

# Respironics California Recalls the V60 Non-invasive Ventilator Due to Faulty Cable Pins That May Cause the Device to Shut Down Unexpectedly

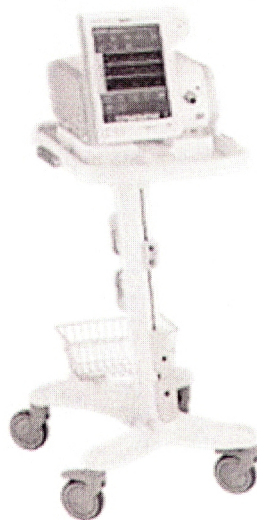
*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death*

## Recalled Product

- Respironics V60 Non-invasive Ventilators
- Serial numbers: **See list**  
**<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=154944>**
- Manufacturing dates: April 2, 2009 to September 15, 2015
- Distribution dates: April 4, 2009 to September 14, 2015
- Devices recalled in the U.S.: 20,690 units nationwide

## Device Use

The Respironics V60 Non-invasive Ventilator provides continuous or intermittent breathing support to pediatric patients weighing at least 44 pounds to adult patients. This ventilator is used in hospitals or other health care facilities under the direction of qualified medical professionals such as physicians, nurses, and respiratory therapists.



Respironics V60 Non-invasive Ventilator

## Reason for Recall

Respironics is recalling the V60 Non-invasive Ventilator because the pins within the internal cable that connects the ventilator's motor to the control board may become loose over time due to low frequency vibration. The loose pins may prevent data to be transferred between the motor and the control board, triggering the ventilator to shut down unexpectedly and to sound an alarm. An unexpected stop in ventilation therapy may cause serious adverse health consequences, including death.

## Who May Be Affected

- All patient groups receiving ventilation therapy for breathing support using this device
- Health care providers who monitor patients receiving ventilation therapy with this device

## What to Do

On May 8, 2017, Respironics California sent an "Urgent: Medical Device Recall" letter to its consumers. The letter provided the following information to customers:

- Appropriately trained personnel may continue using the V60. The incidence of failure is low.
- Ensure an alternative form of ventilation is available at all times, including intra-hospital transport (e.g. manual ventilation bag).
- Operate the ventilator as directed in the operator's manual including:
  - promptly attend all alarms presented by the ventilator;
  - use an external oxygen monitor, and to set the alarm thresholds appropriately;
  - ensure the correct circuits and masks identified in the operator's manual are being used;
- When possible, connect the ventilator to a remote call system.
- If the V60 shuts down, alarms, and displays any of the error codes 100A, 1006, 1007, 1008:
  - turn the V60 off
  - discontinue use of the V60
  - use an alternate ventilator
  - call your local customer service contact and report the failure by referencing FCO86600037A.
- Complete and return the "Acknowledgment and Receipt Form" to Philips' by fax to 1-877-499-7223, email to [recall.response@philips.com](mailto:recall.response@philips.com) (<mailto:recall.response@philips.com>), or mail to:

Kerry Chase (Mailstop #4202)  
Philips Healthtech 3000 Minuteman Road  
Andover, MA 01810-10032

## Contact Information

Health care professionals and consumers with questions about this device are instructed to contact Respironics California at 1-800-345-6443.

## Date Recall Initiated

April 24, 2017

## How Do I Report a Problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>) either online, by regular mail or by FAX to 1-800-FDA-0178.

**More in Medical Device Recalls**  
**(/MedicalDevices/Safety/ListofRecalls/default.htm)**

**2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)**

**2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)**