

URGENT – Medical Device Correction Field Safety Notice

Philips V60 Ventilators May Be Impacted by Unresponsive Touchscreen

Dear Customer,

A problem has been detected in certain Philips V60 Ventilators which could pose a risk for patients or users. This FSN86600042 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 to 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.

You can check the serial number of a V60 Ventilator to verify if it may be subject to this correction without pausing or discontinuing patient use. The following page includes directions on how to view the serial number of a V60 ventilator while it is in use.

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



Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

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AFFECTED PRODUCTS	V60 Ventilators that have a serial number listed in the attachment. 
PROBLEM DESCRIPTION	The touchscreen must be used to change certain therapy settings. The touchscreens in affected units may become frozen and fail to respond to touch commands. Consequently, if a patient requires a change in a ventilator therapy setting, e.g., FiO ₂ , the change could not be made. Although it would be immediately apparent to the user that the changes cannot be made, there is no advance warning of touchscreen failure.
HAZARD INVOLVED	If the touchscreen on the V60 Ventilator malfunctions, therapy adjustment is delayed because the ventilator settings cannot be changed. A delay in therapy adjustment may lead to a drop in the patient's SpO ₂ level and subsequently result in Hypercarbia and/or Hypoxemia. Note: The V60 ventilator will continue to function at the predetermined and accepted settings required to support the patient. In addition, patient settings, alarms, on-screen warnings, and waveforms are accurately displayed, visible, and alarms are annunciated.
HOW TO IDENTIFY AFFECTED PRODUCTS	Check the serial number of the ventilator against the attached list of affected units. Labeling containing device serial number information can be seen located at the rear of the ventilator. (See Figure 1)  FIGURE 1: BACK VIEW OF V60 VENTILATOR

HOW TO IDENTIFY AFFECTED PRODUCTS

Alternatively, the serial number of the ventilator may also be accessed/reviewed from the display while the ventilator is in operation. Select the **Menu** tab at the bottom of the screen then select **Vent Info**. (See **Figure 2** and **3**)

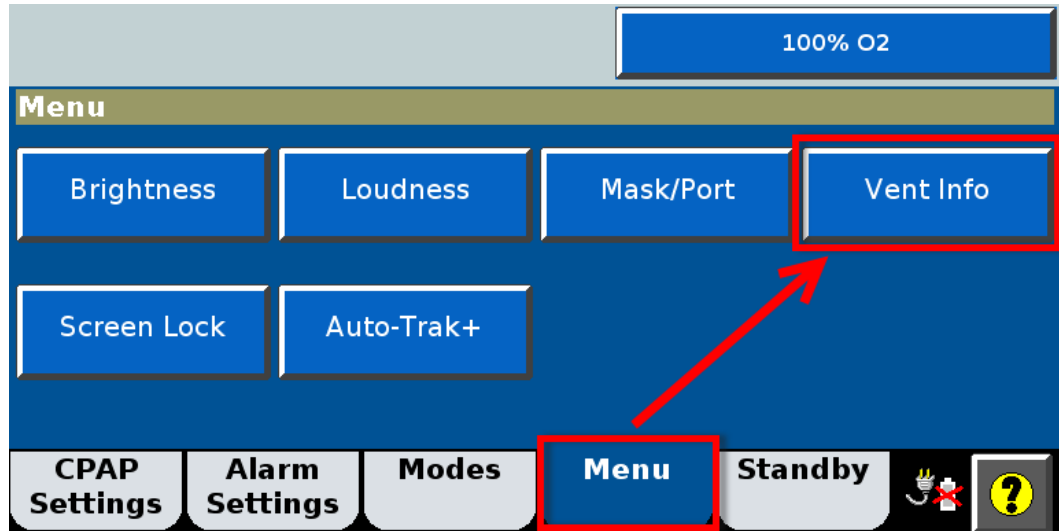


FIGURE 2: ACCESSING VENTILATOR SERIAL NUMBER FROM ON-SCREEN DISPLAY

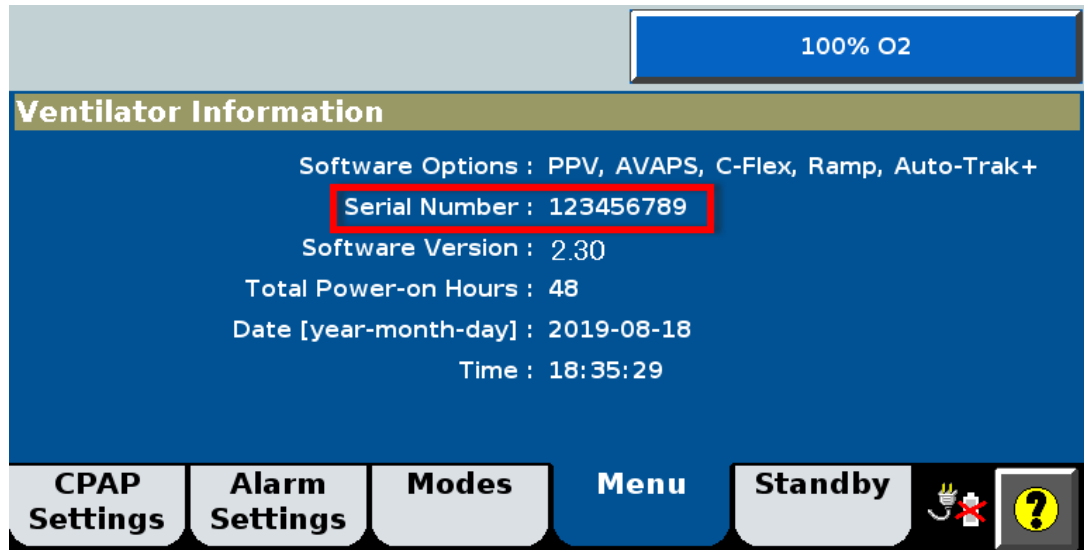


FIGURE 3: SERIAL NUMBER OF VENTILATOR AS VIEWED FROM THE VENT INFO SCREEN

<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<ol style="list-style-type: none"> 1) If in use on a patient, continue to use the ventilator if an alternative non-invasive ventilator is not available. 2) If a touchscreen failure is detected, disconnect the patient and immediately start ventilation with an alternate device. Contact your local customer service representative to report the failure. Please reference FCO86600042A. 3) To minimize the risk of patient injury, operate the V60 Ventilator as defined in the operator's manual and promptly attend to all alarms presented by the ventilator. 4) As recommended in the operator's manual, use an external O₂ monitor/analyzer and set the alarm thresholds appropriately. 5) As recommended in the operator's manual, have an alternative means of ventilation available whenever the ventilator is in use. 6) Acknowledge receipt of this notification 7) Receipt of this notification by any of the following methods:
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Philips will provide the following support for V60 customers by installing new touchscreens on affected V60 ventilators, at no cost to the customer.</p> <p>Philips Engineer or Philips Approved Service Provider Philips will contact each consignee to schedule an appointment to perform this correction. Philips Engineers or Philips Approved Service Providers will either repair any affected V60 ventilator at the customer's site or temporarily remove it for repair.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>Monday through Friday between 8:00am and 5:00 pm US Pacific Time</p> <p>Firm responsible for this Medical Device Correction and Field Safety Notice: Respirationics California, LLC 2271 Cosmos Court Carlsbad, CA 92011</p> <p>Primary Contact Melissa Abbott Sr. Post Market Surveillance Manager Phone: +1 (760) 918-7300 E-mail: melissa.abbott@philips.com</p> <p>Local Contact</p>



MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Philips V60 Ventilators may be Impacted by Unresponsive Touchscreen

Acknowledgement and Receipt Form

Response is Required

Customer Information:

Form Completed by and Title:	
Contact Name and Title:	
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

Have any adverse events associated with an unresponsive touchscreen occurred at your site? Yes No

If yes, have you informed Philips of the event? Yes No

If yes, please provide Philips Case Number _____ and if applicable, add any details below:

Details:

Signature: _____

Date: _____

Please return the completed and signed Acknowledgement and Receipt Form to: