Dear BIDMC Patients,

On June 14, 2021, the device manufacturer Philips issued a **recall for some devices used for treating breathing problems during sleep**, such as sleep apnea, as well as **night-time ventilators** for patients with chronic respiratory failure.

If you do **not** use such a device, then you can disregard this letter. If you **do** use such a device, please read this entire letter to determine what you need to do next.

**This voluntary recall applies to these Philips models:**

<table>
<thead>
<tr>
<th>Recalled Models</th>
<th>Not being recalled:</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMstar SE Auto</td>
<td>DreamStation 2 series (black exterior)</td>
</tr>
<tr>
<td>System One and System One ASV4</td>
<td>Trilogy Evo ventilator</td>
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<tr>
<td>DreamStation (white exterior)</td>
<td>Devices from other manufacturers</td>
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<tr>
<td>DreamStation Go</td>
<td></td>
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<tr>
<td>Dreamstation ASV and Dreamstation ST, AVAPS</td>
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<tr>
<td>Dorma 400 or 500</td>
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<tr>
<td>C-series ASV, C-series S/T &amp; AVAPS</td>
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<tr>
<td>Omnilab Advanced+</td>
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<tr>
<td>Trilogy 100 or 200</td>
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<tr>
<td>Garbin Plus, Aeris, Lifevent</td>
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<tr>
<td>A-Series BIPAP A40 or A30 or V30 Auto</td>
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</table>

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. While Philips has received no reports of serious illness, a very small number of people who used these devices in 2020 (about 3 out of every 10,000 people) described headache, sore throat, cough, or sinus congestion that may be from the foam. Those reports are what prompted the recall.

**What should you do?**

1. **Figure out if your device is being recalled or not**
   - Find the name of your device and compare it to the Philips list of recalled devices. If you are unsure what device you have, contact the durable medical equipment (DME) company that supplied you with the device, your mask, tubing, and other supplies.
     - a. If your device is **not** being recalled, please continue to use it as prescribed.
     - b. If your device is **being** recalled, go to step 2.

2. **Register on Philips registry**
   - Use this link to register yourself on Philips registry for replacement of the foam in your device: [https://www.philipssrcupdate.expertinquiry.com/](https://www.philipssrcupdate.expertinquiry.com/)
   - If you need help with registering, please contact your DME company.
   - If your device is over 5 years old, you are likely eligible for a replacement with a new machine.

*NOTE: Given worldwide demand, it may take some time for your device to be repaired or replaced.*
3. Determine whether you should stop using your device

Determine what type of recalled device you have

Trilogy 100 ventilator

Do not stop using the device
Do call your BIDMC care team as soon as possible to speak with your physician or nurse practitioner, and in the meantime do follow the “Risk Reduction Tips” on the next page.

CPAP or BIPAP devices

Please review the guidance below.

If immediately after using your device, you have noticed symptoms of headache, sore throat, cough, or sinus congestion, please contact your BIDMC care team for more guidance.

Do you have at least one of these conditions?

- Severe breathing difficulties
- Severe daytime sleepiness before you started treatment with your device
- Significant pulmonary, cardiovascular or neurologic conditions
- Work in a safety-critical position (e.g. professional driver, pilot, heavy equipment operator, etc.)

Yes

Do not stop using your device before you speak with your care team. Do use the “Risk Reduction Tips” noted on the next page.

No

Philips recommends you stop using your device until it can be repaired or replaced. If you do so, take the following steps:
- Watch for fatigue or sleepiness with driving
- Sleep on your side; elevate the head of the bed
- Avoid using alcohol close to bedtime

No, but I have a lot of difficulty sleeping without my device

We recognize that some people may feel that the benefits of continuing to use their device outweigh the risks of exposure to the particles or vapor from the foam.

If you prefer to continue using your machine (while waiting for it to be repaired or replaced), please follow the “Risk Reduction Tips” on the next page.

Continue on the next page
4. “Risk Reduction Tips”
Suggestions which may help reduce risk while you wait for device to be repaired/replaced

- **Stop using any cleaning devices to clean your equipment**, especially any ozone cleaning devices. 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. We recommend that you do not use CPAP cleaning devices even after you obtain a new device.

- **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 device does *not* appear to be a factor in accelerating degradation of the foam.

- **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

Please contact your BIDMC care team by phone or through PatientSite, with any questions or concerns you may have.

We understand how unsettling this situation is, and we are here to help you figure out what is best for you. Thank you for entrusting your care to BIDMC.

Respectfully,

Mary LaSalvia, MD, MPH
Associate Chief Medical Officer – Ambulatory Services

Michael Cocchi, MD
Associate Chief Medical Officer – Inpatient Services