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Field Safety Notice
Philips Respironics - Hospital Respiratory Care

Philips Respironics V680 Ventilator Market Removal (2022-CC-HRC-013)

13-January 2023

This document contains important updated information regarding your Philips Respironics V680 device.

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.

Dear Valued Customer,

The purpose of this letter is to communicate a **market removal over the next six months of the Philips Respironics V680 (V680) ventilator.** Although the original plan was to continue servicing the V680 ventilator through December 2025, Philips Respironics has made a business decision to **no longer support this product past July 2023**.

The V680 ventilator, product model number 850011, was launched in 2014 and production was discontinued in December 2020. Philips Respironics has subsequently launched the Trilogy EV300, which is also a mixed-mode ventilator, and is invasive and non-invasive. The Philips Respironics Trilogy EV300 is registered in many countries and is a viable alternative for the V680 ventilator.

As a reminder, there are two safety issues affecting the V680 ventilator that were shared in two prior communications:

1. During dual-limb invasive ventilation, a patient cough of sufficient magnitude to drive circuit pressures above 95 cmH_2O for longer than 150 milliseconds may cause a "Vent Inoperative 1008: Machine and Proximal Pressure Sensors Failed" alarm. This will cause the V680 ventilator to cease therapy and the ventilator will not function, however, the ventilator will remain powered on. (2020-CC-HRC-004: May 2022))

2. All 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. (2021-CC-HRC-003: April 2022)

Please see the Appendix A for full details of mandated mitigations per the previous FSN letters.

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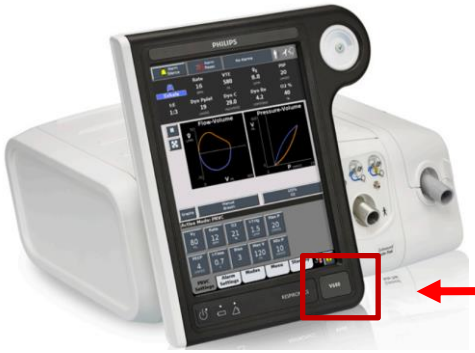

Figure 1: V680 Ventilator Identification (Button will read V680)

Product Number	Models
850011	V680 Ventilator

The following actions should be taken by the customer/user to prevent risks for patients

1. Please communicate this removal notice to all who need to be aware within your organization, or to any organization where the potentially affected devices have been transferred.
2. Call your local Philips Respironics Representative or distributor to discuss a transition plan to be executed within the next 6 months.

Philips Respironics Service Representative will also be contacting you to schedule an appointment to remove your V680 ventilator(s).

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

If you need any further information or support concerning this issue, please contact your local Philips Respironics service representative:

Primary Service Contact

<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Authorities where applicable.

We appreciate your patience and recognize that this will cause inconvenience for your patients, staff and hospital. We will do everything we can to keep you informed about the process and streamline the trade-in of your ventilator if this is an option you would like to consider.

Sincerely,

Michael Mizrachi

Michael Mizrachi
Head of Quality Assurance
Philips Hospital Respiratory Care

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FIELD SAFETY NOTICE RESPONSE FORM
2022-CC-HRC-013

Reference: Removal of the V680 ventilator from global markets

Instructions: Please complete and return this form to Philips Respironics 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 Letter and confirm that the information from this Letter has been properly distributed to all users that handle 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 Respironics by the following method:
<Philips representative contact details to be completed by the KM / country>.

If you experience difficulty in carrying out the instructions contained in this communication, contact your local Philips Respironics representative: <Philips representative contact details to be completed by the KM / country>.

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Appendix A

Per our previous FSN communications, customers/users must continue to implement **at least one of the mitigations** provided in the April 2022 letter/2021-CC-HRC-003 (repeated below) to mitigate the risk of the hazard caused by the 35V Rail issue.

External Oxygen Monitoring. 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 V680 to a nurse call/remote alarm.

- 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 non-annunciating alarms, verify the operation of any nurse call/remote alarm before use.
- 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 V680 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 the V680 ventilator 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 V680 User Manuals, an alternative means of ventilation should be available/accessible whenever the ventilator is in use. If a 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. There have been zero (0) deaths or serious injuries with the 35V Rail issue for the V680 ventilator.