



To:

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

**ALL PRIVATE PHARMACIES & DRUG STORES**

After Compliments,

Please find attached our Circular No 57 dated 28/3/2023 Regarding NCMDR Field Safety Notice of Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300 from (mfr: Philips Respironics).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 57/2023

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Moving Forward  
with Confidence



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28-03-2023

**Field Safety Notice of Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300 from Philips Respironics.**

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18476">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18476</a>
Product	Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300.
Description	Ventilators.
Manufacturer	Philips Respironics.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	All distributed Trilogy Evo O2, Trilogy Evo Universal, Trilogy EV300 devices are impacted by this issue.
Reason	Accuracy of delivered oxygen may deviate below the required tolerance of 5% from setpoint when providing high concentration oxygen therapy. Additionally, if equipped, the internal FiO2 sensor may indicate a value higher than the device is actually delivering.
Action	1. Until a solution is provided by Philips Respironics, please follow the instructions in the FSN letter. Philips Respironics will release a software update that will address the issue. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General



**URGENT Field Safety Notice**

Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, Trilogy EV300  
Accuracy of FiO<sub>2</sub> Delivery

01 MAR 2023

To: Name / Title / Customer Name  
Street Address  
City, State, Zip Code

**This document contains important information for the continued safe and proper use of your equipment.**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

A problem has been identified within the Philips Respironics Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, and Trilogy EV300 ventilators that could pose a risk for patients if not mitigated. This URGENT Field Safety Notice is intended to inform you of the problem. Please note, these devices can continue to be safely used in line with the mitigations described within as well as in accordance with the Instructions for Use.

**1. Description of the issue**

Philips Respironics has discovered, through internal testing, that accuracy of **delivered** oxygen may deviate below the required tolerance of 5% from **setpoint** when providing high concentration oxygen therapy. Additionally, if equipped, the internal FiO<sub>2</sub> sensor may indicate a value higher than the device is actually delivering. This may vary based on the patient's lung capacity, lung resistance, use of a particulate filter, or circuit configuration. In the worst case, this may lead to under delivery of oxygen.

**2. Potential hazards associated with the issue.**

Philips Respironics has assessed the issue and has determined that across the range of tested conditions the following hazard could be present for the most vulnerable patient populations that use these devices. If actual oxygen delivery deviates from the prescribed concentration, beyond the labeled tolerance of 5%, and the patient is not appropriately monitored, the patient may experience oxygen desaturation or hypoxemia.

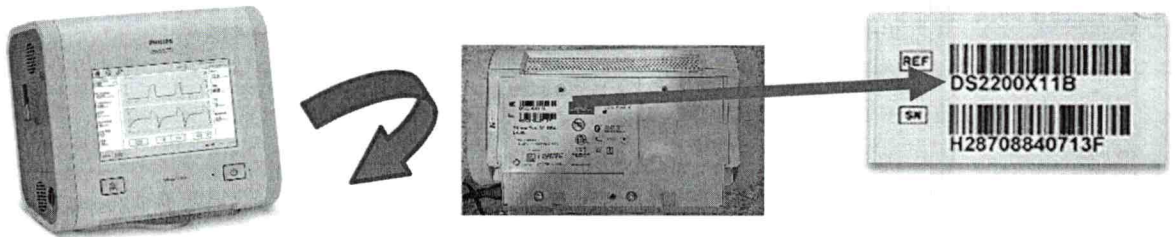
The potential for this hazard is most likely to occur when the Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, or Trilogy EV300 high pressure oxygen blending module (OBM) is used to manage patients requiring high volumes of oxygen such as scenarios requiring **FiO<sub>2</sub> setpoint greater than or equal to 70%**.

### 3. Affected products and how to identify them.

All distributed Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, Trilogy EV300 devices are impacted by this issue. Each of these devices can use oxygen blending hardware to incorporate externally supplied high-pressure oxygen with ventilated air for high concentration oxygen (FiO<sub>2</sub>) therapy.

**Trilogy Evo**, which is not configured with a high-pressure oxygen blending module (OBM), is **not impacted by FiO<sub>2</sub> under delivery**.

To identify the model, refer to the part number on the bottom of the device with the attached list of impacted part numbers:



### 4. Actions that should be taken by the user in order to prevent risks for patients.

Until a solution is provided by Philips Respironics, patients prescribed Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, or Trilogy EV300 that use high pressure oxygen, the following precautions must be observed:

1. Continuously monitor oximetry (SpO<sub>2</sub>) of the patient and follow your institution's protocol for monitoring of arterial blood gas measurements to ensure that the patient is receiving adequate oxygenation.
2. Use an external FiO<sub>2</sub> monitor for any patient requiring **FiO<sub>2</sub> ≥70%** to identify under delivery of oxygen. Switch to an alternative ventilator if an external FiO<sub>2</sub> monitor is not available.
3. Maintain an immediately available back-up device that will allow rapid transition to a different oxygen delivery method or alternative ventilator if monitoring suggests FiO<sub>2</sub> is not being sufficiently delivered.

**Distribute this notice to all employees in your organization that need to be aware.**

## 5. Actions planned by Philips Respironics to correct the problem.

Philips Respironics will release a software update that will address the issue. This software will be available free of charge to all Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, and Trilogy EV300 users. Additional details will be provided when the update is available. In the interim, please take the actions above in order to prevent risk for your patients.

If you need any further information or support concerning this issue, please contact your local Philips representative: [met.quality@philips.com](mailto:met.quality@philips.com)

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,



Tom Fallon  
Head of Quality – Philips Respironics

## Impacted Devices Models

Model	Description
DS2100X11B	Trilogy Evo, O2, USA
IN2100X15B	Trilogy Evo, O2, International
IN2100X19	Trilogy Evo, O2, International
FX2100X15B	Trilogy Evo, O2, INT
JP2100X16B	Trilogy Evo, O2, Japan
AU2100X15B	Trilogy Evo, O2, Australia
LA2100X15B	Trilogy Evo, O2, Latin America
CA2100X12B	Trilogy Evo, O2, Canada
CN2100X17B	Trilogy Evo, O2, China
BR2100X18B	Trilogy Evo O2, Brazil
KR2100X15B	Trilogy Evo O2, Korea
IA2100X15B	Trilogy Evo O2, India
PP2100X10	Trilogy Evo O2, Postponement
FP2100X10	Trilogy Evo, O2, Postponement
FR2100X14B	Trilogy Evo O2, France
ND2100X15B	Trilogy Evo O2, Nordics
IT2100X21B	Trilogy Evo O2, Italy
ES2100X15B	Trilogy Evo O2, Iberia
DE2100X13B	Trilogy Evo O2, Germany
BL2100X15B	Trilogy Evo O2, Benelux
GB2100X15B	Trilogy Evo O2, Great Britain
EU2100X15B	Trilogy Evo, O2, EU
EU2100X19	Trilogy Evo, O2, EU (Non-BT)
EE2100X15B	Trilogy Evo O2, Eastern Europe
TR2100X15B	Trilogy Evo O2, Turkey
SP2100X26B	LifeVentEVO2
DS2200X11B	Trilogy EV300, USA
IN2200X15B	Trilogy EV300, INTL
FX2200X15B	Trilogy EV300, INT w/ OBM
CA2200X12B	Trilogy EV300, Canada
CN2200X17B	Trilogy EV300, China
BR2200X18B	Trilogy EV300, Brazil
KR2200X15B	Trilogy EV300, Korea
IA2200X15B	Trilogy EV300, India
FR2200X14B	Trilogy EV300, France
ND2200X15B	Trilogy EV300, Nordics
IT2200X21B	Trilogy EV300, Italy

Model	Description
ES2200X15B	Trilogy EV300, Spain
DE2200X13B	Trilogy EV300, Germany
BL2200X15B	Trilogy EV300, Benelux
GB2200X15B	Trilogy EV300, Great Britain
EU2200X15B	Trilogy EV300, EU
EU2200X19	Trilogy EV300, EU (Non-BT)
EE2200X15B	Trilogy EV300, Eastern Europe
TR2200X15B	Trilogy EV300, Turkey
RU2200X15B	Trilogy EV300, Russia
DS2000X11B	Trilogy Evo Universal Ventilator
UDS2100X11B	Trilogy Evo O2, USA-Recert
RDS2100X11B	Trilogy Evo O2, USA-Rental

## URGENT FIELD SAFETY NOTICE RESPONSE FORM

**Subject: Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, and Trilogy EV300 Accuracy FiO<sub>2</sub> Delivery**

Philips Respironics Reference: 2022-CC-SRC-049

**Instructions:** Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City/State/ZIP/Country: \_\_\_\_\_

### Customer Actions:

- Forward this notice to members of your organization, as necessary.
- Ensure all patients using Trilogy Evo O<sub>2</sub>, Trilogy Evo Universal, Trilogy EV300 high pressure oxygen:
  - Continuously monitor oximetry (SpO<sub>2</sub>) of the patient and follow your institution's protocol for monitoring of arterial blood gas measurements to ensure that the patient is receiving adequate oxygenation.
  - Use an external FiO<sub>2</sub> monitor for any patient requiring **FiO<sub>2</sub> ≥70%** to identify under delivery of oxygen. Switch to an alternative ventilator if an external FiO<sub>2</sub> monitor is not available.
  - Maintain an immediately available back-up device that will allow rapid transition to a different oxygen delivery method or alternative ventilator if monitoring suggests FiO<sub>2</sub> is not being sufficiently delivered.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that manage the device.

### Name of person completing this form:

Signature: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Email Address: \_\_\_\_\_

Date  
(DD/MM/YYYY): \_\_\_\_\_

Please email the completed form to [met.quality@philips.com](mailto:met.quality@philips.com).