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URGENT Field Safety Notice

BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro
Interruptions and/or loss of therapy due to a Ventilation Inoperative Alarm

20 Mar 2024,

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.

Please retain this letter for your records.

Dear Customer,

Philips Respironics has received complaints regarding interruptions and/or loss of therapy in the Philips Respironics BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices. This URGENT Field Safety Notice is intended to inform you about:

1. What the problem is and under what circumstances it can occur

The affected products feature a Ventilator Inoperative alarm, which occurs when the ventilator detects an internal error or a condition that may affect therapy. This may manifest in the following ways:

- The device may reboot intermittently for 5-10 seconds (stops providing therapy, screen goes blank during the reboot, and there is a single audible alert), restarting therapy, and returning to delivering therapy with same patient settings.

OR

- The device may reboot intermittently for 5-10 seconds (stops providing therapy, screen goes blank during the reboot, and there is a single audible alert), restarting therapy, and returning to delivering therapy but with factory default settings.

OR

- When there are three (3) reboots within a 24-hour period, the device will enter a Ventilator Inoperative state (therapy stopped, audible and visual alarms present).

OR

- The device may enter a Ventilator Inoperative state without a reboot preceding this condition.

2. Hazard/harm associated with the issue

Any of the above scenarios could result in interruption and/or loss of therapy which may lead to hypoventilation, mild to severe hypoxemia, hypercarbia, respiratory failure/insufficiency, or potentially death in the most vulnerable patients.

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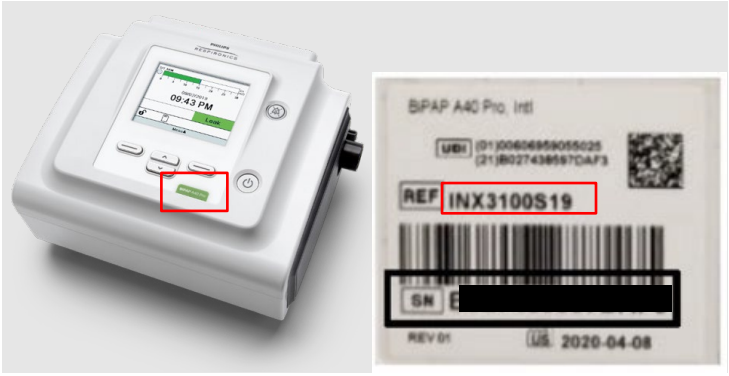
3. Affected products and how to identify them

- All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices are affected.
- Refer to labeling on the device (as shown below).



- Refer to Instructions for Use or User Manual.
- Contact the provider of your device and/or your supervising physician.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users.

As a general reminder, prior to placing a patient on the ventilator, please refer to the user manual (including contraindications, see **Appendix A**) and perform a clinical assessment to ensure that:

- The device is appropriately set for patient requirements.
- Alternative ventilation equipment is available; and
- Where appropriate, alternative monitoring (i.e. an alarming Pulse Oximeter or Respiratory Monitor) is used.

Patients Requiring a Minimal Level of Ventilatory Support

- For patients whose health conditions can withstand interruptions or loss of therapy, **consider using:**
    - Patient monitoring equipment (i.e. an alarming Pulse Oximeter or Respiratory Monitor).
    - An alternate source of ventilation if you are concerned about adverse impact on their health.
- For home-based patients, contact your healthcare/equipment provider for assistance.
- For hospital/institutional patients, contact Philips Respironics for assistance.

Patients Requiring a Moderate Level of Ventilatory Support

- For patients whose health conditions may not be able to withstand interruptions or loss of therapy, **it is recommended that**:
    - Patient monitoring equipment is used (i.e. an alarming Pulse Oximeter or Respiratory Monitor).
    - The patient is removed from the device and placed on an alternate source of ventilation.
- For home-based patients, contact your healthcare/equipment provider for assistance.
- For hospital/institutional patients, contact Philips Respironics for assistance.

Patients Requiring a High Level of Ventilatory Support

- For patients whose health conditions cannot withstand interruptions or loss of therapy, **it is strongly recommended that**:
    - Patient monitoring equipment is used (i.e. an alarming Pulse Oximeter or Respiratory Monitor) until the patient can be safely removed from the device.
    - A caregiver should closely monitor the patient.
    - The patient is removed from the device and placed on an alternate source of ventilation as soon as possible.
- For home-based patients, immediately contact your healthcare/equipment provider for assistance.
- For hospital/institutional patients, contact Philips Respironics for assistance.

5. Actions planned by Philips Respironics to correct the problem

Philips Respironics is currently investigating this issue. Philips Respironics will be in contact as soon as additional appropriate actions have been determined.

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

Philips Respironics regrets any inconveniences caused by this problem. Please be assured that Philips Respironics has patient health and safety at the heart of what we do each and every day. We are committed to improving people's health around the world.

Sincerely,

Thomas J. Fallon
Head of Quality for Sleep and Respiratory Care

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URGENT FIELD SAFETY NOTICE RESPONSE FORM

Reference: 2023-CC-SRC-039

Instructions: Please complete and return this form to Philips Respironics promptly i.e., no later than 30 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 Actions:

- Read and Acknowledge the Urgent Field Safety Notice
- Complete the form and return it to Philips Respironics

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 people that handle/use the affected device.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please email complete form to your local Philips Respironics representative.

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Appendix A.

Excerpt from BiPAP A40 User Manual "Contraindications"

1.4 Contraindications

The BiPAP A40 ventilator is not a life support device.

AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg (22 lbs.).

If the patient has any of the following conditions, consult their health care professional before using the device in a non-invasive mode:
• Inability to maintain a patent airway or adequately clear secretions
• At risk for aspiration of gastric contents
• Diagnosed with acute sinusitis or otitis media
• Epistaxis, causing pulmonary aspiration of blood
• Hypotension

Excerpt from BiPAP A40 Pro, BiPAP A40 EFL User Manual "Contraindications"

1.3 Contraindications

BiPAP A40 Pro and BiPAP A40 EFL

The BiPAP A40 Pro and BiPAP A40 EFL devices are not life support devices.

The device system should not be used on patients with the following conditions:
• Inability to maintain a patent airway or adequately clear secretions
• At risk for aspiration of gastric contents
• Diagnosed with acute sinusitis or otitis media
• Epistaxis, causing pulmonary aspiration of blood
• Hypotension
If the patient has any of the above conditions, consult their health care professional before using the device in a non-invasive mode.
(BiPAP A40 Pro) AVAPS-AE therapy mode is contraindicated for invasive use and patients less than 10 kg (22 lbs.).