

URGENT FIELD SAFETY NOTICE



29th January, 2014

FSCA Reference: O2 sensor label update 01/14

MHRA Reference: 2014/001/024/081/010

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:

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- 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.
- **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.
- Sign and return the Acknowledgement form to Amanda.woolven@covidien.com or fax it to 01329 224418

Additional important information:

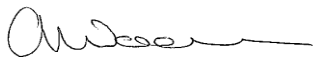
- If a sensor becomes nonfunctional during use and cannot be recalibrated, an external oxygen monitoring device with oxygen alarm capability may be required to monitor the supplied level of oxygen from the ventilator and to provide appropriate alarms.
 - A nonfunctional O₂ sensor does not affect the 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 Medicines and Healthcare Products Regulatory Agency (MHRA).

If you have any questions about this letter or need to report any issues with a Puritan Bennett ventilator, contact your local Covidien representative 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,



Amanda Woolven
Regulatory Affairs Specialist UK

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

Acknowledgement letter