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URGENT Field Safety Notice

BiPAP A30, BiPAP A40 and OmniLab Advanced+
Motor Stator Material Non-Conformance

Date: <DD/MM/YYY>

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.

Dear Customer,

A problem has been identified with a limited population of Philips Respironics BiPAP A30, and BiPAP A40 and OmniLab Advanced+ devices that could pose a risk for patients or users. This Field Safety Notice is intended to inform you about:

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

In April 2021, as a result of a supplier notification, Philips Respironics determined that certain devices were built with motor assemblies that could contain non-conforming plastic material. If the non-conforming plastic is present in the device motor, it could lead to off-gassing and structural failure causing the immediate and sudden failure of the device during use. Additional review of the supplier's records identified that additional devices were potentially manufactured with the same non-conforming material, leading to this expansion of the affected units list.

2. Hazard/harm associated with the issue

The patient may be exposed to the following hazards if the non-conforming material is present:

- Exposure to off-gassing not normally present creating a potential biosafety or toxicological hazard.
- Sudden failure of the device causing a Ventilator Inoperative condition with the potential for asphyxia if not immediately identified and addressed by the care provider. Please contact your physician or healthcare provider before making any changes to your prescribed therapy or stopping use. You must stop using the devices listed above in order to avoid these hazards.

Philips Respironics has received limited complaints about this issue but no reports of death or serious injury.

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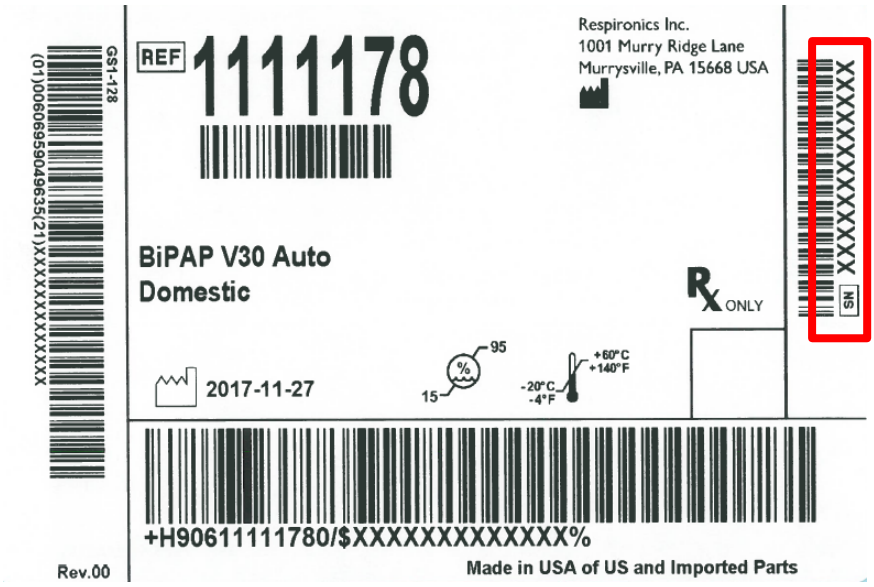
3. Affected products and how to identify them

Please note, if your device has already been corrected through the field action/recall issued by Philips Respironics in June 2021 (Reference number 2021-06-A for sound abatement foam), you do not need to return your device for further servicing as the affected components have already been replaced. Please indicate this on the business reply form.

Your device is part of the impacted population if the device serial number matches any of the serial number listed on the attached. The device serial number is located on the bottom of the device on the product label or on the device packaging label as shown below.



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

1. Please contact your physician or healthcare provider before making any changes to your prescribed therapy and to determine the most appropriate options for continued treatment.

2. This notice needs to be passed on to all those who must be aware within your organization or to any organization where the impacted devices have been transferred.

3. Fill out the Field Safety Notice Response Form that has been provided with this letter and return the form to your Philips Respironics Representative. This form serves as official acknowledgement that you have fully performed your obligations to complete this Field Safety Notice

Please transfer this notice to other organizations on which this action has an impact. (If appropriate)

5. Actions planned by Philips to correct the problem

Philips Respironics is taking action by recalling and replacing all impacted devices. Philips Respironics is planning to address the issue with the affected assembly with replacement at the same time that they are remediated for the PE-PUR Foam. <Philips Local Market to determine if this is appropriate> <Philips will arrange for shipping of the device to our repair bench, repair, and return shipping when that remediation begins, pending remediation approvals.> Philips Respironics has issued Corrective Actions to our supplier to ensure that this issue, or similar issues, will be prevented in the future.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details **to be completed by the Market/Business***>

This notice has been reported to the appropriate Regulatory Agencies.

Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,

Thomas Fallon
Head of Quality Assurance
Philips Respironics

Affected Serial Numbers (<Philips Respironics to complete>)

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URGENT Field Safety Notice Response Form

Reference: 2022-CC-SRC-005

Instructions: Please complete and return this form to Philips Respironics promptly and no later than 30 days from receipt. 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:_____

We acknowledge receipt and understanding of the accompanying Field Safety Notice/ and confirm that the information from this Letter has been properly distributed to all users that handle the affected BiPAP A30, BiPAP A40, or OmniLab Advanced+ device(s).

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Upon completion and Acknowledgment return the Field Safety Notice Response Form to Philips Respironics by emailing the completed and signed form to

<Philips representative contact details to be completed by the Market>