Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Medical Devices Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips Continuous and Non- Continuous Ventilators

<table>
<tr><td>Device/ Product Description:</td><td>CPAP and Bi-Level PAP Devices</td></tr>
<tr><td>Affected product:</td><td>
<table>
<tr><th colspan="2">All Devices manufactured before 26 April 2021,
All serial numbers</th></tr>
<tr><td rowspan="6">Continuous Ventilator, Non-life Supporting</td><td>DreamStation ASV</td></tr>
<tr><td>DreamStation ST, AVAPS</td></tr>
<tr><td>SystemOne ASV4</td></tr>
<tr><td>C-Series ASV</td></tr>
<tr><td>C-Series S/T and AVAPS</td></tr>
<tr><td>OmniLab Advanced+</td></tr>
<tr><td rowspan="6">Noncontinuous Ventilator</td><td>SystemOne (Q-Series)</td></tr>
<tr><td>DreamStation</td></tr>
<tr><td>DreamStation Go</td></tr>
<tr><td>Dorma 400</td></tr>
<tr><td>Dorma 500</td></tr>
<tr><td>REMstar SE Auto</td></tr>
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</td></tr>
<tr><td>Manufacturer:</td><td>Philips Respironics</td></tr>
<tr><td>Problem:</td><td>Issues can result in serious injury which can be life threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment:

1) polyester-based polyurethane (PE-PUR) foam may degrade into particles which may enter the device’s air pathway and be ingested or inhaled by the user
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, and off-gassing may occur during operation.</td></tr>
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Recommendation /Actions:	• 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. • Follow the instructions as indicated in the attached Field Safety Corrective Action. • You can refer to below link for questions and answers: https://www.philips.sa/en/healthcare/e/sleep/communications/src-update • Contact the authorized representative for required corrective action. For more information, please click here. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999)unified call center	
Devices/Products photo:	Devices/Products Photos are available at the following link: https://www.philips.sa/en/healthcare/e/sleep/communications/src-update	
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