Prodigy Sleep Monitor

Operator Manual

Label Information and Manufacturer's Notes:

Younes Medical Technologies (YMT)
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Winnipeg, MB, Canada, R3L 2P4
Canada
1-888-942-6774

Technical Support

Our customer support staff can be reached through the following methods:
Toll-free: 1-888-942-6774
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IC Company Number: 20415
FCC ID: 2AFGB

Package Contents:

Prodigy Sleep Monitor (100001-001), ORP-YY-XXX, which includes:

- Head-Mounted Unit (HMU, “Head Sensor”, 100013-002) PROTO-XXXX-002-HXXXXXX
- Table-Top Unit (TTU, “Touch Screen Monitor”, 100002-002) PROTO-XXXX-002-TXXXXXX
- Power Supply MENB1020A0903B01 (800115-000)

Expiry Date: Five (5) years from date of manufacture (see HMU and TTU labels for manufacture date)

Problem Reporting

All problems relating to the performance characteristics or safety of the Prodigy Sleep Monitor 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 10.

Copyright

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Acronyms

AAA	Battery Type
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 Monitor (ORP System) is intended to provide means of obtaining information about sleep quality and level of vigilance. It is a physiological data recorder that collects, records and analyzes data from electrodes placed on the head and generates a signal that reflects level of vigilance or sleep quality (Odds Ratio Product, or ORP). It is intended for use by or under the direction of a physician, either in a hospital/laboratory setting or by prescription for remote home study.

Indications for Use

- Diagnostic evaluation of adult patients with possible sleep disorders.
- Real time determination of depth of sleep or state of vigilance.
- Patients suspected of having a sleep disorder that affects sleep quality including respiratory or motor disorders and insomnia.
- Patients with medical, psychiatric or neuro-cognitive disorders where poor sleep quality is suspected of playing a role in the disorder, including fibromyalgia, depression, anxiety disorders, Alzheimer's disease.
- For continuous monitoring of level of vigilance in activities requiring a high level of alertness.

Contraindications

The following is a list of contraindications for this device:

- Patient 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

- Device shall be used only on the order of a physician.
- 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. Clean and disinfect according to instructions.
- Equipment needs to be installed and put into service in accordance with the information provided in the accompanying documents, including this operator manual.
- 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.
- Keep away from sources of heat, including household heaters or open flame.
- Do not use components that appear to be physically damaged.
- 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.

CAUTION

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

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 20 cm 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 20 cm 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 clinical personnel and patients.

2. System Overview

The Prodigy Sleep Monitor system consists of two main components: the Prodigy Head Sensor and the Prodigy Monitor. The Head Sensor uses four to eight EEG electrodes depending on the configuration for the sleep study. Proper electrode placement is described in section 3 of this manual. The Head Sensor transmits data wirelessly to the Monitor unit. The Monitor unit receives and stores the EEG data transmitted by the Head Sensor. The Monitor also has outputs for connecting to external systems and uses a class 2 medical grade power supply.

The Prodigy Sleep Monitor is supplied with the following accessories:

- Power supply (qty. 1)
- New AAA Batteries (qty. 2 pre-installed in Head Sensor, plus qty. 2 spare)
- 3M Red Dot 2560 disposable wet gel electrode with snaps (qty. 1, plus qty. 1 spare) – or equivalent
- AMBU Neuroline 72000-S/25 disposable wet gel electrodes with snaps (qty. 3, plus qty. 3 spares) – or equivalent
- AMBU Neuroline 72001-K/12 disposable wet gel electrodes with connectors (qty. 4, plus qty. 4 spares) – or equivalent
- Alcohol Swabs (qty. 5)
- Micro USB to USB cable, 6ft length (qty. 1)
- 3.5mm to 3.5mm male-male mono cable, 6ft length (qty. 4)

Prodigy Head Sensor

The Head Sensor is a small body worn device that is attached to the forehead via EEG electrodes during use. It contains the two AAA batteries and has connectors to connect the EEG electrodes.

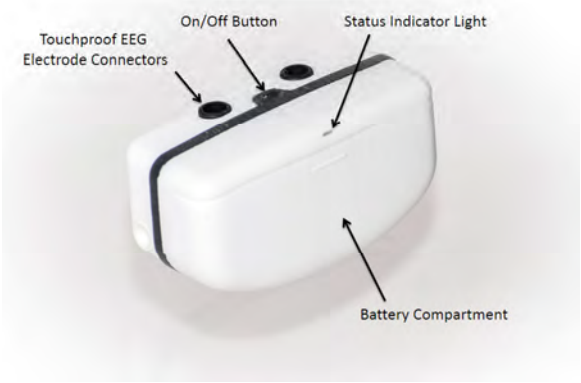


Figure 1 – Prodigy Head Sensor Front View

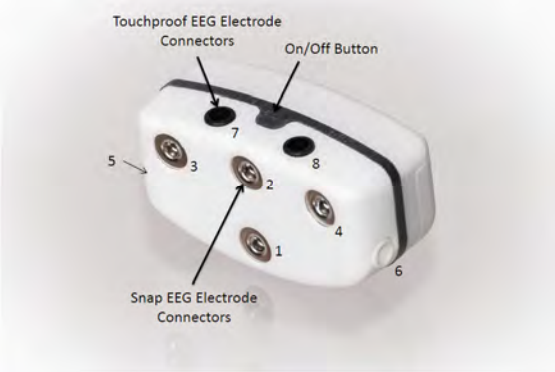


Figure 2 – Prodigy Head Sensor Rear View

The Head Sensor is powered by two AAA batteries and the device is rated to operate continuously for at least 12 hours. To ensure adequate battery life, the batteries must be replaced after each sleep study is conducted.

WARNING

Use only the alkaline AAA batteries provided with the device. Do not use rechargeable batteries or those that are not fully charged or combine new and old batteries.

Refer to the Technical Description in section 6 for additional information about the Prodigy Head Sensor.

Prodigy Monitor

The Prodigy Monitor is a portable device that is equipped with a touch screen that is used for operation of the device. It is powered by the external power supply that is provided to the user with the system.

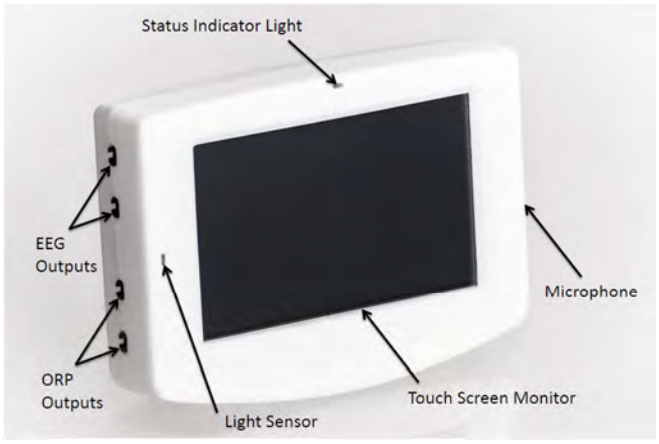


Figure 3 – Prodigy Monitor Front View

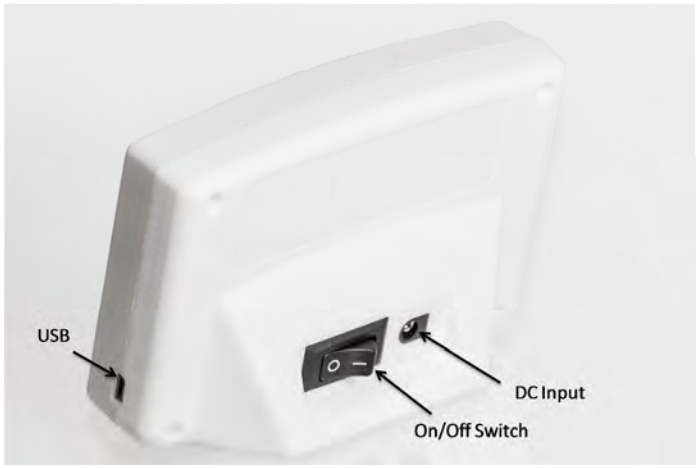


Figure 4 – Prodigy Monitor Rear View

Refer to the Technical Description in section 6 for additional information about the Prodigy Monitor.

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

Power Supply

The Prodigy Sleep Monitor system comes with a medical grade class 2 power supply that is plugged into a wall outlet and connects to the Monitor to supply power. Please make sure you use the correct adapter for your electrical outlet.

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 5 – Monitor 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).

Refer to the Technical Description in section 6 for additional information about the power supply.

Use Environment

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

Duty Cycle

The Prodigy Sleep Monitor 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 Monitor. The Operator Manual – along with descriptions of functions of the PC Application – comprises the primary training material for use of the Prodigy Sleep Monitor. 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. Additional training may be provided on-site, by telephone and/or via video by YMT personnel. If a French version of this Operator Manual is required, please contact YMT and one will be provided at no cost.

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 Sensor and Monitor units. Check to ensure that all components and their respective quantities listed on the inside of the back cover of this manual are included in the case. 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. Defribulator protection requires use of manufacturer specified accessories.

WARNING

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

CAUTION

Keep out of reach from children and animals. Large parts such as the Prodigy Monitor and Sensor 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 Head Sensor away from other conductive parts including earth.

Figure 6 – Example EEG Electrodes

Place the Monitor on a table close to your bed in your bedroom where you plan to perform the sleep study. Ideally, this should be located within 3m of where you will be sleeping for optimal wireless signal strength.

CAUTION

Ensure the table surface area is level, clean and dry. Avoid placing objects that contain liquids such as glasses of water near the tabletop unit 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 power supply into the wall outlet using the correct adapter, and then into the back of the Monitor unit labeled "DC in". The location of the DC power input is shown in Figure 4.

The Monitor unit is equipped with a light sensor to detect when the room is dark during the sleep study. Keep the Monitor away from light sources during the study (e.g. sunlight, lamps). The Monitor is also equipped with a sound level sensor that can detect audible snoring sounds. Keep the Monitor away from sources of noise (e.g. fans, speakers).

Connecting to External Devices (optional)

This section describes the procedure to connect the Monitor to compatible external devices. This is not required for home sleep studies and should be done by authorized service personnel only.

- The Monitor unit is equipped with output connections that can be used to output either raw analog EEG or ORP data to a hospital or other EEG Monitoring devices. The connectors are 3.5mm mono type and can be connected to compatible external devices with the supplied 3.5mm cables. Compatible devices include hospital data recording systems, data acquisition systems, and other system that can accept 0-5 VDC signals. The specifications for the four outputs are listed below: EEG output #1 is a real time output of the sampled EEG from the left frontal electrode, represented as a scaled output between +/- 5V. The output value is derived from the sampled EEG in the ranges of +/- 250uV with a scaling factor of 20,000.
- EEG output #2 is a real time output of the sampled EEG from the right frontal electrode, represented as a scaled output between +/- 5V. The output value is derived from the sampled EEG in the ranges of +/- 250uV with a scaling factor of 20,000.
- ORP output #1 is a 3 second averaged ORP value, represented as a voltage between 0-2.5V.
- ORP output #2 is a 30-second averaged ORP value, represented as a voltage between 0-2.5V.

Figure 7 – 3.5mm Mono Cable for Monitor Outputs

CAUTION

These outputs are for information reference purposes only. There is an inherent data transmission delay and therefore this data shall not be used for real-time patient monitoring applications.

WARNING

Connecting to equipment not described in this manual may be unsafe. Do not connect the outputs to power supplying devices, as this may result in electrical shock or fire hazards and injury to the patient or others near the device.

Overview of Touch Screen Monitor

Figure 8 – Touch Screen Monitor Overview

The Head Sensor battery level is indicated on the upper left corner of the touch screen Monitor as shown in Figure 8. New batteries are installed by the service provider before sending home with the patient, so this should always indicate fully charged (green icon) at the beginning of each sleep study. The icon will be red if insufficient capacity is remaining for a complete sleep study as shown in Figure 9.

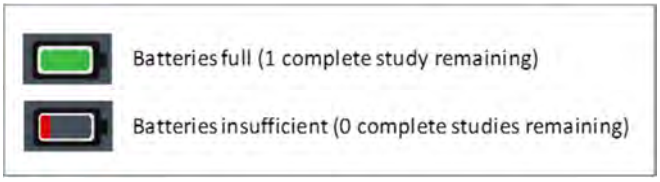


Figure 9 – Battery Status Indicator States

Overview of LED Indicator States

Both the Monitor unit and Head Sensor unit have LED indicators that display the current state of the device as shown in Figure 1 and Figure 3. Below is a description of the possible states and their meanings:

Prodigy Head Sensor Light Indicator States

LED	State
Off	Device is off, or system is operational during a sleep study
White	On button pressed, system starting up
Green	Device is on, validated, and functioning properly
Blue	Device is starting, or finishing a sleep study (default idle state)
Blue (blinking)	Device is shutting down and powering off
Yellow	Device is on, but validation failed (system not ready). Check touch screen Monitor for more info.

Prodigy Monitor Light Indicator States

LED	State
Off	Device is off
Green	Device is on, validated, and functioning properly
Blue	Device is starting, or finishing a sleep study (default idle state)
Yellow	Device is on, but validation failed (system not ready). Check touch screen Monitor for more info.

EEG Electrode Configurations

The home sleep study will require either 4, 6, or 8 EEG electrodes to be applied to your forehead. Different configurations are required for different applications, and this section will present what each of the three configurations look like.

The device is to be configured by the service provider prior to sending it home with a patient. As such, the patient 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.

The number of electrodes attached to the Head Sensor indicates the configuration to be used for your sleep study (e.g. 4 electrodes attached means the four electrode configuration is to be used). Additionally, the ‘Quick Start’ guide indicates the electrode configuration for your sleep study.

Four Electrode Configuration

Every study requires the first 4 snap electrodes to be connected as shown in Figure 10.

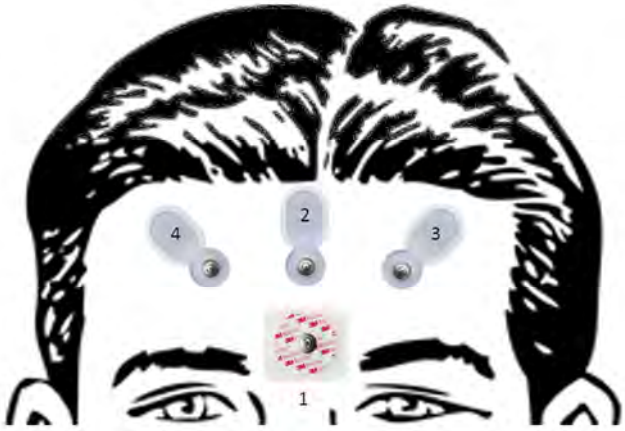


Figure 10 – Optimal 4 EEG Electrode Placement on Forehead

Six Electrode Configuration

After the first four snap type electrodes are connected, two additional 'touch proof' style electrodes are attached to the forehead as shown in Figure 11 and connected to inputs 5 and 6 on the Head Sensor unit.

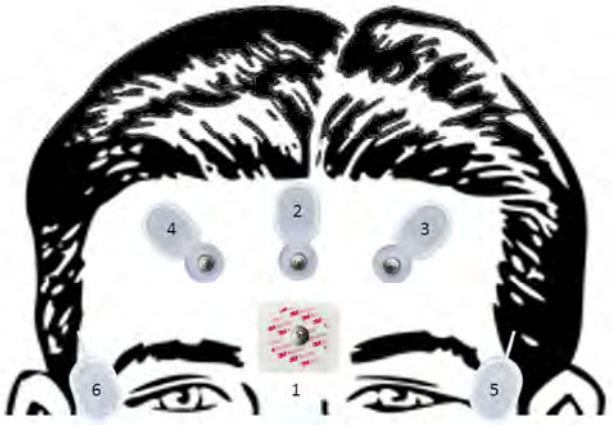


Figure 11 – Optimal 6 EEG Electrode Placement on Forehead

Eight Electrode Configuration

In this configuration, two additional 'touch proof' style electrodes are attached to the forehead as shown in Figure 12 and connected to the Head Sensor unit inputs 7 and 8.

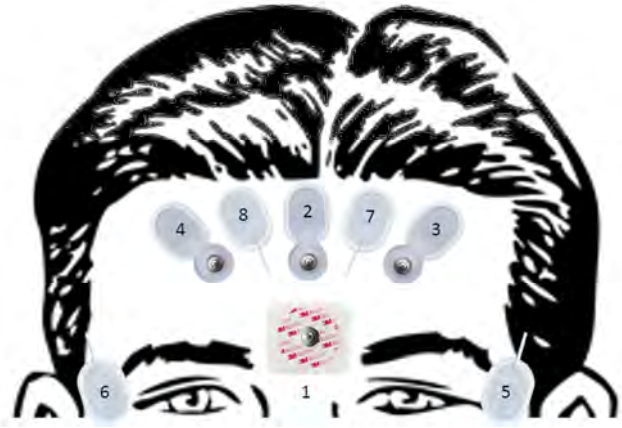


Figure 12 – Optimal 8 EEG Electrode Placement on Forehead

Frequently Used Functions

- Plugging or removing the power supply from the wall outlet, as well as the back of the Monitor unit labeled “DC in.”
- Turning the Monitor on or off by pressing the power switch button.
- Touching the Monitor screen to set up the study, use the device, and end the study.
- Snapping and plugging 4, 6, or 8 EEG electrodes into or out of the wireless battery powered module.
- Applying or removing 4, 6, or 8 EEG electrodes to your forehead.
- Turning the wireless battery powered module on or off by pressing the power button.

WARNING

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

CAUTION

If possible remove the Head Sensor before defribulation, as the discharge of a defribulator on a patient may damage the device.

Starting the Sleep Study

Once you are ready to go to sleep and begin the sleep study, follow the steps outlined within this section.

> **CAUTION**
> To prevent the Prodigy Sleep Monitor 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.

> **WARNING**
> If any signs of skin irritation become present (e.g. itchiness, redness, swelling) while handling the Prodigy Sleep Monitor system discontinue use immediately.

1. Inspect Prodigy Sleep Monitor system for damage prior to use.

> **WARNING**
> If any component of the system is damaged and a replacement component is not provided, do not proceed with the sleep study. Return components to travel 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 patient or others near the device.

2. Push the power switch on the Prodigy Sleep Monitor so that the switch is in the “on” position.

> **CAUTION**
> Keep all fluids away from the Monitor. Fluid ingress can cause electrical faults.

3. Using your finger, touch the green button on the touch screen Monitor to select your language (English or French).

Figure 13 – Language Select Screen

4. Touch the green button on the screen to select your name. If your name is not shown, DO NOT PROCEED. Please contact your service provider.

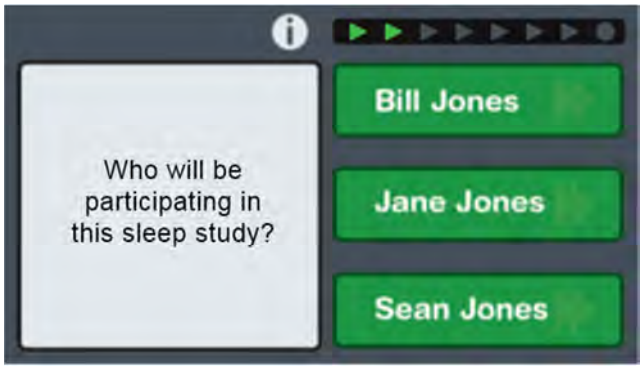


Figure 14 – Name Selection Screen

NOTE

If you do not see your name on the selection screen, do not proceed with the sleep study. Return components to travel case and contact your service provider.

If the text on the screen indicates 'No patients found,' DO NOT PROCEED. Please contact the number provided on the screen.

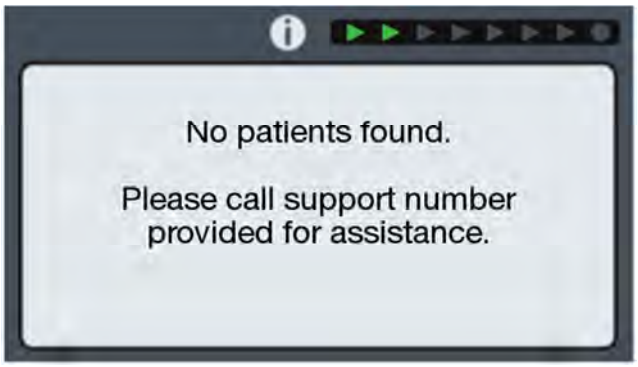


Figure 15 – No Patient Found Screen (Support)

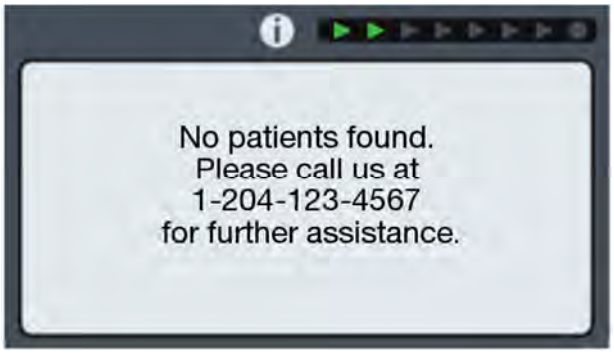


Figure 16 – No Patients Found Screen (Number Listed)

5. The Monitor will help guide you through the process to set up and use the device.

Figure 17 – Welcome Screen

NOTE

If the wrong name is selected, press the 'Previous' button.

6. Press the green 'Continue' button when you are ready to proceed. The screen will instruct you to secure the Head Sensor unit to your head. Steps 7-11 outline how to secure the Head Sensor to your head.

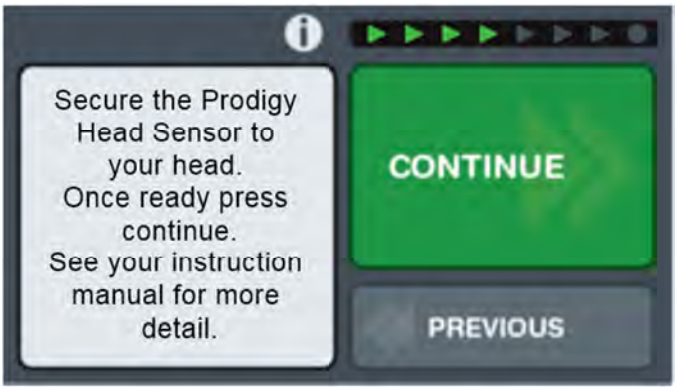


Figure 18 – Instructions Screen

NOTE

It is not necessary to replace the AAA batteries in the Head Sensor unit. The device has been provided to the patient with fully charged batteries.

7. Before the Head Sensor can be secured to your head, your forehead and the skin beside the outside of the eyes must be vigorously wiped with the provided alcohol swabs for EEG prep use. Alcohol swabs are designed for single use only and shall be discarded after use.
8. Take the Head Sensor out of the case. Check to ensure that all electrodes required for your study are attached to the Head Sensor. The 'Quick Start' guide indicates the electrode configuration for your sleep study – use the pictures and descriptions from this document to check that all electrodes required for the study are present and are attached properly.

CAUTION

Ensure that all electrodes are connected to the correct inputs as per the instructions in this manual. 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 wet-gel EEG electrodes that have been provided with the device. Use of non-approved devices may result in loss of equipment functionality or personal injury.

9. Turn on the Head Sensor by pressing and holding the button on the top of the unit. The light indicator will be white initially, and then switch to the colour blue within approximately 2 seconds.
10. Once your skin is dry, unsnap the electrode labelled 1 in Figure 10 from the Head Sensor and remove the protective backing from the adhesive on the electrode. Before pressing on the electrode to secure it, make sure to align the electrode's sticky side to the forehead, arranging it as follows:
    a) Place it so the shorter side is vertical and the longer side is horizontal. In other words, it should be wider than taller.
    b) The bottom edge of the electrode should be roughly level with the eyebrows, or the bottom most point where the forehead is still flat. The electrode should not be touching on the bridge of the nose or any uneven surface.

    Once the electrode is aligned properly as described in a) and b), hold it to the forehead without pressing down, and then run your finger firmly along the entire outside only of the electrode to ensure a secure fix to the forehead.

CAUTION

Do not press on the sensor area in the center 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.

11. Connect the Head Sensor to the electrode labelled 1 in Figure 10 through snapping the mating pieces together, ensuring that the flat portion of the Head Sensor is at the top. Peel the cover off electrode 2 and align it on your forehead as shown in Figure 10 before running your finger firmly along the entire outside of the electrode to ensure a secure fix to the forehead. In numerical order, continue securing the remaining electrodes to the forehead following the aforementioned instructions and positioning in Figure 10, Figure 11, and Figure 12.

NOTE

Correct placement on the forehead is easier with assistance. If available, ask someone to help you position the assembly on your forehead and ensure the electrodes are secure.

WARNING

If any signs of skin irritation become present (e.g. itchiness, redness, swelling), remove all electrodes from the skin and discontinue use immediately.

12. Look in the mirror and check to ensure the positions of the electrodes match the positions assigned to you for your sleep study. Additionally, check to ensure that all electrode are securely connected to the Head Sensor and skin,

CAUTION
Incorrect placement of the EEG electrodes may result in loss of functionality or inaccurate data collected.

CAUTION
Ensure electrodes are connected properly. Loose connections may cause incorrect or insufficient data to be collected.

As mentioned in Step 6, press the green "Continue" button on the Monitor screen when you are ready to proceed. Once "Continue" has been selected, the Monitor will verify it can communicate with the Head Sensor.

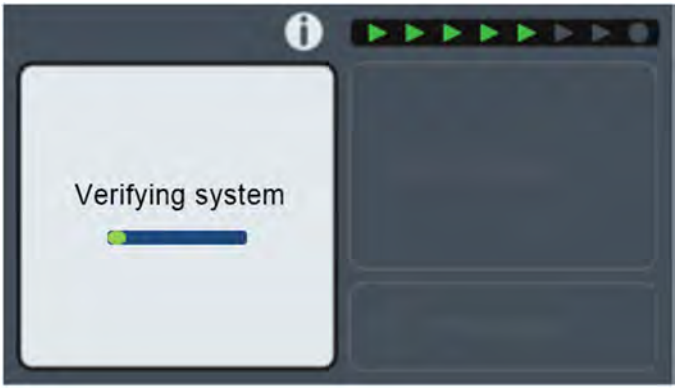


Figure 19 – Verification Screen

13. In the unlikely event that the verification fails, you will see one of the following screens:

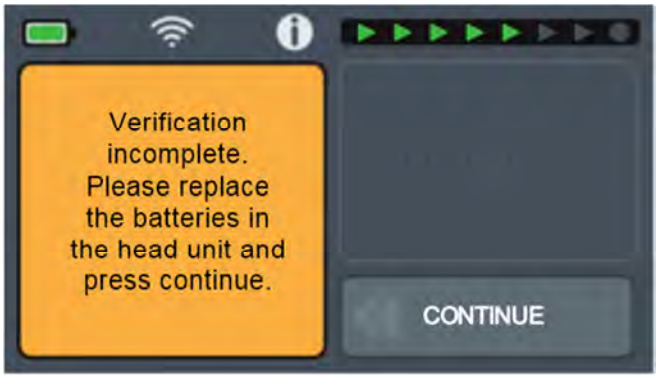


Figure 20 – Verification Fail Screen (batteries)

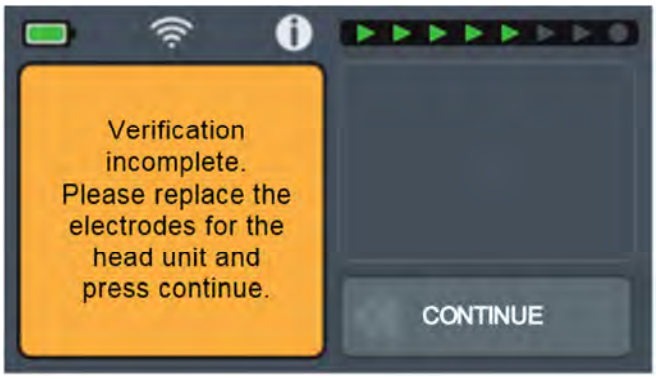


Figure 21 – Verification Fail Screen (electrodes)

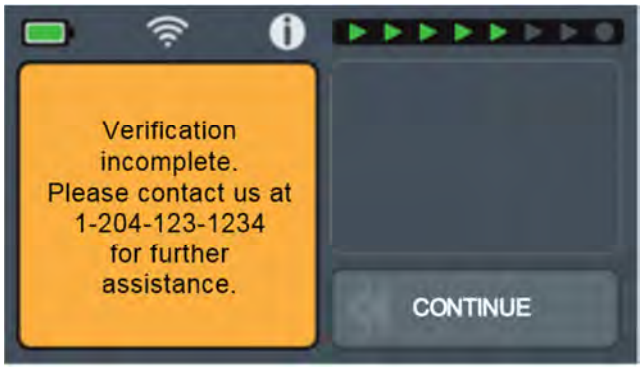


Figure 22 – Verification Fail Screen (contact)

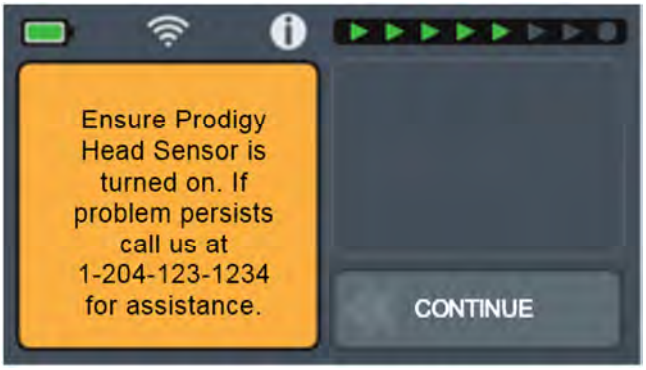


Figure 23 – Verification Fail Screen (off, contact)

NOTE

Do not attempt to call the phone number listed in Figure 22 or Figure 23, as it is not a real phone number. Instead, call the phone number provided on your Monitor screen if you are in need of assistance.

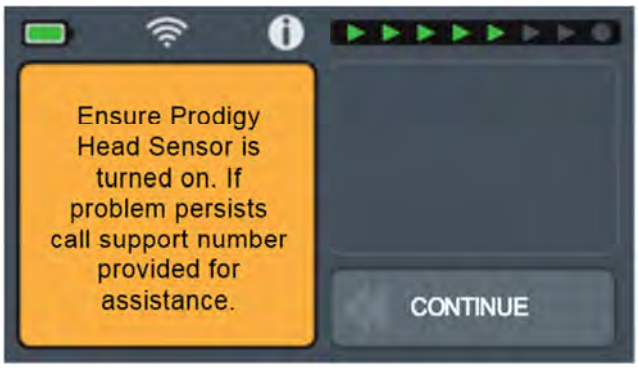


Figure 24 – Verification Fail Screen (off, support)

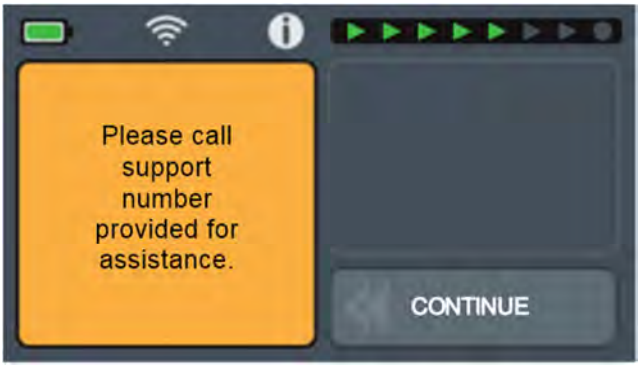


Figure 25 – Verification Fail Screen (support)

14. Once verification is complete, the Monitor will read "Verification complete. Press start study when you are ready to go to sleep." Press the "Start Study" button on the Monitor touch screen when you are ready.

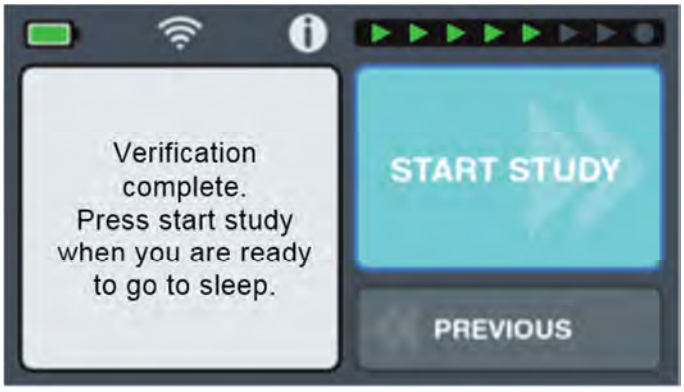


Figure 26 – Verification Complete Screen

NOTE

Do not obstruct the front of the Monitor during the sleep study. The light sensor will not function properly if covered.

15. Go to sleep as you normally would. DO NOT power off the Monitor; it will turn off within a few seconds so the light from the Monitor screen will not disturb you as you sleep. The Head Sensor light will remain on for a few seconds and then turn off as well. Pressing the Head Sensor power button momentarily will light the green indicator to show that it is powered on and working. The light will turn off after a few seconds.

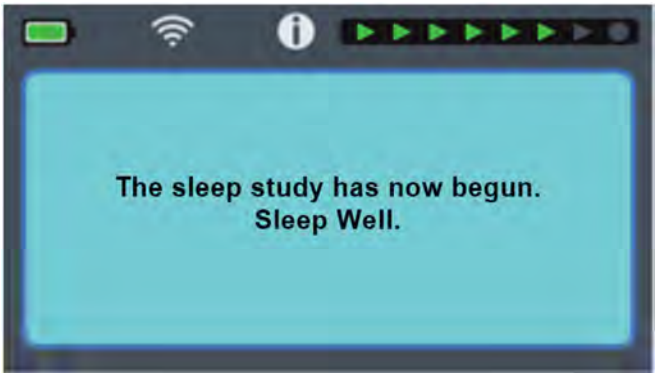


Figure 27 – Study Start Screen

Ending the Sleep Study

Once you are awake in the morning and have completed the sleep study, follow these steps:

1. Press the touch screen Monitor and select "End Study".

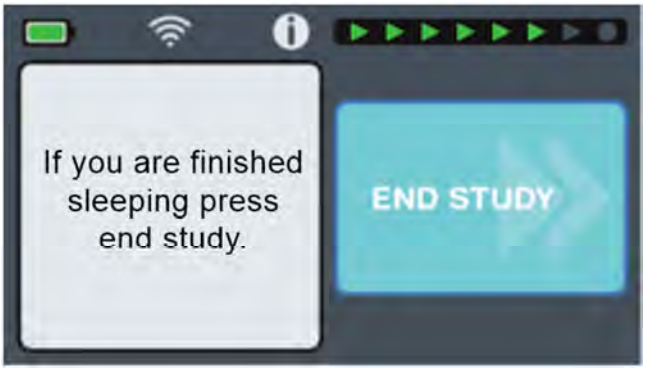


Figure 28 – Study Finished Screen

2. An evaluation screen will appear as shown in Figure 29.

Figure 29 – Evaluation Screen

One of the following screens will be shown after the data has been evaluated:

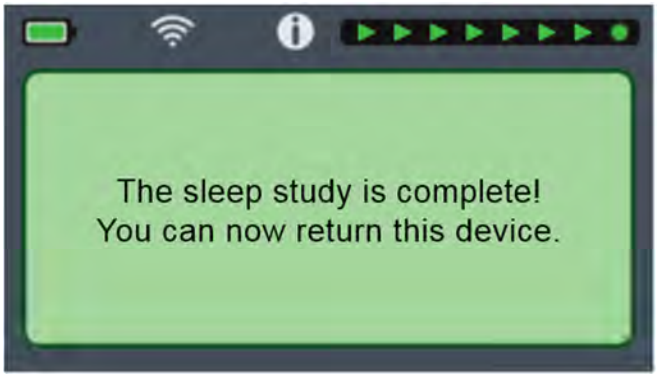


Figure 30 – Sleep Study Complete Screen

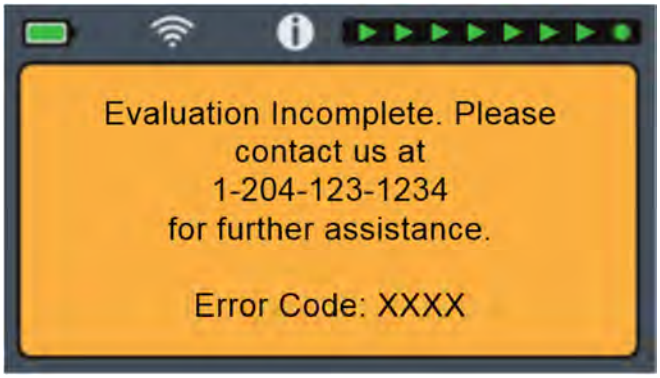


Figure 31 – Sleep Study Incomplete Screen (contact)

NOTE

Do not attempt to call the phone number listed in Figure 31, as it is not a real phone number. Instead, call the phone number provided on your Monitor screen if you are in need of assistance.

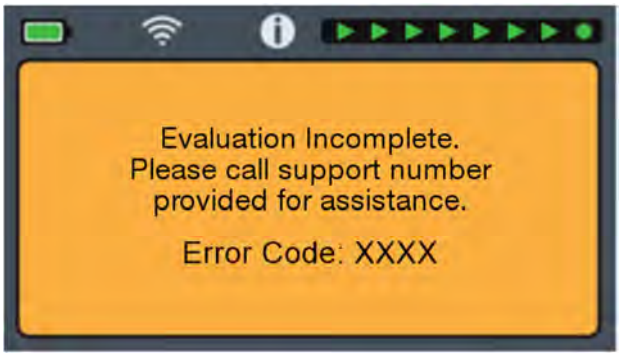


Figure 32 – Sleep Study Incomplete Screen (support)

3. Proceed as per instructions on the screen.
4. Push the power switch on the Prodigy Sleep Monitor so that the switch is in the “off” position.
5. Unplug the power supply from the wall and Prodigy Sleep Monitor.
6. Unplug and remove the electrodes from the Head Sensor unit. Use care to remove the connectors from the Head Sensor by pulling on the connector rather than the wire.
7. Turn the Head Sensor off.
8. Carefully peel the adhesive backed electrodes off of your skin.
9. Discard the disposable electrodes.
10. Place the components back into the case as they were when you received the device, including the Head Sensor unit, Monitor unit, and power supply.
11. If you have completed your sleep study and are done with the device, return the device to the service provider.

Special Instructions

Power Failure During Study

In the event of power loss during the sleep study, the Monitor will lose power and stop functioning. The data will have been saved to the internal memory up until the time that the power went out. If the power turns back on within 2 hours, the system will continue the sleep study. If power is restored after more than 2 hours of being powered off, the study will need to be re-started. If less than 4 total hours of sleep are recorded, the post-study validation will fail and the study will need to be repeated.

Resetting and Restarting the System

The system may be reset by completely powering off both the Monitor and Head Sensor and then restarting. If you have restarted the system during a sleep study, you will need to start a new study.

Replacing Head Sensor Batteries

In the event that the batteries in the Head Sensor are insufficient for use during a complete sleep study, the Head Sensor battery indicator on the Monitor will be yellow. To replace the 2 AAA batteries from the Head Sensor, simply open the battery cover by sliding it away from the Head Sensor, as shown in Figure **33**.

Figure 33 **– Action required to remove battery cover from Head Sensor**

Once the cover is removed, place the two batteries in the battery holder as per the instructions on the holder shown in Figure 34.

Figure 34 – Head Sensor with Battery Cover Removed

The batteries should appear as shown in Figure 35 before attaching the battery cover back on the Head Sensor.

Figure 35 – Head Sensor with Batteries

To close the battery compartment line up the guides on the cover and the Head Sensor, and slide the cover into place. The cover is attached if you cannot see any gaps between the Head Sensor and battery cover, and you hear a clicking noise.

Damaged Components

If any components are damaged during the sleep study (e.g. Head Sensor is dropped and enclosure is cracked) and a replacement component is not provided, do not proceed with the sleep study. Return the components to the case and contact your service provider.

WARNING

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

PC Application Software Installation Procedure

The instructions in this section are for **authorized service personnel only**.

Instructions

In order for the data stored on the Monitor to be retrieved, the Windows-based Prodigy Sleep Monitor Software must be installed. Follow the instructions below to install the Prodigy Sleep Monitor application. See page 48 for instructions on the software update process. The software is compatible with Windows 7 and later operating systems.

NOTE

During the install process, if a Windows pop-up asking if 'filename.exe' is allowed to make changes to this computer, 'Yes' must be selected to enable the installation.

To initiate the software installation process, double click on the "Prodigy_vX_XX_XXX.exe" icon, shown in Figure 36, which is provided as part of the Prodigy Sleep Monitor software distribution. The program is: "Prodigy_vX_XX_XXX.exe", where the X represents specific version numbers of the software.

Figure 36 – Prodigy Sleep Monitor Application Icon for Installation

Depending on your settings, one or more "Open File – Security Warning" windows may appear after initiating the installation process. In each instance, select Run. A Microsoft Windows message may appear asking if you want to allow the following program from an unknown publisher to make changes to this computer. Select "Yes" if you wish to proceed with the installation.

A window will appear asking if you want to install the Prodigy Sleep Monitor, as shown in Figure 37. Select "Yes" to proceed with the installation.

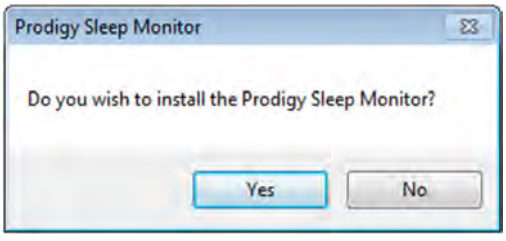


Figure 37 – Prodigy Sleep Monitor Application Installation Prompt Window

A WinZip Self-Extractor will appear as shown in Figure 38 and will begin unzipping the following programs that are required for installation:

- Microsoft .NET Framework 4.5;
- Microsoft Visual C++ 2010 x86 Redistributable.
- The Prodigy Sleep Monitor installer

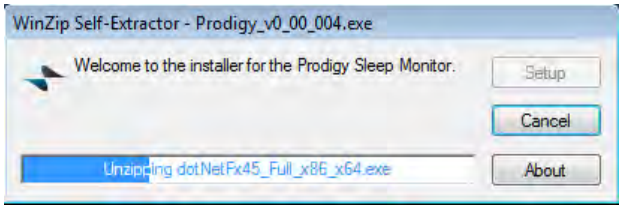


Figure 38 – Prodigy Sleep Monitor Application WinZip Self-Extractor Window

If the target PC has all of the above-listed programs installed, the Prodigy Setup Wizard shown in Figure 45 will appear. If the target PC does not have all of the above-listed programs installed, the Prodigy Sleep Monitor setup process will attempt program installation automatically. In each case, the user will be required to read and accept license terms, and confirm installation. For example, if the target PC does not have Microsoft® .NET Framework 4.5 and Microsoft® Visual C++ 2010 installed, the following messages shown in Figure 39 through Figure 44 will appear.

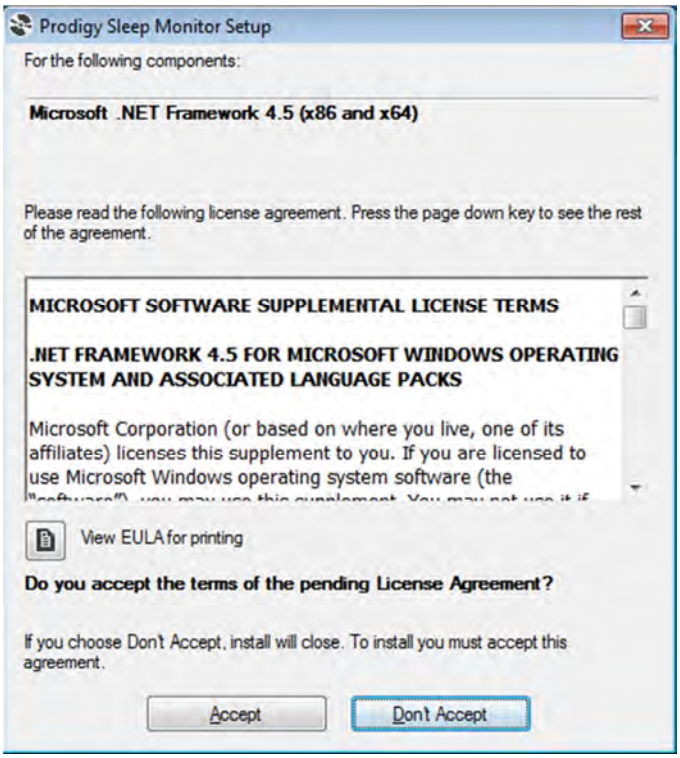


Figure 39 – Prodigy Sleep Monitor Application Microsoft .NET Framework 4.5 License Agreement Window

A Microsoft window will appear asking the user to accept the install of the .NET Framework. Once "Accept" has been selected, the Prodigy Setup window shown in Figure 40 will appear.

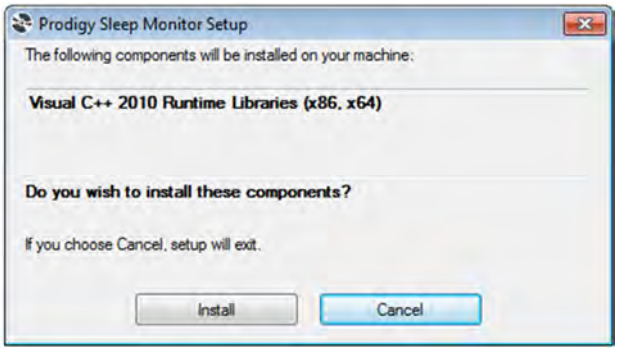


Figure 40 – Prodigy Sleep Monitor Application Visual C++ 2010 Installation Prompt Window

Select "Install." This installs the Microsoft® Visual C++ 2010 component libraries. If this does not happen automatically – i.e. if the window does not appear as shown in Figure 41– run the installation manually after completing the Prodigy software installation by double clicking on the file "vcredist_x86.exe" that was included in the Prodigy installation package and proceed as described below.

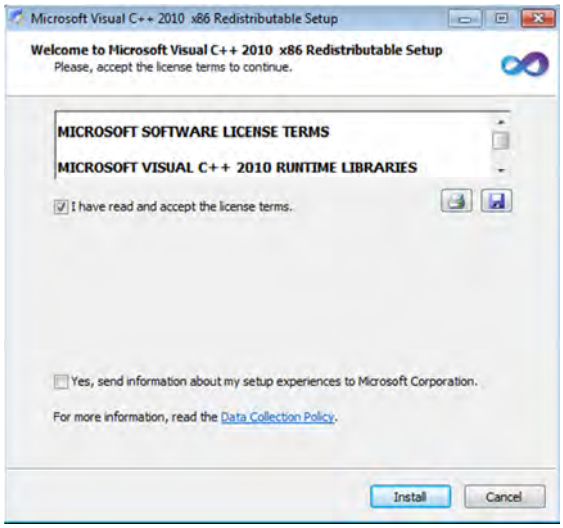


Figure 41 – Prodigy Sleep Monitor Application Visual C++ 2010 License Terms Window

Click on the "I have read and accept the license terms" checkbox, and then click on the "Install" button. The installation progress will be displayed as shown in Figure 42.

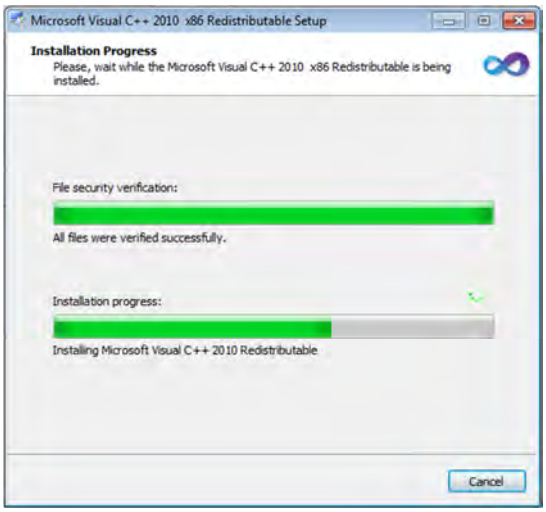


Figure 42 – Prodigy Sleep Monitor Application Installation Progress Window for Visual C++ 2010

After installation of C++ is complete, the screen will appear as shown in Figure 43. Select "Finish."

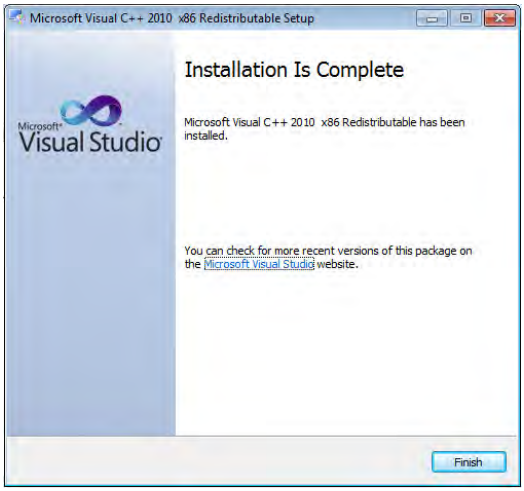


Figure 43 – Prodigy Sleep Monitor Application Visual C++ 2010 Installation Complete Window

After the Microsoft® Visual C++ 2010 component libraries are installed, the installer will automatically install the .NET Framework. The window shown in Figure 44 will be displayed while it is being installed.

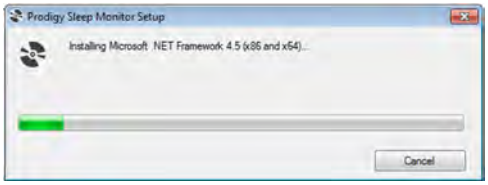


Figure 44 – Prodigy Sleep Monitor Application Installation Progress Window for .NET Framework

The Prodigy Setup Screen will open up next, as shown in Figure 45. Select “Next.”

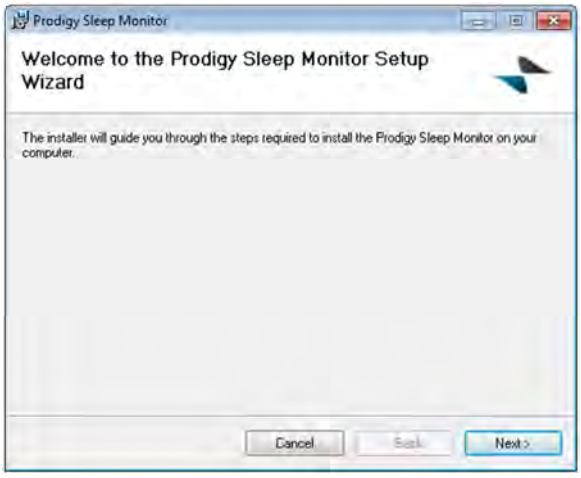


Figure 45 – Prodigy Sleep Monitor Application Welcome Window

A window displaying a License Agreement will open, as shown in Figure 46. Read the agreement and select “I Agree,” then “Next” to proceed with the installation. Note that the License Agreement may not be written as shown in Figure 46, and furthermore, may be provided as a separate document that the end user must sign and return to YMT prior to being able to complete the installation of the Prodigy Sleep Monitor application.

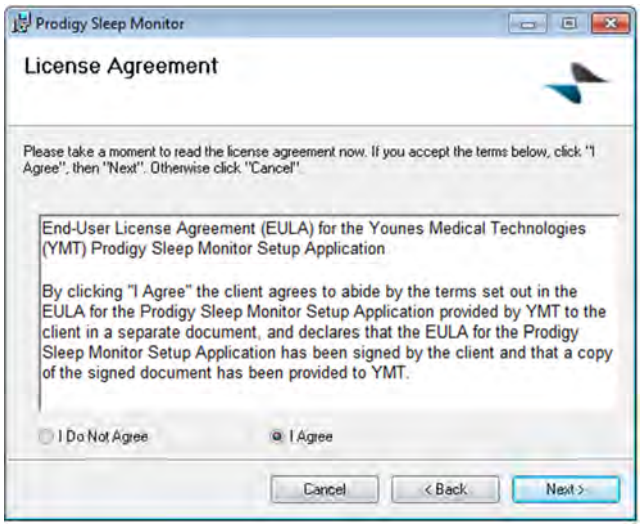


Figure 46 – Prodigy Sleep Monitor Application License Agreement Window

Once “Next” is selected, the installer will prompt you to choose an installation folder. For the installation folder dialog, shown in Figure 47, it is recommended to choose “Everyone” and to keep the default location as is for all installations. Choosing “Everyone” will allow any user account on the computer to

access the Prodigy Sleep Monitor application. Choosing "Just me" will only allow the Prodigy Sleep Monitor application to be utilized by the same account used in installation.

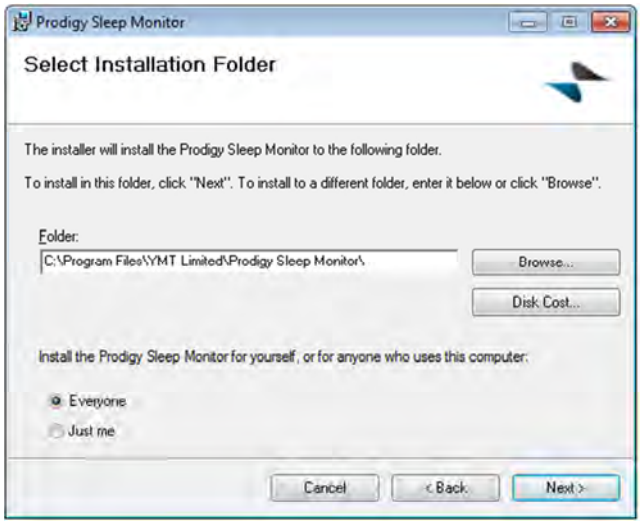


Figure 47 – Prodigy Sleep Monitor Application Select Installation Folder Window

The Autostart service will automatically detect when a Prodigy Sleep Monitor has been plugged into the PC, and will promptly launch the application. This is an optional service, and you may choose whether or not to install it as per Figure 48. Once you have made your selection select "Next" to proceed.

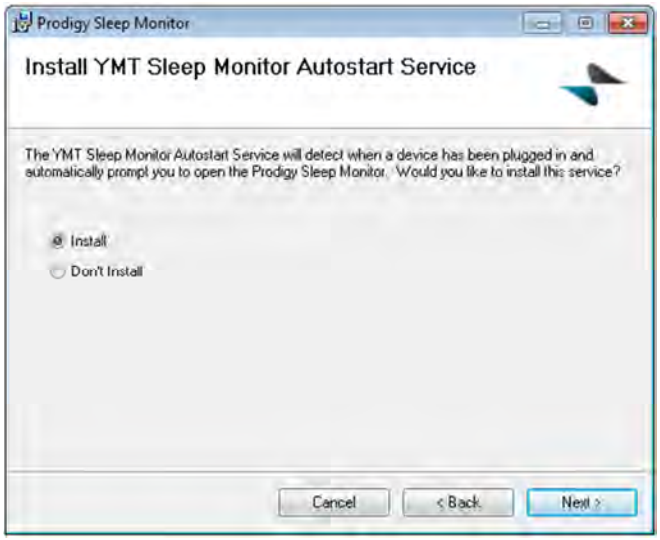


Figure 48 – Prodigy Sleep Monitor Application Autostart Service Window

Once the installation has been configured, a Confirm Installation dialog will be shown as per Figure 49. Select "Next" to proceed.

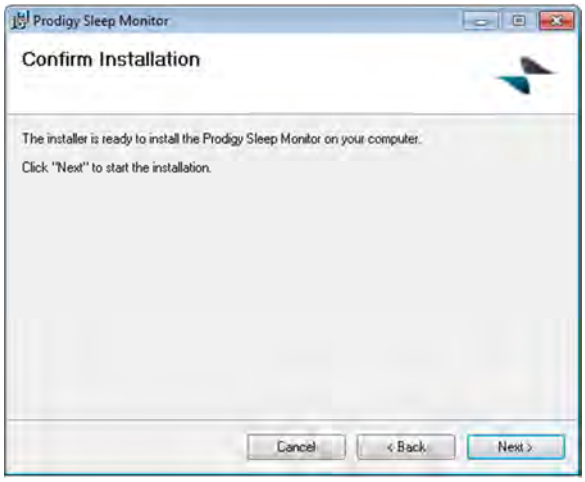


Figure 49 – Prodigy Sleep Monitor Application Confirm Installation Window

You will then see a progress bar indicating the installation status as shown in Figure 50.

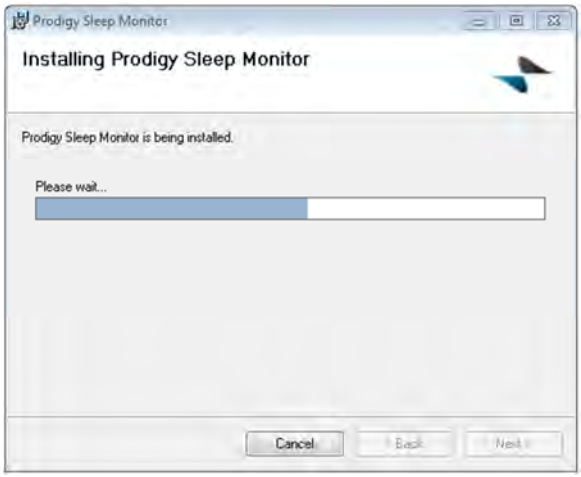


Figure 50 – Prodigy Sleep Monitor Application Installation Progress Window

Once installation has completed a message box will appear, as shown in Figure 51, and the installation dialog will show installation complete, as shown in Figure 52.

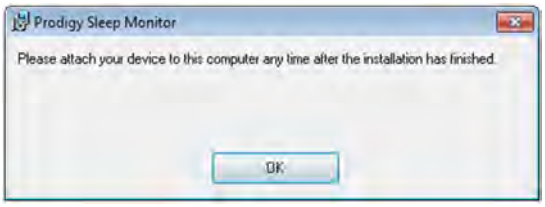


Figure 51 – Prodigy Sleep Monitor Application When To Attach Your Device Notification Window

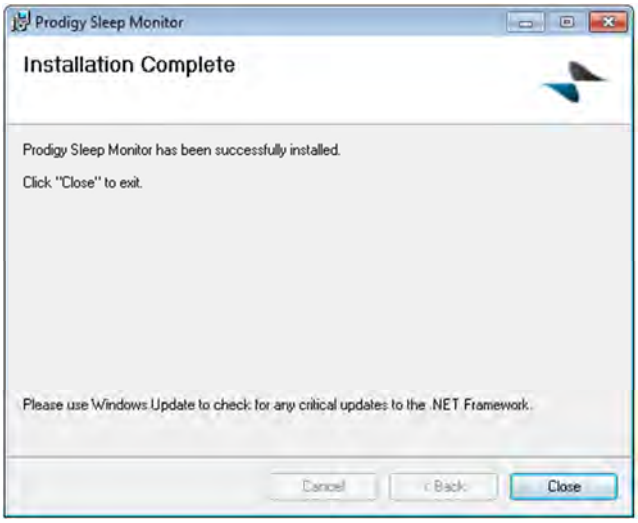


Figure 52 – Prodigy Sleep Monitor Application Installation Complete Window

After closing you will be prompted to restart you PC, as shown in Figure 53. The application may not function correctly if launched before restarting.

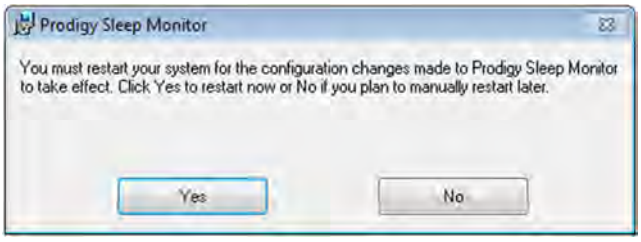


Figure 53 – Prodigy Sleep Monitor Application Restart Window

The Prodigy Sleep Monitor application should then appear as an icon on the desktop, as shown in Figure 54.

Figure 54 – Prodigy Sleep Monitor Application Icon

NOTE

Do not attempt to start the Prodigy Sleep Monitor application yet. Continue with the installation process described below.

As described earlier, the Prodigy Sleep Monitor setup process will attempt to automatically install each program that is required to use the Prodigy Sleep Monitor application. To determine whether the programs have installed automatically follow these steps:

1) Go to “Add or Remove Programs” in the Control Panel.
2) Review the “Currently installed programs” list to determine whether all of the following software is listed. Any program that is not listed will need to be installed from the Prodigy Sleep Monitor installation disk.
    a. Prodigy Sleep Monitor
    b. Microsoft .NET Framework 4.5
    c. Microsoft Visual C++ 2010 Redistributable

If any of these are missing, uninstall the others and run the installer again. After this is done, repeat steps (1) and (2) to ensure that the programs are installed correctly. If the install fails multiple times, contact YMT support.

Once all programs are correctly installed, the Prodigy Sleep Monitor application is ready to be launched. To launch the Prodigy Sleep Monitor application, either double click on the Prodigy Sleep Monitor icon shown in Figure 54 – Prodigy Sleep Monitor Application Icon, or access the Prodigy Sleep Monitor through the Windows Start menu, where the Prodigy Sleep Monitor should be contained within a folder labeled “YMT Limited” which also contains shortcuts to the uninstaller, the release notes, and the User Manual.

Software Update Instructions

Periodically, YMT will update the Prodigy Sleep Monitor application. These updates will not be available until you have entered your login information into the Prodigy Sleep Monitor application. Once your information had been entered, by default, these updates will be downloaded onto your computer automatically from YMT servers whenever an update is available. To submit your information follow the steps below.

1. Launch the Prodigy Sleep Monitor application and click the “Settings” button highlighted in Figure 55.

Figure 55 – Windows PC Prodigy Application Screen With "Settings" Button Highlighted

2. Click the "Automatic Updates" button highlighted in Figure 56.

Figure 56 – Windows PC Prodigy Application Screen With "Automatic Updates" Button Highlighted

3. Enter the YMT Login ID and password provided by YMT in the black boxes highlighted in Figure 57.

Figure 57 – Windows PC Prodigy Application Login Screen

If your facility utilizes a proxy server, click on the "No" button in Figure 57. Upon clicking "No," the button will change to "Yes" and additional information will become available, as shown in Figure 58.

Figure 58 – Windows PC Prodigy Application Login Screen (Connecting Through Proxy Server)

4. Once your information has been entered, select the "Test" button to login. If your information is received, a green check mark will appear on the screen if your information.

By default, updates are automatic. This feature can be disabled by clicking the "YES" button highlighted in Figure 59.

Figure 59 – Windows PC Prodigy Application Screen With "YES" Button Highlighted

If the automatic updates feature is disabled, the user can follow steps 1-3 and then select the "Check for Updates" button to find out about updates. If the automatic updates feature is not disabled and an update is downloading, it will be indicated by an alert in the user's bottom right corner of their monitor, as shown in Figure 60.

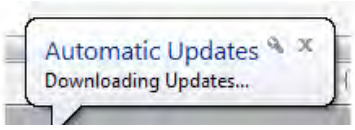


Figure 60 – Prodigy Sleep Monitor Application Automatic Updates Notification

Once the update has finished downloading, a window will appear on the user's monitor as shown in Figure 61. Select "OK" and close the Prodigy Sleep Monitor application. Users will notice a window appear asking if they wish to install the new Prodigy Sleep Monitor, as shown in Figure 62. Select "Yes," and the installation of the new Prodigy Sleep Monitor will commence.

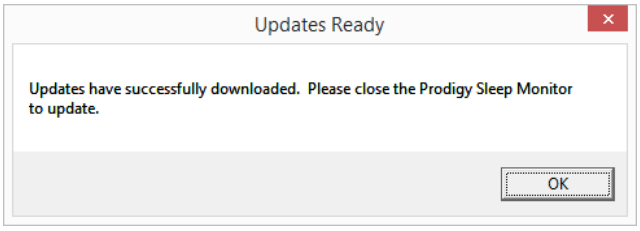


Figure 61 – Prodigy Sleep Monitor Application Updates Ready Window

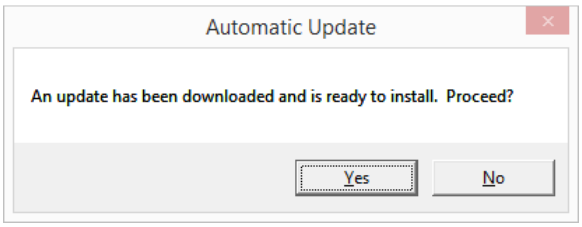


Figure 62 – Prodigy Sleep Monitor Application Automatic Update Window

Figure 63 shows the software gathering information about the current version and tools that are currently loaded on the computer. During this step you may be prompted to close the USB service, as shown in Figure 64; if you are, select the first option and click "Ok." You may also be prompted to restart your PC, as shown in Figure 65; if this happens, select "No."

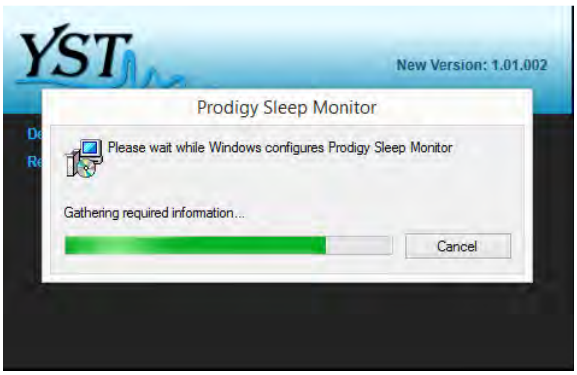


Figure 63 – Prodigy Sleep Monitor Application Gathering Information Window

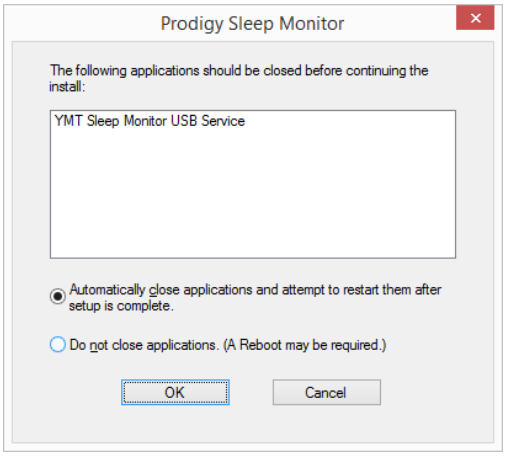


Figure 64 – Prodigy Sleep Monitor Application Close USB Service Window

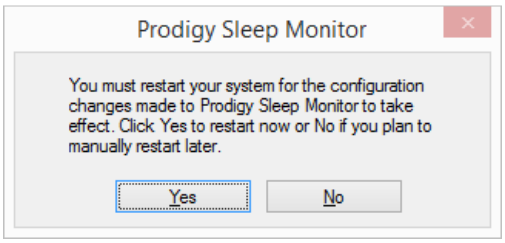


Figure 65 – Prodigy Sleep Monitor Application Prompt Window 5

Figure 66 shows the window that will appear when the old version of the software has been removed and the updated version is being installed. At this point a window may pop up asking you to approve the installation of the software. Select "Yes" to proceed.

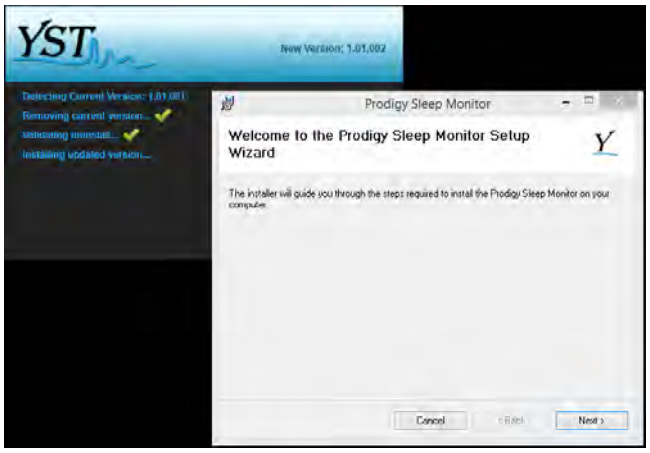


Figure 66 – Prodigy Sleep Monitor Application Setup Wizard Window

The Prodigy Sleep Monitor Setup Wizard Window will appear as indicated in Figure 66. Select "Next" to proceed. The installation of the new Prodigy Sleep Monitor will follow the steps shown in the original install procedure, indicated between Figure 45 and Figure 53. When prompted to restart the PC click "No" (you may click "Yes" if you do not wish to view release notes at this time).

A final status window will appear, as shown in Figure 67. This window provides the user the option of viewing the release notes pertaining to the update installed. Release notes can also be viewed in the Prodigy Sleep Monitor Application. The PC will now need to be manually restarted.

Figure 67 – Prodigy Sleep Monitor Application Final Status Window

On rare occasions, critical software updates may be required. End users are required to implement these updates immediately. End users will receive a message that an update is available when a critical update is required. When a critical update is available, core features are disabled until the update is installed.

Data Retrieval

The instructions in this section are for authorized service personnel only.

Retrieving the data stored on the Monitor after a sleep study is to be done by an authorized service provider using a computer with the PC Application for the Prodigy System installed. It is important to note that this function is only intended for use by trained personnel in lab settings, and if a patient attempts to plug the Monitor into any electronic device capable of receiving input from a micro-USB cable, no interaction with the Monitor will be possible.

There are two modes that can be used to retrieve data from the Monitor: Wizards and Advanced User Mode.

Wizards Mode

The “Wizards” mode is the first of two modes that can be used to retrieve data, amongst other things. This mode is slower than the “Advanced User” mode, but there is more guidance and explanation associated with your choices.

1. Put on protective disposable gloves.
2. Connect the power supply to the Monitor and power the device on.
3. Connect the micro-USB cable to the Monitor USB port and the other end to the Windows PC.
4. Open the Windows PC Prodigy application. The application window shall appear as shown in Figure 68.

Figure 68 – Windows PC Prodigy Application Start Screen (Connected)

Ensure the Windows PC Prodigy application is connected to the Monitor by checking the connection status. If the Monitor is not turned "On" or not connected with the USB cable to the computer, the application window shall appear as shown in Figure 69.

Figure 69 – Windows PC Prodigy Application Start Screen (No Device)

Once the Monitor is "On" and connected to the computer, the application shall appear as shown in Figure 68. If you wish to manually disconnect the Monitor from the computer, click the "Yes"

button. The application window shall appear as shown in Figure 70. To reconnect the device simply click the “No” button and the screen will appear as shown in Figure 68.

Figure 70 – Windows PC Prodigy Application Start Screen (Disconnected)

5. Once connected, select “Download Study” shown highlighted in Figure 71.

Figure 71 – Windows PC Prodigy Application Screen With “Download Study” Button Highlighted

6. The application window shall appear as shown in Figure 72. The “Download Study Wizard” can also be accessed through selecting “Wizards” and then selecting “Download Study Wizard.” Read the

information shown on the screen and then click “Start” in the bottom right corner when you are ready to begin.

Figure 72 – Windows PC Prodigy Application Introduction Screen (Download Study Wizard)

7. As shown in Figure 73, a list of patients on the device will be displayed. Select the patient that has a study you wish to download, and click “Next”.

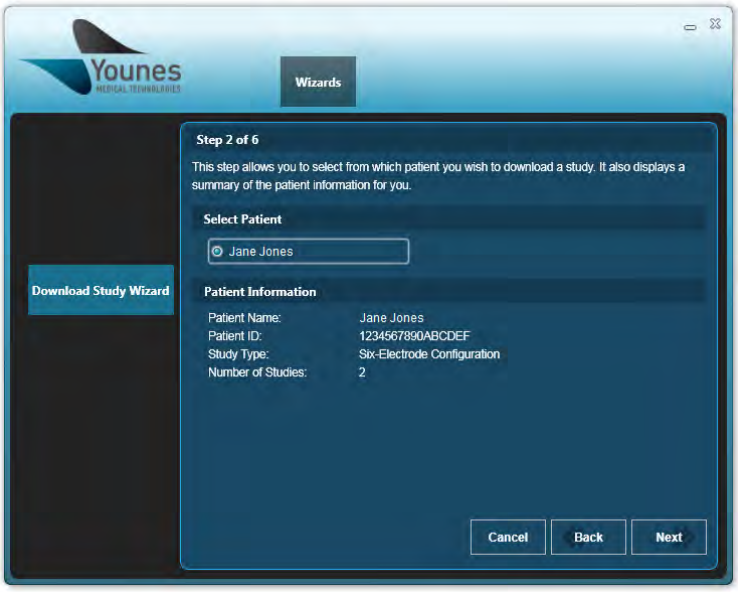


Figure 73 – Windows PC Prodigy Application Patient Information Screen (Download Study Wizard)

8. As shown in Figure 74, a list of studies associated with the patient you selected will be displayed. Select the study you wish to download, and click “Download”. This will provide you with the ability to select where to save the file, shown in Figure 75. While a download is in progress, you will be unable to navigate to another section of the PC Application. Download progress is shown after a file location has been chosen, as shown in Figure 76.

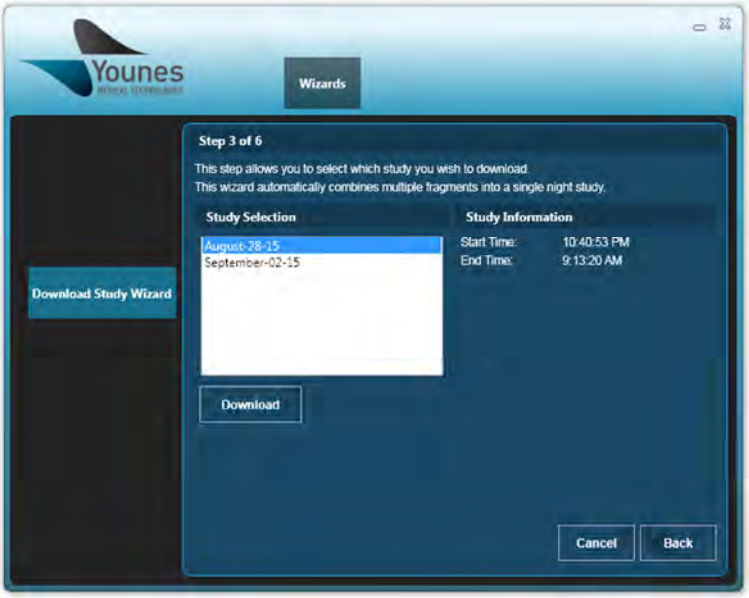


Figure 74 – Windows PC Prodigy Application Study Selection Screen (Download Study Wizard)

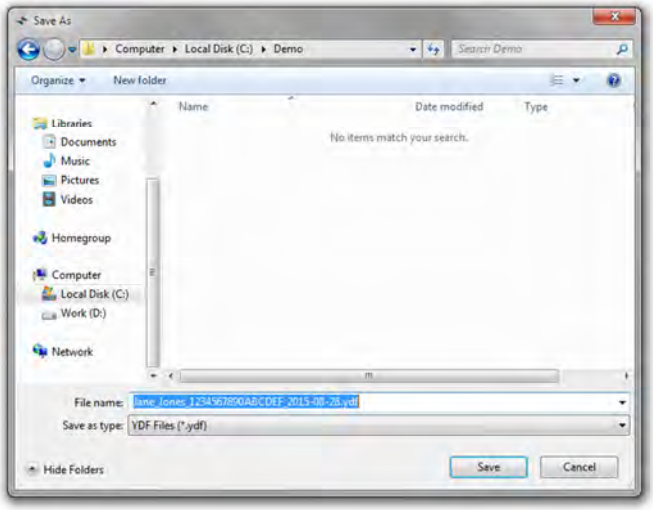


Figure 75 – Windows PC Prodigy Application File Save As Screen

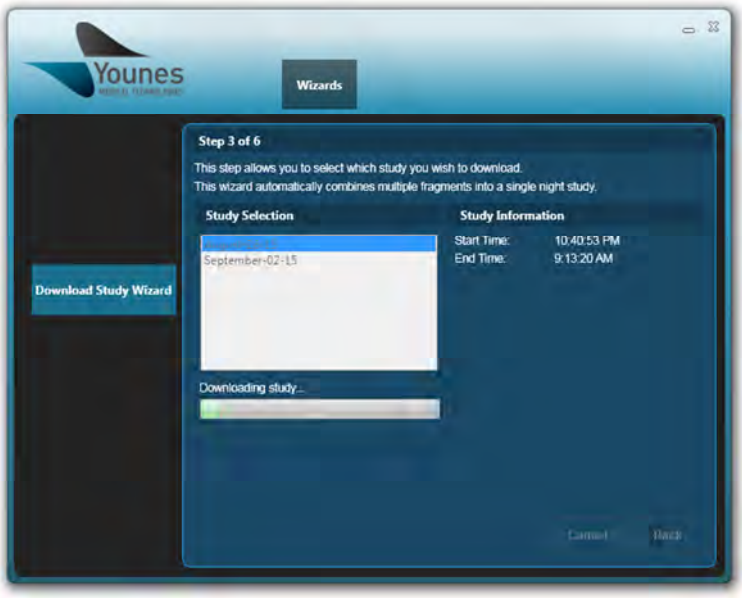


Figure 76 – Windows PC Prodigy Application Download Progress Screen (Download Study Wizard)

9. Once the study has finished downloading, you will be asked if you want to combine the downloaded study with a separate file, as shown in Figure 77.

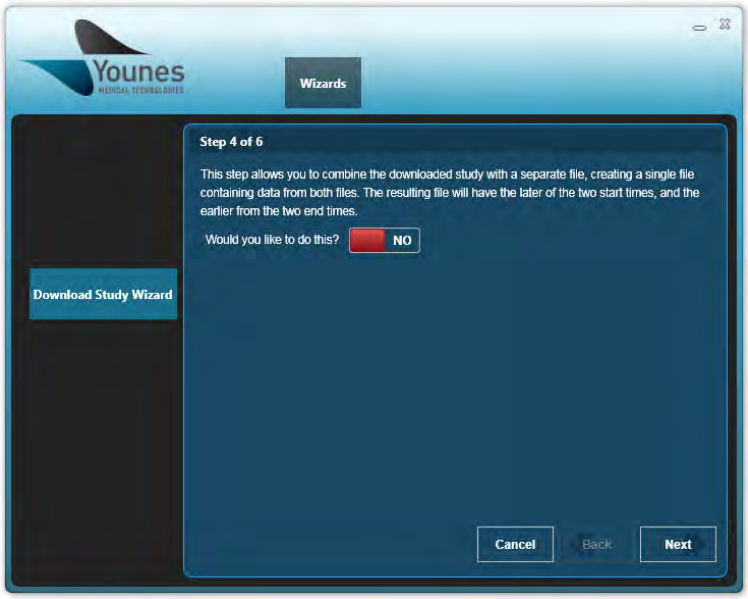


Figure 77 – Windows PC Prodigy Application Don't Combine Studies Screen (Download Study Wizard)

If you do not wish to combine the downloaded study with a separate file, click "Next." However, if you do wish to combine the downloaded study with a separate file, click the "No" button so that

the button says “Yes.” The application screen shall appear as shown in Figure 78 if the “No” button is selected.

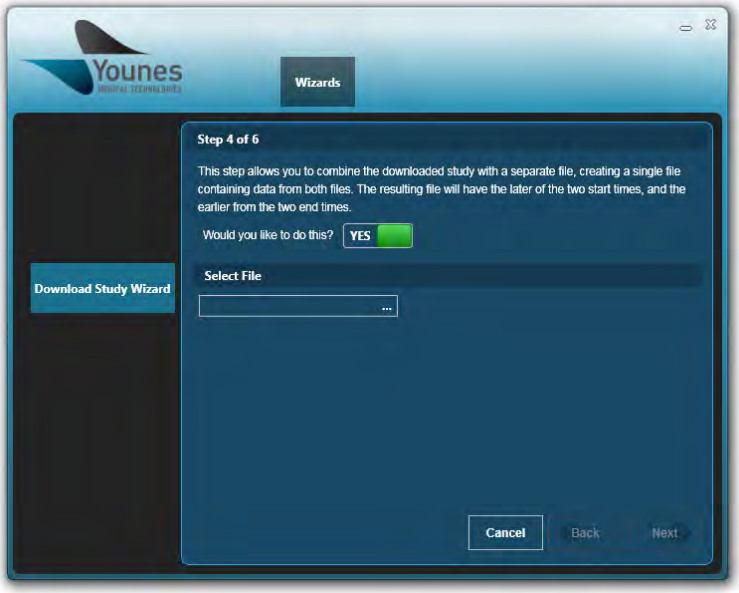


Figure 78 – Windows PC Prodigy Application Combine Study Screen (Download Study Wizard)

To select a file, click anywhere in the rectangle highlighted in Figure 79. A window will appear like that shown in Figure 80, which provides you with the ability to open a sleep study file.

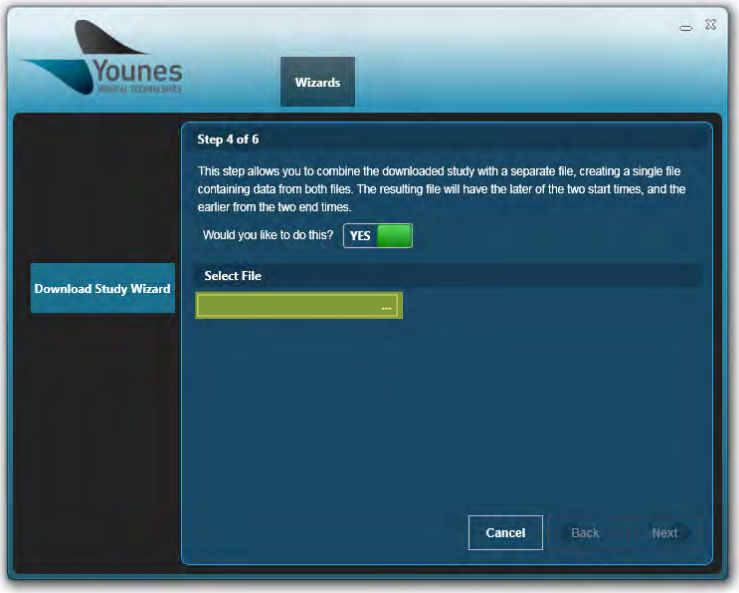


Figure 79 – Windows PC Prodigy Application Screen With “Select file” Box Highlighted (Download Study Wizard)

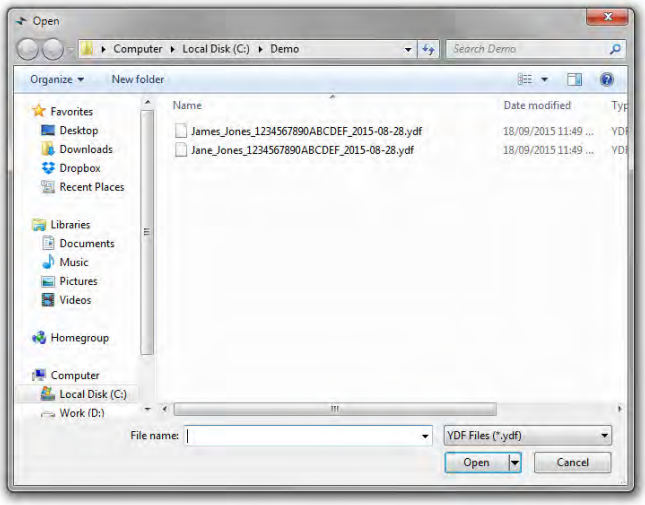


Figure 80 – Windows PC Prodigy Application File Open Screen

If the files cannot be successfully combined, the screen will appear as shown in Figure 81. If there is another study you wish to combine the current downloaded study with, you can try to download a different study by clicking anywhere in the rectangle highlighted in Figure 79. If there is no other study you wish to combine the current downloaded study with, you must click “Cancel” and repeat steps 6-8 in this manual.

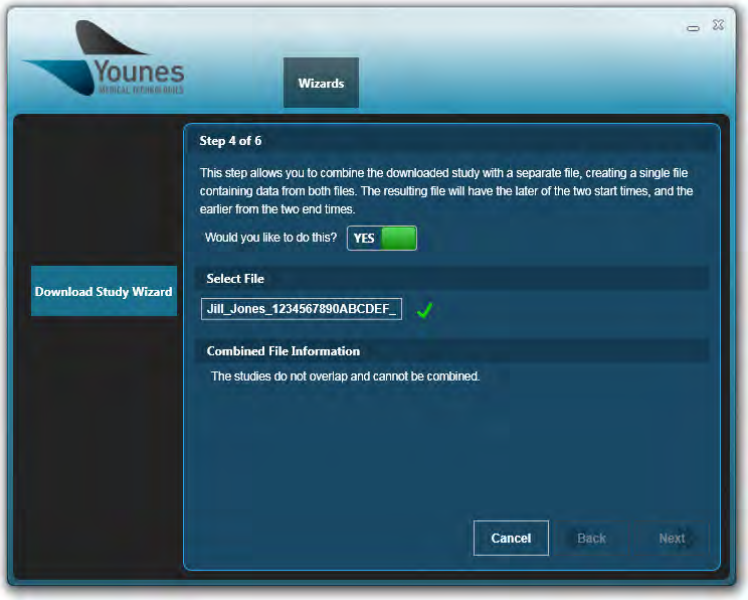


Figure 81 – Windows PC Prodigy Application Combine Study Failure Screen (Download Study Wizard)

If the files can be successfully combined, the screen will appear as shown in Figure 82. Click “Combine” to continue.

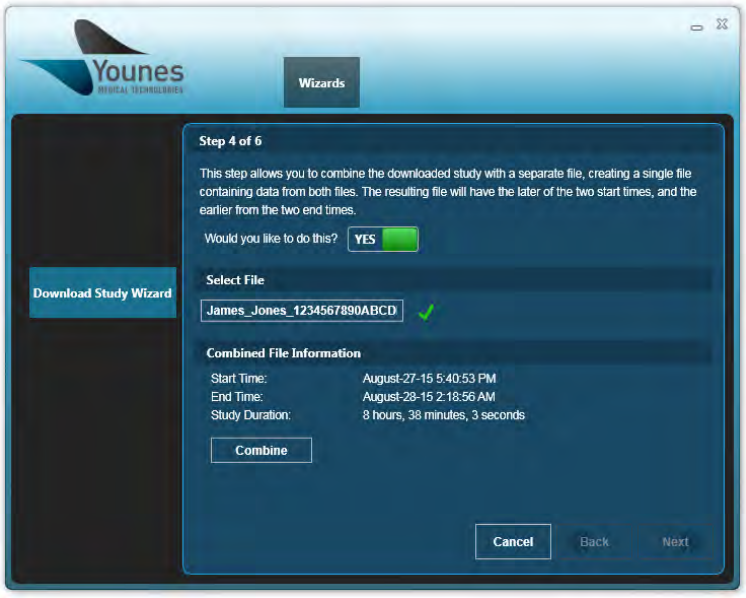


Figure 82 – Windows PC Prodigy Application Successfully Combined Study Screen (Download Study Wizard)

10. Once the study has been downloaded and combined (optional), you will be provided an opportunity to review the data, as shown in Figure 83. You can progress through the study by either using the mouse wheel or the scroll bar located below the study data.

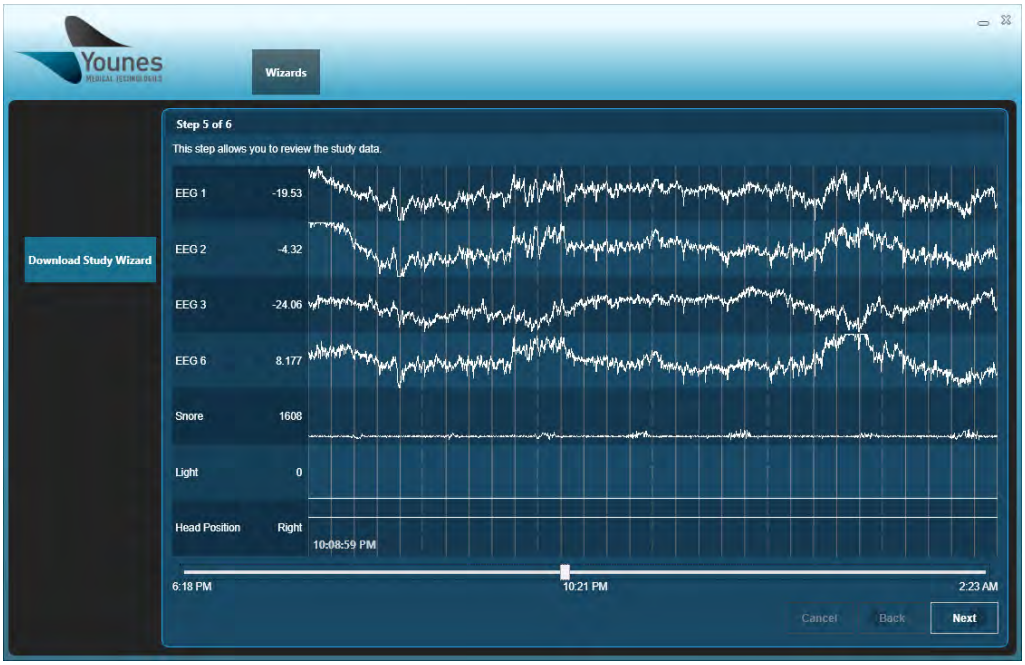


Figure 83 – Windows PC Prodigy Application Data Screen (Download Study Wizard)

11. Once you have finished reviewing the study, click “Next,” which advances to the final screen, shown in Figure 84.

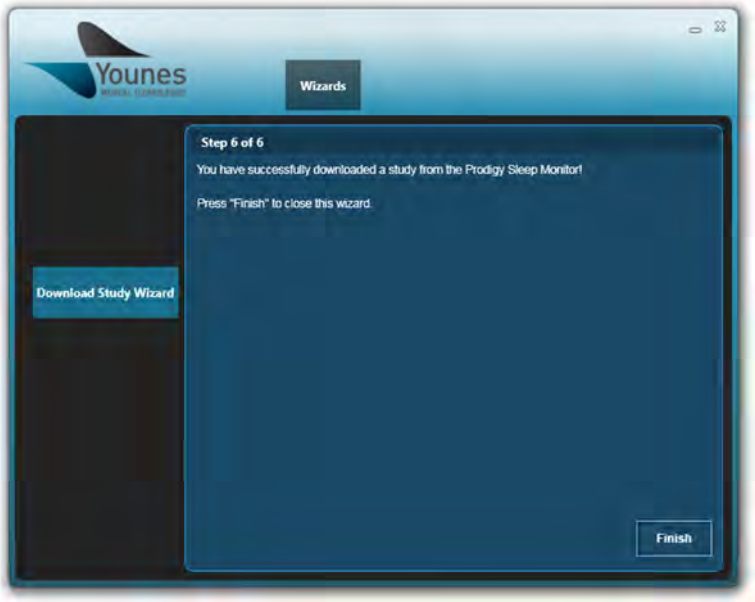


Figure 84 – Windows PC Prodigy Application Download Complete Screen (Download Study Wizard)

12. Click “Finish” to unlock access to the other functionality of the PC Application.

Advanced User Mode

The “Advanced User” mode is the second of two modes that can be used to retrieve data, amongst other things. This mode is quicker to use than the “Wizards” mode as there is less guidance and explanation associated with your choices.

1. To access “Advanced User” mode, first follow steps 1-4 (starting on page 52) and then click the “Settings” button highlighted in Figure 68.
2. Next, select the “No” button to the right of “Enable Advanced User Mode” in Figure 85.

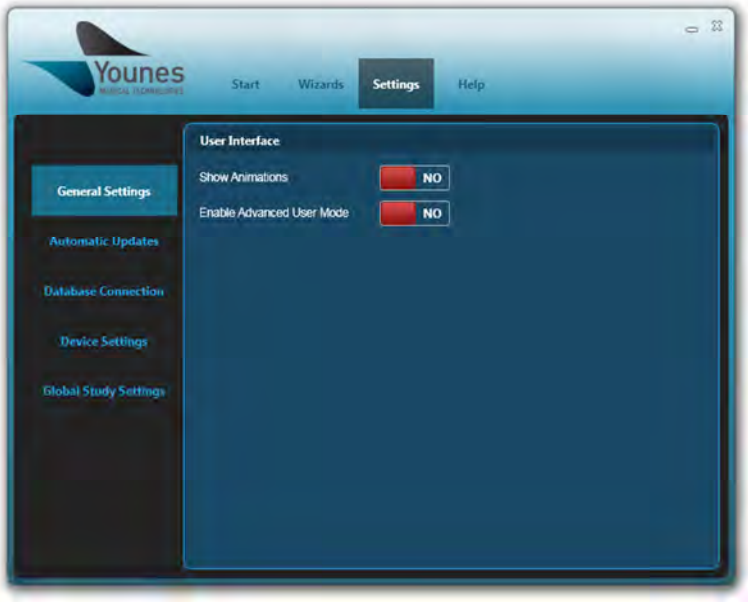


Figure 85 – Windows PC Prodigy Application User Interface Screen (General Settings)

3. Upon clicking "No," the button will change to "Yes," as shown in Figure 86. Click the "Advanced User Mode" button highlighted in Figure 86 to proceed to the "Advanced User" mode tools.

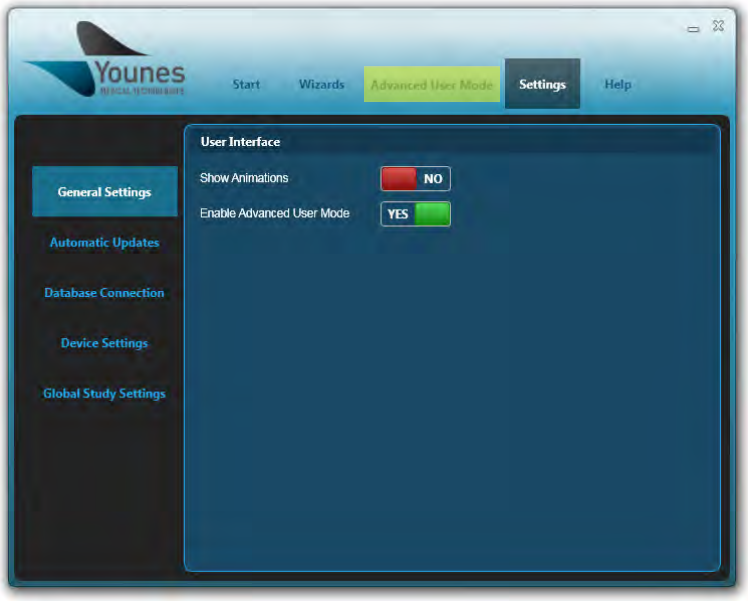


Figure 86 – Windows PC Prodigy Application Screen With "Advanced User Mode" Button Highlighted (General Settings)

4. Select the "Manage Studies" button highlighted in Figure 87.

Figure 87 – Windows PC Prodigy Application Screen With "Manage Studies" Button Highlighted (Manage Patients)

5. All patients on the device will be listed, as well as all studies associated with the selected patient, as shown in Figure 88. To download a study, select the "Download" button. If more than one study exists for a single patient, select the study you are interested in downloading before selecting "Download."

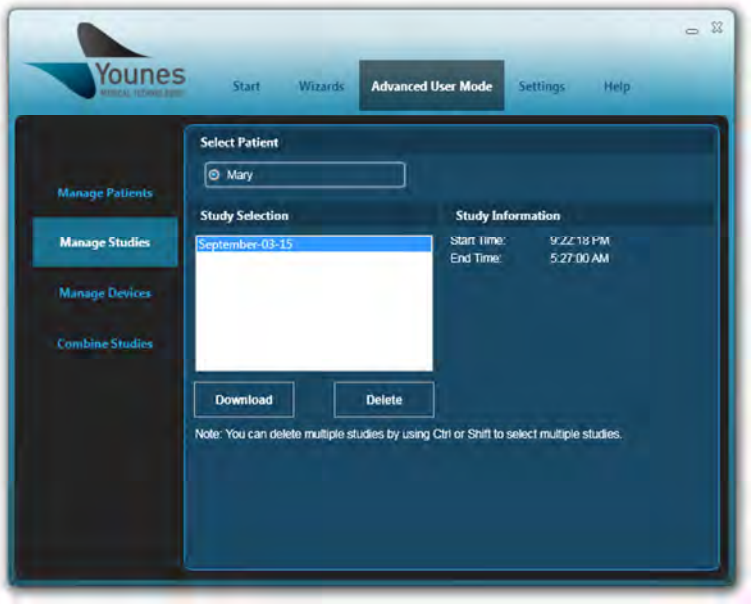


Figure 88 – Windows PC Prodigy Application Download Study Screen (Manage Studies)

6. A dialog box will appear providing you with the opportunity to select where to save the file and to choose the file name, as shown in Figure 75. Select "Save."

7. The Windows PC Prodigy application will display the progress of the download after a file location has been chosen, as shown in Figure 89.

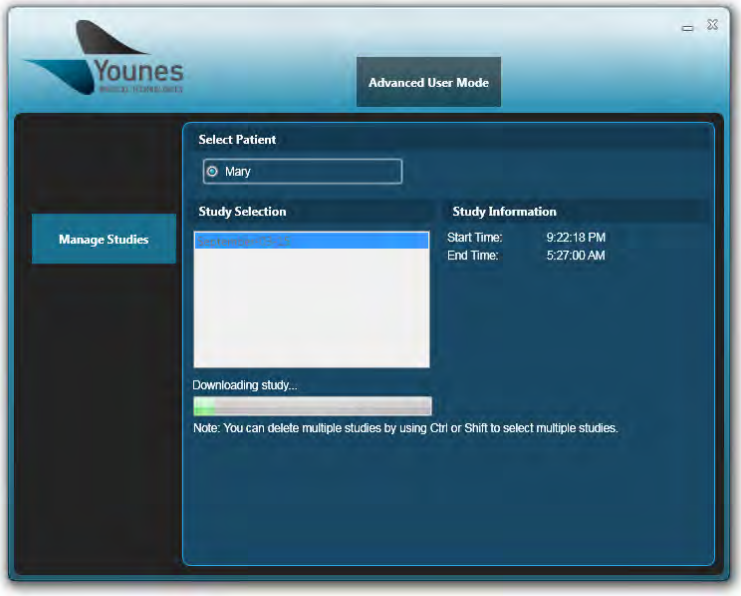


Figure 89 – Windows PC Prodigy Application Download Progress Screen (Manage Studies)

8. When the study has been successfully downloaded the screen will appear as shown in Figure 90.

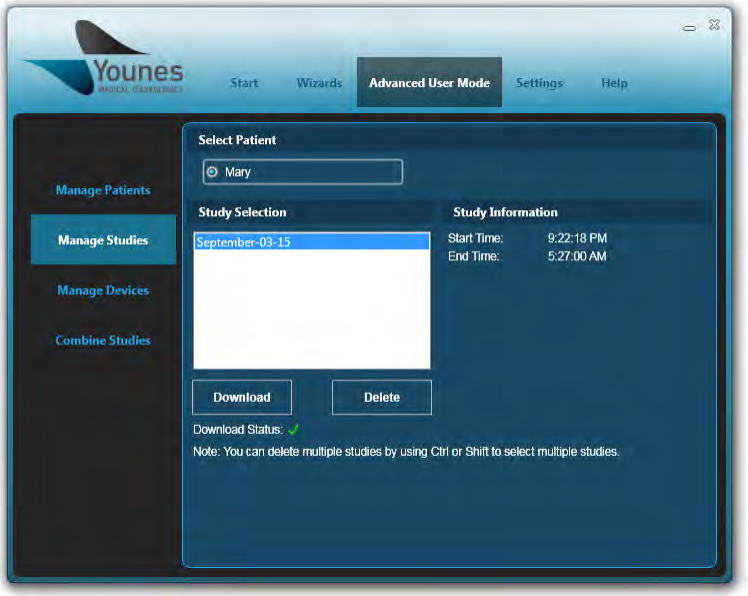


Figure 90 – Windows PC Prodigy Application Successful Download Screen (Manage Studies)

Viewing Data

The instructions in this section are for authorized service personnel only.

Viewing data can be achieved through downloading a study off of a Monitor with the "Download Study Wizard." This process was described in the Data Retrieval section of this Manual. Viewing data can also be achieved through loading an already downloaded study off of a computer with the "Review Study Wizard." This process will be described within this section.

1. To view a study, first follow steps 1-4 (starting on page 52) and then click the "Review Previously Downloaded Study" button highlighted in Figure 91.

Figure 91 – Windows PC Prodigy Application Screen With "Review Previously Downloaded Study" Button Highlighted

2. Read the information provided on the screen, then select the "Load Study" button highlighted in Figure 92.

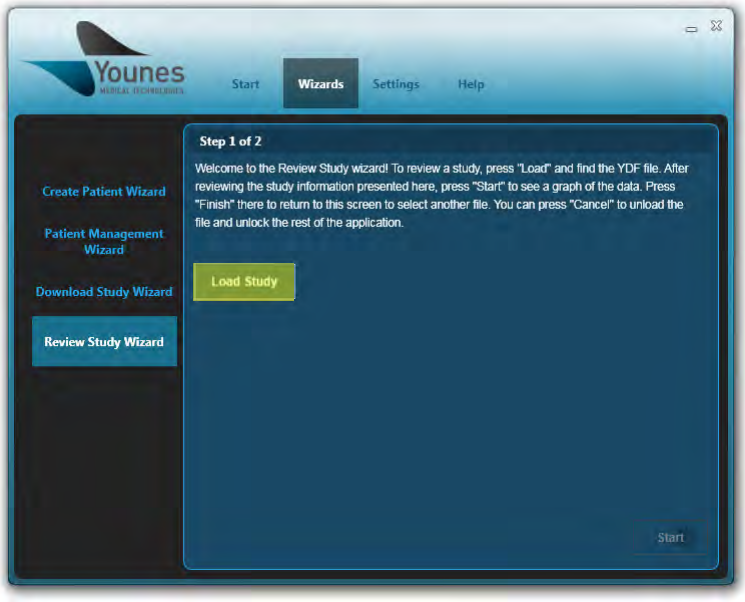


Figure 92 – Windows PC Prodigy Application "Load Study" Button Highlighted (Review Study Wizard)

3. A dialog box will appear providing you with the opportunity to choose the file you wish to see, as shown in Figure 80. Select a file and then select "Open."
4. The Windows PC Prodigy application will display all information associated with the study you selected, as shown in Figure 93. Select "Start" to view the file.

Figure 93 – Windows PC Prodigy Application Loaded Study Information Screen (Review Study Wizard)

5. The study will appear as shown in Figure 94. You can progress through the study by either using the mouse wheel or the scroll bar located below the study data.

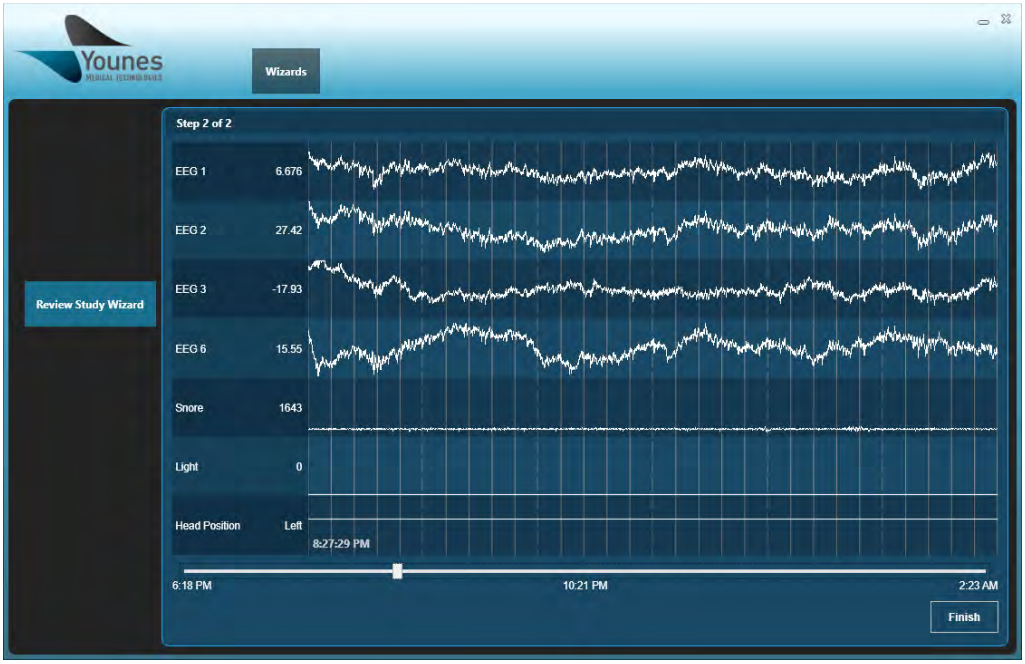


Figure 94 – Windows PC Prodigy Application Study Data Screen (Review Study Wizard).

6. When you are finished viewing the study, select “Finish” to unlock access to the other functionality of the PC Application.

Combining Data

The instructions in this section are for authorized service personnel only.

Two studies can be combined through the process of downloading a study off of a Monitor with the “Download Study Wizard.” This process was described in the Data Retrieval section of this Manual. Two studies can also be combined through loading two already downloaded studies off of a computer with the “Combine Studies” tool. This process will be described within this section.

1. If “Advanced User” mode is not activated, follow steps 1-3 (starting on page 61). If it is activated, select the “Advanced User Mode” button listed at the top of the Windows PC Prodigy application screen.
2. Select the “Combine Studies” button highlighted in Figure 95.

Figure 95 – Windows PC Prodigy Application Screen with "Combine Studies" Button Highlighted (Manage Patients)

3. Read the information provided on the screen. To select one of the files you would like to combine click anywhere within the box highlighted in Figure 96.

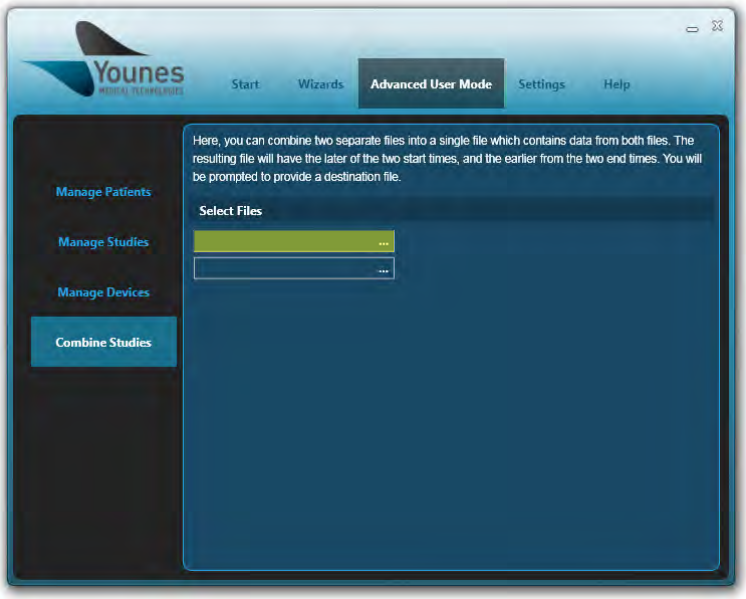


Figure 96 – Windows PC Prodigy Applications Screen With File Box 1 Highlighted (Combine Studies)

4. A dialog box will appear providing you with the opportunity to choose the file you wish to see, as shown in Figure 80. Select a file and then select "Open."
5. As shown in Figure 97, the name of the file you selected will appear in the box highlighted in Figure 96.

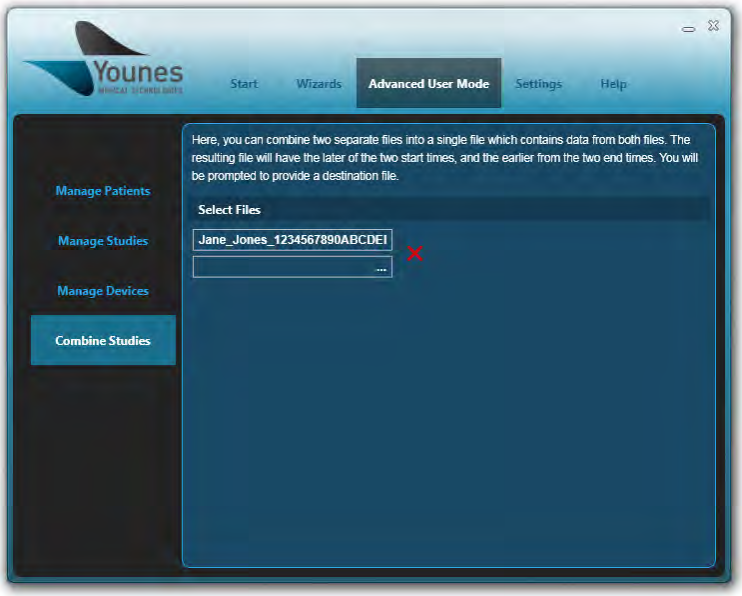


Figure 97 – Windows PC Prodigy Applications Screen With File 1 Uploaded (Combine Studies)

6. To select the second file you would like to combine with the first, click anywhere within the box highlighted in Figure 98.

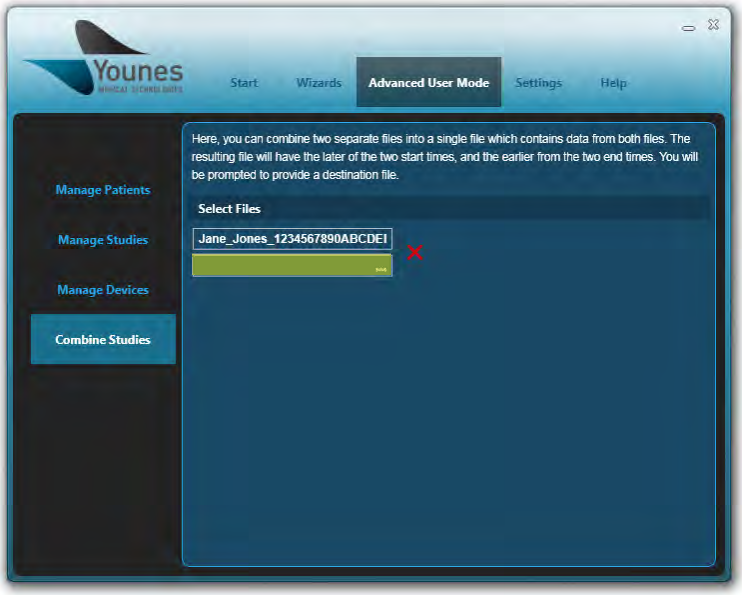


Figure 98 – Windows PC Prodigy Applications Screen With File Box 2 Highlighted (Combine Studies)

7. A dialog box will appear providing you with the opportunity to choose the file you wish to see, as shown in Figure 80. Select a file and then select “Open.”

8. If the files cannot be successfully combined, the screen will appear as shown in Figure 99. If there are other studies you wish to combine, click anywhere in the rectangles highlighted in Figure 96 and Figure 98 to replace the files.

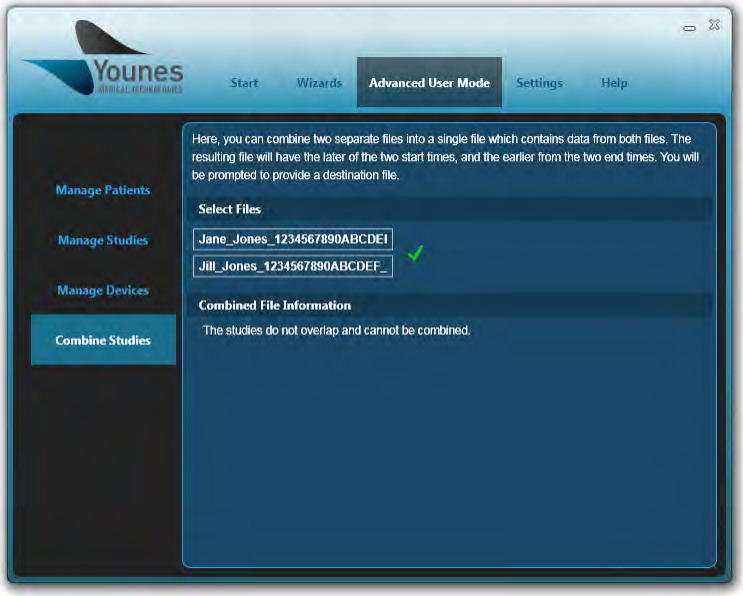


Figure 99 – Windows PC Prodigy Application Files Selected Fail To Overlap (Combine Studies)

If the files can be successfully combined, the screen will appear as shown in Figure 100. Select "Combine" to continue.

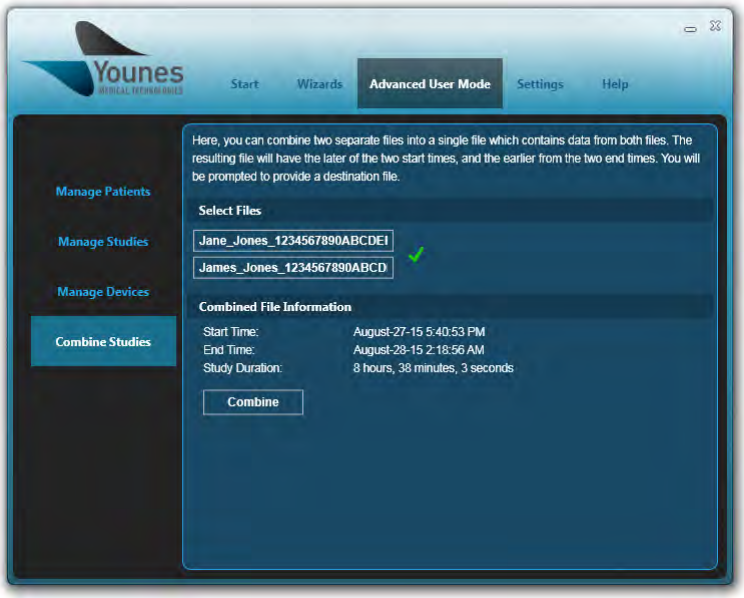


Figure 100 – Windows PC Prodigy Application Files Selected Overlap (Combine Studies)

9. A dialog box will appear providing you with the opportunity to choose where to save the combined file and to choose the file name, as shown in Figure 80. Choose a location and name for the file, then select "Save."
10. The Windows PC Prodigy application will display the progress of the studies being combined after a file location has been chosen, as shown in Figure 101.

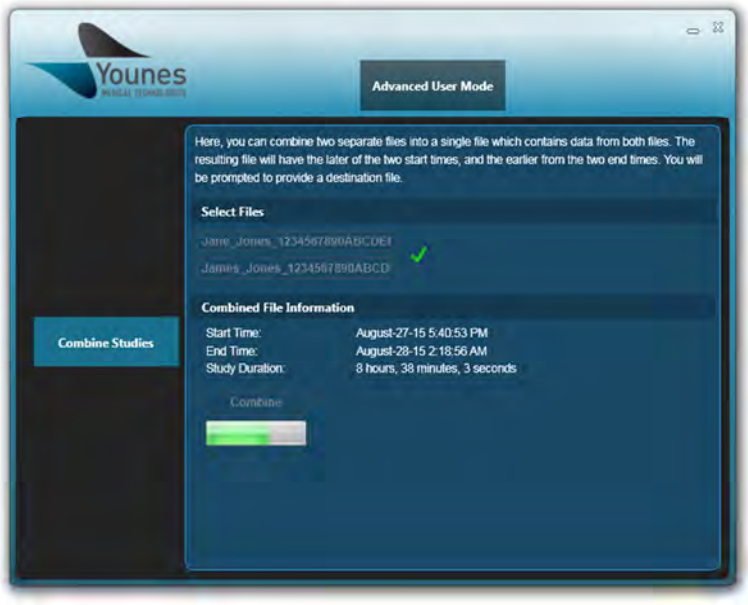


Figure 101 – Windows PC Prodigy Application Combination Progress Screen (Combine Studies)

11. When the combination is complete, the screen will appear as shown in Figure 102.

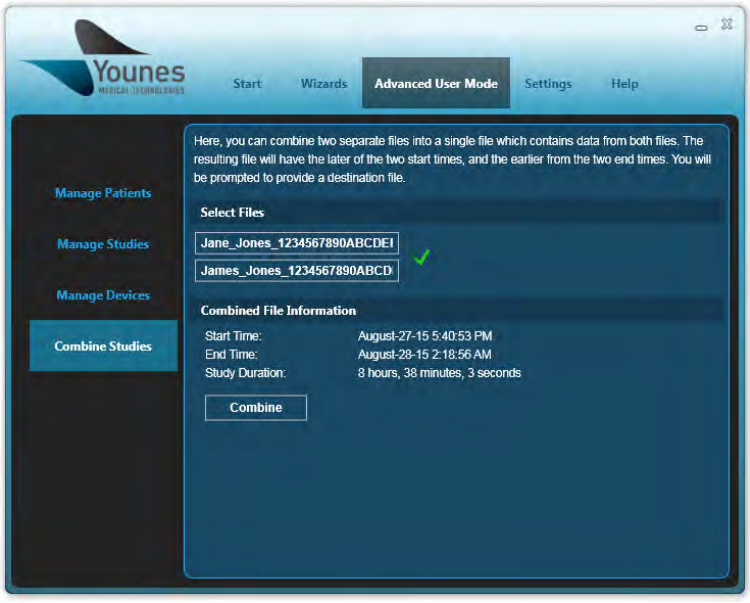


Figure 102 – Windows PC Prodigy Application Successful Combination Screen (Combine Studies)

4. Re-Processing

The Prodigy Sleep Monitor device 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, with the exception of replacing the batteries in the Head Sensor unit which may be done by the patient.

WARNING

Unauthorized personnel shall not open the device (other than the Head Sensor accessible battery compartment) 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 patients in a clean and disinfected condition, so there is no need for the patient 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.

EEG electrodes are designed for single use only and shall be discarded after use. Do not attempt to reprocess used electrodes. Additionally, 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 MSDS 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 Head Sensor, Monitor, 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 Head Sensor and Monitor are powered off. Additionally, open the battery compartment of the sensor by sliding the battery cover away from the device and remove the used AAA batteries. Disposal or recycling of used batteries shall be in compliance with local regulations. Disconnect the power supply from the Monitor before pre-cleaning.

Moisten a soft cloth with warm water and mild detergent and thoroughly wipe the Head Sensor, Monitor, 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

After pre-cleaning, the components must be cleaned. 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.

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 Head Sensor, Monitor, 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 Monitor (e.g. power input, USB connector) and the Head Sensor (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

After cleaning, the components must be disinfected. 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 patients in-hospital.

Wear protective disposable gloves and a mask during the disinfecting procedure. Wipe the Head Sensor, Monitor, 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, the components are to be quarantined and the service provider is to contact YMT.

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

Programming

The device must be programmed before sending home with each patient for a home sleep study. This is done through the Windows application software. There are two modes that can be used to program the Monitor: Wizards and Advanced User Mode.

Wizards Mode

The "Wizards" mode is the first of two modes that can be used to program the device for the next sleep study, amongst other things. This mode is slower than the "Advanced User" mode, but there is more guidance and explanation associated with your choices.

1. Before a patient can be added to a Monitor, all existing studies shall be removed. To remove patients from the Monitor, first follow steps 1-4 (in the "Wizards Mode" section) and then click the "Manage Patients" button highlighted in Figure 103.

Figure 103 – Windows PC Prodigy Application Screen With "Manage Patients" Button Highlighted

2. Once the "Manage Patients" button has been selected, the screen will appear as shown in Figure 104.

Figure 104 – Windows PC Prodigy Application "No" Introduction Screen (Patient Management Wizard)

3. Click the "No" button once you have read and understood the warning presented in Figure 104. Upon clicking "No," the button will change to "Yes," as shown in Figure 105. Click "Start" to begin.

Figure 105 – Windows PC Prodigy Application "Yes" Introduction Screen (Patient Management Wizard)

4. A list of patients will be provided on the screen, as shown in Figure 106. To delete a patient, select their name and click the "Delete" button.

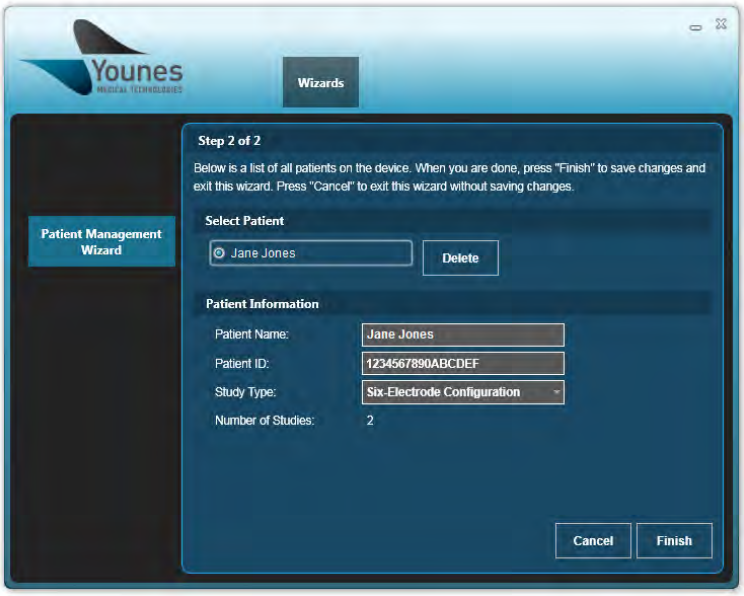


Figure 106 – Windows PC Prodigy Application List of Patients and Patient Information Screen (Patient Management Wizard)

5. If there are still patients on the Monitor, the screen will appear as shown in Figure 106 with a list of all patients that have not been deleted. As patients are deleted, their names will disappear from the list. Once all patients have been deleted, the screen will appear as shown in Figure 107. Select "Finish" to save your changes or "Cancel" to exit the wizard without saving your changes.

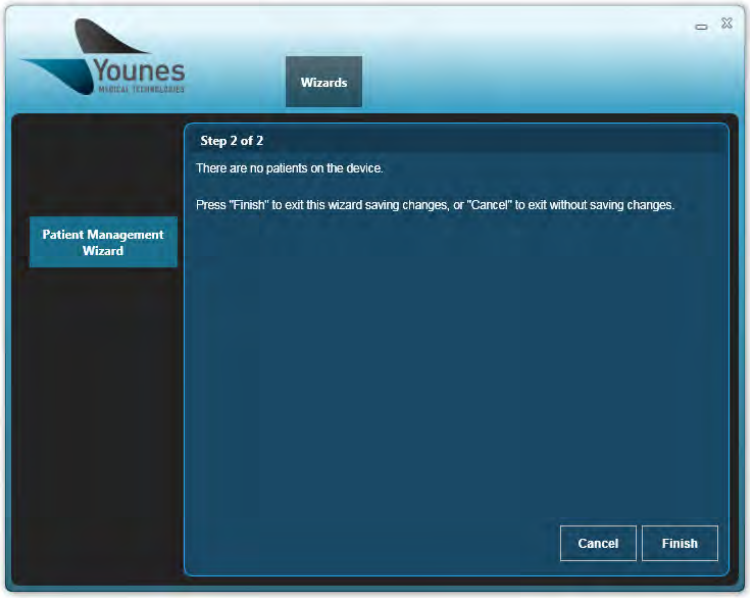


Figure 107 – Windows PC Prodigy Application No Patients Screen (Patient Management Wizard)

6. If either option is selected, you will be directed to the screen shown in Figure 108. Now that all patients have been removed from the Monitor, a patient can be added. Select the “Create Patient Wizard” button highlighted in Figure 108.

Figure 108 – Windows PC Prodigy Application Screen With “Create Patient Wizard” Button Highlighted (Patient Management Wizard)

7. Read the information on the screen. To load a support number onto the device and/or recalibrate the screen, click the “Edit” button highlighted in Figure 109.

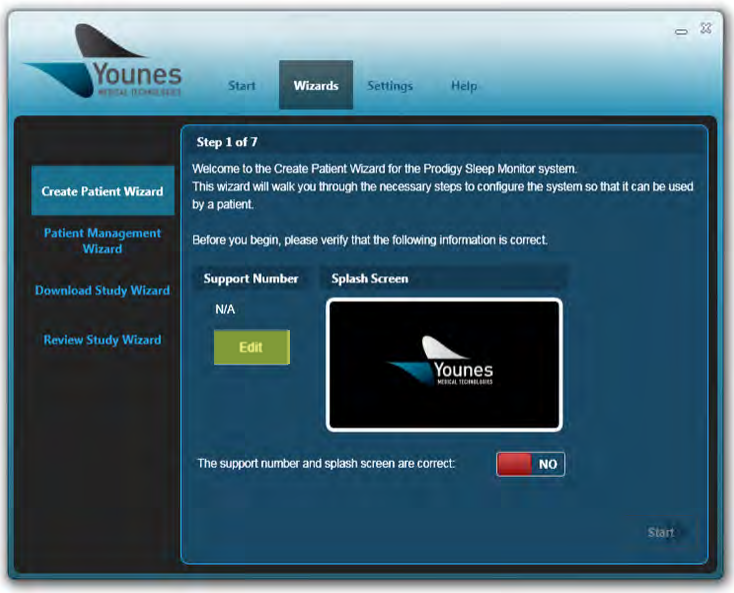


Figure 109 – Windows PC Prodigy Application Screen With “Edit” Button Highlighted (Create Patient Wizard)

8. Once “Edit” is selected, the screen appears as shown in Figure 110. Read the information provided on the screen. To load a support number onto the device simply click anywhere in the black box beside “Support Number:” and type in the number you would like.

NOTE

The support number loaded onto the Prodigy Sleep Monitor will appear exactly as entered in the Windows PC Prodigy application.

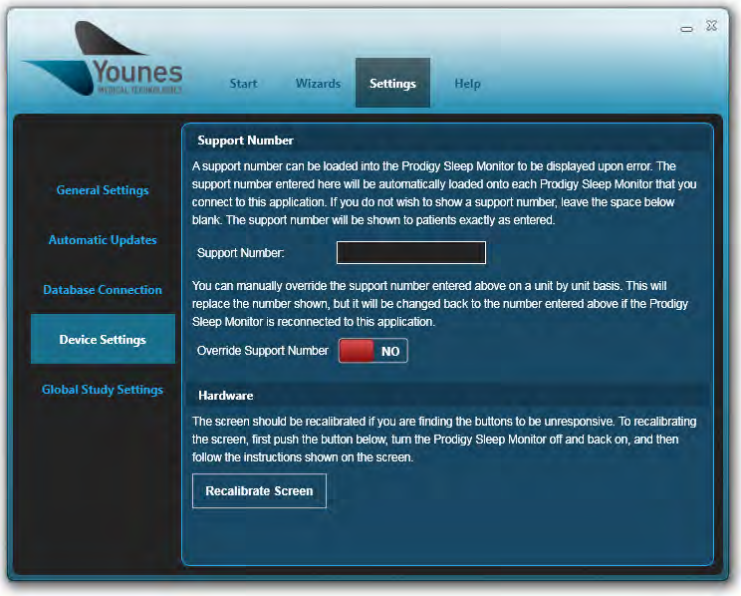


Figure 110 – Windows PC Prodigy Application Edit Screen (Device Settings)

If a support number is already listed and you would like to provide a specific support number for a patient, click the “No” button so that it says “Yes.” A black box will appear for you to enter a replacement support number, as shown in Figure 111.

Figure 111 – Windows PC Prodigy Application Support Number Override Screen (Device Settings)

To recalibrate your screen click the “Recalibrate Screen” button highlighted in Figure 112. If you do not wish to recalibrate your screen, click “Wizards.”

Figure 112 – Windows PC Prodigy Application Screen With “Recalibrate Screen” Button Highlighted (Device Settings)

A green check mark will appear beside the “Recalibrate Screen” button once it is selected, as shown in Figure 113.

Figure 113 – Windows PC Prodigy Application Recalibration Complete Screen (Create Patient Wizard)

As instructed on the screen, turn the Prodigy Sleep Monitor off and then back on again by toggling the power switch. Upon turning the Prodigy Sleep Monitor on, the screen on the Prodigy Sleep Monitor will appear as shown in Figure 114.

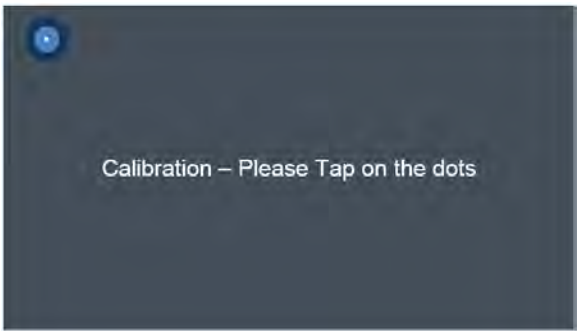


Figure 114 – Prodigy Sleep Monitor Calibration Screen

Tap on the dots as they appear on the Prodigy Sleep Monitor Screen. When there are no dots left to tap, click “Wizards” on the Windows PC Prodigy application screen. The screen shall appear as shown in Figure 115.

Figure 115 – Windows PC Prodigy Application Introduction Screen With Updated Support Number (Create Patient Wizard)

9. If the support number and splash screen are correct, select “No.” Upon clicking “No,” the button will change to “Yes,” as shown in Figure 116. Click “Start” to begin.

Figure 116 – Windows PC Prodigy Application Welcome Screen with updated Support Number (“Yes”)

10. If at least one recorded study is stored internally, the screen shown in Figure 117 will be displayed. If you wish to ignore the warning on the screen and proceed with adding a patient, click the “No” button. If you do not wish to proceed, click “Finish” and you will be directed back to the screen shown in Figure 115.

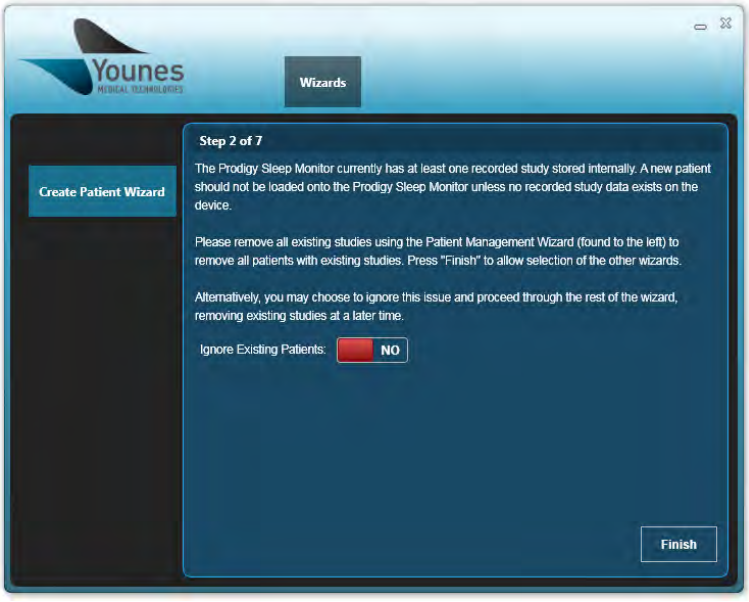


Figure 117 – Windows PC Prodigy Application Do Not Ignore Existing Patients Screen (Create Patient Wizard)

Upon clicking "No," the button will change to "Yes," as shown in Figure 118. Click "Next" to continue.

Figure 118 – Windows PC Prodigy Application Ignore Existing Patients Screen (Create Patient Wizard)

11. As instructed in Figure 119, power on the companion Head Sensor, then click the “Connect” button.

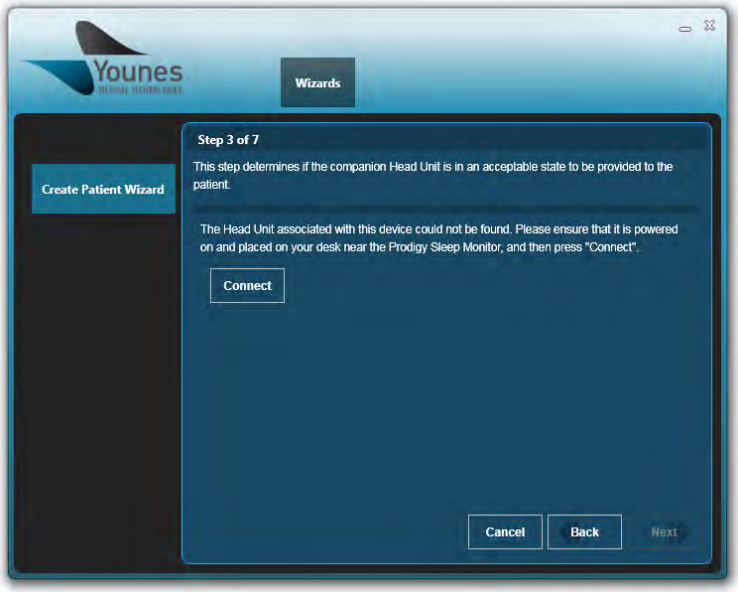


Figure 119 – Windows PC Prodigy Application Head Sensor Acceptable State Screen (Create Patient Wizard)

While the application is attempting to locate the Head Sensor, the screen will appear as shown in Figure 120.

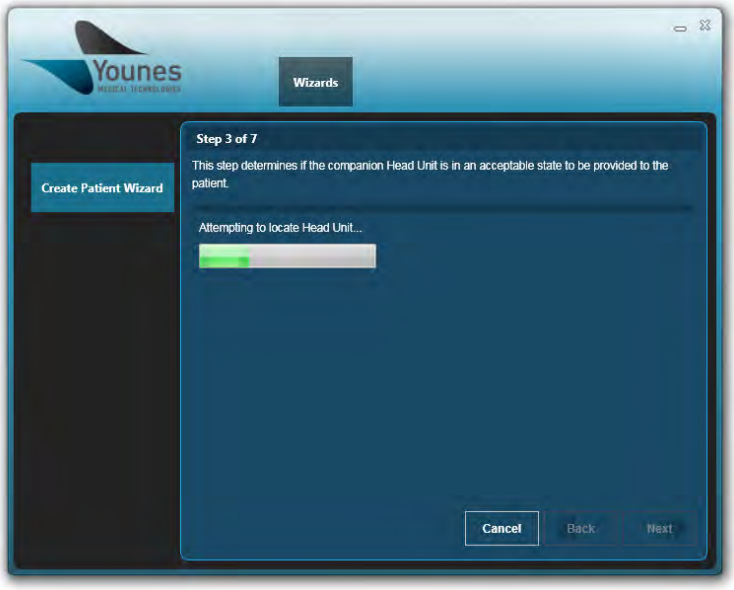


Figure 120 – Windows PC Prodigy Application Attempting To Locate Head Sensor Screen (Create Patient Wizard)

If the search status fails, the screen shown in Figure 121 will appear. The search status will fail if the paired Head Sensor is off, or the Head Sensor is not paired with the Prodigy Sleep Monitor in

use. Call the support number included at the front of the Manual if the Head Sensor is powered on and the PC Prodigy Application is still unable to locate the Head Sensor.

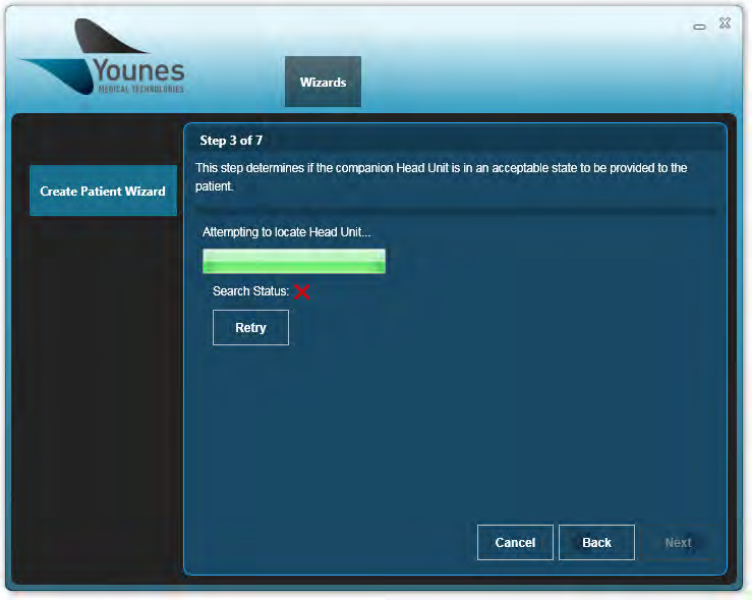


Figure 121 – Windows PC Prodigy Application Search Status Failure Screen (Create Patient Wizard)

If the search status is complete, but the batteries are insufficient to run a study, the screen shown in Figure 122 will appear.

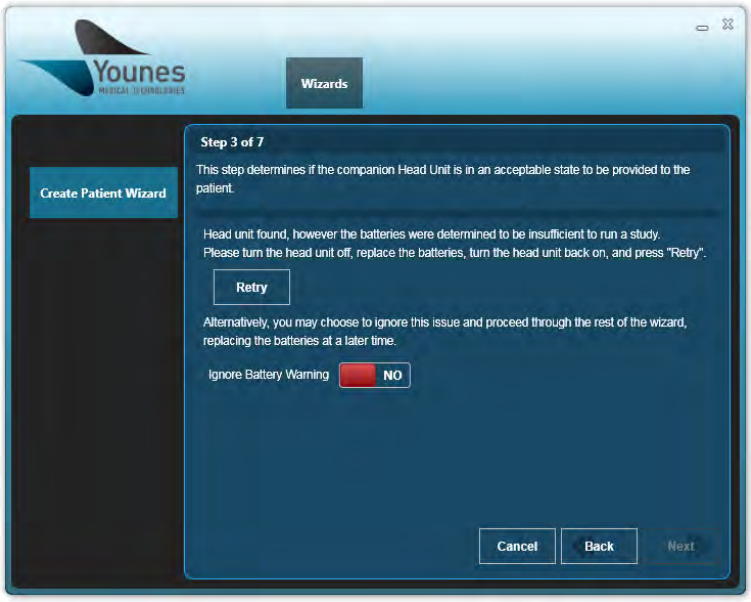


Figure 122 – Windows PC Prodigy Application Search Status Replace Batteries Screen (Create Patient Wizard)

If the batteries are replaced with new batteries and the steps listed in Figure 122 are followed, the screen shown in Figure 123 will appear. Figure 123 will also appear if you choose to ignore the battery warning and replace the batteries at a later time by clicking the “NO” button and then clicking “Next.” Select the “Next” button in Figure 123 when you are ready to advance to the next step.

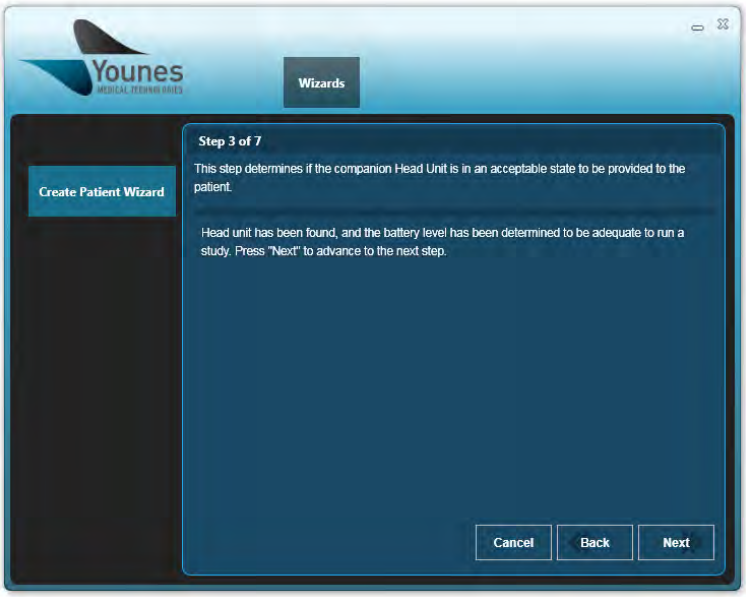


Figure 123 – Windows PC Prodigy Application Search Status Completion Screen (Create Patient Wizard)

12. Click anywhere in the black boxes shown in Figure 124 to enter the patient’s information. When the patient’s information has been entered, select “Next.”

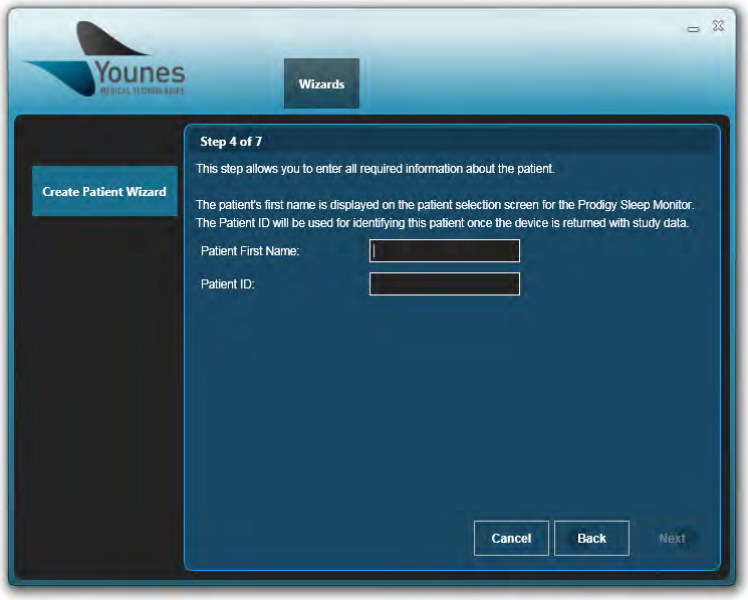


Figure 124 – Windows PC Prodigy Application Patient Name and ID Entry Screen (Create Patient Wizard)

13. The three electrode configurations are displayed on the screen, as shown in Figure 125. Select the electrode configuration that has been prescribed to the patient and then select "Next."

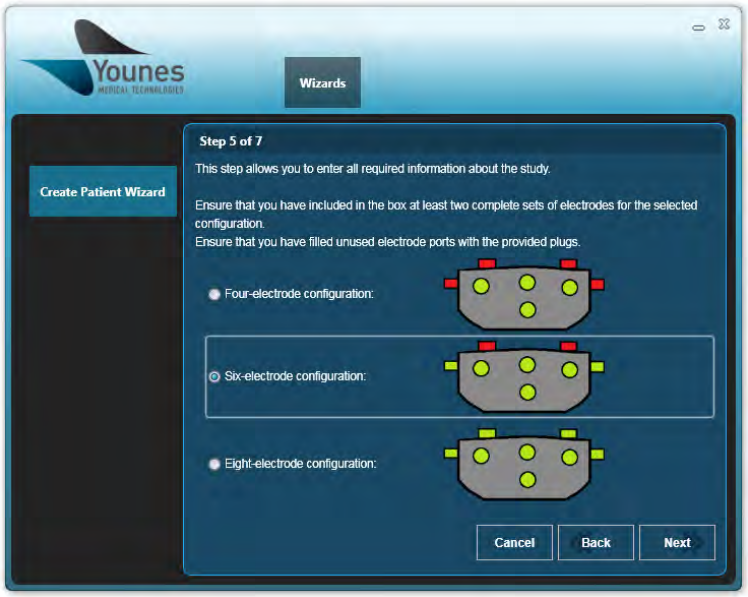


Figure 125 – Windows PC Prodigy Application Electrode Configuration Screen (Create Patient Wizard)

14. A summary of all patient information entered will be displayed on the screen, as shown in Figure 126.

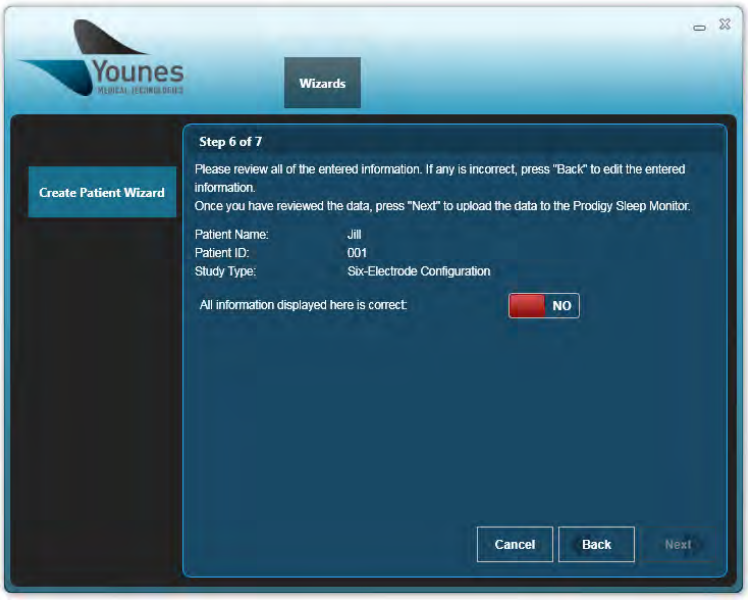


Figure 126 – Windows PC Prodigy Application Patient Information Not Confirmed Screen (Create Patient Wizard)

If all information displayed is correct (compare with prescription information), select "No." Upon clicking "No," the button will change to "Yes," as shown in Figure 127. Click "Next" to continue.

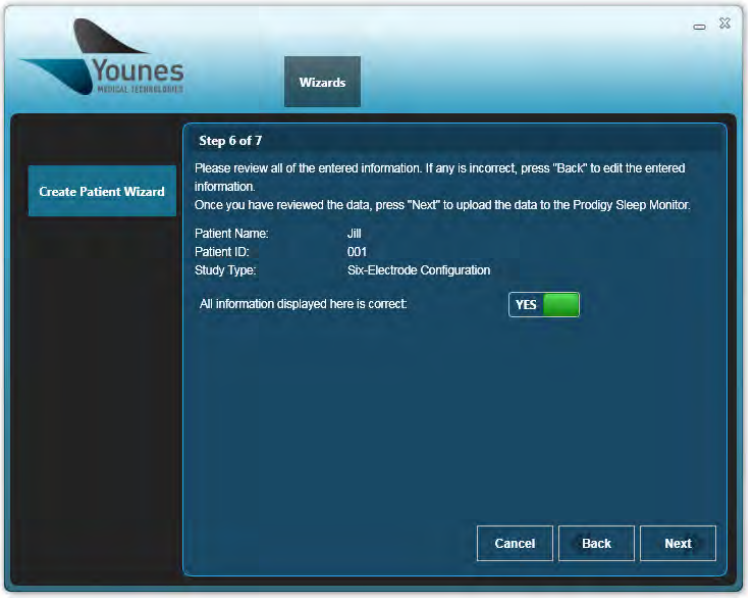


Figure 127 – Windows PC Prodigy Application Patient Information Confirmed Screen (Create Patient Wizard)

15. The screen will now indicate that a patient has been uploaded onto the Prodigy Sleep Monitor, as shown in Figure 128. Select "Finish" to exit the wizard.

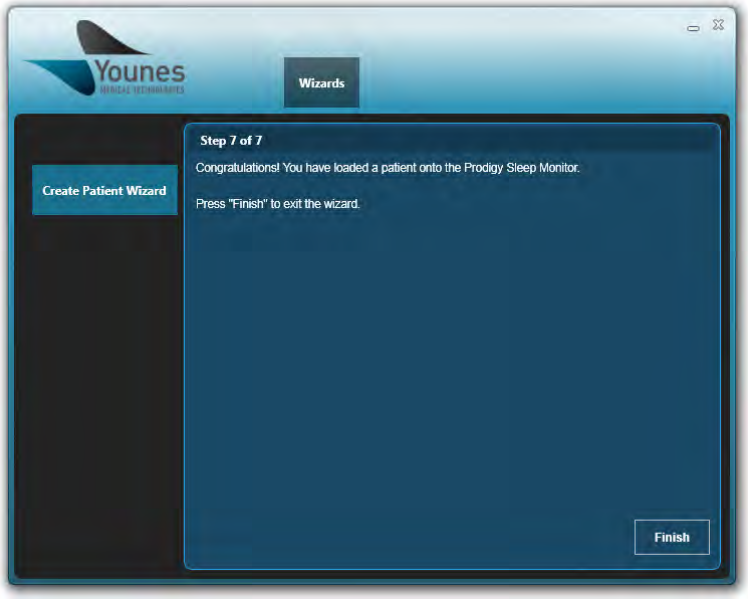


Figure 128 – Windows PC Prodigy Application Screen Indicating Patient Successfully Loaded (Create Patient Wizard)

Advanced User Mode

The “Advanced User” mode is the second of two modes that can be used to program the device for the next sleep study, amongst other things. The “Advanced User” mode can also be used to delete all studies associated with a patient, but keep the patients name, ID and study type on the device. This mode is quicker to use than the “Wizards” mode as there is less guidance and explanation associated with your choices.

1. If “Advanced User” mode isn’t activated, follow steps 1-3 (starting on page 61). If it is activated, select the “Advanced User Mode” button listed at the top of the Windows PC Prodigy application screen.
2. If the next patient to use the Monitor is already programmed on the device, the studies associated with that patient can be erased, while the patient’s name, ID, and study type can be kept. To erase all studies associated with a patient select the “Manage Studies” button shown in Figure 129.

Figure 129 – Windows PC Prodigy Application Screen With "Manage Studies" Button Highlighted (Manage Patients)

The studies associated with the selected patient will be listed on the screen, as shown in Figure 130.

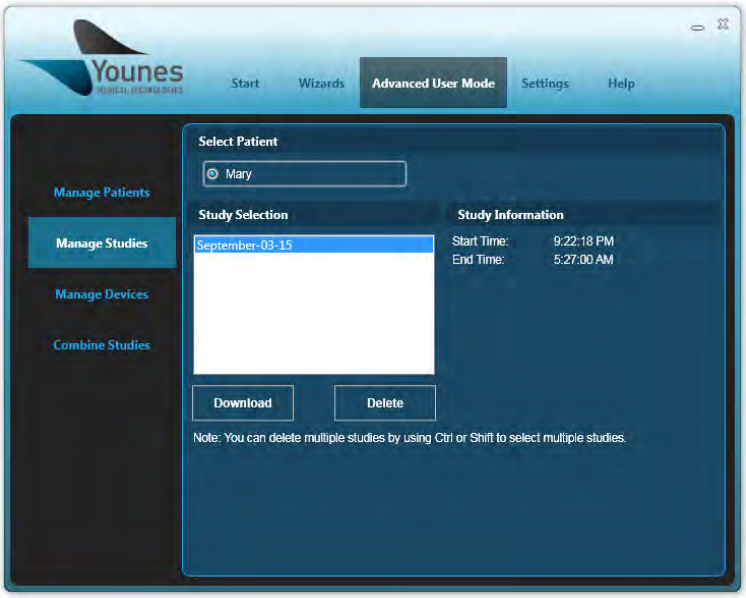


Figure 130 – Windows PC Prodigy Application Patient List, Study List and Study Information Screen (Manage Studies)

To delete multiple studies at a time, use the "Ctrl" or "Shift" key when selecting studies to delete. When you have selected all studies, select the "Delete" button. As shown in Figure 131, after "Delete" has been selected all studies are removed, but the patient's name remains.

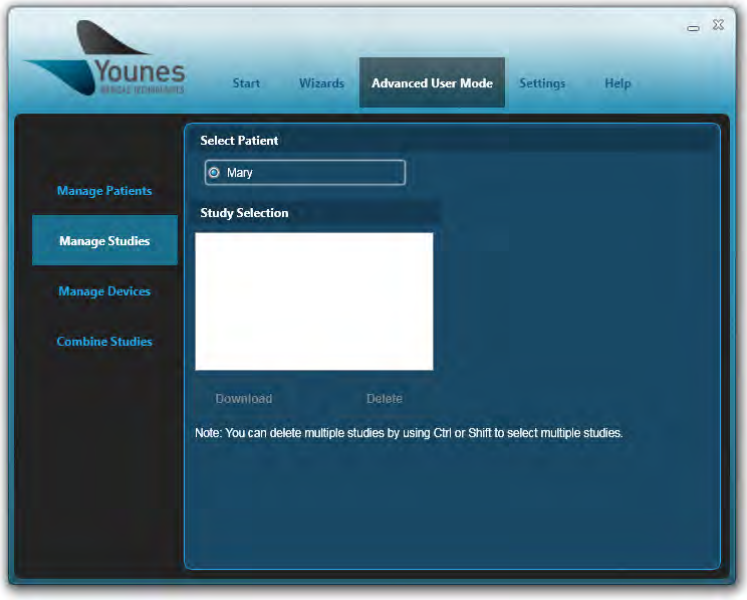


Figure 131 – Windows PC Prodigy Application Studies Deleted Screen (Manage Studies)

3. If the next patient to use the Monitor is not programmed into the device, all patients must first be removed and then the new patient must be added. There are two tools within the "Advanced User" mode that can be used to remove all patients from the device.
    a. The first tool called "Manage Patients" allows you to delete patients one at a time. The default tool when the "Advanced User" mode is chosen is the "Manage Patients" tool, as shown in Figure 132.

Figure 132 – Windows PC Prodigy Application Summary of Patients and Patient Information Screen (Manage Patients)

To delete a patient, select their name and then select the “Delete” button highlighted in Figure 133.

Figure 133 – Windows PC Prodigy Application Screen With “Delete” Button Highlighted (Manage Patients)

The patient you selected to delete will disappear from the list of patients, as shown in Figure 134. To save your changes, select “Save.”

Figure 134 – Windows PC Prodigy Application Screen With Patient Deleted (Manage Patients)

Your changes will not save if you select another button before the “Save” and “Cancel” button have reappeared. While the changes are being saved, the screen will appear as shown in Figure 135.

Figure 135 – Windows PC Prodigy Application Screen During Saving Process After Deletion (Manage Patients)

Continue to delete all patients as per the steps described above until no patients are on the device, as shown in Figure 136.

Figure 136 – Windows PC Prodigy application Screen No Patients (Manage Patients)

b. The second tool called “Manage Devices” erases everything from the device all at once. To access the “Manage Devices” tool, select the “Manage Devices” button highlighted in Figure 137.

Figure 137 – Windows PC Prodigy Application Screen With "Manage Devices" Button Highlighted (Manage Patients)

A warning will be displayed on the screen indicating that you will not be able to recover any data once it is deleted. Select the "No" button in Figure 138 to proceed with erasing all data on the Monitor.

Figure 138 – Windows PC Prodigy Application Do Not Erase Sleep Monitor Screen (Manage Devices)

Upon clicking "No," the button will change to "Yes," as shown in Figure 139. Select the "Erase Device" button in Figure 139 to permanently remove all data from the device.

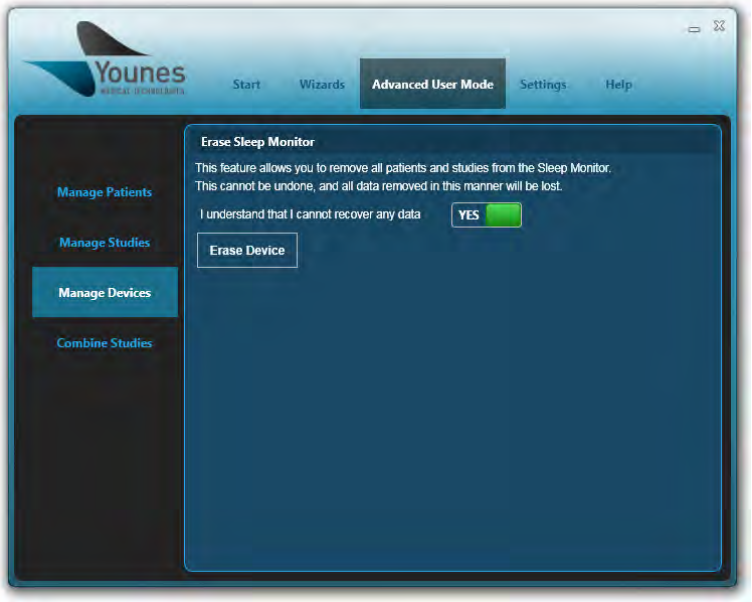


Figure 139 – Windows PC Prodigy Application Erase Sleep Monitor Screen (Manage Devices)

While all data on the device is being removed, the screen will appear as shown in Figure 140.

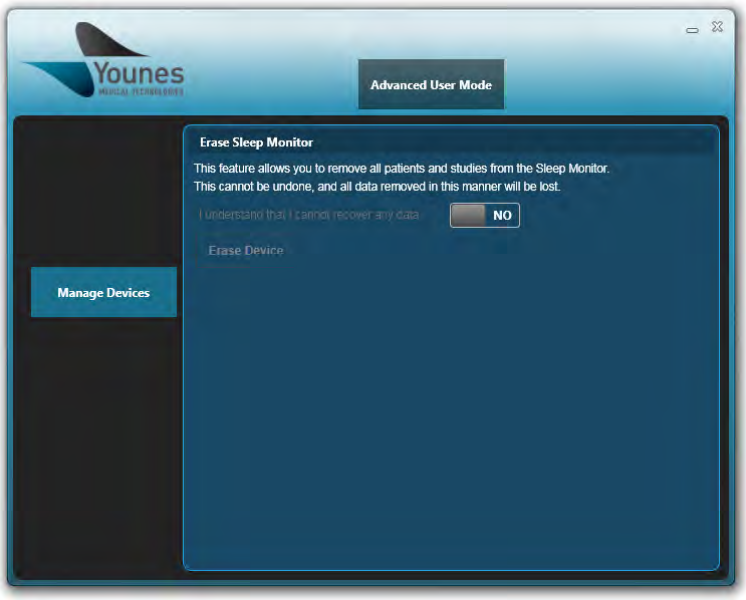


Figure 140 – Windows PC Prodigy Application Erase Sleep Monitor Saving Changes Screen (Manage Devices)

When all data has been removed, the screen will appear as shown in Figure 141.

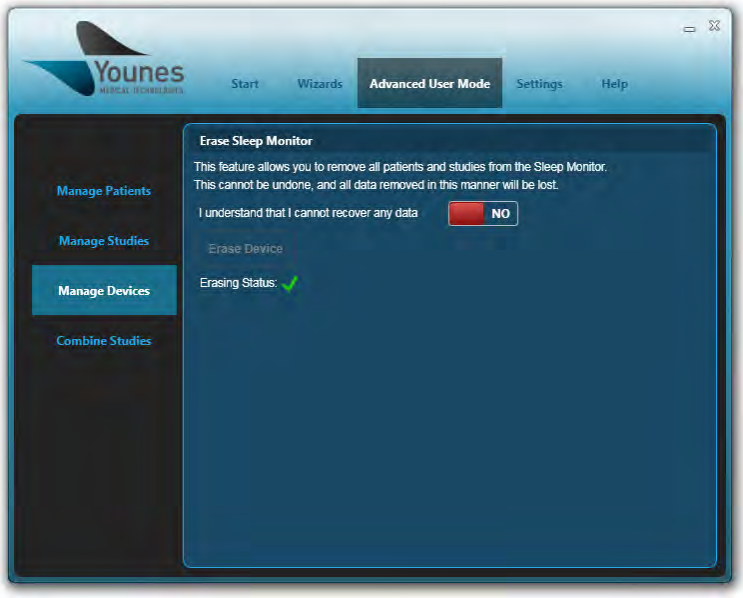


Figure 141 – Windows PC Prodigy Application Erase Sleep Monitor Successful Screen (Manage Devices)

4. Now that all patients have been deleted from the device, proceed to add a patient to the device by selecting the “Manage Patients” button shown highlighted in Figure 142.

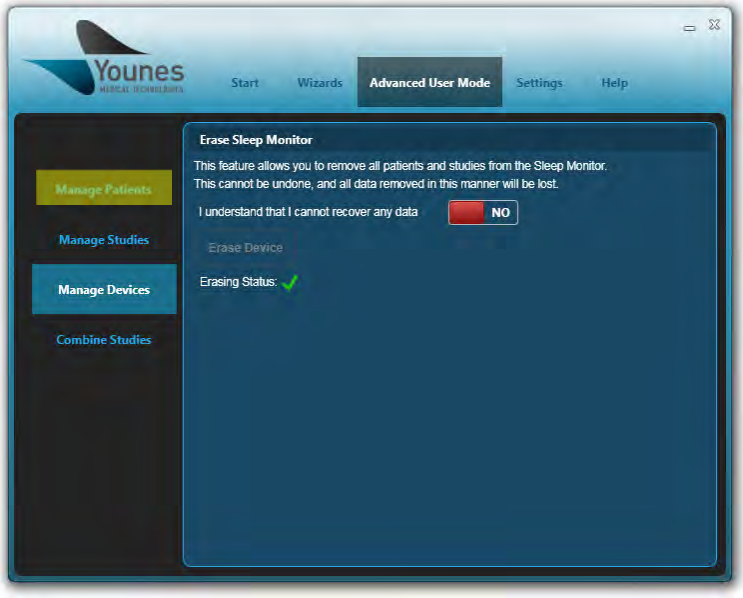


Figure 142 – Windows PC Prodigy Application Screen With “Manage Patients” Button Highlighted (Manage Devices)

5. Determine the name, ID and study type for the next patient and then enter the information into the Windows PC Prodigy application in the locations shown in Figure 143. Select “Save” after you have reviewed that the information is correct.

Figure 143 – Windows PC Prodigy Application Introduction Screen (Manage Patients)

Your changes will not save if you select another button before the “Save” and “Cancel” button have reappeared. While the changes are being saved, the screen will appear as shown in Figure 144.

Figure 144 – Windows PC Prodigy Application Screen During Saving Process After Patient Addition (Manage Patients)

6. The patient you submitted information for will now be listed in the application window, as shown in Figure 145 . The patient’s ID, study type, and number of studies will also be listed when their name is selected. A patient’s information can be edited as long as a study has not been recorded.

Figure 145 – Windows PC Prodigy Application Successful Patient Addition Screen

Re-Packaging

Check the expiry date on two new AAA batteries and ensure they are not expired, and the expiry date is not within the next 6 months. If the batteries are expired, or will expire within the next 6 months, dispose or recycle the used batteries following local regulations. If the batteries are not expired open the battery compartment by sliding the battery cover away from the Head Sensor and install the two new AAA batteries in the Head Sensor. To close the battery compartment line up the guides on the cover and the Head Sensor, and then slide the cover into place. The cover is attached if you see no gaps between the Head Sensor and battery cover, and you hear a clicking noise.

WARNING

Use only alkaline AAA batteries provided with the device. Do not use rechargeable batteries or those that are not fully charged or combine new and old batteries.

Power on both the Monitor and Head Sensor 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, the components are to be quarantined and the service provider is to contact YMT. Dispose of all other materials in accordance to local regulations.

CAUTION

If the Head Sensor is not to be used within 2 months, the batteries shall be removed. Batteries shall not be stored in the Head Sensor for greater than 2 months because battery leakage could occur. This can result in equipment damage or injury to users or service personnel.

Collect double the quantity of each electrode type needed for the next patient's sleep study. 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.

Connect the appropriate number of electrodes to the Head Sensor based on the EEG electrode configuration prescribed by the physician, and place the remaining electrodes in the travelling case.

Place the Head Sensor and Monitor 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.

Ensure the total number of each required component is included as described in section 2. Additionally, check to see if the battery cover of the Head Sensor is included. If the battery cover of the Head Sensor has been misplaced, contact YMT with the information provided on the back of the front cover of this manual for a replacement component.

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 patient.

EEG electrodes should be labeled with a "do not reuse" symbol as shown in section 8.

Expected Service Life

This device has been designed with an expected service life of five years. The number of re-processing cycles is dependent on full compliance with the directions of use of the Prodigy Sleep Monitor system. The service provider shall keep records of number of use and re-processing cycles and discontinue use once the service life has been reached. Once the service life has been reached, recycle plastic and electronic components in accordance with local regulations. Additionally, dispose of all other materials in accordance to local regulations.

The expected service life of all accessories are included in Table 1.

Table 1 – Expected Service Life of Accessories

Accessory	Expected Service Life
AMBU Neuroline 72000-S/25 Electrodes	1 use
AMBU Neuroline 72001-K/12 Electrodes	1 use
3M Red Dot 2560 Electrode	1 use
AAA Batteries	1 use
Alcohol Swabs	1 use
Micro USB to USB cable, 6ft length	2 years
3.5mm to 3.5mm male-male mono cable, 6ft length	2 years

As the shelf life of an opened bag of electrodes is less than the expected service life of the Prodigy Sleep Monitor System, the time period in which the electrodes specified in this manual can still be used by are provided in Table 2. The shelf life of an unopened bag of electrodes is also provided in Table 2.

Table 2 – Shelf Life of Accessories

Accessory	Shelf Life in months	
	Opened	Unopened
AMBU Neuroline 72000-S/25 Electrodes	1	24
AMBU Neuroline 72001-K/12 Electrodes	1	12
3M Red Dot 2560 Electrode	~1.5 (45 days)	24

5. Troubleshooting

Monitor shows Head Sensor cannot establish wireless connection with Monitor.

- Make sure the Head Sensor is powered on.
- Make sure you have set up the Head Sensor and EEG electrodes as described in this manual.
- Ensure that the Head Sensor unit is within 3m of the Monitor unit.
- Turn the unit off, and then back on again.
- Contact customer support if the problem persists and return the device to the travelling case until noted otherwise.

Monitor shows EEG electrodes not connected properly.

- Make sure the Head Sensor is powered on.
- Make sure you have connected the electrodes as described in this manual.
- Press the connector firmly into the input on the Head Sensor.
- Ensure the EEG electrodes are making good contact with the skin. Press lightly in the center of the electrode to ensure good contact.
- Remove the connector and inspect for signs of damage. Replace if damaged.
- Turn the unit off, and then back on again.
- Contact customer support if the problem persists and return the device to the travelling case until noted otherwise.

Monitor shows low batteries in Head Sensor.

- Make sure the Head Sensor is powered on.
- Replace batteries with new AAA batteries.
- Turn the unit off, and then back on again.
- Contact customer support if the problem persists and return the device to the travelling case until noted otherwise.

Monitor keeps turning off.

- The Monitor is designed to turn off after 10 seconds without input during a sleep study. This is to ensure the light from the Monitor does not disturb the user's sleep. Simply touch the Monitor screen and it will turn back on.

Monitor reads "evaluation incomplete" after I end the study.

- Contact customer support to discuss how to proceed further and return the device to the travelling case until noted otherwise.

Error Codes

- The Prodigy Sleep Monitor System will display error codes on the Monitor in the event of certain errors. The error codes that may be displayed, their meanings, and resolutions if a patient or service personnel encounter the error are as follows:

Code	Error Meaning
0001	Bad Impedance
0002	Battery Died
0003	Bad Impedance + Battery Died
0004	SD Card Error
0005	Bad Impedance + SD Card Error
0006	Battery Died + SD Card Error
0007	Bad Impedance + Battery Died + SD Card Error
0008	Less than 4 hours of data
0009	Bad Impedance + Less than 4 hours of data
000A	Battery Died + Less than 4 hours of data
000B	Bad Impedance + Battery Died + Less than 4 hours of data
000C	SD Card Error + Less than 4 hours of data
000D	Bad Impedance + SD Card Error + Less than 4 hours of data
000E	Battery Died + SD Card Error + Less than 4 hours of data
000F	Bad Impedance + Battery Died + SD Card Error + Less than 4 hours of data
0010	Bad ORP
0011	Bad ORP + Bad Impedance
0012	Bad ORP + Battery Died
0013	Bad ORP + Bad Impedance + Battery Died
0014	Bad ORP + SD Card Error
0015	Bad ORP + Bad Impedance + SD Card Error
0016	Bad ORP + Battery Died + SD Card Error
0017	Bad ORP + Bad Impedance + Battery Died + SD Card Error
0018	Bad ORP + Less than 4 hours of data
0019	Bad ORP + Bad Impedance + Less than 4 hours of data
001A	Bad ORP + Battery Died + Less than 4 hours of data
001B	Bad ORP + Bad Impedance + Battery Died + Less than 4 hours of data
001C	Bad ORP + SD Card Error + Less than 4

	hours of data
001D	Bad ORP + Bad Impedance + SD Card Error + Less than 4 hours of data
001E	Bad ORP + Battery Died + SD Card Error + Less than 4 hours of data
001F	Bad ORP + Bad Impedance + Battery Died + SD Card Error + Less than 4 hours of data

6. Technical Description

Prodigy Head Sensor

General	8-channel EEG signal capture and wireless transmission device
Dimensions	67 mm (W) x 37 mm (H) x 30 mm (D)
Weight	36 g (without 2xAAA batteries), 48g without 2xAAA batteries
Material	Polyamide 12 enclosure, biocompatible according to ISO 10993-1
Safety	Circuit protection (auto-resettable fuse)
Power	1.5 VDC from 2 x AAA batteries
Interfaces	Wireless communication with Monitor, 2.4 GHz (802.15.4)
Classification	Class II ME Equipment, Type BF applied part
Operating Temperature	

Prodigy Monitor

General	Touch screen based data receiver system
Dimensions	150 mm (W) x 104 mm (H) x 56 mm (D)
Weight	328 g
Material	Polyamide 12 enclosure, biocompatible according to ISO 10993-1
Safety	Circuit protection (auto-resettable breaker)
Power	9 VDC 2A (18W max power) from class II medical grade power supply
Interfaces	Wireless communication with Head Sensor, 2.4 GHz (802.15.4) Micro USB port 3.5mm jacks for ORP and EEG output Microphone Ambient light sensor
Classification	Class II ME Equipment
Operating Temperature	

Power Supply

Datasheets	MENB1020
Product Training Modules	Level V and ErP Phase II Power Supplies Medical Power Supply Market Test & Measurement Power Supply Market
Category	Power Supplies - External/Internal (Off-Board)
Series	MENB1020
Region Utilized	North America
Form	Wall Mount
Input Type	Multi-Blade (Sold Separately)
Voltage - Input	100 ~ 240 VAC
Voltage - Output	9V
Current - Output (Max)	2A
Power (Watts)	18W
No Load Power Consumption	300mW (Max)
Polarization	Positive Center
Applications	Medical
Efficiency	Level V
Operating Temperature	0°C ~ 40°C
Output Connector	Barrel Plug, 2.5mm I.D. x 5.5mm O.D. x 9.5mm
Size / Dimension	3.27" L x 1.85" W x 1.50" H (83.0mm x 47.0mm x 38.0mm)
Approvals	CE, cURus
Power (Watts) - Max	18W
Input Connector	Multi-Blade
Cord Length	59" (1.5m)
Weight	0.331 lb (150.14g)
Class of ME Equipment	II

7. Additional Information

Equipment Classification

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

Table 3 – Equipment Classification

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

Technical Specification

The system measures audio, EEG, light and position at the frequency range, bandwidth, and accuracy shown in Table 4. Additionally, a description of waveform displays (if applicable) and the functions performed by the Prodigy Sleep Monitor to measure audio, EEG, light and position are included in Table 4.

Table 4 – Technical Specification of Prodigy Sleep Monitor

	Frequency Range	Bandwidth	Functions	Displays	Accuracy
Audio	20-1000 Hz	980 Hz	Sampled, written to SD card	None	Total harmonic distortion: 0.5%, SNR: 65dB
EEG	0-60 Hz	60 Hz	Sampled, filtered, downsampled, transmitted wirelessly, transmitted serially, referenced, output on analog outs, written to SD card	Output on analog outs, mapping of [-250uV, 250UV] to [-5V, 5V]. Not displayed as a waveform on the device.	Noise per channel: 0.20 uVrms, SNR: 120 dB
Light	Visible Light (430 nm to 800 nm)	370 nm	Sampled, written to SD card	None	10% between 430 nm and 800 nm
Position	N/A	N/A	Sampled, transmitted wirelessly, transmitted serially, written to SD card	None	+/- 10 degrees

Electromagnetic Compliance

Information pertaining to electromagnetic compliance is presented in Table 5 through Table 10.

Table 5 – IEC 60601-1-2:2007 Table 1 Requirements

The Prodigy Sleep Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep Monitor should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – Guidance**
RF Emissions CISPR 11	Group 1	The Prodigy Sleep Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Prodigy Sleep Monitor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

		that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Prodigy Sleep Monitor or shielding the location.

The Prodigy Sleep Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep Monitor should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – Guidance**
RF Emissions CISPR 11	Group 1	The Prodigy Sleep Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Prodigy Sleep Monitor is 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 Monitor are not used.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table 6 – Table 7 – IEC 60601-1-2:2007 Table 2 Requirements

The Prodigy Sleep Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep Monitor should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 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	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95 % dip in *U*T) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	<5% *U*T (>95 % dip in *U*T) for 0,5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Prodigy Sleep Monitor requires continued operation during power mains interruptions, it is recommended that the Prodigy Sleep Monitor be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at 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 of the test level.			

Table 8 – IEC 60601-1-2:2007 Table 4 Requirements

<table>
<tr><td colspan="4">The Prodigy Sleep Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Prodigy Sleep Monitor should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment – Guidance</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Prodigy Sleep Monitor including cables, than the recommended separation
distance calculated from the equation applicable to the
frequency of the transmitter.

Recommended separation distance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td>$d = 1.2\sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td><td>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 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). 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:

  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, 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.</td></tr>
</table>

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 Monitor is used exceeds the applicable RF compliance level above, the Prodigy Sleep Monitor 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 Monitor. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 9 – IEC 60601-1-2:2007 Table 6 Requirements

Recommended separation distances between portable and mobile RF communications equipment and the Prodigy Sleep Monitor			
The Prodigy Sleep Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prodigy Sleep Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prodigy Sleep Monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency transmitter in meters**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum 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 guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 10 – Electromagnetic Compliance

Component	**Wireless protocol**	**Frequency**
Prodigy Head Sensor	IEEE 802.15.4	2.405 – 2.480 GHz
Prodigy Monitor	IEEE 802.15.4	2.405 – 2.480 GHz

Environmental Conditions

The environmental conditions for transport and storage, and during operation, are presented in Table 11 and Table 12, respectively.

Table 11 – Transport and Storage Conditions

Component	Environmental Condition	Range
Prodigy Head Sensor	Temperature	-25°C to +70°C
Prodigy Monitor	Relative humidity (non-condensing)	5% to 93%
Power supply	Barometric pressure	90 kPa to 106 kPa

Table 12 – Operating Conditions

Component	Environmental Condition	Range
Prodigy Head Sensor	Temperature	5°C to 40°C
Prodigy Monitor	Relative humidity (non-condensing)	15% to 93%
Power supply	Barometric pressure	90 kPa to 106 kPa

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 specified in this document is the only component that has high integrity characteristics.

Risks

All potential risks associated with this device are listed here. All risks have been mitigated through risk control measures.

1. A patient, operator, or service personnel may receive electrical shock if
    a. there is an electrical circuit fault in the Head Sensor.
    b. the user attempts to open the Head Sensor and service the product.
    c. the user attempts to open the Monitor and service the product.
    d. the Head Sensor is damaged, as this can result in exposed electrical wires.
    e. the Monitor is damaged, as this can result in exposed electrical wires.
    f. the Head Sensor short circuits due to damage.
    g. the Monitor short circuits due to damage.
    h. the Head Sensor is damaged and allows fluid ingress causing electrical faults.
    i. the Monitor is damaged and allows fluid ingress causing electrical faults.
    j. the Monitor allows fluid ingress and damages circuit causing faults.
    k. the Head Sensor allows fluid ingress, as this can cause electrical faults.

2. A person may receive electrical shock if they put the Monitor's DC power supply connector inside their mouth.
3. A patient may receive electrical shock if
    a. they sweat and it enters the Head Sensor, as this can cause electrical faults.
    b. the Head Sensor is cleaned by the user with water or other fluid and it penetrates the enclosure, which can cause electrical faults.
    c. the Monitor is cleaned by the user with water or other fluid and it penetrates the enclosure, which can cause electrical faults.
4. A user may receive electrical shock or burns if the device is attempted to be cleaned or dried by putting the device in the dryer or microwave, for example.
5. A service personnel may receive electrical shock if live wires in the Monitor are touched.
6. A patient may be burned if
    a. they connect the wrong power supply to the Monitor, as the wrong power supply can cause electrical faults and overheating.
    b. wireless power output is too high.
    c. they attempt to open the Monitor and service the product.
    d. AAA batteries malfunction, as this can result in overheating of the Head Sensor.
    e. AAA batteries are installed incorrectly in the Head Sensor.
    f. electrical faults occur in the Monitor, as this can result in a fire.
    g. the Head Sensor overheats due to inadequate cooling or excessive heating.
    h. the Monitor overheats due to inadequate cooling or excessive heating.
    i. they install Lithium batteries in the Head Sensor, as overheating will occur due to damage or short circuit.
7. A patient may experience interference with other devices because of wireless emissions.
8. A patient, operator, or service personnel may experience skin irritation or a rash if the materials of the device are not biocompatible with the skin.
9. A patient, operator, or service personnel may experience an allergic reaction if the materials of the device are not biocompatible with the skin.
10. A patient, operator, or service personnel may be infected if the Head Sensor is contaminated with bacteria or disease from contact with a patient.
11. A patient, operator, or service personnel user may be infected if the Monitor is contaminated with bacteria or disease from contact with a patient.
12. A patient may choke if small components fall off the Head Sensor during use and into their mouth.
13. A patient may injure their eye if small components fall off the Head Sensor during use and into their eye.
14. A patient may injure their neck if the Head Sensor is too heavy and it causes neck strain.
15. A patient may experience pressure sores caused by the weight of components on their head for prolonged periods of time.
16. Wrong diagnosis may result if
    a. electrical malfunction causes data error.

b. wireless interference causes data corruption.
c. device is susceptible to external EMI and causes faults or malfunctions.
d. a patient selects wrong items on user interface for study.
e. a service provider supplies incorrect electrodes to a patient.
f. electrodes are placed incorrectly on the head.
g. a patient connects the EEG electrodes to incorrect inputs on the Head Sensor.
h. a patient connects too many electrodes to the Head Sensor.

8. Symbols Used for Prodigy Sleep Monitor

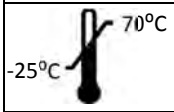
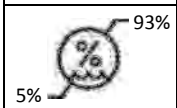
Table 13 – Regulatory Symbols

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 UL 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 14 – 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 15 – 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.