Advanced Body Sensing, LLC
60 Prescott Street
Worcester, MA 01605
USA
(508) 831-4130
E-mail: Absensing.com

BALSM Receiver Unit
&
Pulse Oximeter Sensor

Operator's Manual

Table of Contents

Introduction 4
Forehead Sensor Module 4
Power Supply 5
Forehead Sensor Activation 5
Forehead Sensor Attachment 6
BALSM Receiver Unit 7
Temperature Capsule Activation 7
PC Application Program 8
Data Log Files 10

⚠ Warnings

- This prototype device is intended for limited testing by PSI and is not certified for clinical use.
- Do not use the unit in an explosive atmosphere.
- Do not use the unit in an MRI environment.
- Check frequently the application site of the sensor on the forehead to make sure that skin circulation is not impaired and adverse skin reaction is not visible.
- The material used in the headband and sensor module of this product version has not been tested for biocompatibility and may cause allergic reactions.
- Extended use of the forehead sensor is not recommended as this may cause tissue ischemia and skin necrosis if not properly applied.
- If discomfort or skin irritation occurs, discontinue the use of this device.
- Follow the precautions and warnings regarding the activation and use of the temperature capsule according to the capsule manufacturer.

⚠ Cautions

- Do not use the unit in the vicinity of very bright light sources.
- General operation of the unit may be affected by RF interferences.
- General operation of the unit may be affected by motion artifacts. Proper operation of this unit is limited to resting conditions.
- Readings displayed by this prototype have not been calibrated or validated with a standard clinical monitor.
- The unit should only be used in conjunction with other medically approved devices to diagnose clinical symptoms.
- Significant levels of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin, may affect measurement accuracy.
- The unit may not function in cold environments due to reduced blood circulation to the forehead.
- Do not immerse the unit is liquid or other cleaning solutions as this may cause permanent damage.
- To prevent damage, do not sterilize the forehead sensor or receiver unit.
- Do not clean the surface of the optical sensor with abrasive materials.
- Do not use cleaning solutions other than wiping the optical window with a damp cloth moistened with water.
- To preserve battery life, turn off the unit if not in use.
- Do not attempt to remove, replace, or dispose of the battery.
- Changes or modifications not expressly approved by Advanced Body Sensing could void the user's authority to operate the equipment.

This manual serves as a preliminary operator's manual for the alpha prototype of the BALSM receiver unit. Advanced Body Sensing reserves the right to make changes to the system and this manual at any time without notice or obligations.

BRU FCC ID: WKC-BRU001
Pulse Oximeter FCC ID: WKC-POX001

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 or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

-- Reorient or relocate the receiving antenna.
-- 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 or an experienced radio/TV technician for help.

Introduction

This section describes the operation of the wireless BALSM receiver unit (BRU). The dual-use BRU is designed to measure core body temperature from an ingestible capsule thermometer as well as arterial oxygen saturation (SpO_2), heart rate (HR), respiration rate (RR), body motion and posture from a forehead-mounted optical wireless reflectance sensor. The BRU can be used to activate the two sensors independently and record data wirelessly for real-time rapid status assessment of vital physiological information. The unit is lightweight and is intended for monitoring of adult subjects in field applications lasting up to 84 hours. It is not recommended during applications where excessive motion artifacts are expected. The unit has not been calibrated or certified for clinical use.

Forehead Sensor Module

The forehead worn sensor module (SM) contains a small and lightweight optical reflectance sensor, signal processing circuitry, and a RF transceiver integrated into an elastic headband (Fig. 1). Dedicated software is used to filter the signals and compute SpO_2, HR, and RR based on the relative amplitude and frequency content of the optical reflectance signals. Data from the SM are sent to the BRU via low-power peer-to-peer short-range (~3 – 6ft) wireless communication. A tri-axis MEMS accelerometer detects changes in body activity, and the information obtained through the tilt sensing property of the accelerometer is used to determine the orientation of the person wearing the device.

Fig. 1. Forehead Sensor Module

Power Supply

The SM is powered by a special coin cell battery which should allow for at least 200 hours of continuous monitoring at room temperature. To extend battery life, the SM is turned off using a magnet. Do not attempt to remove, replace, or dispose of the battery. The BRU receives power from the PC through the USB interface cable.

Forehead Sensor Activation

The SM must be activated using a small activation magnet built into the BRU. To activate and pair the pulse oximeter sensor with the BRU:

(1) Bring the pulse oximeter sensor up to the BRU (sensor should be on side as shown in diagram and sensor label should be approximately in line with the white arrow on the BRU).

The sensor LED will turn red and start flashing.

(2) Within 10 seconds turn the sensor on its edge so the square detector is in front of the BRU optical activation window.

Press the Activate Sensor button on the BRU.

If successfully paired, then the Activate Sensor LED on the BRU will turn green and then flash green at 1 second intervals. The sensor LED will glow constantly red.

If pairing fails, the sensor will turn off after 10 seconds. The sensor can be turned on again and pairing tried again.

To turn off the sensor, bring it up to the BRU as described in step 1 until the sensor LED are turned off.

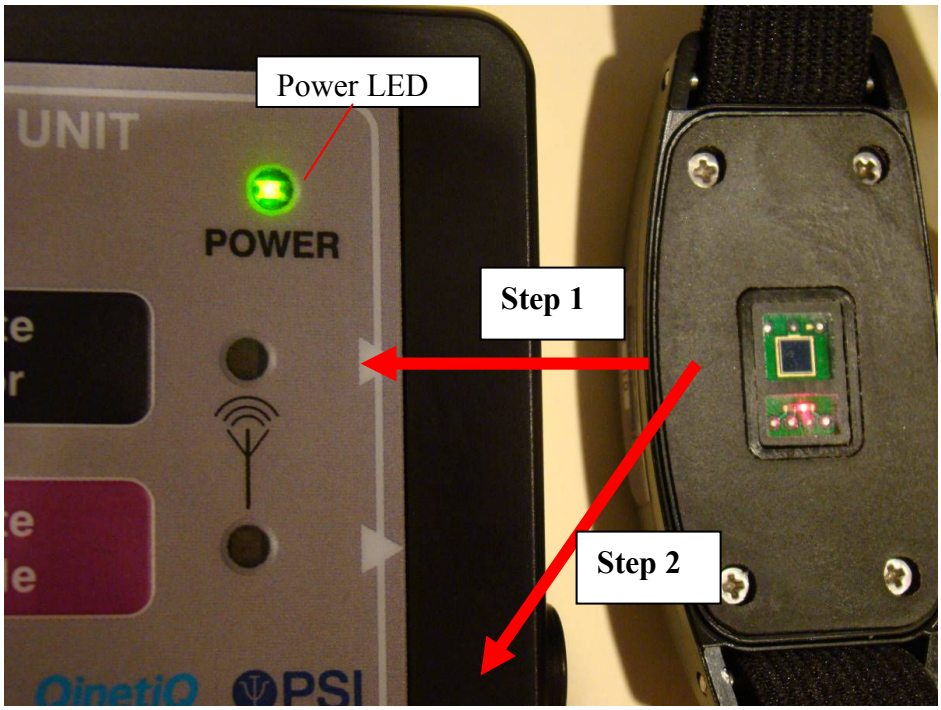

Fig. 2. Forehead Sensor Activation

Notes: The BRU is currently running in a demo mode, i.e. every time the power is cycled on the BRU, the SM must be activated again. If the activation is not successful, the sensor LED will turn red for about 1 sec. Try again by repeating the above steps.

Forehead Sensor Attachment

The monitoring site should be cleaned prior to sensor placement. Place the SM properly around the forehead using the adjustable headband, as illustrated in Fig. 3. Orient the clear optical sensor window towards the skin in the center of the forehead above the eyes. Make sure that the label affixed to the side of the SM is oriented upward. To avoid inaccurate readings, ensure that the headband is not applied too loosely or tightly around the head as this may cause erroneous readings.

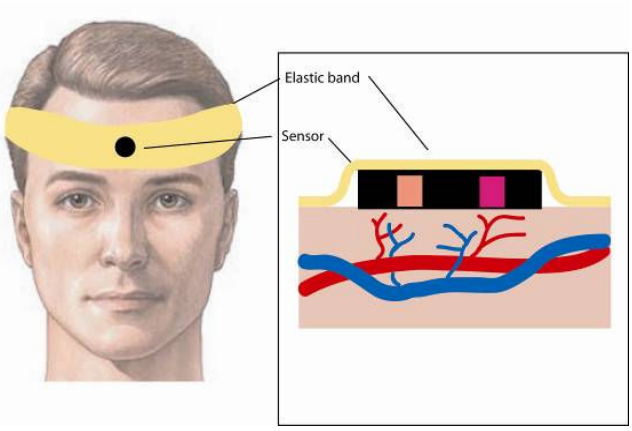

Fig. 3. Sensor Attachment on Forehead

After the SM is positioned on the forehead and is activated, it will begin sensing. Allow at least 20 seconds for the readings to stabilize. If you are not able to achieve stable readings, try repositioning the SM on the forehead or adjusting the headband. Correct positioning of the sensor on the forehead is critical to achieve accurate measurements. Note: a very loose or too tightly mounted sensor will cause a degraded or loss of the PPG signals, leading to erroneous or inaccurate readings.

BALSM Receiver Unit

To turn on the BRU, plug the USB cable attached to the unit into any USB port on your PC. Once the unit is connected with the PC, the green "Power" LED would turned on. Note that the "Sensor" and "Capsule" LEDs will not light up unless the forehead sensor and temperature capsule have been previously activated.

Temperature Capsule Activation

Note: Follow the precautions and warnings regarding the activation and use of the temperature capsule according to the capsule manufacturer.

In order to activate the temperature capsule, place a non-activated temperature capsule into the IR port on the side of the BRU housing indicated by the white capsule arrow as illustrated in Fig. 4.

1. Press the "Activate Capsule" button to start the activation process. During the activation process, the "Capsule" LED will blink red for 10sec or until activation is complete.

2. If activation is successful, the capsule LED will turn green for about 1sec. Once the temperature capsule is activated, the capsule LED will blink green every 15 sec when a successful data packet is received. If the packet from the capsule is corrupt, or the communication with the capsule failed, the capsule LED will blink red every 15 seconds.

3. If the activation failed, the capsule LED will turn red for about 1 sec. Remove and re-insert the capsule into the activation port and repeat the activation process.

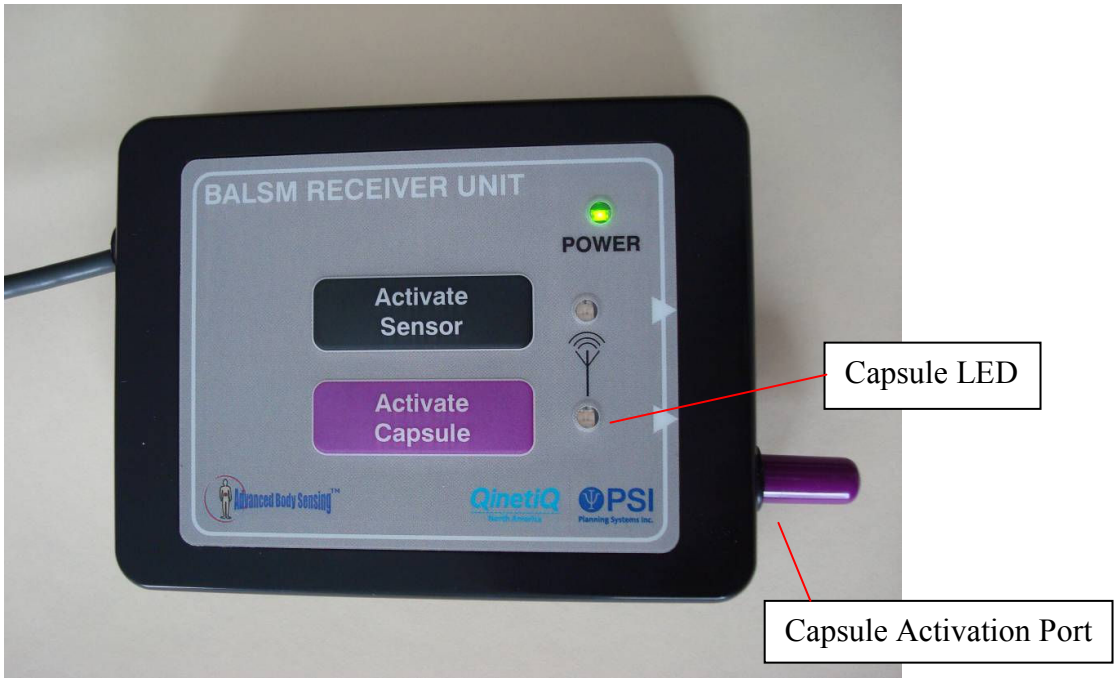

Fig. 4. Temperature Capsule Sensor Activation

PC Application Program

A special windows utility program is provided for real-time communication between the BRU and a PC. The PC program has two user log files: One file is used to display the information received from the SM and another file to display the data received from the temperature capsule.

The program displays a scrolling horizontal trace and numerical values of the most recently acquired data corresponding to HR, SpO_2 and RR values received from the SM and core body temperature received from the ingestible capsule. To start or stop the program, the user must click the “start” or “stop” buttons, respectively. To log data into a text file, select the “log data” option before you start the program. A sample log file is shown below. After the program and sensor are activated, numerical values in the System Info window will indicate the corresponding receiver and sensor addresses and the link status window will display “Good” in green. When the program is stopped, the Link Status window will display “Stopped” in red. While the program is running and data is received by the USB receiver, the Sensor Info window will display Sensor Status, Battery Status, Battery Voltage and sensor Temperature information. The Activity window includes a horizontal green bar graph corresponding to the relative level of sensor movements. In addition, changes in sensor orientation are described by a text label and depicted by a corresponding icon.

Until a capsule is activated, the Capsule Link Status will display "NOT ACTIVATED" and all the other capsule fields will be blank, including the temperature graph. Once a new capsule is activated, the corresponding Capsule ID, Capsule Type, and the received Diagnostics byte from the capsule are displayed in the respective information boxes. The Link Status will display "GOOD".

The last received temperature data from the capsule will be displayed both on the scrolling data graph and data box. The temperature trace will scroll every second using the last received value even though the capsule data is received and updated only every 15 seconds, so that a continuous graph can be displayed.

If another temperature capsule is activated, the new capsule will override the previous capsule data and all the information will be updated accordingly.

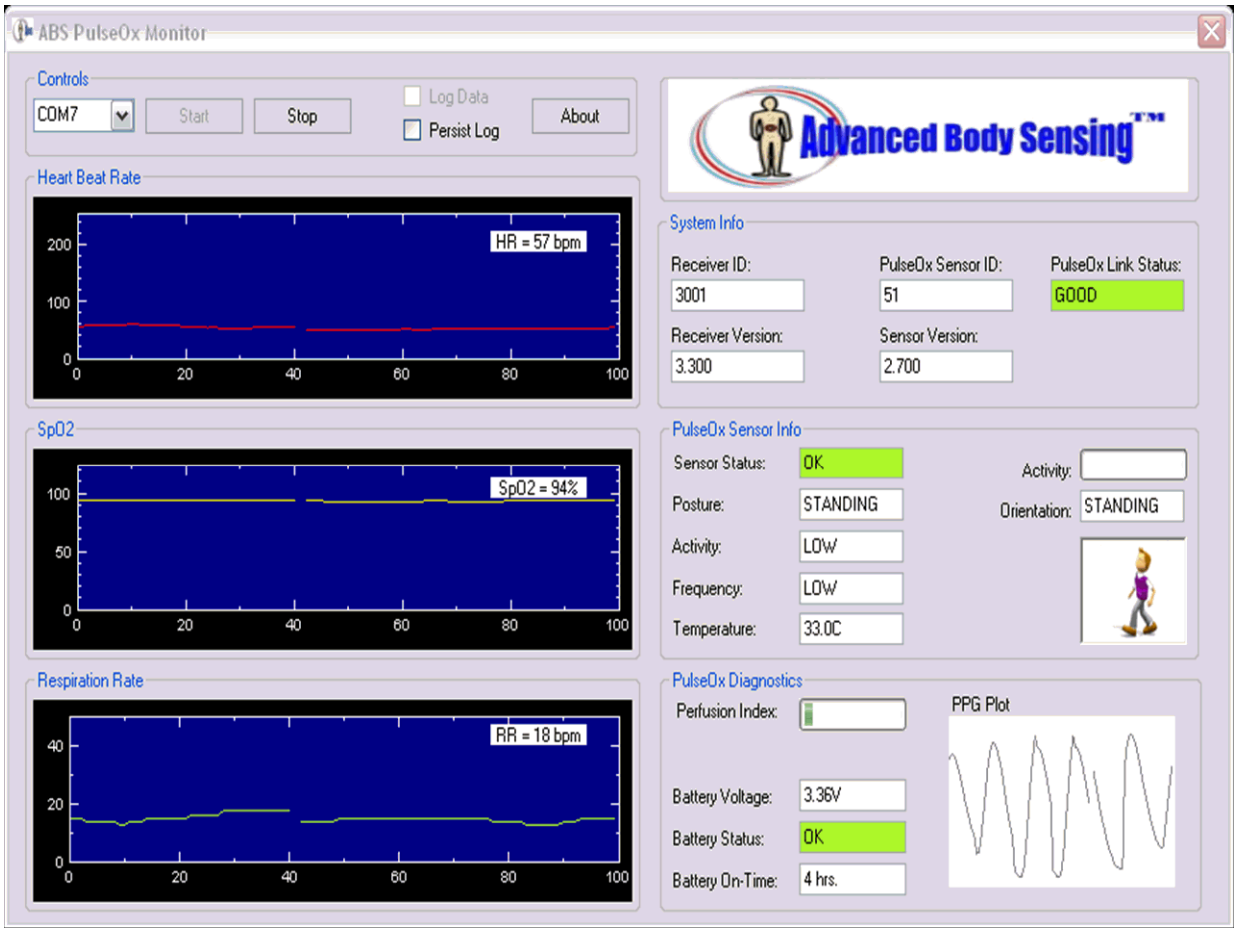

Fig. 5b. Windows utility program

Data Log Files

ABS Wireless PulseOximeter Log file created on 2/27/2008 4:20:17 PM.
Receiver ID = 1009, Receiver Version = 1.001

Time Stamp	Sensor ID	Heartbeat Rate (bpm)	SpO2 (%)	Respiration Rate (bpm)	Sensor Status	Battery Status	Battery Voltage (V)	Environment Temperature (C)	Orientation	Activity	Link Status
4:20:18 PM	1009	60	94	13	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:19 PM	1009	59	94	13	OK	OK	3.15	28.5	STANDING	5	GOOD
4:20:20 PM	1009	59	94	13	OK	OK	3.13	28.5	STANDING	0	GOOD
4:20:21 PM	1009	57	95	13	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:22 PM	1009	58	95	11	OK	OK	3.13	28.5	STANDING	0	GOOD
4:20:23 PM	1009	57	95	11	OK	OK	3.13	28.5	STANDING	0	GOOD
4:20:24 PM	1009	56	96	11	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:25 PM	1009	56	96	13	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:26 PM	1009	57	96	13	OK	OK	3.13	28.5	STANDING	0	GOOD
4:20:27 PM	1009	56	96	13	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:28 PM	1009	54	96	16	OK	OK	3.13	28.5	STANDING	0	GOOD
4:20:29 PM	1009	56	97	16	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:30 PM	1009	55	96	16	OK	OK	3.15	28.5	STANDING	0	GOOD
4:20:31 PM	1009	56	96	16	OK	OK	3.15	28.5	STANDING	5	GOOD
4:20:32 PM	1009	56	96	16	OK	OK	3.13	28.5	STANDING	5	GOOD
4:20:33 PM	1009	57	96	16	OK	OK	3.15	28.5	STANDING	10	GOOD
4:20:34 PM	1009	57	96	16	OK	OK	3.15	28.5	STANDING	5	GOOD
4:20:35 PM	1009	58	96	16	OK	OK	3.13	28.5	STANDING	5	GOOD
4:20:36 PM	1009	58	96	16	OK	OK	3.15	28.5	STANDING	20	GOOD
4:20:37 PM	1009	58	95	16	OK	OK	3.15	28.5	STANDING	175	GOOD
4:20:38 PM	1009	58	94	13	OK	OK	3.09	28.5	LYING DOWN	185	GOOD
4:20:39 PM	1009	58	94	13	OK	OK	3.11	28.5	LYING DOWN	15	GOOD
4:20:40 PM	1009	58	94	13	OK	OK	3.11	28.5	LYING DOWN	0	GOOD
4:20:41 PM	1009	58	94	15	OK	OK	3.11	28.5	LYING DOWN	0	GOOD

ABS BRU Capsule Log file created on 2/27/2008 4:20:17 PM.
BRU ID = 1009, BRU Version = 1.001

Time Stamp	Capsule ID	Core Temperature (C)	Capsule Diag	Link Status
4:20:19 PM	533	23.83	0	GOOD
4:20:34 PM	533	23.85	0	GOOD
4:20:49 PM	533	23.85	0	GOOD