Philips Remediated Trilogy 100 & 200 Recall FAQ

1. **Is Philips recalling the Trilogy 100 & 200 ventilators again?**
   Philips has detected an issue impacting Trilogy 100 and Trilogy 200 devices that were previously corrected by Philips as part of the ongoing fix to the PE-PUR sound abatement foam. Post market surveillance data received by Philips indicated that these devices, which were remediated with new foam, could experience a malfunction.

   This does not affect CPAP or BiPAP sleep apnea devices.

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

2. **What is the issue?**
   The replacement silicone sound abatement foam installed into the remediated Trilogy 100 and Trilogy 200 devices may separate from the attached plastic backing. If this were to happen, the foam could potentially block air inlet, resulting in a reduction in delivered therapy volume or pressure and could cause the device to alarm. A remediated device is a one that had received a FDA-approved fix by Philips for the PE-PUR foam under recall and was returned to the home medical equipment provider.

   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.

   If the adhesive binding the new silicone-based sound abatement foam fails, the material may shift its position within 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. **Who is affected?**
   This recall of remediated Trilogy 100 & 200 devices affects all devices that had PE-PUR foam replaced with new silicone foam that may have been put back into service with patients between September 13 and December 7, 2022, that patients received under the original Philips recall. Patients may have received a remediated device either to replace their recalled vent or as a new patient.

4. **How do I know if my replacement device is experiencing this issue?**
   Your device may trigger an alarm if the new replacement foam has detached, but not all alarms mean that the foam has detached.

   If alarms do occur, caregivers must investigate the source of the alarm. If the situation cannot be resolved immediately, please contact SuperCare Health for further assistance at (800) 206-4880, option 2 then option 5. If the alarm still cannot be resolved, the ventilator must be exchanged for a replacement ventilator.

Philips has identified the following possible alarm triggers if the new silicone foam separates from airpath:

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

5. **I received a replacement device from the original recall. What should I do?**
   Philips is responsible for the full repair or replacement of Trilogy 100 & 200 vents affected by the initial recall of PE-PUR foam and the second recall of fixed units that may experience detachment of the new silicone foam. Philips is working on a new fix for the current issue for the detaching silicone foam and it will need to be approved by FDA before it can be implemented.

   SuperCare Health is contacting patients with a remediated ventilator and will work on transitioning you to an alternate device. Please let us know if you have been experiencing any signs of detached silicone foam so your transition can be prioritized. Your device is set up with a bacterial filter so concern about any residual PE-PUR foam is at a lower urgency.

   SuperCare Health will support you as best we can, but any potential transition to an alternative or newly fixed device is dependent on device availability from manufacturers.

6. **I still haven't received my remediated ventilator from the original recall. What should I do?**
   Philips is responsible for the full repair or replacement of Trilogy 100 & 200 vents affected by the initial recall of PE-PUR foam and the second recall of fixed units that may experience detachment of the new silicone foam. Philips is working on a new fix for the current issue for the detaching silicone foam and it will need to be approved by FDA before it can be implemented.

   The original recommendations from Philips regarding the recall of PE-PUR foam still applies. Patients should continue to use their vents until Philips provides repairs. Considering the additional delay due to issues with the current fix, SuperCare Health will be working with your physician and clinical care team to see if you need to be transitioned to an alternate device, subject to product availability and viability.

   SuperCare Health will support you as best we can, but any potential transition to an alternative or newly fixed device is dependent on device availability from manufacturers.

7. **Can I continue to use my replacement Trilogy 100 or 200 vent?**
   Philips Respironics is recommending that patients with remediated devices affected by detaching silicone foam, talk to their physicians and clinical care team about the possibility of transitioning to an alternate device. SuperCare Health provides a bacterial filter with ventilators, which minimizes exposure if there is any residual PE-PUR foam.

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8. **How do I get a replacement for my replacement Trilogy 100 or 200?**
   Philips is responsible for the full repair or replacement of Trilogy 100 & 200 vents affected by the initial

recall of PE-PUR foam and the second recall of fixed units that may experience detachment of the new silicone foam. Philips is working on a new fix for the current issue for the detaching silicone foam and it will need to be approved by FDA before it can be implemented.

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SuperCare Health will support you as best we can, but any potential transition to an alternative or newly fixed device is dependent on device availability from manufacturers.

9. **I do have a remediated device that is affected by the new recall? When will I get a new vent? I need it to breathe.**
   Philips is responsible for the full repair or replacement of Trilogy 100 & 200 vents affected by the initial recall of PE-PUR foam and the second recall of fixed units that may experience detachment of the new silicone foam. Philips is working on a new fix for the current issue for the detaching silicone foam and it will need to be approved by FDA before it can be implemented.

   SuperCare Health will support you as best we can, but any potential transition to an alternative or newly fixed device is dependent on device availability from manufacturers.