URGENT FIELD SAFETY NOTICE

DAY MONTH, 2014

FSCA Reference: Oxygen Sensor instructions for PBPB840 & 700 Series Ventilators XX/13

Dear Covidien Customer,

Covidien is conducting a voluntary field safety notification with updated labeling to clarify the operational life of the oxygen sensor (O2 sensor), PN 4-072214-00 used in the Puritan Bennett™ PB840 ventilator system and PN G-061143-00, used in Puritan Bennett™ 740 & 760 ventilator systems. The ventilator's oxygen sensor has a nominal life of one year from date of manufacture depending on the operating conditions.

Previously, conflicting information may have been provided to PBPB840 customers concerning the operational life of the oxygen sensor in a labeling Addendum for the PBPB840. The PBPB840 Operator's Manual states the sensor has a nominal life of one year from the date of manufacture while a PBPB840 Addendum incorrectly stated to replace the sensor every two (2) years. The 740 and 760 Operator's Manual and Service Manual also states 2 years.

To determine the correct expiration date of the oxygen sensor, the expiration date label on the sensor package identifies when the sensor may no longer be used. The enclosed labeling update, Attachment I, provides detailed information related to sensor life and usage with your PB840 or 740/760 ventilators. The enclosed update supplements the information in the current Operator's Manual of your PB840 system and replaces information in the aforementioned PB840 Addendum or Operator's Manual and Service Manual of the PB700 Series Ventilator Systems. See Attachment I.

Covidien has validated another oxygen sensor, PN 10097599, in addition to the existing O2 sensor, PN 4-072214-00, to provide additional sensor supply options. The enclosed update provides information related to both sensors and how to understand the operational life of the sensors. The enclosed update also includes information related to addressing O2 sensor alarms and managing situations where the sensor may become non-functional while the ventilator is being used on a patient. See the excerpted information in Attachment II, Attachment III and Attachment IV for additional information related to maintenance and alarms.

As always, please ensure you are familiar with the instructions for operating your ventilator and are aware of all precautions and warnings associated with its proper use.

Actions to be performed in relation to 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 ensure optimal operation is achieved when using your ventilator.
- **For the Puritan Bennett PB840 ONLY:** If you have Addendum, PN 066009A 09/02, remove and replace with this new information. Otherwise please add this new information to your current operators' manual. Please dispose of the Addendum, PN 066009A 09/02.
- **For the Puritan Bennett 740 & 760 ONLY:** Please add this new information 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.

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- Should a sensor become non-functional during use and cannot be recalibrated, an external oxygen monitoring device may be required to monitor the supplied level of oxygen to the ventilator.
    - A non-functional O2 sensor does not affect the concentration of oxygen delivered to the ventilator nor control the flow of gases.
- If a sensor becomes non-functional and facility protocol requires transfer of a patient to an alternate ventilator, patient conditions must be evaluated to determine the best time for transfer to reduce risk to the patient.
- Ventilators are not intended to be a comprehensive monitoring device. An alternative source of ventilation should always be available when using a critical care ventilator.
- Using the ventilator's selectable alarm volume range, be sure to select an alarm volume level that can be discerned above background noise levels

This notification is being issued with the knowledge of the [add local Competent Authority]. Should you have any questions regarding this letter or need to report any issues with the Puritan Bennett ventilators 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 PB840 and PB 700 Series Ventilators
Attachment II - Oxygen Sensor Maintenance and Alarms for PB840 Ventilator
Attachment III - Oxygen Sensor Replacement for the PB840 Ventilators
Attachment IV - Oxygen Sensor Maintenance and Alarms for PB700 Series Ventilators

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Attachment I

Oxygen Sensor Operational Life Labeling Update for PB840 and PB 700 Series Ventilators

Please note the following important operational life and installation information, related to the O2 sensors and ensure that all usage and maintenance be performed by trained and qualified personnel.

Part Number	PN: 4-072214-00 (PBPB840) PN: G-062010-00 (PB740/PB760)	PN: 10097559 (PBPB840/PB740/PB760)
O2 Sensor		
Date Code	 For this date code format (MM YY), the 'Expiration Date 10 14' means that the sensor is no longer useable after October 2014. It 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 2014.
O2 Sensor Life	The nominal life of the O2 sensor is 1 year from date of manufacture.	For this date code format (MM YY), the 'Install by: 08 14' means that the sensor must be installed in a Ventilator before August 2014. It has one year of operational life if installed before the 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 O2 sensor Life	Sensor life depends on operating environment; operation at higher temperature or high O2 % levels can shorten the sensor life.	

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Attachment II

Oxygen Sensor Maintenance and Alarms for PB840 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 MAINTANCE (PART/ MAINTENANCE)	REFERENCE SOURCE
Daily or as necessary	Oxygen Sensor. Press the 100% O2 CAL 2 MIN key or INCREASE O2 2min 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 Page TR 13-20

Base message	Urgency	Analysis message	Remedy message	Comments
O2 SENSOR	Low	Ventilation unaffected.	O2 sensor out of calibration/failure. Press 100% O2 CAL or INCREASE O2 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 O2%	The O2% measured during any phase of breath cycle is 7% (12% during the first hour of operation) or more below the O2% parameter for at least 30 seconds. The percentage window increases by 5% for four minutes after you increase the set O2% value.	Check the patient, the air and oxygen supplies, the oxygen analyzer, and the ventilator. Calibrate oxygen sensor (press 100% O2/CAL 2 min key). See page TR 15-6 for information on calibrating the oxygen sensor. Use an external O2 monitor and disable the O2 sensor.
O2 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% O2 CAL or INCREASE O2 2 min to recalibrate the oxygen sensor. Disable the oxygen sensor. Replace the oxygen sensor. Replacement of the sensor should only be performed by a trained/qualified individual.

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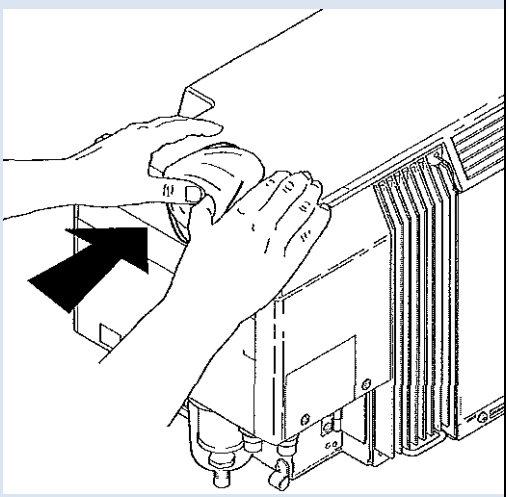
Attachment III

Oxygen Sensor Replacement for the PB840 Ventilators

There are 2 configurations of the PBPB840 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 allows for direct access to the oxygen sensor. Please refer to the pictures below to identify which configuration(s) your facility may have.

PB840 Ventilator with O2 access port **PB840 Ventilator without O2 sensor access port**

Instructions for accessing Oxygen Sensor for the PB840 Ventilator with O2 Access Port

Instructions	Reference: PB840 Ventilator System Service Manual
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 oxygen sensor	

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Instructions for accessing the Oxygen Sensor for the PB840 Ventilator without O2 sensor access port – Reference: PB840 Ventilator System Service Manual

If your BDU unit does not have an access port on the top right edge of the housing, use the following instructions to replace the oxygen 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 your Service Manual for detailed instructions related to oxygen sensor replacement.

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Attachment IV

Oxygen Sensor Maintenance and Alarms for PB700 Series Ventilators

Specific information related to the O2 sensor maintenance and alarms for the PB700 Series ventilators is described below for reference. Please refer to precautions and warnings in the operator's manuals for proper use of the ventilators.

700 SERIES VENTILATOR OPERATORS MANUAL

PREVENTIVE MAINTENANCE SCHEDULE (FREQUENCY)	PREVENTIVE MAINTANCE (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	***-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) **NOTE: (Covidien) recommends calibrating the oxygen sensor once a week or with each new patient.** ***-O_2 Alarm Info:*** Allows you to enable or disable the oxygen sensor. ***-O_2 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.	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 *O2 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.

700 SERIES VENTILATOR SYSTEM SERVICE MANUAL ALARM MESSAGES

WHEN YOU SEE THIS MESSAGE:	IT MEANS…	DO THIS…
% O2 HIGH (NO DIAGNOSTIC CODE LOGGED)	HIGH-PRIORITY ALARM, Measured oxygen percentage more than 10 percentage points above setting for at least 30 seconds. Auto reset when measured % O2 is within 10 percentage points of setting.	1. Check air intake filter for occlusion. Replace if necessary. 2. Check oxygen supply. 3. Verify that an oxygen sensor is installed. 4. Check remaining sensor life (via service summary) and replace sensor if required.

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WHEN YOU SEE THIS MESSAGE:	IT MEANS…	DO THIS…
		Replacement of the sensor should only be performed by a trained/qualified individual. 5. Perform FIO2 calibration check. 6. Replace Pressure Solenoid PCB. Replacement of the solenoid should only be performed by a trained/qualified individual.
% O2 LOW (NO DIAGNOSTIC CODE LOGGED)	HIGH PRIORITY ALARM, Measured oxygen percentage more than 10 percentage points below setting for at least 30 seconds. Auto reset when measured %O2 is within 10 percentage points of setting. The ventilator may have been calibrated at a high altitude then moved to a lower altitude.	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. Replacement of the sensor should only be performed by a trained/qualified individual. 5. Perform FIO2 calibration check. 6. Perform these calibrations: O2 Pressure Calib, than, if applicable, Reg Altitude Calib 7. Replace Pressure Solenoid PCB. Replacement of the solenoid should only be performed by a trained/qualified individual.
REPLACE O2 SENSOR (DIAGNOSTIC CODE 6022)	HIGH PRIORITY ALARM, Technical Alert. Oxygen Sensor missing or reading out of range. Alarm does not auto reset; you must press alarm reset key.	1. Make sure an oxygen sensor is installed and securely connected to ventilator head harness. 2. Perform FIO2 calibration check. 3. Replace Oxygen Sensor. Replacement of the sensor should only be performed by a trained/qualified individual.

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