

URGENT Field Safety Notice
Puritan Bennett™ 980 Series Ventilator System

October DD, 2014

FSCA *PB980 Backlight inverter board replacement 10/14*

Reference:

Dear Valued Customer,

The purpose of this letter is to advise you that Covidien is issuing a Field Safety Corrective Action (FSCA) for all Puritan Bennett™ 980 ventilators related to an issue identified from customer complaints.

The issue is related to a capacitor failure in the backlight inverter printed circuit board assembly (PCBA) in the ventilator display that can cause a dimming of the display that may be accompanied by a burning odor. In complaints reported to date, the Puritan Bennett™ 980 ventilator remained functional and ventilatory support to the patient continued when this failure occurred. The PCBA must be replaced to preclude possible failure of the component.

Covidien has had no reports of serious patient injury or death associated with this issue.

Actions to be taken by the customer/user

Covidien is taking prompt action to address this issue and a Covidien representative will replace the backlight inverter PCBA on your ventilator(s) as soon as possible. **You may continue to use your ventilator(s) during this time.**

According to our records, the following PB980 ventilator units were sold to your facility:

PB980 Ventilator Part Number	Serial Number

Please complete the attached verification form in full and fax or e-mail it to the Covidien contact indicated on the form. If you need further assistance, contact local Covidien representative **RA COUNTRY SPECIFIC TELEPHONE NUMBER.**

Important Safety Reminders

Always follow the instructions described in the Puritan Bennett™ 980 ventilator operator's manual.

- In case of fire or a burning smell, immediately take the following actions if it is safe to do so: disconnect the patient from the ventilator and disconnect the ventilator from the oxygen supply, facility power, and all batteries. Provide alternate method of ventilatory support to the patient, if required (1.3 Safety Information - Warnings regarding fire hazards).

- Patients on mechanical ventilation should be monitored by clinicians for proper patient ventilation. **(General Warnings)**
- An alternative source of ventilation, such as a self-inflating, manually powered resuscitator (as specified in ISO 10651-4 with mask) should always be available when using the ventilator. **(General Warnings)**

This notification is being issued with the knowledge of the [add local Competent Authority]. Please communicate this important information within your facility as required.

If your facility has distributed Puritan Bennett™ 980 ventilators to other persons or facilities, please promptly forward a copy of this letter to those recipients. Please maintain awareness on this notice and resulting action for an appropriate time period to ensure effectiveness of the corrective action.

Should you have any questions regarding this letter or to report any issues with the Puritan Bennett™ 980 ventilator contact your local Covidien representative at [COUNTRY SPECIFIC TELEPHONE NUMBER], to ensure proper device reporting procedures are followed.

Sincerely,

[Local Signature]