PHILIPS

Sleep and Respiratory Care Bulletin #8

We are committed to supporting clinicians through the complete remediation process and will provide a range of resources to help you better inform, instruct, and support your patients. This bulletin was created to help address common questions and concerns as well as provide a status update on remediation efforts as they become available. Please find below some recent information that we wanted to bring to your attention. Be sure to visit **our clinicians information page** regularly for the most current information for you and your patients.

1. System One Remediation Approach

One of the more complex aspects of the voluntary recall has been creating remediation options for older devices, such as the System One. Our System One, 50-series and 60-series devices were discontinued in the US in 2013 and 2017 respectively, meaning that prior to the voluntary recall, we had ceased US production. **These devices are now past both their warranty period and their useful life, typically 5 years. Therefore, we are offering patients the option to opt for a replacement device or financial payment.**

Patient Remediation Policy for System One

We cannot offer System One patients a new or repaired version of their current product. We are offering the following options to patients with affected System One devices. Patients must select one of the following two options by logging into the Patient Portal and making their selection. In the absence of making a selection, no action can be taken.

1. **Financial payments of $25 per 50-series device and $50 per 60-series device:** This will be paid upon receipt of the affected unit.
2. **The ability to elect for a replacement device:** For patients who would like to remain in the remediation pathway, they will need to provide their current prescription. A Philips Respironics team member will call patients directly about obtaining their prescription through yourselves.

Philips Respironics will be communicating directly with patients who have registered System One devices to notify them of this update to our approach and remediation process and that they will be required to choose one of the two options above.

If a patient who registered a System One 60-series advanced therapy device (BiPAP AVAPS or BiPAP S/T), chooses to elect a replacement, this device will be sent to the DME for DME remediation. All other System One devices, including System One 50-series advanced therapy devices (BiPAP AVAPS or BiPAP S/T) will be remediated directly via Philips Respironics.

(continued on next page)

2. Mask Notification

We know that you and your patients may have questions regarding the September 6th notification regarding certain sleep apnea masks. This notice is unrelated to the PE-PUR foam recall and is to alert users of strengthened warnings and added contraindications in updated instructions and labeling of specific sleep apnea masks that contain magnetic headgear. Use of the mask is contraindicated for patients and their household members, caregivers and bed partners that may be in close vicinity to patients using the masks, that have implanted metallic medical devices/metallic objects that may be affected by magnets. **These masks may continue to be used according to the updated instructions and labeling if patients or people in close proximity to them do not have implanted metallic medical devices or metallic objects in the body. You can learn more here.**

3. Obtaining therapy settings from patients

It is critical for Philips Respironics to make every effort to remediate all registered devices. In cases where we have not received the relevant information from the Durable Medical Equipment provider (DME), we may be reaching out to patients to get their therapy settings and manage them directly. This is essential to ensure that patients with affected devices receive them as soon as possible. As mentioned in the August Bulletin #7, there is the possibility that either the patient or Philips may be contacting you to obtain the prescribed settings.

The following is the document that will be required to be completed prior to setting up and shipping the remediation device to your patients. Delays in completing the form will delay shipment of a new or refurbished piece of equipment.

For more information, visit Philips.com/src-update

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Fax Message

Respironics Colorado, Inc.

To: **Contact Name or Doctor** **Drs Name or Clinic** Fax: **fax#**

From: Respironics Colorado, Inc. Tel: 1-857-758-7090

Customer Service Fax: 1-331-233-0129

P O Box 590 Email: RecallPrescriptions@philips.com

Eastlake, CO 80614

USA Date: **x/xx/xxxx**

Subject: **Patients Name**

As part of Philips repair and replacement program related to the sleep therapy recall, please review the request for a replacement CPAP for your patient.

Please review the attached prescription request for medical necessity and if you agree, complete with CPAP settings, including your NPI and/or state license number, sign, and date at the bottom.

Please fax the completed prescription to FAX# 331-233-0129

If you have any questions about the device on the attached prescription request form, or any issues with the prescription request, please contact us at 1-857-758-7090.

Thank you.

Respironics Colorado, Inc., a Philips company

DURABLE MEDICAL EQUIPMENT ORDER

Supplier: Respironics Colorado, Inc., a Philips company
Address: P O Box 590
Eastlake, CO 80614

Phone: 1-857-758-7090
FAX: 331-233-0129
Email: RecallPrescriptions@philips.com

As part of Philips repair and replacement program related to the sleep therapy recall, please review the request for a replacement CPAP for your patient. Please review the request for medical necessity, make changes as necessary, and if you agree, complete with settings, sign and date at the bottom and return to us as soon as possible.

Patient Name: _____ **DOB:** _____

Address: _____ **City:** _____ **State:** _____ **Zip:** _____

Diagnosis:
- ☐ G47.33 - Obstructive Sleep Apnea (adult) (pediatric)
- ☐ G47.39 – Other sleep apnea
- ☐ G47.37 - Central sleep apnea in conditions classified elsewhere
- ☐ R06.81 – Apnea, not elsewhere classified
- ☐ Other ICD10/Description: _____

Item(s) Ordered: Philips CPAP

Settings (please completely fill out one of the boxes below):

☐ **CPAP**

CPAP Pressure: _____
cm H_2O (4-20 cm H2O)

Patient Controls and Patient Data: ☒ **ON**

Comfort Features Unlocked: ☒ **YES**

(Please note with patient controls and patient data on, the patient has access to comfort features of device and usage data.)

OR

☐ **Auto CPAP***

*** Auto Minimum Pressure:** _____ **cm H_2O**
(4 cm H2O to the Auto Maximum Pressure Setting)

*** Auto Maximum Pressure:** _____ **cm H_2O**
(Auto Minimum Setting to 20 cm H2O)

Patient Controls and Patient Data: ☒ **ON**

Comfort Features Unlocked: ☒ **YES**

(Please note with patient controls and patient data on, the patient has access to comfort features of device and usage data.)

Physician's Name, Phone, Fax:

I certify that I am the treating physician, and this order has been reviewed and signed by me. I certify the medical necessity for the ordered item(s) listed above and that the information provided is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in the above section may subject me to civil or criminal liability.

Physician's Signature: _____ **Date:** _____

Physician's NPI: _____ **State License Number:** _____

UPON COMPLETION, PLEASE FAX THIS FORM TO **FAX#** 331-233-0129, or email: RecallPrescriptions@philips.com