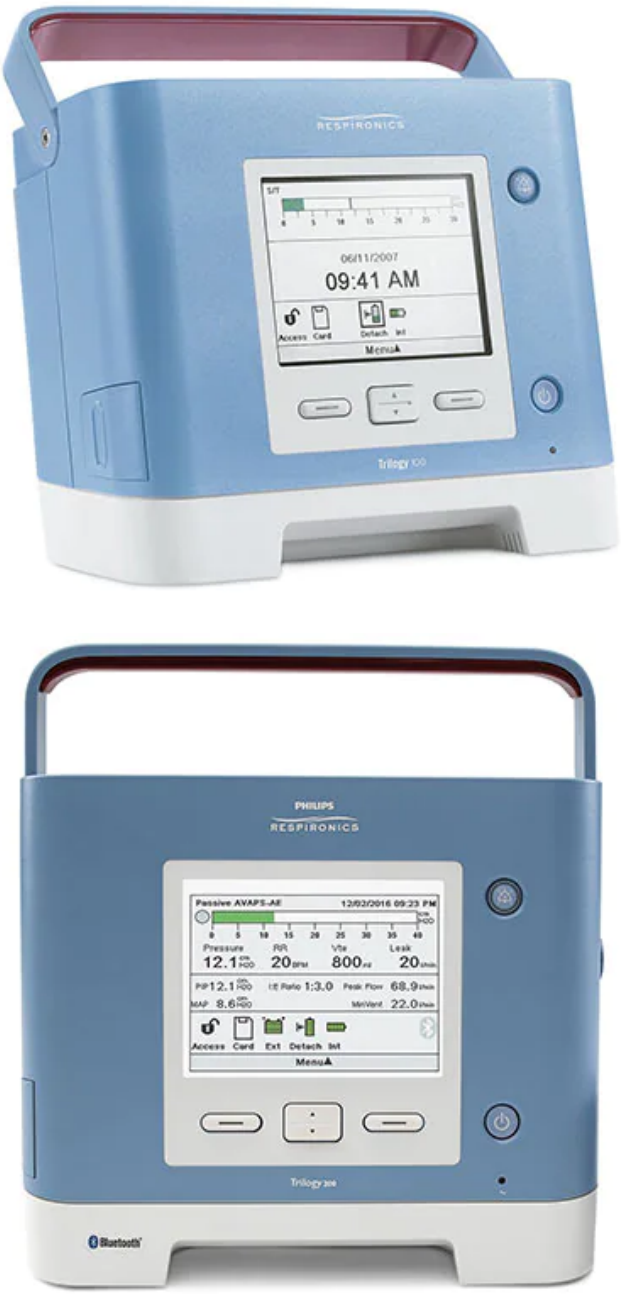
Nov 21, 2022

Philips Respironics update related to Trilogy 100/200 repairs

Estimated reading time: 1-3 minutes

On June 14, 2021, Philips' subsidiary Philips Respironics, initiated a voluntary recall notification/field safety notice to address potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam in specific CPAP, BiPAP and mechanical ventilator devices. Philips Respironics expects to repair or replace approximately 5.5 million devices globally, and approximately 95% of the registered affected devices are CPAP and BiPAP sleep apnea devices. The repair and replacement program involves the replacement of the PE-PUR sound abatement foam by silicone foam. The repair and replacement of CPAP and BiPAP sleep apnea devices is well underway globally.

Following the preparations and relevant clearances, the repair of Trilogy 100/200 ventilators (approximately 3% of the registered affected devices globally) has started in recent months. Philips Respironics has now detected two problems with corrected Trilogy 100/200 ventilators following a limited number of complaints from the US and Japan. These problems only affect the Trilogy 100/200 ventilators that have already been repaired.



Philips Respironics Trilogy 100 and 200 devices

These problems do not affect any of the CPAP or BiPAP sleep apnea devices that have been remediated.

The identified problems for repaired Trilogy 100/200 devices are the following:

- *Silicone Foam Separation* - Post market surveillance data received from Japan and the US indicate that silicone sound abatement foam installed in reworked Trilogy 100/200 devices may potentially separate from the plastic backing to which it is adhered. Separation of the foam could impact the performance of the device by potentially blocking the air inlet and thus lowering the inspiratory pressure. If the air pressure is significantly impacted, the device could issue a ventilator alarm, such as the *Low Inspiratory Pressure* alarm. As of November 1, 2022, the observed occurrence rate of reportable events is less than 0.015 percent of corrected Trilogy 100 devices. Based on information available to date, the root cause is associated with an assembly step in inserting the silicone foam.

- *Presence of trace amounts of air pathway particulate matter after the repair/rework* - Post market surveillance data received from the US indicate that trace amounts of particulate matter have been found in the air pathway after the devices were reworked. Particulate samples were sent to a third-party lab for evaluation, and in certain cases the particulates were confirmed to be PE-PUR foam, while in other cases, the particulates were confirmed to be environmental debris. The investigation is ongoing.

Philips Respironics has reported the two problems to the relevant competent authorities globally and expects to complete its investigation and root cause analysis of both problems before the end of this month. Based on the results of the investigation, Philips Respironics will take appropriate action if required. While Philips Respironics investigates these issues, the company has temporarily suspended the repair of Trilogy 100/200 devices.

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