

Philips Recall: CPAP, BiPAP, home ventilators and PAP titration devices



Children'sSM
Healthcare of Atlanta

Frequently asked questions

On June 14, 2021, Philips issued a voluntary recall impacting 3 to 4 million home continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP) devices, home ventilators for continuous support, and Sleep Lab positive airway pressure (PAP) titration devices.

What is the reason for the recall?

On June 14, 2021, Children's Healthcare of Atlanta along with impacted families were notified by Philips of a recall for certain CPAP, BiLevel PAP devices (sleep apnea machines) and mechanical ventilators. The recall was due to a noise reducing foam found in certain devices that *could* break down and potentially release very small pieces of plastic and chemical gases into the tubing which could then be inhaled or swallowed.

Which devices are affected by the recall?

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPS
- OmniLab Advanced Plus
- SystemOne Q series
- DreamStation CPAP, AutoCPAP, BiPAP
- DreamStation GO CPAP, APAP
- Dorna 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100
- Trilogy 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

What symptoms should I watch for in my child?

Philips has received reports of headache, sinus infection, irritation (skin, eye, nose or throat), asthma, airway inflammation, cough, chest pressure and potential toxic carcinogenic effects. If you suspect that your child may have been affected by the foam, please report it to the Philips Hotline at 877-907-7508.

What do I do if my child is using a recalled CPAP or BiPAP unit at home?

While Philips has recommended that patients stop using their recalled CPAP and BiPAP devices, this may not be a safe option for your child. At this time, we do not recommend that you discontinue use of the recalled device without speaking with your child's doctor first. While there are some scenarios where we believe it would be safe to temporarily stop use of the device (i.e. the use of CPAP/BIPAP for mild to moderate obstructive sleep apnea), these devices are preventing life-threatening complications in other cases.

What do I do if my child is using a recalled ventilator (i.e. Trilogy) at home?

If a ventilator is being used as a life sustaining device, the risk of stopping the ventilator is far greater than the risk of continuing to use it. If your child is on a ventilator, do not stop using it without speaking with your child's pulmonologist first. We are assessing potential options for transitioning certain patients to different ventilators. It is very important for you to speak with your child's pulmonologist about next steps.

I currently have a child in the hospital. Does this recall affect the ventilator being used on my child while he is hospitalized?

This recall does not impact hospital models of these devices. However, if your child has been transitioned to a home version of these devices, it may be affected.

Will this recall affect my child's upcoming CPAP or BiPAP titration?

Because the Children's Sleep Labs are currently equipped with Philips devices, all titrations scheduled for July have been rescheduled as we work to acquire a new system. We understand that you and your child have been waiting for this study and apologize for the inconvenience. All other sleep studies are unaffected. The Sleep Scheduling team is calling patients affected by this recall. If you have questions about whether your child's sleep study is impacted, call the Sleep Scheduling team at 404-785-2974.

What is being done about the recall?

Philips is offering a repair and replacement program for families who have a recalled device, but the timeline for resolution is currently unclear. Philips requests that you register your child's device by visiting www.philipssrcupdate.expertinquiry.com or calling Philips at 877-907-7508.

Where can I read the full recall statement from Philips?

Visit www.usa.philips.com/healthcare/e/sleep/communications/src-update to view the full statement from Philips.

Who can I contact if I want more information?

Call 877-907-7508 to speak with a Philips' representation. You may also visit www.philips.com/SRC-update for additional recall information.

