PHILIPS

Philips update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification*

Frequently Asked Questions – as of November 25, 2021

What is this update about?

On June 14, 2021, Philips' subsidiary, Philips Respironics, initiated a voluntary recall notification* for certain sleep and respiratory care products to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in these devices.

In connection with the recall, the US Food and Drug Administration (FDA) recently 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:

- Philips takes this matter very seriously and will fully collaborate with the FDA.
- Philips Respironics will submit its response to the inspectional findings for review by the FDA, in accordance with normal practice and timeline.
- An FDA investigator's list of inspection observations does not constitute a final FDA determination of whether any condition is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations.
- The FDA has not changed its recommendation to patients and healthcare providers in relation to affected devices.
- 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.
- It is Philips Respironics' expectation that the FDA announcement of November 12, 2021, will not result in a delay of the repair and replacement process.

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 were evaluated and addressed on a case-by-case basis. Issues relating to VOCs started to surface more recently, with testing and interpretation subsequently taking place with certified third-party experts, leading to the actions in the first half of 2021.

The FDA indicates that Philips Respironics' silicone foam, which is used in DreamStation 2, failed VOC testing in one instance for a product marketed outside the US. Is this correct?

The test referenced by the FDA did not relate to DreamStation 2, but to an unreleased design change related to the silicone replacement foam in the A-Series PAP device. This particular A-Series design is not marketed, nor has it been placed on the market globally. In accordance with normal practice and timeline, Philips Respironics will submit its explanation to this particular finding for review by the FDA, as other VOC testing of the A-Series PAP device with the silicone foam demonstrated acceptable results.

The testing to support the use of silicone foam in the DreamStation 2 device was previously submitted to the FDA and demonstrated acceptable results.

Did the FDA request additional independent lab testing? Will this delay Philips Respironics' repair and replacement program?

Philips Respironics is working with the FDA to clarify the scope of its request related to the use of an independent laboratory. Philips Respironics has been working with the FDA and other competent authorities to assure that our remediation process is fully compliant and meets all regulatory requirements. For completeness, Philips Respironics regularly works with certified third-party research firms and test labs, and is currently utilizing several certified third-party labs for its testing.

It is Philips Respironics' expectation that the FDA announcement of November 12, 2021, will not result in a delay of the repair and replacement process.

Does the further testing that Philips Respironics plans to share with the competent authorities already include the silicone foam, or will Philips Respironics have to initiate further testing on that?

The testing to support the use of silicone foam in the DreamStation 2 device was previously submitted to the FDA and demonstrated acceptable results.

The additional, ongoing testing is related to the PE-PUR foam to better assess and scope potential patient health risks, and Philips Respironics is engaging third-party experts to provide assessments. Philips Respironics plans to make more data available to the relevant competent authorities as soon as possible after completing the assessment of the above mentioned research and tests, which is anticipated to take place in the fourth quarter of 2021.

Is the FDA's announcement of November 12, 2021 in reaction to anticipated results of further testing that Philips Respironics plans to share? Did Philips Respironics already share the testing results with the FDA?

We are planning to make the data available to the relevant competent authorities including the FDA as soon as possible after completing the assessment of the PE-PUR foam research and tests, which is anticipated to take place in the fourth quarter of 2021.

When did Philips Respironics become aware of the Form-483 observations and the FDA's findings?

Philips Respironics became aware of the FDA's Form-483 observations on November 9, 2021. The FDA provided a list of their observations to Philips Respironics. In accordance with normal practice and timeline, Philips Respironics will submit its response to the inspectional findings for review by the FDA.

Importantly, an FDA investigator's list of inspection observations does not constitute a final FDA determination of whether any condition is in violation of the Federal Food, Drug, and Cosmetic Act or any of its implementing regulations. Additionally, the FDA has not changed its recommendation to patients and healthcare providers in relation to affected devices.

* Voluntary recall notification in the US/field safety notice outside the US

Forward-looking statements

These statements contain certain forward-looking statements with respect to the financial condition, results of operations and business of Philips and certain of the plans and objectives of Philips with respect to these items. Examples of forward-looking statements include statements made about the strategy, estimates of sales growth, future EBITA, future developments in Philips' organic business and the completion of acquisitions and divestments. By their nature, these statements involve risk and uncertainty because they relate to future events and circumstances and there are many factors that could cause actual results and developments to differ materially from those expressed or implied by these statements.