MEDI-RENTS & SALES INC.

800-540-7252

To Our Patients,

We are writing you regarding the recent recall from Philips Respironics that affects equipment you received from us. This recall is for Philips Respironics CPAP, BiPAP, BiPAP ST and Trilogy100/200 ventilators.

This recall affects Medi-Rents & Sales, Inc. as well as all DME companies nationwide and will have implications on the manufacturing and shipment of CPAP, BiPAP and home ventilators for the foreseeable future. At this time, we do not have the inventory available nor is it available from other manufacturers to switch your equipment out at this time. Philips Respironics is working on a solution to replace your equipment but the time frame is unknown.
Please see the enclosed recall notices and recommended actions. Please discuss next steps with your physician based off of these recommendations. Further information is also available at www.usa.philips.com/healthcare/e/sleep/communications/src-update
Philips Respironics Phone # 877-907-7508

If you and your physician decide that the benefits out way the risks of the recall, please complete the next page and fax or email it back to us.

Thank you for your patience and understanding as we work together during these unprecedented times.

Sincerely,

Christopher Petr

COO

BiPAP & CPAP

Philips Respironics Respiratory Equipment Continued Use After Recall

I *(patient name)* _____ have received notification of the Philips Respironics recall and understand at this time that a replacement device is not available. I have discussed the recall with my physician and have concluded that the benefits of continued use of the Respironics BIPAP or CPAP outweighs the risks of not using it. I will not hold Medi-Rents & Sales, Inc. liable for my decision to continue using the equipment after the manufacturer recall.

Patient or Caregiver Signature Date

FAX TO: 844-818-9293

or

EMAIL TO: recall@medirents.net

URGENT: Medical Device Recall

Philips Respironics
CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

Dear Device Customer,

Philips Respironics is voluntarily recalling the below devices due to two (2) issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non-Continuous Ventilators: 1) PE-PUR foam may degrade into particles which may enter the device's the air pathway and be ingested or inhaled by the user, and 2) the PE-PUR foam may off-gas certain chemicals. 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.

These issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment. 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 also has received reports of headache, upper airway irritation, cough, chest pressure and sinus infection. The potential risks of particulate 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. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects. There have been no reports of death as a result of these issues.

All Devices manufactured before 26 April 2021, All serial numbers	
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+
Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Immediate Actions to be taken by You, the User:

1. 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. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in this letter.

2. Register your device on the recall website www.philips.com/src-updates
    d. The website provides you current information on the status of the recall and how to receive permanent corrective action to address the two (2) issues.
    e. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    f. Call 1-877-907-7508 if you cannot visit the website or do not have internet access.

Permanent Corrective Action to be Taken by the Company:
Philips is deploying a permanent corrective action to address the two (2) issues described in this Recall Notice. As part of the registration process above, you will be provided information on the next steps to implement the permanent solution.

Other Information:
If you need any further information or support concerning this issue, please contact the recall support hotline or visit the website:

1-877-907-7508
www.philips.com/src-update

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail or fax.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Sincerely,

Rodney Mell
Head of Quality and Regulatory
Philips Respironics - Sleep & Respiratory Care