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Update: Urgent Medical Device Correction
Philips Respironics - Hospital Respiratory Care

V60/V60 Plus Ventilator
35V Rail – 2021-CC-HRC-003

30 June 2022

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

Please review the following updated 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,

The purpose of this letter is to provide you an update on Philips Respironics's actions to address an issue related to the internal source ("35V Rail") that powers the V60/V60 Plus ventilators. Specifically:

- To address the issue with the 35V Rail, Philips Respironics will be deploying a technical solution (changing two resistors within the ventilator) that will cause the V60/V60 Plus ventilators to alarm in all cases should the ventilator experience an issue with the 35V Rail. Philips Respironics will be contacting customers to schedule an appointment to implement the technical solution in your V60/V60 Plus ventilator(s) starting in October 2022.

- Should a customer be unable to implement one of the mitigations provided in the April 2022 customer letter, Philips Respironics is offering customers a loaner Trilogy EV300 ventilator while awaiting deployment of the technical solution to its V60/V60 Plus ventilators.

All other information provided in the April 2022 customer communication is unchanged. This notice needs to be provided to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Follow the actions below that should be taken by the customer/user to prevent risks for patients

While awaiting deployment of the technical solution, customers must continue to implement **at least one of the mitigations** provided in the April 2022 letter (repeated below) to mitigate the risk of the hazard caused by the 35V Rail issue.

External Oxygen Monitoring. The V60/V60 Plus User Manual provides the following **WARNING**: Provide external oxygen monitoring to minimize patient risk in case of O_2 supply loss or ventilator failure. External oxygen monitoring can include:

- **Oxygen Analyzer.** Install oxygen analyzer/monitor, and follow the manufacturer's instructions for setup, alarms and calibration, *and/or*

- **Pulse Oximetry.** Use pulse oximetry to inform the clinician of a change in the patient's condition.

Connect the Philips Respironics V60/V60 Plus to a nurse call/remote alarm. Philips Respironics V60/V60 Plus ventilators can be connected to a nurse call/remote alarm.

- The V60/V60 Plus User Manual provides the following **WARNING**: The nurse call/remote alarm should be considered a backup to the ventilator's primary alarm system. The nurse call/remote alarm will provide a backup signal to the clinician even if the ventilator's primary alarm system does not activate. To prevent possible patient injury due to nonannunciating alarms, verify the operation of any nurse call/remote alarm before use.

- For details about connecting the V60/V60 Plus to a remote alarm, refer to Appendix B: Communications Interface: Remote Alarm Port section of the V60/V60 Plus User Manual.

- Respond to Alarms. As directed in Chapter 9 of the V60/V60 Plus User Manual, alarms and messages on the ventilator alert you to situations that require your attention. Promptly respond to all low priority alarms and immediately respond to all high-priority alarms presented by the ventilator. High priority alarms flash black and red on both the V60/V60 Plus ventilators with a repeating sequence of 5 tones.

In addition to the above, other actions to be taken by the customer/user are as follows:

- **Access to Alternative Ventilation Device.** Per the **WARNING** in the V60/V60 Plus User Manuals, an alternative means of ventilation should be available whenever the ventilator is in use. If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with such a device. The ventilator must be removed from clinical use and serviced by authorized service personnel.

If the customer/user is **unable** to implement **any** of the actions above, they should do the following:

- Where acceptable for your patient population, request loaner Trilogy EV300 ventilator(s). The Trilogy EV300 is not identical to the V60/V60 Plus ventilator and may require patient acclimation, but offers a temporary option for certain non-invasive ventilation applications. To request a Trilogy EV300 Loaner device, please send an email request to **HRC.NA.V60_V60Plus.Support@Philips.com**.

- Where loaner Trilogy EV300 ventilator(s) are not acceptable, conduct a risk/benefit analysis to evaluate whether you should continue to use the impacted devices. Philips Respironics is aware of one (1) death and two (2) serious injuries associated with the 35V Rail issue for the V60/V60 Plus where the device was alleged not to have alarmed. The total number of serious injuries with the 35V Rail issue for the V60/V60 Plus, where the device was alleged to have alarmed, is three (3).

Acknowledge Receipt of this Urgent Medical Device Correction Letter. Acknowledge receipt of this notification by fax or e-mail, via the attached "URGENT MEDICAL DEVICE CORRECTION RESPONSE FORM".

Should your V60/V60 Plus unexpectedly cease function (with or without alarms), contact your local Philips customer service representative to report the issue.

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

Upon request, Philips can provide technical assistance to implement the nurse call/remote alarm capability while you await servicing.

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.

If you need any further information or support concerning this issue, please contact your local Philips representative: Call 24/7 - Customer Care Solutions Center +1-800-722-9377.

This notice has been reported to the appropriate Regulatory Authorities. Philips Respironics is committed to addressing the issue and regrets any inconvenience caused by this problem.

Sincerely,

Michael Mizrachi
Head of Quality Assurance
Philips Hospital Respiratory Care

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URGENT MEDICAL DEVICE CORRECTION RESPONSE FORM

Field Correction Regarding the V60/V60 Plus 35V Rail

Customer Number:

Instructions: *Please use QR code OR 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 Correction Letter, understanding of the issue, and required actions to be taken.*

Customer/Consignee/Facility:

Street Address:_____

City/State/ZIP/Country:_____

We acknowledge receipt and understanding of the accompanying notification and confirm that the information from this Letter has been properly distributed to all users that handle Philips Respironics V60/V60 Plus Ventilators.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Upon completion and Acknowledgment return it to Philips by either of the following methods:

1. Utilize QR code at the top of this page and follow instructions
2. Email the completed and signed form to HRC.Recall.Response@Philips.com
3. Fax the completed and signed form to 1-833-371-1023