

# Commonwealth of the Northern Mariana Islands Office of the Attorney General

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For Immediate Release

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#### **Recall of Philips Respironics Ventilators, BiPAP,** and CPAP Machines Due to Potential Health Risks

**Office of the Attorney General, Saipan** – The Office of the Consumer Counsel is alerting the public and healthcare providers in the Commonwealth of a recall of certain Philips Respironics products due to potential health risks.

The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway, causing the user to inhale or swallow the debris.

If you own one of the following affected devices, the U.S. Food and Drug Administration recommends the following:

- Speak to your healthcare provider immediately
- Stop using the device
- Use another similar device that is not part of the recall.
- Use alternative treatments for sleep apnea, such as positional therapy or oral appliances.
- Initiating long term therapies for sleep apnea, such as losing weight, avoiding alcohol, stopping smoking, or, for moderate to severe sleep apnea, consider surgical options.
- If you do not have an alternative, and your healthcare provider determines that the benefits outweigh the risks, continue to use your device.

#### Affected Devices: CPAP and BIPAP Devices Continuous Ventilator Minimum Ventilatory Support, Facility Use:

• Model E30

### **Continuous Ventilator, Non-life Supporting:**

- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C-Series ASV
- C-Series S.T and AVAPS
- OmniLab Advanced+

#### Non-continuous Ventilators:

• SystemOne (Q-Series)

- DreamStation
- DreamStation Go
- Dorma 400
- Dorma 500
- REMSTAR SE Auto

#### Ventilators Continuous Ventilat

## **Continuous Ventilators**

- Trilogy 100
- Trilogy 200
- Garbin Plus, Aeris, LifeVent

#### Continuous Ventilator, Minimum Ventilatory Support, Facility Use

- A-Series BiPAP Hybrid A30 (not marketed in the US)
- A-Series BiPAP V30 Auto

#### **Continuous Ventilator, Non-life Supporting**

- A-Series BiPAP A40
- A-Series BiPAP A30

For more information contact Assistant Attorney General Hunter Hunt of the Office of the Consumer Counsel at the Office of the Attorney General at (670) 237-7500. You may also send an email to <u>consumer\_counsel@cnmioag.org</u>.

Established within the Office of the Attorney General, the Office of the Consumer Counsel investigates and enforces violations of the Consumer Protection Act. The office also promotes and protects the interest of the consumers in the Commonwealth to ensure a competent and fair marketplace.

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