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Update - Field Safety Notice
Philips Respironics - Hospital Respiratory Care

Philips V680 Ventilator
Software correction regarding error code 1008 - 2020-CC-HRC-004/ FCO86600058

13-May-2022

This document contains important updated 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,

This is a follow up to Philips Customer Letter from November 2020 to inform you that Philips has released a Software Version 1.40 to correct a problem that has been identified with the Philips V680 ventilators that could pose a risk for patients or users. Philips will be contacting you to schedule an appointment to update your V680 device(s) to Software Version 1.40.

The information below is to remind you of the issue previously communicated in November 2020 that will be corrected by Software Version 1.40 and the mitigations you should be implementing while you await recipet of Software Version 1.40.

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

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 (image shown below), which will cause the V680 ventilator to cease therapy and the ventilator will not function, however, it will remain powered on.

V680 Ventilator Identification

Philips has received one (1) report of a serious injuriy associated with the 1008 Error Code on V680 devices.

2. Describe the hazard/harm associated with the issue

As stated above, if there is a "Vent Inoperative 1008: Machine and Proximal Pressure Sensors Failed" alarm, this will cause the V680 ventilator to cease therapy. A cessation of ventilator therapy while in use on a patient could potentially lead to severe hypoxemia and hypercarbia.

3. Affected products and how to identify them

All V680 ventilators are potentially affected.

Product Number	Models
850011	V680 Ventilator

4. Describe the actions that should be taken by the customer / user in order to prevent risks for patients or users

Consistent with the Philips V680 Customer Letter sent in November 2020, please continue to follow the below actions when utilizing the V680 Ventilator while you await receipt of Software Version 1.40:

Philips V680 ventilators may remain in service but continue to follow warnings and instructions for use.

Follow the WARNINGS in the V680 User Manual, including but not limited to the following:

- **WARNING**: An alternative means of ventilation should be available whenever the ventilator is in use.
- **WARNING:** If a fault is detected in the ventilator, disconnect the patient from it and immediately start ventilation with an alternative device. The ventilator must be removed from clinical use and serviced by authorized service personnel.

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- **WARNING:** Nebulization or humidification can increase the resistance of breathing system filters. When using a nebulizer or humidifier, monitor the breathing system filter frequently for increased resistance and blockage.

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

Complete, sign, and return the Field Safety Notice Response Form (the last page of this letter).

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

As described above, Philips will be deploying Software Version 1.40 which includes a change to prevent the 1008 error code from occurring as a result of a patient cough.

Philips will be contacting you to schedule an appointment to update your V680 device(s) software to Version 1.40.

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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 your local Philips 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.

Philips regrets any inconvenience caused by this problem.

Sincerely,

…
Head of Quality Assurance
Philips Hospital Respiratory Care

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FIELD SAFETY NOTICE RESPONSE FORM
2020-CC-HRC-004

Reference: Software correction regarding error code 1008, V680 Ventilator,

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 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 by the following method:

<Reply form return 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 representative: <Philips representative contact details to be completed by the KM / country>.