Prodigy Sleep System

Operator Manual

Label Information and Manufacturer's Notes:

Younes Medical Technologies (YMT)
Unit 5 – 55 Henlow Bay
Winnipeg, MB, Canada, R3Y 1G4
Canada
1-888-942-6774

Technical Support

Our customer support staff can be reached through the following methods:
Toll-free: 1-888-942-6774
Email: support@younesmedical.com

Problem Reporting

All problems relating to the performance characteristics or safety of the Prodigy Sleep System must be recorded, addressed and reported to regulatory authorities by YMT as necessary. In addition, any incidents involving serious injury or death must be reported to YMT. To report problems, please contact YMT directly at 1-888-942-6774.

Warnings and Cautions:

The warnings and cautions associated with use of this device are identified throughout this Operator Manual with appropriate symbols, described on page 6.

Copyright

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Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
DC	Direct Current
C	Celsius
CDC	Centers of Disease Control and Prevention
dB	Decibel
EEG	Electroencephalogram
FCC	Federal Communications Commission
ft	Feet
g	Gram
Hz	Hertz
IEC	International Electrotechnical Commission
IP	Ingress Protection
LED	Light Emitting Diode
lb	Pound
m	Meter
mm	Millimeter
MSDS	Material Safety Data Sheet
ORP	Odds Ratio Product
Pa	Pascal
PC	Personal Computer
PPE	Personal Protective Equipment
Qty	Quantity
RSS	Radio Standards Specification
USB	Universal Serial Bus
V	Volts
VAC	Volts Alternating Current
VDC	Volts Direct Current
Vrms	Root Mean Square Voltage
W	Watts
YMT	Younes Medical Technologies

Warning, Caution, and Note Statements

Warning, Caution, and Note statements are used throughout this manual prior to operating or maintenance procedures, practices, or conditions considered essential to the protection of personnel or equipment and property. A Warning, Caution, or Note will apply each time the related step is repeated. Prior to starting any task, the Warnings, Cautions, and Notes included in the text for that task must be reviewed and understood.

The following definition applies to Warnings, Cautions, and Notes:

WARNING

A warning statement is used to emphasize operating procedures, practices, etc. which could result in servere personal injury of loss of life if not followed correctly.

CAUTION

A caution statement is used to emphasize operating procedures, practices, etc., which could result in minor or moderate injury to the user and/or damange to or destruction of equipment if not followed correctly.

NOTE

A note statement is used to highlight procedures, events, or practices which are desirable or essential for efficient operations.

1. Introduction

This manual contains information to instruct the user how to use the various components of the system. Special skills and training are not required of the user, but it is imperative that all users have a full understanding of the entire system and the associated safety precautions before using the device.

INTENDED USE

The Prodigy Sleep System is intended to provide means of obtaining information about sleep quality, as well as other physiological signals from adult users. It is a physiological data recorder that acquires, records, and transmits data. Signals include: Electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), electromyogram (EMG) signals, airflow (nasal cannula), respiratory effort (chest and effort), pulse rate and oxyhemoglobin saturation from the finger.

The Prodigy Sleep System is intended for use by users in a home setting, or for prescription use in a healthcare facility.

INDICATIONS FOR USE

The Prodigy Sleep System acquires, records and transmits physiological signals to aid in sleep management in adult patients in an unsupervised (home) environment, and under a physician's care, to aid in evaluation and diagnostic support of adult users in an unsupervised (home) or supervised (hospital) environment.

- The signals include electromyogram (EMG), electroencephalogram (EEG), electrooculogram (EOG), pulse oximetry (photoplethysmographic), electrocardiogram (ECG), airflow (nasal cannula), respiratory effort (chest and abdomen), pulse rate, and oxyhemoglobin saturation. Different configurations are available which collect data from different subsets of the signals listed above.

WARNING

The Prodigy Sleep System is not indicated for real time monitoring of EEG activity during resucitation.

CONTRAINDICATIONS

The following is a list of contraindications for this device:

- User is under the age of 18.
- Cognitive impairment (inability to follow simple instructions) resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task.

- Physical impairment resulting in inability to apply the home sleep testing equipment when another individual is not available to assist with this task.

GENERAL SAFETY INFORMATION

- Magnetic and electrical fields are capable of interfering with the proper performance of the Prodigy Sleep System. Make sure that all external devices operated in the vicinity of the unit comply with the relevant EMC requirements.
- This device shall not be used for life support or critical applications. It may stop operating in the event of a power interruption or system fault.
- Do not use in the vicinity of flammable liquids or gases (such as flammable anesthetics).
- Do not sterilize any component of the device. Cleaning and disinfection should only be done according to instructions and by trained service personnel.
- Equipment needs to be set-up and put into service in accordance with the information provided in the accompanying documents, including this operator manual.
- Do not use the Prodigy Sleep System if you are connected to a high-frequency surgical instrument as this could cause skin irritation or burns under the electrodes.
- If any signs of skin irritation become present (e.g. itchiness, redness, swelling) while handling the Prodigy Sleep System discontinue use immediately
- Do not use the Prodigy Sleep System when other electronic medical devics are also attached to your body as this may cause improper operation.

- External defibrillation of a person wearing Prodigy Sleep System components can injure the person with risk of burns under the electrode sites during defibrillation. To eliminate any risk, remove all Prodigy Sleep System components before defibrillation paddles are applied.
- Interference from other RF wireless and mobile communication devices is possible. Refer to Table 6 - Recommended separation distances between portable and mobile RF communications equipment and the Prodigy Sleep Systemfor recommended distances between Prodigy Sleep System components and other RF devices
- Handle the components with care and avoid dropping or otherwise rough handling of the components.
- There are no user serviceable parts inside the device. The user shall not open the device and make any adjustments or attempt to service the device.
- Avoid contact with liquids. Keep all liquids away from device components.
- Avoid placing components in direct sunlight or in close proximity to intense heat, including household heaters or open flame.Keep Prodigy Sleep System components clean and do not expose to lint, dust, or other particulate matter. The contamination of such material within component openings or on electrode surfaces can negatively impact device performance.
- The presence of children, pets, and vermin does not normally affect the proper functioning of the Prodigy Sleep System. However, it is advised to keep Prodigy Sleep System away from

children, pets and vermin and to make sure that these sources do not contaminate any components.

- Do not use components that appear to be physically damaged, degraded, or contaminated.
- Read and follow all instructions listed in this manual.

WARNING

No modifications of this equipment are allowed, as this could potentially result in an unsafe situation.

WARNING

Connecting this equipment to other equipment not described in this manual is potentially unsafe and is therefore not allowed.

FCC Regulator Statements

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.

NOTE: THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

RF Exposure Information

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, human proximity to the antenna shall not be less than 5 mm during normal operation and must not be collocated or operating in conjunction with any other antenna or transmitter.

IC Regulator Statements

This device complies with Industry Canada license-exempt RSS standard(s). 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 of the device.

This Class B digital apparatus complies with Canadian ICES-003.

RF Exposure Statement:

This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This transmitter must be installed to provide a separation distance of at least 5 mm from

all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

INTENDED OPERATOR

The intended operator of this device includes both technicians and users.

2. System Overview

The Prodigy Sleep System is composed of three primary physical components: the Head Mounted Unit (HMU), Chest Mounted Unit (CMU) and the Table Top Unit (TTU). These components work in tandem to allow recording data necessary for a sleep study. Each component has a primary purpose in the system:

- The HMU collects electrical signals from the user via electrodes located on the head, and wirelessly transmits that data to the TTU.
- The CMU collects respiratory signals from the user via a collection of sensors (respiratory bands, nasal cannula, and electrodes) located on the user, and wirelessly transmits that data to the TTU.
- The TTU collects miscellaneous data that does not need a physical sensor located on the user to collect (ex: ambient light, ambient audio). The TTU acts as a wireless base station for the HMU, CMU, and the oximeter; storing all collected data internally, and providing the majority of the interaction a user will have with the system.

⚠ CAUTION
Ensure that all electrodes are connected to the correct input as per the instructions for use. Electrodes connected to the wrong inputs will result in loss of functionality.

⚠ CAUTION
Wipe electrode snaps and connectors (both male and female ends) with a dry cloth if lint or dust is present. Using electrodes with a dirty surface can degrade the performance of the device.

⚠ CAUTION
Use only approved electrodes that have been provided with the device. Use of non-approved electrodes may result in loss of equipment functionality or personal injury.

PRODIGY SLEEP SYSTEM HMU

The HMU is a small body worn device that is attached to the forehead via EEG electrodes during use. It has connectors to connect the EEG electrodes.

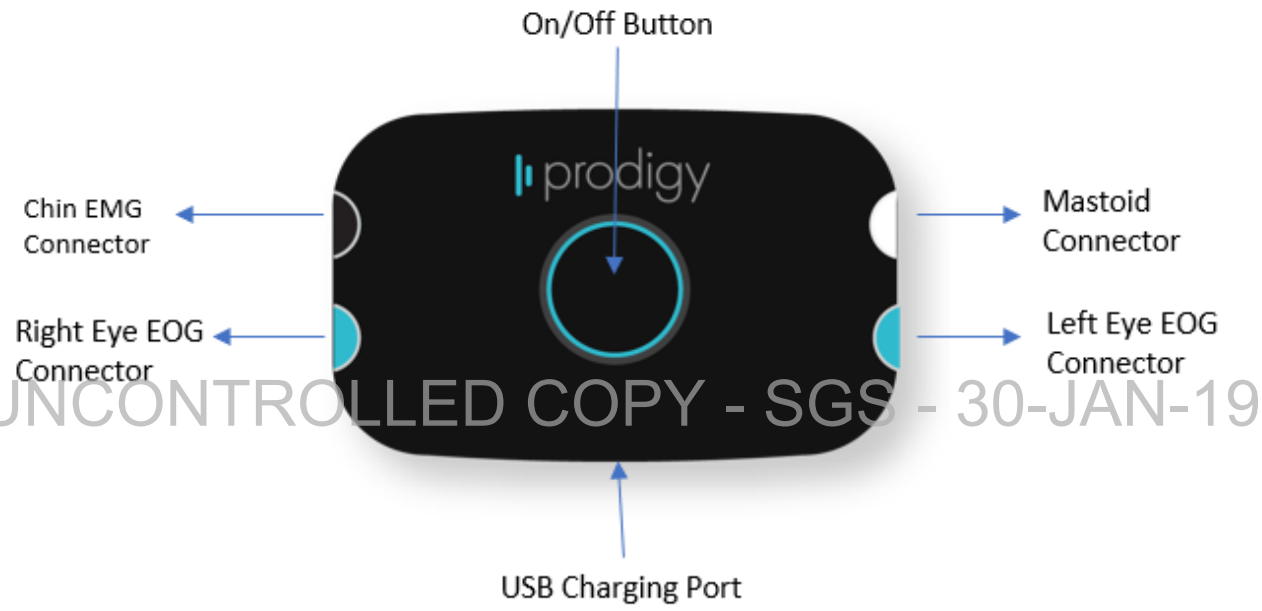


Figure 1 – Prodigy Sleep System HMU Front View

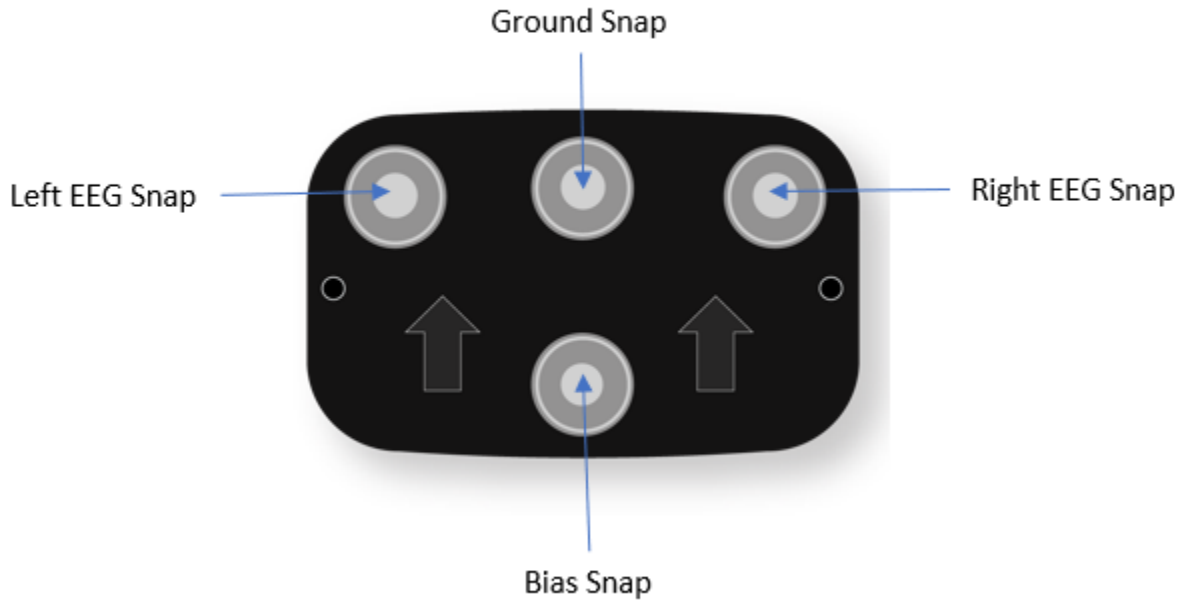


Figure 2 – Prodigy Sleep System HMU Rear View

The HMU is powered by a rechargeable lithium polymer battery and the device is rated to operate continuously for at least 9 hours. To ensure adequate battery life, the batteries must be recharged after each sleep study is conducted.

Refer to the Technical Description in Section 7 for additional information about the Prodigy Sleep System HMU.

PRODIGY SLEEP SYSTEM CMU

The CMU is a small body worn device that is attached to the chest via thoracic belt during use. It has connectors to connect the thoracic belt, abdominal belt and ECG/EMG electrodes.

Figure 3 – Prodigy Sleep System CMU Front View

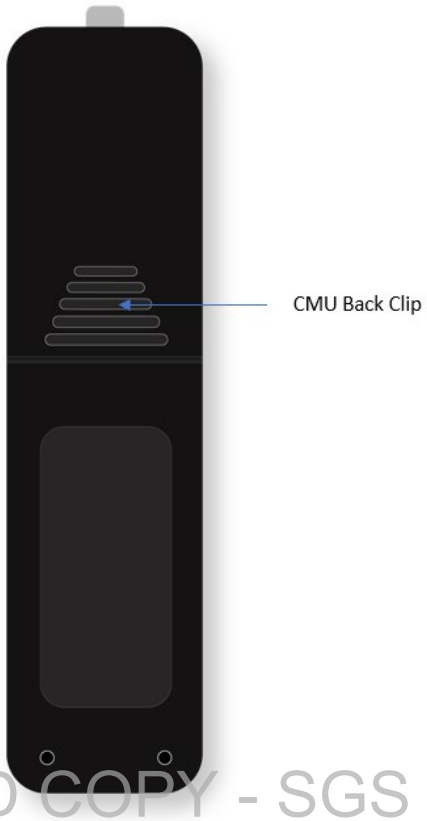


Figure 4 - Prodigy Sleep System CMU Rear View

The CMU is powered by a rechargeable lithium polymer battery and the device is rated to operate continuously for at least 9 hours. To ensure adequate battery life, the batteries must be recharged after each sleep study is conducted.

Refer to the Technical Description in Section 7 for additional information about the Prodigy Sleep System CMU.

PRODIGY SLEEP SYSTEM TTU

The Prodigy Sleep System TTU is a portable device that is equipped with a touch screen that is used for operation of the device. The TTU is powered by a 3000mAh non removable battery. To recharge the battery, the Charger/USB cable port is located at the bottom of the device. Insert the supplied charger and plug it into a power outlet.

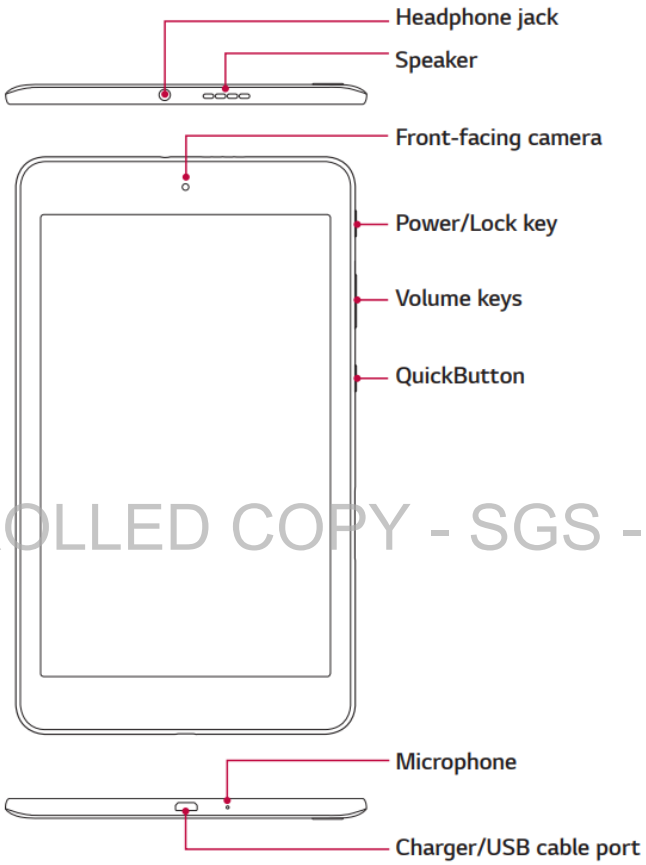


Figure 5 – Prodigy Sleep System TTU Front View

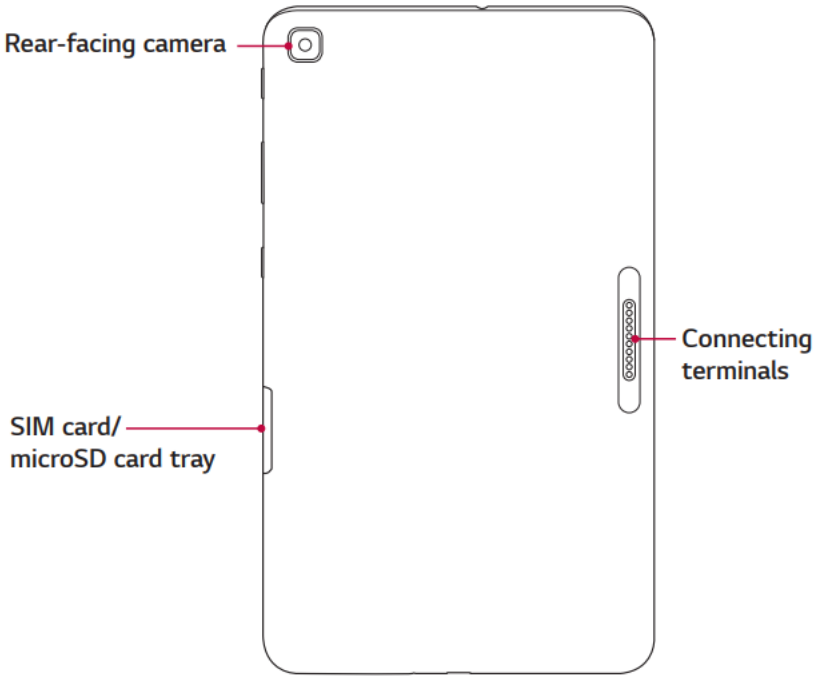


Figure 6 – Prodigy Sleep System TTU Rear View

Refer to the Technical Description in Section 7 for additional information about the Prodigy Sleep System TTU.

WARNING

Connect only items that have been specified in this manual as compatible.

POWER SUPPLY CMU & HMU

WARNING

Use only the provided power supply. Use of unapproved or incompatible power supplies may result in equipment damage, electrical shock, or overheating which may result in personal injury or property damage.

WARNING

Keep away from children. Electrical shock can result if the power supply is put inside a person's mouth.Refer to the Technical Description in Section 7 for additional information about the power supply

POWER SUPPLY TTU

WARNING

Use only the provided power supply. Use of unapproved or incompatible power supplies may result in equipment damage, electrical shock, or overheating which may result in personal injury or property damage.

WARNING

Keep away from children. Electrical shock can result if the power supply is put inside a person's mouth.

Figure 7 – Prodigy Sleep System TTU Power Supply

CAUTION

Do not position the power supply such that it is difficult to disconnect (e.g. behind a dresser or large/heavy object).

CAUTION

To prevent the Prodigy Sleep System from being damaged, ensure that the device is being used and stored in an environment where the humidity and temperature can be controlled. Damage can be caused to the equipment if it is operated or transported outside the environmental conditions specified in section 7 of this Operator Manual.

Refer to the Technical Description in Section 7 for additional information about the power supply.

The Prodigy Sleep System is supplied with the following accessories:

CMU Accessories


Effort Belts (2x)


Dual Connector Effort Belt Cables (2x)


Nasal Cannula (1x)


Dual Snap Lead Cables for Legs (2x)


Dual Snap Sensor Pads for Legs (2x)


Single Snap Lead Cables for Chest (5x)


Single Snap Sensor Pads for Chest (5x)


USB Wall Adapter with USB-C Cable

HMU Accessories


Dual Snap Sensor Pad (1x)


Single Snap Sensor Pads (2x)


Wired Sensor Pads (4x)


USB Wall Adapter with USB-C Cable

TTU Accessories

Use Environment

All components described in this manual are suitable for use in the user environment, including hospital, clinical, or home use environments.

Duty Cycle

The Prodigy Sleep System is rated for continuous operation.

3. Instructions for Use

USER TRAINING

This Operator Manual provides a comprehensive description of the full capabilities of the Prodigy Sleep System. The Operator Manual comprises the primary training material for use of the Prodigy Sleep System. It is strongly recommended that users read this Operator Manual at least once prior to using the device, and that users refer to the Operator Manual as often as needed in conjunction with use of the device. If additional assistance is required in setting up, using, or maintaining the Prodigy Sleep System equipment, please contact the manufacturer who may provide training on-site, by telephone and/or via video.

PREPARATION

Before handling the equipment, ensure your hands are clean by washing with soap and water.

Carefully un-package the components from the case including the Head Mounted Unit (HMU), Chest Mounted Unit (CMU) and the Table Top Unit (TTU). Check to ensure that the following have been included in the case:

- Prodigy Sleep System HMU (qty. 1)
    - Dual Snap Sensor Pad (qty.1)
    - Single Snap Sensor Pads (qty. 2)
    - Wired Sensor Pads (qty. 4)
    - USB Wall Adapter with USB-C Cable
- Prodigy Sleep System CMU (qty.1)
    - Effort Belts (qty. 2)
    - Dual Connector Effort Belt Cables (qty. 2)
    - Nasal Cannula (qty. 1)
    - Dual Snap Lead Cables for Legs (qty. 2)
    - Dual Snap Sensor Pads for Legs (qty. 2)
    - Single Snap Lead Cables for Chest (qty. 5)
    - Single Snap Sensor Pads for Chest (qty. 5)
    - USB Wall Adaptor with USB-C Cable (qty. 1)
- Prodigy Sleep System TTU (qty. 1)
    - USB Wall Adapter with micro USB Cable
- Pulse Oximeter with Finger Sensor (qty. 1)
- Alcohol Swabs (qty. 5)
- Medical Tape

If any of the listed components are missing, please call your service provider before proceeding.

WARNING

Use of accessories not described in this manual is potentially unsafe and is therefore not recommended. Use of unapproved accessories may result in increased emissions or decreased immunity of this equipment.

WARNING

Keep out of reach from children. Small parts such as the electrodes, plastic bags, and small components may be a choking or suffocation hazard.

CAUTION

Keep out of reach from children and animals. Parts such as the Prodigy Sleep System HMU, CMU and TTU can become damaged if dropped or pushed off of a surface.

WARNING

Use only the provided electrodes. Use of unapproved or incompatible electrodes may result in equipment damage, electrical shock, or overheating which may result in personal injury or property damage.

WARNING

Keep the conductive parts of electrodes and the associated connectors on the CMU and HMU away from other conductive parts including earth.

Figure 8 – Example Electrodes

Place the Prodigy Sleep System TTU on a table close to your bed in your bedroom where you plan to perform the sleep study. Ideally, this should be located within 3 meters of where you will be sleeping for optimal wireless signal strength and audio recording.

⚠ CAUTION

Ensure the table surface area is level, clean and dry. Avoid placing objects that contain liquids such as glasses of water near the Prodigy Sleep System TTU to prevent possible spillage and equipment damage or electric shock.

⚠ CAUTION

Keep away from heat sources such as electric heaters, radiators, fireplaces, or other sources of heat. Excessive heat may cause overheating and loss of functionality.

Plug the TTU power supply into the wall outlet using the correct adapter, and then into the bottom of the TTU.

The TTU is equipped with a light sensor to detect when the room is dark during the sleep study. Keep the TTU away from light sources during the study (e.g. sunlight, lamps, etc.). The TTU is also equipped with a sound level sensor that can detect audible snoring sounds. Keep the TTU away from sources of noise (e.g. fans, speakers, etc.) and sources of blocking the TTU audio recording (i.e. paper, books, etc.)

CHARGING THE DEVICES

Charging the CMU

1. To charge the CMU, connect the USB-C adaptor to the charging port on the CMU and plug the wall adapter into a power outlet.
2. Once the device is connected to the charger and plugged in, the LED light around the power button will immediately turn white, and remain white for several seconds and will output the charging status.
    a. Purple indicates charging
    b. Green indicates charged
    c. Yellow or Red – refer to troubleshooting section
3. Charging should take no more than 3 hours.

⚠ CAUTION

Do not leave the CMU charging for extended periods of time.

⚠ WARNING

Do not use the CMU while it is charging.

Charging the HMU

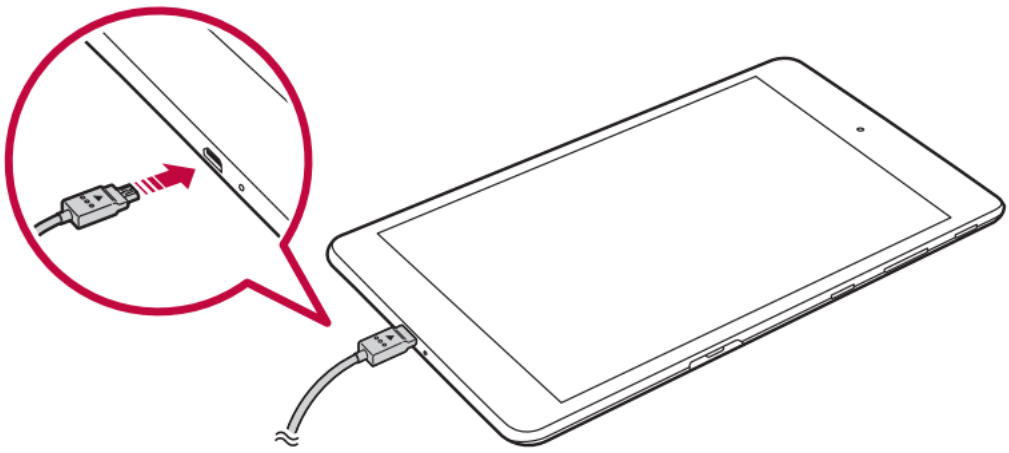
1. To charge the HMU, connect the USB-C adaptor to the charging port on the HMU and plug the wall adapter into a power outlet.
2. Once the device is connected to the charger and plugged in, the LED light around the power button will immediately turn white, and remain white for several seconds and will output the charging status.
    a. Purple indicates charging
    b. Green indicates charged
    c. Yellow or Red – refer to troubleshooting section
3. Charging should take no more than 3 hours.

CAUTION
Do not leave the HMU charging for extended periods of time.

WARNING
Do not use the HMU while it is charging.

Charging the TTU

The Charger/USB cable port is located at the bottom of the device. Insert the charger and plug it into a power outlet.



Charge the battery before using it for the first time. Use the charger included with your device to charge the battery. The TTU should be plugged in during the sleep study.

WARNING

Use only YMT approved chargers and cables. The use of unapproved chargers or cables may cause a battery charging delay or display a pop-up message regarding slow charging. It can also cause the battery to explode or damage the device.

CAUTION

The TTU has an internal rechargeable battery. For your safety, do not remove the embedded battery.

OVERVIEW OF PRODIGY SLEEP SYSTEM APP

The Prodigy Sleep System App provides a simple and user friendly interface, guiding the user through setting up peripherals, and performing the sleep study. The app will provide constant updates on peripheral status through the study.

The Prodigy Sleep System App has two different modes:

1. Technician Mode
2. User Mode

TECHNICIAN MODE

The TTU will come pre-programmed with the Prodigy Sleep System App. When you power on the TTU the app will launch automatically. The Technician mode is used to:

1. Manually configure sleep study
2. Configure sleep study via remote server
3. Manually download sleep study
4. Manually delete sleep study

Manually Configure Sleep Study

A technician must configure the TTU for the end user prior to distributing the Prodigy 2 System. In order to manually configure a sleep study the technician will follow the steps below.

1. Power on TTU, Prodigy Sleep System App will launch automatically
2. Press 'Manually Configure Study'
3. Fill in the following fields
    a. User First Name
    b. Study ID
    c. Sleep Study Type
        i. PSG Full

ii. Level 2
iii. HMU Only

d. HMU MAC Address
e. CMU MAC Address (if applicable)
f. Oximeter MAC Address (if applicable)

4. Press 'Save Study Configuration'
5. Press 'Enter User Mode'
6. Power off TTU

Configure Sleep Study via Remote Server

A technician can configure a sleep study via remote server. If the technician selects this method, follow the steps below:

1. Power on TTU, Prodigy Sleep System App will launch automatically
2. Press 'Run TTU Diagnostics'
    a. Should get message that states 'This tablet is suitable for use'
    b. If you get a message that states 'This tablet is not suitable for use' refer to Section 6 – Troubleshooting to resolve the issue
3. Press 'Configure Server URL' and enter the URL of the Remote Server
    a. This step only needs to be completed the first time a sleep study is configured via the remote server

4. Press 'Fetch Configuration'
5. Press 'Enter User Mode'
6. Power off TTU

Upload Sleep Study to Remote Server

Uploading a sleep study to a remote server is only available if the study was configured via remote server. If a user is unable to upload the study to the remote server or if the upload isn't fully complete, the technician should:

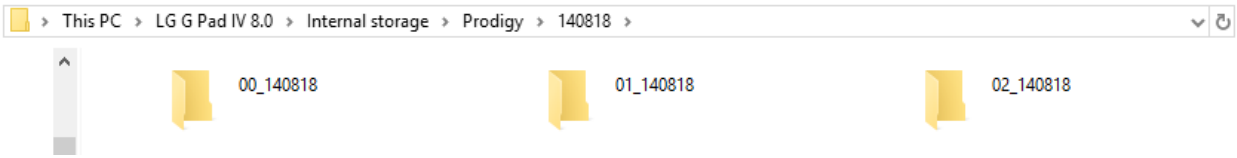
1. Power cycle the TTU if the tablet is returned powered on
2. In technician mode, press 'Process Upload Queue'
3. Study will upload to remote server and the sleep study data will automatically be removed from the TTU
    a. If the TTU is unable to upload the study refer to Section 6 – Troubleshooting to resolve the issue

Manually Download Sleep Study

To manually download a sleep study the technician should:

1. Power on TTU, Prodigy Sleep System App will launch automatically

2. Press ‘Leave Kiosk Mode’
3. Press ‘Proceed’ when prompted to Enable USB Access
4. Plug in USB and connect to computer
5. Swipe down from top of screen
    a. Select Charging – Tap to change USB options
    b. Select ‘File Transfer’, ‘Just Once’
6. Navigate to LG G PAD IV 8.0/Internal Storage/Prodigy/Folder labelled with Study ID



7. Copy sleep study data folder to your computer
    a. Multiple folders indicate multiple sleep studies for that user

Manually Delete Sleep Study

To manually delete a sleep study the technician should:

1. Power on TTU, Prodigy Sleep System App will launch automatically
2. Press ‘Delete Sleep Studies’ and enter password

SLEEP STUDY CONFIGURATIONS

The Prodigy Sleep System can be configured for different types of studies. Different configurations are required for different applications, and this section will present what each configuration looks like.

The device is to be configured by the service provider prior to sending it home with a user. As such, the user is not required to perform any device configuration. The service provider also ensures that the inactive electrodes are "turned off" in the software and the packaging indicates which electrode configuration will be used for the sleep study.

Full PSG Configuration Overview

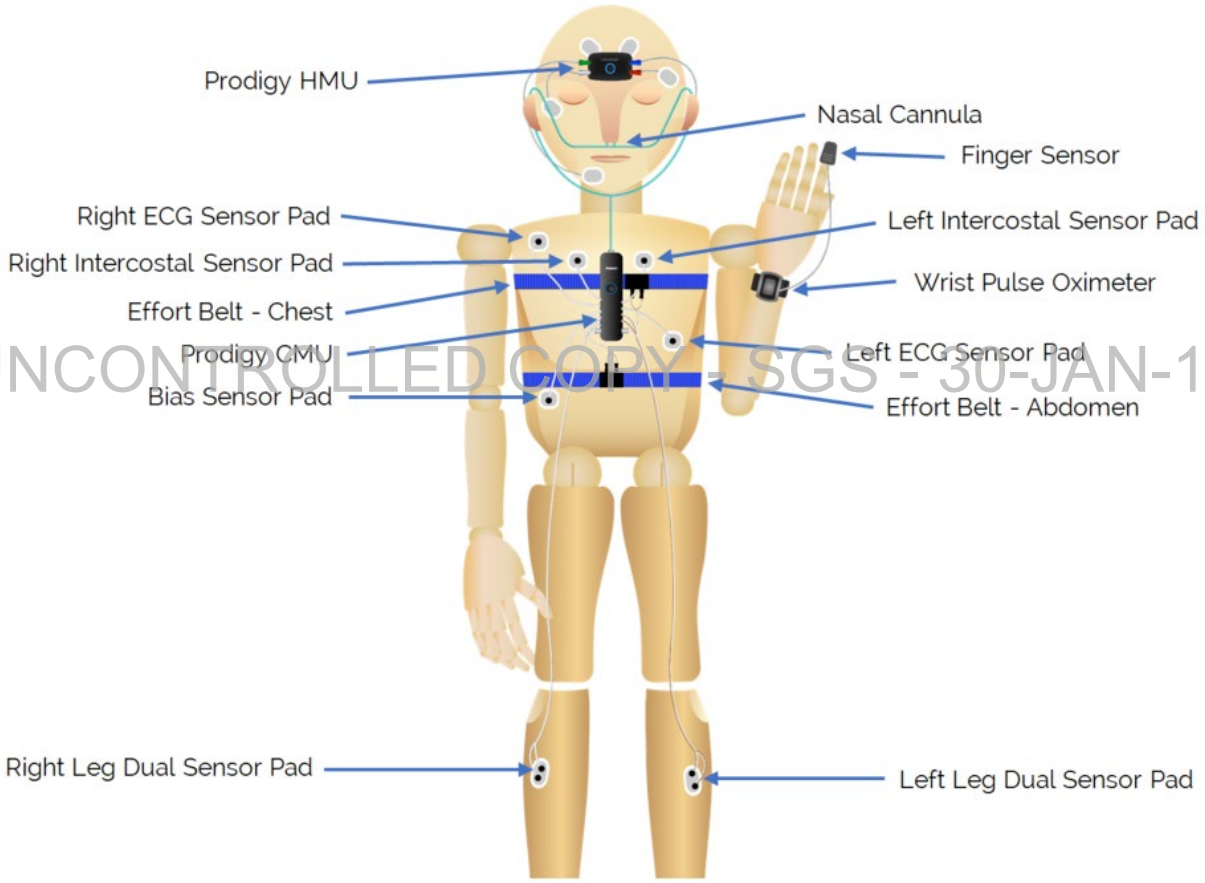


Figure 9 - Full PSG Configuration

Level II

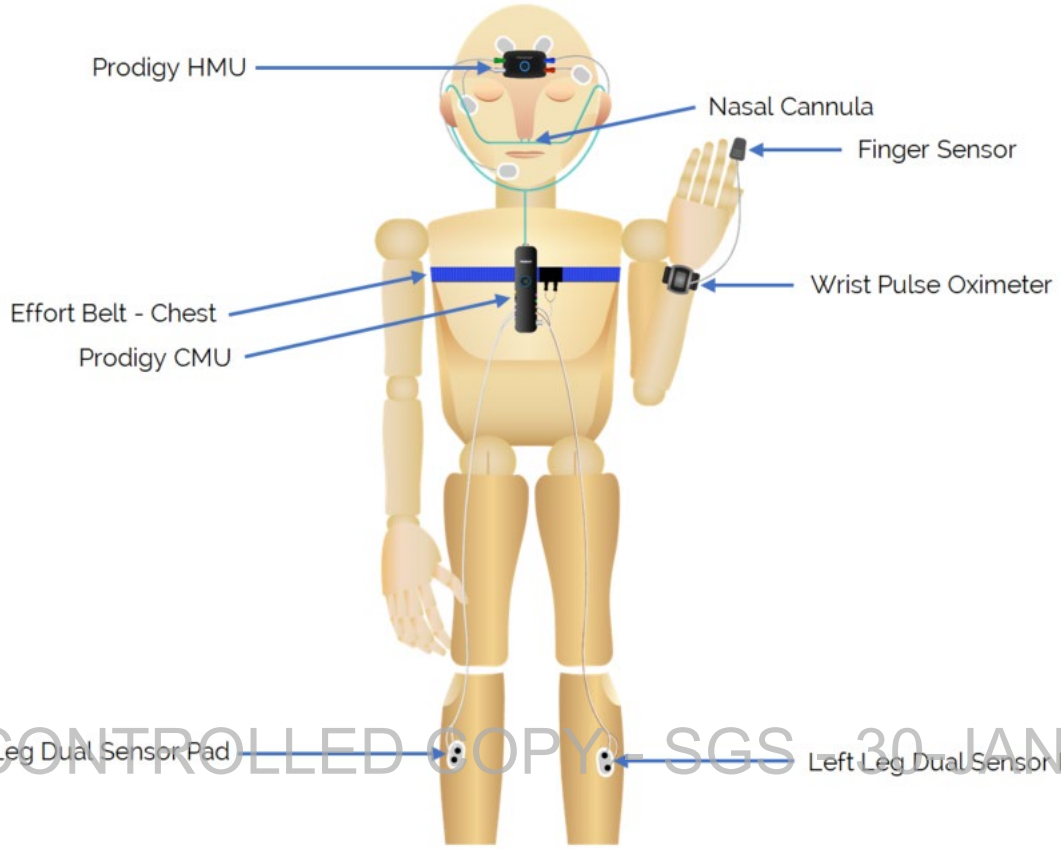


Figure 10 -Level II PSG Configuration

HMU Only

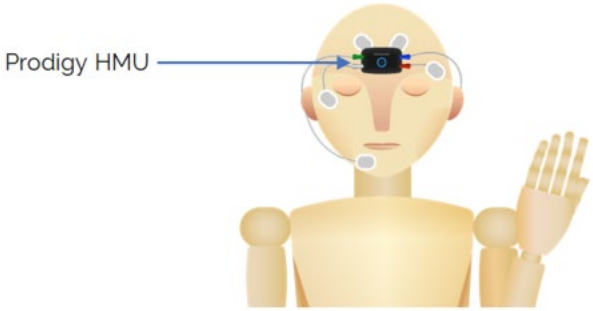


Figure 11 - HMU Only PSG Configuration

FREQUENTLY USED FUNCTIONS

- Plugging or removing the power supply from the wall outlet, as well as the back of the TTU.
- Plugging or removing the power supply from the wall outlet, as well as the bottom of the CMU.
- Plugging or removing the power supply from the wall outlet, as well as the back of the HMU.
- Turning the TTU on or off by pressing the power switch button.
- Touching the TTU screen to set up the study, start the study, and end the study.
- Snapping or plugging in the EEG and EMG electrodes into or out of the CMU.
- Plugging in the EKG and EMG electrodes into or out of the HMU
- Applying or removing EEG, EKG and EMG electrodes from your face, body and legs.
- Turning the CMU on or off by pressing the power button.
- Turning the HMU on or off by pressing the power button.

WARNING

Do not perform service or maintenance on this device while in use.

CAUTION

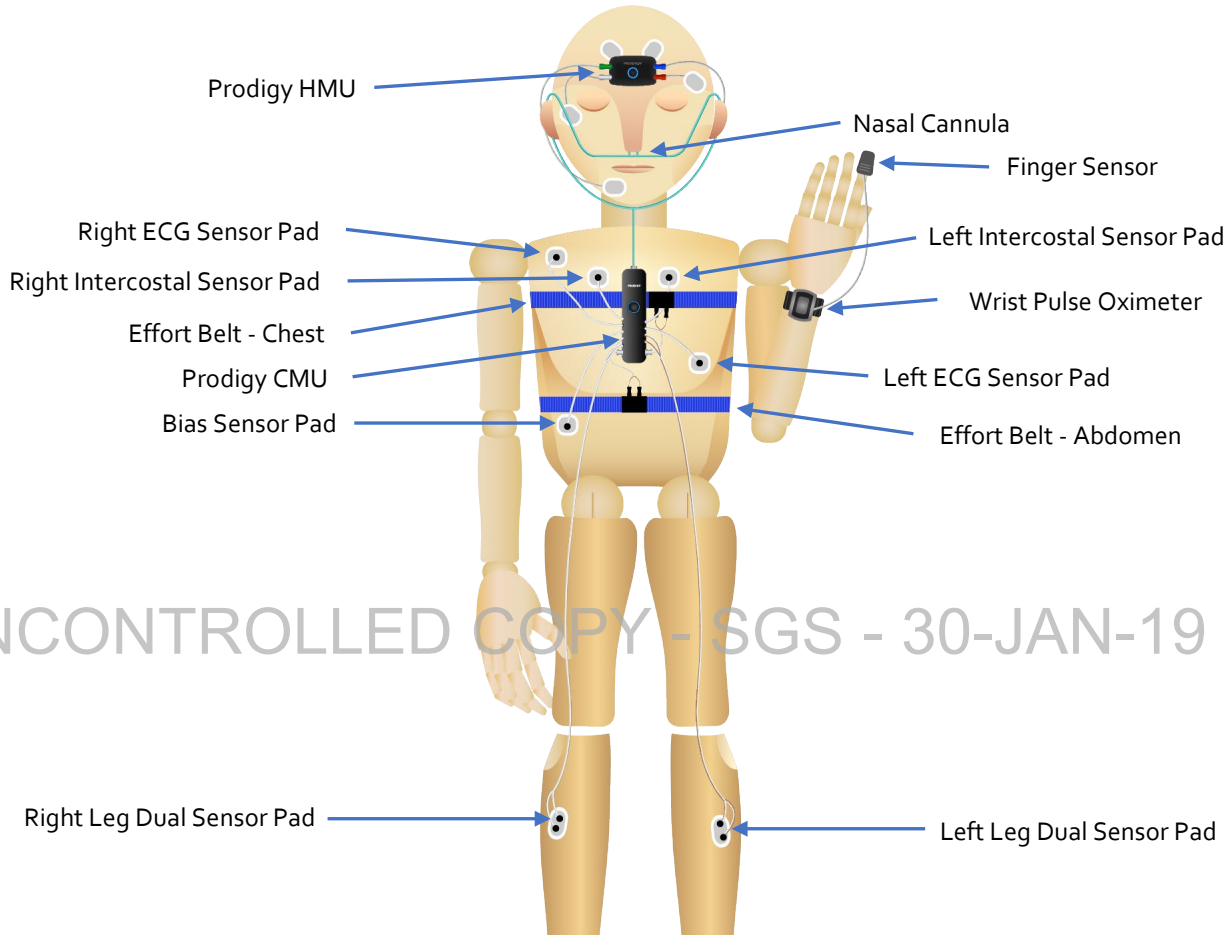
When turning on the devices by pressing the power button, if the LED does not turn BLUE, please consult the troubleshooting section.

CAUTION

Remove the HMU & CMU before defribulation, as the discharge of a defribulator on a user may damage the device.

4. User Setup

FULL PSG CONFIGURATION OVERVIEW



Preparing for your study:

- ☐ **Review these instructions in full prior to applying the equipment.**
- ☐ Allow the Prodigy HMU and CMU to charge for at least 60 minutes. A black USB wall adapter and black USB-C cable is provided for each unit.
- ☐ A sensor pad is applied to the chin, so this area **must be clean-shaven**. If you have facial hair on your chin and do not want to shave, you will have the option to use an alternative placement for the sensor.
- ☐ Thoroughly wash your face and behind your ears so your skin is free of hair, lotions and natural oils.
- ☐ Please shave any areas that contain thick hair where the chest and leg sensor pads will be placed in advance of applying the equipment.

- Setup the Prodigy Sleep System in front of a mirror.
- It is recommended that you wear a thin t-shirt or pajama top along with loose pants/shorts.
- It should take approximately 30 minutes to apply the equipment.

Important setup information:

- Application of the equipment will be in the following order:
  1. Prodigy CMU 2. Prodigy HMU 3. Nasal Cannula 4. Pulse Oximeter
- Use of the TTU will begin after you have applied the equipment.
- Do not remove the paper/plastic backings ofthe sensor pads until the cable leads are connected and you are ready to apply each sensor pad to the skin.
- Prior to applying each sensor pad to your skin, use the provided alcohol swabs to wipe clean the area. Allow 30 seconds for the area to dry before applying the sensor.

SECTION 1: PRODIGY CMU SETUP

Components needed:


Prodigy CMU


Effort Belts (2x)


Dual Connector Effort Belt Cables (2x)


Dual Snap Lead Cables for Legs (2x)


Dual Snap Sensor Pads for Legs (2x)


Single Snap Lead Cables for Chest (5x)


Single Snap Sensor Pads for Chest (5x)


Alcohol Swabs & Medical Tape

Step 1: Apply the leg sensors.

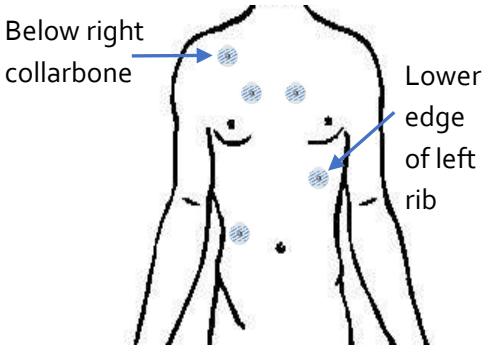
→ There is one dual snap sensor pad for each leg.

→ Connect a dual snap lead cable to each dual snap sensor pad. Colours can be connected in any order.

→ Remove clear plastic backing and apply sensor pad to the cleaned area on each leg, ensuring it is not applied to the shin bone.

→ Run unconnected end of each cable underneath your pant/short legs.

Step 2: Apply the chest sensors.



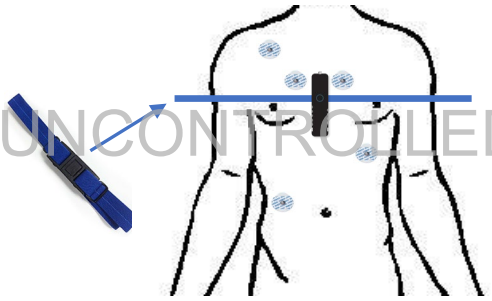
→ **Recommend your shirt be removed for this step.**

→Connect a single snap lead cable to each of the five single snap sensor pads while ignoring the colour of each cable.

→ Remove white paper backing and apply sensor pads to the cleaned areas as shown in the diagram to the left *(we recommend your shirt be removed for this step)*.

→ After putting your shirt on, feed the top 4 cables through the neck of your shirt and the remaining cable through the bottom.

Step 3: Setup the chest effort belt.

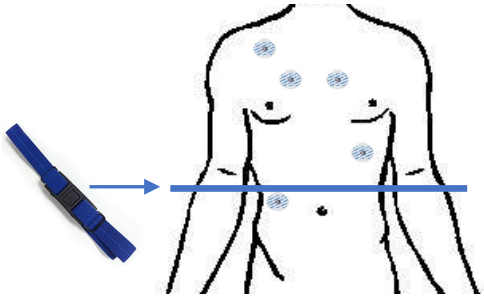


→ Place the effort belt with the Prodigy CMU already attached around your upper chest and <u>*over your shirt.*</u>

→ Adjust the length for a snug fit, positioning the belt just under your armpits. The belt should hug your chest and move with your breathing *(first apply too tight since it is easier to loosen than tighten once buckled)*.

→ Insert the two black connectors from the effort belt cable into the two holes on the belt.

Step 4: Setup the abdomen effort belt.



→ Place the effort belt without the Prodigy CMU already attached around your abdomen and <u>*over your shirt.*</u>

→ Adjust the length for a snug fit, positioning the belt just above your naval (belly button). The belt should comfortably hug your abdomen and move with your breathing.

→ Insert the two black connectors from the effort belt cable into the two holes on the belt as previously shown.

Step 5: Connect the cables to the Prodigy CMU.

→ With your shirt on, connect the chest, legs, and effort belt cables to the CMU as shown below.

→ Push the connectors firmly into the CMU to ensure the connection is secure.
Each leg has two connectors to attach to the CMU, It does not matter which connector goes in the bottom connector and which connector goes above the bottom connector. Left leg connectors go in the left side of the CMU, right leg connectors go on the right side (see diagram below).

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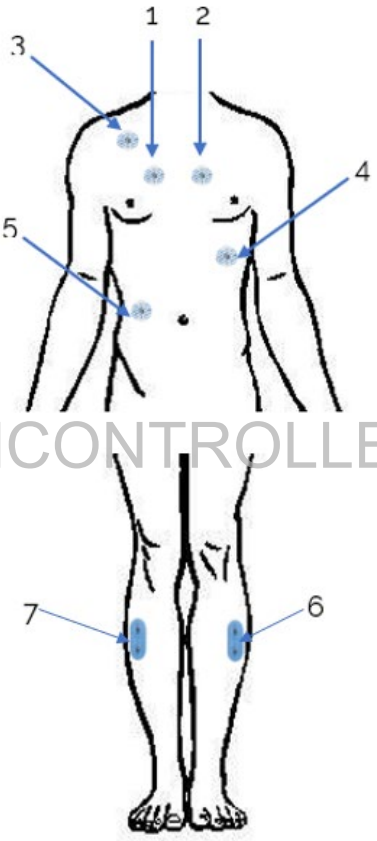
→ Coil excess slack from the leg cable leads and secure with the provided medical tape.



SECTION 2: PRODIGY HMU SETUP

Components needed:


Prodigy HMU


Dual Snap Sensor Pad (1x)


Single Snap Sensor Pads (2x)


Wired Sensor Pads (4x)


Alcohol Swabs & Medical Tape

Step 1: Connect the snap sensor pads to the Prodigy HMU.

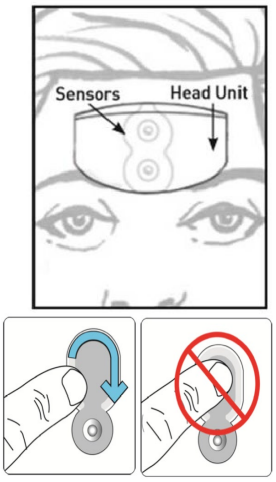
→ Without removing the clear plastic backings, connect the dual snap sensor pad and two single snap sensor pads to the HMU.

Step 2: Connect the wired sensor pads to the Prodigy HMU.

→ Match and insert coloured connectors of the wired sensor pads to HMU. (be sure to connect the wire connectors into the colour matched input on the HMU)

→ Push the connectors firmly into the HMU.

Step 3: Adhere the Prodigy HMU to your forehead.



→ Remove the plastic backing off of the dual and single snap sensor pads without touching the sensor gel.

→ Before applying to your skin, center the HMU on your forehead with the bottom of the device aligned with your eyebrows as shown below.

→ Adjust the left and right single snap sensor pads to avoid your hairline.

→ Press the HMU firmly against your forehead and hold for five seconds.

→ Secure the left and right single snap sensor pads to your forehead by rubbing the outer edges with your finger as shown below.

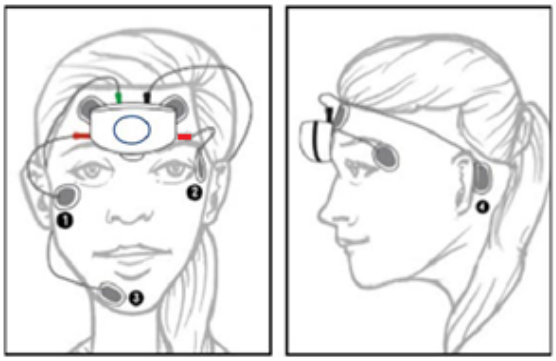
Step 4: Apply the wired sensor pads.

→ Remove clear plastic backing of the wired sensor pad without touching the sensor gel.

→ Secure each sensor pad to the areas as shown below by rubbing the outer edge

→ Replace any sensors which fail to adhere and use medical tape to secure any loose wires.

→ If you have facial hair, alternative placement for sensor pad 3 is the soft tissue below the bony area behind the right ear.



1. Outside and slightly below midline of right eye.
2. Outside and slightly above midline of left eye.
3. Right side of chin (wrap wire behind right ear).
4. Bony area behind the midline of left ear.

SECTION 3: NASAL CANNULA SETUP

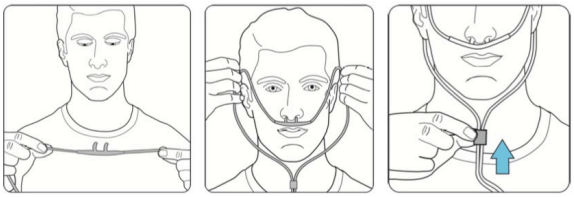
Components needed:

Prodigy CMU

Nasal Cannula (1x)

Medical Tape

Step 1: Connect the nasal cannula.



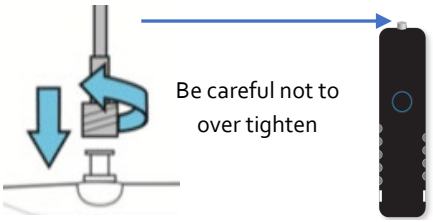
→ Place the nasal cannula in nostrils, drape over ears, & remove some slack as shown below.

Adjust slider just a little to remove some slack

→ Apply two pieces of medical tape as shown below.

The slider should feel secure, but not uncomfortable. The tape will keep the cannula in the correct position all night. It is important the nasal cannula does not fall out during the night to ensure a successful study.

→ Screw the free end of the cannula onto the white fitting of the Prodigy CMU until snug as shown below.



SECTION 4: PULSE OXIMETER SETUP

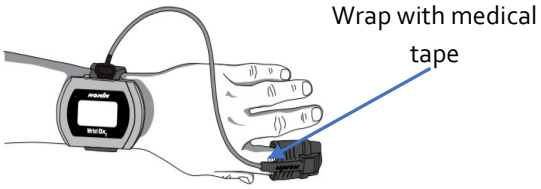
Components needed:


Wrist Pulse Oximeter


Finger Sensor


Medical Tape

Step 1: Setup the pulse oximeter.



→ Slip on the wrist pulse oximeter so you can read the label and tighten the strap.

→ Place your index finger into the finger sensor with the cable facing up.

→ Wrap a piece of medical tape around the stem of the finger sensor as shown below.

Be sure not to apply the tap too tightly

SECTION 5: PRODIGY TTU SETUP

Components needed:


TTU


USB Wall Adapter
with micro USB
Cable

Step 1: Setup the TTU.

→ Plug the micro USB cord into the USB power adapter and connect to the TTU.

→ Plug the wall power adapter into an outlet making sure the TTU is within arm's reach from the edge of your bed.

→ Turn on the Prodigy HMU and CMU by pressing the center power button and holding for five seconds *(the blue light indicates the unit is on)*.

→ Tap the TTU's screen until it wakes from the black screen, then follow the prompts to start your study.

→ The TTU will automatically check your sensors and identify if there are any problems with the connections.

→ Press "Start Study". **You are now already to sleep!**

During the night

Sleep in any position that is comfortable to you. It is fine to lie on the wires, but avoid applying too much pressure on the Prodigy HMU and CMU.

The study will not be interrupted if you get out of bed during the night. If you need to get up during the night, the equipment needs to be left on. When you return to your bed the devices will automatically continue to record. Do not turn off the devices unless you want to end the study.

Ending the study

When you are ready to stop the study, tap the TTU screen unit it wakes from the black screen and follow the prompts.

After selecting "stop study" on the TTU, press and hold the On/Off Button on the Prodigy HMU and CMU for five seconds to turn off the devices.

Returning the equipment

The following items need to be returned:


Prodigy HMU


Prodigy CMU


TTU


Wrist Pulse Oximeter


Finger Sensor


Effort Belts (2x)


Dual Connector Effort Belt Cables (2x)


Single Snap Lead Cables for Chest (5x)


Dual Snap Lead Cables for Legs (2x)


USB Wall Adapter with micro USB Cable


USB Wall Adapter with USB-C Cable (2x)

Any unused sensors, medical tape, and alcohol swabs

SPECIAL INSTRUCTIONS

Power Failure During Study

During some scenarios, the battery charge in the device may not be at an ideal level to remain functional throughout the entire study length. Ensure that the device is charged by using the provided power supply and power cable at least 1 hour prior to the commencement of the study.

In case of any power failure during study the device shall power off and no further data will be collected by the system. The TTU will be notified that the device has disconnected and will result in an invalid study. The user will be notifed by the distributor of the study regarding further instructions.

Resetting and Restarting the System

In cases where the HMU or CMU cannot communicate with the TTU the following may be performed,

- Ensure devices are powered on, light ring is illuminated on front face
- Ensure devices are charged, insert charging cable using provided power supply and power cable
- Power cycle all devices (TTU, CMU, HMU)
- Contact support line

Damaged Components

If any components are damaged during the sleep study (e.g. HMU & CMU is dropped and enclosure is cracked) and a replacement component is not provided, do not proceed with the sleep study. Return components to case and contact your service provider. Using damaged components for a sleep study, may result in electrical shock, fire hazards, and/or injury to the user of the device or others near the device.

WARNING

Do not use damaged components for sleep study, as electrical shock, fire hazards, and/or injury to the user or others near the device may result.

CAUTION

Do not press on the sensor area in the centre of the electrode, as this can cause the gel covering the backside of the electrode to leak. Gel leakage may cause data to be insufficiently collected.

⚠ CAUTION

Incorrect placement of the electrodes may result in loss of functionality or inaccurate data collected. Ensure electrodes are connected properly. Loose connections may cause incorrect or insufficient data to be collected.

Unexpected Events

If any unexpected operation of components is encountered or any unexpected events with the Prodigy Sleep System occur please contact the manufacturer to report and receive further instructions.

5. Re-Processing

The Prodigy Sleep System is a reusable medical device that is intended to be re-processed by cleaning and disinfection between every use. Re-processing is to be done by authorized service personnel only in a designated cleaning area.

WARNING

Unauthorized personnel shall not open the device in attempt to service or otherwise modify the components of the device, as this may damage components or result in electrical shock.

The components are supplied to users in a clean and disinfected condition, so there is no need for the user to clean the device. Re-processing should also be performed promptly after use to prevent microbial growth and organic contamination. For additional education on reusable devices see the clinical guidelines of the CDC.

Electrodes are designed for single use only and shall be discarded after use. Do not attempt to reprocess used electrodes.

Wrist Pulse Oximeter, Effort Belts, Effort Belt Cables and Snap Lead Cables are reusable medical devices that are intended to be re-processed by cleaning and disinfections between every use. Re-processing is to be done by authorized service personnel only in a designated clearing area. Do not reprocess the device if it is damaged or soiled with blood.

WARNING

Do not re-process the device if it is damaged. If damaged, dispose of components in accordance to local regulations. Handling damaged components may result in electrical shock, fire hazards, and/or injury to the handler or others near the device.

CAUTION

Keep device in protective case when not in use. If the device comes in contact with blood, it shall be discarded immediately and not reprocessed to avoid blood born pathogens from spreading.

All cleaning personnel shall review safety instructions and Material Safety Data Sheets prior to performing any cleaning procedures.

⚠ CAUTION

Wear personal protective equipment while reprocessing the device. Failure to wear personal protective equipment may result in contamination of the service personnel from the soiled components.

PRE-CLEANING

Promptly after use the HMU, CMU, TTU, and power supply shall be pre-cleaned. Pre-cleaning prevents soil from drying on the devices, which makes them easier to clean.

Wear protective disposable gloves and a mask during the pre-cleaning procedure. Ensure that both the Prodigy Sleep System HMU, CMU and TTU are powered off. Furthermore, disconnect the power supplies from the TTU before pre-cleaning.

Moisten a soft cloth with warm water and mild detergent and thoroughly wipe the HMU, CMU, and power supply outside surfaces. Also wipe down the packaging case surfaces, handle, and any other accessible surfaces that may have been soiled. Thoroughly wipe the components with a soft cloth moistened with clean fresh water to remove all traces of cleaning solution. Once all traces of cleaning solution are removed, dry the components with a dry cloth.

⚠ CAUTION

Do not apply liquids to the device or submerge the device in water or other liquids. Device is not rated for submersion in liquids and may lead to fluid ingress, equipment damage or electric shock.

CLEANING

Cleaning is a process that involves the physical removal of foreign material, e.g. dust, soil, organic material such as excretions. Cleaning physically removes this material with water, detergents, and mechanical action. Cleaning is essential prior to disinfection.

Third-party medical devices should be cleaned per the manufacturer's instructions.

WARNING

Cleaning must be performed prior to disinfection. If a device is not cleaned soil can prevent the proper action of disinfection from occurring, as soil can protect microorganisms. Consequently, a soiled device can become a source for transmission of microorganisms.

Wear protective disposable gloves and a mask during the cleaning procedure. Moisten a soft cloth with warm water and mild detergent and thoroughly wipe the HMU, CMU, and power supply outside surfaces. Also wipe down the packaging case surfaces, handle, and any other accessible surfaces that may have been soiled. Thoroughly wipe the components with a soft cloth moistened with clean fresh water to remove all traces of cleaning solution. Avoid getting fluid into the openings of the Prodigy TTU (e.g. power input, USB connector) and the additional openings on the HMU & CMU (e.g. EEG electrode connectors and snap EEG electrode connectors) during cleaning. Fluid ingress can be avoided by not wringing out the cloth on the device, and using a moist cloth rather than a wet one. Additionally, wipe the outside of the components only.

Once all traces of cleaning solution are removed, dry the components with a dry cloth and let stand for 6 hours or until all moisture is gone.

CAUTION

Let the components air dry. Do not dry the components with heat or by any other means which may result in equipment damage.

DISINFECTING

Disinfection is a process that involves killing pathogens and other microorganisms via physical or chemical means. Germicidal cloths can be used for low level disinfection; these cloths contain isopropyl alcohol or hydrogen peroxide. Germicidal cloths must meet CDC and OSHA guidelines, are bactericidal, tuberculocidal, virucidal, and fungicidal. Examples include Accel TB Wipes (www.virox.com) with product number ACCWIP1-TB and Sani-Cloth plus (www.pdipdi.com) with store keeping unit Q89072. For in-hospital studies, use cleaners/disinfectants approved for use by the hospital infection control service for non-critical reusable equipment and items for users in-hospital.

Wear protective disposable gloves and a mask during the disinfecting procedure. Wipe the HMU, CMU, TTU, and power supply outside surfaces and any surface on the packaging case that may have been soiled with germicidal cloths and allow to remain wet as per the instructions of the manufacturer of the germicidal cloth. After the time designated by the manufacturer has elapsed, wipe dry and let stand for 6 hours or until all moisture is gone.

WARNING

Germicidal cloths may cause eye irritation and may be harmful if absorbed through the skin. Avoid contact with eyes or clothing. Wash thouroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

INSPECTION

Once all components have been cleaned and disinfected, they should be visually inspected for any signs of remaining dirt or soil. If the components appear dirty, repeat cleaning as described above until clean.

Visually inspect for signs of damage, for example cracks or loose connectors in the plastic enclosures. Do not re-package or re-use components that are showing signs of damage. If components do show signs of damage, recycle plastic and electronic components in accordance with local regulations. Additionally, dispose of all other materials in accordance to local regulations.

Ensure all components are completely dry before bagging and re-packaging.

RE-PACKAGING

Power on the HMU, CMU and TTU to test the system and ensure it is functional before packaging.

NOTE

It is important to test whether the system is functional before packaging because sending a non-functional product to the user will lead to a delay in time before the next sleep study can be performed and the user could establish a dislike for the product.

Do not repackage components that are not fully functional or otherwise damaged. If components are not fully functional, please contact the manufacturer for instructions. Additionally, dispose of all other materials in accordance to local regulations. Repackaging can occur once components have been fully recharged per instructions in charging the device section.

Place the HMU, CMU and TTU each in a separate small plastic bag. Fold the open end of the bag over and apply a label marked "clean" to hold the bag closed. This label will be ripped by the user when they open the bag which will indicate that it has been used.

Place the components back into the reusable case.

CAUTION

Do not transport the device outside of the protective case, as this may result in damage to the equipment.

Count the total number of each type of electrode and re-stock the case with the necessary replacements. Remember to check the expiry date on the electrode packaging before re-stocking the case with new electrodes.

CAUTION

Do not supply electrodes that are expired. Degraded electrodes can result in degraded performance.

Ensure the total number of each required component is included as described in section 3.

A re-packaging checklist is provided in the appendix of this document. It is recommended that this checklist is filled out for each time the system is reprocessed to ensure the kit is complete.

To help identify which sets have been cleaned, it is recommended that clean sets be placed in controlled inventory for clean devices to distinguish them from used components. Another recommendation is to apply a temporary label "clean" to the outside of the case to identify it as a cleaned system ready for use by the next user.

Electrodes should be labeled with a "do not reuse" symbol as shown in Table 12 - Packaging Symbols

EXPECTED SERVICE LIFE

The HMU and CMU devices are powered by a rechargeable polymer lithium-ion battery with an 800mAh capacity. The battery will self-discharge over time, and if unused for an extended amount of time at low charge the battery could be irreparably damaged. Assuming battery is full charged prior to being placed in long term storage, and an average discharge rate of 4% per month, the minimum expected shelf life of the battery is 25 months.

The battery manufacturer recommends batteries to be charged to 50-70% prior to being placed in long term storage and undergo a full charge/discharge cycle every 3 months. Following the manufacturer recommendations will extend the shelf life of the battery.

The expected service life of all accessories is included in

Table 1.

Table 1 – Expected Service Life of Accessories

Accessory	Expected Service Life
Effort Belts with Dual Connector	2 years
Nasal Cannula	1 use
Dual Snap Lead Cables for Legs	2 year
Dual Snap Sensor Pads for Legs	1 use
Single Snap Lead Cables for Chest	2 year
Single Snap Sensor Pads for Chest	1 use
USB Wall Adapter with USB-C Cable	2 year
Dual Snap Sensor Pad	1 use
Single Snap Sensor Pads	1 use
Wired Sensor Pads	1 use
USB Wall Adapter with Micro USB Cable	2 year

6. Troubleshooting

- HMU or CMU do not turn on when button pressed
    - Connect device to charger and allow to charge
    - If device does not turn on once charged return to manufacturer for repair
- HMU or CMU do not turn on connected to charger
    - Return to manufacturer for repair
- HMU or CMU LED is yellow when charging
    - Wait up to three hours for problem to resolve. If problem persists return to manufacturer for repair
- HMU or CMU LED is red when charging
    - Return to manufacturer for repair
- HMU or CMU LED is red when power button is pressed
    - Return to manufacturer for repair
- TTU does not turn on when power button is pressed
    - Connect device to charger and allow to charge
    - If device does not turn on once charged return to manufacturer for repair

- TTU does not turn on or start charging when USB is inserted
    - Leave connected to charger for 5 minutes
    - Return to manufacturer for repair
- TTU software does not start when device powered on
    - Return to manufacturer for repair
- TTU software not installed
    - Return to manufacturer for repair
- HMU or CMU do not connect to the TTU
    - Power cycle device
    - If device still does not connect power cycle TTU and all peripherals
    - If device still does not connect ensure device is assigned to TTU
- HMU or CMU display Device Error on the TTU
    - Power cycle device
    - If device still does not connect power cycle TTU and all peripherals
- Oximeter does not connect to the TTU
    - Power cycle device

  - If device still does not connect power cycle TTU and all peripherals
  - If device still does not connect ensure device is assigned to TTU
- Oximeter displays Device Error on the TTU
  - Power cycle device
  - If device still does not connect power cycle TTU and all peripherals
- HMU signal(s) do not transition to 'Good'
  - Ensure all electrodes connected to HMU
  - Ensure all electrodes securely attached to skin
  - Remove and replace electrodes according to Section 4
- CMU EMG or EKG signal(s) do not transition to 'Good'
  - Ensure all electrodes connected to CMU
  - Ensure all electrodes securely attached to skin
  - Remove and replace electrodes according to Section 4
- CMU Belt signal(s) do not transition to 'Good'
  - Ensure belt(s) connected to CMU
  - Ensure belt is setup according to Section 4

- HMU signals good but still shows 'Needs Attention'
  - If wireless indicator is less than full move the TTU closer to the user
  - If battery indicator is less than 95% HMU will need to be charged prior to running study
- CMU signals good but still shows 'Needs Attention'
  - If wireless indicator is less than full move the TTU closer to the user
  - If battery indicator is less than 95% CMU will need to be charged prior to running study
- Oximeter signals good but still shows 'Needs Attention'
  - Replace batteries in Oximeter
- Peripherals good but 'Start Study' disabled
  - Ensure the TTU is connected to charger
- Signal goes bad during the night
  - If belt, cannula, or oximeter signal report as bad, adjust according to Section 4
  - If EEG/EOG/EMG/EKG signal report as bad, ensure the electrode is connected to device (touchproof, snap)
  - If signal continues to report as bad, allow study to continue with bad signal

        - *Rationale: System designed with redundancy, study may still be able to be scored with missing signals. If study is not able to be scored a repeat study will be required*

- Device dies during the night
    - TTU will determine if sufficient data was collected prior to device dying
    - If insufficient data was collected a repeat study will be required
- TTU dies during the night
    - Connect TTU to charger and power on, study will automatically resume
- TTU displays local validation failure
    - Insufficient data collected, a repeat study will be required
- TTU displays local validation pass but file fails to upload
    - Ensure TTU has internet connection and retry upload
    - If TTU cannot gain internet connection, the system can be returned to warehouse where study will be uploaded by technician
- TTU displays remote validation fail
    - A repeat study may be required
- TTU displays 'This tablet is not suitable for use' after running diagnostics
    - If the error is 'No SIM Card', ensure that the SIM card is present and properly inserted
        - Note: The TTU can be used without a SIM card, but will not be able to upload data over cellular
    - If the error is 'Server could not be reached', ensure that the correct server URL is entered, and that the TTU has network connectivity
        - Note: The TTU can be used with server connectivity, but must be set up manually
    - If the error is 'Insufficient Storage', ensure all studies have been removed from TTU, then power cycle TTU. If this fails to correct the issue, return to manufacturer for repair
    - If the error is 'Hotspot' or 'Bluetooth', return to manufacturer for repair
- TTU displays local validation pass but file fails to upload
    - Ensure TTU has internet connection and retry upload
    - If TTU cannot gain internet connection, the system can be returned to warehouse where study will be uploaded by technician

7. Technical Description

PRODIGY SLEEP SYSTEM HMU

General	6-channel bio-potential signal capture and wireless transmission device
Dimensions	63x38x28 cm
Weight	56 g
Material	Medical Grade ABS-PC
Safety	Protection Circuit Module (Battery Pack), Device Level Circuit Protection
Power	Operating: 3.7 VDC, Max. 800mAh Li/CoO2 Charging: 5.0 VDC, Max. 500 mA
Interfaces	Wireless communication with TTU, 2.4 GHz (802.11)
Classification	Class II ME Equipment, Type BF applied part
Operating Temperature	-5 °C to 40 °C

PRODIGY SLEEP SYSTEM CMU

General	9-channel bio-potential signal capture and wireless transmission device
Dimensions	140x36x24 cm
Weight	81 g
Material	Medical Grade ABS-PC
Safety	Protection Circuit Module (Battery Pack), Device Level Circuit Protection
Power	Operating: 3.7 VDC, Max. 800mAh Li/CoO2 Charging: 5.0 VDC, Max. 500 mA
Interfaces	Wireless communication with TTU, 2.4 GHz (802.11)
Classification	Class II ME Equipment, Type BF applied part
Operating Temperature	-5 °C to 40 °C

PRODIGY SLEEP SYSTEM TTU

General	LG G PAD ™ IV 8.0 FHD
Dimensions	21.6 x 12.7 x 0.7 cm (8.5 x 5 x 0.3 in)
Weight	290 g
Material	Plastic
Power	3000 mAh Li-Po
Interfaces	Wi-Fi 802.11 a/b/g/n/ac (Dual Band)

Classification	N/A
Operating Temperature	0 °C to 40 °C

8. Appendices

APPENDIX A EQUIPMENT CLASSIFICATION

The system belongs to protection class II with a BF applied part according to ANSI/AAMI ES60601-1:2005/(R)2012 with amendments.

Table 2 - Equipment Classification

	Equipment Type	Class of ME Equipment	Type (B/BF/CF)	IP Rating	Disinfection	Operating mode
Prodigy Sleep System HMU	Body-Worn, Internally Powered	II	BF	IP 22	Cleaning products containing 15 to 55% isopropyl alcohol	Continuous
Prodigy Sleep System CMU	Body-Worn, Internally Powered	II	BF	IP 22	Cleaning products containing 15 to 55% isopropyl alcohol	Continuous
Prodigy Sleep System TTU	Portable	N/A	N/A	N/A	Cleaning products containing 15 to 55% isopropyl alcohol	Continuous
HMU & CMU Power supply	Portable	II	N/A	N/A	Cleaning products containing 15 to 55% isopropyl alcohol	Continuous
Prodigy Sleep System TTU Power supply	Portable	N/A	N/A	N/A	Cleaning products containing 15 to 55% isopropyl alcohol	Continuous

This device has a rating of IP22 in accordance with IEC 60529:1989+AMD1:1999+AMD2:2013 which means it is protected against:

a) Solid particle protection: greater than 12.5mm (e.g. fingers or similar objects).
b) Liquid ingress protection: vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15 degrees from its normal position.

APPENDIX B TECHNICAL SPECIFICATION

The system measures audio, EEG, EMG, respiratory effort, light and body position at the frequency range, bandwidth, and accuracy shown in Table 3 - Technical Specification of Prodigy Sleep System Additionally, a description of waveform displays (if applicable) and the functions performed by the Prodigy Sleep System to measure audio, EEG, EMG, respiratory effort, light and body position are included in Table 3 - Technical Specification of Prodigy Sleep System

Table 3 - Technical Specification of Prodigy Sleep System

	Component	Frequency Range	Bandwidth	Functions	Displays	Accuracy
Audio	TTU	20-20000 Hz	19980 Hz	Sampled, written to SD card	None	Total harmonic distortion: 0.5%, SNR: 65dB
EEG	HMU	0-250 Hz	250 Hz	Sampled, transmitted wirelessly, written to SD card	None	Noise per channel: 0.20 uVrms, SNR: 120 dB Resolution: 0.022352uV
Light	TTU	Visible Light (430 nm to 800 nm)	370 nm	Sampled, written to SD card	None	10% between 430 nm and 800 nm Resolution: N/A (Unitless Quantity)
Body Position	CMU & HMU	N/A	N/A	Sampled, transmitted wirelessly, written to SD card	None	+/- 10 degrees Resolution: N/A (Unitless Quantity)
EMG (Legs, Chin, Chest)	CMU & HMU	0-250 Hz	250 Hz	Sampled, transmitted wirelessly, written to SD card	None	Noise per channel: 0.20 uVrms, SNR: 120 dB Resolution: 0.023842uV
Respiratory Effort (Nasal Cannula)	CMU	N/A	N/A	Sampled, transmitted wirelessly, written to SD card	None	+/- 1% Resolution: 0.00129kPA

Respiratory Effort (Belt)	CMU	N/A	N/A	Sampled, transmitted wirelessly, written to SD card	None	+/- 1% Resolution: N/A (Unitless Quantity)

APPENDIX C ELECTROMAGNETIC COMPLIANCE

The Prodigy Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep System should assure that it is used in such an environment.

When the Prodigy Sleep System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behaviour. For instance, the measured traces may become obscured, the software may crash, or, in cases of very high level transient voltage events (e.g. ESD), parts of the system may even become defective.

Information pertaining to electromagnetic compliance is provided in Table 4 through Table 7

Table 4 - Guidance and manufacturer's declaration - Electromagnetic emissions

Emissions Test	Compliance	Electromagnetic environment
RF Emissions CISPR 11	Group 1	The Prodigy Sleep System uses RF energy only for its internal function. Therefore, its RF emissons are very low and not likely to cause any interference in nearby electronic equipment.
RF Emmissions CISPR 11	Class A	The EMISSIONS characteristics of the Prodigy Sleep System make it suitable for use in areas in industrial areas and hospitals (RF Emmissions CISPR 11 class A). Harmonic emissions and Voltage Fluctuations/Flickers emissions are not applicable for the device.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Emissions Test	Compliance	Electromagnetic environment
RF Emissions CISPR 11	Group 1	The Prodigy Sleep System uses RF energy only for its internal function. Therefore, its RF emissons are very low and not likely to cause any interference in nearby electronic equipment.
RF Emmissions CISPR 11	Class B	The EMISSIONS characteristics of the Prodigy Sleep System
Harmonic emissions IEC 61000-	N/A	

3-2		make it suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the EEG and ORP outputs on the Prodigy Sleep System are not used. RF Emmissions CISPR 11 compliance class A, Harmonic emissions and Voltage Fluctuations/Flickers emissions are not applicable for the device.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	N/A	

Table 5 - Guidance and manufacturer's declaration - Electromagnetic immunity

The Prodigy Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep System should assure that it is used in such an environment.

When the Prodigy Sleep System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behaviour. For instance, the measured traces may become obscured, the software may crash, or, in case of very high level transient voltage events (e.g. ESD), parts of the system may even become defective.

Due to the device's intended use of data collection, a deviation in testing was made to test to lower compliance levels. It should be noted that in the event of higher ESD levels, there is no risk of harm to patient or environment, and this does not present a chance of misdiagnosis.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Guidance**
Electrostatic Discharge (ESD)IEC 61000-4-2	±8 kV (contact) ±15 kV (air)	±4 kV (contact) ±8 kV (air)	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines ±2 kV for AC and DC powerlines	N/A	Mains power quality should be that of a typical commercial or hospital equipment.
Surge IEC 61000-4-5	±1 kV diferential mode ±2 kV common mode	N/A	Mains power quality should be that of a

			typical commercial or hospital equipment.
Voltage dips, short interruptions and volatage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0, 5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 70 % U_T (30 dip in U_T) for 25 cycles 0 % U_T (100% dip in U_T) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital equipment. If the user of the Prodigy Sleep System requires continued operation during power mains interruptions, it is recommended that the Prodigy Sleep System be powered from an uninterruptable power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application test level.			

The Prodigy Sleep System is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep System should assure that it is used in such an environment.

When the Prodigy Sleep System is exposed to electromagnetic (EM) disturbances, the system may show abnormal behavior. For instance, the measured traces may become obscured, the software may crash, or, in case of very high level transient voltage events (e.g. ESD), parts of the system may even become defective.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms for ISM bands	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Prodigy Sleep System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$; from 150 kHz to 80 MHz

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 6 GHz 27V/m 385 MHz 28V/m 450 MHz 9 V/m 710/745/780 MHz 28 V/m 810/870/93O MHz 28 V/m 1720/1845/1970 MHz 28 V/m 2450 MHz 9 V/m 5240/5500/5785 MHz	3 V/m	$d = 1.2\sqrt{P}$; from 80 MHz to 6 GHz $d = 2.3\sqrt{P}$; from 80 MHz to 6 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). The Prodigy Sleep System is fairly sensitive to conducted and radiated RF. Disturbance of the Prodigy Sleep System trace is possible at and below the specified test level. It may be necessary to relocate the Prodigy Sleep System or to apply shielding. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of known RF transmitting devices and equipment marked with the following symbol: 

NOTE 1 - At 80 MHz and 6 GHz, the higher frequency range applies.

NOTE 2 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prodigy Sleep System is used exceeds the applicable RF compliance level above, the Prodigy Sleep System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Prodigy Sleep System.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 6 - Recommended separation distances between portable and mobile RF communications equipment and the Prodigy Sleep System

The Prodigy Sleep System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Prodigy Sleep System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prodigy Sleep System components as recommended below, according to the maximum output power of the communications equipment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the Prodigy Sleep System, or those peripherals as specified in Section 2 and throughout this Operator Manual by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter (W)	Separation distance according to frequency transmitter in meters (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 6GHz $d = 1.2\sqrt{P}$	800 MHz to 6 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meterms (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is he maxmimum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidances may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 7 – Electromagnetic Compliance

Component	Wireless protocol	Frequency
Prodigy Sleep System HMU	IEEE 802.11	2.412 – 2.472 GHz
Prodigy Sleep System CMU	IEEE 802.11	2.412 – 2.472 GHz
Prodigy Sleep System TTU	IEEE 802.11	2.412 – 2.472 GHz

APPENDIX D ENVIRONMENTAL CONDITIONS

The environmental conditions for transport and storage, and during operation, are presented in Table 8 and Table 9 - Operating Conditions, respectively.

Table 8 - Transport and Storage Conditions

Component	Environmental Condition	Range
Prodigy Sleep System HMU	Temperature	-25°C to +70°C
Prodigy Sleep System CMU	Temperature	-25°C to +70°C
Prodigy Sleep System TTU	Relative humidity (non-condensing)	5% to 93%
Power supply	Barometric pressure	90 kPa to 106 kPa

Table 9 - Operating Conditions

Component	Environmental Condition	Range
Prodigy Sleep System HMU	Temperature	5°C to 40°C
Prodigy Sleep System CMU	Temperature	5°C to 40°C
Prodigy Sleep System TTU	Relative humidity (non-condensing)	15% to 93%
Power supply	Barometric pressure	90 kPa to 106 kPa

APPENDIX E COMPONENTS WITH HIGH INTEGRITY CHARACTERISTICS

When a component can generate an unacceptable risk due to a fault, such a component should have high integrity characteristics. The medical grade power supply, rechargeable lithium polymer battery, and components of the power system (transient voltage suppressors, voltage regulators, battery controllers, battery chargers, and protection diodes) are specified in this document as components that have high integrity characteristics.

⚠ CAUTION

If required, please contact customer support to obtain circuit diagrams, component part lists, descriptions, calibration instructions, or other information as needed for proper servicing of Prodigy Sleep System.

APPENDIX F CRITICAL COMPONENTS

- ABS medical grade plastics: CMU/HMU
- FR-4 printed circuit boards: CMU/HMU
  - Printed circuit boards
  - Rigid Connector board
  - Rigid Snap board
- Power and polarity protection components
  - ESD protection Diode
  - Reverse polarity protection
- Wi-Fi communication components
  - Wi-Fi Network Processor
  - Wireless antenna
- Main processor
- Biosignal recorder
  - Bio-potential analog front end: CMU/HMU
  - Multilayer band Pass Filter
- Lithium Battery
  - Battery Cell
  - Secondary Li battery gas gauge
- Flow measurement components
  - Inductance to digital converter
  - Pressure transducer

APPENDIX G SYMBOLS USED ON PRODIGY SLEEP SYSTEM LABELING

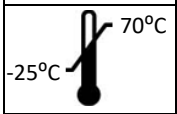
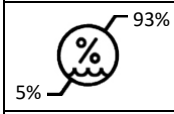
Table 10 - Regulatory Symbols

Symbol	Description and Usage
SN	Symbol for "SERIAL NUMBER" Used to identify the manufacturer's serial number.
REF	Symbol for "REFERENCE NUMBER" Used to identify manufacturer's reference number.
	Symbol for "MANUFACTURER" Used to identify the manufacturer's name and address.
	Symbol for "DATE of MANUFACTURE" Used to identify the date of manufacture.
	Symbol for "OPERATING INSTRUCTIONS" Used to direct the user to operating instructions when using the product.
	Symbol for "CAUTION, CONSULT ACCOMPANYING DOCUMENTS" Used to direct the user to safety warnings when using the product.
CE	Symbol for CE Used to identify a device that complies with European Directive MDD 93/42/EEC.
	Symbol for "TYPE BF APPLIED PART" Used to identify the level of protection against electric shock of a component. Type BF Applied parts are generally conductive and have medium/long term contact.
c US	Symbol for "UL RECOGNIZED COMPONENT MARK" Used to indicate the component is UL recognized for use in Canada and the United States of America.
	Symbol for "RF TRANSMITTER" Used to identify device containing non-ionizing radiation.
IPN_1N_2	Symbol for "IP RATING" Used to indicate the ingress protection of a device. N_1 indicates the type of solid ingress protection and N_2 indicates the type of water ingress protection.

Table 11 - Electrical Symbols

Symbol	Description and Usage
	Symbol for “DIRECT CURRENT” Used to identify direct current.
	Symbol for “ALTERNATING CURRENT” Used to identify alternating current.
	Symbol for “ON” Used to identify when product is on (power).
	Symbol for “OFF” Used to identify when product is off (power).
	Symbol for “CLASS II ELECTRICAL DEVICE” Used to identify a Class II electrical device, or double insulated electrical device.
RoHS	Symbol for “RoHS” Used to indicate that electrical or electronic equipment contains a negligible amount of toxic substances such as mercury, Cadmium, Hexavalent chromium, lead, PBB, and PBDE.
	Symbol for “INTERNATIONAL EFFICIENCY” Used to indicate the international efficiency for external power supplies.

Table 12 - Packaging Symbols

Symbol	Description and Usage
	Symbol for “USE BY” Used to indicate that the device shall not be used after the date shown.
	Symbol for “DO NOT REUSE” Used to identify products that are non-reusable.
	Symbol for “DO NOT DISPOSE OF IN NORMAL WASTE” Used to indicate that electrical and electronic equipment shall not be disposed of in normal waste.
	Symbol for “TEMPERATURE RANGE” Used to indicate packages shall be kept within a specific temperature range of -25°C to +70°C during transport, handling, and storage.
	Symbol for “HUMIDITY RANGE” Used to indicate packages shall be kept within a specific humidity range of 15% to 93% during transport, handling, and storage.
	Symbol for “BAROMETRIC PRESSURE RANGE” Used to indicate packages shall be kept within a specific barometric pressure range of 70kPa to 106kPa during transport, handling, and storage.