PHILIPS

Sleep and Respiratory Care Update

Information and Resources for Durable Medical Equipment Providers and Physicians

PHILIPS

Table of contents

Letter from David Ferguson,
Executive Vice President and Business Leader,
Sleep and Respiratory Care 3

Sleep and Respiratory Care update:
summary of information and resources 4

Frequently Asked Questions 5

Additional resources for your review and use with patients and referring physicians are available for download at philips.com/src-update.

Sleep and Respiratory Care update

To our valued customers:

There is nothing we take more seriously than providing patients with high quality products that are safe and reliable. If an issue arises, we are proactive in communicating and addressing it as we work tirelessly towards a resolution.

Philips Respironics announced a voluntary recall for Continuous and Non-Continuous Ventilators (certain CPAP, BiLevel PAP and Ventilator Devices) due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in these devices: 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 initial operation and may possibly continue throughout the device's useful life. For information on the Recall Notice, a complete list of impacted products, and potential health risks, visit philips.com/src-update.

For the past 40 years we have centered our business around our commitment to patient care, with solutions that are aimed at improving the lives of people with respiratory and sleep challenges. We recognize the importance of providing safe and effective therapy. To that end, I want to reaffirm our commitment to patient care, and to you, our valued customers.

We are committed to holding ourselves to the highest standards of product quality and safety in an effort to do what is right for you, and the patients who trust you with their care.

We are committed to resolving this issue and providing you with transparent, ongoing communication as we navigate the next steps.

We are committed to providing you with tools and resources to help you communicate with your patients effectively and efficiently. Enclosed you will find several resources – including FAQs attached within this document, as well as communications templates available for download via philips.com/src-update.

As the new leader of Sleep and Respiratory Care, I am confident in our ability to make lasting change and live up to our commitment to you, our valued customers, and your patients.

I encourage you to reach out to your customer representative with any questions so that we can continue to meet your needs and minimize any inconvenience to you, your business, and your patients.

Thank you for your continued trust.

David Ferguson
Executive Vice President, Philips Business Leader
Sleep and Respiratory Care

For more information, call 877-907-7508 or visit philips.com/SRC-update.

PHILIPS

Sleep and Respiratory Care update

Summary of information and resources

Philips Respironics announced a voluntary recall for Continuous and Non-Continuous Ventilators (certain CPAP, BiLevel PAP and Ventilator Devices) due to two issues related to the polyester- based polyurethane (PE-PUR) sound abatement foam used in these devices: 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 initial operation and may possibly continue throughout the device's useful life. For information on the Recall Notice, a complete list of impacted products, and potential health risks, visit philips.com/src-update.

Detailed information associated with this recall and the impacted device populations was sent to your attention via a Recall Notice with directive action required for you to take.

Trust is the bedrock of our ongoing partnership, and we strive to earn that trust every day. We understand the impact this may have on your business and your patients, therefore, we have created specific resources and tools to support you. Provided within this PDF are FAQs for durable medical equipment providers and physicians. Additional resources for you to use when communicating with your patients and your referring physicians are available for download by logging into the portal at philips.com/src-update.

Downloadable resources to use with your patients:

1. Frequently Asked Questions
2. Template webpage copy for use on your website

Downloadable resources to use with your referring physicians:

1. Physician engagement letter

We appreciate your support as we work to maintain quality of care.

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

PHILIPS

Sleep and Respiratory Care update

Frequently asked questions

1. Why is Philips issuing a recall notification for certain CPAP, BiLevel PAP and mechanical ventilators?

- On April 26, 2021, Philips provided an important update regarding proactive efforts to address identified issues with a component in certain products of our Sleep and Respiratory Care portfolio.
- At that time, out of an abundance of caution and based on available information, Philips advised of potential health risks related to sound abatement foam used in specific Philips Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators. The company also indicated that analysis of potential health risks was ongoing, and that further information would be provided when available.
- As a result of extensive ongoing analysis following this announcement, on June 14, 2021, the company issued a recall notification for specific affected devices.
- The recall notification informs customers and users of potential impacts on patient health and clinical use related to this issue. Possible health risks include exposure to degraded sound abatement foam, for example caused by unapproved cleaning methods such as ozone, and exposure to chemical emissions from the foam material. High heat and high humidity environments may also contribute to foam degradation in certain regions.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

- To date, Philips has received a limited number of reports of possible patient impact due to foam degradation, and no reports to date regarding patient impact related to chemical emissions. The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which we operate.
- The recall notification advises patients and customers to take the following actions:
  - **For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.
  - **For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**
- Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods.
- Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.
- We are treating this matter with the highest possible seriousness, and are working to address this issue as efficiently and thoroughly as possible.
- The company has developed a comprehensive plan to replace the current sound abatement foam with a new material that is not affected by this issue, and has already begun this process.
- For more information on the recall notification, as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update. In the US, affected parties may also call, toll free, 877-907-7508.

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

2. What devices are affected by the recall notification?

- The recall notification provides customers with information on how to identify affected products.
- Additionally, the device Instructions for Use provide product identification information to assist with this activity.
- Products affected by this recall notification include:

CPAP and BiLevel PAP Devices

All Affected Devices Manufactured Before 26 April 2021, All Device 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

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

Mechanical Ventilators

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers	
Continuous Ventilator	Trilogy 100 Trilogy 200 Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in the US) A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40 (not marketed in the US) A-Series BiPAP A30 (not marketed in the US)

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

3. What products are not affected and why?

- Products that are not affected may have different sound abatement foam materials, as new materials and technologies are available over time. Also, sound abatement foam in unaffected devices may be placed in a different location due to device design.

- **Products not affected by this recall notification include:**

1. Trilogy Evo
2. Trilogy Evo OBM
3. EV300
4. Trilogy 202
5. A-Series Pro and EFL
6. M-Series
7. DreamStation 2
8. Omnilab (original based on Harmony 2)
9. Dorma 100, Dorma 200, & REMstar SE
10. All oxygen concentrators, respiratory drug delivery products, airway clearance products.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

4. Are affected devices safe for use? Should affected devices be removed from service?

- The recall notification advises patients and customers to take the following actions:
  - **For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.
  - **For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**
- Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods.
- Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.

5. What is the safety hazard associated with this issue? Has Philips received any reports of patient harm due to this issue?

- The recall notification informs customers and users of potential impacts on patient health and clinical use related to this issue. Possible health risks include exposure to degraded sound abatement foam, for example caused by unapproved cleaning methods such as ozone, and exposure to chemical emissions from the foam material. High heat and high humidity environments may also contribute to foam degradation in certain regions.

  Philips continues to monitor reports of potential safety issues through our post-market surveillance activities as required by medical device regulations and laws in the markets in which we operate.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

In the event of exposure to degraded foam:

- The potential risks of degraded foam 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 effects.
- 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.

In the event of exposure to chemical emissions:

- The potential risks of exposure due to chemical emissions from affected foam include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.
- To date, Philips has not received reports of patient impact or serious harm as a result of this issue.

6. When will the correction for this issue begin? How long will it take to address all affected devices?

- Philips is notifying regulatory agencies in the regions and countries where affected products are available.
- We are providing agencies with required information related to the initial launch and ongoing implementation of the projected correction.
- The company will replace the current sound abatement foam with a new material that is not affected by this issue, and has already begun this process.
- At this time, the company is working to address all affected devices within the scope of this correction as expeditiously as possible.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

7. Are affected devices continuing to be manufactured and/or shipped?

- At this time, affected devices are on manufacturing and ship hold as the company prepares to implement the repair / replacement program for affected devices, to install new sound abatement foam material not affected by the reported issues.

8. Is this a recall? Have regulatory authorities classified the severity of the recall?

- The issuance of the recall notification is a recall according to regulatory agency criteria.
- This recall notification has not yet been classified by regulatory agencies.

9. How will Philips address this issue? Are affected devices being replaced and/or repaired? Are customers entitled to warranty replacement, repair, service or other mitigations?

- We are treating this matter with the highest possible seriousness, and are working to address this issue as efficiently and thoroughly as possible.
- As a result of extensive ongoing analysis, on June 14, 2021, the company issued a recall notification for specific affected Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators.
- The recall notification informs customers and users of potential impacts on patient health and clinical use related to this issue. Possible health risks include exposure to degraded sound abatement foam, for example caused by unapproved cleaning methods such as ozone, and exposure to chemical emissions from the foam material.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

- Philips is notifying customers and users of affected devices that the company will replace the current sound abatement foam with a new material that is not affected by this issue. Affected devices currently will be either replaced with a new or refurbished unit that incorporates the new material, or repaired to replace the sound abatement foam in customer units. The new material will also replace the current sound abatement foam in future products.
- Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods.
- Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.
- The company has dedicated significant resources to address this issue, and has developed a comprehensive plan for this correction, and has already begun this process. This effort includes wide-scale, global ramping up of manufacturing, repair, services, supply chain and other functions to support the correction.
- Philips deeply regrets the inconveniences caused by this issue, and we are dedicating significant time and resources to give affected patients and customers the service they expect and deserve as we resolve this matter as our top priority.
- For more information on the recall notification, as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update. In the US, affected parties may also call, toll free, 877-907-7508.

10. Are there any steps that customers, patients, users and/or clinicians should take regarding this issue?

- Customers, patients, users and clinicians are instructed to follow the guidance contained in the recall notification.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

- The recall notification advises patients and customers to take the following actions:
  - **For patients using BiLevel PAP and CPAP devices:** Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.
  - **For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps.**
  - Register affected devices on the recall website, philips.com/SRC-update.
    i. The website provides current information on the status of the recall and how to receive permanent corrective action to address the two issues.
    ii. The website also provides instructions on how to locate an affected device Serial Number and will guide users through the registration process.
    iii. In the US, call 877-907-7508 Service Hotline if you cannot visit the website or do not have internet access.
- The company has developed a comprehensive plan for this correction, and has already begun this process.
- Philips is recommending that customers and patients halt use of ozone-related cleaning products, and adhere to their device Instructions for Use for approved cleaning methods.
- Additionally, Philips is reminding customers and patients to review the age of their BiLevel PAP and CPAP devices, as they are typically recommended to be replaced after five years of use.
- Philips deeply regrets the inconveniences caused by this issue, and we are dedicating significant time and resources to give affected patients and customers the service they expect and deserve as we resolve this matter as our top priority.
- For more information on the recall notification, as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update. In the US, affected parties may also call, toll free, 877-907-7508.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

11. What is the cause of this issue? Was it a design, manufacture, supplier or other problem?

- Based on Philips analysis, the root cause of this issue is related to the sound abatement foam currently used in specific identified products of the Sleep and Respiratory Care portfolio.

12. How did this happen, and what is Philips doing to ensure it will not happen again?

- Philips has a robust Quality Management System and has followed our review and analysis processes to help identify and address this issue.
- The products were designed according to, and in compliance with, appropriate standards upon release. As new standards are developed, they require assessment of product characteristics according to quality and regulatory processes. Philips Quality Management System has been updated to reflect these new requirements.
- However, while standards have been updated, products developed on the prior standard are still in compliance with medical device regulations. The foam degradation and chemical emission issues were discovered as part of our Quality Management System processes, and are being corrected in accordance with appropriate regulatory requirements.
- Philips has been in full compliance with relevant standards upon product commercialization.

13. What is meant by “high heat and humidity” being one of the causes of this issue?

- Philips has determined that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*, and certain environmental conditions involving high humidity and temperature.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

- The environmental conditions that may be one of the causes of this issue refer to the climate and regional temperatures of the countries where the devices are used and stored.
- This factor does not refer to heat and humidity generated by the device for patient use.

* Potential Risks Associated With The Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories: FDA Safety Communication

14. Do affected units exhibit features that customers / users should watch out for? Particles or other visible issues?

- Users should consult with their physicians as directed in the recall notification.

15. Can Philips replace products under warranty or repair devices under warranty?

- Affected devices may be repaired under warranty.
- Philips will provide further information regarding warranty replacement procedures during this issue when it is available.

16. In those regions where Philips provides both patient care and devices, will new patients be set up with devices? Will existing patient devices that fail be replaced?

- At this time, Philips is unable to set up new patients on affected devices. Philips may work with new patients to provide potential alternate devices.
- Philips may repair / replace ventilator units that patients are reliant on in emergency situations such as device failure during required treatment, to ensure continuity of care.
- Philips CPAPs cannot be replaced during ship hold.

(continued on next page)

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

17. Is Philips certain that this issue is limited to the listed devices? Is there any possibility others are affected?

- Philips has completed our analysis in accordance with our Quality Management System and identified all affected products, which are included in our notifications to regulatory agencies and customers.
- No further products are affected by this issue.

All media and industry analyst inquiries:

Mario Fante
Senior Press Officer, Philips Group Press Office
Direct Phone: 603-560-9226
Email: mario.fante@philips.com

Or

Steve Klink
Head of Philips Group Press Office
Direct Phone: +31 6 108 888 24
Email: steve.klink@philips.com

For more information:

Call 877-907-7508 or visit philips.com/SRC-update.

MCI 4110901 v00