

URGENT - Field Safety Notice **Philips V680 Ventilators**

Information regarding the backup battery

Dear Customer,

A problem has been detected in the Philips V680 ventilators that, if it were to re-occur, could pose a risk to patients or users. This field safety notice is intended to inform you about

- what the problem is and under what circumstances it can occur,
- the actions that should be taken by the customer/user in order to prevent risks for patients or users, and
- the actions planned by Philips to correct the problem.

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.

The V680 ventilators may experience two potential issues with the battery (see table below for additional information).

1. The ventilator may exhibit a high priority Check Vent: Battery Failed alarm if the battery is allowed to over discharge.
2. The battery may fail to charge if the ventilator is stored for an extended period of time without being plugged into AC power.

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 Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

David McGrath
Head of Quality and Regulatory, HRC

AFFECTED PRODUCTS	Philips V680 ventilators
PROBLEM DESCRIPTION	<p>V680 ventilators may experience two potential issues with the battery.</p> <ol style="list-style-type: none"> 1. The ventilator may exhibit a high priority Check Vent: Battery Failed alarm if the battery is allowed to over discharge. 2. The battery may fail to charge if the ventilator is stored for an extended period of time without being plugged into AC power. <p>The probability of harm associated with these issues is low. Philips investigated all V680 battery complaints received over a two-year period and found the following:</p> <ul style="list-style-type: none"> - Battery failure alarms during patient use and while connected to AC mains power occurred at a rate of 0.044 failures per million hours (FPMH) of use, with no reports of patient harm. - Battery failures during intra-hospital patient transport or mains power loss occurred at a rate of 0 FPMH. - Battery failure alarms during testing occurred at a rate of 3.9 FPMH. <p>Philips has received no reports of deaths or serious injuries associated with V680 battery failures.</p>
HAZARD INVOLVED	<p>If the ventilator exhibits a high priority Battery Failed alarm while connected to AC power, the V680 ventilator will annunciate an audible and visual alarm. The ventilator will continue to deliver prescribed therapy; however, the audible and visual alarm will continue until the device is powered down; therefore, the patient should be transferred to an alternate source of ventilation as soon as one becomes available. The hazard associated with transferring a patient to an alternate source of ventilation is a temporary loss of therapy leading to potential hypercarbia or hypoxemia (moderate).</p> <p>If AC power fails and the backup battery is not functioning, an audible and visual alarm will annunciate for at least two minutes. The ventilator will no longer be operative, resulting in a total loss of therapy. The patient will require an alternate source of ventilation. The hazard associated with a ventilator shutdown is a total loss of therapy leading to potential hypercarbia or hypoxemia (severe).</p>
HOW TO IDENTIFY AFFECTED PRODUCTS	All V680 ventilators are potentially affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	<p>Follow instructions in the V680 user manual and in this field safety notice to reduce any risk associated with potential battery issues.</p> <ol style="list-style-type: none"> 1) Avoid allowing the ventilator battery to become completely discharged. Otherwise, the battery may become over-discharged and require long recharge times of up to 16 hours or more. The over-discharged condition may permanently damage the battery so that it is unable to recharge. To prevent the occurrence of a non-recoverable over-discharged battery, always keep the ventilator connected to an AC outlet when not being used for transport. 2) If the battery is not fully charged after 16 hours, or the ventilator annunciates a battery failed check vent alarm, have the ventilator serviced.

	<ol style="list-style-type: none">3) To reduce the risk of power failure to the ventilator, pay close attention to the battery's charge level. The battery's operation time is approximate and is affected by ventilator settings, discharge and recharge cycles, battery age, and ambient temperature.4) Philips recommends that the ventilator battery be fully charged before ventilating a patient or beginning patient transport. If the battery is not fully charged and AC power fails, pay close attention to the level of battery charge.5) A new backup battery should be installed and charged within one year of the date of manufacture identified on the battery and on the shipping box.6) Use an external SpO2 monitor.7) Promptly attend to all ventilator alarms.8) Ensure that an alternative means of ventilation is available whenever the ventilator is in use.
ACTIONS PLANNED BY PHILIPS	Philips is releasing this field safety notice to make customers and consignees aware of the potential battery issues described above and how to address them.
FURTHER INFORMATION AND SUPPORT	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p><Philips representative contact details to be completed by the KM / country></p>

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Acknowledgement and Receipt Form **Response is Required**

Customer Information:

Form Completed By & Title:	
Contact Name:	
Telephone Number:	
Email Address:	
Facility Name:	
Street Address:	
City, State, Zip Code:	
Country:	

I have read and understand the instructions provided in the notification letter. Yes No

Signature: _____

Date: _____

Please return the completed and signed reply form to: **<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>**.