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 & 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.
- Following ongoing dialogue with the FDA, Philips has updated the guidance in its June 14, 2021 U.S. recall notifications for certain CPAP, BiPAP and Mechanical Ventilator devices to align them with the U.S. FDA's recommendations in connection with these recalls. This updated guidance is not based on new test results and is intended to provide broader options for physicians advising patients of affected devices to better account for a wide variety of clinical use cases for patient medical conditions.

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- The 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.
- 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 / field safety notice via our Quality Management System, in accordance with the medical devices regulations and laws in the markets that we serve.
- The notification advises patients and customers to take the following actions:
- The November 2021 update provides broadened guidance regarding affected CPAP, BiLevel PAP and Mechanical Ventilator devices as follows:
  - **For patients using BiLevel PAP and CPAP devices, talk to a health care provider to decide on a suitable treatment for medical conditions, which may include:**
    - Stopping use of an affected device.
    - Using another similar device that is not part of the recall.
    - Continuing to use an affected device, if a patient's health care provider determines that the benefits outweigh the risks identified in the recall notification.
    - Using alternative treatments for sleep apnea.

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- **For patients using life-sustaining mechanical ventilator devices, they should not stop or change ventilator use until they have talked to their health care providers regarding factors including:**
    - Whether in the judgement of the treating clinical team the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.
    - Consultation with health care providers about using an inline bacterial filter with ventilators, which may help to filter out particles of foam, as indicated in the Philips recall notification, which also notes limitations of this option and areas of caution.

- 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 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 www.philips.com/SRC-update.

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2. What devices are affected by the recall notification / field safety notice?

- 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)

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. EV300
  4. Trilogy 202

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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

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

- The June 2021 U.S. recall notice (updated in November 2021) provides the following guidance regarding affected CPAP, BiLevel PAP and Mechanical Ventilator devices:
  - **For patients using BiLevel PAP and CPAP devices, talk to a health care provider to decide on a suitable treatment for medical conditions, which may include:**
    - Stopping use of an affected device.
    - Using another similar device that is not part of the recall.
    - Continuing to use an affected device, if a patient's health care provider determines that the benefits outweigh the risks identified in the recall notification.
    - Using alternative treatments for sleep apnea.

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- **For patients using life-sustaining mechanical ventilator devices, they should not stop or change ventilator use until they have talked to their health care providers regarding factors including:**
    - Whether in the judgement of the treating clinical team the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.
    - Consultation with health care providers about using an inline bacterial filter with ventilators, which may help to filter out particles of foam, as indicated in the Philips recall notification, which also notes limitations of this option and areas of caution.

- 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 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 in the U.S.? 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.
- On September 1, 2021, Philips announced the start of the repair and replacement in the U.S.: Philips starts repair and replacement program - News | Philips. We anticipate completion of the repair and replacement program in the U.S. by approximately September 2022.

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- At this time, Philips is producing repair kits and replacement devices in large quantities. We have increased the production capacity of repair kits and replacement devices in the third quarter of 2021 to 55,000 per week, and we aim to further increase that capacity to 80,000 units per week in the fourth quarter of 2021. As our production capacity is fully focused on the repair and replacement actions, we are currently not taking orders for sleep therapy devices for new patients.
- For more information on the U.S. recall notification, as well as instructions for customers, users and physicians, affected parties may contact their local Philips representative or visit www.philips.com/SRC-update.
- Philips deeply regrets the inconveniences caused by this issue. 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.
- We are absolutely committed to supporting the worldwide community of patients who rely on our Sleep & Respiratory Care solutions for their health and quality of life, and the physicians and customers who are dedicated to meeting patient needs.

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

- To correct this issue for affected patients, Philips is currently manufacturing and shipping similar CPAP, BiLevel PAP and Mechanical Ventilator platforms with a different design, including a new sound abatement foam material not affected by the potential risks noted in the June 2021 U.S. recall notification (updated in November 2021).

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 a 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.

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- 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.

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), Bi-Level Positive Airway Pressure (BiLevel PAP) devices, and Mechanical Ventilators. This recall notification was updated in the U.S. in November 2021.
- The 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.
- 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 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 recommended to be replaced after five years of use.

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- The company has dedicated significant resources to address this issue, 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 (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 www.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 notification advises patients and customers to take the following actions:
  - **For patients using BiLevel PAP and CPAP devices, talk to a health care provider to decide on a suitable treatment for medical conditions, which may include:**
    - Stopping use of an affected device.
    - Using another similar device that is not part of the recall.
    - Continuing to use an affected device, if a patient's health care provider determines that the benefits outweigh the risks identified in the recall notification.
    - Using alternative treatments for sleep apnea.

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- **For patients using life-sustaining mechanical ventilator devices, they should not stop or change ventilator use until they have talked to their health care providers regarding factors including:**
    - Whether in the judgement of the treating clinical team the benefit of continued usage of these ventilator devices may outweigh the potential risks identified in the recall notification.
    - Consultation with health care providers about using an inline bacterial filter with ventilators, which may help to filter out particles of foam, as indicated in the Philips recall notification, which also notes limitations of this option and areas of caution.
- Register affected devices on the recall / field safety notice website, www.philips.com/SRC-update.
    - The website provides current information on the status of the recall / field safety notice and how to receive permanent corrective action to address the two issues.
    - The website also provides instructions on how to locate an affected device Serial Number and will guide users through the registration process.

- The company has developed a comprehensive plan for this correction and has already begun this process.
- 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 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.

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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 & 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.
- 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.

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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 may provide a repair kit for select devices to select customers in lieu of a replacement device; for these select customers, Philips will compensate a fair market value for labor incurred involved in the repair process; in this case, advanced exchange is also no longer applicable.
- All products and repairs are subject to warranty.
    - All refurbished and new units come with a two-year warranty.
    - All repaired units (RP Kit) come with a one-year warranty (parts are covered for one year and labor is covered for 90 days).

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.

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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.

18. Has my (new) machine been ordered? How can I track that?

- Registration is what formally starts the repair / replacement process.
- If a DME registers a product for a patient, the DME will manage the replacement process and be in contact regarding the status and expected time frame.
- If a patient registers their product, Philips and the DME will consult to determine which organization will manage the replacement process. If the DME authorizes Philips to perform the replacement, Philips will be in contact regarding the status and expected time frame. This process is necessary to move forward and may take some time.

19. What does Philips do once my device is registered? What is the process?

- Providing you with a safe therapy device as soon as possible is our primary focus. While our patients are registering their devices, Philips is working to release replacement product and repair kits within each country and begin remediation.
- After your affected device has been registered, Philips will confirm your information and work to provide a replacement device. While we have already made progress in shipping new devices and have increased our production capacity, the replacement process will take approximately 12 months to complete.
- We truly appreciate your patience and are committed to making sure that you can return to therapy as soon as possible. Please remember to save your registration confirmation number for future communications.

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