



Universal Bluetooth Sleep Transceiver System

User's Guide

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Rev: 9/03
Manual P/N: OMXXXX

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CHAPTER 1: PRODUCT OVERVIEW

UNIVERSAL TRANSCEIVER PROFILE

The Universal Bluetooth Sleep Transceiver System is specifically designed to assist the clinician in the diagnosis of sleep-disordered breathing. The Transceiver units measure 54mm (W) x 85.5mm (L) x 10mm (H) and weigh only 100 grams.

The System uses sensors to record airflow, snoring, thoracic and abdominal respiratory effort, and periodic limb movement. The System is designed to be used in a supervised (hospital/institutional) or unsupervised (home) environment. It is capable of Recording 12 hours of patient data on a single charge. The data is stored on a host computer system.

FEATURES AND BENEFITS

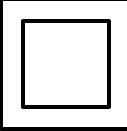
- Nasal/Oral Airflow and Snoring
- Thoracic and Abdominal Respiratory Effort
- Periodic Limb Movement
- Long Battery Life
- Wireless system interconnection

PACKAGE CONTENTS

- TBD
- User's Guide

SYMBOLS

The following symbols are used on the front and back panels of the Transceivers.

Symbol	Name	Function
STATUS	Transceiver Status	LED that indicates the status of the Transceiver
	Type B Equipment	Degree of protection against electrical shock (IEC 60601-1)
	Class II Equipment	Class II Equipment
	Attention!	Consult Accompanying Documents
IPX1	Drip-proof equipment	Protected against dripping water
	Non-ionizing Radiation	Non-ionizing Radiation, a class 2 Bluetooth wireless transceiver
SN	Serial Number	Serial Number of the Transceiver

WARRANTY

Pro-Tech Services, Inc. warrants this product to be free from defects in materials and workmanship for a period of one year. Should the Transceiver module fail prematurely, the sole liability of Pro-Tech Services, Inc. is limited to repair, or at its option, replacement of the product, with a new or like unit, with no charge for parts or labor. Under no circumstances shall Pro-Tech Services, Inc. be liable for any loss or damage, direct, consequential, or incidental, including property damage or personal injury arising from the use of, or the inability to use this product. This warranty is rendered void and Pro-Tech Services, Inc. cannot be held liable for conditions resulting from: damage, marginal performance or malfunctions caused by:

misuse, abuse, neglect, improper line voltage, power fluctuations, or any adverse environmental conditions, tampering, unauthorized modifications, adjustments or repairs to the product or its accessories. This warranty is in lieu of all other warranties, expressed or implied and is extended only to the original purchaser. Features and specifications are subject to change without notice.

FCC COMPLIANCE STATEMENT (Part 15.19)

This device complies with Part 15 of the FCC Rules and with RSS-210 of Industry Canada.

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.

INDUSTRY CANADA STATEMENT

The term "IC" before the certificate/registration number only signifies that the Industry Canada technical specifications were met.

CHAPTER 2: WARNINGS, CAUTIONS, AND NOTES

INTENDED USE

The Universal Bluetooth Transceiver System is intended for use in the recording of biophysical parameters for the purpose of assisting in the diagnosis of sleep disorders.

INDICATIONS FOR USE

The Universal Bluetooth Transceiver System is used to aid diagnosing respiratory disorders, such as sleep apnea.

ENVIRONMENT OF USE AND PATIENT POPULATION

The Universal Bluetooth Transceiver System is intended for the hospital or institutional environment (attended) and the home environment (unattended).

WARNINGS

A warning indicates the possibility of injury to the patient or operator.

Warning (Part 15.21)

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

The Universal Bluetooth Transceiver System is not intended for use as apnea monitor or life support equipment such as vital signs monitoring in intensive care units.

The Universal Bluetooth Transceiver System is only to be used under the direction and supervision of a physician, PSG technologist or clinician. It will not prevent or restore the interruption or loss of any physiological system.

The Universal Bluetooth Transceiver System is not to be used in the presence of flammable anesthetic mixture air or with oxygen or nitrous oxide.

Use only sensors and accessories that are specified by Pro-Tech Services, Inc. for the Universal Bluetooth Transceiver System. Non-approved sensors and accessories can compromise safety, performance and certification of the Transceiver unit and will void Pro-Tech Services' product warranty.

To ensure the Transceivers operate throughout the entire sleep session, be sure the batteries are fully charged.

Inaccurate measurements may be caused by:

- Incorrectly using the sensors
- Electromagnetic interference
- Excessive movement
- Electro-surgical interference

All connectors between the sensors and the Transceiver have been designed to prevent their insertion into any other outlets. However, it is the user's responsibility to read and understand the instructions in this manual before using this device to prevent any electrical shock hazard.

The Universal Bluetooth Transceiver System has no apnea alarm and is not to be used as an apnea monitor.

CAUTIONS

A caution indicates the possibility of damage to the device.

To avoid damaging the sensors or Transceivers, do not allow the patient to shower or bathe while wearing the sensors or the Transceivers.

Pressure airflow interfaces require the use of an appropriate safety filter to prevent the possible transfer of airborne disease from patient to patient and to protect the internal pressure transducer from premature failure due to moisture contamination. Pro-Tech disposable airflow sensor cannulas incorporate the necessary filters.

Do not allow detergent solutions or cold sterilization agents to leak into the electronic components. Use extra caution around connectors and panel edges.

Do not use abrasive cleaners.

Caution: Federal law restricts this device to sale by or on the order of a physician.

NOTES

A note places emphasis on operating characteristics of the device.

CONTRAINDICATIONS

The Universal Bluetooth Transceiver System is not intended for use during Magnetic Resonance Imaging (MRI) procedures or in a MRI environment.

ELECTROMAGNETIC COMPATIBILITY

The Universal Bluetooth Transceiver System complies with Electromagnetic Compatibility standards for medical devices. If you suspect the Transceivers are interfering with the operation of other appliances (television, radio, cell phone, etc.) or if they are interfering with the operation of the Transceivers, move the Transceivers away from the appliance.

CHAPTER 3: INSTALLATION AND SETUP

VERIFYING THE TRANSCEIVER OPERATION

TBD

CONFIGURING WITH A PERSONAL COMPUTER

TBD

For instructions on using the host software, refer to the host software manual.

CHAPTER 4: PRERECORDING ACTIVITIES

PRE-RECORDING ACTIVITIES

This section describes the procedures that ensure that the System is ready to record data. These procedures should be preformed before the patient arrives at the care center.

The Transceivers and sensors should be arranged, tested for functionality, and made ready for use.

The following items should also be accessible:

1. Adhesive tape
2. Mild anti-bacterial hand cleaning agent
3. Mild, non-abrasive cleaner
4. Alcohol
5. Soft cloth

ACTIVATING THE TRANSCEIVERS

TBD

CHAPTER 5: RECORDING ACTIVITIES

RECORDING ACTIVITIES

A correct diagnosis depends on accurate data. To ensure accurate data, follow these activities and tips:

1. Make sure the Transceiver batteries are charged.
2. Connect all of the sensors to the Transceivers.
3. Monitor the signals with a PC to ensure that all signals are operating properly.
4. Talk to the patient about how to properly apply the sensors (if applicable).

THORACIC EFFORT BELT INSTALLATION

TBD

ABDOMINAL EFFORT BELT INSTALLATION

TBD

PLM SENSOR INSTALLATION

TBD

PRESSURE AIRFLOW MODULE INSTALLATION

TBD

CANNULA INSTALLATION

Put the cannula under your nose with the nasal prongs in your nostrils and then run the tubing up over your ears. Tighten the cinch tubing under your chin until it is comfortable. If you are using a nasal/oral cannula, trim the oral prong in accordance with the cannula instructions.

CONTROLS AND INDICATORS

User Controls

There are no physical user controls; a PC controls the Transceivers with Host Software through a Bluetooth connection.

LED Indicator

TBD

Sensor Input

TBD

Charger Input

TBD

RECORDING DATA ON HOST SOFTWARE

TBD

TRANSCEIVER SYSTEM DIAGRAM

TBD

CHAPTER 6: PRINCIPLES OF OPERATION

The Universal Bluetooth Sleep Transceiver System is designed to record physiological data during sleep to assist the clinician in forming diagnostic impressions for patients with sleep disordered breathing.

The System consists of a number of battery-operated wireless transceivers, sensors, and a host computer to display and record data.

The System's intended purpose is to collect and store data that will be used to generate reports. Using the Host Software, real-time, full disclosure data may also be displayed.

AIRFLOW AND SNORING

TBD

RESPIRATORY EFFORT

Respiratory effort is measured using two reusable effort belts; one around the patient's thorax (rib cage) and one around the patient's abdomen.

PERIODIC LIMB MOVEMENT (PLM)

Periodic Limb Movement is measured using a piezo actimeter attached to either the wrist or ankles via Velcro straps.

CHAPTER 7: CLEANING, MAINTENANCE, TROUBLESHOOTING

CLEANING AND DISINFECTION

Reusable sensors and the Transceiver should be cleaned between sleep studies.

Cleaning Effort Sensors

1. Disconnect the sensor from the Transceiver.
2. The sensor may be safely soaked clean in a warm hospital grade laundry detergent and then air-dried.
3. The wire set may be wiped down with soapy water or a bleach or alcohol towelette. Do not immerse in liquids.

Cleaning the PLM Sensors

1. Disconnect the sensor from the Transceiver.
2. The PLM sensor may be wiped with a hospital approved disinfectant.
Caution: The PLM sensor is not liquid tight; do not soak the PLM sensor in cleaning solution.
3. The Velcro may be soaked in a hospital-approved disinfectant and then air-dried.

Cleaning the Transceivers

1. Dampen a soft cloth with a mild non-abrasive detergent and gently rub the Transceiver to remove dirt and oil.
2. Dry the Transceiver with a soft cloth.

MAINTENANCE

There are no operator-serviceable parts in the Transceiver.

CALIBRATION

The Transceiver requires no periodic calibration.

TROUBLESHOOTING

TBD

CHAPTER 8: SPECIFICATIONS

Size.....70mm(W) x 126mm(L) x 24mm(H)

Weight (with battery), Transceiver100 grams

PowerBattery, Rechargeable lithium

Battery life 12 hours
Operating Temperature.....5C (40F) to 40C (104F)
Storage Temperature..... -20C (-4F) to 60C (140F)
Operating and Storage Humidity: 15 to 95% Non-condensing
Type of protection against shock.....Internally Powered Equipment
Degree of protection against shockType B Applied Part
Degree of protection against water.....Drip Proof Equipment (IPX1)
Mode of operation.....Continuous Operation