Summary

On June 14, Philips issued a recall for some of their Bi-Level Positive Airway Pressure (Bi-Level PAP), Continuous Positive Airway Pressure (CPAP), and mechanical ventilator devices manufactured on, or before, April 26, 2021. These impacts are industry-wide and do not just affect Florida Blue members.

Details

Background

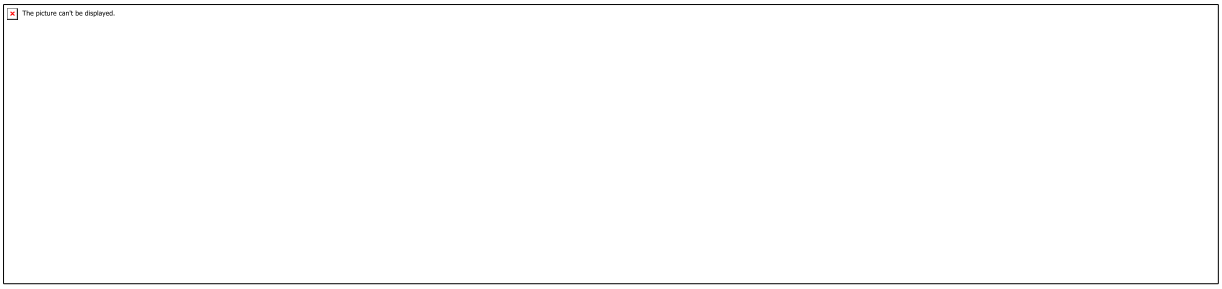
- This recall impacts more than 4 million consumers worldwide. At this time, Philips has advised the corrective action is either to repair or replace the device; however, they have not communicated how that corrective action will be executed. The U.S. Food and Drug Administration (FDA) also issued a statement on their website on June 15.

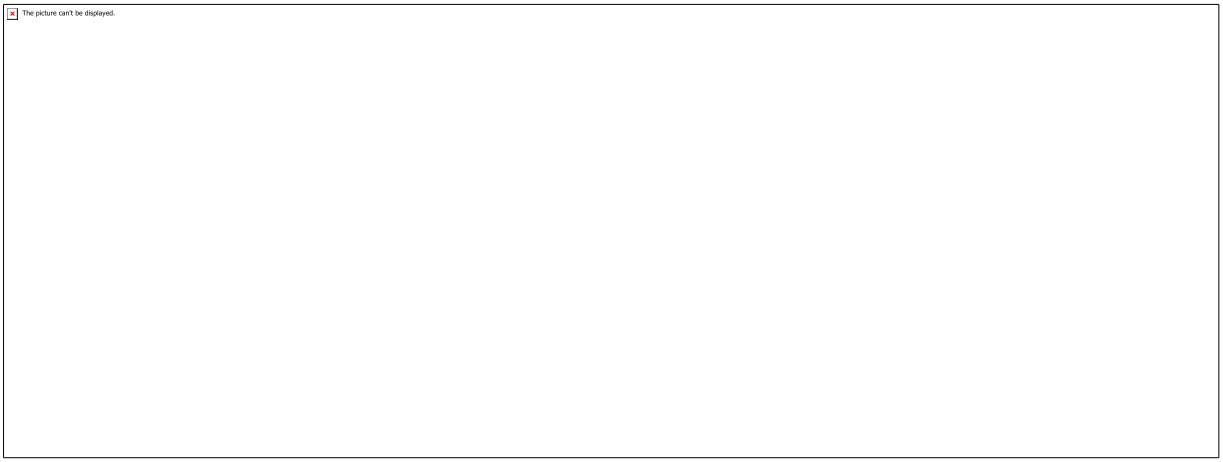
- In the meantime, we have provided some talking points related to steps members can take now while we wait for further direction. Taking these steps now will ensure members who have a device on the recall list are taking the appropriate action(s) to resolve the matter.

FAQ

- **How do I know if my device is on the recall list?**

Below is a list of impacted models:

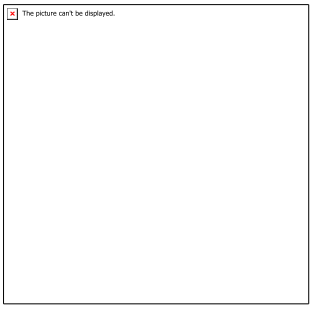




- **What do I do if my device is on the list?**

Philips is working on a solution to repair and replace devices included in the recall. To make sure your device is on the list, either to be repaired or replaced, please register your device by visiting the Philips website, or by dialing toll-free **877-907-7508**.

Note: You will need to locate the serial number on the device.



- **registered my device on the Philips website, but I am not receiving any help from the manufacturer.**

Florida Blue Members: CareCentrix telephone number,860-528-4038. As our contracted Durable Medical Equipment (DME) care coordinator, CareCentrix is working very closely with the manufacturer and can provide updated information on the action plan.

Out of State Members/Policies: Please dial the phone number located on the back of your membership card to speak with a representative who can further assist you with your home health or DME needs.

- **For patients using life-sustaining mechanical ventilator devices:**

DO NOT discontinue or alter prescribed therapy without consulting your doctor to determine appropriate next steps.

- **If it's not life-sustaining, should I discontinue using my current device?**

For patients using Bi-Level PAP and CPAP devices, the manufacturer is advising users to discontinue use of affected units and consult with their doctor to determine the benefits of continuing therapy and potential risks

- **I have registered my recalled device on Philips' website. What should I expect now?**

The FDA is working with Philips Respironics to assure the company sufficiently evaluates the device problems, the scope of the recall, and the most appropriate mitigation strategies, including adequate corrective actions by the company. The FDA will continue to share updates with the public as new information becomes available.

- **Who is responsible for correcting the issue with the affected Philips Respironics devices?**

The recalling firm, Philips Respironics, is responsible for correcting the issue and developing a recall strategy that considers the following factors as they apply to this recall:

- Results of health hazard evaluation
- Ease in identifying the product
- Degree to which the product's deficiency is obvious to the consumer or user
- Degree to which the product remains unused in the marketplace

- Continued availability of essential products

The FDA is reviewing the adequacy of Philips Respironics' proposed recall strategy as it becomes available from Philips and is recommending changes as appropriate.

- **Is this a Florida Blue issue?**

All insurance carriers and private-pay customers are experiencing this issue and awaiting direction from the manufacturer.

- **When will the correction for this issue begin? How long will it take to address all affected devices?**

Currently, Philips is working with the FDA to address all affected devices within the scope of this situation as expeditiously as possible.