TEXAS OXYCARE, INC.
MEDICAL EQUIPMENT & SUPPLIES

Texas OxyCare, Inc.
30 S Main St
San Angelo, Texas 76903

July 5, 2021

URGENT: PHILIPS RESPIRONICS DEVICE RECALL

Dear Texas OxyCare, Inc. Customer,

The purpose of this letter is to advise you that Philips Respironics is voluntarily recalling certain products in their Sleep and Respiratory Portfolio, which include Philips Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP), and Mechanical Ventilators.

Reason for the Voluntary Recall:

This recall has been initiated due to health risks associated with exposure to degraded sound abatement foam, caused by unapproved cleaning methods such as ozone and exposure to chemical emissions from the foam material. High heat and high humidity environments may also contribute to foam degradation in certain regions.

Risks to Health/How to Identify Device Failure:

In the event of exposure to degraded foam:

- The potential risks of degraded foam exposure include:
    - Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects.
- To date, Philips Respironics has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask). Philips has also received reports of headache, upper airway irritation, cough, chest pressure and sinus infections.

In the event of exposure to chemical emissions:

- The potential risks of exposure due to chemical emissions from affected foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.

- To date, Philips has not received reports of patient impact or serious harm as a result of this issue.

Action to be taken by the Customer/User:

The recall notification advises the patient and customers to take the following actions:

For patients using life sustaining mechanical ventilators: Do not stop or alter your prescribed therapy until you have talked to your physician.

For patients using BiLevel PAP and CPAP devices: 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. Your physician can help evaluate the benefits of treatment vs the risk of exposure.

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.

Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.

Next, you may access our website texasoxycare.com and go to the Philips website and look up your device's serial number to begin a claim if the unit is affected. If you want to access the Philips website directly, go to Philips.com/src-update. You may also contact Philips at 877-907-7508 if you don't have internet for additional assistance.

All patients, please complete the enclosed form and return to our office by September 15, 2021.

Plan for Addressing Issue by Philips:

Philips is notifying customers and users of affected devices that the company will replace the current sound abatement foam with a new material that is unaffected by this issue. Affected devices currently will be either replaced with a new or refurbished unit that incorporates the new material, or repaired to replace the sound abatement foam in customer units. The new material will also replace the current sound abatement foam in future products.

Please feel free to call our office if you have any additional questions or need assistance. If your physician recommends continued use of the affected device, please follow the cleaning procedure per the Instructions for Use.

Note: while proper cleaning and may help to identify presence of particles within the device, as a patient you are still at risk of exposure to degraded sound abatement foam particles and emissions.

Texas OxyCare, Inc. regrets any inconveniences caused by this problem. Completing the enclosed form will assist our office in tracking your device through Philips.

Sincerely,

Brandi Leonard, RN MSN CNS-BC
Vice President Texas OxyCare, Inc.

Please complete the following form and return to Texas OxyCare, Inc. to have your affected unit registered for Philips Respironics Device Recall by September 15, 2021.

Today's Date: _____

Patient Name: _____

Patient Shipping Address: _____
(Include City, State, and Zip Code)

_____

Date of Birth: _____ **Telephone Number: _____**

Email: _____

Product Name Recalled: _____

Serial Number: _____

Brief Description of Device: _____

Did you obtain the device from Texas OxyCare, Inc?
(Texas OxyCare, Inc. can still process recall if not obtained directly from our office.)

_____ YES **_____ NO**

Are you currently using the device? **_____ YES** **_____ NO**

Have you experienced any effects noted in the recall notice included?

_____ YES **_____ NO**

If YES, provide brief description:

_____

Have you registered your device on the *texasoxycare.com* or *Philips.com/src-update* website?

_____ YES **_____ NO**

****Please indicate if you no longer have the device in question.**

I do have the device. _____ **I no longer have the device. _____**

Mail completed form to
Texas OxyCare, Inc.
30 S Main St
San Angelo, TX 76903

OR email to texasoxycare@yahoo.com
OR fax to 325-658-3993