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URGENT Medical Device Correction

Trilogy EV300, Trilogy Evo O_2, Trilogy Evo Universal
Accuracy of FiO_2 Delivery

01 MAR 2023

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 EV300, Trilogy Evo O2, and Trilogy Evo Universal ventilators that could pose a risk for patients if not mitigated. This URGENT Medical Device Correction Letter 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_2 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 EV300, Trilogy Evo O_2, or Trilogy Evo Universal high pressure oxygen blending module (OBM) is used to manage patients requiring high volumes of oxygen such as scenarios requiring **FiO_2 setpoint greater than or equal to 70%.**

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3. Affected products and how to identify them.

All distributed Trilogy EV300, Trilogy Evo O_2, and Trilogy Evo Universal 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_2) therapy.

Trilogy Evo, which is not configured with a high-pressure oxygen blending module (OBM), is **not impacted by FiO_2 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 EV300, Trilogy Evo O_2, or Trilogy Evo Universal that use high pressure oxygen, the following precautions must be observed:

1. Continuously monitor oximetry (SpO_2) 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_2 monitor for any patient requiring **FiO_2 ≥70%** to identify under delivery of oxygen. Switch to an alternative ventilator if an external FiO_2 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_2 is not being sufficiently delivered.

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

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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 EV300, Trilogy Evo O_2, and Trilogy Evo Universal 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 or Philips Respironics Customer Service at 1 (800) 345-6443.

This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Tom Fallon
Head of Quality – Philips Respironics

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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

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URGENT MEDICAL DEVICE CORRECTION RESPONSE FORM

Subject: Trilogy EV300, Trilogy Evo O_2, and Trilogy Evo Universal Accuracy FiO2 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 Medical Device Correction Letter, 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 EV300, Trilogy Evo O2, or Trilogy Evo Universal high pressure oxygen:
    - Continuously monitor oximetry (SpO_2) 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_2 monitor for any patient requiring **FiO_2 ≥70%** to identify under delivery of oxygen. Switch to an alternative ventilator if an external FiO_2 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_2 is not being sufficiently delivered.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Correction Letter 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 pms.fac@philips.com or fax to 1-888-220-9274