

Adult Foster Home Provider Alert

Policy updates, rule clarifications and announcements

Date: February 26, 2014

Topic: Recall of Trilogy Ventilator by Philips Respironics

Provider: APD (Older Adults and Adults with Physical Disabilities)

DD (Developmental Disabilities)

Trilogy Ventilator Models 100, 200 and 202 by Philips Respironics: Recall - Failure to Deliver Mechanical Breaths

ISSUE: Respironics, Inc., a Philips Healthcare business, announced a worldwide recall of approximately 600 Philips Respironics Trilogy Ventilators due to a potentially defective component on the Trilogy Ventilator power management board, which could affect the function of the device. If this issue is not corrected it is possible that the ventilator may fail to deliver mechanical breaths and that the alarm functionality may be reduced to indicate ventilatory failure, resulting in serious adverse health consequences or death.

BACKGROUND: The Philips Respironics Trilogy Ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. During production testing Philips Respironics discovered that the Trilogy ventilators contain a potentially defective ferrite component on the power management board of the device.

This recall affects models 100, 200 and 202, shipped between December 31, 2013, and January 30, 2014. Countries where affected devices have been shipped include the United States, France, United Kingdom, Hong Kong, India, Italy, Korea, Kuwait, Netherlands, and Singapore.

RECOMMENDATION: Customers should remove affected devices from service and to return them to Philips for replacement. All distributors, providers, and customers with potentially affected Trilogy devices will have their units replaced.

Philips Respironics has notified all United States and international distributors, providers, and customers that may have devices subject to this recall, and has provided affected device serial numbers for identification. Serial numbers of affected devices are located on the back of the device. See product image.



Customers who have questions about the recall or require further information or support concerning this issue, may contact their local Philips Respironics representative via the Customer Care Center phone number: 1-800-345-6443, which is active 24/7.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the Press Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm386561.htm>