

**URGENT Field Safety Notice**  
**Puritan Bennett™ 980 Series Ventilator System**

October DD, 2014

**Reference:** *PB980 Ventilator inoperative condition, gas supply sources 10/14*

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.

This issue is software related and can lead to a “Ventilator Inoperative” condition when the ventilator should resume ventilation. Normally, if the ventilator is in use and both oxygen and air gas sources are disconnected (leaving the ventilator with no supply of compressed air or oxygen for ventilation of the patient), the ventilator annunciates a high priority “No Air Supply” and “No O<sub>2</sub> Supply” alarm. The ventilator then enters a “Safety Valve Open” condition, as described in Table 6-6 of the Puritan Bennett™ 980 ventilator operator’s manual. Usually this is immediately recoverable when a gas supply source is reconnected. However, due to a software issue, in some cases the ventilator may transition with a “Ventilator Inoperative” condition upon reconnection of a gas supply source. A software update is required to preclude this issue from occurring.

The following PB980 ventilator software versions are affected by this issue:

<b>Language</b>	<b>Part Number</b>	<b>Software Revision</b>
FRENCH	10097145	G, J, M & N
PORTUGUESE	10097146	G, J, M & N
SPANISH	10097147	G, J, M & N
GERMAN	10097148	G, J, M & N
ITALIAN	10097149	G, J, M & N
RUSSIAN	10097151	G, J, M & N
POLISH	10097152	G, J, M & N
SWEDISH	10097155	G, J, M & N
DANISH	10097156	G, J, M & N
FINNISH	10097157	G, J, M & N
NORWEGIAN	10097158	G, J, M & N
GREEK	10097159	G, J, M & N
CZECH	10097160	G, J, M & N
HUNGARIAN	10097161	G, J, M & N
SLOVAKIAN	10097162	G, J, M & N
DUTCH	10097163	G, J, M & N
BULGARIAN	10097164	G, J, M & N
SLOVENIAN	10097165	G, J, M & N
TURKISH	10097166	G, J, M & N
CROATIAN	10097167	G, J, M & N
SERBIAN	10097168	G, J, M & N
ROMANIAN	10097169	G, J, M & N

To maintain continued ventilatory support, **always keep one adequate gas source connected** to the Puritan Bennett™ 980 ventilator when disconnecting and reconnecting gas sources. Please refer to Section 3.5.2 of the Puritan Bennett™ 980 ventilator operator's manual for additional information. During a "Ventilator Inoperative" condition, the patient is not provided ventilatory support, but depending on the clinical condition of the patient, they may breathe room air spontaneously through the open safety valve. **If you encounter a ventilator inoperative condition, immediately provide alternative ventilation in conjunction with your institutional protocols to minimize risk to the patient.**

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 update the software on your ventilator(s) as soon as possible. **You may continue to use your ventilator(s) during this time pending the software correction as long as two gas sources are connected to the ventilator during its operation.**

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 your 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.

- 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)**
- Always connect at least two gas sources to the ventilator to ensure a constant gas supply is available to the patient in case one of the gas sources fails. **(General Warnings)**
- To ensure proper ventilator operation, perform the maintenance procedures at the recommended intervals as summarized in Table 7-1 in the operator's manual.

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.

Thank you for your attention to this issue.

Sincerely,

**Local Signature**