

URGENT FIELD SAFETY NOTICE



DAY MONTH, 2014

FSCA Reference: O2 sensor label update 01/14

Oxygen sensor instructions for the Puritan Bennett™ 840 ventilator and Puritan Bennett™ 700 series (740 and 760) ventilators

Dear Covidien Customer,

Covidien is conducting a voluntary field correction with updated labeling to clarify the operational life of the oxygen sensor (O₂ sensor) P/N 4-072214-00 used in the Puritan Bennett 840 ventilator, P/N G-062010-00 used in the Puritan Bennett 700 series ventilators (Puritan Bennett 740 and 760 ventilators) and PN G-062009-00 (O₂ sensor kit) used with either the Puritan Bennett 840 ventilator or the Puritan Bennett 700 series ventilators.

The oxygen sensor for the ventilators has a life of one year from date of manufacture of the sensor, depending on the operating conditions.

Conflicting information was provided to Puritan Bennett 840 ventilator customers in a labeling addendum (P/N 066009A 09/02) stating that the oxygen sensor should be replaced every two years. The correct operational life is one year from the date of manufacture as stated in the Puritan Bennett 840 ventilator operator's manual. The sensor, P/N 4-072214-00 & sensor kit, PN G-062009-00 should not be used after the expiration date printed on the oxygen sensor package.

The Puritan Bennett 700 series ventilator operator's and service manuals also state that the oxygen sensor should be replaced every two years. The sensor, P/N G-062010-00 & sensor kit, PN G-062009-00 should not be used after the expiration date printed on the oxygen sensor package.

The enclosed labeling update, Attachment I, provides detailed information related to the life of oxygen sensors used with the Puritan Bennett 840, 740 and 760 ventilators. This update supplements the information in the current Puritan Bennett 840 ventilator operator's manual, and replaces information in the addendum to the Puritan Bennett 840 ventilator operator's manual and Puritan Bennett 700 series ventilator manuals.

To provide more options for sensor replacement, Covidien has validated another oxygen sensor, P/N 10097559, for use in the Puritan Bennett 840, 740 and 760 ventilators. Information about that sensor is also included in the update in Attachment I.

Attachment II, Attachment III and Attachment IV include information about how to address O₂ sensor alarms and managing situations where the sensor may become nonfunctional while these ventilators are in use.

Please be sure you understand the instructions for operating your ventilator and all precautions and warnings associated with its proper use.

Actions to be performed for this field safety notice:

- Read and understand the enclosed information and communicate this information to those who need to be aware of this labeling update. Following this information will help ensure optimal operation of your ventilator.

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- **For the Puritan Bennett 840 ventilator only:** If you have addendum P/N 066009A 09/02, remove and discard the addendum and replace it with the new information in Attachment I. **For the Puritan Bennett 740 and 760 ventilators only:** Please add the new information in Attachment I to your current operator's manual and service manual.
- Please ensure all O₂ sensors in use or in inventory conform to the instructions in this notification.

Additional important information:

- If a sensor becomes nonfunctional during use and cannot be recalibrated, an external oxygen monitoring device with oxygen alarm capability may be required to monitor the supplied level of oxygen from the ventilator and to provide appropriate alarms.
 - A nonfunctional O₂ sensor does not affect the concentration of oxygen delivered from the ventilator and does not control the flow of gases.
- If a sensor becomes nonfunctional and facility protocol requires transfer of a patient to an alternate ventilator, the patient must be clinically evaluated to determine the best conditions for transfer to reduce risk to the patient.
- Ventilators are not intended to be a comprehensive monitoring device.
- Read and understand the warnings, cautions and notes related to safety, ventilator use and operation that are contained in the Preface of the Operator's Manuals.

This notification is being issued with the knowledge of the [add local Competent Authority].

If you have any questions about this letter or to report any issues with a Puritan Bennett ventilator, contact your local Covidien representative at [COUNTRY SPECIFIC TELEPHONE NUMBER] or your Technical Support Department to ensure proper device reporting procedures are followed.

We apologize for any inconvenience this may cause and thank you for your prompt attention to this matter.

Sincerely,

[Regional
Regulatory Affairs]

Attachment I - Oxygen Sensor Operational Life Labeling Update for Puritan Bennett™ 840 Ventilator and Puritan Bennett™ 700 Series Ventilators

Attachment II - Oxygen Sensor Maintenance and Alarms for the Puritan Bennett™ 840 Ventilator

Attachment III - Oxygen Sensor Replacement for the Puritan Bennett™ 840 Ventilator

Attachment IV - Oxygen Sensor Maintenance and Alarms for Puritan Bennett™ 700 Series Ventilators





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Attachment I

Oxygen Sensor Operational Life Labeling Update for the Puritan Bennett™ 840 and Puritan Bennett™ 700 Series (740 and 760) Ventilators

Please note the following important operational life and installation information related to the oxygen sensors and ensure that all use and maintenance is performed by trained and qualified personnel.

Part Number	P/N: 4-072214-00 (Used with the Puritan Bennett 840 ventilator) P/N: G-062010-00 (Used with the Puritan Bennett 740 and 760 ventilators) PN G-062009-00 (O₂ sensor kit) used with either the Puritan Bennett 840 ventilator or the Puritan Bennett 700 series ventilators.	P/N: 10097559 (For use with the Puritan Bennett 840, 740 and 760 ventilators)
O ₂ Sensor		
Date Code	 For this date code format (MM YY), "Expiration Date 10 14" means that the sensor is no longer usable after October 31, 2014. In this example the sensor should not be installed or used in a ventilator after this date.	 For this date code format (MM YY), the "Install by: 08 14" means that the sensor must be installed in a ventilator before August 31, 2014. It has one year of operational life from the installation date as long as it is installed before the date on the label. In this example the sensor should not be installed or used after August 31, 2015.
O ₂ Sensor Life	The life of the O ₂ sensor is one year from date of manufacture depending on operating conditions.	Once the sensor is installed the operational life is 12 months if it is installed on or before the "Install By:" date on the label.
Customer Maintenance Information	Ensure that maintenance logs for the ventilator contain information identifying when the sensor needs to be replaced to ensure it is not used on a patient where the useful life may expire while in use.	
Factors affecting O ₂ sensor Life	Sensor life depends on operating environment; operation at higher temperature or high O ₂ % levels can shorten the sensor life.	