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URGENT Medical Device Recall

BiPAP V30 Auto

Interruptions and/or loss of therapy due to a Ventilation Inoperative Alarm

04-APR-2024,

To: Medical Device Recall - Respiratory / US Med-Equip
7028 GESSNER RD
HOUSTON, TX 77040-3308

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,

Philips Respironics has received complaints regarding interruptions and/or loss of therapy in BiPAP V30 Auto devices. This URGENT Medical Device Recall Letter is intended to inform you about:

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

Philips Respironics has received complaints regarding interruptions and/or loss of therapy in the Philips Respironics BiPAP V30 Auto devices.

The devices feature a Ventilator Inoperative alarm, which occurs when the ventilator detects an internal error or a condition that may affect therapy.

This issue may manifest in any of the following ways:

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

OR

- The device may reboot intermittently for 5-10 seconds (it stops providing therapy, the screen goes blank during the reboot, and there is a single audible alert), restart therapy, and return 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 stops, audible and visual alarms are present).

OR

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

2. Describe the 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 V30 Auto devices are affected.
- Refer to labeling on the device (as shown below).

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

4. Describe the 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.
- Contact Philips Respironics for assistance regarding the affected device.

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.
- Contact Philips Respironics for assistance regarding the affected device.

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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.
- Immediately contact Philips Respironics for assistance regarding the affected device.

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.

As BiPAP V30 Auto devices are included in the Sound Abatement Foam Recall, the existing actions determined within the Sound Abatement Foam Recall Remediation Update are applicable, they are as follows:

- Receive a credit for each affected and returned device.
- Continue to wait for additional remediation options to become available.

If you need any further information or support concerning this issue, please contact your local Philips Respironics representative: 1-800-345-6443, prompts 4, 5 or email at respironics.clinical@philips.com

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 MEDICAL DEVICE RECALL RESPONSE FORM

To: Medical Device Recall - Respiratory / US Med-Equip
7028 GESSNER RD
HOUSTON, TX 77040-3308

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 Medical Device Recall Letter, understanding of the issue, and required actions to be taken.

Customer Actions:

- Read and Acknowledge the Urgent Medical Device Recall Letter
- You may either complete this form and return it to Philips Respironics at pms.fac@philips.com
  Or
  Scan the QR code below using your mobile device camera to complete this form and submit online

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall 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 this completed form to Philips Respironics at pms.fac@philips.com

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Appendix A. Excerpt from V30 User Manual "Contraindications"

1.4 Contraindications

The BiPAP V30 Auto is not a life support device.

The device system should not be used on patients with the following conditions:
- Patients without a spontaneous respiratory drive
- Existing respiratory failure (failure to treat; risk of increased work of breathing due either to incomplete reversal of upper airway obstruction or to breathing at high lung volume, leading to worsening respiratory failure)
- Pneumothorax or pneumomediastinum
- Emphysematous bullae or a past history of pneumothorax (risk of pneumothorax)
- Acute decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion (risk of further hypotension or reduction in cardiac output)
- Massive epistaxis or previous history of massive epistaxis (risk of recurrence)
- Pneumocephalus, recent trauma or surgery (ex. pituitary or nasal) that may have produced cranio-nasopharyngeal fistula (risk of entry of air or other material into the cranial cavity)
- Acute sinusitis, otitis media, or perforated ear drum
- Acute or unstable cardiac failure
- Nocturnal or resting angina (risk of infarction or arrhythmias)
- Unstable arrhythmias
- Severely obtunded or heavily sedated patients
- At risk for aspiration of gastric contents
- Impaired ability to clear secretions

If patients are dehydrated or volume depleted, or have persistent atrial fibrillation, their cardiac filling pressures may be low. In these cases, as with any CPAP or ventilatory support, use of the device may lead to a dangerous reduction in cardiac output. The device should not be used in patients who are dehydrated or volume depleted, and should be used with extreme care in patients with atrial fibrillation.
The AVAPS-AE mode is contraindicated for pediatric use.