PHILIPS-RESPIRONICS (PHILIPS) Voluntary Recall

On June 14th, 2021, PHILIPS-RESPIRONICS (PHILIPS) announced a voluntary recall of a majority of their continuous positive airway pressure, (CPAP), Bi-PAPA and Adaptive servo ventilator (ASV) units. This includes but is not limited to DreamStation 1 CPAP and BiPAP units, DreamState Go travel units, SystemOne (Q series), and REMStar SE.

The basis for the recall is that a specialized sound dampening foam used in the device has been shown to possibly degrade into particles which can enter into the device's air-pathway and then could be inhaled or ingested by you as the user.

PHILIPS has recommended that all patients discontinue the use of these devices unless the benefit outweighs the very small risk identified to date which is approximately 3 out of every 10,000 patients. PHILIPS is currently working on a solution.

As it has been reported by PHILIPS, currently .03% of the patients using these devices have complained of the following symptoms:

1. Headaches/Nausea;
2. Irritation and/or inflammation of the eyes or respiratory system;
3. Inflammatory response;
4. Hypersensitivity;
5. Adverse effects to other organs;
6. Skin irritation; and
7. Possible toxic and carcinogenic effects.

Based upon the information that is currently available, we recommend the following:

1. Go to the following website and check if your device model is listed: https://www.philipssrcupdate.expertinquiry.com/
2. If you determine that your device is listed or have other concerns you can register your device at philips.com/src-update, or call the PHILIPS Support Hotline at 877-907-7508.
3. Philips will work with you to remedy this issue by either refurbishing or replacing the affected device. In the event that your machine is affected, one recommendation by PHILIPS is to seek recertification for CPAP, if your device is over five years old. You may also contact you DME to discuss if any alternatives are available.
4. If you have severe sleep apnea and/or difficulty functioning without the use of your device, consider continuing the use of it until you have a new device or PHILIPS offers a resolution.
5. Stop using the device if you are having any of the symptoms listed above, or notice any black debris in the air-path, or have any other concerns.
6. If you choose to continue to use your device, please use the cleaning methods as instructed by PHILIPS.
7. If you would like to discuss any of this in further detail, please contact us at 304-598-4285 or feel free to send a MyChart message to your sleep provider.

We will continue to provide you with any and all updates as we received them. However, please do not hesitate to contact our office if you have any questions.

Sincerely,

Robert Stansbury, M.D.
Director West Virginia University Sleep Evaluation Center
Associate Professor
Section of Pulmonary, Critical Care and Sleep Medicine
WVU Department of Medicine