Patient Recommendations Regarding Philips Respironics Device Recall

September 2, 2021

On June 14, 2021, WellSpan Health was notified by Philips Respironics of their voluntary recall for certain CPAP, BiLevel PAP devices (sleep apnea machines) and mechanical ventilators due to issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices.

For information on the Philips Respironics device recall notice, a complete list of impacted products, potential health risks, further information, or to register your device to check if it is affected, please visit: philips.com/src-update.

We urge all patients with an affected Philips Respironics device to register the device as soon as possible directly with Philips Respironics. If your device is part of the recall, you will be prompted to fill out an additional information form to start the recall process.

You may also call Philips Respironics directly at 877-907-7508, Mon.-Fri., 8 a.m. to 8 p.m. EST.

Philips also advises users to avoid using ozone products to clean your PAP device and avoid using your device in areas of excessive heat and humidity. Philips reports that ozone-related cleaners may help wear down the foam in the device. Clean your device with soap and water only.

For many patients, the consequences of discontinuing CPAP or BiPAP use may be worse than the potential consequences which have led to the recall. Patients should discuss the decision to continue use of the recalled device with a provider.

If a patient's recalled device is a **life-sustaining mechanical ventilator**:

- **DO NOT** stop using the device.
- Call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. – 5 p.m.) to discuss the Philips device recall and to register to receive additional information from WellSpan.

If your recalled device is a **CPAP or BPAP device** for sleep apnea:

- The FDA advises you to talk to a health care provider to decide on a suitable treatment for your condition.
- Call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. – 5 p.m.) to discuss the Philips device recall and to register to receive additional information from WellSpan.

Based on new guidance from Philips Respironics, WellSpan does not recommend the use of inline bacterial filters with a CPAP or BiPAP device. Philips recently posted new guidance related to use of bacteria filters on their website. The information very clearly discourages the use of any bacteria filters with the recalled CPAP and BiPAP devices. Based upon this new information, with the safety of our patients in mind, WellSpan no longer offers bacteria filters for use with the recalled Philips devices.

Philips Respironics Devices Affected by Voluntary Recall

All devices manufactured before April 26, 2021 (DreamStation 2 is not affected):

- DreamStation ASV
- DreamStation ST
- AVAPS
- SystemOne ASV4
- C-Series ASV
- C-Series S/T and AVAPS
- OmniLab Advanced+
- SystemOne (Q-Series)
- DreamStation
- DreamStation Go
- Dorma 400
- Dorma 500
- REMstar SE Auto
- E30 (Emergency Use Authorization)

Frequently Asked Questions Regarding Philips Respironics Device Recall

- **How can I get a new machine/device?**
  Make sure your device is registered with Philips Respironics. They will contact you with updates regarding replacement of your recalled device.

  Philips has begun the process of addressing this problem by replacing affected devices. Unfortunately, this will likely take Philips considerable time to complete. Depending on your personal situation and factors such as availability and health coverage benefits, you may be able to purchase a device from a different manufacturer. If your device is five years old or more, you may be eligible for a new device. Contact your insurance provider for additional information.

- **Why can't I get a replacement machine if mine has been recalled?**
  The supply of potential replacement devices is limited, and the current demand is very high. A large number of Philips device users have been affected by the recall. Durable medical equipment (DME) suppliers in the area may be able to recommend replacement devices. Depending on your personal situation and factors such as health coverage benefits, you may be able to purchase a device from a different manufacturer. If your device is five years old or more, you may be eligible for a new device. Contact your durable medical equipment supplier or insurance provider for additional information.

- **Should I continue to wear/use my recalled device?**
  Philips is advising patients to stop using the recalled CPAP/BiPAP devices. If patients continue using the devices, they should consult with their medical providers for advice regarding the risks and benefits.

  For many patients, the consequences of discontinuing CPAP or BiPAP use may be worse than the potential consequences which have led to the recall. Discuss the decision to continue use of the recalled device with your care provider.

  If your recalled device is a **life-sustaining mechanical ventilator**:

  - **DO NOT** stop using the device.
  - Please call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. to 5 p.m.) to discuss the Philips device recall and your treatment options.

  If your recalled device is a **CPAP or BPAP device** for sleep apnea:

  - The FDA advises you to talk to your health care provider to decide on a suitable treatment for your condition. For many patients, the consequences of discontinuing CPAP or BiPAP use may be worse than the potential consequences which have led to the recall.
  - Please call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. to 5 p.m.) to discuss your treatment options.

- **What other treatment options are available for my sleep apnea?**
  Depending on the severity of your sleep apnea and other health factors, alternative treatment options may be considered. You should discuss your situation and treatment with your provider, but alternative treatment options may include:
    - Oral Appliance Therapy
    - Oral Surgery
    - Weight Loss Therapy
    - Positional Therapy
    - Surgical interventions such as Inspire Therapy, which is an FDA approved implant device

- **When will Philips Respironics fix/replace my device?**
  Philips Respironics has begun the process of addressing this problem by replacing affected devices. We understand that this will take time, and we cannot provide you with a timeframe for replacement. It is important that you try to stay connected to information being shared by Philips Respironics.

- **How can WellSpan help me?**
  Unfortunately, WellSpan is also reliant on Philips to remedy this problem. Our Pulmonary physicians feel that the benefits of using your device are greater than the risk of not using it. If you choose to stop using your device, there may be alternative treatment options available. Call your provider to discuss.

If your recalled device is a **life-sustaining mechanical ventilator**:

- **DO NOT** stop using the device.
- Please call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. to 5 p.m.) to discuss the Philips device recall and your treatment options.

If your recalled device is a **CPAP or BPAP device** for sleep apnea:

- The FDA advises you to talk to your health care provider to decide on a suitable treatment for your condition. For many patients, the consequences of discontinuing CPAP or BiPAP use may be worse than the potential consequences which have led to the recall.
- Please call the WellSpan Information line at 1-855-851-3641, option 4 (Mon.-Fri., 8 a.m. to 5 p.m.) to discuss your treatment options.

- **Can I use a replacement filter with my device?**
  Based on new guidance from Philips, WellSpan does not recommend the use of inline bacterial filters with your CPAP or BiPAP device. Philips recently posted new guidance related to use of bacteria filters on their website. The information very clearly discourages the use of any bacteria filters with the recalled CPAP and BiPAP devices. Based upon this new information, with the safety of our patients in mind, WellSpan no longer offers bacteria filters for use with the recalled devices. If you are currently using a bacteria filter with your device, please remove it from your circuit.

- **What are the risks if I continue to use the device?**
  According to the information provided by Philips Respironics**,** the potential risks of degraded foam exposure may include:
  - Irritation (skin, eye, and respiratory tract)
  - inflammatory response
  - headache
  - asthma
  - adverse effects to other organs (e.g. kidneys and liver), and
  - toxic carcinogenic affects.

  To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection.

  In the event of exposure to chemical emissions:

  The potential risks of exposure due to chemical emissions from affected foam include headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. To date, Philips has **not** received reports of patient impact or serious harm as a result of this issue.