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<URGENT Field Safety Notice>

All BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 Pro devices
Interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm

May 2026

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

Philips Respironics previously distributed Field Safety Notice (FSN) 2023-CC-SRC-039 Revision D in April 2025 to all users of BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, and A40 Pro devices, which provided an update for Field Safety Notice (FSN) 2023-CC-SRC-039 regarding interruptions and/or loss of therapy due to a Ventilator Inoperative Alarm condition. This follow-up letter informs users of the updates since the issuance of 2023-CC-SRC-039 Revision D.

In the 2023-CC-SRC-039 Revision D FSN sent in April, Philips Respironics communicated clarifications to the BiPAP A40 and BiPAP A40 Pro intended use to remove "Respiratory Failure" and the following additional guidance for 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."*

Since sending Revision D of the FSN, all A-Series devices have been discontinued, and no new devices will be placed in the field. (See Appendix 3 and 4 to view the discontinuation notices for these products). As a result, Philips Respironics has made the decision to forgo releasing the updated User Manuals for the BiPAP A40 and BiPAP A40 Pro devices and is, instead, reinforcing the previously communicated guidance and labeling clarifications (see Appendix 1) through this version (Revision G) of the FSN.

Philips Respironics will continue to manage the affected BiPAP A30, BiPAP A30 Hybrid, BiPAP A40, and BiPAP A40 Pro devices in the market with the following options designed to minimize disruption to customers and patients while ensuring access to safe therapy:

- **Continued Use:** For all impacted devices, this determination should be made under the guidance of a physician. Further information is provided in **Actions that should be taken in order to prevent risks for patients or users** section below.
  NOTE: For BiPAP A40 Pro, this determination should be made with consideration of the updated guidance provided in Revision D of the FSN (italicized above).

OR

- **Alternate Device*:** Philips Respironics will provide an alternative therapy device as clinically applicable (DreamStation BiPAP S/T or DreamStation BiPAP AVAPS – please see the Intended Use below) to minimize disruption in therapy, after which the impacted device must be returned to Philips Respironics. Further information is provided in **Actions that should be taken in order to prevent risks for patients or users** section below.

- **DreamStation BiPAP S/T Intended Use:** The BiPAP S/T 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.
- **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.

**Depending on alternate device availability.*

OR

- **Financial Credit:** The customer will be issued credit based on the depreciated value of the device in exchange for the return of the impacted device if this option is chosen.

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

- Physicians should evaluate the appropriateness of the BiPAP A40 and BiPAP A40 Pro device for the patients in their care when considering the information in Appendix 1.
- In the case of a Ventilator Inoperative Alarm, instructions on how to perform the hard reboot to potentially restore device function can be found in Appendix 2.
- Retain a copy of this FSN with the device labeling to ensure users can refer to most up-to-date information.
- Distribute this Field Safety Notification (FSN) and all appendices to the identified customer list (e.g. physicians, clinicians, and patient/users).
- The customer should contact Philips Respironics regarding an alternate device or financial credit at the following: Confidential business information

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

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience this issue may have caused and appreciates your understanding.

Sincerely,

Philips

Attachments:
Appendix 1: Clarified Intended Use for BiPAP A40 and BiPAP A40 Pro Devices only
Appendix 2: Instructions on Performing the Hard Reboot
Appendix 3: BiPAP A30 & BiPAP A40 Discontinuation Notice
Appendix 4: BiPAP A40 Pro Discontinuation Notice
Appendix 5: BiPAP A40 Pro Ventilator Discontinued Part Numbers

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<URGENT Field Safety Notice Response Form>

Reference: FSN 2023-CC-SRC-039 Revision G

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt Confidential business information 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: _____

Customer Actions:

- Read and Acknowledge the Urgent Field Safety Notice
- Complete the form and return it to Philips Respironics
- Review and understand the **Actions that should be taken in order to prevent risks for patients or users** section

We acknowledge receipt and understanding of the accompanying urgent field safety notice and confirm that the information contained in this notice has been properly distributed to all persons handling/using the devices in the scope of application.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Facility/Hospital Name: _____

Address: _____

City: _____

State/Province: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please send this completed form to Philips: Confidential business information

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Appendix 1: Clarified Intended Use for BiPAP A40 and BiPAP A40 Pro Devices only

Note: All of this information was previously communicated through 2023-CC-SRC-039 Revision C

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.

Clarified 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.

Clarified 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 those devices' intended use does not include "Respiratory Failure". However, the same instructions in this FSN are applicable to these models and the same options are available.

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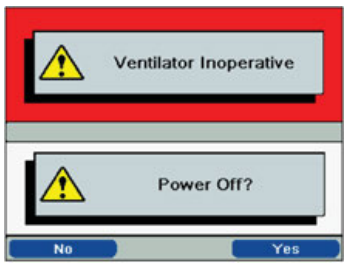
Appendix 2: Instructions on Performing the Hard Reboot (Previously communicated in 2023-CC-SRC-039 Revision B)

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:

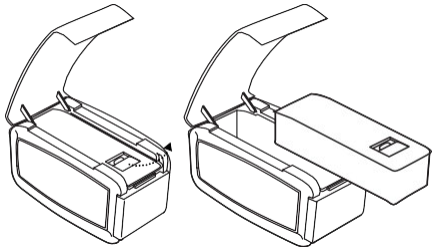
1. **Disconnect from the device.**
2. **Power off the therapy device.**
   - Press the Start/Stop button (⏻).
   - If the ventilator display is operational, the “Power Off” confirmation screen will appear, as shown below.



   - 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.**

   ## 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).



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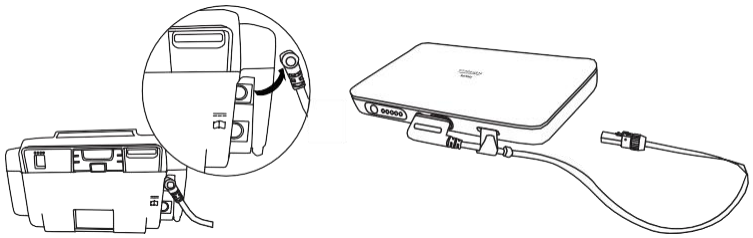
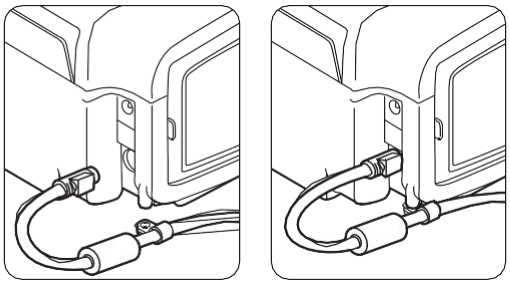
Li Ion Battery Pack

- 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.**

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Appendix 3: BiPAP A30 & BiPAP A40 Discontinuation Notice

Philips Respironics is committed to maintaining transparency and supporting our customers and their patients with clear information about our product portfolio. We are reinforcing that, as communicated in April 2024, Philips Respironics has discontinued the sale and distribution of BiPAP A30 and BiPAP A40 Ventilators ("Discontinued Models") globally, except for in China and Japan.

Philips Respironics is continuing to (a) support service for existing sold and rented Discontinued Model units and (b) provide access to service parts and accessories, subject to availability. The end of service date for the Discontinued Models continues to be May 31, 2029. Please refer to below for the complete list of discontinued part numbers:

BiPAP A30 Devices		
1111143	1111145	1111150
1111144	1111146	BR1111143
CN1111143	1111147	1111144L
1111149	1111148	1111144M
AR1111143	1116155	1111144V
1111154		

BiPAP A40 Devices		
1111169	1111173	1116156
1111170	1111174	BR1111169
AR1111169	1111172	IT1111169
1111171	1111175	
IA1111169	1111170S	

Philips Respironics remains committed to respiratory care and to delivering safe, effective therapy solutions to our customers and their patients who rely on them.

If you have any questions, your Philips Respironics representative is available to support you. Thank you for your continued partnership.

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Appendix 4: BiPAP A40 Pro Discontinuation Notice

Re: Philips Respironics BiPAP A40 Pro Ventilator Global Discontinuation

Dear Valued Customer,

Philips Respironics is committed to maintaining transparency and supporting our customers and their patients with clear information about our product portfolio.

We are reaching out to inform you that Philips Respironics will discontinue sale and distribution of BiPAP A40 Pro Ventilator, globally, effective immediately. Philips Respironics will continue to support service and provide access to available service parts and accessories, subject to supply availability, but not beyond the end-of-service date of December 31, 2028. Please reference the attached appendix (Appendix 5) for a complete list of discontinued part numbers.

Philips Respironics continues to support the home noninvasive ventilation space and is developing future therapy solutions intended to address these patient needs. We look forward to sharing more information soon.

Philips Respironics remains committed to respiratory care and to delivering safe, effective therapy solutions to our customers and their patients who rely on them.

If you have any questions, your Philips Respironics representative is available to support you.

Thank you for your continued partnership.

Personal data

Sincerely,

Personal data

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Appendix 5: BiPAP A40 Pro Ventilator Discontinued Part Numbers

BiPAP A40 Pro Ventilator		
ARX3100S19	IAX3100T19	BRX3100B18
AUX3100S19	INX3100H19	CAX3100B12
BLX3100S19	INX3100S19	CNX3100S17
BRX3100S18	INX3100T19	CNX3100H17
CAX3100S12	ITX3100H21	CNX3100T17
CAX3100T12	ITX3100S21	IAX3100B19
DEX3100S13	ITX3100T21	JPX3100S16
EEX3100S19	NDX3100S19	KRX3100S19
ESX3100H19	SPX3100S19	KRX3100H19
ESX3100S19	RINX3100S19	KRX3100T19
ESX3100T19	RAUX3100S19	NDX3100H19
FRX3100H14	RBLX3100S19	NDX3100T19
FRX3100S14	RBRX3100S19	RNDX3100S19
FRX3100T14	RCAX3100S12	RESX3100S19
GBX3100H19	RDEX3100S13	RGBX3100T19
GBX3100S19	REEX3100S19	RGBX3100H19
GBX3100T19	RFRX3100S19	
IAX3100H19	RGBX3100S19	
IAX3100S19	RITX3100S21	