Voluntary Recall Issued For Limited Number Of Trilogy Ventilators

/PRNewswire/ -- Respironics, Inc. announced today that it is voluntarily recalling 80 Trilogy Model 100 and five Trilogy Model 202 ventilators in the United States. The recall was initiated on April 27, 2012 and is being conducted to replace a potentially defective electronic component. Respironics has received no reports from users of ventilator malfunction, injury or death related to this issue.

The Trilogy 100 ventilator provides volume and pressure support ventilation for adult and pediatric patients in both invasive and noninvasive home, institution/hospital, and portable applications. The Trilogy 202 is for hospital use and allows blending of external oxygen with volume and pressure support. The Trilogy 200 ventilator model distributed in the United States is not affected by this recall.

The defective component is in the power supply of the ventilators, and if it fails, there may be a reduction or cessation of ventilator therapy and/or the ventilator may fail to alarm and alert caregivers to this situation. Failure of a caregiver to respond to a failed device could result in harm to a ventilator dependent patient.

Respironics has notified all United States distributors, providers, sales personnel and customers that may have devices subject to this recall. Replacement units have been shipped to all affected customers. To date, all affected Trilogy 202 devices have been returned, and Respironics is working to arrange the return of the nine affected Trilogy 100 units that remain with customers. Customers with questions about this recall may contact Respironics Customer Service at 1-877-387-3311.

Respironics has notified the U.S. Food & Drug Administration (FDA) of its decision to voluntarily recall the affected product. Any adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch. Adverse reactions and/or quality problems should also be reported to Philips Respironics at 1-800-345-6443.

SOURCE Respironics, Inc.