Central Drugs Standard Control Organization

Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in

Food & Drugs Administration Bhavan,
Kotla Road, New Delhi.

F.No.29/Misc/03/2021-DC(185)

Date: 30th June 2021

MEDICAL DEVICE ALERT

DEVICE

Continuous Ventilator, Minimum Ventilatory support, Facility Use, Continuous Ventilator, Non-life Supporting & Non-continuous Ventilator.

BACKGROUND

M/s Philips India Limited, Gurugram is voluntarily recalling the above mentioned devices due to two issues related to the polyster-based polyurethane (PEPUR) sound abatement foam used in Continuous and Non-continuous Ventilators".

PROBLEM

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.
2. 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 initial operation and may possibly continue throughout the device's useful life.

IMMEDIATE ACTION TO BE TAKEN BY USER

- Discontinue use of your device and work with your physician or Durable Medical Equipment provider to determine the most appropriate options for continued treatment. To continue use of the device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therepy with your device outweights the risks identified in this later.
- Register your device on the recall website www.philips.com/src-updates
- The firm is deploying a permanent corrective action to address the two issues described in the recall notice.

Affected items

All Devices manufactured before 26 April 2021, all series numbers	
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, Life Vent
Continuous Ventilator, Minimum Ventilatory support, Facility Use	A-Series BiPAP Hybrid A30 (not market in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

All Devices manufactured before 26 April 2021, all series 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+
Non-continuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s Philips India Limited, Gurugram, Haryana had issued a Field Safety Notice which is attached herewith this alert.

M/s Philips India Limited,
Unit No. 402, 4th Floor, Tower 3,
World Mark 3, Maidawas Road
Sec-66, Gurugram, Haryana
Direct line: +91-124-4606000

URGENT: FIELD SAFETY NOTICE

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
    a. 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.
    b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
    c. 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

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconveniences caused by this problem.

Thanking You,

PHILIPS INDIA LIMITED

Sudhakar Mairpadi
Director- Regulatory & Govt Affairs
Philips India Limited
9958371371

URGENT: FIELD SAFETY NOTICE

Philips Respironics
Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

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 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 operation.

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.

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	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

Immediate Actions to be taken by You, the User:

1. Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.

2. If your physician determines that you must continue using this device, **use an inline bacterial filter.** Consult your Instructions for Use for guidance on installation.

3. Register your device(s) on the recall website www.philips.com/src-update

   a. 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.
   b. The website also provides you instructions on how to locate your device Serial Number and will guide you through the registration process.
   c. 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:
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Other Information:
If you need any further information or support concerning this recall/issue, please contact the recall support hotline or visit the website:

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

This notice has been reported to the appropriate Regulatory Agencies.

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