

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Nellcor Puritan Bennett, 980 Ventilator System - Software Issue May Stop Ventilator

Recall Class: Class I

Date Recall Initiated: October 1, 2014

Devices: Puritan Bennett 980 Ventilator System

- Manufacturing Dates: March 3, 2014 through August 19, 2014
- Distribution Dates: March 3, 2014 through August 22, 2014

See list of recalled serial numbers

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=130226>).

Use: The Nellcor Puritan Bennett 980 Ventilator System provides constant breathing support for adults, children, and premature babies that weigh at least 10.6 ounces. The ventilator is used in hospitals or during patient transport.

Recalling Firm:

Nellcor Puritan Bennett Inc. (doing business as Covidien LP)
6135 Gunbarrel Avenue
Boulder, Colorado 80301-3214

Reason for Recall: Puritan Bennett 980 Ventilator Systems with software versions below 2.8 may have a software problem that causes the ventilator to stop working after the air and oxygen gas supply lines are disconnected and then reconnected. This can lead to serious health problems or death if the healthcare provider does not connect the patient to another ventilator or to a different form of breathing support.

Public Contact: For assistance, contact Covidien's Technical Support Department at 1 (800) 255-6774, option 4, and then option 1, Monday through Friday, 6 a.m. to 4 p.m., Pacific Time.

FDA District: Denver District Office

More Information about this Recall:

A Covidien representative will update the software on the ventilators as soon as possible.

Covidien sent an Urgent Field Corrective Action letter dated October 3, 2014 to its customers with the following information.

Important Safety Reminders:

- Always follow the instructions found in the operator's manual. See Section 3.5.2 for information about disconnecting and reconnecting gas sources.
- Always closely watch patients on ventilators.

- Always keep another source of breathing support nearby when using the ventilator.
- Always connect at least two gas sources to the ventilator to make sure a constant gas supply is ready for the patient in case one of the gas sources fails.
- Maintain the ventilator at the suggested times as found in Table 7-1 in the operator's manual.

Additional Instructions:

- Customers may continue to use these ventilators until Covidien updates the software as long as two gas sources are connected to the ventilator at all times.
- Always keep at least one gas source connected to the ventilator when disconnecting and reconnecting gas sources.
- If the ventilator stops, provide another source of breathing help according to the hospital's rules to reduce patient risk.
- To receive the software update, complete the acknowledgement and receipt form attached to the correction letter. Fax it to the Covidien contact found on the form.
- Forward a copy of the Urgent Field Corrective Action letter to other healthcare settings or individuals who received the Puritan Bennett 980 Ventilator.

About Class I Recalls:

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 (<https://www.accessdata.fda.gov/scripts/medwatch/>)** either online, by regular mail or by FAX.