



## URGENT MEDICAL DEVICE RECALL NOTICE

January 31, 2015

ATTN: Regulatory Affairs Manager, Risk Manager, Hospital Administrator, OxyTOTE Distributor, OxyTOTE Wholesaler, Oxygen Service Provider, Health Care Provider

RE: Western/Scott Fetzer OxyTOTE products which include the following models: OxyTOTE, OxyTOTE 3000, OxyTOTE NG, OxyTOTE 3000 NG, AirTOTE, and oxyQuik Series Valve Integrated Pressure Regulators (VIPR), as well as private label versions of these products.

Dear Valued Customer:

**Western/Scott Fetzer is implementing a voluntary recall for OxyTOTE/oxyQuik/AirTOTE products**, including OxyTOTE, OxyTOTE 3000, OxyTOTE NG, OxyTOTE 3000 NG, AirTOTE, and oxyQuik Series Valve Integrated Pressure Regulators, and all private label versions of these products. Hereafter, they will be referred to as “OxyTOTE/oxyQuik/AirTOTE”. See *Attachments 1 and 2 for details and instructions for identification of affected product.*

### **Description of the Product** –

The OxyTOTE/oxyQuik/AirTOTE family of Valve Integrated Pressure Regulators (VIPR's) subject to this recall are those mounted on **aluminum** Oxygen cylinders and used to dispense Oxygen at prescribed flow rates to patients for therapeutic purposes. Those mounted to steel cylinders are not subject to this recall.

### **Description of the Problem** –

Western has received reports of three ignition events resulting in serious injuries, including one fatality. These events occurred unexpectedly and without warning, although handling may have been a contributing factor. All three ignition events occurred in the time period from March 2014 to January 2015, and all three events occurred following the Oxygen cylinder refilling process, not during product use in a healthcare setting. Launched in 2004, Western has distributed approximately 280,000 OxyTOTE/oxyQuik/AirTOTE systems throughout the US and North America, and millions of fill cycles occur each year without incident. Based upon an analysis of the events, Western has concluded that OxyTOTE/oxyQuik/AirTOTE units manufactured with a certain type of cylinder sealing o-ring are more prone to this rare but serious type of event, and this recall will mitigate the risk of further occurrences.

All OxyTOTE/oxyQuik/AirTOTE units on aluminum cylinders manufactured prior to October 2014 are subject to this recall. Units manufactured from October 2014 to present are not subject to this recall (these units include a “T” stamp per Attachment 2).

Please take care to minimize any sudden impact to the cylinder or VIPR and refer to the safe handling practices as indicated in the Safety Advisory Bulletin sent out in October 2014 (included as Attachment 3).



## **Description of the Resolution and *Actions Required* -**

**Western/Scott Fetzer** is implementing a voluntary recall to prevent recurrence of these events. This corrective action is to be conducted **only** by Western/Scott Fetzer authorized service centers, and involves removing the OxyTOTE/oxyQuik/AirTOTE Valve Integrated Pressure Regulator from the Oxygen cylinder, removing the sealing o-ring, utilization of a validated cleaning process to clean the threads and adjacent surfaces on the regulator and cylinder, reassembly with a new o-ring, and marking the devices to provide visual differentiation of remediated product. See Attachment 2 for detail on the product marking scheme for remediated/corrected product. **Note that the entire system (OxyTOTE/oxyQuik/AirTOTE Valve Integrated Pressure Regulators and the Oxygen cylinders to which they are mounted) is included in this correction.**

## **OxyTOTE/oxyQuik/AirTOTE 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, Oxygen tank certification service providers, etc. 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 per Attachments 1 and 2, 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 (see Attachments 1 and 2). We will begin scheduling product for remediation on February 17, 2015. **Western/Scott Fetzer** has multiple contact methods available to provide product information and schedule this corrective action. Please refer to the contact information below.
- 4) **Please complete the *Recall Acknowledgement and Receipt Form*** and return it to Western/Scott Fetzer as soon as complete responses are available (see Attachment 4).

**OxyTOTE/oxyQuik/AirTOTE 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: refer to Attachment 1 for detailed information.
- 2) **Review the instructions (Attachment 2) 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.**



**Western/Scott Fetzer Contact Information:** If you have any questions or concerns regarding this notification, please visit the website for additional details or contact Western/Scott Fetzer:

Website: [www.westernenterprises.com/recall](http://www.westernenterprises.com/recall)

By Email: [recall@WesternEnterprises.com](mailto:recall@WesternEnterprises.com)

By Phone: (800) 783-7890, extension 2516

Monday – Friday, between the hours of 9:00AM – 4:00PM EST.

By Mail:

Recall Coordinator  
Western/Scott Fetzer Company  
875 Bassett Road  
Westlake, OH 44145

By Fax: (440) 835-8283

Western's primary concern is the safety of our customers. We thank you in advance for your cooperation and understanding in this matter and sincerely apologize for any inconvenience this action may cause.

Sincerely,

David C. Simo  
Director of Quality and Regulatory

**Attachment 1: OxyTOTE/oxyQuik/AirTOTE Product Identification**

**Identify the subject product** based upon the information below.

The OxyTOTE and oxyQuik products have the following general appearance:



OxyTOTE

oxyQuik

**OxyTOTE, OxyTOTE 3000, OxyTOTE NG, OxyTOTE 3000 NG, AirTOTE, and private label versions** of these products are similar in appearance, with variations in the regulator housing as indicated below. OxyTOTE brand products are readily identified by the name “OxyTOTE” on the regulator housing and/or handle.



OxyTOTE

OxyTOTE 3000

OxyTOTE NG

OxyTOTE 3000 NG

AirTOTE

**Private Label versions of the affected OxyTOTE products** are identical in form/size/shape, but are readily identified as indicated in the pictures below.

- 1) Note that the specific “private label” name appears in the areas indicated below.
- 2) For ALL private label variants, the Western/Scott Fetzer identity can be confirmed on the back of the regulator housing as indicated.
- 3) The color of the regulator housing can vary (green, black, etc.).



Customer “private label” replaces “OxyTOTE”

Back indicates “Western /Scott Fetzer”

**The oxyQuik product** has a significantly different appearance:



**Attachment 2: Identification of Affected Product and Product Marking after the Corrective Action has been conducted**

**Locate the following markings on the device:**

- 1) **ALL** OxyTOTE/oxyQuik/AirTOTE products are subject to this recall **EXCEPT** units that are marked with a hard stamped “T” on BOTH the Oxygen cylinder AND the brass portion of the regulator body. Refer to the following illustrations. **These OxyTOTE units were manufactured from October 2014 to date, and are NOT subject to this recall action.**



OxyTOTE with “T” stamp on regulator

Oxygen cylinder with “T” stamp on shoulder area

- 2) **Any OxyTOTE/oxyQuik/AirTOTE products that DO NOT include the hard stamped “T” on BOTH the Oxygen cylinder AND Valve Integrated Pressure Regulator (VIPR) body ARE INCLUDED IN THIS RECALL.**
  - a. If you cannot find a hard stamped “T” during an inspection of the shoulder area of the Oxygen cylinder, then BOTH the regulator AND cylinder assembly are subject to the recall.
  - b. If you cannot find a hard stamped “T” during an an inspection of the regulator body in the location indicated, then BOTH the regulator AND cylinder assembly are subject to the recall.
- 3) **ALL oxyQuik brand products are subject to the recall.**
- 4) **ALL AirTOTE brand products are subject to the recall.**

**Product Marking after the Recall Corrective Action has been conducted**

Upon completion of the remediation under this recall, all OxyTOTE product will be hard stamped with a “G” on BOTH the Oxygen cylinder shoulder AND the regulator body.



**OxyTOTE and OxyTOTE**

**OxyTOTE NG and 3000 NG**

In addition, a green “G” label will be affixed to BOTH the Oxygen cylinder AND the regulator body to facilitate efficient identification of remediated product during and after the recall.



**OxyTOTE and OxyTOTE**

**OxyTOTE NG and 3000 NG**



## **Attachment 3: OxyTOTE Safety Alert**

October 23, 2014

# **Urgent: Medical Device Safety Notification**

Attention: Quality / Regulatory Affairs Department

To Whom It May Concern:

The purpose of this letter is to advise you that Western/Scott Fetzer Company ("Western," a.k.a., Western Enterprises, Western Medica) is issuing a safety advisory for the OxyTOTE and OxyTOTE NG Series Valve Integrated Pressure Regulators (also known as VIPRs or All-in-One pressure regulators) manufactured for use on Aluminum cylinders. The subject devices were sold as a Kit (VIPR head only) or as a Portable Oxygen Cylinder Systems (VIPR mounted on an Aluminum cylinder). The VIPR and Portable Oxygen Cylinder System are used to dispense Oxygen at prescribed flow rates (i.e., Liters Per Minute) to patients for therapeutic purposes.

Western has received two reports of ignition events involving this product mounted on aluminum cylinders. Both the events involved a rupture of the pressurized aluminum cylinder.

**Serious injury and/or death could occur due to the failure mode associated with this advisory. Western has reports of 1 death and 1 injury associated with this failure mode.**

### **Storage, Transportation and Handling Precautions**

1. Store the system securely to prevent damage from falling over. DO NOT store the system in an elevated place or where the system could fall over or be damaged.
2. Take care to secure the cylinder so it will not tip or fall during assembly or when being filled.
3. Store OxyTOTE and OxyTOTE NG systems indoors in a safe area where they will not fall over or be damaged by falling objects.
4. Never store a system in an elevated location because a fall could seriously damage the regulator or cylinder. If a system is dropped or knocked over, check to see that components are not damaged and connections remain secure.
5. Handle systems safely. Portable oxygen therapy systems are inherently subject to greater abuse than are stationary units. Avoid jarring or dropping the system.
6. A failure can occur unexpectedly and without warning and has been reported to be associated with some type of impact blow such as a drop, fall, or incidental contact with others cylinders due to improper handling.



7. Western stresses that all cylinder systems **MUST** be secured and protected from falling or tip-over during fill, during transport and at point of use. Never store the cylinder system in an elevated area where a fall could severely damage the unit. At all times, be certain to handle systems safely and avoid jarring or dropping the system.

Western stresses the critical importance that safe and careful protocols are followed in the handling, transportation, and storage of all Oxygen pressurized systems. Minimize to the extent possible any sudden impact to the cylinder or VIPR.

Although these ignition events are extremely rare (0.00123% or approximately 1 event in 81,400 units), based on our preliminary investigation and the unexpected and potentially serious nature of the event, it is with an abundance of caution in the interest of public safety that Western has decided to issue this safety alert.

Depicted below, are illustrations of the OxyTOTE and OxyTOTE NG Models affected by this advisory.

Western would appreciate your acknowledgement of receipt of this notification by:

Email - [osnotice@westernenterprises.com](mailto:osnotice@westernenterprises.com)  
Phone - Monday – Friday 9:00-4:00 EST  
(800) 783-7890 Ext 1516

Western thanks you for your cooperation and attention to this matter.

Sincerely,



David C. Simo  
Director of Quality & Regulatory





**Attachment 4**

**RECALL ACKNOWLEDGEMENT AND RECEIPT FORM**

(Response Required)

**Western/Scott Fetzer OxyTOTE products**

**(Including OxyTOTE, OxyTOTE 3000, OxyTOTE NG, OxyTOTE 3000 NG, AirTOTE, and oxyQuik Series Valve Integrated Pressure Regulators (VIPR), including private label versions of these products)**

1) I have received the recall notification letter from Western. Yes \_\_\_ No \_\_\_

2) I have read and understand the recall notification letter instructions. Yes \_\_\_ No \_\_\_

3) Do you have any units affected by the recall in your possession/inventory? Yes \_\_\_ No \_\_\_

If yes, how many? \_\_\_\_\_

4) If further distributed, have your accounts been notified of this recall? Yes \_\_\_ No \_\_\_

If No, why? What are your intentions? \_\_\_\_\_

\_\_\_\_\_

5) Have the units been remediated as instructed in the notification letter? Yes \_\_\_ No \_\_\_

If No, why? What are your intentions? \_\_\_\_\_

\_\_\_\_\_

6) Have you received any reports of adverse events associated with the use of this product?

Yes \_\_\_ No \_\_\_ If Yes, explain. \_\_\_\_\_

\_\_\_\_\_

7) I have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_ **(specify date and method of notification)**;

Alternately, attached is a list of customers who received/may have received this product. Please notify my customers.

Signature of Respondent: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed)	
Title	
Telephone	
Email address	



**Response Box: (Please provide any additional information, if applicable)**

**Please return the completed form as indicated below:**

**Western/Scott Fetzer Contact Information:** If you have any questions or concerns regarding this notification, please visit the website for additional details or contact Western/Scott Fetzer:

Website: [www.westernenterprises.com/recall](http://www.westernenterprises.com/recall)

By Email: [recall@WesternEnterprises.com](mailto:recall@WesternEnterprises.com)

By Phone: (800) 783-7890, extension 2516  
Monday – Friday, between the hours of 9:00 – 4:00 EST.

By Mail:  
Recall Coordinator  
Western/Scott Fetzer Company  
875 Bassett Road  
Westlake, OH 44145

By Fax: (440) 835-8283