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>Continuous Ventilator</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="3">Continuous Ventilator</td><td>Trilogy 100</td></tr>
<tr><td>Trilogy 200</td></tr>
<tr><td>Garbin Plus, Aeris, LifeVent</td></tr>
<tr><td rowspan="2">Continuous Ventilator, Minimum Ventilatory Support, Facility Use</td><td>A-Series BiPAP Hybrid A30</td></tr>
<tr><td>A-Series BiPAP V30 Auto</td></tr>
<tr><td rowspan="2">Continuous Ventilator, Non-life Supporting</td><td>A-Series BiPAP A40</td></tr>
<tr><td>A-Series BiPAP A30</td></tr>
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<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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<tr><td>Recommendation /Actions:</td><td colspan="2">

Make sure that this document is reached to the end-users.
Ensure that all devices affected are identified.
Follow the instructions as indicated in the attached Field Safety Corrective Action.
Do not stop or alter a prescribed therapy before a discussion with the physician. At the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.
Use an inline bacterial filter If the physician determines to continue using this device, Consult the Instructions for Use for guidance on installation.
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
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<tr><td>Devices/Products photo:</td><td colspan="2">Devices/Products Photos are available at the following link:
https://www.philips.sa/en/healthcare/e/sleep/communications/src-update</td></tr>
<tr><td rowspan="4">Authorized Representative Details</td><td>AR name:</td><td>Philips Healthcare Saudi Arabia Ltd.</td></tr>
<tr><td>Assigned Contact Person:</td><td>Mohammed Alsamhan</td></tr>
<tr><td>Mobile/Phone:</td><td>+966 503879145</td></tr>
<tr><td>Email:</td><td>SFDA.SA.MET@Philips.com
KSA.CCC@Philips.com</td></tr>
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