



Phillip's Recall of BiPAP/CPAP Machines and Ventilators

On June 30, the U.S. Food and Drug Administration (FDA) issued an alert that Philips Respironics was undertaking a <u>level-one recall</u> of certain ventilators, BiPAP, and CPAP machines due to potential health risks.

According to the FDA, "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. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device."

The FDA cautioned further that: "These issues can result in serious injury, which can be lifethreatening, cause permanent impairment, and require medical intervention to prevent permanent damage."

The devices in question were manufactured between **2009 and April 26, 2021**. The urgent recall notices from Philips, with model names and serial numbers, are at **this link**.

Given the potential medical implications, VEHI encourages you to take the following steps if you have a Philips machine subject to recall:

- 1. **Talk to your doctor** to decide on a suitable treatment for your condition.
- 2. Read the Philips FAQ, and note the recommended action steps for (a) BiLevel PAP and CPAP devices and (b) life-saving, mechanical ventilator devices.
- 3. Register your device(s) on Philips Respironics' recall website External Link Disclaimer.
- You will find a section here for "Patients, Users, or Caregivers," with directions and links on how to register your device with Philips and begin a claim. For example, you can activate the registration process at: Home | Philips Recall (expertinguiry.com/.
- There is a telephone number you can call for direct assistance: 877-907-7508.
- There is <u>a three-minute video</u> posted on YouTube by Philips to help you navigate the registration process.

 This website also has the names and serial numbers of the machines being recalled, along with illustrations of them.

VEHI does <u>not</u> know how long it will take Philips to repair or replace defective machines at no cost to patients after a claim is registered; however, wait times by some accounts could be a year or more.

If your doctor advises you to stop using a Philips machine and to replace it, be advised that purchasing a new one (from Philips or another company) could cost you money, depending on your out-of-pocket obligations at the time you order the machine. As we understand it, Philips is not obligated to reimburse you at this time for out-of-pocket expenses you may incur because of this recall...and it is not clear yet if they ever will be.

If VEHI learns more about this recall that would be beneficial to share, we will do so. Again, though, if you have a Philips' machine subject to recall, please talk to your doctor right away if you have not already done so.

This notification has been sent to School Business Officials, Health Members, Local Union Officials and Human Resources

If forwarding, please do not change the wording in the original email.

All email communications from VEHI can be found here: VEHI Campaign Monitor Archive

You're receiving this notification because your school and/or SU are a member of our program.

52 Pike Drive Berlin, VT 05602 (802) 223-5040

Edit your subscription | Unsubscribe