



California Medical Device Recall Information



Recall Name

Covidien Recalls Puritan Bennett 840 Series Ventilator Due to a Software Problem

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|--------------|---|--------------------------------|---|
| 12/16/13 | Puritan Bennett 840 Series Ventilator | Covidien Boulder, CO | <p><i>Due to a software problem, a diagnostic code (XB0069) may be triggered.</i></p> <p><i>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.</i></p> <p><i>This may cause serious adverse health consequences, including death.</i></p> |
| Recall Class | Product Identification | Distribution | Affected Dates |
| I | <u>Software Part Number:</u> 4-070212-85, Rev. AB-AG | CA , nationwide | <p><u>Manufactured:</u> April 30, 1998 to March 12, 2010</p> <p><u>Distributed:</u> August 1, 2008 to October 31, 2010</p> |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm381044.htm>