Update to Urgent Product Correction

Final Copy

June 2025

Philips Healthcare
Locked Bag 30
North Ryde
NSW 1670
Australia

Update to 2023-CC-SRC-039

TGA Reference #:	RC-2024-RN-00257-1
Product / Device Name / Model #	BiPAP A30, BiPAP A40, BiPAP A40 Pro
ARTG Ref #	133794, 200289, 329407, 329408
Short Problem Description	Interruptions and/or loss of therapy due to a Ventilation Inoperative Alarm

This is an update to RC-2024-RN-00257-1 (2023-CC-SRC-039-C) sent in November 2024.

Update: Based on feedback from global regulators, Philips Respironics is issuing this letter as an additional update to the previous notice. For patients who **cannot tolerate** interruption or loss of therapy, **including patients who use a BiPAP A40 Pro device for more than 8 hours a day and/or who are invasively ventilated, an alternative ventilator is required.** This determination should be made under the guidance of a physician.

The following update and actions as previously communicated are still applicable:
Philips Respironics is clarifying the labeled intended use of the BiPAP A40 and BiPAP A40 Pro by removing "Respiratory Failure." Refer to Appendix A1
Note: Philips Respironics is not pursuing design changes relevant to these products for this problem.

Customer Action:
In Australia, Philips Australia has been contacting affected customers and patients regarding the remediation. This includes replacement with an alternate Philips device or alternative options. If you still have active devices in your possession, please review this update and if you have not yet done so, please contact Philips Customer Support on 1800 830 517 or email clinical-philips@easyconnectsrc.zendesk.com to organise a suitable remediation.

Updated Information for Device Distributors and Healthcare Providers

Philips Respironics previously distributed the Update to Notice reference *2023-CC-SRC-039-C* in November 2024 to all users of BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, and BiPAP A40 Pro devices, which provided an update for Notice reference 2023-CC-SRC-039 regarding interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm condition. Based on feedback from global regulators, Philips Respironics is issuing this letter as an additional update to that Notice.

The purpose of this updated product correction notice is to clarify the patient population who **cannot tolerate** interruptions or loss of therapy. For patients who **cannot tolerate** interruption or loss of therapy, including patients **who use a BiPAP A40 Pro device for more than 8 hours a day** and/or **who are invasively ventilated**, an alternative ventilator is required. This determination should be made under the guidance of a physician.

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Philips Australia will offer the following remediation options to users:

- For users who **can tolerate** therapy interruptions, the device can continue to be used while an alternate Philips device is made available at the discretion of the patient, caregiver or physician, or an appropriate compensation has been provided.
- For users who **cannot tolerate** interruptions or loss of therapy, alternate therapy is required, Philips is providing an appropriate compensation. For further information and to discuss your remediation options please contact Philips Customer Support on 1800 830 517 or email clinical philips@easyconnectsrc.zendesk.com

For further information on the options listed above, please see **Section 5:** *Actions planned by Philips Respironics*.

It is important to note that BiPAP A30, BiPAP A40, and BiPAP A40 Pro devices are not intended for life support and are not intended to ventilate patients suffering from respiratory failure.

Please review this letter in its entirety, as some information may be new or updated from what was previously communicated.

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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.

Purpose of this Letter

The purpose of this letter is to provide customers and healthcare providers with critical information pertaining to use of the products, in accordance with the intended use, to prevent risk to the patient. In addition, this letter provides updated actions that Philips Respironics will be taking to address the Ventilator Inoperative alarm problem.

Philips Respironics advises that physicians/healthcare professionals review this Urgent Product Correction notification and assess whether the patients under their care are able to tolerate interruptions of therapy with this device to ensure that they continue to receive the most appropriate therapy. It is important to note that these devices are not life support devices.

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

The products in scope are designed with a Ventilator Inoperative condition, which occurs when the ventilator detects an unrecoverable condition that may affect therapy. If the device enters a Ventilator Inoperative condition, a corresponding audible and visual alarm will alert the patient or caregiver. The device is designed to shut down if the condition indicates that the device cannot deliver therapy to the proper specifications; the device monitors for scenarios which may trigger a Ventilator Inoperative condition. Despite having a very low probability of occurrence, interruptions and/or loss of therapy due to a Ventilator Inoperative condition have been reported to result in health outcomes that were not expected for the intended patient population.

2. Hazard/harm associated with the problem

If the device enters the Ventilator Inoperative state, interruption and/or loss of therapy may occur. This may lead to anxiety, confusion/disorientation, increased/decreased respiratory rate (RR), dyspnea, tachycardia

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(high heart rate), abnormal chest wall movement, mild to severe hypoxemia/low oxygen saturation, hypercarbia/respiratory acidosis, hypoventilation, respiratory failure, or potentially death in the most vulnerable patients.

Symptoms can include nausea and vomiting, tiredness (fatigue) or lethargy, shortness of breath, increased work of breathing, dizziness, slow, shallow or labored breathing, bluish skin, lips or nails (cyanosis), coughing, wheezing, headaches, and paranoia.

As of January 2025, Philips Respironics has received 1,518 in-use complaints related to Ventilator Inoperative alarm occurrences. Twelve (12) reports included an allegation of serious injury, and eight (8) cases reported a patient death associated with this problem.

3. Products in scope and how to identify them

- All BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, and BiPAP A40 Pro Devices, all of which are designed with a Ventilator Inoperative condition, are in scope of this Notice.

Affected Model numbers in Australia:

1076581	BiPAP A30 Australia
1076582	BiPAP A30 Australia, Core Package
1076583	BiPAP A40, Australia
1111145	BiPAP A30 Australia Silver Series
1111171	BiPAP A40 Australia Silver Series
AUX3100S19	BiPAP A40 Pro
1111145	A30
1111171	A40

- Refer to labeling on the device (as shown below) and the Instructions for Use or User Manual.

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Figure 1 Device Name Location

- Contact the provider of your device and/or your supervising physician.

4. Actions that should be taken in order to prevent risks for patients or users

The following actions are advised to ensure that the device is prescribed and used in accordance with the intended use for which the device was designed.

Actions for All Recipients:

- Review the intended use for devices in scope of this problem. These devices are not intended to ventilate patients suffering from respiratory failure. Please note the clarifications to the intended use for BiPAP A40 and BiPAP A40 Pro Devices as detailed in **Appendix A1:** *Intended use for BiPAP A40 and BiPAP A40 Pro devices only*.

- Please note that all device models in scope of this problem are not indicated to be used as life support devices (**Appendix A2:** *Contraindications and Warnings*).

Actions for Physicians/Healthcare Professionals:

- Philips Respironics is recommending that physicians/healthcare professionals assess whether the patients under their care, who are using the devices in scope, are able to tolerate interruptions of therapy to help ensure that they continue to receive the most appropriate therapy.

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- For patients who **can tolerate** interruptions in therapy:

  Submit a request at the following: contact Philips Customer Support on 1800 830 517 or clinical-philips@easyconnectsrc.zendesk.com, regarding alternate device options. For further information, **please see Section 5**: *Actions planned by Philips Respironics*.

  - If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **please see Appendix D:** *Instructions on Performing the Hard Reboot***.**

- As indicated in the user manuals for the following devices: BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, and BiPAP A40 Pro, these devices are not suitable for ventilator-dependent patients (i.e., patients who are dependent on artificial ventilation for their immediate life support). If interruptions of therapy **cannot** be tolerated, including if a BiPAP A40 Pro device is being used for more than 8 hours a day and/or the patient is invasively ventilated:

  - **Transition patient to an alternative ventilator as soon as practicable.**

  - If a Ventilator Inoperative alarm occurs and an alternative ventilator is not available immediately, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot.*

- Philips is providing an alternative form of appropriate compensation. For further information and to discuss your patients' remediation options please contact Philips Customer Support on 1800 830 517 or email clinical philips@easyconnectsrc.zendesk.com

Actions for Patients and Users:

- If your physician has indicated you are a patient that **can tolerate** interruptions in therapy, please see the following options:

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Submit a request at the following: contact Philips Customer Support on 1800 830 517 or clinical-philips@easyconnectsrc.zendesk.com, regarding alternate device options. For further information, **please see Section 5**: *Actions planned by Philips Respironics*.

- If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **please see Appendix D:** *Instructions on Performing the Hard Reboot***.**

- If your physician has indicated you are a patient that **cannot tolerate** interruptions in therapy, **including patients that use a BiPAP A40 Pro device for more than 8 hours a day and/or who are invasively ventilated,** please see the following:

    - Contact your physician to expedite transition to an alternative ventilator.

    - If a Ventilator Inoperative alarm occurs and an alternative ventilator **is not available immediately**, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, please see **Appendix A3:** *Instructions on Performing the Hard Reboot*.

- Philips is providing an alternative form of appropriate compensation. For further information and to discuss your remediation options please contact Philips Customer Support on 1800 830 517 or email clinical philips@easyconnectsrc.zendesk.com.

Actions for Distributors:

- Distribute this Notification and all appendices to the identified customer list (e.g. physicians, and patient/users) that may still have active devices in their possession.
- If you have not yet done so, please contact Philips Customer Support on 1800 830 517 or email clinical philips@easyconnectsrc.zendesk.com to organise a suitable remediation.

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5. **Actions planned by Philips Respironics**

1. Philips Respironics is clarifying the labeled intended use of the BiPAP A40 and BiPAP A40 Pro by removing "Respiratory Failure." These devices are not intended to ventilate patients suffering from respiratory failure. This clarification is intended to prevent potential misinterpretation as the product is not designed or intended for life support applications**.** For further information on the clarified intended use, please see **Appendix A1:** *Intended use for BiPAP A40 BiPAP A40 Pro devices only***.**
2. Based on patient conditions, Philips Australia will offer the following remediation options to users:

Options for patients who Can Tolerate interruptions in therapy

1 **Alternate Device:** Independent of a Ventilator Inoperative alarm, at the discretion of the patient, caregiver or physician, the customer will be provided with an alternative therapy device (DreamStation BiPAP AVAPS) and the A-series device should be returned to Philips Respironics. This will be done with a method that minimises disruption in therapy.

2 If a Ventilator Inoperative alarm occurs, the hard reboot option can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **see Appendix D**: *Instructions on Performing the Hard Reboot*.

DreamStation BiPAP AVAPS Intended Use:
The BiPAP AVAPS device is intended to provide non-invasive ventilatory support to Obstructive Sleep Apnea (OSA) and Respiratory Impairment patients weighing over 18 kg. This device may be used in the hospital or home.
1. **Appropriate compensation will be offered**. To discuss your options please contact Philips Customer Support on 1800 830 517 or email clinical-philips@easyconnectsrc.zendesk.com**.**

Option for patients who Cannot Tolerate interruptions in therapy

1. **Appropriate compensation will be offered**, to discuss your options please contact Philips Customer Support on 1800 830 517 or email clinical-philips@easyconnectsrc.zendesk.com**.**

• If a Ventilator Inoperative alarm occurs and an appropriate life support ventilator **is not available** immediately, as a temporary measure, a hard reboot can be performed and may restore device function. When performing the hard reboot, the patient should be removed from the device until therapy is restored. For detailed information, **see Appendix D:** *Instructions on Performing the Hard Reboot.*

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Next Steps: Please review this update if you still have active devices in your possession.
If you have not yet done so, please contact Philips Customer Support on 1800 830 517 or email clinical-philips@easyconnectsrc.zendesk.com to organise a suitable remediation.

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconveniences caused by this problem. We are committed to improving people's health around the world.

Sincerely,

Princess Nochefranca

Princess Nochefranca
Quality Specialist
Philips Healthcare Australia and New Zealand

Attachments:
Appendix A1: *Intended use for BiPAP A40 and BiPAP A40 Pro devices only*
Appendix A2: *Contraindications and Warnings*
Appendix A3: *Instructions on Performing the Hard Reboot*

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Appendix A1: *Intended use for BiPAP A40 and BiPAP A40 Pro devices only*

Applicable to BiPAP A40 and BiPAP A40 Pro:
Please note the Intended Use for the BiPAP A40 and BiPAP A40 Pro devices is being clarified by removing "Respiratory Failure." The device was not designed and is not intended for use as a life support ventilator, and it is acknowledged that "Respiratory Failure" could be misinterpreted as conflicting with this guidance. These devices are not intended to ventilate patients suffering from respiratory failure. Please review the clarified Intended Use below.

Updated BiPAP A40 Intended Use:
The BiPAP A40 ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. It is intended to be used in home, institutional/hospital, and portable applications such as wheelchairs and gurneys. It is not intended to be used as a transport ventilator, and is not intended for life support.

Updated BiPAP A40 Pro Intended Use:
The BiPAP A40 Pro ventilator is intended to provide invasive and non-invasive ventilatory support to treat adult and pediatric patients weighing over 10 kg (22 lbs) with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. This device is not intended for life support. It is not intended to be used as a transport ventilator. It is intended to be used both in the home and clinical settings such as hospitals, sleep laboratories, sub-acute care institutions, and portable applications such as wheelchairs and gurneys.

Not Applicable to BiPAP A30 and BiPAP A30 Hybrid:
The change outlined above is not applicable to the BiPAP A30 and BiPAP A30 Hybrid as this device's intended use does not include "Respiratory Failure". However, the same instructions in this FSN are applicable to this model and the same options are available.

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Appendix A2: *Contraindications and Warnings*

BiPAP A40:

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

BiPAP A40 Pro:

1.3 Contraindications

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.).

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BiPAP A30:

1.4 Contraindications

This ventilator is not suitable for a ventilator-dependent patient (i.e., patients who are dependent on artificial ventilation for their immediate life support).

If the patient has any of the following conditions, consult their health care professional before using
the device:
- 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

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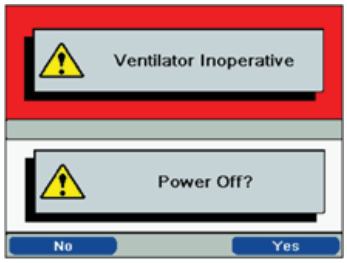
Appendix A3: *Instructions on Performing the Hard Reboot*

Performing a Hard Reboot

If a Ventilator Inoperative alarm occurs, the display screen turns red and the Ventilator Inoperative message appears on-screen, as shown below.

To perform the hard reboot, please follow the instructions below:

1. **Disconnect from the device.**
2. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the “Power Off” confirmation screen will appear, as shown below.



   - Select the button on the right side, “Yes” to shut off the device and silence the alarm.
3. **Unplug the power cord from the wall or from the device itself.**
4. **If the device does not have a detachable battery pack or an external battery pack, skip Step 5. If the device does have a detachable battery pack or an external battery pack, continue to Step 5.**
5. **Remove the battery from the therapy device.**

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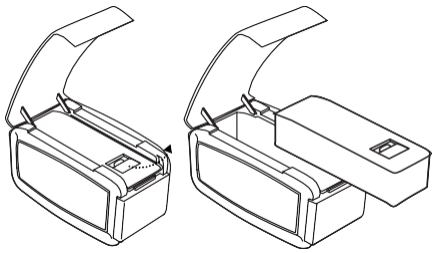
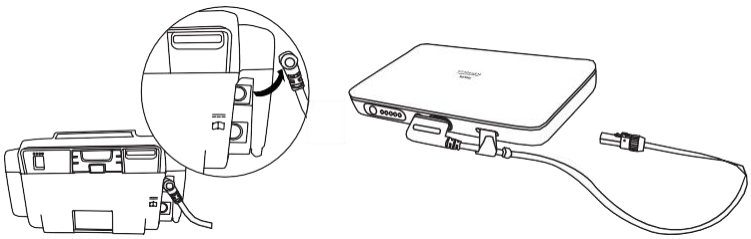
Detachable Battery Pack

- If the detachable battery pack is used, open the battery compartment at top of the detachable battery module accessory.
- Lift battery out using release lever on top of the battery (see below).

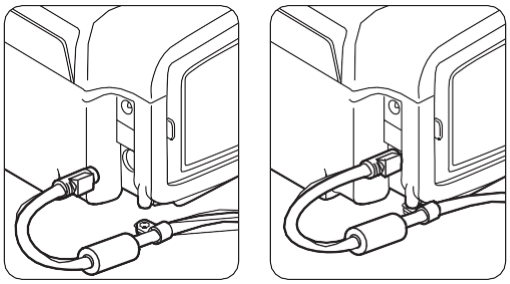


Li Ion Battery Pack

- If an external battery pack is used, unplug the battery pack cord from the back of the ventilator (see below).



6. **Disconnect the device from the power source (battery and/or power cord) for at least 30 seconds.**
7. **After 30 seconds, reconnect the device to the applicable power source (battery and/or power cord).**
8. **Plug the power cord in to the wall or to the therapy device itself.**



9. **Power on the device by pressing the Start/Stop button ( ).**
10. **Once the ventilator powers back on, therapy may be restarted.**