Product Defect Alert

PHILIPS

Philips Healthcare
Locked Bag 30
North Ryde
NSW 1670
Australia

July 2022

2021-CC-HRC-003

TGA Reference #:	RC-2022-RN-00515-1
Product / Device Name / Model #	Philips V60/V60 Plus/V680 Ventilator
ARTG Ref #	285664, 230065
Short Problem Description	Main electrical circuit ("35V Rail") powering the ventilator and alarm

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,

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 and V680 ventilators. Specifically:

- To address the issue with the 35V Rail, Philips Respironics will be deploying a technical solution (changing two resistors within the ventilator). This solution will cause the V60/V60 Plus and V680 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. The V680 field action is expected to start in Q1 2023.

All other information provided in the April 2022 customer communication is unchanged. . Users are reminded this issue may result in the affected devices unexpectedly shutting down (with or without alarm). 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

TGA recommends that where possible, remove affected ventilators from use and source alternative ventilators for your organisation until such time as this issue has been resolved.

In the event your facility does not have access to alternative means of ventilation, 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. 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*

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- **Pulse Oximetry.** Use pulse oximetry to inform the clinician of a change in the patient's condition.
- **In Australia, independent capnography (CO_2) monitoring should be used when practical and appropriate.** Alarm limits on this monitoring should be set, as appropriate for the patient. The purpose of capnography is to provide reassurance that the patient is breathing and that there is airflow through the machine. It should not be used as a substitute for blood sampling to monitor CO_2 levels.

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 the customer/user is **unable** to implement **any** of the actions above, then they should conduct a risk/benefit analysis to evaluate whether they should continue to use the impacted devices. Philips Respironics is aware of one (1) death and two (2) serious injury associated with the 35V Rail issue for the V60/V60 Plus where the device was alleged not to have alarmed (unchanged since the April 2022 communication). Since the April 2022 communication, Philips Respironics has updated the total number of serious injuries with the 35V Rail issue for the V60/V60 Plus where the device was alleged to have alarmed (four (4) total serious injuries). 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 Customer Acknowledgement Form within 3 business days, even if you do not have any affected stock. Return via ***email: qr_anz@philips.com or fax: 02 99470240 Attn. - Q&R Department.***

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Should your V60/V60 Plus or V680 ventilator 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 Philips or to the local competent authority.

If you need any further information or support concerning this issue, please contact our **Philips Service Delivery Team on 1800 251 400.**

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,

Princess Nochefranca
Post Market Surveillance Specialist
Philips Healthcare Australia and New Zealand

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Customer Acknowledgement Form

Please complete this form within 3 business days, *even if you do not have any affected stock.*
Return via email: qr_anz@philips.com or fax: 02 99470240 Attn. - Q&R Department.

On behalf of this organisation, I acknowledge receipt of this notice relating to the above product.

Site / Hospital Name:			
Your Name & Position			
Your Contact details: Phone Fax Email address			
Site's Email Address to send Product Defect Alert:			
Signature		**Date**	

Affected Stock

If you have no affected stock, tick this box: ☐
If you have affected stock, please complete the stock details table below.

List the Devices on site with serial # and software version

Distributed and the actions taken/other relevant details *e.g. All staff was made aware of the required action as stated.* (Attach a separate sheet if required)

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ **No**	☐ **Yes**	☐ **Yes**

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	I/we will forward all the recall information to the suppliers/distributors/customers	(please supply names and contact information of the organisations)