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

Covidien, Puritan Bennett 980 Ventilators - Amount of Air Delivered May Be Lower Than Programmed

Recall Class: Class I

Date Recall Initiated: July 16, 2015

Device: Puritan Bennett 980 Ventilator System

- Lot numbers: All lots with the products codes below are affected
- Manufactured from: March 2014 to June 2015
- Distributed from: March 1, 2014 to June 17, 2015
- Devices Recalled in the U.S.: 657

Product Codes: 980U1ENDIUU, 980U1ENDIUUS, 980U3ENDIUU, 980U3ENDIUUS, 980N1ENDIUU, 980N1ENDIUUS, 980N3ENDIUU, 980N3ENDIUUS

Use: The Puritan Bennett 980 (PB980) Ventilator System provides constant breathing support for adults, children, and premature babies weighing at least 10.6 ounces. The ventilator is used in hospitals or during patient transport.

Recalling Firm:
Covidien LP (now part of Medtronic, formerly Nellcor Puritan Bennett, Inc)
6135 Gunbarrel Avenue
Boulder, CO 80301

Reason for Recall: When the ventilator is in neonatal Volume Control Plus (VC+) mode with active humidification, a software error may cause the amount of air being delivered to the patient (tidal volume) to be lower than the amount programmed by the clinician.

If a patient does not receive the amount of air set on the machine, they may need to be removed from the ventilator and placed on a different system. A patient not receiving enough oxygen, can result in possible injury or death.

Public Contact: Customers with questions may contact Covidien's Technical Support Department at 800-255-6774 (option 4, then option 1).

FDA District: Denver District Office

More Information about this Recall:

On July 17, 2015, Covidien sent an Urgent: Field Corrective Action Notice to customers informing them that Covidien intends to implement a software update to correct the error. Service engineers will contact customers to help coordinate this process. Until the update is implemented, Covidien recommends the following:

- Assess all neonatal patients on a PB980 ventilator using VC+ in NeoMode to ensure each patient is receiving sufficient ventilation.
- Transfer patients to an alternative ventilator when the patient is clinically stable Patients can remain on PB980 ventilators until it is safe to transfer them to a different ventilator.
- Immediately notify all users of the PB980 ventilator with the NeoMode feature about this action.
- If the PB980 ventilator is being used with the NeoMode feature in only pressure control modes, transfer the patient to another ventilator as soon as possible.
- Universal model ventilators being used for adult or pediatric patients may remain in use until it is safe to remove the ventilator from use and change the configuration to disable the NeoMode feature.
- Notify any users who the PB980 ventilator was distributed to.
- Complete the form attached to the notice and return it to Covidien.
- Work with Covidien System Engineers to allow them to update the ventilator to remove NeoMode software from the system.

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/)** online, by regular mail or by FAX.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)