URGENT PRODUCT DEFECT CORRECTION

Philips Respironics

Mechanical Ventilators

CPAP and Bi-Level PAP Devices

All Devices manufactured before 26 April 2021,

All serial numbers

Following consultation with the Therapeutic Goods Administration, Philips is conducting an Urgent Product Defect Correction of Philips Respironics CPAP and Bi-Level PAP Devices and Ventilator Machine because of 2 issues:

1) The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and

2) the PE-PUR foam may off-gas certain chemicals.

The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and off-gassing may occur during operation.

Please contact and make an appointment with your physician or care provider. Together with your physician, determine if the benefit of continuing therapy with your device outweighs the risks identified and discuss long-term therapy options.

For people who use affected ventilator machines, do not stop or change ventilator use until you have talked to your health care provider.

Further information including the full list of impacted devices, the status of the Urgent Product Defect Correction and permanent corrective action can be found by visiting the Philips website: www.philips.com/src-update or by scanning the QR code below.