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URGENT Medical Device Recall

Trilogy 100 and Trilogy 200
Silicone Sound Abatement Foam Delamination

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

Dear Customer,

Philips Respironics has detected an issue impacting Trilogy 100 and Trilogy 200 devices that were previously corrected by Philips Respironics as part of the ongoing correction of PE-PUR sound abatement foam. Post market surveillance data received by Philips Respironics indicate that these devices, which were remediated and now contain new foam, could experience a malfunction.

This letter is intended to inform you of this issue, the potential hazard your patients may experience, the steps you must take to ensure safe and effective use of the equipment, and how Philips Respironics will correct the issue.

A list of your equipment impacted by this issue is included with this letter.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

This does not affect CPAP or BiPAP sleep apnea devices.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1 (800) 345-6443.

1. What the issue is and under what circumstances it can occur

The replacement silicone sound abatement foam installed into the Trilogy 100 and Trilogy 200 devices identified in this letter may separate from the plastic backing to which it is attached. If this were to happen, the foam could potentially block air inlet, which could result in a reduction in delivered therapy volume or pressure and could cause the device to alarm. Additionally, Philips Respironics has observed residual PE-PUR sound abatement foam in some devices that were returned to the field. These cases were limited but further exposure to PE-PUR sound abatement foam should be avoided.

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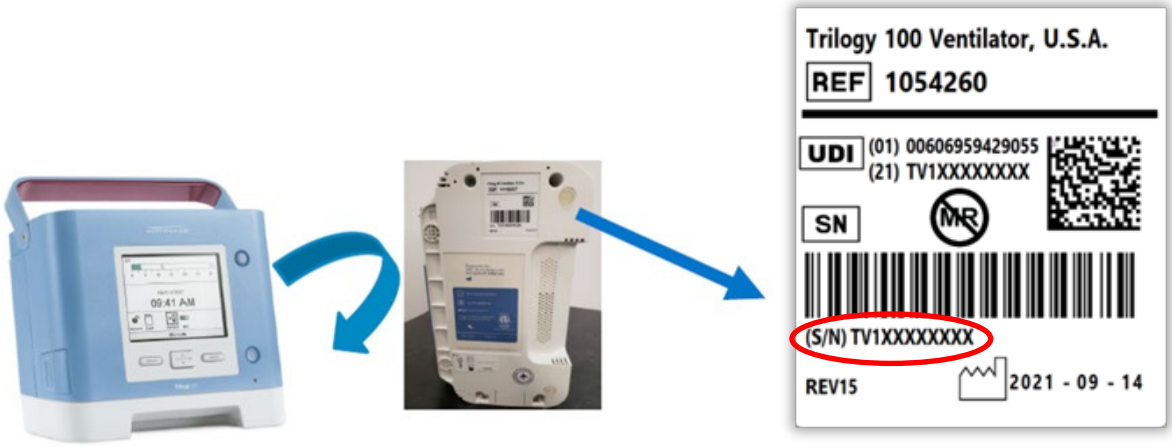
2. Description of the hazard associated with the issue

If the adhesive binding the silicone-based sound abatement foam fails, the material may shift its position within the inlet airpath housing of the Trilogy ventilator, potentially obstructing the airpath, which could cause a reduction in delivered therapy volume or pressure and could also cause the device to alarm. If an alarm is not recognized or acted upon, the patient could experience asphyxia, hypoventilation, or hypoxemia. These hazards could be life threatening if not recognized and mitigated by the care provider.

3. Affected products and how to identify them

A list of equipment affected by this issue is included with this letter. The devices are identified by Serial Number. The Serial Number is located on the bottom of the Trilogy Ventilator.



4. Actions you must take as a device owner or healthcare provider to prevent risks for patients.

Device is on patients:

For affected Trilogy 100 and Trilogy 200 devices that are on patients, ensure that your clinical assessment of the patients is up to date, reflecting the true acuity of the patients and their respiratory therapy requirements. Your patient may experience serious harm if their device malfunctions and immediate intervention is not available. Until Philips Respironics is able to correct this problem you must adhere to the instructions below. Further instructions are provided below for devices that are not on patients.

- **For ventilator dependent patients:**
  1. Consider transitioning ventilator dependent patients to an alternative life-support ventilator if, as determined by the clinical assessment for the individual patient in consultation with the patient's healthcare provider, a malfunction would lead to serious injury if timely access to a backup ventilator is not possible.
  2. Quarantine all impacted devices that are removed from service.
  3. **Please indicate which Serial Numbers must be removed from service in exchange for an alternative device**

- **For all other patients:**
  1. Ensure that device alarm settings are configured appropriately for your patient's needs, with special consideration for the alarms listed below. Ensure that alternative ventilation equipment is available, as appropriate to patient need, in case of emergency issues with alarms that cannot be resolved.

2. Ensure that backup monitoring is configured as required by the clinical assessment. Pulse oximetry, ECG, heart rate, blood pressure, or respiratory rate may provide additional advanced warning of and lead to faster intervention if hypoxemia were to occur. If these accessories are prescribed, ensure patients advised of proper use.
3. Consider using an inline bacterial filter which may help filter out particles of PE-PUR foam. It is important to note the following considerations:
    - Filters may affect ventilator performance because they may increase resistance of airflow 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 replacement.
    - Consult your Instructions for Use for guidance on installation.

The following alarms could be triggered if the silicone foam separates from airpath:

- Low Inspiratory Pressure
- Low Minute Volume
- High Temperature
- Check Circuit
- Low Circuit Leak

If alarms do occur, caregivers or healthcare professionals must investigate the source of the alarm. If the situation cannot be resolved, then the ventilator must be exchanged for a back-up ventilator.

Device is not on patients:

1. Immediately quarantine any affected remediated Trilogy 100 and Trilogy 200 devices that are not currently on patients and await further instructions from Philips Respironics for returning this inventory.
2. **Indicate which Serial Numbers have been quarantined in your response to this letter.**

5. Actions Planned by Philips Respironics to correct the problem

Interim Options:

Philips Respironics is offering Trilogy Evo devices on loan (as supply is available) for patients that must be transitioned due to the acuity of their care. In addition, customers may elect to receive a credit for returned affected Trilogy 100 and Trilogy 200 devices instead of remediation. Further information regarding these two programs will be shared separately.

Supporting material is available to assist caregivers in transitioning Trilogy 100 and Trilogy 200 users to Trilogy Evo devices.

Permanent Corrective Action planned by Philips Respironics:

Philips Respironics is developing a permanent corrective action in coordination with competent authorities. Once available, Philips Respironics will contact you to begin the correction process.

If you need any further information or support concerning this issue, please contact your local Philips representative or Philips Customer Service at 1 (800) 345-6443.

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This notice has been reported to the appropriate Regulatory Agencies. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax.

We understand the frustration this may cause. We remain committed to transparency throughout the process and will provide an update as soon as possible. Thank you for your continued patience and trust.

Sincerely,

Tom Fallon
Head of Quality
Philips Respironics

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Impacted Equipment

Examples for completing the table:

- **Device is on patient and therefore not yet quarantined. Alternative device is needed. Please complete model number and serial number. Indicate 'NO' for device quarantined and 'YES' for alternative device needed.**
- **Device is in inventory and has been quarantined. An alternative device is not needed. Please complete model number and serial number. Indicate 'YES' for device quarantined and 'NO' for Trilogy Evo needed.**

Model Number	Product Description	Serial Number	Device Quarantined?	Trilogy Evo Needed?
CA1054096B	Trilogy 100	TV119032514	☐ YES ☐ NO	☐ YES ☐ NO
CA1054096	Trilogy 100	TV114071008	☐ YES ☐ NO	☐ YES ☐ NO
CA1032800B	Trilogy 200	TV218050852	☐ YES ☐ NO	☐ YES ☐ NO
CA1032800B	Trilogy 200	TV21903063D	☐ YES ☐ NO	☐ YES ☐ NO

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URGENT MEDICAL DEVICE RECALL RESPONSE FORM

Reference: Trilogy 100 and Trilogy 200, Silicone Foam Malfunction – 2022-CC-SRC-045

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Medical Device Recall Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:

Street Address:

City/State/ZIP/Country:

Customer Actions:

1. Quarantine any affected Trilogy 100 and Trilogy 200 devices that are not currently on patients. **Please indicate which Serial Numbers have been quarantined in your response to this letter**
2. Identify patients that will be transferred to an alternative device. **Please indicate which Serial Numbers must be removed from service in exchange for an alternative device**

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Trilogy 100 and Trilogy 200 devices.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please email the completed form to pms.fac@philips.com or fax to 1-888-220-9274