Philips Respironics Recalls V60 and V60 Plus Ventilators Equipped with High Flow Therapy Software Versions 3.00 and 3.10 Due to Risk of Receiving Reduced Oxygen

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Note: This recall is separate and **unrelated** to the June 2021 Philips Respironics ventilator, BiPAP, and CPAP machine recall (https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks).

Recalled Product

- V60 Plus ventilators and all V60 ventilators upgraded to enable High Flow Therapy (software version 3.00 and 3.10)
- Distribution Dates: May 1, 2009 to June 2, 2021
- Devices Recalled in the U.S.: 16,535
- Date Initiated by Firm: June 18, 2021

Device Use

V60 and V60 Plus ventilators equipped with high flow therapy are used to provide patients with breathing assistance at high concentration of oxygen at a higher flow than typical oxygen therapy. These devices include a design safety mechanism limiting the amount of flow that can be delivered to a patient in situations where the system pressure reaches a default maximum pressure limit, due to a partial obstruction in the breathing circuit.

Reason for Recall

Philips Respironics is recalling the V60 and V60 Plus ventilators that provide High Flow Therapy (Software Version 3.00 and Software Version 3.10) due to the risk to the patients who rely on the ventilator to provide high flow oxygen therapy if the system pressure reaches the default maximum limit. This can occur if the oxygen flow is partially blocked for any reason. If

the issue causing maximum system pressure is not resolved by the health care provider, the ventilator will continue to provide the patient with lower oxygen flow rate and issue a low priority alarm. This could lead to serious adverse events, including death.

There have been 61 incidents, 25 injuries, and no deaths reported for this issue.

Who May be Affected

- Health care providers using affected Respironics ventilators
- Patients who require care using affected Respironics ventilators

What to Do

On June 18 2021, Philips Respironics sent an "Urgent Field Safety Notice" letter to all affected customers and provided the following instructions when using this device for high flow oxygen therapy:

- Monitor the patient's oxygen saturation continuously.
- Provide constant and close monitoring of all patients who are dependent on supplemental oxygen and at risk of clinical deterioration to prevent dangerous drops in blood oxygen levels, work of breathing, respiratory distress and resulting escalation in medical treatment.
- Respond to all alarms urgently, regardless of alarm priority.
- Do not use high flow therapy if the patient cannot be constantly and closely monitored by the clinician.
- Refer to and follow the user manual addendum (attached to the safety notice) titled "V60 Plus User Manual Addendum: High-Flow Therapy Safety and Alarm Page 3 of 8 Features". This user manual addendum provides additional technical details about the "Cannot Reach Target Flow" (CRTF) alarm functionality.
- Watch the "**Understanding HFT** (https://www.learningconnection.philips.com/en/V60_V60Plus-education) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)" video for additional information and education regarding this issue.
- Complete, sign, and return the Acknowledgment and Receipt Form sent with the letter

Contact Information

Customers with questions about this recall should contact their local Philips Respironics representative.

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=187952)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.