

URGENT FIELD SAFETY NOTICE



Covidien Deutschland GmbH · Gewerbepark 1 · D-93333 Neustadt/Donau



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.

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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.
- **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 Swissmedic

If you have any questions about this letter or to report any issues with a Puritan Bennett ventilator, contact your local Technical Support Department at +49 (0)9445 959 380 or your Covidien representative 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,



Alexander Walter
Regulatory Affairs Manager DACH & Norden

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 (O ₂ 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	 <p>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.</p>	 <p>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.</p>
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.	

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Attachment II

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

Puritan Bennett 800 Series Ventilator System Operator's and Technical Reference Manual, Operator preventive maintenance procedures and frequency, Pages OP 7-11, OP 7-12

PREVENTIVE MAINTENANCE SCHEDULE (FREQUENCY)	PREVENTIVE MAINTENANCE (PART/ MAINTENANCE)	REFERENCE SOURCE
Daily or as necessary	Oxygen sensor. Press the 100% O ₂ CAL 2 MIN key or INCREASE O ₂ 2 min key to calibrate the oxygen sensor. Refer to Appendix D in this manual to test the oxygen sensor calibration.	Puritan Bennett 800 Series Ventilator System Operator's and Technical Reference Manual

Puritan Bennett 800 Series Ventilator System Operator's and Technical Reference Manual, Alarm Summary Table 13-2

Base message	Urgency	Analysis message	Remedy message	Comments
O ₂ sensor	Low	Ventilation unaffected	O ₂ sensor out of calibration/failure. Press 100% O ₂ CAL or INCREASE O ₂ 2 min, replace or disable.	Background checks have detected a problem. Resets when operator successfully calibrates oxygen sensor, or disables oxygen sensor.

Puritan Bennett 800 Series Ventilator System Operator's and Technical Reference Manual, Alarm Messages, Pages OP 5-13, OP5-15

WHEN YOU SEE THIS MESSAGE:	IT MEANS...	DO THIS...
Low delivered O ₂ %	The O ₂ % measured during any phase of breath cycle is 7% (12% during the first hour of operation) or more below the O ₂ % parameter for at least 30 seconds. The percentage window increases by 5% for four minutes after you increase the set O ₂ % value.	Check the patient, the air and oxygen supplies, the oxygen analyzer, and the ventilator. Calibrate oxygen sensor (press 100% O ₂ /CAL 2 min key). See page TR 15-6 for information on calibrating the oxygen sensor. Use an external O ₂ monitor and disable the O ₂ sensor.

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O ₂ sensor	Background checks have detected a problem with the oxygen sensor (sensor failure or it is out of calibration). Patient ventilation is unaffected.	Press 100% O ₂ CAL or INCREASE O ₂ 2 min to recalibrate the oxygen sensor. Disable the oxygen sensor. Replace the oxygen sensor. Only a trained / qualified individual should replace the sensor.
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Attachment III

Oxygen Sensor Replacement for the Puritan Bennett™ 840 Ventilator

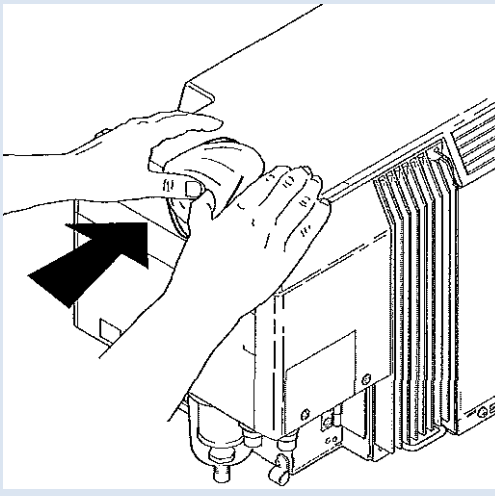
There are two configurations of the Puritan Bennett 840 ventilator that influence the method required to change the oxygen sensor. One configuration has an access port located along the top right edge of the breath delivery unit (BDU) cabinet that enables direct access to the oxygen sensor. Please refer to the pictures below to identify your facility's configuration. Only a trained and qualified individual should replace the sensor.

Puritan Bennett 840 ventilator with O₂ access port

Puritan Bennett 840 ventilator without O₂ sensor access port



Instructions for accessing oxygen sensor for the Puritan Bennett 840 ventilator with O₂ access port

Instructions	Reference: Puritan Bennett 840 Ventilator System Service Manual
<ol style="list-style-type: none">1. Locate the flexible oxygen sensor access cover on the top edge of the cabinet.2. Firmly push the center of the lower flap of the access cover until the lower flap is dislodged from the cabinet.3. Pinch the bottom and top flaps of the access cover firmly together and pull the access cover away from the cabinet to remove the	

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oxygen sensor	
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Instructions for accessing the oxygen sensor for the Puritan Bennett 840 ventilator without O₂ sensor access port – Reference: Puritan Bennett 840 System Service Manual

If your BDU unit does not have an access port on the top right edge of the housing, follow these instructions to replace the oxygen sensor. Only a trained and qualified individual should replace the sensor.

1. Remove the inspiratory module
2. Disconnect oxygen sensor harness from the sensor. Be sure to press the wire retainer tab inside the recess of the oxygen sensor to release the connector.
3. Unscrew oxygen sensor from PSOL manifold. Please refer to the service manual for detailed instructions related to oxygen sensor replacement.

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Attachment IV

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

Specific information related to the O₂ sensor maintenance and alarms for the Puritan Bennett 700 series ventilators is described below. Please refer to precautions and warnings in the operator's manual for proper use of the ventilators.

PURITAN BENNETT 700 SERIES VENTILATOR OPERATOR'S MANUAL

PREVENTIVE MAINTENANCE SCHEDULE (FREQUENCY)	PREVENTIVE MAINTENANCE (PART/MAINTENANCE)	REFERENCE SOURCE
As necessary	Oxygen sensor. Perform a calibration by selecting Calibrate O ₂ Sensor from the MENU key's Oxygen Sensor function.	G-061874-00, Section A Page 7, Table A-2
CALIBRATION	ACTIVITY	REFERENCE SOURCE
Oxygen sensor	<p>Calibrate O₂ Sensor: Allows you to perform a two-point calibration of the oxygen sensor. Only available before normal ventilation begins (patient must not be connected)</p> <p>NOTE: Covidien recommends calibrating the oxygen sensor once a week or with each new patient.</p> <p>O₂ Alarm Info: Allows you to enable or disable the oxygen sensor.</p> <p>O₂ Sensor Display: Allows you to enable or disable displaying the oxygen sensor reading (unless an alarm is active) in the message window, which is updated several times per second.</p>	10066984, Section 6 Table 6.1, Menu Functions Summary
Oxygen sensor	If the calibration is not successful, contact service. To continue ventilating (if indicated by your institution's protocol); disable the oxygen sensor (select O ₂ alarm info from the Oxygen Sensor menu function).Covidien recommends using an external oxygen monitor whenever the ventilator's oxygen sensor is disabled.	10066984, Section 6-5

Please note the following important safety reminders should an O₂ sensor alarms occur during use.

PURITAN BENNETT 700 SERIES VENTILATOR SYSTEM SERVICE MANUAL ALARM MESSAGES

WHEN YOU SEE THIS MESSAGE:	IT MEANS...	DO THIS...
% O ₂ HIGH (NO DIAGNOSTIC CODE LOGGED)	HIGH-PRIORITY ALARM, Measured oxygen percentage more than 10 percentage points above setting for at least 30 seconds.	<ol style="list-style-type: none"> 1. Check air intake filter for occlusion. Replace if necessary. 2. Check oxygen supply. 3. Verify that an oxygen

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WHEN YOU SEE THIS MESSAGE:	IT MEANS...	DO THIS...
	Auto reset when measured O ₂ % is within 10 percentage points of setting.	<p>sensor is installed.</p> <ol style="list-style-type: none"> 4. Check remaining sensor life (via service summary) and replace sensor if required. Only a trained / qualified individual should replace the sensor. 5. Perform FiO₂ calibration check. 6. Replace pressure solenoid PCB. Replacement of the solenoid should only be performed by a trained/qualified individual.
% O ₂ LOW (NO DIAGNOSTIC CODE LOGGED)	<p>HIGH PRIORITY ALARM, Measured oxygen percentage more than 10 percentage points below setting for at least 30 seconds.</p> <p>Auto reset when measured O₂% is within 10 percentage points of setting.</p> <p>The ventilator may have been calibrated at a high altitude then moved to a lower altitude.</p>	<ol style="list-style-type: none"> 1. Check patient. 2. Check oxygen supply. 3. Verify than an oxygen sensor is installed. 4. Check remaining sensor life (via service summary) and replace sensor if required. Only a trained / qualified individual should replace the sensor. 5. Perform FiO₂ calibration check. 6. Perform these calibrations: O₂ pressure calibration and then, if applicable, reg. altitude calibration. 7. Replace pressure solenoid PCB. Replacement of the solenoid should only be performed by a trained/qualified individual.
REPLACE O ₂ SENSOR (DIAGNOSTIC CODE 6022)	<p>HIGH PRIORITY ALARM, Technical Alert. Oxygen sensor missing or reading out of range.</p> <p>Alarm does not auto reset; you must press alarm reset key.</p>	<ol style="list-style-type: none"> 1. Make sure an oxygen sensor is installed and securely connected to ventilator head harness. 2. Perform FiO₂ calibration check. 3. Replace oxygen sensor. Only a trained / qualified individual should replace the sensor.