Medical Devices

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Hamilton Medical, Inc., HAMILTON-T1 Ventilators with Software Versions 1.1.2 and Lower

Recall Class: Class I

Date Recall Initiated: January 11, 2013

Product: HAMILTON-T1 ventilators with software versions 1.1.2 and lower; part numbers 161005 and 161006

This device was manufactured and distributed from February, 2012 through December, 2012.

Use: The HAMILTON-T1 ventilator provides continuous or intermittent breathing support to adults and pediatric patients.

Recalling Firm:
Hamilton Medical Inc.
4990 Energy Way
PO Box 30008
Reno, Nevada 89502-4123

Manufacturer:
Hamilton Medical AG
Via Crusch 8
Bonaduz, Switzerland

Reason for Recall: During ventilation of small pediatric patients with high airway resistance and low lung function, there may be unexpected high internal oxygen consumption by HAMILTON-T1 ventilators with software versions 1.1.2 and lower. This may cause miscalculation of the required oxygen needed for long time applications with limited oxygen supply. The HAMILTON-T1 oxygen capacity must be calculated using a larger margin than originally expected.

This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions may call the company at 1-800-426-6331, extension 215.

FDA District: San Francisco

FDA Comments:
On January 11, 2013, Hamilton Medical mailed a letter notifying their customers of the problem and informed them that the firm is working on a software version with reduced oxygen consumption. The letter included a "Medical Device Safety Alert and Corrective Action" document. The firm asked their customers to review this document for details regarding the root cause and corrective action with the current 1.1.2 or lower software.

Customers will be notified upon completion of the new software. Arrangements will be made to provide a loaner unit while the customer's T1 ventilator is returned to the firm's Reno Service Department for the software upgrade.

The firm also directed their customers to update their T1 Operator Manuals with an included Oxygen Consumption formula page which provides revised information for calculating oxygen capacity.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

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