Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

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:

- REMstar SE Auto
- System One and System One ASV4
- DreamStation (white exterior)
- DreamStation Go
- Dreamstation ASV and Dreamstation ST, AVAPS
- Dorma 400 or 500
- C-series ASV, C-series S/T & AVAPS
- Omnilab Advanced+
- Trilogy 100 or 200
- Garbin Plus, Aeris, Lifevent
- A-Series BIPAP A40 or A30 or V30 Auto

Note that the following devices are *NOT* being recalled:

- DreamStation 2 series (black exterior)
- Trilogy Evo ventilator
- Devices from other manufacturers

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/
   - 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.

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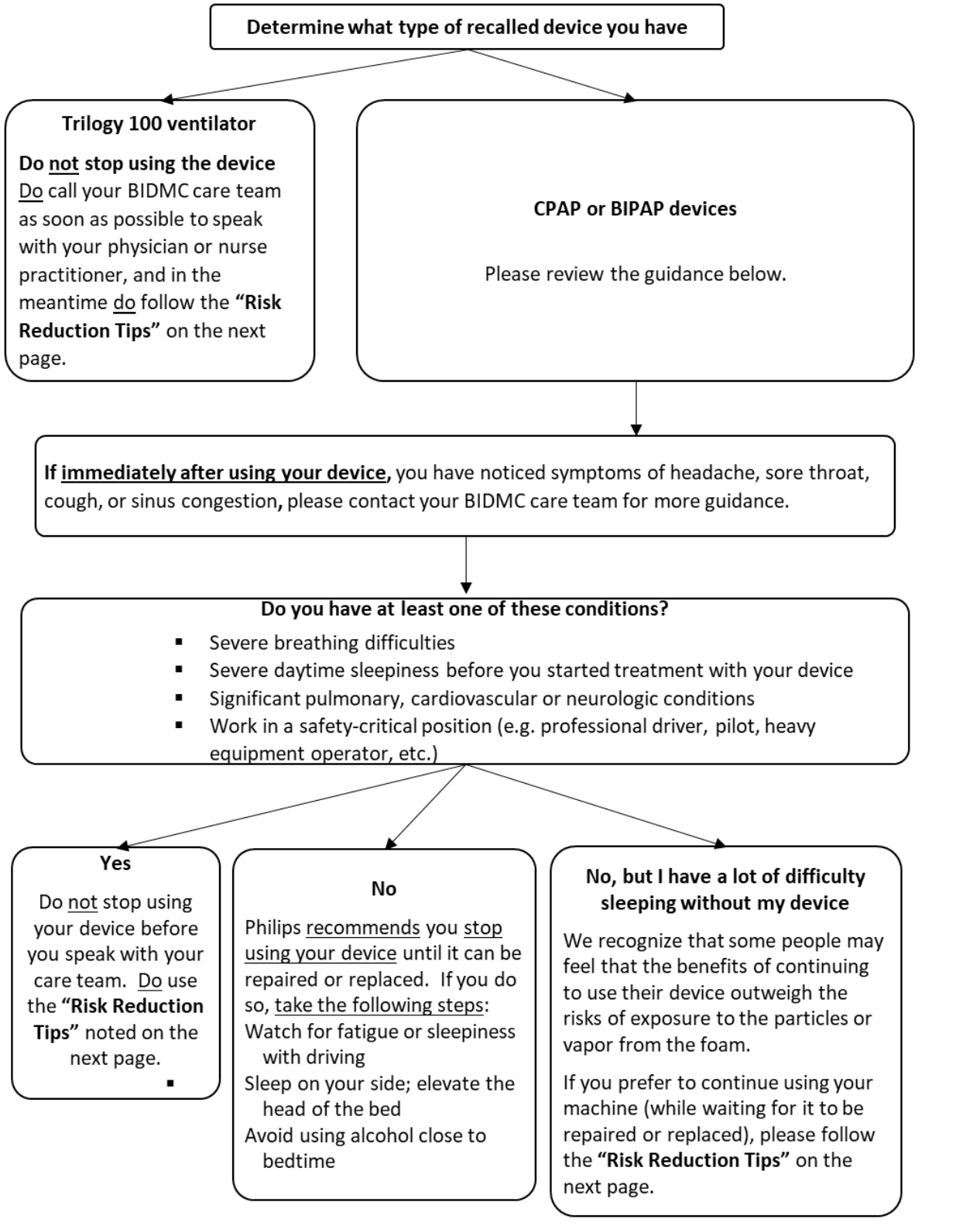
3. Determine whether you should stop using your device



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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