

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Western/Scott Fetzer Company OxyTOTE Portable Oxygen Unit May Ignite and Burst

f [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTP%3A%2F%2FWWW.FDA.GOV%2FMEDICALDEVICES%2FSAFETY%2FLISTOFRECALLS%2FUCM458740.HTM\)](https://www.facebook.com/sharer/sharer.php?u=http%3A%2F%2Fwww.fda.gov%2Fmedicaldevices%2Fsafety%2Flistofrecalls%2Fucm458740.htm)

t [TWEET \(HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=WESTERN%2FSCOTT%20FETZER%20COMPANY%20OXYTOTE%20PORTABLE%20OXYGEN%20UNIT%20MAY%20IGNITE%20AND%20BURST&URL=HTTP%3A%2F%2FWWW.FDA.GOV%2FMEDICALDEVICES%2FSAFETY%2FLISTOFRECALLS%2FUCM458740.HTM\)](https://twitter.com/intent/tweet/?text=Western%2FScott%20Fetzer%20Company%20OxyTOTE%20Portable%20Oxygen%20Unit%20May%20Ignite%20And%20Burst&url=http%3A%2F%2Fwww.fda.gov%2Fmedicaldevices%2Fsafety%2Flistofrecalls%2Fucm458740.htm)

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e [EMAIL \(MAILTO:?SUBJECT=WESTERN%2FSCOTT%20FETZER%20COMPANY%20OXYTOTE%20PORTABLE%20OXYGEN%20UNIT%20MAY%20IGNITE%20AND%20BURST&BODY=HTTP%3A%2F%2FWWW.FDA.GOV%2FMEDICALDEVICES%2FSAFETY%2FLISTOFRECALLS%2FUCM458740.HTM\)](mailto:?subject=Western%2FScott%20Fetzer%20Company%20OxyTOTE%20Portable%20Oxygen%20Unit%20May%20Ignite%20And%20Burst&body=http%3A%2F%2Fwww.fda.gov%2Fmedicaldevices%2Fsafety%2Flistofrecalls%2Fucm458740.htm)

Recall Class: Class I

Date Recall Initiated: 1/31/2015

Devices:

- [Affected Lot and Model Numbers](#)



<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=132378>

- Manufacturing and Distribution Dates: January 1, 2009 to September 30, 2014
- Number of Units Distributed in the U.S.: 161,674

Use: Portable oxygen units provide oxygen to patients to help regulate their breathing while allowing them to travel around. Pressurized oxygen is stored in a special container and is delivered to the patient through tubing that is placed in the nostrils or through a mask.

The primary users of these devices are hospitals, nursing homes, and clinics.

Recalling Firm:

Western/Scott Fetzer Company
875 Bassett Rd
Westlake, Ohio 44145-1142

Reason for Recall:

The company received reports that when the OxyTote is mishandled or dropped, the oxygen cylinder may ignite causing an internal flash fire and the canister to burst.

The firm has received a total of 2 reports of incidents in which the device has malfunctioned, including 1 injury and 1 death. When the injury occurred, the unit was dropped from 4 feet; where the death occurred, the employee did not drop the gas cylinder, but set it down by his side.

Public Contact: For questions or concerns regarding this notification, visit the Western/Scott Fetzer [website \(http://westernenterprises.com/recall/\)](http://westernenterprises.com/recall/)

[\(http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm\)](http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

or contact Western/Scott Fetzer by phone at (800) 783-7890, extension 2516

FDA District: Cincinnati District Office

More Information about this Recall:

Western/Scott Fetzer Company informed customers of these issues in a January 31, 2015 letter and provided the following instructions.

Distributors and Oxygen Service Providers:

1. Notify and provide this letter to all accounts/customers to which you have distributed (by sale, consignment, rental, or through any other arrangement) any OxyTOTE/oxyQuik/AirTOTE products.

These customers include but are not limited to: Distributors, Hospitals, Health Care Facilities, Health Care Service providers, EMS staff, ambulance service providers, Oxygen service providers, Oxygen tank fillers, and Oxygen tank certification service providers.

Alternately, please provide a list of customers who received affected product and Western/Scott Fetzer will notify them on your behalf.

2. Referring to the instructions for OxyTOTE/oxyQuik/AirTOTE Users and User Facilities below, follow up with each account/customer to ensure that they locate and identify all affected product and establish the number of units in their possession subject to the recall.
3. Contact Western/Scott Fetzer to schedule remediation for any affected OxyTOTE/oxyQuik/AirTOTE product included under this notice. Western/Scott Fetzer will begin scheduling products for remediation on February 17, 2015. Western/Scott Fetzer has multiple contact methods available to provide product information and schedule this corrective action.
4. Please complete the Recall Acknowledgement and Receipt Form and return it to Western/Scott Fetzer as soon as complete responses are available.

Users and User Facilities (Hospitals, Health Care Facilities, Health Care Service providers, etc.):

1. Locate and identify any OxyTOTE/oxyQuik/AirTOTE product in your possession.
2. Review the instructions to determine if the product IS or IS NOT marked and if remediation is needed.

3. Contact your OxyTOTE/oxyQuik/AirTOTE supplier or Medical Gas Provider directly to schedule the remediation of product in your possession.

Additionally, the firm reminded customers about the importance of general safe storage and handling practices.

About Class I Recalls



Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX.

Other Resources

- [Medical Device Recall Notice \(http://westernenterprises.com/recall/medical-device-recall-notice/\)](http://westernenterprises.com/recall/medical-device-recall-notice/) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

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More in Medical Device Recalls

(/MedicalDevices/Safety/ListofRecalls/default.htm)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)