URGENT Field Safety Notice

Trilogy Evo and Trilogy Evo O_2 Ventilators Instructions for Use

xxNov2023

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.

Dear Customer,

During an internal review of the Trilogy Evo and Trilogy Evo O_2 Ventilators Instructions for Use (IFUs) manuals, Philips Respironics determined that the Contraindications Statement was incomplete. This URGENT Field Safety Notice is intended to inform you of all contraindications for the devices. Please note, the devices can continue to be safely used in line with the mitigations described in this document. There have been no safety issues reported from the field in relation to this issue.

- **The following contraindications apply to the Trilogy Evo and Trilogy Evo O_2 Ventilators:**

  Instructions for Use Contraindications:

  If the patient has any of the following conditions, consult the patient's health care professional before using noninvasive ventilation:

  - *An inability to maintain a patent airway or adequately clear secretions*
  - *At risk to aspirate gastric contents*
  - *Acute sinusitis or otitis media*
  - *Epistaxis, causing pulmonary aspiration of blood*
  - *Hypotension*

  The AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg.
  The AVAPS feature is contraindicated for patients less than 10 kg.

  The contraindications listed above in bold, are either omitted or listed in other locations within the Instructions for Use and Clinical Manual. These have been added to the attached manual addendum for insertion into your current manuals.

- **Hazard/harm associated with this issue:**

  Potential harms identified with the use of the Trilogy Evo and Trilogy Evo O_2 Ventilators on contraindicated patients:

  1. Barotrauma
  2. Hypoventilation/hypercapnia
  3. Rebreathing of excessive CO_2

  These harms can arise:

  1. If patients weighing between 2.5kg and 10kg are treated with the device using the AVAPS feature.
  2. If patients weighing between 2.5kg and 10kg are treated with the device in AVAPS-AE therapy mode.
  3. If the device is used invasively while in AVAPS-AE therapy mode for all patients (including less than 10kg).

- **Affected products and how to identify them:**

  The errors found affect the device IFUs for the Trilogy Evo and Trilogy Evo O2 Ventilators.

  The Trilogy Evo and Trilogy Evo O_2 Ventilators provide continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. Trilogy Evo and Trilogy Evo O_2 Ventilators are intended for pediatric through adult patients weighing at least 2.5 kg. The ventilator is

suitable for use in institutional, home, and nonemergency transport settings for example wheelchair, or personal vehicle. It may be used for both invasive and non-invasive ventilation.

- **Required actions to be taken by the customer / user to prevent risks to patients:**

1. Keep a copy of this letter and attached addendum with your Trilogy Evo or Trilogy Evo O_2 Ventilator IFUs.
2. When using the Trilogy Evo or Trilogy Evo O_2 devices, refer to the following contraindications:

   Instructions for Use Contraindications:

   If the patient has any of the following conditions, consult the patient's health care professional before using noninvasive ventilation:

   - *An inability to maintain a patent airway or adequately clear secretions*
   - *At risk to aspirate gastric contents*
   - *Acute sinusitis or otitis media*
   - *Epistaxis, causing pulmonary aspiration of blood*
   - *Hypotension*

   The AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg.
   The AVAPS feature is contraindicated for patients less than 10 kg.

3. Please communicate this Field Safety Notification notice to all who need to be aware within your organization, or to any organization where the potentially affected devices have been transferred.

   DISTRIBUTORS: Because Philips Respironics sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, please send a copy of the attached Field Safety Notice to any customer to whom you have distributed any of the affected devices.

4. Complete the Field Safety Notice Response Form that has been provided with this letter and return the form to your Philips Respironics Representative. This form serves as official acknowledgement that you have fully performed your obligations to complete this Field Safety Notice.

- **Actions planned by Philips to correct the problem:**

Philips Respironics is correcting the IFUs related to the Trilogy Evo and Trilogy O_2 Ventilator referenced in this letter. An addendum to your current manual has been provided with this letter.

If you need any further information or support concerning this issue, please contact your local Philips representative:

Call 1-(877)-387-3311 or email at patientsupport@philips.com

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,

[redacted]

Thomas J Fallon
Head of Quality
Sleep and Respiratory Care

URGENT Field Safety Notice Response Form

Reference: 2023-CC-SRC-011 Trilogy Evo and Trilogy Evo O_2 Ventilator IFUs – Missing Contraindications

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

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the affected Trilogy Evo and Trilogy Evo O_2 ventilators.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Upon completion and Acknowledgment return the Field Safety Notice Response Form to Philips Respironics by emailing the completed and signed form to:

pms.fac@philips.com