the use of emergency oxygen including providing oxygen to both breathing and non-breathing patients, and safe use and handling of emergency oxygen equipment.
- Training can be obtained through the American Red Cross, American Heart Association, or other EMT training programs, or by reviewing the oxyQuik Emergency Training Program.
- An oxyQuik Emergency Oxygen Training Affidavit should be signed by every customer, to attest to either having a current Emergency Oxygen training certificate, or to having read the oxyQuik Emergency Training program/Medic First Aid Emergency Training Guide prior to purchase or filling.
  - a. If oxyQuik is sold to a commercial venue with a designated individual who has prior Emergency Oxygen Training, no training is required. However, the affidavit still should be signed.

### Who keeps the signed affidavit?

- The retail facility that sold or filled the oxyQuik to the end customer must keep the affidavit with the sales record.

### What is the Good Samaritan Law?

- Below are general guidelines, as stated in the Medic First Aid Emergency Oxygen Student Guide:

"Being sued as a result of providing assistance in an emergency is a fear for some people. "Good Samaritan Laws" have lessened much of this fear.

These laws apply directly to administering oxygen in an emergency. Generally, these laws protect a person who: Voluntarily provides assistance which he or she would not otherwise be legally obligated to provide. Expects nothing in return, and is not "grossly negligent" which means completely reckless or careless in rendering care."

State Regulations can be found on this site:

<http://www.cprinstructor.com/legal.htm>

#### Is the OxyQuik FDA approved?

- FDA does not approve medical devices. However, the oxyQuik unit is manufactured under the quality system requirements for medical device manufacture. It is subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act which are contained in the final procedural regulations in Title 21 Code of Federal Regulations Part 800-1200 ([21 CFR Parts 800 - 1299](#)). These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring its performance once the device is on the market.

#### What FDA device class is the OxyQuik?

- Device: Class 1,
- Device: Regulator, Pressure, gas cylinder
- Product Code: CAN

#### DOT Regulations for shipping oxyQuik

- Shipment of filled oxyQuik units must comply with the DOT regulations The Department of Transportation (DOT).

## II. General Questions

#### Where can I get an oxyQuik filled?

- Western has information regarding establishments who have indicated that they are capable of filling your unit. Contact Western for information regarding these fillers in your area or visit the oxyQuik website: [www.oxyQuik.com](http://www.oxyQuik.com). You may also contact a local HME, DME, or compressed gas filler for additional guidance.

#### Where should oxyQuik be placed?

- We advise oxyQuik to be placed or mounted next to a fire extinguisher/AED/First Aid center. The location must be away from heat and easily accessible.

#### How is oxyQuik packaged?

- oxyQuik units are packaged individually
- Multiple units ship in a master box of 4, individually packaged units

## III. Technical Questions

#### How is oxyQuik refilled?

OxyQuik can be filled/refilled in two ways:

- Take off the door on the back of the unit. The retention screw and the filling door will remain attached to the shroud. The filling valve is easily accessible through this door.
- Remove the shroud entirely, by unscrewing 4 screws, three on the back and 1 on the front – under the mask lid.
- Fill pressure: 1850 – 2200 PSI

**What is the shelf life of the unit if it is not used?**

- Oxygen content is sufficient, as long as the contents gauge is in the green zone
- Cylinders must be hydrostatically re-qualified by a Gas Provider every 5 years, in accordance with the DOT regulations.

**What kind of valve is the oxyQuik?**

- The device is a valve integrated pressure regulator. (Cylinder valve and regulator in one device)

**Does it require periodic calibration?**

- It is recommended that all products of this type have flow rates re-verified every five years. This coincides with the cylinder re-qualification.

**How does the alarm operate?**

- How it works:
  - a. Mini Theft Stopper is mounted next to the door or in the cabinet and its reed switch unit is mounted on the door jam. The matching magnet is mounted on the door near it and when the door is opened, the device sounds a 105 dB warning horn.
- How does the alarm turn off once it is activated?
  - a. A deactivation pin is provided for service by authorized personnel.
  - b. Three minute automatic reset upon activation.

**Can oxyQuik be repaired by a customer?**

- The regulator cannot be serviced by anyone other than Western Enterprises. Other replacement parts may be available for sale (see the Accessories price list).

