IMPORTANT PRODUCT NOTICE

05 June 2024

RE: Trilogy Evo devices failing to meet Obstruction Alarm Standards Requirements

Dear Customer,

Philips Respironics has become aware that Trilogy Evo, Trilogy Evo O2, and Trilogy EV300 devices do not comply with the Obstruction Alarm requirements specified within ISO 80601-2-12 Clause 201.12.4.108 and ISO 80601-2-72 Clause 201.12.4.107.

This Important Product Notice is intended to inform you about:

1. **What the Obstruction Alarm compliance failure is and under what circumstances it can occur**

The design requirements of the Trilogy Evo devices do not align with the requirements of the ISO standards. The standards specify that the maximum delay from obstruction to alarm shall be no more than 2 breath cycles or 5 seconds, whichever is greater. However, the current obstruction alarm delay is 65 seconds, which is a delay of 60 seconds greater than required by the standards.

Philips Respironics has assessed this issue and determined that it does not result in any risk to patients. In addition to the obstruction alarm, other medium and high priority alarm(s) will occur in the case of an obstruction. No adverse events, including death or injuries, have been reported.

2. **Affected products and how to identify them**

Trilogy Evo, Trilogy Evo O2, and Trilogy EV300.

3. **The actions that you as a customer can take to minimize the effect of the issue**

Please refer to the most current version of the IFU, following the guidance provided in the event of an obstruction. Do not rely solely on the Obstruction Alarm to determine if there is an obstruction event. In accordance with Section 6.9.2 of the IFU, ensure the alarms mentioned below are activated. Additional relevant alarms that may occur during an obstruction include:

- High Inspiratory Pressure
- Circuit Disconnected
- Low Tidal Volume
- Low Minute Ventilation
- Low Respiratory Rate
- Low Peak Inspiratory Pressure
- Rebreathing Detected

4. **The actions planned by Philips**

Philips Respironics will release a software update to resolve this issue, aligning Obstruction Alarm trigger conditions with standard requirements. A separate notification will be provided when a software solution is available.

5. Additional Information and Support

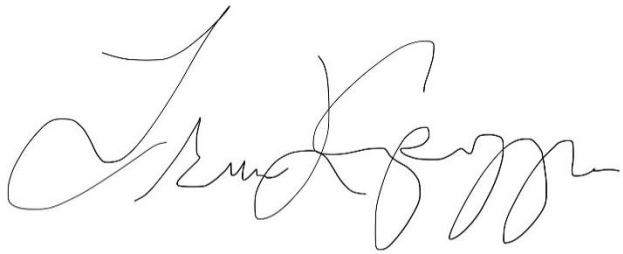
If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

Email: ukisfco@philips.com

Philips regrets any inconvenience caused by this problem.

Sincerely,



Tracie Capozzio
Sr. Director, Head of Quality Therapy Platforms
Sleep and Respiratory Care

IMPORTANT PRODUCT NOTICE RESPONSE FORM

Reference: Trilogy Evo devices failing to meet Obstruction Alarm Standard Requirements
Trilogy Evo, Trilogy Evo O2, and Trilogy EV300
2024-CC-SRC-002

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Important Product Notice, understanding of the issue, and required actions to be taken. This form can be completed by filling out the required fields, scanning, and emailing to **safetynoticeuki@philips.com.**

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle the Trilogy Evo, Trilogy Evo O2, and Trilogy EV300.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **safetynoticeuki@philips.com**