URGENT – Field Safety Notice
Respironics V60 Ventilator
Power Management (PM) Printed Circuit Board Assembly (PCBA)
PIC Software Update

Dear Customer,

Respironics California, Inc., a division of Philips Healthcare, has initiated a mandatory field action for its V60 ventilator. You are receiving this notification because our records indicate that you have one or more of the devices affected by this action. Please reference the "Affected Products" list below.

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
- 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 field action is being conducted to correct an issue with the V60 ventilator Power Management PCBA's software that was discovered through routine product monitoring.

In the rare event a component fails, the following sequence of events may occur: 1) Power Management Board Assembly VMAIN shorts to ground, 2) the ventilator shuts down, 3) the software repeatedly cycles through part of its initialization sequence and Power On Self Test (POST), the alarm may not sound to indicate that ventilation therapy has ceased.

Patient safety, product quality and customer satisfaction is our ultimate priority. We continuously monitor our manufacturing and field performance data to proactively identify any potential issues that could manifest as a reliability, quality, or safety concern and work to address them immediately.

If you need any further information or support concerning this issue, please contact a Philips Respironics representative **<Philips representative contact details to be completed by the KM/country for international markets>.**

This notice has been reported to the appropriate regulatory agencies.

Philips apologizes for any inconveniences caused by this problem.

URGENT – Field Safety Notice
Respironics V60 Ventilator
Power Management (PM) Printed Circuit Board Assembly (PCBA)
PIC Software Update

Sincerely,

Jack Sowin
Director, Regulatory Affairs/Quality Assurance
Respironics California Inc.

URGENT – Field Safety Notice
Respironics V60 Ventilator
Power Management (PM) Printed Circuit Board Assembly (PCBA)
PIC Software Update

AFFECTED PRODUCTS	All Respironics V60 Ventilators shipped from the manufacturer prior to April 1, 2013.
PROBLEM DESCRIPTION	In the rare event a component fails, the following sequence of events may occur: 1) Power Management Board Assembly VMAIN shorts to ground, 2) the ventilator shuts down, 3) the software repeatedly cycles through part of its initialization sequence and Power On Self Test (POST), the alarm may not sound to indicate that ventilation therapy has ceased.
HAZARD INVOLVED	If the V60 ventilator were to cease functioning during use it would result in failure to deliver therapy to a patient due to loss of ventilation with potentially no audible alarm.
HOW TO IDENTIFY AFFECTED PRODUCTS	The Respironics V60 Ventilators impacted by this issue were shipped under the material numbers listed below.

Description	Respironics Material P/N	Philips 12 Digit P/N
V60 Ventilator	850008	850008
	1053613	989805628251
	1053614	989805612101
	1053615	989805613391
	1053616	989805613661
	1053617	989805611761
	1053618	N/A
	R1053618	N/A
	1076709	N/A
	R1076709	N/A
	1076715	989805627411
	1076716	989805627431
	1076717	989805627441
	DU1053617	989805616411
	U1053614	989805636641
	U1053617	989805636631

A Philips Field Service Representative, Approved Service Provider or Distributor has a list of all affected V60 units.

URGENT – Field Safety Notice
Respironics V60 Ventilator
Power Management (PM) Printed Circuit Board Assembly (PCBA)
PIC Software Update

ACTION TO BE TAKEN BY CUSTOMER / USER	Pending the completion of the update, the V60 ventilator may continue to be used in accordance with its directions for use. As a reminder, please be advised of the following**:** 1) Use the Respironics V60 Ventilator on spontaneously breathing patients only. It is an assist ventilator and is intended to augment the ventilation of a spontaneously breathing patient. It is not intended to provide the total ventilatory requirements of the patient. 2) Use an external oxygen monitor to verify the oxygen concentration in the delivered gas. The oxygen monitor will annunciate an alarm when the oxygen concentration in the inspired gas is below the set range. 3) An alternate means of ventilation shall be available when the ventilator is in use. Please refer to your user manual for additional information on warnings
ACTIONS PLANNED BY PHILIPS	A Philips Field Service Engineer, Approved Service Provider or Distributor has a list of all affected units and will be contacting you to: Schedule a no-cost update of the Power Management Board Assembly software on all V60 ventilators shipped from the manufacturer prior to April 1, 2013.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative at **<Philips representative contact details to be completed by the KM/country for international markets>.**