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Philips Respironics recall notification/field safety notice* announced on June 14, 2021
Frequently Asked Questions – as of 6 May 2026

General

What is the component quality issue in certain of Philips Respironics sleep and respiratory care products?
In 2021, Philips Respironics determined from user reports and initial testing that there were possible risks to users related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in specific CPAP, BiPAP and ventilator devices. Following the issuance of the recall notification/field safety notice* in June 2021, Philips Respironics initiated a global program to remediate the affected devices.

Additionally, together with five independent, certified testing laboratories and qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE- PUR foam to better assess and scope potential patient health risks related to possible emission of particulates from degraded foam and volatile organic compounds. Philips Respironics provided test result updates on December 23, 2021, June 28, 2022, December 21, 2022, May 16, 2023, and July 24, 2023. Based on the comprehensive testing and analysis as published most recently in July 2023, Philips Respironics concluded that use of its sleep therapy devices is not expected to result in appreciable harm to health in patients.

In October 2023, following ongoing communications with the US Food and Drug Administration (FDA), Philips Respironics confirmed that it has agreed with the FDA's recommendations to implement additional testing to supplement current test data. The FDA stated that the testing to date is extensive and conducted with independent parties and expressed no concerns with the validity or objectivity of the testing. The additional testing as requested by the FDA in October 2023 has now been completed and confirms the validity of the earlier findings. Further testing related to the ventilator devices remains ongoing.

Which sleep and respiratory care products are affected by the recall notification/field safety notice*?
The affected CPAP, BiPAP sleep therapy and ventilator devices can be found at www.philips.com/src-update. The CPAP and BiPAP sleep therapy devices represent the vast majority of the registered affected devices globally.

What material is used for sound abatement in the DreamStation 2 and other replacement devices?

The repaired and new replacement sleep therapy devices all contain silicone sound abatement foam. Silicone is a widely applied rubber-like material that is used in many applications of daily life, such as bakeware for cupcakes, and also in medical applications, including sleep therapy devices. This includes sleep therapy devices manufactured by other companies.

* Voluntary recall notification in the US/field safety notice for the rest of the world.

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Test and research program

Why has Philips Respironics been conducting a test and research program?
At the time the recall notification/field safety notice* was issued, Philips Respironics relied on an initial, limited data set and toxicological risk assessment, and assumed a worst-case scenario for the possible health risks out of an abundance of caution. Together with five independent certified testing laboratories and qualified third-party experts, Philips Respironics has been conducting a comprehensive test and research program on the PE- PUR foam to better assess and scope potential patient health risks related to the possible emission of particulates from degraded foam and volatile organic compounds.

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Remediation program

When do you expect to complete the remediation of ventilator devices?
The remediation of affected ventilators remains ongoing in coordination with the relevant competent authorities.

Consent Decree

Why did the FDA and DOJ seek a consent decree from Philips Respironics?
Following Philips Respironics' voluntary recall of certain CPAP, BiPAP and mechanical ventilator devices in June 2021, the FDA's inspection of Philips Respironics' Murrysville facility in the second half of 2021, and the FDA's issuance of a Form 483 with inspectional observations, the FDA and US Department of Justic (DOJ) began discussions with Philips in July 2022 regarding the terms of a proposed consent decree. In the first half of 2024, Philips Respironics reached an agreement on the terms of a consent decree with the DOJ, acting on behalf of the FDA, to resolve the identified issues in relation to the Respironics recall. The consent decree primarily focuses on Philips Respironics' business operations in the US. The decree provides Philips Respironics with a roadmap of defined actions, milestones and deliverables to demonstrate compliance with regulatory requirements and to restore the business.

What are the main terms of the consent decree?
The main terms include:

- Philips Respironics' business operations must demonstrate continued compliance with the Current Good Manufacturing Practice requirements for medical devices, as incorporated in FDA's Quality System Regulation

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- Philips Respironics will retain independent quality system experts to supervise the compliance improvement program
- Philips Respironics will retain independent design and quality system experts to review various aspects of the recall remediation.
- In the US, Philips Respironics will continue to service sleep and respiratory care devices already with healthcare providers and patients, and to provide accessories (including patient interfaces), consumables and replacement parts; will resume sales of new CPAP or BiPAP sleep therapy devices or other respiratory care devices only when the relevant requirements are met.
- Agreed to disgorgement payments from sales of Medically Necessary Devices. Sales of Patient Interfaces (masks) and other consumables and accessories in the US are allowed under a separate exemption, which does not have a disgorgement requirement.
- Outside the US, Philips Respironics will continue to provide new sleep and respiratory care devices, accessories (including patient interfaces), consumables (including patient circuits), replacement parts (including repair kits) and services, subject to certain requirements. It is common for consent decrees (including this one) to include requirements (e.g. controls and documentation) for exports to prevent reimportation of medical devices into the US.

Can you summarize what are the key relevant requirements to lift the sales injunction and the profit disgorgement obligation?
Sales injunction and disgorgement payments to occur until Covered Respironics Facilities are in compliance with the relevant requirements and the rework, replacement, and refund activities are completed in accordance with the Recall Remediation Plan.

The key relevant requirements are:

- Methods and controls to manufacture, hold and distribute sleep and respiratory care devices are compliant with the relevant requirements.
- Retain a quality system expert to inspect the Covered Respironics Facilities: processes and methods, 483 observations, MDR governance, C&R reporting, design, CAPAs, etc.
- Provide the FDA a certification from retained expert that Covered Respironics Facilities are complying.

Are Patient Interfaces (Masks) subject to profit disgorgement obligation for sales in the US?
Sales of masks and other consumables and accessories in the US are allowed under a separate exemption specific to those items, which does not have a disgorgement requirement.

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