VIRGINIA HEART
Sleep Center

Dear Virginia Heart Sleep Medicine Patient:

This letter is for any of our patients currently using a RESPIRONICS CPAP device.

PHILIPS-RESPIRONICS announced a voluntary recall of a majority of their continuous positive airway pressure (CPAP), Bi-PAP and Adaptive servo ventilator (ASV) units. This includes DreamStation 1 CPAP and BiPAP units, DreamStation Go travel units, SystemOne (Q series), REMStar SE and others.
The reason 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 thus could be inhaled or ingested by the user.
The manufacturer has recommended that all patients discontinue the use of these devices unless the benefit outweighs the very small risk identified to date (3 out of every 10,000 patients). They are working on a solution.

Based upon the information available to us at this time, we recommend the following:

Every patient has a unique benefit and risk profile from using their PAP device. Currently, the limited data noted that patients complaining of symptoms was very small (0.03%). The benefits from using the device may outweigh the potential risks in your case. Given this, our recommendations are as follows:

1) Temporarily discontinue the use of your Respironic CPAP device unless you have severe sleep apnea and have difficulty functioning during the day without its use.
2) If you do have severe sleep apnea and have difficulty functioning during the day without its use, consider continuing to use your device if you feel comfortable doing so until you have a new device or a resolution provided by the company.
3) Stop using your device if you are having any of the symptoms listed on the next page, notice black debris in the air-path circuit or are concerned in any way.
4) If you would like to discuss alternative sleep apnea treatments and if they are right for you, please send our office a My Chart message to schedule an appointment with a sleep provider.
5) If you would like to discuss any of this in more detail, please send our office a My Chart message to schedule an appointment with a sleep provider.
6) **This is important: Please register your device on the recall website (www.philips.com/src-update)** or call Respironics Recall Support Hotline (877-907-7508) to place a claim on your unit.
7) Follow updates from Respironics: www.philips.com/src-update
8) We are currently experiencing longer than normal wait times on the phone. To expedite your communication with us regarding this voluntary recall, we strongly encourage that you use MyChart to send us a message.
    a. If you need assistance accessing MyChart please call 855-694-6682 and select "4" to speak with a MyChart representative.

For further details, please see page 2 of this letter and/or follow updates directly from Respironics at: www.philips.com/src-update. Thank you, we know that this is confusing at this time until more information becomes available from the manufacturer.

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Medical Director, The Sleep Center at Virginia Heart

Why a Voluntary Recall:

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 thus could be inhaled or ingested by the user. Additionally, the foam may "off-gas" certain chemicals as well. *Degradation of the foam may be exacerbated by ozone devices for CPAP cleaning or high heat / humidity environments.*

Possible Health Risks:

The company reported that rate of patient complaint of symptoms was 0.03% (3 out of every 10,000 users) in 2020. To date, no deaths have been reports.

Possible risks to either the particulate exposure or chemical off-gas exposure include but are not limited to:

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

Recommendations from Phillips-Respironics for those using affected devices include*:

1. Discontinuation of the device and working with your Durable Medical Equipment (DME) provider / Sleep Provider to determine best options for them. To continue with use of your device due to lack of alternatives, consult with your physician to determine if the benefit to continuing therapy with your device outweighs the risks identified in the recall notification.

Repair or replacement of the affected devices by Respironics will take time and will not be immediate. Additionally, replacements devices from other manufacturers will be limited due to this new surge in demand.

If you continue with the device:

1. Please watch for symptoms 1-6 noted above or other concerning symptoms.
2. please use an inline bacterial filter (can purchase through your DME provider or check your instruction manual for
3. Use cleaning methods recommended by your DME provider. Do NOT use ozone or other cleaning units.
4. Keep your device in a cool environment, preferably where humidity in the room is low

If you do choose to discontinue your device:

1. Please avoid driving and all other tasks requiring sustained vigilance if feeling sleepy
2. Try to avoid sleeping on your back if possible or consider a wedge pillow or other positional sleep device.
3. Please avoid alcohol, muscle relaxants or other sedatives before bedtime as these can exacerbate sleep apnea
4. Contact our office on My Chart to schedule an appointment with a Sleep Provider to discuss alternatives to PAP.