December 19, 2024

URGENT: MEDICAL DEVICE RECALL

JMC5A Ni/TruAire-5 Oxygen Concentrator, Model: O2C5L

Dear Valued Customer,

Please note the updates to this letter from the one that you previously received from us. The purpose of this letter is to advise you that the manufacturer (Jiangsu Jumao X-Care Medical Equipment Co., Ltd.) is voluntarily recalling TRUAIRE-5 O2 CONCENTRATORS (O2C5L) manufactured between 11/3/2023 and 1/8/2024 (within serial number range: JA2311000001-JA2401000740). The TRUAIRE-5 O2 CONCENTRATOR (O2C5L) is intended to provide supplemental oxygen to patients with respiratory disorders by separating nitrogen from room air by way of a molecular sieve. It is not intended to sustain or support life.

Our records show that you may have purchased a TRUAIRE-5 O2 CONCENTRATOR (O2C5L) manufactured between 11/3/2023 and 01/8/2024 (within serial number range: JA2311000001-JA2401000740).

Compass Health Brands Corp. places patient health and safety first and foremost and wants to ensure the safety and effectiveness of all of our products. We are working with the manufacturer to support and facilitate this recall. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Reason for the Voluntary Recall:

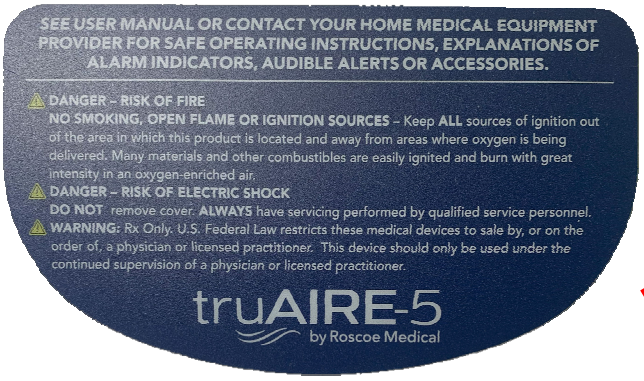
There have been nine incidents of device melting and fire during the use of the oxygen concentrators. Jiangsu Jumao X-Care Medical Equipment Co., Ltd. is recalling all units from the affected serial number range.

Please note that we have not received any reports of deaths, serious injuries, or minor injuries associated with this device.

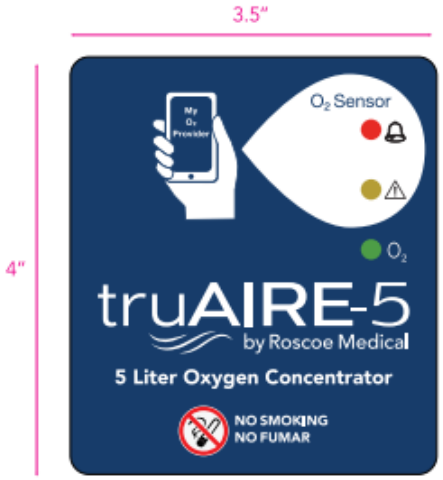
Following is a representative photo of the device:

Following is a representative label for the device:

- TruAire-5 Warning Label



- Control Panel Label



➢ O2C5L UDI Label (4.75"W X 1.5"H)

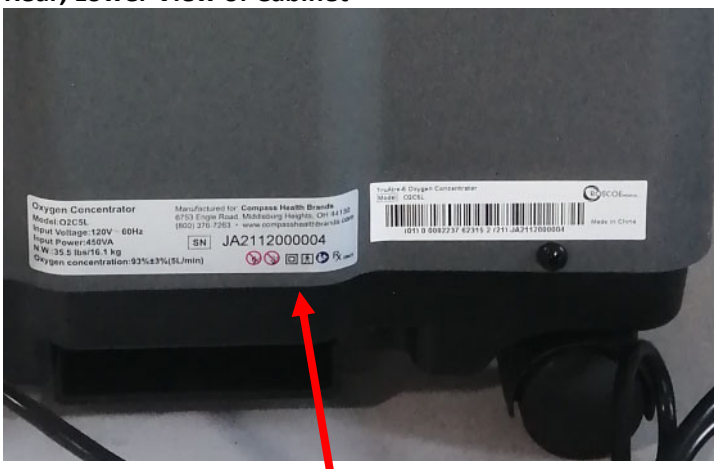
TruAire-5 Oxygen Concentrator
Model O2C5L

ROSCOE MEDICAL

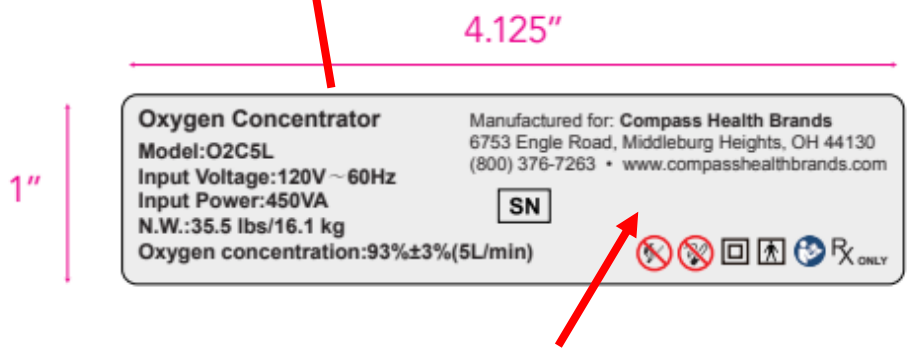
(01)00092237623152(21)JAYYMM000000

Made in China

Rear, Lower View of Cabinet



➢ **TruAire-5 Specification Label**



truAIRE-5 Concentrator's unique Serial Number

Risk to Health:

While we have not received any reports of deaths, serious injuries, or minor injuries associated with this device, a patient or caretaker's exposure to excess heat and fire could lead to burns.

How to Recognize That the Device May Fail:

We are not aware of any outward signs or other indication that a unit is prone to this failure, prior to the failure occurring.

REQUIRED ACTIONS (Actions to be taken by the Customer/User). Please take the following actions IMMEDIATELY:

- All units from the specified serial number range **MUST** be immediately discontinued from use and removed from service and promptly returned to Compass Health Brands. These devices will then be returned to Jiangsu Jumao X-Care Medical Equipment Co., Ltd. for inspection and investigation of possible causes for these incidents. You may use the text in this notification for notifying your own consignees/customers.

  Compass Health Brands will replace all units returned with units from other serial number ranges that have not suffered this failure. Contact Compass Health Brands to arrange for device return.

- **NOTIFY YOUR CUSTOMERS** that have received units within the affected serial number range to alert them to this recall and the requirement to replace their oxygen concentrator.

- **COMPLETE AND RETURN** the attached medical device recall return response acknowledgement and receipt form to Compass Health Brands within fifteen (15) calendar days of receipt.

  RESPONSE FORM **MUST** BE RETURNED EVEN IF YOU HAVE NO STOCK OR HAVE NO RECORD OF PURCHASING THIS DEVICE (FDA requires documentation of our notification to you). This will ensure the timely replacement of units from the specified serial number range. ***Upon receipt of the completed form, Compass Health Brands Corp. will reach out to you to coordinate the return and replacement of the recalled devices.***

Compass Health Brands Corp. appreciates your immediate attention to this urgent matter. If you have any questions, please contact:

Compass Health Brands Corp. – ATTN: RECALL
Address: 6753 Engle Rd., Middleburg Heights, OH 44256, USA
Telephone: **1-800-376-7263 x444**
Monday-Friday 8:00 am EST - 5:00 pm EST
recall@compasshealthbrands.com

This voluntary Recall notification is being conducted with the knowledge of the United States Food and Drug Administration (FDA) in accordance with U.S. regulations. Please note that adverse reactions or quality problems experienced with the use of this product may be reported directly to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax. Details are at https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program