



Respironics California, LLC
2271 Cosmos Court
Carlsbad, CA 92011

Date: Sept. 2020

Subject: Update on Field Action – *“Philips V60 Ventilators May Shut Down Unexpectedly Due to a Premature Component Failure”* (FSN86600049)

Dear Valued Philips Customer –

In April 2020 Philips Respironics, LLC provided an initial update on a medical device Field Safety Notice FSN86600049 entitled *“Philips V60 Ventilators May Shut Down Unexpectedly Due to a Premature Component Failure”* (FSN86600049) for a subset of V60 ventilators and described its planned correction. This second update provides our latest status on this Field Safety Notice.

A meaningful portion of Philips’ supply chain was negatively impacted by COVID-19. This disruption coincided with extraordinary increase in demand for ventilators worldwide and caused Philips to delay initiation of a field correction for affected units. In our April 2020 letter we re-enforced the mitigations users should take to minimize risk.

Since our April update, Philips has worked diligently with vendors to expand supply chain capacity to meet these global needs and build the service kits for affected units. We now anticipate that replacement kits will begin to become available by the end of September, with all kits available by the end of 2020. A Philips representative will contact you to schedule a replacement as these repair kits become available.

In the meantime, it is important to continue to follow the directions in the operator’s manual and the Field Safety Notice to minimize any potential risk associated with an R31 failure. This includes using the ventilator’s remote alarm feature as well as an external O2 monitor / analyzer. The remote alarm will provide a backup annunciation even in the rare case of an intermittent R31 failure described in FSN86600049. Directions for connecting a remote alarm system can be found in the Operator’s Manual. If a unit experiences a Power Management PCBA failure, Philips will take prompt action to replace the PCBA at no cost to the customer.

If you have any questions regarding this communication or the V60 ventilator, please contact your local Philips representative. Thank you for your patience and for being a valued Philips customer.

Sincerely,

David McGrath

Head of Quality & Regulatory,
Philips Hospital Respiratory Care

