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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

Updated Information for Device Distributors and Healthcare Providers

<DD-MMM-YYYY>

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code>

This letter is an update to the previous Field Safety Notice, *2023-CC-SRC-042*, sent in June 2024, regarding the High Internal Oxygen Alarm sensor, affecting the following devices: BiPAP A30 EFL, BiPAP A40 Pro, and BiPAP A40 EFL. This letter informs users of the updated actions Philips Respironics will take to address this issue.

Active Devices on the Market: Philips Respironics is proceeding with a plan for impacted products on the market to enable continued use. To provide users with appropriate therapy options, the following actions will be taken by Philips Respironics as listed below.

Actions

Philips Respironics is pursuing two design changes to correct the High Internal O2 Alarm issue:

• A-Series embedded software changes which will prevent erroneous High Internal O2 Alarms over the entirety of the 5-year expected life.

• Supplier driven component changes with a focus on improved sensor design.

Timeline

The design changes described above are currently expected to be fully verified, validated and released for production and service/repair by the end of 2025. While acknowledging that this is an extended timeline due to the substantial design and test efforts, it is important to note that Philips Respironics considers the devices safe to be used whilst following the instructions provided in the FSN, specifically to switch to alternative therapy if the High Oxygen Alarm occurs.

Options:

Loaner program: In recognition of the timeline to deploy corrective actions for the High Internal O2 Alarm issue, Philips Respironics is mobilizing a loaner program. In order to support customers and patients who experience a High Internal O2 Alarm that cannot be cleared, a Dream Station ST/AVAPS device will be made available free of charge to be used until a repair is completed on the affected A-series device.

- In the event, you decide to no longer wait for the repair device then you are able to request to keep the loaner device free of charge. However, the A Series device will no longer be repaired and returned.

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Replacement Device: At the discretion of the patient, caregiver or physician, the customer will be provided with an alternative therapy device DreamStation ST/AVAPS depending on availability, and then the A-series device should be returned to Philips Respironics to minimize disruption in therapy.

In summary, Philips Respironics will continue to manage the affected A-Series installed base with options for customers and patients that have been designed to minimize disruption while ensuring access to safe therapy pending a technical solution for the High Internal O2 Alarm issue.

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 A30 EFL, BiPAP A40 EFL, BiPAP A40 Pro devices.

Next Steps: Please submit a request regarding loaner program or replacement device

(Local Market to include the appropriate URL or email using the Global Customer Support Matrix)

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

Summary of Updates to FSN text

- Updated complaint total (from 1828 to 1488) and associated probability (from 3.9% to 3.2%)
- Removed Appendix C Hard Reboot

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Alarm Malfunction linked to Oxygen Sensor Inside the Ventilator

Information for Device Distributors and Healthcare Providers

<Date of letter deployment,> *<date format: DD-MM-YYYY, e.g. 02-JAN-2021>*

To: Name / Title / Customer Name
Street Address
City, State, Zip Code

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 Philips 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:

[Phone Number]

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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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

<DD-MMM-YYYY>,

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code>

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 four hundred eighty-eight (1,488) in-use 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 3.2%. 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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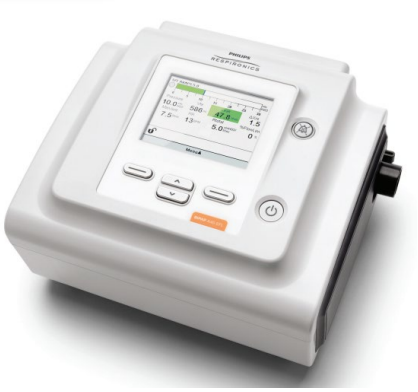
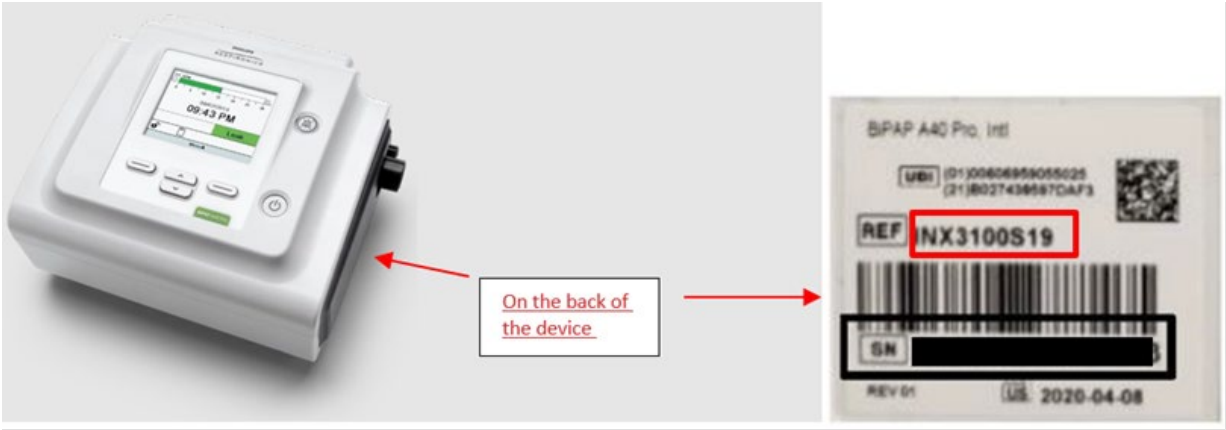
3. Affected products and how to identify them

- 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 patients/users related to FSN* function

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 Respironics representative: *<Philips representative contact details to be completed/verified by the Market/Business>*

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:

- Read and Acknowledge the Urgent Field Safety Notice
- Complete the form and return it to Philips Respironics
- Review and understand the new options Philips Respironics is offering

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 **pms.fac@philips.com**.

Additional sites covered by this response:

Name

Address

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Name

Address

PHILIPS

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.

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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.