BEL-RED SLEEP DIAGNOSTIC CENTER
1414 116th Ave NE, Suite F, Bellevue, 98004

Phone: 425-451-8417 Fax: 425-455-4089

Date: 6/16/2021

This letter is regarding voluntary recall of Philips Respironics devices that are using polyurethane foam due to possible health risks, including headache, irritation, respiratory issues and possible toxic and carcinogenic effects. It appears that the risks may come from foam degradation that could lead to particles being inhaled as well as possible off-gassing of chemicals. There are no reported deaths. Please review the links included at the bottom for reviewing the newsletter released by Philips Respironics for more information.

Statement from Philips Respironics regarding further action:

Repair and replacement program by Philips Respironics: Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company (Philips Respironics) will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible. As part of the program, the first-generation Dream Station product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances.

Decision regarding BiPAP & CPAP device use: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.

There are lot of unknown variables regarding further actions:

- How the affected machines will be swapped out
- How long this process will take,
- The comprehensive list of medical risks from the foam
- Is continued treatment with the CPAP/ BiPAP risky or withholding sleep apnea treatment until replacement is risky?
- Who will notify these patients of the recall (Philips Respironics, Medical Equipment Provider or the treating physician)?

Based on information from resources from Philips Respironics, patients will contact Philips directly to register their devices online, or by calling 1-877-907-7508 to get their machines repaired.

Philips Respironics and AASM (American Academy of Sleep Medicine) are suggesting the patients to contact their physician regarding benefits and risks of stopping the device immediately until replacement. This is a difficult decision since we do not know comprehensive medical risk from the foam including long term versus short term usage.

Instructions from Bel-Red Sleep Diagnostic Center:

At Bel-Red Sleep Diagnostic Center, we are gathering a list of patients who received Philips Respironics Devices in the last 5-7 years to send recall notification and useful information to repair the CPAP/ BiPAP devices. The patients are strongly advised to register their devices and to contact Philips Respironics directly for repair, and to contact the sleep clinic if they have further questions.

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Usually, medical insurance companies authorize a new CPAP or BiPAP every five years. If your CPAP is more than 5-year-old, you will be eligible for a new CPAP/BiPAP. If you had a change in insurance, and old sleep study results are available, you can receive a new CPAP or BiPAP without a new sleep study. If you are wondering about getting a new CPAP, please contact our sleep clinic to discuss further. You may be eligible for a new CPAP if your CPAP is more than 2-year-old and malfunctioning (not applicable for recall).

Bel-Red Sleep Diagnostic Center is currently owned and managed by new administration since April 1,2021. Until April 1st 2021, Bel-Red Sleep Diagnostic Center was owned and managed by experienced sleep technician David Ilagan. Until April 2019, Dr. Stanley Chen provided professional services at Bel-Red Sleep Diagnostic Center under his business title “Sleep and Health Medicine”. Dr. Stanley Chen also provided some medical equipment at this sleep lab. If you received a CPAP/BiPAP at Bel-Red Sleep Diagnostic Center, you might have received it from the Bel-Red Sleep Diagnostic Center or Sleep and Health Medicine or other third party vendors such as Nationwide DME.

We are more than happy to assist you in repairing the recalled CPAP/BiPAP devices even if you received the device from a different business entity such as sleep and health medicine or nationwide DME companies at Bel Red Sleep Diagnostic Center.

We will keep you posted if there are any new updates from Philips Respironics regarding repair of the recalled devices.

Thank you
Sincerely,

Dr. Suresh Mereddy
Medical Director & CEO
Bel-Red Sleep Diagnostic Center. Bellevue, WA 98004

Important links:

https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

https://aasm.org/philips-dreamstation-cpap-recall-notification/