Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

URGENT PRODUCT DEFECT ALERT*

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2022-RN-01396-1

DATE AGREED: 11/11/2022

PRODUCT: **Trilogy 100 portable ventilator devices**

ARTG 159490
(Philips Electronics Australia Ltd - Portable ventilator, electric)

SPONSOR: Philips Electronics Australia Ltd

CONTACT INFORMATION: 1800 009 579 - Local Philips representative

REASON: Philips Electronics is advising that the silicone sound abatement foam installed into the device during the correction for (RC-2021-RN-01372-1) may separate from the plastic backing to which it is adhered, which could affect the performance of the equipment. If separation of the new foam from the plastic backing was to occur to the extent that therapy is impacted, your device will issue a High Priority ventilator alarm, such as "Low Inspiratory Pressure" or "Circuit Disconnect."

This alert relates only to Trilogy 100 ventilators that have already been corrected as part of the ongoing Product Defect Correction (RC-2021-RN-01372-1) related to the PE-PUR sound abatement foam in these devices.

Currently, the observed occurrence rate of reportable events is less than 0.015 % of corrected Trilogy 100 devices, and there has been no reported incidents in Australia.

PROPOSED CUSTOMER ACTIONS: Issue 1 – If a High Priority ventilator alarm, such as 'Low Inspiratory Pressure or 'Circuit Disconnect' sounds, and doesn't resolve

- Patients should switch over to their other device.
- Call Philips and a Philips Clinical Expert will discuss possible options, which may include using a Philips Trilogy Evo as an alternative device.

Issue 2 – Philips will contact state health providers and prescribers, regarding the use of an in-line bacterial filter. If prescribed, Philips will organize delivery and instructions for use of new inline bacterial filters. It is important to note that this is not a fix to the problem, but this may help reduce exposure to any particulate matter.

- Filters may affect ventilator performance because they may increase resistance of air flow through the device.
- You should closely monitor for possible accumulation of foam debris on the filter or resistance-related problems in the breathing circuit after filter placement

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 84 hospitals and health facilities nationally excluding ACT, NT and TAS

Product export status: N/A

This issue was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) – https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-01396-1

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm