PHILIPS

Sleep and Respiratory Care update

Frequently asked questions

1. Why is Philips issuing a recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 (U.S. only) / field safety notice (Outside of U.S.) for specific affected devices.
- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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)

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- At the time of the June 2021 recall / field safety notice, Philips had received a limited number of reports of possible patient impact due to foam degradation, and no reports regarding patient impact related to chemical emissions. Philips continues to monitor complaints received following the recall notification / field safety notice via our Quality Management System, in accordance with the medical devices regulations and laws in the markets that we serve.
- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 do not use ozone-related cleaning products.
- 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 (U.S. only) / field safety notice (Outside of U.S.), as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update.

(continued on next page)

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2. What devices are affected by the recall notification (U.S. only) / field safety notice (Outside of U.S.)?

- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 listed in this 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

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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)

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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 listed in this notification include:**

1. Trilogy Evo
2. Trilogy Evo OBM
3. Trilogy 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. V60 Ventilator
11. V60 Plus Ventilator
12. V680 Ventilator
13. All oxygen concentrators, respiratory drug delivery products, airway clearance products

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

- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 do not use ozone-related cleaning products.
- 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 (U.S. only) / field safety notice (Outside of U.S.) 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.

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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.
- At the time of the issuance of the June 14, 2021 recall / field safety notice, Philips Respironics had 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 had 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.
- At the time of the issuance of the June 14, 2021 recall / field safety notice, Philips had 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?

- The company will replace the current sound abatement foam with a new material that is not affected by this issue.
- At this time, the company is working to address all affected devices within the scope of this correction as expeditiously as possible.
- Philips will provide further clarity on projected dates for implementation of the correction to begin when this information is available.
- The process for preparing the corrections indicated in the recall notification (U.S. only) / field safety notice (Outside of U.S.) has begun.

(continued on next page)

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- This effort includes wide-scale, global ramping up of manufacturing, repair, services, supply chain and other functions to support the correction.
- Philips is notifying regulatory agencies in the regions and countries where affected products are available.
- Our global repair and replacement program for affected devices is being implemented in accordance with appropriate regulatory requirements in each market, which may, in some markets, include review and/or authorization by the relevant regulatory agencies.
- We are providing agencies with required information related to the initial launch and ongoing implementation of the projected correction.

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 notification is a recall in the U.S., and field safety notice outside of the U.S., according to regulatory agency criteria.
- This recall notification / field safety notice has been designated a Class I recall by both the U.S. Food and Drug Administration and Health Canada.
- For more information regarding FDA recall classifications, please visit: https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices
- For the FDA's recommendations regarding this Class I recall, please visit: https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks#recommendations

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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 (U.S. only) / field safety notice (Outside of U.S.) for specific affected Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators.
- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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.
- 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.
- 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.

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- 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 (U.S. only) / field safety notice (Outside of U.S.), as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update.

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 (U.S. only) / field safety notice (Outside of U.S.).
- The recall notification (U.S. only) / field safety notice (Outside of U.S.) 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 notification (U.S. only) / field safety notice (Outside of U.S.) website, philips.com/SRC-update.
    i. The website provides current information on the status of the recall notification (U.S. only) / field safety notice (Outside of U.S.) 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.

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- 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.
- 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 (U.S. only) / field safety notice (Outside of U.S.), as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit philips.com/SRC-update.

11. What is the cause of this issue?

- 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 developed according to the required standards and regulatory registrations at the time of initial release. The Philips Quality Management System has been upgraded to reflect alignment with updated standards.

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- 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.

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.
- 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 (U.S. only) / field safety notice (Outside of U.S.).

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.

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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.

17. Is Philips certain that this issue is limited to the listed devices? Is there any possibility other devices which use the PE-PUR foam are affected?

- Analysis by Philips under the company's Quality Management System has reviewed and identified affected devices that were designed to incorporate the PE-PUR foam.
- In accordance with the Philips Quality Management System, 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.

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

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