

beddrTM

SleepTunerTM

USER MANUAL

These instructions provide the necessary information for proper operation of the Beddr SleepTuner.

INTENDED USE

Beddr is intended to help maintain or encourage a general state of health or healthy sleep. Beddr is for users who are interested in understanding their blood oxygenation level (SpO2), pulse rate and sleeping position. Beddr is not intended for medical use or to inform healthcare decisions. Beddr is not intended to cure, prevent or treat a disease.

INTENDED POPULATION

The intended patient population for the SleepTuner is adults.

WARNINGS

The Beddr SleepTuner is not intended to provide information that leads to healthcare decisions.

Do not use the SleepTuner during Magnetic Resonance Imaging (MRI) or in an MRI environment.

Avoid looking directly at the LED Sensor Array.

Use only the Power Adapter and Charging Cable provided with the SleepTuner to recharge the battery.

CAUTIONS

Do not use the SleepTuner if it appears or is suspected to be damaged.

Do not repair, open or modify the SleepTuner.

Do not use the SleepTuner if the internal parts have been exposed to liquids.

Do not use the SleepTuner for more than 12 hours continuously.

Do not use the SleepTuner while charging.

Do not use the Sleep Tuner if forehead skin shows irritation or damage.

Keep SleepTuner out of reach of pets and children.

Separation from power is only assured through the disconnection of the Power Adapter from the wall outlet. Ensure a clear path to the wall outlet is maintained during charging.

NOTES

Do not immerse in fluid or run fluid over the SleepTuner.

TIPS

When using the SleepTuner with a smart device (smartphone, tablet computer), keep both devices within the recommended range of each other. Moving outside of this range may cause a loss of connection with the smart device.

The Power Adapter is two-pronged and does not require a grounded outlet.

The SleepTuner has a Lithium-ion battery which may be restricted for certain types of travel.

The SleepTuner is not provided sterile.

SleepTuner performance may be affected if used outside the operating ranges specified.

Avoid the following to optimize measurements:

- Improper SleepTuner placement or alignment
- Externally applied skin products such as make-up or skin lotion applied to the sensor location
- Excessive motion

The following health conditions may reduce the accuracy of the measurements:

- Severe Anemia
- Venous congestion
- Venous pulsation
- Extremely low arterial perfusion

PRODUCT OVERVIEW

Product Description: The SleepTuner is a wellness oximeter, a non-invasive continuous monitoring device that measures and displays functional oxygen saturation of arterial hemoglobin (SpO2), stopped breathing events per hour, Pulse Rate (PR), sleeping position and movement.


Oxygen Saturation (SpO2)	The amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen.
Stopped Breathing Events per Hour	Number of times per hour that the device detects a stopped breathing event.
Pulse Rate	Pulse rate, measured in beats per minute (BPM), is based on optical detection of peripheral flow pulse
Sleeping Position	Sleeping position is based upon measurements derived from a 3-axis accelerometer. The SleepTuner is able to track if you are sleeping on your side, back or front or seated upright.

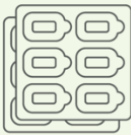

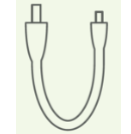
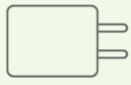
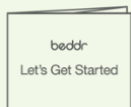
The SleepTuner works in conjunction with an application that runs on a mobile phone. As the mobile application is updated, new information may be presented to the user.

Theory of Operation: The SleepTuner shines light into forehead tissue and analyzes the differences in intensity of the reflected light. The light absorbance in the tissue changes depending on the concentration of oxygenated hemoglobin in the blood. A set of formulas based on the Beer-Lambert law are used to derive the measured SpO2 (peripheral oxygen saturation) from that reflected light.

Sensor Configuration: The SleepTuner sensor is composed of a Light Emitting Diode (LED) emitters that send different wavelengths of light into tissue and detectors that receive and measure those returned wavelengths.

Package Contents:

	SleepTuner (Part Number SA01116)
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	12 Adhesives (Part Number SA01113)
	Case (Part Number PC01109)
	Charging Cable (Part Number PC01114)
	Power Adapter (Part Number PC01115)
	Quickstart Guide (Part Number LB0111)

USING THE SLEEPTUNER

Download the mobile application from the iOS Apple Store for information on product use and troubleshooting.

CLEANING THE SLEEPTUNER

Confirm that the SleepTuner is off, disconnected from power and not applied to the forehead. Wipe the sensor and outer surfaces using a lint-free cloth lightly dampened with water. Do not use any cleaning solution.

SERVICE

Only Beddr-authorized personnel can service the SleepTuner. Do not attempt to service the SleepTuner.

The expected service life of the SleepTuner is 1 year.

For additional help, visit the support section of the Beddr mobile application, our website at www.beddrslee.com/support or email support@beddrslee.com.

DISPOSAL

The SleepTuner is electronic equipment. Please use your local return and collection system for electrical and electronic equipment waste. Improper disposal may have harmful effects on the environment and on public health. Recycle wherever possible.

TECHNICAL SPECIFICATIONS

Clinical Data

Measurement Range	Measured Accuracy (A_{rms})
90% to 100%	$\leq 4\%$
80% to 90%	$\leq 4\%$
70% to 80%	$\leq 4\%$

Performance Specifications

Functional Oxygen Saturation (SpO_2)

Resolution	Measurement Range	Accuracy (A_{rms})
1%	70% to 100%	$\leq 4\%$

Pulse Rate

Resolution	Range	Accuracy (A_{rms})
1 bpm	25 bpm to 240 bpm	3 bpm

Display Ranges

SpO2	0%-100%
Pulse Rate	25 bpm to 240bpm
Sleeping Position	back, side, front, sitting

Battery

Specs	3.7V, 50mAH, Lithium-ion
Life	Approximately 20 hours of continuous operation

Physical Characteristics

Dimensions	33.7mm x 24.5mm x 9.5mm
Weight	5.3 grams

Electrical Specifications

Input	100-240V
Output	50-60Hz; (output) 5V, 1.2A

Environment

Item	Description
Operating Temperature Range	-5C to 40C
Operating Humidity Range	15% to 90%
Storage/Transport Temperature Range	-25°C to 70°C
Storage/Transport Humidity Range	0% to 90%
Operating / Transportation / Storage Atmospheric Pressure	70 to 106 kPa
Ingress Protection (SleepTuner)	IP22 - Protected from touch by fingers and objects greater than 12.5 millimeters. Protected from water spray less than 15 degrees from vertical.
Ingress Protection (Power Adaptor)	IP21 - Protected from touch by fingers and objects greater than 50 millimeters. Protected from water spray less than 15 degrees from vertical.

The SleepTuner has been verified by an independent test institute for compliance with the EN / IEC 60601-1 standard. See www.beddrsleee.com/support for the Guidance and Manufacturer's Declaration on emissions and immunity.

LIMITED WARRANTY

Hancock Medical, Inc. warrants to the original purchaser ("Customer") that hardware provided with the product will be free from material defects under normal intended use for one year from the original purchase date. Hancock Medical's sole obligation under this warranty shall be, in its sole discretion, to replace or repair the defective product, or refund the purchase price. All items returned to Hancock Medical become the property of Hancock Medical. Replacements are warranted for the longer of 90 days or the original warranty period. Customer must contact Hancock Medical within the warranty period to obtain a warranty service authorization. Dated proof of original purchase will be required. Hancock Medical is not responsible for items received without warranty service authorization. Customer bears the risk of loss during shipment. HANCOCK MEDICAL, INC. MAKES NO OTHER WARRANTIES WITH RESPECT TO ANY HARDWARE, SOFTWARE, OR SERVICE, WHETHER EXPRESS OR IMPLIED, AND ALL IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO THOSE FOR MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT ARE DISCLAIMED. This limited warranty is void if defects are caused by misuse, neglect; by unauthorized attempts to open, repair, or modify the product; or by accident, fire, lightning, or other hazards.

FCC

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. Change or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. 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 or more 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.












LICENSE

This product contains software, the use of which licensed by Hancock Medical Inc. to customer for the customer's personal use only, as further provided at www.beddrsleap.com/license which is hereby incorporated herein by reference. Modification, reverse engineering, reverse compiling, or disassembly of the software is expressly prohibited, except to the extent authorized by applicable law.

SYMBOLS

The following symbols appear on the product, product packaging or this User Manual:

SYMBOL DEFINITION

	Device Manufacturer
	Manufacturer's Device Catalogue Number
IP21	IP rating 21
IP22	IP rating 22
	Type BF Applied Part
	Do not dispose the device together with unsorted municipal waste
	Non-Sterile
	Temperature Limitation
	Humidity Limitation
	Follow Instructions for Use
	Not for Continuous Monitoring (No Alarm for SpO2)
	Reusable
FCC ID:	Federal Communications Commission (FCC) Licensing
	Caution: these notes must be observed to prevent any damage to the device.

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TRADEMARK

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LB-01019 Rev B