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Respironics California, LLC
2271 Cosmos Court
Carlsbad, CA 92011

Date: 30 Apr 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 March 2020 Philips Respironics, LLC initiated a medical device correction 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. Because of the recent outbreak of the SARS-CoV-2 virus responsible for COVID-19, Philips is providing this update with additional information about this device correction, to help customers balance the significant pressure they are under to support patients and the implementation of the planned repair actions described in FSN86600049.

Philips continues to work around the clock with its suppliers to increase production of the components needed for the correction described in FSN866600049 but is currently unable to implement the correction as quickly as intended. Similar to other global manufacturers, a meaningful portion of Philips' supply chain has been negatively impacted by COVID-19. This disruption coincides with extraordinary growth in ventilator demand worldwide. Philips does not believe this disruption will be enduring but is experiencing a near-term delay in the availability of replacement components needed for the correction to address FSN86600049. As the COVID-19 related supply disruptions ease, critical components will be directed to activities based on the greatest public health benefit: first to repair failed units, then to new ventilator manufacture, and then to preventative maintenance and recall activities such as those described in FSN86600049. This is a dynamic situation, but Philips anticipates initiating the first field replacements as soon as June and continuing replacements until all units are addressed; however, this will depend on the time course of the COVID-19 pandemic crisis. Despite this time delay in repair of affected units, Philips has set aside parts for repair of ventilators that may fail in the interim. Please contact Philips if one of the affected units should fail.

In the meantime, it is important to follow directions in the operator's manual and the Field Safety Notice to further reduce any potential risk associated with an intermittent R31 failure. This includes using the ventilator's remote alarm feature as well as using 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 potential R31 failure, Philips will take immediate action to replace the PCBA at no cost to the customer.

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With respect to clinical risk to patients, Philips' original analysis concluded that it is not necessary to remove affected Philips V60 ventilators from service due to the rarity of the failure described in FSN86600049. This field action affects 25,467 V60 Ventilators with the R31 component, many of which have been in the field more than 10 years and have logged millions of hours of use. Of these potentially affected V60 Ventilators in service globally, Philips has identified only 44 cases of likely R31 failure. These data indicate a very low lifetime failure rate of 0.17%, and an annual failure rate of 0.023%. One of the potential mitigations of clinical risk is the device alarming, notifying users of a device malfunction. Of the 44 devices with a likely R31 failure, alarming was confirmed to have occurred in 40 cases. In the remaining 4 cases, there was insufficient data to indicate whether alarming occurred. These data show a low failure rate, and therefore Philips recommends the devices remain in use, despite delays in parts availability and implementation of repairs under FSN86600049.

Upon further analysis, and after considering the current world-wide ventilator shortage due to COVID-19, and the life sustaining nature of mechanical ventilation in patients afflicted with COVID-19, Philips maintains that the public health is best protected by leaving non-failed V60s in the field for critical life-sustaining therapeutic use. Performing proactive corrective maintenance at this time would require allocating a limited supply of ventilator components to replace existing functional components while reducing the number of ventilators available to the market.

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

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