



**Criterion 60**  
**Pressure/Oxygen**  
**Monitor**

**User's Manual**



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## Introduction

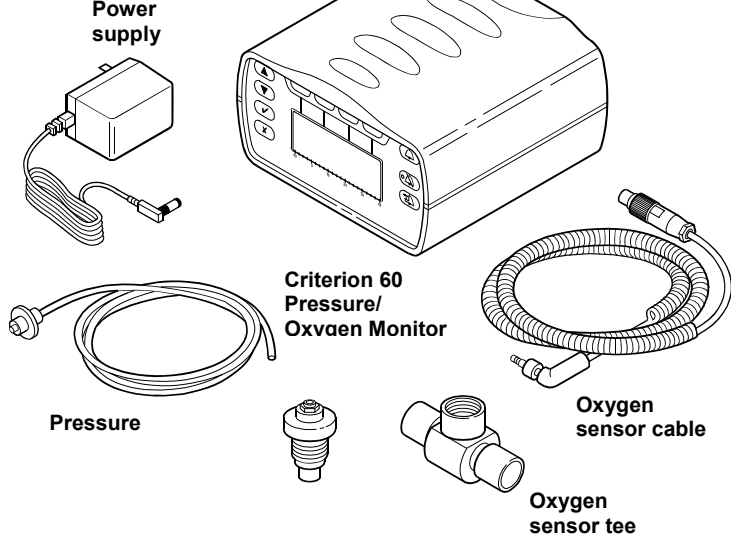
The Criterion 60 Pressure/Oxygen Monitor (Figure 1) monitors patient airway pressure and oxygen concentration throughout the breathing cycle. The monitor uses solid-state pressure transducers to measure circuit and atmospheric pressures, and a galvanic oxygen sensor to measure the partial pressure of oxygen. The oxygen sensor samples gas directly without diverting it from the circuit. The monitor uses the atmospheric pressure and partial pressure of oxygen measurements to derive oxygen concentration.

The Criterion 60 is intended for use with devices that are not capable of monitoring pressure or oxygen concentration (for example, a resuscitation bag or basic ventilator) or as an independent backup for devices that do measure pressure or oxygen.

The Criterion 60 alarms when the airway pressure or oxygen concentration falls outside of the user-selected high and low alarm limits, and displays real-time airway pressure and oxygen concentration.

The Criterion 60 also includes alarm delay (for pressure alarms), alarm silence, and alarm presilence features. Battery backup provides up to 24 hours of backup power in case of AC power failure or when AC power is not available.

**NOTE:** The Criterion 60 is designed for stationary and intra-hospital transport use only.



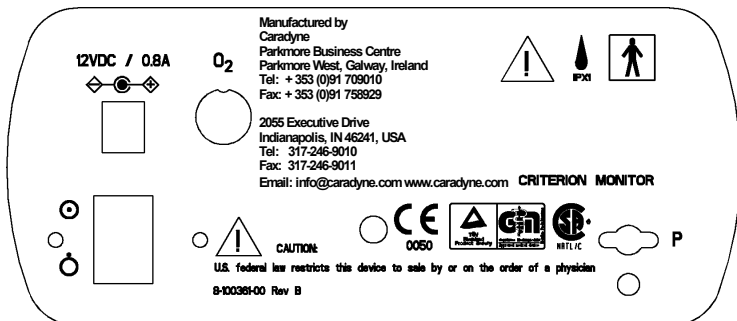
**Figure 1. Criterion 60 Pressure/Oxygen Monitor**

**WARNINGS:**

- To avoid the risk of fire, do not use this device near flammable anesthetics.
- Federal law (U.S.) restricts the sale of this device to, or by the order of, a physician.
- Do not use this device to monitor pressures when patient respiratory rate exceeds 60 breaths per minute.
- This device is not suitable for use in a MRI environment.

## Labels

### Rear panel label



NOTE: The symbol “P” on the back panel label shows the pressure tubing connection, and the symbol “O<sub>2</sub>” shows the oxygen sensor connection.

### Battery compartment label

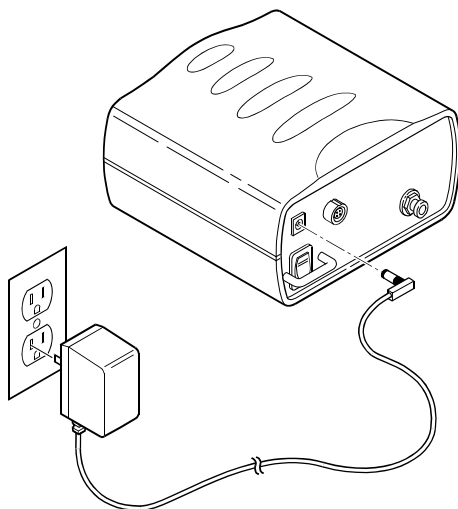


## Connecting the Criterion 60 to power

The Criterion 60 comes with a power supply that accepts mains power (120 or 230 V AC, depending on model/country) and provides a 12 V DC output. Figure 1 shows how the Criterion 60 connects to AC (wall) power. The ON/OFF switch turns monitoring on and off (when the monitor is connected to AC power, the battery can recharge whether the ON/OFF switch is ON or OFF).

### WARNINGS

- To avoid personal injury or equipment damage, keep the power supply cable out of the way of users.
- Use the Criterion 60 Monitor only with Caradyne power supply and battery pack.



**Figure 2. Connecting the Criterion 60 to AC (wall) power**



## Connecting the Criterion 60 to the patient system

The Criterion 60 monitors pressure and oxygen:

- The monitor measures pressure using disposable pressure tubing that includes a hydrophobic filter. The filter protects the monitor from moisture, and reduces the risk of cross contamination.
- The monitor measures oxygen concentration using a reusable oxygen sensor. The sensor is designed for use with the Criterion 60 Pressure/Oxygen Monitor only.

The pressure tubing is typically connected close to the patient airway, while the oxygen sensor is placed in the inspiratory limb upstream of the humidifier. Figure 3, Figure 4, and Figure 5 show how the Criterion 60 can connect to a patient system.

### **WARNING:**

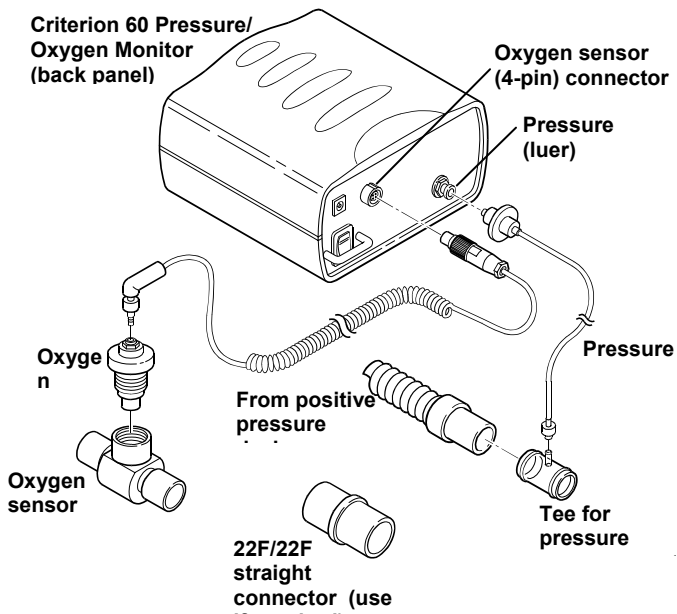
**Do not disassemble the oxygen sensor as it contains harmful caustic substances.**

### **CAUTIONS**

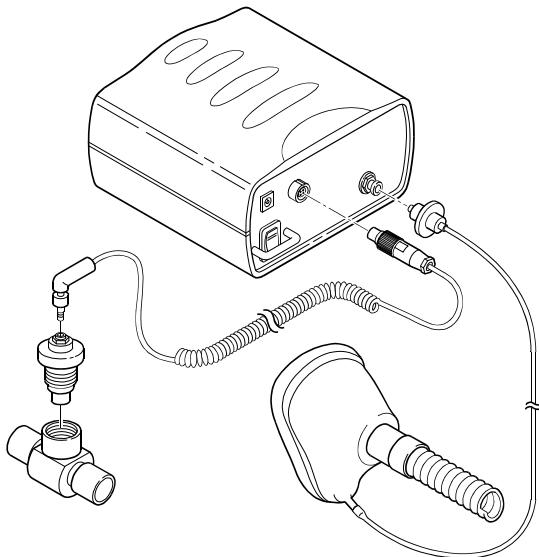
**The sensor will not operate in 100% condensing humidity as the condensing water will block the O<sub>2</sub> supply to the sensor. (It will work in 100% non-condensing O<sub>2</sub>).**

**The sensor should not be handled unnecessarily during calibration or use. Body heat can cause disproportional changes in the sensor compared to the gas, which may produce errors in the readings.**

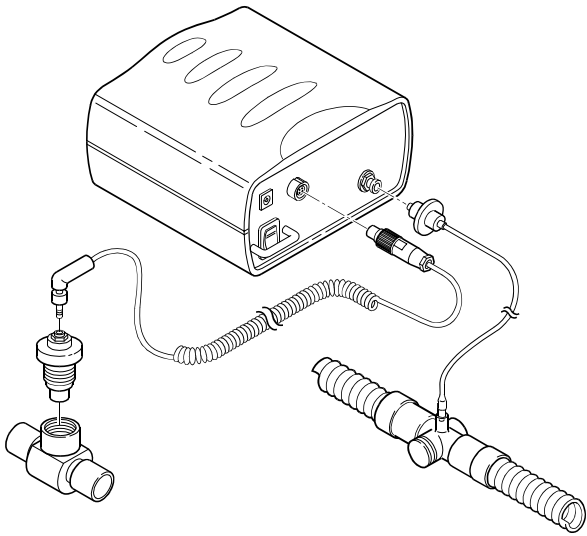
**To avoid monitor damage due to condensation, position the pressure sensor at least 25 cm (10 in.) lower than the monitor.**



**Figure 3. Connecting the Criterion 60 to the patient system**



**Figure 4. Connecting the Criterion 60 to a face mask**

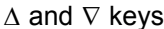








**Figure 5. Connecting the Criterion 60 to a tee or wye and ET tube**

## The Criterion 60 front panel

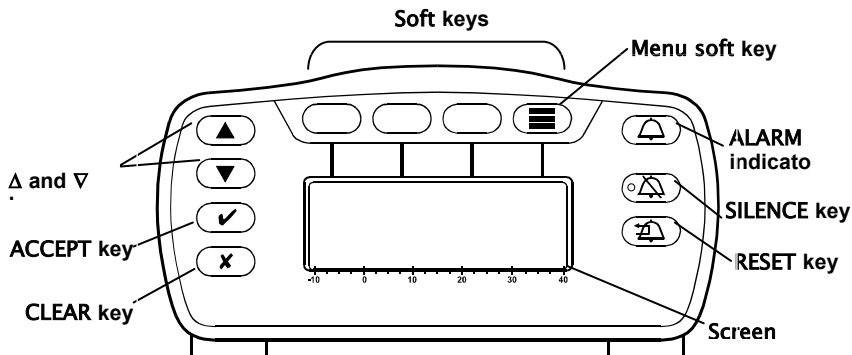
The Criterion 60 front panel (Figure 6) includes the elements summarized in Table 1.

**Table 1. Criterion 60 front panel**

 $\Delta$ and $\nabla$ keys	Scroll up and down to adjust values of selected setting.
 (ACCEPT) key	Saves a new setting or proceeds to next calibration step.
 (CLEAR) key	Cancels a change that has not yet been accepted.
Soft keys	Select a setting or option displayed below each key.
 soft key	The Menu soft key, which selects the pressure or oxygen screen for display.
 (ALARM) indicator	Flashes when an active alarm has not yet been reset (whether or not alarm silence is in effect).
 (SILENCE) key	Silences the audible portion of an alarm for two minutes following the most recent key press. The SILENCE key LED lights when the silence is active and the monitoring screen shows alarm silence time remaining. Also used for alarm presilence feature, which provides two minutes of silence from the most recent key press if pressed before an alarm becomes active.
 (RESET) key	Resets audible and visual alarm indicators, cancels alarm silence, and clears peak pressure displays on the screen (measurement and bar graph).

**Table 1. Criterion 60 front panel**

Screen	Shows screen test and introductory messages, normal monitoring information (alarm settings, oxygen concentration, peak pressure measurement, and bar graph), and calibration prompts.
--------	---



**Figure 6. Criterion 60 front panel**

## Functional test

Before using the Criterion 60 Pressure/Oxygen Monitor, follow these steps to verify that the monitor is functioning properly:

1. Connect AC power and turn the monitor on, then check that the monitor screen turns on each of the screen characters, one block at a time.
2. Once the introductory screen appears, check that the power source indicator displays "AC" to indicate AC power operation.
3. Disconnect the power supply and verify that the screen displays "Bty" to indicate battery operation. Verify that alarm sounds. Reconnect AC power and press RESET.
4. When no pressure is connected to the monitor's luer connector, the monitor should display a Ppk of 0 cmH<sub>2</sub>O and a single line at the zero position on the bar graph.
5. Set the low pressure alarm to 10 cmH<sub>2</sub>O (see *Adjusting alarm settings* in this manual) and verify that the low pressure alarm activates.
6. When exposed to room air, the monitor should display an O<sub>2</sub>% of 21% ± 1%.
7. Set the high O<sub>2</sub>% alarm to 19% oxygen and verify that the high O<sub>2</sub>% alarm activates.

## Normal operation

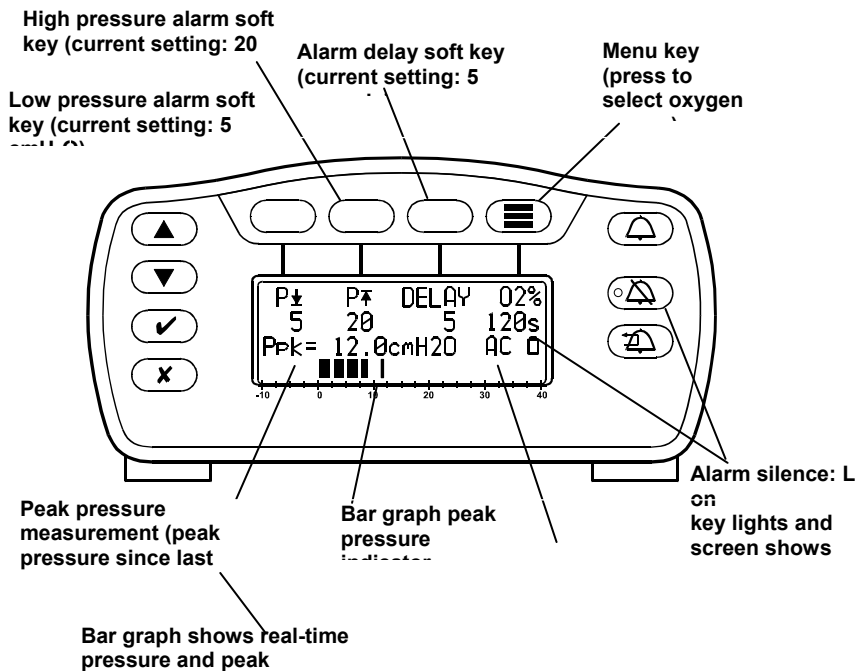
When you turn on the Criterion 60 Pressure/Oxygen Monitor, the monitor screen turns on each screen character, and then displays introductory screen information:

*Criterion 60*

*Pressure/O2 Monitor*

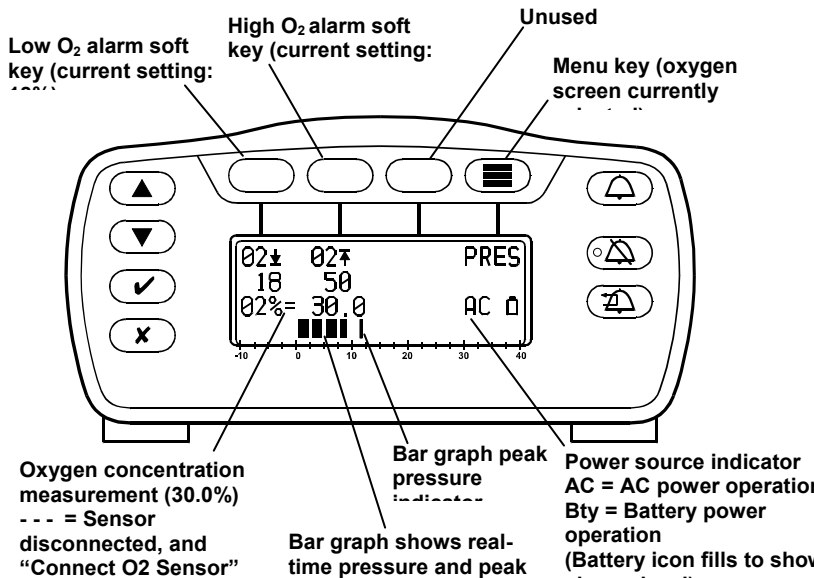
*Rev. x.x*

The Criterion 60 then displays the pressure monitoring screen (Figure 7). Press the menu key to select the pressure monitoring or oxygen monitoring (Figure 8) screen.



**Figure 7. Pressure monitoring screen**





**Figure 8. Oxygen monitoring screen**

### Pressure bar graph

The pressure monitoring and oxygen monitoring screens display a bar graph that shows real-time patient airway pressures from -10 to 39.5 cmH<sub>2</sub>O. If the measured pressure is below -10 cmH<sub>2</sub>O or above 39.5 cmH<sub>2</sub>O, a star (\*) is displayed at that end of the bar graph.

A vertical line (|) indicates the peak pressure since the most recent RESET key press. The pressure monitoring screen displays the peak pressure measurement (Ppk) from 0 to 99.5 cmH<sub>2</sub>O (for pressures above 99.5 cmH<sub>2</sub>O, the monitor displays ">99.5 cmH<sub>2</sub>O"). Pressing RESET clears the Ppk display and the peak pressure indicator on the bar graph.

## Oxygen concentration measurement

- *If the monitor detects an out of calibration condition during normal operation, this message replaces the pressure bar graph:*

*Calibrate O2 sensor*

- *If the monitor measures an oxygen concentration of less than 10% (indicating a sensor disconnect or sensor fault), it displays this message:*

*O2%= - - -*

and the message *Connect O2 Sensor* replaces the bar graph. Reconnecting the oxygen sensor resumes the oxygen display, and the *Calibrate O2 sensor* message replaces the pressure bar graph. Press the RESET key to clear the alarm. The *Calibrate O2 sensor* message remains until the monitor is powered off then on.

- *If the monitor is powered up with no oxygen sensor connected, the monitor does not alarm and the oxygen monitoring screen displays this message:*

*O2%= - - -*

and the message *Connect O2 Sensor* replaces the bar graph. Reconnecting the oxygen sensor resumes the oxygen display, and the *Calibrate O2 sensor* message replaces the pressure bar graph. The *Calibrate O2 sensor* message remains until the monitor is powered off then on.

## Language selection

Follow these steps to select the language for the Criterion 60:

1. Turn the monitor on.
2. At the introductory screen, press the RESET key to display the language menu. The monitor displays this message:  
*Language: English*  
*↑↓ to change*  
*ACCEPT to save*
3. Press the  $\Delta$  and  $\nabla$  keys to select the language.
4. Press ACCEPT to restart the monitor in the selected language.

## Illegal key press

The Criterion 60 sounds an illegal key press tone (a single beep) if you attempt to select an out of range setting or press the same key twice.

## AC power loss

The Criterion 60 alarms if AC power is lost. You can press the RESET key to clear an AC power loss alarm. The screen shows whether AC or battery is powering the monitor. During battery operation, the monitor conserves power by turning off the screen backlight when no key has been pressed for 30 seconds or more. Pressing any key turns the backlight on again.

## Criterion 60 Alarms

Table 2 summarizes the possible Criterion 60 alarms.

**Table 2. Criterion 60 alarms**

<b>If you see and hear this:</b>	<b>It means:</b>	<b>Do this:</b>
Flashing ALARM indicator, flashing high pressure alarm symbol, audible alarm.	High pressure alarm: airway pressure rose above the set high pressure limit.	Check patient. Check patient system for kinks or occlusions. Consider appropriate settings for high pressure alarm and ventilation device.
Flashing ALARM indicator, flashing low pressure alarm symbol, audible alarm.	Low pressure alarm: airway pressure fell below the set low limit.	Check patient. Check patient system for disconnect. Consider appropriate settings for low pressure alarm and ventilation device.
Flashing ALARM indicator, flashing high oxygen alarm symbol, audible alarm.	High oxygen alarm: oxygen concentration rose to the set high limit.	Check patient. Check all gas sources. Consider appropriate settings for high oxygen alarm and ventilation device.
Flashing ALARM indicator, flashing low oxygen alarm symbol, audible alarm.	Low oxygen alarm: oxygen concentration fell to the set low limit.	Check patient. Check all gas sources. Consider appropriate settings for low oxygen alarm and ventilation device.

**Table 2. Criterion 60 alarms**

<b>If you see and hear this:</b>	<b>It means:</b>	<b>Do this:</b>
Flashing ALARM indicator, flashing "Bty", audible alarm. After 30 seconds, screen backlight turns off.	AC power loss alarm: AC power failure or disconnect from AC power source.	Check AC power source and ensure that power supply connections are secure. In case of a deliberate disconnect, press RESET to turn off alarm indicators. (A fully charged battery can power the monitor for up to 24 hours.)
Flashing battery icon, "AC" displayed, no audible alarm. Battery icon indicates that charge is low or depleted.	Low battery voltage or depleted battery alarm, but monitor operating on AC power.	Monitor continues to operate on AC power. Battery is fully charged after 16 hours. If alarm persists, replace battery.
Flashing battery icon, "Bty" displayed, no audible alarm. Battery icon indicates that charge is low.	Low battery voltage alarm, monitor operating on battery power.	Connect monitor to AC power to recharge battery. Battery is fully charged after 16 hours. If alarm persists, replace battery.
Flashing ALARM indicator, flashing battery icon, "Bty" displayed, audible alarm. Battery icon indicates that charge is depleted.	Depleted battery alarm, monitor operating on battery power.	Connect monitor to AC power to recharge battery. Battery is fully charged after 16 hours. If alarm persists, replace battery.

The Criterion 60 allows you to set the alarm limits summarized in Table 3.

**Table 3. Selectable alarm limits**

Alarm	Selectable limit
Low pressure	Alarms when measured patient airway pressure falls below the setting. You can select OFF or a value from 1 to 20 cmH <sub>2</sub> O. (OFF is the setting <i>below</i> 1 cmH <sub>2</sub> O.) The low pressure alarm setting cannot be higher than the high pressure alarm setting.
High pressure	Alarms when measured patient airway pressure rises above the setting. You can select a value from 5 to 99 cmH <sub>2</sub> O or OFF. (OFF is the setting <i>above</i> 99 cmH <sub>2</sub> O.) The high pressure alarm setting cannot be lower than the low pressure alarm setting.
Low oxygen	Alarms when measured oxygen concentration falls to the setting. You can select a value from 18 to 99 %. The low oxygen alarm setting cannot be higher than the high oxygen alarm setting.
High oxygen	Alarms when measured oxygen concentration rises to the setting. You can select a value from 19 to 100 % or OFF. (OFF is the setting <i>above</i> 100 %.) The high oxygen alarm setting cannot be lower than the low oxygen alarm setting.
Delay (pressure alarms only)	<p>Selects the length of time a high or low pressure alarm condition must exist before activating audible and visual alarm indicators. You can select OFF or a value from 1 to 20 seconds.</p> <p>The alarm delay feature can be useful for applications where airway pressure differs between the inspiratory and expiratory phases. For example, you can use the delay feature to detect failure of the patient system to pressurize or return to PEEP. To detect failure to pressurize, set the delay to slightly longer than the expiratory time and set the low pressure alarm below the maximum inspiratory pressure (this allows the monitor to detect low inspiratory pressure and avoids alarming during exhalation). To detect failure to return to PEEP, set the delay to slightly longer than the inspiratory time and set the high pressure alarm just above the PEEP setting (this allows the monitor to detect high pressure during exhalation and avoids alarming during inspiration).</p>

## When an alarm is active

When an alarm becomes active, the Criterion 60 flashes the ALARM indicator and the setting name on the screen and sounds a repeating sequence of three, then two beeps. If not already displayed, the monitor switches to the following screen during an alarm:

- High or low pressure alarm: the pressure monitoring screen.
- High or low oxygen alarm: the oxygen monitoring screen.
- Pressure and oxygen alarm: the monitoring screen for the alarm that occurred most recently.

Press RESET to clear the audible and visual alarm indicators (if the alarm condition no longer exists) or press SILENCE to silence the audible alarm for two minutes. You can change an alarm setting while an alarm is active.

NOTE: To avoid viewing alarms whose conditions no longer exist, be sure to press RESET to clear the alarm indicators. Alarm indicators do not automatically turn off when the alarm condition no longer exists.

## Adjusting alarm settings

Follow these steps to adjust a setting:

1. Use the menu key (the soft key at the far right of the front panel) to select the pressure monitoring screen (for high and low pressure alarms) or the oxygen monitoring screen (for high and low oxygen alarms).
2. Press the soft key for the setting. The setting name flashes on the screen. (If you do not press any key within 30 seconds, the setting stops flashing and the monitor continues to use the previous setting.)
3. Press the  $\Delta$  and  $\nabla$  keys to adjust the value of the setting. (You can hold down the  $\Delta$  or  $\nabla$  key to quickly scroll up or down through the selectable values.)
4. Press ACCEPT to save the new setting, or CLEAR to cancel and return to normal monitoring using the previous setting.

## Alarm silence

The SILENCE key silences the audible portion of an alarm for two minutes following the most recent key press. The SILENCE key has no effect on the visual ALARM indicator. The LED on the SILENCE key lights when alarm silence is active and the monitoring screen shows alarm silence time remaining. Press RESET to cancel an alarm silence.

## Alarm presilence

The Criterion 60 has an alarm presilence feature that is useful for avoiding nuisance alarms during certain procedures. If you press SILENCE before an alarm becomes active, the LED on the SILENCE key lights, the monitoring screen shows alarm silence time remaining, and the audible portion of the next alarm is automatically silenced for two minutes following the most recent key press. Press RESET when alarm presilence is no longer needed.



## Maintenance

Under normal conditions, the Criterion 60 does not require any special maintenance or sterilization. You can clean and disinfect the monitor, sensor, and sensor tee with a damp cloth and Isopropyl alcohol (do not allow liquid to penetrate the monitor or sensor).

### CAUTION:

- **To avoid damage (cracking and crazing of plastic) to monitor surfaces, do not use formaldehyde or phenol-based disinfectants.**
- **The pressure tubing is intended for single patient use only: do not attempt to sterilize or reuse. Follow all applicable federal and local regulations for disposal or recycling of tubing material.**

This section includes information on the following maintenance procedures:

- *Pressure calibration* includes zero and gain calibrations: Perform a *zero calibration* (non-technical user) if the monitor displays a pressure when no pressure is connected. Perform a *gain calibration* (qualified technician) annually or if the Criterion 60 measures pressures incorrectly following a zero calibration.
- *Oxygen calibration* includes 21% and gain (100%) calibrations, (non-technical users). Perform both *21%* and *gain calibrations* weekly, when environmental conditions change significantly, or whenever you suspect inaccurate oxygen concentration measurements.

NOTE: Caradyne recommends performing both the 21% and gain calibrations following an oxygen sensor disconnect.

- *Battery pack recharge.* Recharge the battery pack when low or depleted. A non-technical user can recharge the battery by connecting the monitor to AC power for 16 hours.

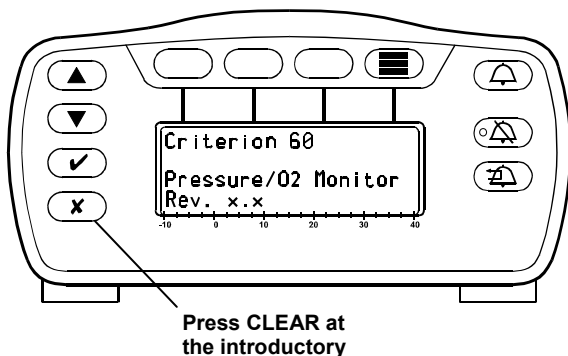
- **Battery pack replacement:** Replace the battery pack every two years, when the monitor has not been used for over a year, or when battery pack voltage remains low after recharge. A qualified technician should replace the battery pack.

## Calibration procedures

NOTE: For maximum accuracy, calibrate the monitor at a temperature similar to the conditions of use.

Follow these steps to select pressure (zero or gain calibrations) or oxygen (21% or gain) calibrations:

1. Turn the Criterion 60 on.
2. At the introductory screen, press CLEAR to enter service mode (Figure 9).



**Figure 9. Entering service mode**

3. When you see this message:

*EXIT PRES O2*

*Select the cal type*

*Patm=xxxxhPa*

Press the EXIT soft key to exit service mode and resume normal monitoring, or press the PRES soft key to select the pressure (zero or gain) calibration, or press the O2 soft key to select the oxygen (21% or gain) calibration. The fourth line displays the current measurement for atmospheric pressure (Patm) in hPa.

### **Zero calibration: pressure (non-technical user)**

The Criterion 60 monitor occasionally requires a *zero* pressure calibration. A zero calibration resets the zero point (the measurement when no pressure is connected). Perform a zero calibration if the monitor displays a non-zero pressure reading when no pressure is connected.

Follow these steps to perform a zero pressure calibration:

1. Turn the Criterion 60 on.
2. At the introductory screen, press CLEAR to enter service mode, then press the PRES soft key to select pressure calibration.
3. Once you've selected pressure calibration, you should see this message:

*EXIT*

*Zeroing Procedure*

*Disconnect pressure*

*and press Accept*

Ensure that there is no pressure connected to the pressure (luer) connector at the Criterion 60 back panel, then press ACCEPT. (Or press the EXIT soft key to cancel the zero calibration and return to normal monitoring.)

4. If you see this message the zero calibration was successfully completed:

*EXITGAIN*

*c = xxx*

*Zeroing Passed*

*Press EXIT to monitor*

Press the EXIT soft key to resume normal operation, or press the GAIN soft key to proceed to the gain calibration. (If the current gain calibration value is out of range, only a GAIN soft key is available.)

**CAUTION: To ensure accurate monitor operation, gain calibrations should only be performed by a qualified technician.**

5. If you see this message the zero calibration failed:

*Zeroing Failure*

*c = xxx*

*Disconnect pressure*

*and press Accept*

Disconnect any tubing connected to the pressure connector on the Criterion 60 back panel, then press ACCEPT to repeat the zero calibration. (If the monitor detected unstable pressure during the zero calibration, it displays: *Pressure Unstable* instead of *c = xxx*.)

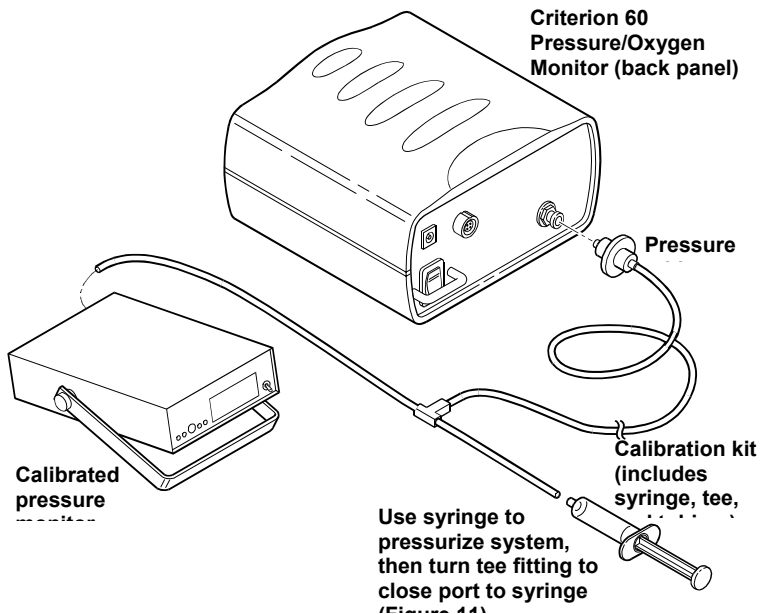
### **Gain calibration: pressure (qualified technician only)**

A gain calibration corrects the accuracy of pressure measurements. A qualified technician should perform gain calibrations. Perform a gain calibration annually, or if the Criterion 60 measures pressures incorrectly following a zero pressure calibration.

NOTE: For maximum accuracy, calibrate the monitor at a temperature similar to the conditions of use.

If the difference between a calibrated pressure monitor and the measured pressure during operation exceeds the pressure accuracy specification (page 33), and a zero calibration does not resolve the problem, perform a gain calibration.

You need a Caradyme Criterion 40/60 gain calibration kit (order code 8-100314-00) and pressure tubing (order code 8-100285-00) to perform a gain calibration. The calibration kit includes a syringe and tubing attached to a tee (Figure 10). You also need a calibrated pressure monitor.



**Figure 10. Calibration kit and setup**

Follow these steps to perform a gain calibration:

1. Turn the Criterion 60 on.
2. At the introductory screen, press CLEAR to enter service mode, press the PRES soft key to select pressure calibration, then perform the zero calibration. At the end of the zero calibration, press the GAIN soft key to proceed to the gain calibration. (If the current gain calibration value is out of range, only a GAIN soft key is available.)

- The monitor displays this message:

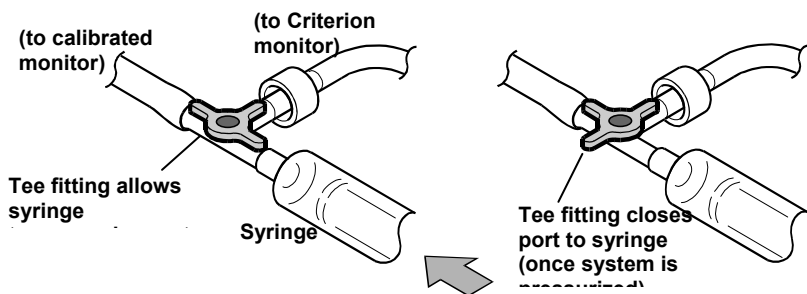
*EXIT*  
*Connect pressure*  
*source*  
*and press Accept*

Connect calibration kit (Figure 9), then press ACCEPT.  
(Or press the EXIT soft key to cancel the gain calibration and return to normal monitoring.)

- At this message, use the syringe to inject 40 to 50 cmH<sub>2</sub>O of pressure, as measured by the calibrated pressure monitor, into the system (Figure 11):

*EXIT*  
*Pressure = xx.x*  
*Scroll keys to Input*  
*And press Accept*

Once the system is pressurized, rotate the tee fitting to close the port to the syringe.



**Figure 11. Pressurizing the system**

- Use the  $\Delta$  and  $\nabla$  keys to enter the value of the injected pressure measured by the calibrated pressure monitor in 0.5 cmH<sub>2</sub>O increments, then press ACCEPT.

6. If you see this message the gain calibration was successfully completed:

*EXIT*  
*Gain Passed*  
*Slope = x.xx*  
*Press EXIT monitor*

Press the EXIT soft key to monitor.

7. If you see this message the gain calibration failed:

*RETEST CANCEL*  
*Gain Failure*  
*Slope = x.xx*  
*CANCEL -> Old Gain*

Press the RETEST soft key to repeat the calibration, or press CANCEL to cancel the gain calibration and resume normal monitoring using the previous gain calibration value. If the monitor does not detect a pressure input, it displays: *Test Source*.

Technical note: A successful zero calibration results in a value for "c" from 183 to 273, and a successful gain calibration results in a value for "Slope" from 0.11 to 0.50.

## **21% calibration: oxygen (non-technical user)**

A 21% calibration resets the oxygen concentration measurement when no oxygen is connected. Perform a 21% calibration weekly or more often if environmental conditions (temperature or humidity) change significantly.

NOTE: Calibration gas (room air) should be at atmospheric pressure. Because performing the 21% calibration in room air allows partial compensation for relative humidity, room air is preferable to a calibrated 21% oxygen dry gas mixture. (See page 38 for more information on the effect of humidity on oxygen measurements.)

Follow these steps to perform a 21% calibration:

1. Turn the Criterion 60 on.
2. At the introductory screen, press CLEAR to enter service mode, then press the O2 soft key to select oxygen calibration.
3. Once you've selected oxygen calibration, you should see this message:

*EXIT  
O2 cal. Procedure  
Place in room air  
and press Accept*

Expose the oxygen sensor to room air (21% O<sub>2</sub>), then press ACCEPT. (Or press the EXIT soft key to cancel the calibration and return to normal monitoring.)

The 21% calibration begins once you press ACCEPT, and continues until the sensor measurement stabilizes.



4. If you see this message the 21% calibration was successful:

*EXITGAIN*

*c = xxx*

*21% Test Passed*

*Press EXIT to resume*

Press the EXIT soft key to resume normal operation, or press the GAIN soft key to proceed to the gain calibration.

5. If you see this message the 21% calibration failed:

*21% Test Failure*

*c = xxx*

*Connect to room air*

*and press Accept*

Expose the oxygen sensor to room air (21% O<sub>2</sub>), then press ACCEPT to repeat the 21% calibration.

### **Gain calibration: oxygen (non-technical user)**

A gain calibration resets the oxygen concentration measurement at 100% oxygen. Performing both 21% and gain calibrations resets the oxygen concentration measurements over the full scale. Perform the 21% calibration weekly and the gain calibration whenever you suspect inaccurate oxygen concentration measurements.

Follow these steps to perform a gain calibration:

1. Turn the Criterion 60 on.
2. At the introductory screen, press CLEAR to enter service mode, then perform the 21% calibration. At the end of the 21% calibration, press the GAIN soft key to proceed to the gain calibration.

3. The monitor displays this message:

*EXIT*  
*Connect 100% O2*  
*and press Accept*

Connect the sensor to a 100% oxygen source (0.5 to 1 L/min flow rate). Press ACCEPT. (Or press the EXIT soft key to cancel the gain calibration and return to normal monitoring.)

The oxygen gain calibration begins once you press ACCEPT, and continues until the sensor measurement stabilizes.

4. If you see this message the gain calibration was successful:

*EXIT*  
*Gain Test Passed*  
*Gain = x.xx*  
*Press EXIT to resume*

Press the EXIT soft key to return to normal monitoring.

5. If you see this message the gain calibration failed:

*RETESTCANCEL*  
*Gain Test Failure*  
*Gain = x.xx*  
*CANCEL -> Old Gain*

Press the RETEST soft key to repeat the gain calibration, or press CANCEL to cancel the gain calibration and resume normal monitoring using the previous calibration value.

Technical note: At sea level, a successful 21% calibration results in a value for "c" from 112 to 191, and a successful gain calibration results in a value for "Gain" from 1.00 to 2.00.

## **Battery pack recharge (non-technical user)**

To recharge the battery pack, connect the monitor to AC power with the ON/OFF switch ON or OFF for 16 hours. If the switch is ON, the monitor recharges the battery pack during normal operation. If the switch is OFF, the monitor displays this message during recharge:

*Battery charging*

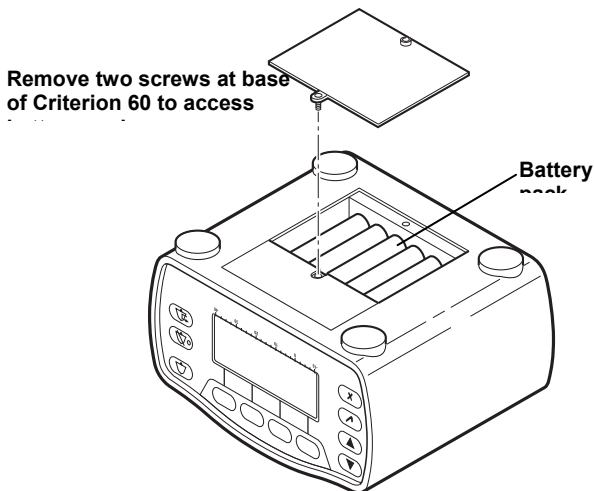
If the battery charge remains low after 16 hours, replace the battery pack.

Recharge the battery pack every 3 months when storing the monitor for 6 months or longer.

## Battery pack replacement (qualified technician only)

Replace the battery pack every two years, when the monitor has not been used for over a year, or if battery charge remains low after 16 hours of recharging. Follow these steps to replace the battery pack:

1. Remove the two pozidriv screws that attach the battery compartment cover to the underside of the monitor (Figure 12).



**Figure 12. Replacing the battery pack**

2. Disconnect the old battery pack cable from the underside of the printed circuit board, and reinstall the new battery pack. Use only Caradyne Criterion 40/60 replacement battery pack (order code 8-100152-00).

**CAUTION: To ensure battery pack operation and avoid damage to the monitor, install the battery cable connector correctly. The battery cable connector is keyed for correct installation.**

3. Reinstall the compartment cover.

## Specifications

### High pressure alarm

Range: 5 to 99 cmH<sub>2</sub>O/hPa, Off.

Resolution: 1 cmH<sub>2</sub>O/hPa.

Accuracy:  $\pm$  (1+ 3% of setting) rounded up to the nearest cmH<sub>2</sub>O/hPa.

### Low pressure alarm

Range: Off, 1 to 20 cmH<sub>2</sub>O/hPa.

Resolution: 1 cmH<sub>2</sub>O/hPa.

Accuracy:  $\pm$  (1+ 3% of setting) rounded up to the nearest cmH<sub>2</sub>O/hPa.

### Pressure bar graph

Displays real-time pressure and peak pressure.

Range: -10 to 39.5 cmH<sub>2</sub>O/hPa.

Resolution: 0.5 cmH<sub>2</sub>O/hPa.

Accuracy:  $\pm$  (1+ 3% of reading) rounded up to the nearest 0.5 cmH<sub>2</sub>O/hPa.

### Peak pressure (Ppk) display

Range: 0 to 99.5 cmH<sub>2</sub>O/hPa.

Resolution: 0.5 cmH<sub>2</sub>O/hPa.

Accuracy:  $\pm$  (1+ 3% of reading) rounded up to the nearest 0.5 cmH<sub>2</sub>O/hPa.

### Pressure measurement

Range: -20 to 100 cmH<sub>2</sub>O/hPa.

Resolution: 0.5 cmH<sub>2</sub>O/hPa.

Accuracy:  $\pm$  (1+ 3% of reading) rounded up to the nearest 0.5 cmH<sub>2</sub>O/hPa.

### High O<sub>2</sub>% alarm

Range: 19 to 100%, Off.

Resolution: 1%.

Accuracy: Exact, to the O<sub>2</sub>% display.

## Low O<sub>2</sub>% alarm

Range: 18 to 99%.

Resolution: 1%.

Accuracy: Exact, to the O<sub>2</sub>% display.

## Oxygen concentration (O<sub>2</sub>%) display

Range: 10 to 100%.

Resolution: 0.5 %O<sub>2</sub>.

Accuracy:  $\pm 3\%$  over the complete operating range.

## Oxygen sensor response time

Reaches 90% of final value within 10 seconds at room temperature.

## Oxygen sensor life

Continuous use: 400,000 oxygen hours (one year of continuous use at 45% oxygen concentration or 4,000 hours at 100% oxygen concentration) at 25 °C dry.

## Power

Normal operation: operates on alternating current (AC) power using an AC/DC converter.

Input range:

U.S./Canada models: 120 V AC, 60 Hz, 20 W.

European models: 230 V AC, 50 Hz, 60 mA.

Battery backup: in case of AC power failure, up to 24 hours of battery backup is available. Monitor automatically recharges battery when connected to AC power.

## Temperature

Operating: 5 to 45 °C at 15 to 95% relative humidity.

Storage: -40 to 60 °C at 95% relative humidity.

## Atmospheric pressure

Operating and storage: 600 to 1100 cmH<sub>2</sub>O/hPa.

## NOTES:

- The Criterion 60 monitor performs as specified immediately upon switching ON (no warm-up period required). The monitor automatically compensates for changes in atmospheric and patient system pressure.

- The Criterion 60 monitor is designed for use with nonflammable anesthetic gases and other interfering gases, such as helium, nitrous oxide, halothane, enflurane, isoflurane, sevoflurane, desflurane, and nitric oxide.

## Service

Full service and repair is available from:

Caradyne	Caradyne
Parkmore Business Centre	2055 Executive Drive
Parkmore West	Indianapolis, IN 46241
Galway, Ireland	USA
Telephone: +353 (0)91-709010	Telephone: 317-246-9010
Fax: +353 (0)91-758929	Fax: 317-246-9011

Or contact your local dealer.

## Warranty

The Criterion 60 Pressure/Oxygen Monitor is warranted against defects in material and workmanship for two years from the time of sale.

## Approvals



The Criterion 60 Pressure/Oxygen Monitor complies with the requirements of directive 93/42/EEC concerning medical devices and therefore bears the CE mark.

The Criterion 60 also complies with EN475, IEC/EN 60601-1, ISO 7767, and prEN12598. The Criterion monitor is not affected by electromagnetic radiation at or below the levels stated in IEC/EN 60601-1. Monitors shipped to the United States comply with UL2601-1 and CSA C22.2 No. 601-1.

IEC/EN 60601-1 classification: Class II, Type BF.

## Manufacturer

Caradyne  
Parkmore Business Centre  
Parkmore West  
Galway, Ireland

Telephone: +353 (0)91-709010

Fax: +353 (0)91-758929

E-mail: [info@caradyne.com](mailto:info@caradyne.com)

Internet: <http://www.caradyne.com>

## Year of manufacture

The fifth and sixth digits of the serial number (on the base of the monitor) indicate the Criterion 60 Pressure/Oxygen Monitor year of manufacture.



## Parts list

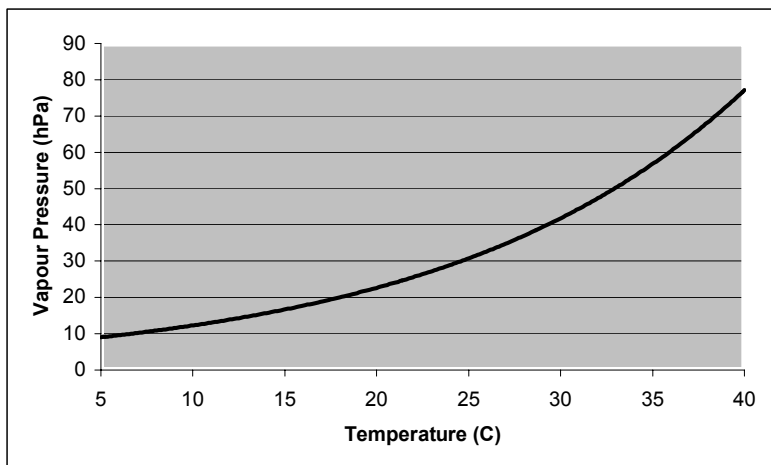
The Criterion 60 Pressure/Oxygen Monitor is compatible with the following Caradyne accessories. Please contact your local Caradyne distributor before using other accessories with the Criterion 60.

<b>Description</b>	<b>Order code</b>
Criterion 60 Pressure/Oxygen Monitor, Europe	8-100351-xx*
Criterion 60 Pressure/Oxygen Monitor, U.K./Ireland	8-100352-00
Criterion 60 Pressure/Oxygen Monitor, U.S./Canada	8-100353-00
Criterion 40/60 pressure tubing, single patient use, box of 10	8-100285-00
Criterion 40/60 pressure tubing for connection to face mask, single patient use, box of 10	8-100401-00
Criterion 60 oxygen sensor	8-100343-00
Cable, oxygen sensor	8-100341-00
Tee, 22M/22M/M16x1 ports	8-100498-00
Straight connector, 22F/22F ports	8-201009-00
Criterion 40/60 power supply, 120 V AC	8-100242-00
Criterion 40/60 power supply, 230 V AC, Europe	8-100313-00
Criterion 40/60 power supply, 230 V AC, U.K./Ireland	8-100323-00
Criterion 40/60 battery pack, nickel metal hydride (NiMH)	8-100152-00
Criterion 40/60 gain calibration kit	8-100314-00
Criterion 40/60 pole mounting kit	8-100315-00
Criterion 60 User's manual	8-100333-00
* Consult your dealer for the language-specific order code extension	

## Appendix: Effect of humidity on oxygen measurements

Ambient air contains significant amounts of three gases: oxygen, nitrogen and water vapor. Because ambient humidity and temperature determine water vapor pressure, those factors also affect oxygen measurements. Follow these steps to determine the effect of humidity and temperature on oxygen measurement:

1. Calculate the *saturated water vapor pressure (SVP)* at the temperature of the gas being measured (Figure 13).



**Figure 13. Saturated water vapor pressure (SVP) of gas (100% RH) versus temperature**

2. Determine the *relative humidity (RH)* of the gas being measured, expressed as a number between 0 and 1.
3. Determine the current *atmospheric pressure (Patm)* in hPa.
4. Calculate the *correction factor (CF)* as follows:

$$CF = Patm / (Patm - (SVP \times RH))$$

5. Multiply the measured % oxygen by the correction factor to calculate the % oxygen that would be measured in the absence of water vapor.

This correction factor applies only to measurements made by a monitor that has been calibrated using dry gases. Caradynne recommends using room air for the 21% oxygen calibration. Using room air calibrates the sensor so it can partially compensate for the effect of humidity and reduce measurement error due to water vapor in a gas mixture. However, if precise relative humidity calibration is required, perform oxygen calibration using dry gas.

**Example:**

A 50% oxygen mixture is being delivered to a patient under the following conditions:

Atmospheric pressure ( $P_{atm}$ ) = 950 hPa

Ambient relative humidity (RH) = 70%

Room temperature = 20 °C.

1. At a temperature of 20 °C, saturated water vapor pressure (SVP) = 23 hPa (see Figure 13).
2. Relative humidity (RH) = 70%, or 0.7.
3. Current atmospheric pressure ( $P_{atm}$ ) = 950 hPa.
4. Calculate the correction factor (CF):  
$$CF = P_{atm} / (P_{atm} - (SVP \times RH))$$
$$CF = 950 / (950 - (23 \times 0.7)) = 1.017$$
5. Multiply the measured oxygen concentration by a correction factor of 1.017 to calculate the oxygen concentration that would be measured in the absence of water vapor.