MANUFACTURER'S RECALL FOR PHILIPS DEVICES

Philips Respironics, one of our sleep apnea device manufacturers, has recently announced a voluntary recall of its continuous and non-continuous ventilators (including some PPC (CPAP) and PAP (BIPAP) bi-level devices, as well as ventilators) due to problems with the polyester-based polyurethane (PE-PUR) soundproofing foam found in the devices:

1) The PE-PUR foam may crumble into small particles that can enter the air supply system and be inhaled by the user.

2) On June 17, we discovered that PE-PUR foam may emit toxic fumes. The deterioration of the foam may be attributed to unapproved cleaning methods, such as those that contain Ozone. (see FDA Safety Communications on the potential risks associated with the use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories) Chemical fumes may be emitted from the very first usage, and may continue throughout the lifespan of the device.

Which devices are affected by this recall?

This recall affects bi-level positive airway pressure (BIPAP) machines, continuous positive airway pressure (CPAP) machines, and mechanical ventilators that were manufactured by Philips between November 2009 and April 2021, specifically certain C-Series models and all DreamStation 1 systems.

- CPAP Auto de voyage Dreamstation Go
- BIPAP AVAPS DREAMSTATION
- BIPAP AUTO SV DREAMSTATION
- BIPAP AUTO DREAMSTATION ET TUBE CHAUFFANT
- BIPAP AUTO SYSTEM ONE SERIE 50
- BIPAP ST SYSTEM ONE SERIE 50
- BIPAP ST-AVAPS SYSTEM ONE SERIE 60
- BIPAP AUTO SV ADVANCED SYSTEM ONE SERIE 50
- BIPAP AVAPS A30 SYSTEM ONE SERIE 60
- BIPAP AUTO SYSTEM ONE SERIE 60
- BIPAP AVAPS A40 SYSTEM ONE SERIE 60
- CPAP REMSTAR PRO SYSTEM ONE SERIE 50
- CPAP REMSTAR PLUS SYSTEM ONE SERIE 50
- CPAP REMSTAR PRO SYSTEM ONE SERIE 50 (V2.01)
- CPAP SYSTEM ONE PRO SERIE 60 AVEC TUBE CHAUFFANT
- CPAP PRO DREAMSTATION
- CPAP REMSTAR AUTO SYSTEM ONE SERIE 50
- CPAP REMSTAR AUTO SYSTEM ONE SERIE 50 (V2.01)
- CPAP SYSTEM ONE AUTO SERIE 60 AVEC TUBE CHAUFFANT
- Appareil PPC Dreamstation Expert
- CPAP AUTO DREAMSTATION

A complete list of the products affected by this recall is available on philips.com/src-update. We recommend that you consult the Affected Devices List on Philips' website to check whether your device is affected by this recall. You can search for your device by serial number.

How can La Clef du Sommeil provide assistance?

La Clef du Sommeil has always strived to exceed industry and safety standards for the satisfaction of our patients. La Clef du Sommeil has made a point of reaching out to ALL of our patients by telephone whose devices may have been affected by this worldwide recall. Even though we did not issue this recall, and this situation is beyond our control, we are ready to provide you with support and assistance on our end, as you wait for instructions and solutions from Philips.

Regarding devices purchased from La Clef du Sommeil Inc. between March 14, 2021 and June 17, 2021:

If you purchased your device between March 14, 2021 and June 17, 2021, we can replace it with a similar device from a different manufacturer. La Clef du Sommeil will reach out to schedule an appointment with your respiratory therapist.

Regarding devices purchased from La Clef du Sommeil Inc. before March 14, 2021:

At La Clef du Sommeil, we understand that some of our clients will prefer to have their Philips device replaced by a device from another manufacturer, rather than wait for Philips to process requests for device replacement. While we cannot provide a timeline for this process, we are dedicated to assisting you and facilitating your request with Philips, the manufacturer, in the replacement of your device.

Be sure to consult your health insurance provider to check if this device is eligible for a replacement.

What are Philips' recommendations?

Philips' recall notice recommends that patients and clients stop using the affected devices, and that they consult with a medical professional as to the benefits, and any potential risks, of continuing treatment.

Philips recommends that patients and clients do not use cleaning products that contain ozone, and that they follow the approved cleaning methods which can be found in the device user's manual.

Philips would also like to remind its clients and patients to check how many years they have owned their CPAP/BIPAP devices; we generally recommend replacing your device every 5 years.

Detailed information pertaining to this recall, including which models are affected, was provided in a recall notice that was emailed by Philips to all of our clients who were affected by the recall. Philips has provided several resources to support you through this process, including a webpage where you can register your device and receive next steps and recommendations related to this large-scale recall. To register visit philips.com/src-update. On our website, you can also find Philips' customer service contact information, available in English and French; they can answer any questions you may have about this recall.

While La Clef du Sommeil Inc. is not responsible for this recall, we would like you to know that we are doing everything we can to provide assistance to our clients. Rest assured, we are monitoring the situation very closely and we are dedicated to communicating with you throughout the process. If you would like to discuss this situation with your respiratory therapist, please don't hesitate to reach out to us!