URGENT – Medical Device Correction
Field Safety Notice
Philips V60 Ventilators User Interface RP-Kits May Be Impacted by Unresponsive Touchscreen

Dear Customer,

A problem has been detected in certain Philips V60 Ventilator touchscreens, which could pose a risk for patients or users. This FSN86600044 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 a replacement V60 User Interface Assembly 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,

[redacted]

David McGrath
Head of Quality and Regulatory, HRC

AFFECTED PRODUCTS	Our records indicate Philips shipped the following serialized User Interface Assembly RP-Kit(s) to your facility. <Market/Local Q&R to populate this section with the following information identifying the UI assembly kit shipped, specific to each customer site indicated on UAL/CAL 86600044> Part Number: Part Description: Kit Serial Number:
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., FiO2, 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	1) The serial number of the User Interface RP-Kit is located on the external surface of the User Interface Touchscreen RP-Kit. See Figures **1, 2,** and **3** below.

Figure 1: Front View UI RP-Kit

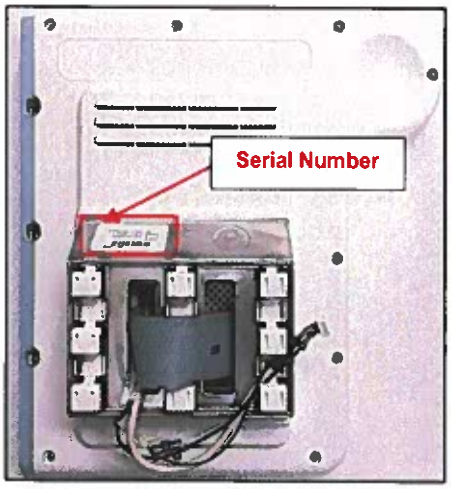

Figure 2: Rear View UI RP-Kit

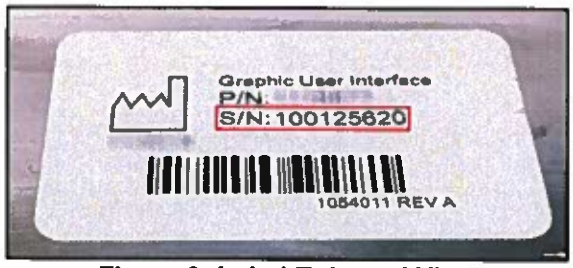

Figure 3: Label Enlarged View

2) If the User Interface Assembly RP-Kit indicated in the **AFFECTED PRODUCTS** section above was installed on a V60 ventilator at your facility, review your maintenance records to determine the serial number of the ventilator that used the kit.

3) If from review of your V60 maintenance records it cannot be determined which V60 has the affected User Interface Assembly RP Kit listed in the **AFFECTED PRODUCTS** section above, the site biomedical engineer or authorized service personnel must check each V60 ventilator on-site to locate the affected User Interface serial number. (**Figures 4** through **10** are pictorials of how to identify the User Interface Assembly serial number when installed on a ventilator.)

Figure 4: Installed UI Assembly Serial Number

a) Remove side and top covers from the ventilator to gain internal access to the UI Assembly's rear bezel retention bracket. (See **Figures 5** and **6)**

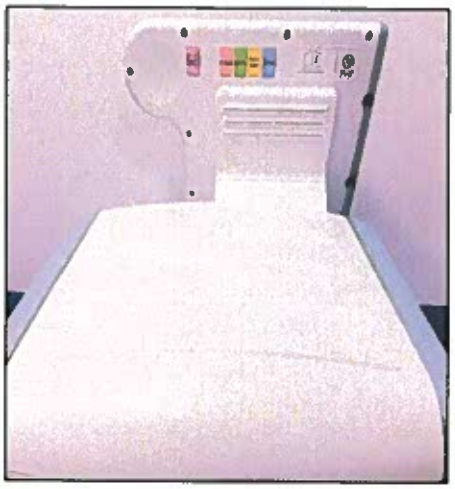

Figure 5

Figure 6

b) Loosen the UI Rear Bezel retention bracket screw, taking care not to separate the captive nylon washer which keeps the screw captive to the bracket when the bracket is lifted to the unlocked (upward) position. (See **Figures 7** and **8)**

Figure 7

Figure 8

c) Lift upward on UI Rear Bezel retention bracket to loosen the fingers of the UI rear Bezel from the retainer. The UI assembly can now be pulled away from the Front Panel enough to view its PN/SN label. (See **Figure 9**)

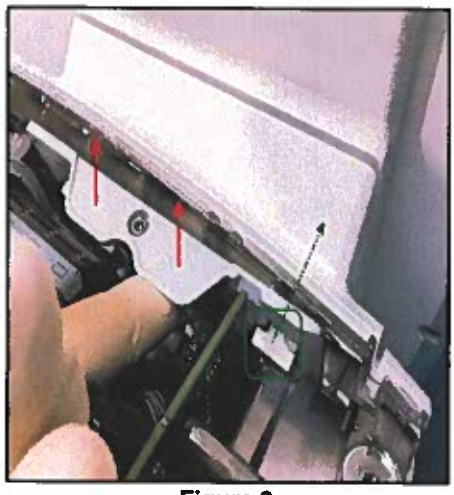

Figure 9

d) Gently pull the UI Assembly away from the Front Panel just far enough to reveal its PN/SN and verify if the serial number indicated on its label, matches the serial number of the affected UI Assembly RP-Kit indicated in the **AFFECTED PRODUCTS** section above. (See **Figure 10)**

Figure 10

e) If serial number indicated on the UI Assembly currently installed in the ventilator **DOES NOT MATCH** the serial number of the affected UI Assembly RP kit indicated in the "Affected Product" section, reassemble the UI Assembly to front panel. Ensure cables are properly seated and were not dislodged/disconnected during the process. Reinstall the top cover and side panels, and conduct the following tests in accordance with the V60 Service Manual.

1. Touchscreen Calibration (section 6.3)
2. View and record Ventilator Information (section 9.3.2)
3. Electrical Safety (Test 1) (section 9.3.3)
4. Controls (Test 3) (section 9.3.5)

f) If the serial number indicated on the UI Assembly currently installed in the ventilator **MATCHES** the serial number of the affected UI Assembly RP kit indicate in the "Affected Product" section, list the serial number of the **VENTILATOR** and the **UI Assembly** on the "Acknowledgement and Receipt Card" attached below. Upon receipt of the "Acknowledgement and Receipt Card," by Philips, appropriate action will be taken by a Philips authorized representative to replace the touchscreen in the ventilator containing the affected User Interface Assembly.

ACTION TO BE TAKEN BY CUSTOMER / USER	1) Identify which V60 Ventilator(s) within your facility contains the affected UI Assembly RP kit serial number(s) listed in the **AFFECTED PROCUCTS** section above, using the instructions provided in the **HOW TO IDENTIFY AFFECTED PRODUCTS** section. 2) If the affected User Interface RP-Kit is installed on a ventilator and in use on a patient, continue to use the ventilator if an alternative non-invasive ventilator is not available. 3) If the affected User Interface RP-Kit is installed on a ventilator, document the serial number of the ventilator and the serial number of the affected User Interface Assembly it contained, on the attached "Acknowledgement and Receipt Form." 4) If the affected UI Assembly could not be found or linked to a V60 ventilator at your site, please indicate this within in the detail section provided on the form. 5) Send the completed and signed "Acknowledgement and Receipt Form" to Philips via the contact information located on the form. 6) Acknowledge receipt of this notification by any of the following methods: INSERT INFO HERE FOR THE APPROPRIATE MARKET
ACTIONS PLANNED BY PHILIPS	Upon receipt of acknowledgement by the customer with indication of the V60 ventilator serial number(s) containing the affected User Interface RP kit(s) indicated in the "AFFECTED PRODUCT" section above, Philips will install new touchscreens on affected V60 ventilator(s) at no cost to the customer using FCO86600042 **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.
FURTHER INFORMATION AND SUPPORT	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** Melissa Abbott Sr. Post Market Surveillance Manager Phone: +1 (760) 918-7300 E-mail: [redacted] **Local Contact** Enter local contact info here

MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Philips V60 Ventilator User Interface RP-Kits 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 ☐

If User Interface RP-Kit was installed on a ventilator, note the ventilator(s) and the User Interface RP-Kit serial numbers and record below:

Ventilator S/N: _____ UI Assembly S/N: _____
Ventilator S/N: _____ UI Assembly S/N: _____
Ventilator S/N: _____ UI Assembly S/N: _____
Ventilator S/N: _____ UI Assembly S/N: _____
Ventilator S/N: _____ UI Assembly S/N: _____

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: <Reply form return details to be completed by the KM / country>