Medical Devices

Covidien, Puritan Bennett 840 Series Ventilator - Software Problem

Recall Class: Class I

Date Recall Initiated: December 16, 2013

Product(s): Puritan Bennett 840 Series Ventilator

Model/catalog/lot numbers: Software Part Number 4-070212-85, Revision AB-AG

Range of manufacturing and distribution dates:
Manufactured: April 30, 1998 to March 12, 2010
Distributed: August 1, 2008 to October 31, 2010

Use: A critical care ventilator that provides continuous ventilation for infant, pediatric, and adult patients.

Recalling Firm:
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301-3214

Reason for Recall: Due to a software problem, a diagnostic code (XB0069) may be triggered. This causes the ventilator to stop functioning, triggering the safety alarm and causing the patient to suddenly be required to breathe on his or her own. These devices are used on critically ill patients who may not be able to continue breathing without the ventilator. This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions regarding this recall can contact Covidien Technical Services at 800-255-6774, Monday through Friday, from 6 AM to 5 PM Pacific Time (Menu option # 4). Customer service (Menu option # 3) is available Monday through Friday from 8 AM to 6:30 PM Eastern Time.

FDA District: Denver District

FDA Comments: On December 16, 2013, Covidien sent its customers an Urgent Medical Device Voluntary Field Correction letter to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to continue using their Puritan Bennett 840 ventilators until they are able to install the software update outlined in the letter.

There are several ways to install the software update. To initiate the process for updating the software and select the method for an individual facility, customers should go to the software update management portal at www.PB840technicalupdate.com[1] and follow the instructions to register.

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[2] either online, by regular mail or by FAX.

Additional Links:

- Firm Recall Webpage[3]

Page Last Updated: 01/09/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. http://www.PB840technicalupdate.com
2. https://www.accessdata.fda.gov/scripts/medwatch/
3. http://www.PB840technicalupdate.com