

## Respironics field action notification announced on June 14, 2021

Frequently Asked Questions – as of April 25, 2022

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

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

### **Was Philips Respironics aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions prior to 2021?**

In prior years, there were limited complaints related to foam degradation, which Philips Respironics evaluated and addressed on a case-by-case basis. Potential issues relating to VOCs began to surface only more recently, leading to the recall notification<sup>1</sup> in the first half of 2021.

### **What does the announced field action provision relate to?**

The provision is related to the cost to repair and/or replace affected systems and includes the cost of intensified communication with physicians and patients, labor cost and logistics. The provision does not include any product liability costs.

### **Is Philips Respironics conducting further testing to better assess and scope potential patient health risks?**

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 certain VOCs.

In December 2021, Philips Respironics provided an update on the positive VOC test results to date for the first-generation DreamStation devices, which indicated that the VOC concentrations are within the limits of safe exposure specified in the applicable safety standards.

It is important to note that the tested DreamStation devices were not exposed to ozone cleaning. Initial testing results indicate that PE-PUR foam degradation is accelerated by repeated exposure to ozone. Philips Respironics' instructions for use do not list ozone as an approved cleaning agent and clearly state that a mild detergent should be used. Further testing and analysis are ongoing and expected to be completed in the second quarter of 2022.

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<sup>1</sup> Voluntary recall in the US/Field safety notice outside the U.S.





Comprehensive particulate testing and analyses are expected to be completed in the second quarter of 2022, and Philips Respironics will continue to provide updates on findings from these assessments.

**Following the results published in December 2021, Is Philips Respironics now excluding the health risk of possible carcinogenic effects?**

Review of the assessment by an outside medical panel and Philips Respironics determined that the level of VOCs identified to date for the first-generation DreamStation devices is not typically anticipated to result in long-term health consequences for patients.

This assessment was limited to the evaluation of VOCs for first-generation DreamStation devices, and does not evaluate the risks of potential foam particulates or cover other devices affected by the recall. These additional testing and analyses are ongoing and expected to be completed in the second quarter of 2022.

**Why will particulate testing only be completed in Q2 2022?**

Philips Respironics is conducting comprehensive testing and analyses with protocols that comply with the full extent of the relevant ISO standards (ISO 18562 and ISO 10993). These tests require long lead times of multiple months and involve significant oversight of the FDA. Comprehensive particulate testing and analyses are expected to be completed in the second quarter of 2022. Philips Respironics will continue to provide updates on results from these assessments.

**Did the first-generation DreamStation product family follow industry standards?**

The first-generation DreamStation devices were designed to meet all relevant standards at the time of development and launch and were approved by the relevant competent authorities.

**Has Philips Respironics started the repair and replacement actions?**

The repair and replacement program is underway. To date, Philips Respironics has produced a total of approximately 2.2 million repair kits and replacement devices.

**How long will it take to address all affected devices?**

Philips Respironics expects to complete over 90% of the production and shipment to customers in 2022.

**Is Philips Respironics selling devices to new patients?**

Because of the prioritization of the repair and replace program, Philips Respironics is currently not taking new orders for sleep therapy systems, while masks and other consumables continue to be sold. Philips Respironics expects to complete over 90% of the repair and replacement program in 2022.



## **Where can I find more information on the recall?**

More information on the recall can be found here: [www.philips.com/src-update](http://www.philips.com/src-update).

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

We have a strong and experienced legal defense team in place. Litigation is in preliminary stages, so it is too early to draw any conclusions on the merits of any claims or to speculate about any potential exposure.

## **Has Philips Respironics taken any provision related to potential litigation exposure?**

No. Litigation is in preliminary stages, and it is too early to speculate about any potential exposure.

## **Does Philips Respironics 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.

## **What does the FDA 518(a) order published on March 10, 2022 direct Philips Respironics to do?**

The order directs Philips Respironics to take certain actions to ensure that users, DMEs / distributors and health professionals receive notice of the recall and the potential health risks presented by the recalled devices within 45 days from the date of the order.

The order also directs Philips Respironics to (1) highlight language regarding the risk of using unapproved ozone cleaners on the recalled devices on its main webpage for the recall; (2) provide access to information regarding available data; and (3) continue to utilize Philips Respironics' mobile application to provide instructions for device users regarding recall updates and information.

## **What is the Form 483 published by the FDA on November, 12 2021 about?**

In connection with the recall, the U.S. Food and Drug Administration (FDA) conducted an inspection of a Philips Respironics manufacturing facility. Following the inspection, the FDA provided a list of their observations to Philips Respironics. On November 12, 2021, the FDA published these observations on its website and distributed a press release on the matter.

Importantly:

- The FDA has not changed its recommendation to patients and healthcare providers in relation to affected devices, nor repaired or replaced devices
- Philips Respironics evaluated the inspectional observations, and has submitted a comprehensive response, as well as a detailed action plan to the FDA



- Philips Respironics continues to engage with the FDA and will work closely with the agency to clarify and follow up on the inspectional findings and its requests
- Philips Respironics is committed to supporting the community of patients who rely on the affected devices, and the physicians and customers who are dedicated to meeting patient needs.

## **What are the next steps in the Form 483 process?**

Philips Respironics evaluated the inspectional observations and has submitted a comprehensive response, as well as a detailed action plan to FDA. Philips Respironics continues to engage with the FDA and will work closely with the agency to clarify and follow up on the inspectional findings and its requests. Philips cannot speak for the FDA on any steps it may or may not take in response to our Form 483 submission.

## **Will Philips Respironics make its responses to the FDA public?**

Philips Respironics continues to engage with the FDA and will work closely with the agency to clarify and follow up on the inspectional findings and its requests. It is important that the company first works through the process with the FDA and other regulators before commenting in detail.

## **Did Philips Respironics engage with the FDA on silicone foam testing?**

In coordination with the FDA, Philips Respironics is conducting additional independent testing to further substantiate the safety of the silicone replacement foam. The testing to support the use of silicone foam in the DreamStation 2 device and first-generation DreamStation devices was previously submitted to the FDA and demonstrated acceptable results.

