

URGENT FIELD SAFETY NOTICE

Puritan Bennett™ 840 Ventilator

DAY MONTH, 2013

FSCA Reference: PB840 Vent12/13

Attention: Medical Director, Quality / Risk Management Director, Biotechnical service & ICU Director

Please forward this communication to any potential users of the product.

Dear Valued Customer,

Covidien is conducting a voluntary field safety corrective action (FSCA) on Puritan Bennett™ 840 ventilator systems with certain software versions in response to customer reports of ventilator diagnostic code XB0069 in which the device stops mechanical ventilation due to a software error. The frequency of occurrence of this code is low. You may continue to use your Puritan Bennett™ 840 ventilators until the software update, outlined below, is installed.

When this diagnostic code occurs, the ventilator:

1. Stops delivering gases to the patient;
2. Immediately initiates a high priority visual and audible alarm to the caregiver;
3. Displays a “device alert” red banner on the ventilator graphic display;
4. Illuminates “vent inop” and “safety valve open” red LEDs, and opens its safety valve to allow the patient with spontaneous breathing efforts to breathe room air; and
5. Shows in the system diagnostic log “Monitor hip fails (XB0069)”.

There have been no patient injuries or deaths reported to Covidien in connection with diagnostic code XB0069. As outlined in the Operator’s Manual, should one of your Puritan Bennett™ 840 ventilators experience this issue, it can no longer be used until it is serviced.

Our records indicate your facility has Puritan Bennett™ 840 ventilators with serial numbers associated with affected software versions shown in the table below. You will need to verify the software version on each one of your ventilators to ensure appropriate steps are taken in connection with this field action. If your current software version is listed in the Non-Impacted Software Versions column, you do not need to take any action regarding this announcement.

840 Localized Language	Part Number	Impacted Software Versions	Non-Impacted Software Versions
Portuguese	4-070205-85	AB – AD	D – AA
Spanish	4-070201-85	AC – AE	E – AB
Non US English	4-070000-85	AE – AK	E – AD
French	4-070202-85	AE – AG	E – AD
German	4-070203-85	AE – AG	E – AD
Italian	4-070204-85	AE – AG	E – AD
Polish	4-070208-85	M – P	A – L
Russian	4-070209-85	L-N	A-K

URGENT FIELD SAFETY NOTICE

Puritan Bennett™ 840 Ventilator

Covidien's failure investigation has determined this issue only impacts certain software versions. For those software versions, the two scenarios in which diagnostic code XB0069 can *potentially* occur are the following:

- When the patient can generate a strong spontaneous effort with a sustained expiratory flow rate of > 90 L/min for ≥ 0.4 seconds AND the difference between the set PEEP and high pressure alarm is <35 cmH₂O.
- When using Volume Control mode with an inspiratory time of > 0.4 seconds AND with Leak Compensation being enabled.

Covidien has developed a software solution to address this issue and it is available now. However, the software update may take an extended period of time to reach all customers. Until the software is updated, users will need to remain vigilant regarding this issue. It is expected that the software update should be installed on all affected systems by the end of 2014.

To initiate the process for updating your software and to select the method that best suits your facility, please complete the attached Verification form and fax it to the Covidien contact indicated on the form. If you need further assistance contact your local Covidien representative RA **COUNTRY SPECIFIC TELEPHONE NUMBER**.

Important Safety Reminders:

Always follow the instructions as described in the Puritan Bennett™ 840 Operator's Manual:

- a) Patients on life-support equipment should be appropriately monitored by medical personnel and suitable monitoring devices (**Preface**);
- b) An alternative source of ventilation should always be available when using a critical care ventilator (**Preface**); and
- c) Using the ventilator's selectable alarm volume range, be sure to select an alarm volume level that can be discerned above background noise levels (**Section 5.5**).

This action is being taken with the knowledge of the **[add local Competent Authority]**. Please maintain awareness on this notice and resulting action for an appropriate time period to ensure effectiveness of the corrective action. Please communicate this important information within your facility as required. If your facility has distributed Puritan Bennett™ 840 ventilators to other persons or facilities, please promptly forward a copy of this letter those recipients.

Should you have any questions regarding this letter or to report any issues with the Puritan Bennett™ 840 ventilator contact your local Covidien representative at **COUNTRY SPECIFIC TELEPHONE NUMBER**, to ensure proper device reporting procedures are followed.

Sincerely,

Country Specific
Regulatory Affairs

Enclosed