PHILIPS RESPIRONICS PAP DEVICE RECALL INFO: Updated 03/11/2022 (updates are in bold)

Update March 14, 2022: In response to numerous reports of problems people have had with the recall, and evidence that many users and healthcare providers are still unaware of the recall, the FDA has issued an enforcement letter to Philips Respironics mandating specific improvements to their handling of the recall. Specifically, the FDA has ordered Philips to:

1. **Provide documentation to the FDA that all users, prescribers, and sellers of recalled devices have been contacted and confirmed understanding of the recall.**
2. **Provide regular updates to users of recalled devices that have registered their machines for replacement.**
3. **Provide, on their website, all available information, without any delay, regarding the risks posed by the recalled devices and the risks of discontinuing therapy while waiting for a replacement.**
4. **Prioritize patients at greatest risk for adverse outcomes to receive replacements on an expedited basis.**

Update Sep 1, 2021: Philips announces that device repair and replacement program has begun.

Philips Respironics announced a voluntary recall for Continuous and Non-Continuous Ventilators (certain CPAP, APAP, BiLevel PAP, ASV and Ventilator Devices) due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices. For information on the Recall Notice, a complete list of impacted products, and potential health risks, visit www.philips.com/src-update.

As of 6/17/2021 the Philips website: www.Philips.com/src-update now has a functional link for you to register your device for replacement. Open the website and scroll down to the blue HELP box on the right side of the screen and click "Begin Registration Process". The next screen lists affected devices, just scroll down and click the radial button indicating that you are a patient / device user / caregiver and use the drop down and select United States and click next. The "Register your unit" page then opens and you will need to enter the serial number from the back of your machine (not the humidifier). Then click "Check Unit" and the site will respond telling you if your machine is affected and if so it will direct you to the registration page. Complete the registration with your name, address, email etc and submit it. Be sure to record your confirmation number.

NOTE: All original DreamStation machines are affected by this recall. If you get a message back that yours is not affected then please re-enter your device serial number carefully. If the problem recurs then call the number on the Philips website.

There is helpful information on the Philips website, yet there remain a litany of unanswered questions. As of yet there is no published scientific article about the problem or the health risks that are outlined in the Philips website information.

1. Philips Respironics recommends: "Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."
    a. This is obviously a difficult guidance and in cases of severe apnea and patients who cannot tolerate sleeping without their device it may not be practical to discontinue AND discontinuation may potentially be associated with even greater health risks than those associated with this recall.
    b. If you have mild or moderate sleep apnea and can follow this guidance then please do so.
    c. For those of you with severe sleep apnea and/or those who cannot tolerate being without their device then we advise you to continue to use your device with the following cautions:
        i. Do not use or keep your equipment in a hot, humid environment.
        ii. Immediately discontinue use of any ozone-based cleaning system. Go back to basic cleaning with soap and water: sleepdoc.com/information
        iii. Philips is no longer recommending the use of an in-line bacterial/viral filter if you opt to continue to use your device.
    d. If your device is more than 5 years old you may qualify for your insurance to provide you with new equipment. We can order new equipment for you from a different manufacturer if you wish.
    e. If you have received the new DreamStation-2 over the past few months that new model is not affected by this recall as it has a different form of insulation. Please make a follow-up appointment to read the new data card and confirm that your apnea is well treated.
    f. If you have mild to moderate sleep apnea you may be a candidate for use of a mandibular advancement appliance as an alternative form of therapy and we can refer you to a dentist board certified in dental sleep medicine to explore this possibility.
    g. If there is a strong positional component to your apnea, specifically the majority occurring while you sleep on your back, then use of a body positioning device to entrain a side sleep position may be an alternative.
    h. If you own a travel device, other than the Philips Respironics DreamStation Go (that is included in this recall), then you may try switching to your travel device for nightly usage.
2. Philips Respironics is setting up a system to repair/replace equipment covered under this recall. Please see the instructions above to register your device. They have also posted a phone number for you to call to register your device: 1-877-907-7508.

    a. We do not have a timeline as yet for the repair/replacement of equipment.

3. For those of you who received your equipment through our office, we have registered your equipment but you must register it as well. We will NOT be involved in the replacement process – you will receive your replacement directly from Philips. Please register your unit for the replacement per the instructions in bold above. Be sure to call us to let us know when you receive your replacement and to set up a brief follow-up to confirm that the replacement equipment is working properly.

4. If you have additional questions please recheck this posting at www.sleepdoc.com for the most current information that we have. We will be updating it frequently as we learn more. You may also email us at PhilipsRecall@sleepdoc.com with specific questions and we will do our best to respond. Please be understanding as there are thousands of patients in our practice on PAP devices and similarly affected. We can manage your questions best by email. You may also set up an appointment to meet with one of our techs (telemedicine or in person) or a practitioner to address specific questions.

5. We understand that this entire situation is extremely anxiety-provoking and equally frustrating for you as patients and for us as providers. We continue to believe that use of safe PAP equipment remains a mainstay of treatment of obstructive sleep apnea. Hopefully, your equipment will be repaired or replaced expeditiously.

Stay safe and sleep well,

Helene Emsellem and the entire Dream Team