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Update: Field Safety Notice
Philips Respironics - Hospital Respiratory Care

V60/V60 Plus/V680 Ventilator
35V Rail – 2021-CC-HRC-003

21 April 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 Distributor,

Philips Respironics previously notified you of an issue impacting all V60/V60 Plus and V680 ventilators. As noted below in items 4 and 5, Philips Respironics is providing new additional information to you concerning this issue in this letter. Specifically, as noted in item 4 disregard the instructions provided in the prior correspondence and implement one of the listed actions to mitigate the potential hazard caused by the issue. If you are unable to implement any of the mitigations, you should conduct a risk/benefit analysis to evaluate whether you should continue to use the impacted devices. As noted in item 5, Philips Respironics is committed to implementing a solution to address the issue and will provide regular updates to you on the solution.

All other sections from the prior correspondence are unchanged but repeated below for your convenience.

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

All V60/V60 Plus and V680 units have been identified to have an issue related to the internal source ("35V Rail") powering the ventilator. In rare and unpredictable cases an anomaly affecting power management may lead to the ventilator shutting down and the patient no longer receiving respiratory assistance.

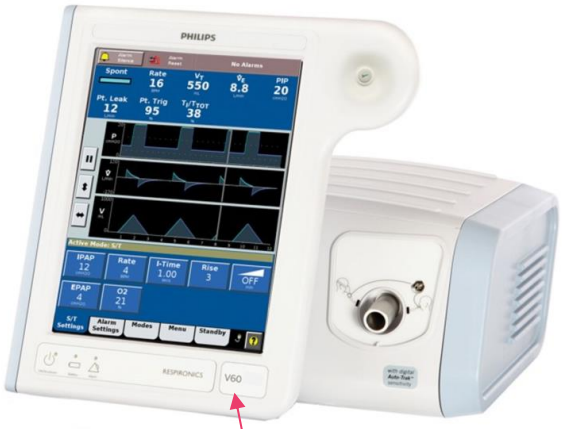
2. Describe the hazard/harm associated with the issue

In most cases when the anomaly occurs, an alarm will sound, prompting the clinician to provide alternative ventilatory support. In a small fraction of the cases, the ventilator may shut down without an alarm. If visual monitoring, or if independent alarm systems, such as external oxygen monitoring (recommended in the instructions for use), a remote nurse call system, or pulse oximetry, are not in place, the clinician may not respond promptly to provide respiratory support. In such circumstances, the patient may experience serious deterioration in health and possibly death. To date, Philips Respironics is aware of one (1) death and one (1) serious injury associated with the 35V Rail issue for the V60/V60 Plus where the device was alleged not to have alarmed, and three (3) serious injuries with the 35V Rail

issue for the V60/V60 Plus where the device was alleged to have alarmed. There have been zero (0) deaths or serious injuries with the 35V Rail issue for the V680 ventilator.

3. Affected products and how to identify them

All V60/V60 Plus ventilators are impacted by this issue regardless of date of manufacture.

How to Identify the Device	 Identifies ventilator model (V60/V60 Plus)  Identifies ventilator model (V680)

4. Disregard the instructions provided in the prior correspondence. Follow the actions below that should be taken by the customer/user to prevent risks for patients

You **must implement** one or more of the following actions 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. As described in Chapter 9 of the V680 User Manual, an external O_2 monitor can be used when O_2 alarms are disabled. 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 or V680 to a nurse call/remote alarm. Philips Respironics V60/V60 Plus and V680 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.
- To connect the Philips Respironics V680 to a remote alarm, follow the directions provided in Section B: Communications Interface: Remote Alarm Port section of the V680 User Manual.
- Respond to Alarms. As directed in Chapter 9 of the V60/V60 Plus and V680 User Manuals, 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 and V680 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 and V680 User Manuals, an alternative means of ventilation should be available/accessible whenever the ventilator is in use. If a V60/V60 Plus or V680 ventilator experiences a failure, or a fault is detected in the ventilator, as per the WARNINGS, immediately remove the ventilator from use by disconnecting the patient from it and immediately start ventilation with an alternate device. The ventilator must be removed from clinical use and serviced by authorized service personnel.

If you are unable to implement any of the actions above, you should conduct a risk/benefit analysis to evaluate whether you should continue to use the impacted devices. As noted above Philips Respironics is aware of one (1) death and one (1) serious injury associated with the 35V Rail issue for the V60/V60 Plus where the device was alleged not to have alarmed and, (3) serious injuries with the 35V Rail issue for the V60/V60 Plus where the device was alleged to have alarmed. There have been zero (0) deaths or serious injuries with the 35V Rail issue for the V680 ventilator.

- **Acknowledge Receipt of this Field Safety Notice Letter.** Acknowledge receipt of this FSN by fax or e-mail, via the attached "FIELD SAFETY NOTICE RESPONSE FORM".

Should your V60/V60 Plus or V680 ventilator shutdown unexpectedly (with or without alarms), contact your local Philips customer service representative to report the issue.

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.

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5. Describe the actions planned by Philips to correct the problem

Philips Respironics is committed to addressing the issue and will provide regular updates to you on the development of its plan to address the issue. The first update will be provided no later than June 30, 2022.

Upon request Philips can provide technical assistance to implement the nurse call/remote alarm capability.

Adverse reactions or quality problems experienced with the use of this product may be reported to Philips or to the local competent authority.

It is imperative that all end-users with affected Philips V60/V60 Plus or V680 ventilators receive this Field Safety Notice. Because Philips sells these products through distributors, including your organization, we may not have the information to contact all users. Therefore, please send a copy of the attached Field Safety Notice to any customer to whom you have distributed one of the affected devices. Note: Philips has sent this notification to all customers to whom Philips shipped directly (i.e. customers in the "Ship To" field on the original invoice).

In addition, please provide your local Philips organization with the names and addresses of the customers to whom you have sold affected devices, so that arrangements can be made to provide the correction.

If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Authorities.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Thomas Fallon
Head of Quality Assurance
Philips Hospital Respiratory Care

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FIELD SAFETY NOTICE RESPONSE FORM

Field Safety Notice Regarding the V60/V60 Plus and V680 35V Rail

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 Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

We acknowledge receipt and understanding of the accompanying Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle Philips Respironics V60/V60 Plus and V680 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:

<Reply form return details to be completed by the KM / country>.