EDMONTON SLEEP INSTITUTE

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MEDICAL DIRECTORS STATEMENT IN RESPONSE TO THE RESPIRONICS RECALL MADE June 14, 2021.

On June 14, 2021 our clinic was notified that Philips Respironics announced a voluntary recall notification / field safety notice for The CPAP devices currently used / sold at our clinic, due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices

1) PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user *(this can cause a black residue to be found in the humidifier chamber, hose, or mask).*

2) the PE-PUR foam may off-gas certain chemicals *(this can be caused when exposed to ozone or high heat/humidity environments).*

The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone (see FDA safety communication on use of ozone cleaners), **and off-gassing may occur during initial operation and may possibly continue throughout the device's useful life.**

Philips is recommending that customers and patients halt use of ozone-related cleaning products and adhere to their device Instructions for Use for approved cleaning methods. If a black residue has been found anywhere in / on your machine to halt use of CPAP / BiPAP device immediately.

To date, the manufacturer has not received reports of patient impact or serious harm as a result of this issue. This is a preventative measure.

(Philips, 2021)

Obstructive Sleep Apnea can be a serious condition if left untreated; please use informed judgement in the decision making process before determining to continue with CPAP therapy, by reviewing the recall notice and all signs and symptoms to be aware of. If other health concerns may affect your decision please consult with your family physician.

This is all the information that has been received by Edmonton Sleep Institute at this time. For all other questions, please refer to the Philips Recall statement found on their website (link below).

Edmonton Sleep Institute is following all advice and information sent forward by Philips Respironics for this issue. As such patients will be contacted by an Edmonton Sleep Institute Staff as soon as possible to register for a replacement machine.

Should you want to process your own replacement please follow the Link below

****Please note upon arrival of your new machine, if you process the replacement yourself, your recalled machine will need to be returned using the provided Waybill and the new machine will need to be brought into the clinic to be set appropriately.**

Patient Return Registration/Recall Notification:

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2