Broadband / Oximetry Accessory

INSTALLATION AND OPERATION GUIDE
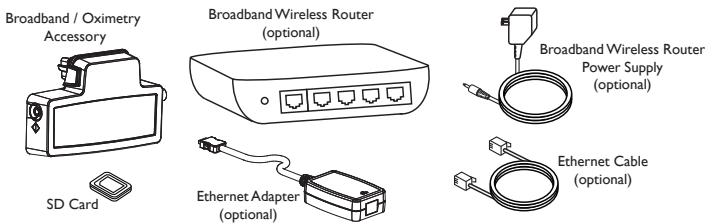
PHILIPS

RESPIRONICS

Intended Use

The Broadband / Oximetry Accessory is an accessory to select Respironics flow generators which allows recorded data to either be transmitted over a broadband internet connection or stored on an internal SD card for later download.

Overview

The Broadband / Oximetry Accessory supports two functions:

1. **Broadband** - When wirelessly connected to the Broadband Wireless Router or connected to an Ethernet cable with the available Ethernet adapter, this Broadband / Oximetry Accessory can transmit data to EncoreAnywhere using the patient's existing home broadband connection. See the *Setup for Broadband Use* section for more information.

2. **Oximetry** - When connected to the appropriate oximeter and sensor, this Broadband / Oximetry Accessory can record patient oxygen saturation and heart rate data, which can be uploaded and viewed in EncoreAnywhere, EncorePro, or EncoreBasic. See the *Setup for Oximetry Use* section for more information.

Package Contents

Broadband / Oximetry Accessory

Broadband Wireless Router (optional)

Broadband Wireless Router Power Supply (optional)

SD Card

Ethernet Adapter (optional)

Ethernet Cable (optional)

Warnings and Cautions

Warnings

- If you notice any unexplained changes in the performance of this device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact Respironics for assistance.
- Repairs and adjustments must be performed by Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- To reduce the risk of bodily injury and damage to the equipment, retain and follow all product safety and operating instructions.
- If you use any other personal medical device, consult the manufacturer of your device to determine if they are adequately shielded from external RF energy. Your physician may be able to assist you in obtaining this information.
- When attaching the oximeter sensor, be careful to route the wires in a manner that will reduce the possibility of strangulation, discomfort, or the sensors becoming detached.
- Use only the Masimo High Performance / Low Power Module and Masimo LNCS Series pulse oximeter sensors. The sensors are manufactured to meet the accuracy specifications for the Masimo High Performance / Low Power oximeter. Using other manufacturers' sensors can result in inaccurate pulse oximeter performance.

- Do not use a damaged sensor.
- Before use, carefully read these instructions and the directions for use provided with the Masimo sensor.

Cautions
- Remove power from the therapy device by unplugging the power supply cord's connector from the power inlet on the back of the device before proceeding with the installation instructions.
- If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before beginning the installation procedure.
- Pins of connectors should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic charge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.
- Ensure that the SD card cover on the therapy device is replaced whenever an accessory is not installed.

Important! From time to time, electronic devices can be affected by irregularities in the electrical power supplies and other electrical equipment. To prevent electrical interference that could affect the performance of your medical equipment, always keep accessories (power supplies, battery packs, etc.) and other electrical devices (telephones, radios, etc.) away from your therapy device when used with this accessory.

Symbol Key

The following symbols may appear on the Broadband / Oximetry Accessory.

Symbol	Definition	Symbol	Definition
◇	Manual Call button	SpO$_2$	Oximeter connection
品	Ethernet connection	📖	Consult accompanying instructions

Setup for Broadband Use

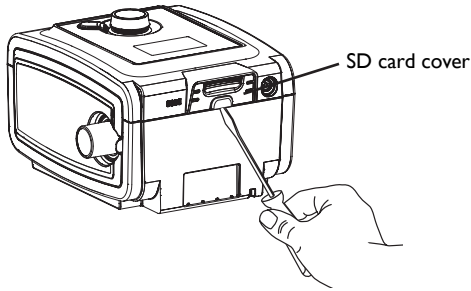### Installing the Accessory into the Therapy Device

Caution! If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before beginning the installation procedure.

In order for the Broadband / Oximetry Accessory to work properly, it must be installed in a therapy device. Refer to the installation steps below.

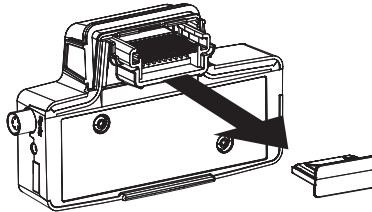If the therapy device already contains a Broadband / Oximetry Accessory, begin with step 5.

1. Remove power from the therapy device by unplugging the power supply cord's connector from the power inlet on the back of the device before proceeding with the installation instructions below.

2. Remove the plastic cover on the back of the device. Using a flat-head screwdriver, carefully lift the plastic SD card cover away from the device. Save this plastic cover for future use.
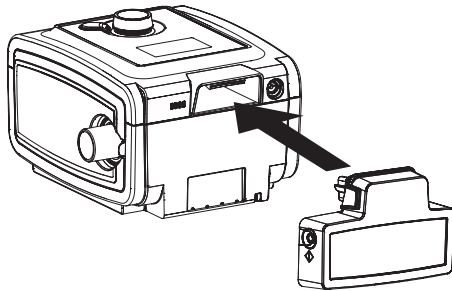

SD card cover

Plastic Cover Removal

3. Remove the plastic cap from the Broadband / Oximetry Accessory, being careful not to touch the metal connectors.

Plastic Cap Removal

4. Insert the Broadband / Oximetry Accessory into the therapy device, as shown below, until it clicks into position. It is not necessary to remove the therapy device's SD card in order to install this accessory.


Accessory Installation

5. Connect the therapy device to an AC power outlet using the supplied power adapter, and the device will automatically turn on. The Broadband / Oximetry Accessory gets its power from the therapy device.

    Note: After powering on, up to 30 seconds may elapse before the accessory is ready for use.

Installing a Wireless Network Connection with the Broadband Wireless Router

First, identify the type of network you currently have installed. Determine which of the following setups, A, B, or C, most closely resembles your current network.

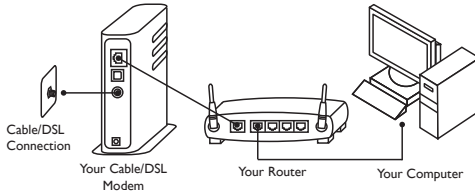A.   If you have a cable or DSL modem with a built-in router:
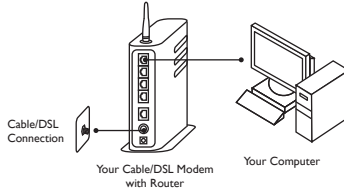
Cable/DSL
Connection

Your Cable/DSL Modem
with Router

Your Computer

•   Connect the Ethernet cable to the yellow port on the Broadband Wireless Router and to an available port on your network.
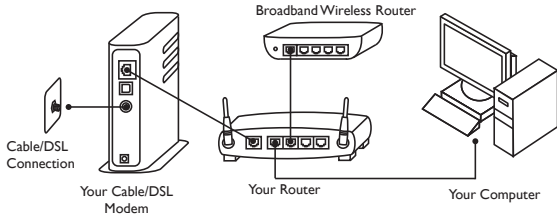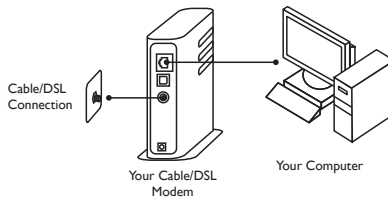

Your Computer

Cable/DSL
Connection

Your Cable/DSL Modem
with Router

Broadband Wireless Router
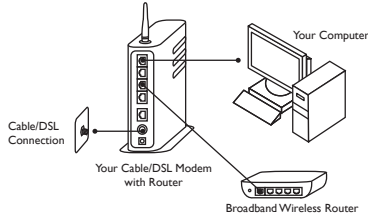
•   Supply power to the Broadband Wireless Router.

B.   If you have a cable or DSL modem connected to a router:

Cable/DSL
Connection

Your Cable/DSL
Modem

Your Router

Your Computer

•   Connect the Ethernet cable to the yellow port on the Broadband Wireless Router and to an available port on your router.

Broadband Wireless Router

Cable/DSL
Connection
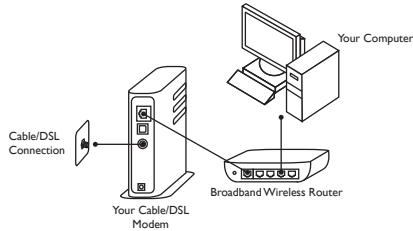
Your Cable/DSL
Modem

Your Router

Your Computer

•   Supply power to the Broadband Wireless Router.

C.   If you have a cable or DSL modem with one port that your computer is currently connected to:

Cable/DSL
Connection

Your Cable/DSL
Modem

Your Computer

- Remove power from your cable/DSL modem. (If your cable/DSL modem contains a battery for back up power, the battery must be temporarily disconnected to remove power from the modem.)
- Disconnect your computer from your cable/DSL modem.
- Connect the Ethernet cable to the yellow port on the Broadband Wireless Router and to your cable/DSL modem.
- Connect your computer to an available gray port on the Broadband Wireless Router.

- Plug the power supply for your cable/DSL modem into a wall outlet or power strip.
- Supply power to the Broadband Wireless Router.

Installing a Wired Network Connection with an Ethernet Cable

Connect the Ethernet Adapter to the Broadband / Oximetry Accessory. Then, connect the Ethernet Adapter to an ethernet jack on your modem or router, using an ethernet cable, as shown below.
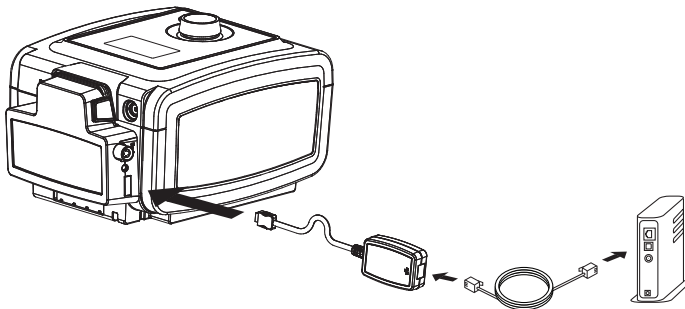

Wired Setup

Connecting to EncoreAnywhere

Normally, the accessory will automatically make a daily call and upload therapy data at predetermined times without human intervention.

You can manually cause the Broadband / Oximetry Accessory to make a call by pressing and holding in the call button for at least two seconds, as shown on the next page. The accessory responds by displaying the appropriate symbol in the device window.

Note: When located near a clock radio, speaker, or other electronic device, an occasional buzzing noise may be heard. Relocate the therapy device and Broadband / Oximetry Accessory away from the electronic device to reduce or eliminate this noise.
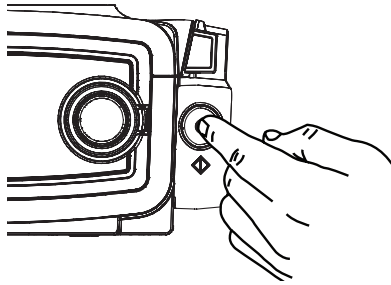
Call Button

Symbols Displayed During Normal Operation

The therapy device will display the Broadband / Oximetry Accessory's network or EncoreAnywhere connection status. This will occur automatically when a connection to EncoreAnywhere is in progress. At all other times, the status can be checked by navigating to the device's status menu or by briefly pressing the manual call button on the side of the Broadband / Oximetry Accessory once (holding the button in for less than one second).

Symbol	Meaning
	Attempting to make a connection
	Connection established
	Connection successfully completed
	Wireless network signal strength 5 (maximum)
	Wireless network signal strength 4
	Wireless network signal strength 3
	Wireless network signal strength 2
	Wireless network signal strength 1 (minimum)
	No wireless network signal, a connection is not possible
	Connected via Ethernet cable

Error Symbols

If a connection attempt fails, one of the following symbols is displayed in the device's window. The accessory will retry the call automatically, if you do not do so manually.

Symbol	Meaning	Action
🕐 1	No network connection.	Verify that the Broadband / Oximetry Accessory has been installed and setup correctly. If the error still occurs, the Broadband / Oximetry Accessory may be located too far from the Broadband Wireless Router. Try relocating the Broadband Wireless Router closer to the Broadband / Oximetry Accessory.
🕐 8	A network error occurred.	Verify that the Broadband / Oximetry Accessory has been installed and setup correctly. If the error still occurs, try removing power from your cable/DSL modem for a few minutes. Then, power the modem up again. Or, try initiating a manual call by pressing and holding the call button (◁▷) on the Broadband / Oximetry Accessory for at least two seconds.
🕐 9	The accessory successfully reached EncoreAnywhere but the server terminated the connection.	Try initiating a manual call by pressing and holding the call button (◁▷) on the Broadband / Oximetry Accessory for at least two seconds.
🕐 10	The accessory successfully reached EncoreAnywhere but the connection stalled.	Try initiating a manual call by pressing and holding the call button (◁▷) on the Broadband / Oximetry Accessory for at least two seconds.
? 1	The accessory is not authorized to connect to EncoreAnywhere.	Contact your equipment provider. Check the user's prescription in EncoreAnywhere.
? 2	EncoreAnywhere cannot correlate the device to a user.	Contact your equipment provider. Check the user's prescription in EncoreAnywhere.
✖	An internal fault occurred.	Contact your equipment provider. Check the user's prescription in EncoreAnywhere.

Setup for Oximetry Use

Overview

This accessory, when used with the Masimo High Performance / Low Power Module and Masimo LNCS Series pulse oximeter sensors, can be used with System One devices to measure functional oxygen saturation of arterial hemoglobin (%SpO$_2$) and pulse rate for adult patients. Home care providers (HCPs) and medical professionals can then use this data as one of several elements to evaluate patient compliance, and if necessary, change the therapy device's settings.

Compatibility

The accessory is compatible with the Masimo High Performance / Low Power Module and the following Philips Respironics System One Devices:

- REMstar
- REMstar Auto A-Flex
- REMstar Plus C-Flex
- BiPAP Pro Bi-Flex
- REMstar Pro C-Flex+
- BiPAP Auto Bi-Flex

The Masimo High Performance / Low Power Module is compatible with the Masimo LNCS Series pulse oximeter sensors.

Warnings

- Use only the Masimo High Performance / Low Power Module and Masimo LNCS Series pulse oximeter sensors. The sensors are manufactured to meet the accuracy specifications for the Masimo High Performance / Low Power oximeter. Using other manufacturers' sensors can result in inaccurate pulse oximeter performance.
- Do not use a damaged sensor.
- Before use, carefully read these instructions and the directions for use provided with the Masimo sensor.

Installing the Accessory into the Therapy Device

Caution!   If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before beginning the installation procedure.

In order for the Broadband / Oximetry Accessory to work properly, it must be installed in a therapy device.

If the therapy device already contains a Broadband / Oximetry Accessory, begin with step 5.

1. Remove power from the therapy device by unplugging the power supply cord's connector from the power inlet on the back of the device before proceeding with the installation instructions below.

2. Remove the plastic cover on the back of the device. Using a flat-head screwdriver, carefully lift the plastic SD card cover away from the device. Save this plastic cover for future use.

SD card cover

Plastic Cover Removal

3. Remove the plastic cap from the Broadband / Oximetry Accessory, being careful not to touch the metal connectors.

Plastic Cap Removal

4. Insert the Broadband / Oximetry Accessory into the therapy device, as shown below, until it clicks into position. It is not necessary to remove the therapy device's SD card in order to install this accessory.

Accessory Installation

5. Connect the therapy device to an AC power outlet using the supplied power adapter, and the device will automatically turn on. The Broadband / Oximetry Accessory, gets its power from the therapy device.
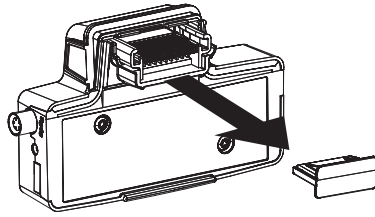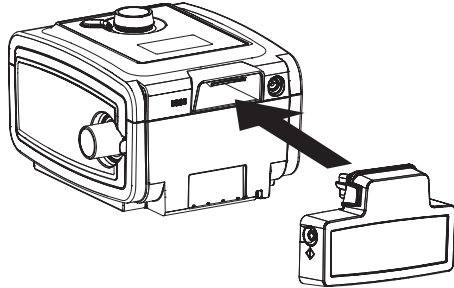
   Note: After powering on, up to 30 seconds may elapse before the accessory is ready for use.

Connecting an Oximeter

After you have installed the accessory into the therapy device, connect the Masimo High Performance / Low Power Module to the round connector as shown below. Be sure to line up the red dots on the connectors when connecting the module.

Align the red dots on the accessory and module connectors.
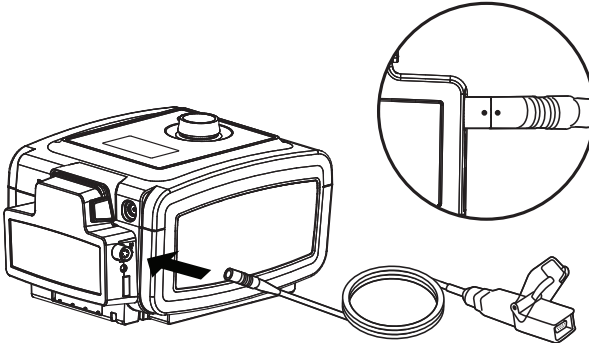
Masimo High Performance / Low Power Module Connection

Then, connect a compatible Masimo LNCS Series pulse oximeter sensor to the Masimo High Performance / Low Power Module, and close the clip to secure the connection. The green LED will flash until the oximeter sensor is connected to a user. Once connected, the LED will remain solid. This indicates that a proper connection has been established, and the device is recording oximetry data. After one minute, the LED will dim.

Oximetry Troubleshooting

| Problem	Action
The green LED continues to flash after a connection.	Verify that the Broadband / Oximetry Accessory has been installed and setup correctly. Check that a valid SD card is correctly installed in the Broadband / Oximetry Accessory, and check that the Masimo High Performance / Low Power Module and Masimo LNCS Series pulse oximeter sensor are properly connected.
The green LED does not light up.	Check that the Masimo High Performance / Low Power Module and Masimo LNCS Series pulse oximeter sensor are properly connected.

Retrieving Data

Compliance data (oximetry and therapy data) may be retrieved from the accessory either by configuring the accessory to function as a broadband modem for remote data transfer or by retrieving the data from the accessory SD card, located on the bottom of the accessory. The SD card should be present in the Broadband / Oximetry Accessory at all times when using the accessory to collect data.
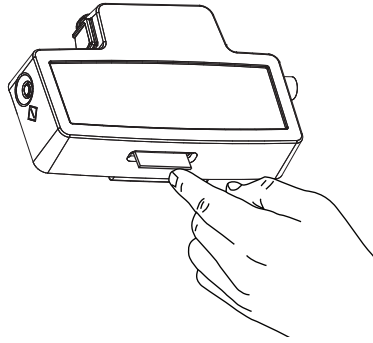
SD Card Removal

To retrieve data from the SD card, remove the card by gently pressing the card in, which will release it from the accessory. Then, upload the data from the SD card to EncoreAnywhere, EncorePro, or EncoreBasic.

SpO$_2$ Specifications

SpO$_2$ and Pulse Rate Accuracy: Refer to the sensor instructions for accuracies.

Data Update Period and Averaging: The Oximetry values are sampled and displayed every 1 second.

Operating Environment:
Temperature and Humidity ranges for operation: 5°C to 35°C (41° to 95° F); 15 to 95%
Temperature and Humidity ranges for storage/transport: -20°C to 60°C (-4° to 140° F); 15% to 95%

> **Note:** For additional information concerning the Masimo sensor (further specifications, cleaning instructions, directions for use, warnings, cautions, and notes) refer to the packaging and documentation supplied with the sensor.

Cleaning

Clean the Masimo High Performance / Low Power Module separately from the sensors.

Caution! Do not immerse the module in liquid. Do not use caustic or abrasive cleaning agents on the module.

Clean the module with a soft cloth dampened with isopropyl alcohol. Do not pour or spray any liquids onto the module, and do not allow any liquid to enter any openings in the device. Allow the module to dry thoroughly before reusing.

For instructions on cleaning Masimo LNCS Series pulse oximeter sensors, refer to the respective pulse oximeter sensor package insert.

Broadband / Oximetry Accessory Temperature and Storage

	Operation	Transport & Storage
Temperature:	5° to 35° C (41° to 95° F)	-20° to 60° C (-4° to 140° F)
Humidity:	15% to 95% non-condensing	15% to 95% non-condensing

Disposal

Separate collection for electrical and electronic equipment per EC Directive 2002/96/EC. Dispose of this device in accordance with local regulations.

Additional Warnings, Cautions, and Notices

Warning!   If you notice any unexplained changes in the performance of this device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact Respironics for assistance.

Warning!   Repairs and adjustments must be performed by Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

Notice: There are no user-serviceable parts within the Broadband / Oximetry Accessory, Masimo High Performance / Low Power Module, or Masimo LNCS Series pulse oximeter sensors.

Notice: EncoreAnywhere, EncorePro, and EncoreBasic are software applications developed by Respironics intended for use by physicians and home care providers.

Notice: The antenna(s) used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

For U.S. Only:

Notice: Use of non-original manufacturer-approved accessories may violate your local RF exposure guidelines and should be avoided.

Notice: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio, TV reception, or other devices which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna (on the radio, TV, or other device).
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer of the device for help.
- The FCC requires the user to be notified that any changes or modifications made to the device that are not expressly approved by Respironics may void the user's authority to operate the equipment.

For Canada Only:

Notice: This ISM device complies with Canadian ICES-001.

Notice: This product meets the applicable Industry Canada technical specifications.

Notice: Operation is subject to the following two conditions; (1) This device may not cause interference and (2) This device must accept any interference, including interference that may cause undesired operation for the device.

The Term "IC:" before the certification/registration number only signifies that registration was performed based on a Declaration of Conformity indicating that Industry Canada technical specifications were met. The term "IC:" before the certification/registration number does not imply that Industry Canada approved the equipment.

Should you experience trouble with this equipment, please contact your home care provider or Respironics (724-387-4000), for repair or warranty information.