

## Philips Respironics field safety notice announced on June 14, 2021

Frequently Asked Questions – as of June 28, 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. 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. Philips Respironics provided test result updates on [December 23, 2021](#), and on [June 28, 2022](#). Further testing is still ongoing.

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

The provision is related to the cost to repair and/or replace affected devices 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. Philips Respironics provided test result updates on [December 23, 2021](#), and on [June 28, 2022](#). Further testing is still ongoing.

### **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 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 notification/field safety notice\*. While these additional testing and analyses are ongoing, Philips Respironics provided an update on [June 28, 2022](#). Philips Respironics will continue with the repair and replacement program.

### **Why is testing taking so much time?**

Philips Respironics is conducting comprehensive biocompatibility testing and analyses according to the relevant ISO standards (ISO 18562 and ISO 10993), as well as other tests.

The test and research program involves hundreds of very time-consuming tests. Philips Respironics is doing multiple tests to assure confidence in the results. Philips Respironics is running comprehensive testing by product category, and for each product category, it is investigating three types of situations: new devices, devices with lab-aged foam, and used devices.



The time taken to test and analyze the data per product category and situation is substantial and impacts throughput time for each test. The complexity of the test results also adds to the throughput time. Philips Respironics will continue to provide regular updates on findings from these assessments.

### **Did Philips Respironics run additional testing on the silicone foam as requested by the FDA?**

In November 2021, the FDA [requested](#) that Philips retain an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by silicone-based foam. Philips Respironics engaged independent testing laboratories to perform additional VOC testing. Based on the draft reports, Philips Respironics has not identified any safety issues. The assessment is being completed, and the final reports are subject to FDA review, which are expected in the coming months.

### **What do the latest testing results show in terms of the impact of ozone on the machines?**

The preliminary results already showed a significant exacerbation of foam degradation as a result of repeated ozone cleaning. As part of the visual assessment of returned devices, Philips Respironics has observed that devices with self-reported ozone use were 14x more likely to have significant visible foam degradation than those with self-reported no ozone use: 777 of 11,309 devices (7%) showed significant visible foam degradation, in comparison with 164 of 36,341 (0.5%) of devices with self-reported no ozone use. Testing is ongoing to assess the impact of repeated ozone cleaning on foam degradation in these devices.

Philips Respironics' 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 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 have been marketed pursuant to the relevant regulations.

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

The repair and replacement program is underway globally. To date, Philips Respironics has produced a total of approximately 2.7 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.

### **How many devices are affected by this recall notification/field safety notice\*?**

Philips Respironics expects to repair or replace a total of around 5.5 million devices (specific CPAP, BiPAP and mechanical ventilator devices) globally, of which approximately half are in the U.S. More than 90% of the registered affected devices to date are CPAP and BiPAP devices.

### **Why is repairing or replacing the devices expected to take so long?**

The repair and replacement program is a complex undertaking, because of the volume of devices to be remediated, and the outreach to every individual patient. In an average year, Philips Respironics produces and distributes around one million sleep devices. The increase of the production rate is



impacted by the supply chain challenges, such as component and freight capacity shortages. In the meantime, Philips Respironics has increased production by a factor of three.

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

Because of the prioritization of the repair and replacement 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 production and shipment to customers in 2022.

### **Where can I find more information on the field safety notice?**

More information on the recall notification/field safety notice\* 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?**

Philips Respironics has a strong and experienced legal defence 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 notification/field safety notice\* 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 notification/field safety notice\*; (2) provide access to information regarding available test data; and (3) continue to utilize Philips Respironics' mobile application to provide notice for device users regarding recall updates and information. Philips Respironics is complying with the order.

### **Has Philips Respironics responded to the proposed Form 518(b) order by the FDA? If so, when does Philips Respironics expect FDA's response on that?**

Philips Respironics has provided a written response to the FDA. Philips Respironics cannot speculate on when the FDA will respond.

### **As per the FDA's proposal to issue a 518(b) order, will patients receive a refund for their device?**

Philips Respironics is working hard to repair or replace the affected devices as quickly as possible, as Philips Respironics believes that is in the best interest of affected patients. Philips Respironics has submitted a written response to FDA's proposal to issue a 518(b) order. Philips Respironics cannot provide further comments at this time.



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

In connection with the recall notification/field safety notice\*, the FDA conducted an inspection of a Philips Respironics manufacturing facility in the US. 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.

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 provide routine updates to the FDA on its progress on the action plan and will continue to work closely with the agency. Philips Respironics cannot speak for the FDA on any steps it may or may not take in response to its Form 483 submission.

## **As stated in FDA's November 2021 Form 483, the FDA search identified 222,000 complaints related to the affected devices. Can you explain the discrepancy between Philips' disclosure and that of the FDA?**

The 222,000 complaints identified by the FDA were the result of broad word searches over multiple years retrieved from the Philips Respironics' database, and thus do not all relate specifically to the issues that led to the field safety notice or the foam issue. Using a validated protocol and a statistical methodology based on an established industry standard, Philips Respironics reviewed the complaints cited by the FDA, and found that approximately 3% of these complaints concerned alleged foam degradation.

## **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' subsidiary Philips Respironics evaluated and addressed on a case-by-case basis. Potential concerns relating to VOCs began to surface only more recently. When members of Philips' Executive Committee became aware of the issue and its potential significance, adequate actions were taken leading to the voluntary recall notification/field safety notice\* in the first half of 2021.

## **Have there been third party clinical studies in connection with the possible health risks?**

Philips Respironics is monitoring and reviewing clinical study publications that may be relevant for the June 2021 field safety notice for specific CPAP, BiPAP and mechanical ventilator devices.

Independent of Philips Respironics, in December 2021, an analysis was [published](#) in the American Journal of Respiratory and Critical Care Medicine that found no significant difference in the risk of incident cancer among obstructive sleep apnea (OSA) patients who used a Philips Respironics PAP device as compared with OSA patients who used a PAP device from other manufacturers, or OSA patients without treatment. The analysis and conclusion were based on data from a large multicenter cohort study involving 6,903 OSA patients on PAP devices between 2012 and 2020, including 1,220 Philips Respironics PAP users, with a median follow-up time of 7.5 years.

More recently, and also independent of Philips Respironics, an analysis was [published](#) online in the European Respiratory Journal in May 2022 that concluded that sustained and adherent CPAP therapy of OSA using Philips Respironics devices, compared with other manufacturers' devices, was not associated with an increased risk of cancer. The analysis and conclusion were based on data





from a large multicenter cohort study involving 4,447 OSA patients on CPAP devices between 2007 and 2018, including 1,648 Philips Respironics CPAP users, with a median follow-up time of 7.2 years.

Philips Respironics has also noted and reviewed the Swedish study, which was [published](#) in the European Respiratory Journal in May 2022. While the study reported an increased all-cancer and lung cancer incidence in counties prescribing  $\geq 80\%$  of CPAP devices containing polyurethane foam (PUF-CPAP) compared to patients from counties prescribing  $< 10\%$  of PUF-CPAP, the association disappeared in the sensitivity analysis excluding a Swedish county with known higher smoking rates. As the authors indicate: 'this finding needs further confirmation in other studies as it was not robust in sensitivity analyses and may be related to regional differences in lung cancer risk factors.'

Philips Respironics will continue to provide updates on relevant clinical studies as appropriate.

### **Can you comment on the FDA's notification regarding the Philips Medical Device Reports update for this recall notification/field safety notice\*?**

As noted in [May 24, 2022 Philips Respironics press release](#), 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 reasonable worst-case scenario for the possible health risks. Following Philips' public statements on the issue and possible risks to users in April 2021, and the announcement of the recall notification/field safety notice in June 2021, Philips Respironics received a steep increase in complaints allegedly associated with possible foam degradation.

This led to an increase from the 30 Medical Device Reports (MDRs) that had been filed by Philips Respironics to the FDA between 2011 and April 2021 prior to the recall notification/field safety notice\* (there were no reports of patient injury or death among these 30 MDRs), to more than 20,000 MDRs filed by Philips Respironics to the FDA between April 2021 and April 2022.

It is important to note that the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event, and that the cause of an event cannot typically be determined from this reporting system alone. Philips Respironics investigates all allegations of device malfunction, death, or serious injury.

### **Is there a change to the Health Hazard Evaluations following the testing results published on 28th June 2022?**

As testing is still ongoing, the Health Hazard Evaluations have not been updated yet.

The latest [update](#) is intended to provide healthcare providers, patients, and other stakeholders with updated information on the testing results to date. Philips will continue to provide regular updates as new test results and assessments become available, as not all tests have been completed to date. The overall guidance for healthcare providers and patients in the recall notification/field safety notice\* remains unchanged at this time.

### **Which remaining test results will Philips announce and when are these results expected?**

Philips Respironics expects to complete the remaining VOC and PM testing for first-generation DreamStation, DreamStation Go and SystemOne CPAP/BiPAP devices, as well as the degraded foam toxicological risk assessments (in accordance with ISO 10993) in the coming months. Philips Respironics will also continue with the tests to assess the impact of repeated ozone cleaning on foam degradation in these CPAP/BiPAP devices, as well as the remaining VOC and PM testing and





the degraded foam toxicological risk assessments for the Trilogy 100/200 and OmniLab ventilator devices.

In November 2021, the FDA requested that Philips retain an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by silicone-based foam. Philips Respironics engaged independent testing laboratories to perform additional VOC testing. Based on the draft reports, Philips Respironics has not identified any safety issues. The assessment is being completed, and the final reports are subject to FDA review, which are expected in the coming months.

**Where has Philips Respironics published the testing results and conclusions to date?**

The update on the PE-PUR testing results and conclusions available to date can be found [here](#).

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

