PHILIPS

Effective 21 February 2017

Respiratory Ventilation FSN 86600034A 21 February 2017

URGENT - Field Safety Notice
Medical Device Correction

V60 Respiratory Ventilator with Version 2.20 Software,

False Detection of Blower Motor Stall leading to Vent-Inop

Dear Customer,

According to our records, you currently have one of the V60 ventilators noted above. This Field Safety Notice (FSN) is to advise you that Respironics California, LLC ("Respironics") is voluntarily recalling all Philips V60 Ventilators that have Version 2.20 Software installed. This letter is being sent to all customers who purchased an affected device from Respironics or another Philips company.

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.

Respironics began distribution of V60's with this software version on August 17, 2016. All V60's manufactured on that date or later are subject to this recall.

V60's manufactured prior to August 17, 2016 were originally shipped with Version 2.10 Software. These ventilators are not subject to this recall unless the device software was subsequently upgraded to Software Version 2.20.

Please refer to the instructions in this letter to determine what software is installed in a V60.

Serious injury or death could result if users do not promptly respond to device alarms triggered by the Version 2.20 software.

If you need any further information or support concerning this issue, please contact your local Philips representative www.healthcare.philips.com.

This notice has been reported to the appropriate Regulatory Agencies. Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Donald J. Sherratt
Head of Quality and Regulatory, Hospital Respiratory Care

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AFFECTED PRODUCTS	All V60 Ventilators manufactured between August 17, 2016 and January 4, 2017 will have Version 2.20 Software. V60's manufactured prior to August 2016 units may have had Version 2.20 Software added in the field.
PROBLEM DESCRIPTION	The V60 Ventilator with Version 2.20 software installed may falsely detect that the blower motor has stalled. If this condition occurs, the software will cause the ventilator to shut down (Vent Inop) and display Error Code 100E. Ventilatory support will cease. An audible high-priority alarm will sound continuously for at least 2 minutes when the V60 shuts down for any Vent Inop condition and is operating on battery power. If the V60 is connected to AC power (mains supply), the alarm will continue to sound until an operator intervenes. If the V60 is connected to a remote alarm system, the alarm system will be activated until action is taken by the operator. Error Code 100E only exists in V60 Version 2.20 software. Therefore, V60's running Version 2.10 software are not subject to this particular Vent Inop condition.An audible high-priority alarm will sound continuously for at least 2 minutes when the V60 shuts down for any Vent Inop condition and is operating on battery power. If the V60 is connected to AC power (mains supply), the alarm will continue to sound until an operator intervenes. If the V60 is connected to a remote alarm system, the alarm system will be activated until action is taken by the operator. Error Code 100E only exists in V60 Version 2.20 software. Therefore, V60's running Version 2.10 software are not subject to this particular Vent Inop condition.
HAZARD INVOLVED	If a Vent Inop event occurs when a patient is connected, pressure support and O_2 support will cease. This may cause the SpO_2 of the patient to drop and may lead to Hypoxemia and/or Hypercarbia if the alarm is not attended to promptly

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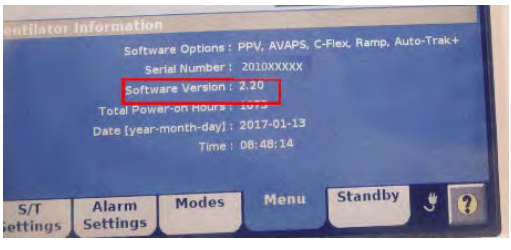
HOW TO IDENTIFY AFFECTED PRODUCTS	Philips Healthcare is directly notifying affected users of this issue via this Field Safety Notice (FSN). To determine if you have a potentially affected product in the "Affected Products" list above, check your system identification. The label with the Serial Number and Date of Manufacturing is located on the back of the V60 Ventilator. See picture below: 
HOW TO DETERMINE IF THE V60 HAS VERSION 2.20 SOFTWARE INSTALLED	1. Turn on the V60 2. Press the Menu Button at the bottom of the screen 3. Press the "Vent Info" button on the right side of the screen. Note the software version and the Serial number will appear. 4. If the software version is 2.20, the ventilator is subject to this recall. 

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ACTION TO BE TAKEN BY CUSTOMER / USER	**IF CLOSE CLINICAL OBSERVATION IS NOT AVAILABLE:** Discontinue use of the V60 until Version 2.10 software is installed **IF CLOSE CLINICAL OBSERVATION IS AVAILABLE:** If no other non-invasive ventilator is available, and other methods of ventilator support are deemed inappropriate or undesirable for the patient, you may continue to use the V60 under the conditions below: 1. Make arrangements to have Version 2.10 Software installed on affected devices as soon as possible. 2. To minimize risks of illness or injury, operate the V60 as defined in the operator's manual and promptly attend to all alarms presented by the V60 Ventilator. 3. As recommended in the operator's manual, use an external O2 monitor/analyzer and set the alarm thresholds appropriately. 4. As recommended in the operator's manual, ensure the correct circuits and masks identified in the operator's manual are used with the V60. 5. Wherever possible, connect the V60 to a remote call system. 6. If the V60 Shuts down, alarms and displays Error Code 100E, turn the V60 off and restart the ventilator. If 100E occurs again, discontinue use of the V60 and use an alternate ventilator. Do not install Version 2.20 software on any V60. **ACKNOWLEDGEMENT OF RECEIPT** You must acknowledge the receipt of this recall notification by any of the following methods: Mail back the completed form attached to the rear of this recall notification to: **Recall Response** **Respironics California, LLC** **2271 Cosmos Court** **Carlsbad** **CA 92011** **Or** E-mail back the completed form attached to the rear of this recall notification to recall.response@philips.com

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ACTIONS PLANNED BY PHILIPS	Philips Healthcare is implementing software update to correct the above-described issue. Respironics and Philips will provide the following support for V60 customers in installing Software Version 2.10 on affected V60 ventilators, where permitted by law, at no cost to the owner:: **Biomedical Engineers** Respironics will enable our support portal to allow Biomedical engineers that have received V60 Service training from Respironics to download V60 Version 2.10 software from Philips service support site and install the software into the V60 following the instructions that will accompany the software download. A special cable was provided during service training that will allow a PC or Laptop to install the Version 2.10 software into the V60. Biomedical engineers that have not received training will not be able to download the software or install the software. In North America, the facility can contact customer service at 1 800-722-9377 to schedule a date for the installation of Version 2.10 software by a Philips Field Service Engineer. **Philips Field Service Engineer** Respironics or Philips will contact each consignee to establish if any of the ventilators are subject to this recall. Philips Field Service Engineers will install the software onto each affected V60 ventilator at the site.

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FURTHER INFORMATION AND SUPPORT	This problem was reported to us via our complaint handling system. There have been 82 complaints of ventilator shut down. There have been two adverse events reported due to false detection of blower motor stalls. **Contact information:** Monday through Friday between 8:00am and 5:00 pm US Pacific Time **Firm responsible for FSN:** Respironics California, LLC 2271 Cosmos Court Carlsbad, CA 92011 **Primary Contact** Donald J. Sherratt E-mail: donald.sherratt@philips.com Phone: +1 760 918 1067 **Alternate Contact** Zoran Psenicnik E-mail: Zoran.psenicnik@philips.com Phone: +1 760 918 7312

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MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

V60 With V2.20 Software

V60 Ventilators with Date of Manufacture from August 17, 2016 to January 4, 2017

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Customer Name:							
Street Address:							
City:		State:		Zip Code:		Country:	
Contact Person:		Telephone Number:		E-mail:			

I have read and understand the recall instructions provided in the January 27, 2017 letter. Yes ☐ No ☐

Have any adverse events associated with recalled product occurred at your site? Yes ☐ No ☐

If yes, please explain:

Affected Product Information: Include information that is applicable for affected product at your site.

Affected Product Information Table			
Serial Number	Serial Number	Serial Number	Serial Number

Return Response Box:

Please provide any additional information, if applicable.

Please return to: recall.response@philips.com or
Mail to: Respironics California, LLC, 2271 Cosmos Ct, Carlsbad, CA 92011, USA