

URGENT – Medical Device Correction Field Safety Notice

Philips V60/V680 Ventilator Serviced With Touchscreen RP Kit 453561511951 May Be Impacted by Unresponsive Touchscreen

Dear Customer,

A problem has been detected in certain Philips V60 and V680 Ventilator touchscreens, which could pose a risk for patients or users. This FSN86600045 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.

Our records indicate that you ordered and were shipped replacement V60/V680 Touchscreen service part kit, containing a potentially defective touchscreen. The following pages provide additional instructions and actions to be taken. Follow the "ACTION TO BE TAKEN BY THE CUSTOMER /USER" section of this notice.

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

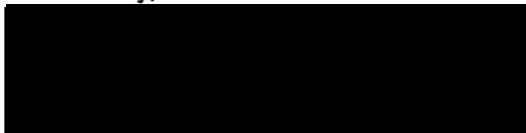
www.healthcare.philips.com

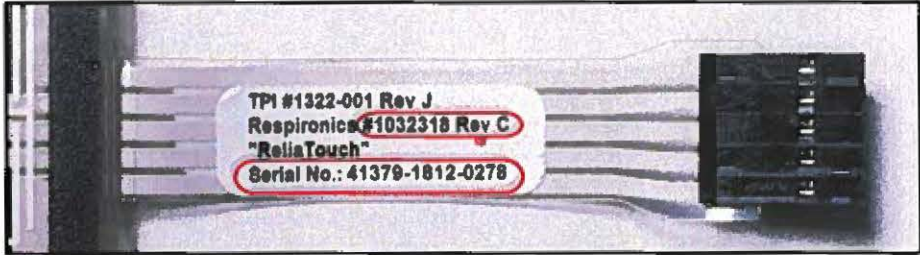
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



<p>AFFECTED PRODUCTS</p>	<p>V60 and V680 Ventilator Service Part: Touchscreen RP kit P/N 453561511951 containing a touchscreen labeled as raw part number 1132318 Revision C and a serial number falling within the range of affected serial numbers indicated by Table 1.</p> <p style="text-align: center;">Table 1</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Touchscreen Serial Number</th> <th style="width: 50%;">Touchscreen Serial Number</th> </tr> </thead> <tbody> <tr><td>41088-1808-0001 to 0179</td><td>41930-1817-0001 to 0092</td></tr> <tr><td>41213-1809-0001 to 0200</td><td>42059-1818-0001 to 0150</td></tr> <tr><td>41305-1811-0001 to 0295</td><td>42059-1818-0151 to 0183</td></tr> <tr><td>41379-1812-0001 to 0250</td><td>42161-1819-0001 to 0117</td></tr> <tr><td>41379-1812-0251 to 0328</td><td>42161-1819-0118 to 0137</td></tr> <tr><td>41540-1813-0001 to 0195</td><td>42232-1820-0001 to 0130</td></tr> <tr><td>41633-1814-0001 to 0275</td><td>42232-1820-0131 to 0146</td></tr> <tr><td>41633-1814-0276 to 0285</td><td>42334-1822-0001 to 0134</td></tr> <tr><td>41724-1815-0001 to 0140</td><td>42334-1822-0135 to 0141</td></tr> <tr><td>41724-1815-0141 to 0183</td><td>42471-1823-0001 to 0143</td></tr> <tr><td>41838-1816-0001 to 0107</td><td>42471-1823-0144 to 0175</td></tr> <tr><td>41838-1816-0108 to 0165</td><td>42805-1828-0001 to 0138</td></tr> </tbody> </table>	Touchscreen Serial Number	Touchscreen Serial Number	41088-1808-0001 to 0179	41930-1817-0001 to 0092	41213-1809-0001 to 0200	42059-1818-0001 to 0150	41305-1811-0001 to 0295	42059-1818-0151 to 0183	41379-1812-0001 to 0250	42161-1819-0001 to 0117	41379-1812-0251 to 0328	42161-1819-0118 to 0137	41540-1813-0001 to 0195	42232-1820-0001 to 0130	41633-1814-0001 to 0275	42232-1820-0131 to 0146	41633-1814-0276 to 0285	42334-1822-0001 to 0134	41724-1815-0001 to 0140	42334-1822-0135 to 0141	41724-1815-0141 to 0183	42471-1823-0001 to 0143	41838-1816-0001 to 0107	42471-1823-0144 to 0175	41838-1816-0108 to 0165	42805-1828-0001 to 0138
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<p>PROBLEM DESCRIPTION</p>	<p>If a patient requires a change in therapy, there is no warning associated with an unresponsive touchscreen, and therefore the clinician would have no prior indication of a touchscreen failure and would be unable to change ventilator settings.</p>																										
<p>HAZARD INVOLVED</p>	<p>If the touchscreen on the V60/V680 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 SpO₂ level and subsequently result in Hypercarbia and/or Hypoxemia.</p> <p>Note: The V60/V680 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.</p>																										
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>1) Check your unused Touchscreen RP kits ordered/received as PN 453561511951 by referring to the part number/serial number label located on the flex cable of the touchscreen inside the kit, and verify its serial number against the affected serial numbers listing of Table 1 in the "Affected Products" section.</p> <div style="text-align: center;">  <p>Touchscreen Serial Number Location</p> </div>																										

<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<ol style="list-style-type: none"> 1) Check your site's V60 or V680 Ventilator service part stock for any unused Touchscreen RP kit as Part Number 453561511951 and verify if the serial number of the touchscreen contained within the kit, is within the range of affected touchscreen serial numbers indicated in Table 1 of the Affected Products section. 2) If the serial number of the touchscreen contained in the unused kit is within the range of serial numbers specified in Table 1, please indicate the serial number of the touchscreen from that kit on the "Acknowledgement and Receipt Form" provided with this notice. 3) If your site has already installed, or was serviced with Touchscreen RP Kit 453561511951 between April 1 2018 to May 31 2019, please report any V60 or V680 ventilator failures involving inaccurate touchscreen response, touchscreen non-responsiveness, and/or the touchscreen's failure to calibrate, to your local Philips representative. 4) Send the completed and signed "Acknowledgement and Receipt Form" to Philips via the contact information located on the form. 5) Acknowledge receipt of this notification by any of the following methods: INSERT INFO HERE FOR THE APPROPRIATE MARKET
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Upon receipt of acknowledgement by the customer with the affected serial number(s) of any unused touchscreen RP Kit 453561511951 at their site, Philips will provide to the customer P/N 453561539071 (1032318 Rev E) at no charge.</p> <p>Additionally, customers who ordered and installed Touchscreen RP Kit PN 453561511951, or were serviced by Philips or Third Part biomedical engineers using PN 453561511951, are requested to contact Philips if the V60 or V680 ventilator touchscreen fails. A Philips Engineer or an Approved Service Provider will evaluate the cause and if applicable, replace the touchscreen at no charge to the customer per the appropriate FCO document.</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>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</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 Enter local contact info here</p>

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Philips V60/V680 Ventilator Serviced With Touchscreen RP Kit 453561511951 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:	

Please check applicable option below:

- I certify that our facility received, read and understand the Medical Device Correction document FSN86600045A.
- I confirm that our facility received and still has unused stock of the Touchscreen RP kit P/N 453561511951, and have verified the serial number of the touchscreen it contains (listed below) is within the range of affected touchscreen serial numbers indicate in Table 1 of the notice.

Touchscreen Kit P/N:	Serial Number of affected touchscreen:

- I certify that our facility does not have any unused stock of Touchscreen RP kit P/N 453561511951.

Signature: _____

Date: _____

Please return the completed and signed Acknowledgement and Receipt 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>*