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URGENT Field Safety Notice

BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator

Alarm Malfunction linked to Oxygen Sensor Inside the Ventilator

Information for Device Distributors and Healthcare Providers

Philips Respironics has become aware of a potential safety issue with all BiPAP A40 Pro Ventilators, BiPAP A40 EFL Ventilators, and BiPAP A30 EFL Ventilators. These ventilators may incorrectly generate a "High Internal Oxygen" alarm. **The device will continue to provide therapy while the alarm is addressed.** To date, there have been no instances of patient harm or injury reported to Philip Respironics.

As a distributor or healthcare provider managing these devices and patients, you must ensure that users of these devices are appropriately informed of this issue and have adequate support if a device malfunctions. BiPAP A40 Pro, BiPAP A40 EFL, and BiPAP A30 EFL devices do not need to be removed from service as a result of this letter. You must support patients and users of these devices with replacement or alternative therapy options if their device malfunctions. **Please continue to use the device in accordance with the User Manual. If the alarm occurs, then follow the steps within this letter.**

Philips Respironics will continue to provide coverage to any claim of a malfunction raised for the issue disclosed herein. Report all claims of malfunction and adverse event to Philips Respironics by contacting:

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

This letter must be distributed to all members of your organization responsible for setting up and supervising patients that use these devices. This letter must also be provided to any organizations to which you have further distributed BiPAP A40 Pro Ventilators, BiPAP A40 EFL Ventilators, and BiPAP A30 EFL Ventilators.

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Alarm Malfunction linked to Oxygen Sensor Inside the Ventilator

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 or patients that are using the device.

- Please retain this letter for your records.

Philips Respironics has received one thousand eight hundred twenty-eight (1,828) reports of incorrectly generated a "High Internal Oxygen" alarm for all BiPAP A40 Pro Ventilators, BiPAP A40 EFL Ventilators, and BiPAP A30 EFL Ventilators which is a probability rate of 3.9%. To date, there have been no instances of patient harm or injury reported to Philip Respironics. This URGENT Medical Device Letter is intended to inform you about this issue.

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

The "High Internal Oxygen" alarm is intended to detect oxygen accumulation within the ventilator that may occur while supplemental oxygen is being provided to a patient. Philips Respironics has identified issues in this oxygen's sensor manufacturing process that can cause the sensor to malfunction, inaccurately reporting elevated oxygen levels to the device when elevated levels are not present. When this happens, it can cause the device to incorrectly detect elevated oxygen concentration, even when supplemental oxygen is not connected to the device. **The device will continue to provide therapy while the alarm is addressed (in accordance with the User Manual).** This issue can manifest itself in the following forms:

- The device continuously raises the "High Internal Oxygen" alarm, while supplemental oxygen is connected.
- The device continuously raises the "High Internal Oxygen" alarm, while supplemental oxygen is not connected.

2. Hazard/harm associated with the issue

If users are oxygen-dependent and they disconnect the oxygen supply without switching to a supplemental source, they could experience hazards that include hypoxemia. Ventilator and oxygen-dependent patients are advised to have suitable backup therapies available in the event of any device malfunction.

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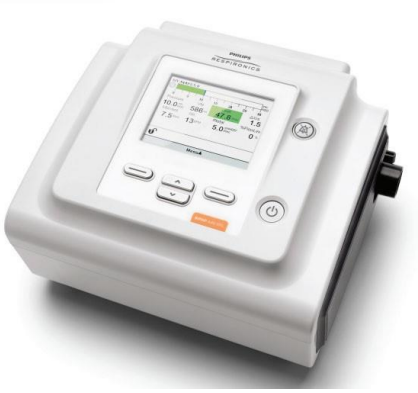
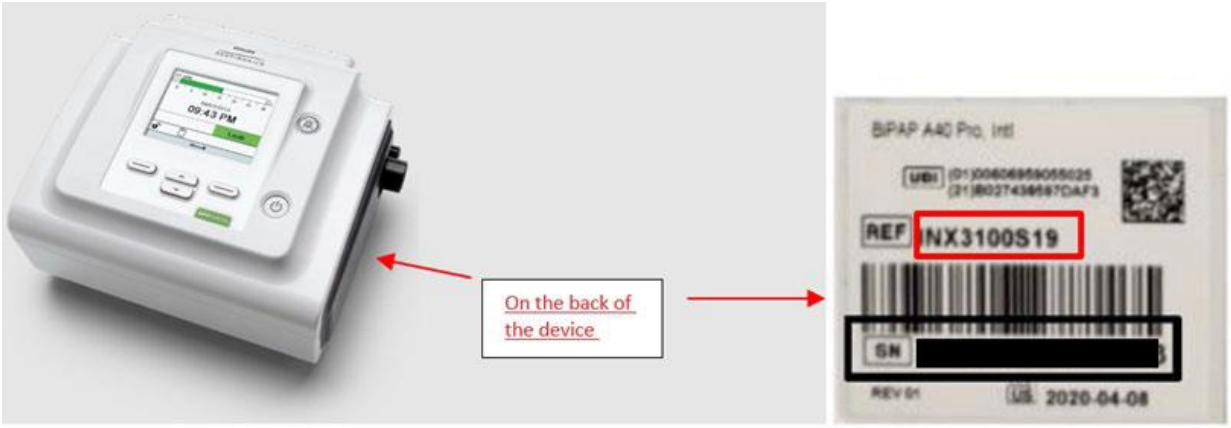
3. Affected products and how to identify them

- This issue affects all BiPAP A40 Pro Ventilators, BiPAP A40 EFL Ventilators, and BiPAP A30 EFL Ventilators.
- A list of impacted part numbers is provided with this letter.
- Refer to labeling on the device (as shown below).



To identify the model, refer to the part number on the bottom of the device with the attached list of impacted part numbers:



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

The User Manual instructs to disconnect the oxygen supply when the “High Internal Oxygen” alarm occurs. This may not clear the alarm if the sensor malfunctions.

- All alarms must be responded to following the instructions provided by the device User Manual.
- Any patient that is dependent on their device should have suitable backup therapies available in the event of a device malfunction. This includes situations where an alarm cannot be cleared.
- Remove the patient from the device and switch to an alternative therapy device if you experience a “High Internal Oxygen” alarm that cannot be cleared.

- Contact your device distributor/healthcare provider if you experience an alarm or malfunction that cannot be resolved following the device User Manual.

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Actions for Physicians:

- Refer to **Appendix A:** *Guidance for physicians/healthcare professionals related to FSN*
- Complete the response form attached if this came directly to you from Philips Respironics

Actions for Patients and Users:

- **Follow these steps if** "High Internal Oxygen" alarm **occurs:**

  For facility-based clinicians, if the High Oxygen Alarm occurs, immediately remove the patient from the device and connect them to an alternate source of ventilation.

  For home-based patients, if the High Oxygen Alarm occurs, immediately remove the device and connect to an alternative device, if available. Contact your home care equipment provider for service and/or an alternative device.

- Refer to **Appendix B:** *Guidance for end users/home care providers related to FSN.* As an optional action, you may perform a "hard reboot" (forced device restart) that may temporarily restore device function. The details and instructions for performing this hard reboot are contained in **Appendix C**, shown below.

  - After a hard reboot is performed, please confirm that the ventilator settings are correct.

Actions for Distributors/DMEs:

- Identify the customer list where you have distributed this product and notify them immediately.
- Distributors should have customers complete and return the Customer Response form to your organization for your reconciliation purposes within 30 days.
- Complete and return the attached Customer Response Form to Philips Respironics following completion of your reconciliation activities.

5. Actions planned by Philips Respironics to correct the problem

Philips Respironics is currently investigating this issue and will implement appropriate actions to prevent recurrence.

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

Email: ukisfco@philips.com

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Philips Respironics regrets any inconveniences caused by this problem.

Sincerely,

Tracie Capozzio
Head of Quality Therapy Platforms

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URGENT Field Safety Notice Response Form

Affected Products: BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator

Problem: Alarm Malfunction linked to Oxygen Sensor Inside the Ventilator

Philips Respironics C&R Reference Number: 2023-CC-SRC-042.

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 the required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

If this response applies to additional sites, please identify them on the last page of this response form.

Customer Actions:

- All alarms must be responded to by following the instructions provided in the device User Manual
- Ensure suitable backup therapies are available for device-dependent patients in the event of a device malfunction
- Remove the patient from the device and switch to an alternative therapy if "High Internal Oxygen" alarm cannot be cleared
- Contact your device distributor/healthcare provider if you experience an alarm or malfunction that cannot be resolved following the device User Manual
- Complete and return this form to **safetynoticeuki@philips.com**

We acknowledge receipt and understanding of the accompanying Urgent FSN Letter and confirm that the information from this Letter has been properly distributed to all people that handle and/or use the affected ventilators.

Name and contact information of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please email this completed form to Philips Respironics at **safetynoticeuki@philips.com**.

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Additional sites covered by this response:

Name

Address

Name

Address

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Impacted Devices/Models

A40Pro		
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	APX3100T19
FRX3100T14	RCAX3100S12	APX3100H19
GBX3100H19	RDEX3100S13	RNDX3100S19
GBX3100S19	REEX3100S19	RESX3100S19
GBX3100T19	RFRX3100S19	RGBX3100T19
IAX3100H19	RGBX3100S19	RGBX3100H19
IAX3100S19	RITX3100S21	

A40 EFL		
ITX3000S21	ITX3000H21	CNX3000T17
ESX3000S19	ITX3000T21	IAX3000B19
FRX3000S14	NDX3000S19	JPX3000S16
GBX3000S19	BRX3000S18	KRX3000S19
AUX3000S19	ARX3000S19	KRX3000H19
CAX3000S12	RINX3000S19	KRX3000T19
CAX3000T12	RAUX3000S19	NDX3000H19
DEX3000S13	RBLX3000S19	NDX3000T19
INX3000H19	RBRX3000S18	DSX3000S11
INX3000T19	RCAX3000S12	DSX3000H11
IAX3000S19	REEX3000S19	DSX3000T11
IAX3000H19	RFRX3000S14	APX3000H19
IAX3000T19	RDEX3000S13	APX3000T19
BLX3000S19	RGBX3000S19	BRX3000B18
EEX3000S19	RITX3000S21	CAX3000B12
ESX3000H19	RNDX3000S19	CNX3000S17
ESX3000T19	RESX3000S19	CNX3000H17
FRX3000H14	GBX3000H19	
FRX3000T14	GBX3000T19	

A30 EFL
DEX2900S13

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Appendix A: Guidance for physicians/health care professionals related to FSN 2023-CC-SRC-042

Dear Physician/Healthcare Professional,

Philips recently sent a Field Safety Notice, entitled "*BiPAP A30 EFL, BiPAP A40 EFL, BiPAP A40 Pro Ventilator Alarm Malfunction linked to Oxygen Sensor Inside the Ventilator" to* DME (Durable Medical Equipment) suppliers and medical institutions that have patients who are using these devices. A copy of this Field Safety Notice is included with this letter.

To support physicians/healthcare professionals who manage patients using ventilatory devices in the home setting, Philips is providing additional guidance regarding the continued use of these devices.

Philips is recommending that physicians/healthcare professionals assess whether the patients under their care can tolerate interruptions of therapy to help ensure that they continue to receive the most appropriate therapy.

For Patients/User:

If the High Oxygen Alarm occurs, the patient/user caregiver will have instructions to remove the patient from the device and place them on an alternate device.

- If they do not have an alternative device, they can contact their equipment provider or DME for assistance with obtaining an alternative device.

Optional Step: Patients (or lay caregivers) may perform a "hard reboot" after High Oxygen Alarm occurs:

The hard reboot **in some cases may** temporarily restore therapy to the patient which could allow them to continue to use the device while waiting for an alternate device from their DME or equipment supplier.

***Please refer to **Appendix C** (attached) Instructions on Performing the Hard Reboot. ***

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Appendix B: Guidance for patients/users related to FSN 2023-CC-SRC-042 FSN

Background:

- The ventilator has an alarm called the “High Internal Oxygen” alarm. The “High Internal Oxygen” alarm is intended to detect oxygen accumulation within the ventilator that may occur while supplemental oxygen is being provided to a patient. Philips Respironics has identified issues in this sensor’s manufacturing process that can cause the sensor to malfunction, inaccurately reporting elevated oxygen levels to the device. When this happens, it can cause the device to incorrectly detect elevated oxygen concentration, even if supplemental oxygen is not connected to the device. The device will continue to provide therapy while the alarm is addressed (accordance with instructions for use). If using **supplemental oxygen,** please consult physician on next steps

Please share and discuss the attached physician letter (Appendix A) and the FSN (Field Safety Notice) with your physician/health care professional for their awareness and to allow them to make relevant recommendations for your treatment.

What to do if the High Oxygen Alarm Happens:
If this High Oxygen Alarm occurs, immediately remove the ventilator and if required, connect to an alternate source of ventilation. Contact your home care equipment provider or DME (Durable Medical Equipment) for service and assistance.

Optional Step:
You (or someone taking care of you) can perform a “hard reboot” (or restart) on your ventilator which may allow for temporary usage of the device until you can be placed on an alternative ventilator. If reboot is done and alarm comes back, please contact your DME. If no alarm occurs again, the device is fine to use while waiting for replacement device.

***Please refer to **Appendix C** (attached) Instructions on Performing the Hard Reboot. ***

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Appendix C: Instructions on Performing the Hard Reboot

Performing a Hard Reboot

If a High Oxygen alarm occurs, the alarm will sound, and an error will be logged as shown below.

Warning: Immediately remove the patient from the ventilator and if required, connect them to an alternate source of ventilation. Contact your home care equipment provider for service. Meanwhile, as an option you may follow these steps to try to temporarily restore ventilatory function while waiting for a replacement device and/or professional medical intervention.

1. Power off the therapy device.
    - Wait 30 seconds to restart the 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.
    - If the High O2 alarm returns after the hard reboot, the alarm cannot be reset, and supplemental oxygen should be removed
    - If the High O2 alarm does not return, the device can be used with supplemental oxygen again
2. Unplug the power cord from the wall or from the device itself.
3. If applicable, 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).