

Stanford Health Care
Sleep Medicine

Philips Recall of Sleep-Breathing Machines
Recommendations for Patients

On June 14, 2021, [Philips issued a recall](#) of devices for sleep-related breathing disorders (such as obstructive sleep apnea) and for continuous non-invasive ventilator support.

Check this website often if you have one of the sleep devices listed below. We will update this website based on new information from Philips and Durable Medical Equipment (DME) suppliers.

Most of the Philips devices are in the first-generation product group called DreamStation. The recalled devices include those listed below.

- Continuous positive airway pressure (CPAP) devices
- Bilevel positive airway pressure (bilevel PAP) devices
- Ventilators for sleep-related breathing disorders or chronic breathing ventilator support

This recall responded to potential health risks of foam (polyester-based polyurethane [PE-PUR]) in the devices. The foam was intended to reduce noise from the machine.

Philips reported a low complaint rate (0.03% in 2020); however, they found in tests that the foam can degrade into particles. These particles may be ingested or inhaled by the user. The foam may also off-gas certain chemicals (e.g., volatile organic compounds [VOCs]).

Philips says using unapproved ozone cleaning devices (including SoClean) can worsen foam breakdown. High heat and humidity may also worsen foam breakdown.

In light of this, we recommend the following steps.

1. Register your device for repair or replacement at the following Philips recall notification website: <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update>
2. **If you are using a life-sustaining mechanical ventilator device on the recall list, Philips says do not stop using your device. Talk to your doctor to decide your next steps.**

Continue to use this device until it is repaired or replaced. If your device is 5 years old, your insurance may cover a new one. If not, you can buy one, but be aware these devices can be expensive.

You can also obtain an inline bacterial filter. It may help filter out the foam particles but it will not filter out the off-gases.

You can obtain an inline bacterial filter in multiple ways:

- It can be shipped to you if you register your device through Philips. See the link above to register.
- It can be purchased online.
- It can be prescribed for you if you contact us. The prescription will be filled through your medical equipment supplier.

If you have questions, please contact us through MyHealth or by calling 650-723-6601.

3. **If you use a CPAP or bilevel PAP** that is on the recall list, Philips says to **stop** using your device. Talk with your doctor or Durable Medical Equipment (DME) supplier to decide your best treatment options.

If your device 5+ years old, your health insurance may cover a new one. You can also buy one, but please be aware it can be expensive.

It may be difficult to get a new device by the above methods. We believe the decision of whether to continue or stop using the device is a personal one.

Until Philips can repair or replace your device, there are several factors to consider.

General issues

- Philips states they aim to address all affected devices as soon as possible; however, there are millions of affected devices. It is unclear when they will be repaired or replaced.
- The severity of your obstructive sleep apnea is important. So is the degree of your daytime sleepiness.
 - An apnea-hypopnea index (AHI, number of abnormal sleep-related breathing events per hour of sleep) of 5-14.9 is mild and 15-30 is moderate.
 - More than 30 is severe.
 - The more severe your obstructive sleep apnea and daytime sleepiness, the greater your need for treatment.
- There are other treatment options besides CPAP and bilevel PAP. They include oral appliances¹ and orthodontia/upper airway surgery.²

These options depend partly on your personal preference. They also depend on whether you are eligible. The severity of your obstructive sleep apnea is one of the factors that determine your eligibility.

Reasons to continue using your device

- If you stop, there are risks from untreated obstructive sleep apnea. That's especially true for apnea in the moderate and severe range.

Risks include car accidents from sleepiness, high blood pressure, heart attacks, and stroke. There are also risks of heart arrhythmia, diabetes, depression, and reduced ability for the brain to process information.

- The risks of stopping the device may worsen conditions you may already have. That applies to many heart conditions (including but not limited to heart attack, transient ischemic attacks, stroke, heart failure, atrial fibrillation or other serious arrhythmia, and high blood pressure). It can also affect lung disease (such as chronic obstructive pulmonary disease [COPD]) and neurological disease (such as diseases involving muscle weakness) resulting in breathing problems.
- Stopping the device may lead to near-misses or auto accidents due to drowsiness, especially if you have had episodes like this before. Accidents related to drowsiness can also affect people working as airline pilots and truck or bus drivers. It can also affect heavy equipment operators.

Reasons to stop using your device

- There is a risk of exposure to foam particles and off-gases. This may result in headaches, irritation, inflammation, breathing issues, hypersensitivity, and nausea or vomiting. The potential risk of toxic and cancer-causing effects cannot be estimated at this time.
- The foam is more likely to break down in high heat or humidity. It is also more likely to break down when using an ozone cleaning device.
- You may see foam particles emitted from your device.

You may decide to keep using your CPAP or bilevel PAP. If so, you don't need to notify us. You should still register with Philips to have it repaired or replaced.

If you have questions, you can contact us through MyHealth or by calling 650-723-6601.

You may decide to stop using your CPAP or bilevel PAP device until it is repaired or replaced. If so, you should consider other treatment options.

Please contact us if you notice any of the following events:

- Periods of sleepiness during the day

- Near-misses or car accidents from sleepiness
- Any heart or breathing changes related to your stopping CPAP or bilevel PAP

You can talk to your health care team about this. Please send us a message through MyHealth or make an appointment by calling 650-723-6601.

Other treatments for sleep breathing disorders

¹ **An oral appliance** is a mouth guard or retainer that is used only during sleep. It typically moves your lower jaw forward to open the airway behind your tongue.

You can usually open your mouth with the device in place. It clips onto your upper and lower teeth. A hinge or tab just moves the lower jaw forward.

It tends to be less effective in treating obstructive sleep apnea. It works at one point of the airway (behind the tongue), since there are limits to how much the lower jaw can move forward. In general, though, most people find it more comfortable than a CPAP or bilevel PAP device.

The oral appliance has some side effects.

- It may cause teeth to move.
- It can cause teeth pain.
- It can cause or worsen a jaw condition called temporomandibular joint (TMJ) disease.

² **Other devices and surgery**

One option is distraction osteogenesis maxillary expansion (DOME), or a surgical procedure to have a device placed on the roof of your mouth. The appliance is adjusted by an orthodontist gradually to expand your upper jaw and airway.

There is also another mouth **device** that you wear during sleep. It also gradually opens your airway over time.

There are several different types of surgery done on the upper airway to treat obstructive sleep apnea. Sleep surgery was pioneered here at Stanford.

- One of the surgeries is hypoglossal nerve stimulation (**Inspire**), which is done if you have a certain type of upper airway collapse during sleep.
- In this surgery, an electrode is placed around a nerve in your tongue. A wire passes under your skin to a pacemaker-like device above your chest wall.
- The device detects your breathing cycle. It gives a small electric shock to stimulate your tongue muscle to move forward and open up your airway
- The mild shock is not strong enough to wake you up.