



**Recall notification for certain sleep and respiratory care products
announced on June 14, 2021**

Frequently Asked Questions – as of October 18, 2021

What is the component quality issue in certain of Philips' sleep and respiratory care products?

Philips determined from user reports and testing that there are possible risks to users related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in certain sleep and respiratory care devices. The risks include that the foam may emit certain volatile organic compounds and/or degrade under certain circumstances.

What was the patient complaint rate about this product historically?

Philips has historically used PE-PUR sound abatement foam without any significant issues or complaints, and all products complied with the regulatory standards in place at the time the products were released onto the market and received regulatory approvals. Only in very recent years did Philips see an increase in complaints related to the affected products.

Is the PE-PUR foam degradation issue limited to the listed devices?

Yes, Philips has reviewed and identified all affected devices that were designed to incorporate the PE-PUR foam. The majority of the affected devices globally is in the first-generation DreamStation product family.

What is the impact of ozone as cleaning agent?

The use of unapproved cleaning methods such as ozone may exacerbate the foam degradation. Our instructions for use do not list ozone as an approved cleaning agent and clearly state that a mild detergent should be used.

Did the first generation DreamStation devices follow industry standards?

The first generation DreamStation devices were designed to meet all relevant standards at the time of its development and launch, and were approved by relevant regulatory agencies.



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Has Philips started the repair and replacement actions?

Philips has initiated the repair and replacement program in the US and other markets.

On September 1, Philips received authorization from the FDA for the rework of the affected first-generation DreamStation devices, which consists of replacement of the PE-PUR sound abatement foam with a new material. In addition to the rework, Philips had already started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. Philips remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan.

How long will it take to address all affected devices?

The company intends to complete the repair and replacement program within 12 months of regulatory approval received.

What is the current production capacity for the repair and replacement programs and how will that increase in the next few months?

Philips has already increased the overall production of DreamStation 2 devices and DreamStation 1 repair kits to 55K units per week as of the start of the third quarter 2021 and are on track to reach 80K units per week in the fourth quarter.

What is the split between repair and replace?

Philips currently estimates that the mix will be approximately one-third repair and two-thirds replace.

Is Philips selling devices to new patients?

Because of prioritization of the repair and replace program, Philips is currently not taking new orders for sleep therapy systems, while masks and other consumables continue to be sold.

Where can I find more information on the recall?

More information on the recall can be found here:

<https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-physicians-and-providers>



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What is the company's view on the class action and personal injury claims filed against the company?

The company is aware of more than one hundred lawsuits filed in the US, most of them putative class actions and certain individual cases. The putative class actions are asserting overlapping economic loss and medical monitoring claims, while the individual cases assert claims for alleged personal injury.

It is too early to draw any conclusions or to comment on the merits of any economic loss or personal injury claims or speculate about the company's potential exposure. Following our voluntary recall notification and our coordination with the FDA and other regulatory authorities, the company continues to conduct research and testing to more fully understand and scope possible patient risk and make a full assessment on the merits of the claims that are filed.

As the claims will raise similar factual questions and will require common discovery regarding the development and safety of the recalled devices and the potential harm that can be caused by the alleged defect, the United States Judicial Panel on Multi District Litigation transferred the cases to the Western District of Pennsylvania for pretrial proceedings. The company believes the Western District of Pennsylvania is an appropriate forum for pretrial proceedings as the manufacturer of the affected devices is headquartered there (Murrysville, PA) and many cases are pending there. The company supported the consolidation to promote efficiency and consistency.

The time horizon at which the claims may be resolved is not yet clear, but the company expects that most of the next year will be focused on the fact discovery process.

Outside the US, the company is a defendant in class action lawsuits in Australia, Canada, and Israel, with substantive allegations that are similar to the cases filed in the US. Like in the US, these cases are in their early stages.

Has Philips taken any provision related to potential litigation exposure?

No. It is too early to draw any conclusions or to comment on the merits of any economic loss or personal injury claims or speculate about the company's potential exposure.

Does Philips have insurance for product liability?

Philips does have product liability insurance in place, but does not share policy details such as limits and terms externally. Philips is focusing now on the repair and replacement actions.

