Beth Israel Lahey Health
Lahey Hospital & Medical Center

Dear Patients,

Our records show that you were prescribed a machine to treat breathing problems during sleep. On June 14th, Philips (a company that makes medical equipment) issued a recall for several of these types of machines.

We do not know whether you received a machine made by Philips but wanted to make you aware of the recall and the steps you can take to get more information and make decisions about whether you need your machine repaired or replaced.

The recall applies to these Philips Respironics models:

- CPAP, BIPAP, auto-CPAP, auto-BIPAP, ASV, and AVAPS machines
  - REMstar series
  - System One series
  - Dreamstation (white colored unit) series
  - Dreamstation Go travel unit

- Ventilator
  - Trilogy 100
  - Trilogy 200
  - Garbin Plus
  - Aeris
  - Life Vent

These devices are being recalled because the foam used to make the devices less noisy (a polyester-based, polyurethane foam, also known as “PE-PUR foam”) may break down and cause particles or vapors (also known as volatile compounds) to be breathed in, or inhaled. This can lead to adverse health effects including the risk for cancer. This foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone and under high temperature/humidity environments.

Note that the Philips Dreamstation 2 series (black colored unit) and Philips Trilogy Evo ventilator and devices from other manufacturers are NOT affected by this recall.

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What should you do?

1) Please check the brand & model of your machine.

2) If you are using a recalled device, we recommend that you register your device with Philips who will either repair your device or replace your device with a different unit which is not affected by this recall. To register your device with Philips, use the internet link below or contact your DME Company.
   https://www.philipssrcupdate.expertinquiry.com/

3) Note that given worldwide demand, it may take some time for your device to be repaired or replaced.

4) Note also that if your device is over 5 years old, you are likely already eligible for a replacement with a new device.

Should you continue to use your CPAP/BIPAP machine while you wait for replacement or repair?

1) Philips is recommending that patients who have the recalled CPAP/BiPAP devices should stop using these and should contact their health care providers for further recommendations.

2) The FDA's guidance in regards to this recall can be found here:

   https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks

3) For some patients, the benefits of PAP therapy may outweigh the risks that caused the recall. There are known adverse cardiac and other health risks associated with untreated sleep apnea including the risk for sleepiness while driving and motor vehicle accidents. We recommend that you should continue to use your PAP device (while waiting for replacement/repair), if you have severe breathing difficulties, severe daytime sleepiness before you started treatment, significant cardiac, pulmonary, or neurologic disease, work in a safety-critical position (e.g. professional driver, pilot, heavy equipment operator, etc.), or have difficulty sleeping and functioning without PAP therapy.

4) Please contact your health care provider for more guidance if immediately after using your device, you have noticed symptoms of headache, sore throat, cough or sinus congestion.

5) If you plan on not using your device till it has been repaired/replaced:

   - Watch for fatigue or sleepiness while driving
   - Sleep on your side; elevate the head of the bed
   - Avoid using alcohol close to bedtime

Should you continue to use your ventilator while you wait for replacement or repair?

1. Please do not stop using these devices.
2. Please contact your health care provider for further guidance.

Risk Reduction Tips – suggestions which may help reduce your risk if you continue to use your device while you wait for it to be repaired/replaced

1) Stop using any cleaning devices to clean your equipment, especially any ozone cleaning devices (such as the SoClean device). Instead, clean your mask, tubing and water chamber with soap and water, or a mixture of 1 part vinegar to 3 parts water solution, followed by rinsing in water.

2) We recommend that you do not use CPAP cleaning devices even after you obtain a new device.

3) Consider purchasing a bacterial/viral CPAP filter. Such filters are available for purchase from several online vendors. They are not FDA approved for use with PAP machines but are frequently used with these devices in hospital settings to reduce exposure to bacterial and viral particles. Because they are not FDA approved, you may need to purchase them on your own and not through your DME Company. If they interfere with the airflow or humidification of your PAP, then please discontinue use. Please note that such filters will not filter out vapors from the foam.

4) Use the device in a cool dry space. The foam appears to break down faster in climates that are hot and humid. Note that the use of heat and humidification within the devices does not appear to be a factor in accelerating degradation of the foam.

5) Run your device for 5 minutes before applying it to help blow off any vapors.

If you would like more information about the recall, you can visit the Philips website:

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update