

URGENT Field Safety Notice

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

Dear Distributor,

Philips is initiating a Field Safety Corrective Action due to a problem identified in certain Philips BiPAP A30, BiPAP A40 and OmniLab Advanced devices that could pose a risk for patients.

It is imperative that all customers with affected products receive the attached Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- The actions that the customer/user should take to prevent risk for patients
- The actions planned by Philips to correct the problem

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

The products affected by the identified problem are in scope of ongoing remediation following Field Safety Corrective Actions 2021-05-A and 2021-06-A. The hazards described in the Field Safety Notice are considered worst case scenarios based on the limited information that is available to Philips. Full characterization of potential hazards has not been possible. Because Philips is not able to provide further risk qualification of the here identified problem, the replacement or repair of the here impacted products should be prioritized within the ongoing remediation for Field Safety Corrective Actions 2021-05-A and 2021-06-A.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- o Please prioritize these devices as part of the ongoing remediation of these devices in reference to the foam degradation FSCA.
- o <Submit this Field Safety Corrective Action to the Regulatory Agency>. <In case of any inquiries from the Regulatory Agency, contact Philips>.
- o Add your contact information in the Response Form attached.
- o Send the attached Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than 30 days, together with the Reply Card.
- o Perform a good faith effort to get the Reply Form completed and returned from customer within 90 days and inform Philips about the responses received.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative at the UK Philips Customer Care Service Centre on 0870 532 9741 or Ireland Philips Customer Care Service Centre on +353 1 7640229. Philips Respironics regrets any inconvenience caused by this problem.

Sincerely,