

Sep 01, 2021

Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification*

Amsterdam, the Netherlands – [Royal Philips](#) (NYSE: PHG; AEX: PHIA) today announced an update in connection with the June 14, 2021 recall notification* for specific Philips sleep and respiratory care devices that was issued to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in these devices. More than half of the affected devices in use globally are in the US. The vast majority (>80%) of the registered affected devices in the US to date are in the first-generation DreamStation product family.

Philips received authorization from the US Food and Drug Administration (FDA) for the rework of the affected first-generation DreamStation devices [1], which consists of replacement of the PE-PUR sound abatement foam with a new material. Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has 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 in the US [2].

Philips is initiating the repair and replacement programs in other countries as well and expects to have these underway in the majority of its markets by the end of September 2021. The company intends to complete the repair and replacement programs within approximately 12 months.

“We fully recognize that the timeframe for remediation of the affected devices places patients in a difficult situation,” said Frans van Houten, CEO of Royal Philips. “We are mobilized to deliver a solution to them as fast as possible. We have significantly increased our production, service and rework capacity, and further intensified our outreach to our customers and their patients. We urge patients with affected active devices to register these on the dedicated recall notification website.”

More information on the recall notification, as well as instructions for customers, users, and physicians can be found at www.philips.com/src-update. Patients with affected devices currently in use are requested to register their products on this website to facilitate the repair and

* This is a recall notification for the US only, and a field safety notice for the rest of the world. In the US, the recall notification has been [classified by the FDA as a Class I recall](#).

[1] This includes DreamStation CPAP, Auto CPAP; Dream Station Bi-Level PAP; DreamStation ASV; and DreamStation ST, AVAPS devices.

[2] The remaining affected devices for remediation in the US can be found at www.philips.com/src-update.

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Contacts



Ben Zwirs

Philips Global Press Office

Tel: +31 6 1521 3446



Derya Guzel

Philips Investor Relations

Tel: +31 20 59 77055

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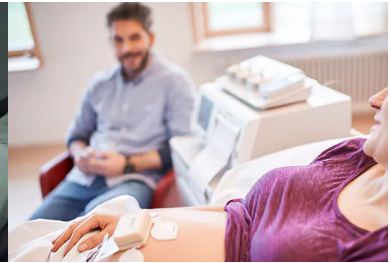
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