PHILIPS RESPIRONICS NOTICE
MEDICAL DEVICE RECALL INFORMATION

On June 14, 2021 PHILIPS RESPIRONICS issued a voluntary recall of certain durable medical devices to address identified issues and potential health risks related to sound abatement foam used in specific PHILIPS RESPIRONICS Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators.

PHILIPS RESPIRONICS GUIDANCE TO PATIENTS

The recall notification (U.S. only) / field safety notice (International Markets) advises patients and customers to take the following actions:

For patients using life-sustaining mechanical ventilator devices:

- Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.
- If your physician determines that you must continue using this device, use an inline bacterial filter. Consult your Instructions for Use for guidance on installation.

For patients using BiLevel PAP and CPAP devices:

- Discontinue the use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.

Continue to follow updates at http://www.philips.com/src-update or call 877-907-7508 to contact PHILIPS RESPIRONICS directly.

You can access the Phillips Q&A at
http://www.usa.phillips.com/healthcare/e/sleep/communications/src-update#questions_and_answers

Great Elm Healthcare strongly recommends all patients impacted by this recall consult with their medical doctor/clinician responsible for prescribing their CPAP, BiPAP, and/or Ventilator for clinical direction on the further use or discontinuation of your medical equipment.

GREAT ELM HEALTHCARE STATEMENT TO PATIENTS

Great Elm Healthcare is in communication with Phillips Respironics about this recall and we will do our best to communicate information to you, our patients. This recall is our top priority, and we are working tirelessly with our patients, physicians, payers, and manufacturers to identify and create solutions for all parties affected by this recall.