UVA Health

Clinical Engineering Services
Urgent Medical Device Recall
Philips Sleep & Respiratory Care Products

ADVISORY

UVA is aware of a medical device recall issued by Philips on certain ventilation and positive-airway pressure devices. Foam used for sound abatement may leak into the airway circuit and cause adverse health effects. Philips has advised that use of these devices be discontinued if medically permissible.

AFFECTED DEVICES

- DreamStation ASV, ST, AVAPS, CPAP, Auto CPAP, BiPAP devices
- DreamStation GO CPAP, APAP
- SystemOne ASV4, Q series
- C Series ASV, S/T, AVAPS
- OmniLab Advanced Plus In-Lab Titration Device
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100, 200 Ventilators
- Garbin Plus, Aeris, LifeVent Ventilators
- A-Series BiPAP V30 Auto, BiPAP Hybrid A30, BiPAP A30 and A40
- E30 Continuous Ventilator

ACTIONS TO BE TAKEN BY USER:

- **Hospital Owned/Operated Devices:** Respiratory Therapy is mitigating risk in using hospital-owned devices affected by this recall by utilizing an in-line bacterial filter until such time as our affected devices can be repaired or replaced.
- **Patient-owned Devices Used in the Medical Center:** Devices affected by this recall will not be allowed to be used in the Medical Center. If a ventilatory support device is required to safely deliver care, either a hospital-owned device should be used or the procedure/visit should be postponed.
- Patients owning affected devices should be notified of this recall by their care provider and directed to contact their DME provider or device vendor for repair or replacement.

CORRECTIVE ACTION

We will be working with Philips to coordinate the repair or replacement of our affected devices.

Recommended Actions:

- **Communicate the advisory notice with staff**
- **Inform affected patients of recall status of their personal equipment**
- **A copy of the Urgent Device Recall Notice is attached.**