[Insert name of Sleep Center] utilizes certain Philips Respironics (“**Philips**”) positive airway pressure devices. These PAP devices are used to begin and adjust treatment during certain sleep studies. Philips has issued a voluntary recall (the “**Recall**”) of certain PAP devices (“**Philips PAP Device**”) used by patients at home and at the Sleep Center. The recall is related to the type of foam used to reduce the noise made by the devices.

**This Acknowledgement, Consent, and Release provides information on the potential risks specific to the use of a Philips PAP Device during your sleep study. Please read this form carefully.**

## Potential Risks Described by Philips

Over time, the foam inside the Philips PAP Device may fall apart into black particles. These particles can enter the humidifier, tubing and mask. As a result, you may inhale the particles when using the device.

Philips has received reports of the following complaints from exposure to foam particles:

* headache
* upper airway irritation
* cough
* chest pressure
* sinus infection

Philips reports that other potential risks from exposure to foam particles include:

* irritation (skin, eye, and respiratory tract)
* inflammatory response
* headache
* asthma
* adverse effects to other organs (e.g. kidneys and liver)
* toxic carcinogenic affects

Testing by Philips also found that the foam can produce unsafe chemical levels. These “volatile organic compounds” are released as gases. They could be inhaled while using the Philips PAP Device. **Testing results suggest that these emission levels are highest during the initial days of use of a new device**. Philips has received no reports of patient impact or serious harm due to this issue.

Philips reports that the potential risks of chemical exposure include:

* headache/dizziness
* irritation (eyes, nose, respiratory tract, skin)
* hypersensitivity
* nausea/vomiting
* toxic and carcinogenic effects

**Based on the information provided by Philips, the risk related to a single night of potential exposure is unknown.**

|  |
| --- |
| You can find more details about the recall at **philips.com/src-update**.Contact Philips Respironics at **SRC.Support@philips.com** or **(877) 907-7508**. |

## Safety Precautions

The Sleep Center will carefully examine Philips PAP Devices before and after use. All Philips PAP Devices will be used, cleaned and stored as Philips recommends. The Sleep Center may use additional filters if available and recommended by Philips.

## Acknowledgement, Consent, and Release

I have fully reviewed and understand the information in this form. I understand the potential risks that could occur from use of a Philips PAP Device subject to the Recall during my sleep study at the Sleep Center. I acknowledge that I have received information about the Recall. I have had the opportunity to ask questions about the Recall and this form. All my questions have been answered.

I acknowledge that the Sleep Center is taking reasonable steps to reduce known potential risks of use of a Philips PAP Device subject to the Recall. **I acknowledge that no actions can eliminate all risks to patients during sleep studies at the Sleep Center**. I agree to assume all risk of injury or harm from the use of a Philips PAP Device subject to the Recall during my sleep study at the Sleep Center. I further agree to release the Sleep Center, its physicians, other caregivers, and employees from all liability, claims, demands, damages, costs, expenses, and causes of action due to my death, injury, harm, loss, or damage of any kind.

**By signing below, I consent to the use of a Philips PAP Device during my sleep study and agree to release the Sleep Center, its physicians, other caregivers, and employees from all liability, as set forth above.**

Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Patient:­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Patient Date of Birth \_\_\_/\_\_\_/\_\_\_

Patient Telephone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

[Printed Name of Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

*Updated July 16, 2021*