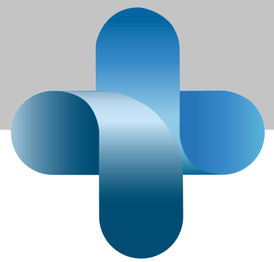
WatchPAT400
Operation Manual



WatchPAT™400

ZOLL itamar®

REF OM2196900 | Rev 1 | Aug-2024

DISCLAIMER

Itamar Medical Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this WatchPAT™ other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto and according to the terms of the warranty provided in the License Agreement available at https://www.itamar-medical.com/terms-and-conditions/.

This product and/or method of use is covered by one or more of the following US patents: 6319205, 6322515, 6461305, 6488633, 6916289, 6939304, 7374540, 7621877, 7806831, 7819811, 8485448, 9770190, as well as any pending US patent applications and corresponding patents and/or applications filed in other countries.

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

Rx only

REVISION HISTORY

This section reviews the revision history.

REV	DATE
1	Aug - 2024

NOTE:

- Latest version of the WatchPAT™ System Operation Manual is available at:

https://www.itamar-medical.com/support/downloads/

- Printed copy will be provided within 7 calendar days if requested at no additional cost.

HOME

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1. GENERAL INFORMATION

This chapter contains general information for WatchPAT400 and includes:

1.1 INTENDED USE

The WatchPAT™400 (WP400) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP400 is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP4 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP400's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP400's PSTAGES, snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

1.1.1 Intended Population

PAT Apnea/Hypopnea Index - central (pAHIc) and PAT Respiratory Disturbance Index (PRDI) are indicated for patients 17 years of age and older. All other parameters are indicated for 12 years and older.

1.1.2 Restrictions of Use

1. The WatchPAT should be used only in accordance with a physician's instructions. For precautions see Precautions.
2. Only qualified medical personnel may authorize the use of the WatchPAT.
3. Qualified medical personnel must instruct the patients (and accompanying individual if needed) how to attach and use the WatchPAT prior to use.
4. In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
5. The WatchPAT system in whole, or in part, may not be modified in any way.
6. The WatchPAT is used as an aid for diagnostic purposes only and should not be used for monitoring.
7. Only suitably trained and qualified personnel should be authorized to prepare the WatchPAT equipment prior to use.
8. Itamar Medical Ltd. makes no representation whatsoever, that the act of reading the Manual renders the reader qualified to operate, test or calibrate the system.
9. The tracings and calculations provided by the WatchPAT system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
10. In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this Manual, you should refer to the Troubleshooting section. If necessary, in any case of serious incident or harm, contact Itamar Medical Help Desk and report the incident to the competent authority of your country.
11. The WatchPAT is not intended for patients with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT device.
12. The WatchPAT is not intended for use by children less than 12 years old.
13. The AHIc was not clinically assessed for patients who are in high altitudes or for patients using opioids.

14. Patients with sustained* non-sinus cardiac arrhythmias should be considered for sleep study in a laboratory polysomnograph (PSG) rather than a home sleep testing (HST).

    ** In the setting of sustained arrhythmia the WatchPAT's automated algorithm might exclude some periods of time, resulting in a reduced valid sleep time. A minimum valid sleep time of 90 minutes is required for an automated report generation.*
15. The WatchPAT Operation Manual should be carefully studied by the authorized operators and kept where it is easily accessible. Periodic review of the Manual is recommended.
16. The step by step instructions should be carefully followed when attaching the unit.
17. The eligibility of a patient for a PAT™ study is entirely at the discretion of a physician and is generally based upon the patient's medical status.
18. The WatchPAT is not intended to be used as a diagnostic device for any cardiac arrhythmia and is not intended to replace traditional methods of diagnosis of cardiac arrhythmia. The WatchPAT arrhythmia function is to be used for informational use only as additional information to the sleep indices.

    The arrhythmia output flags patients suspected of having arrhythmias thereby aiding the physician to decide if further arrhythmia investigation is needed.
    A suspected arrhythmia flagging in the sleep report does not necessarily imply an arrhythmia condition is present but rather suggests that further investigation should be considered.
    The absence of arrhythmia flagging in the sleep report does not rule out any arrhythmia in some patients, in particular those with a high density of premature beats or AFib, the device may under-detect arrhythmic events (both premature beats and AFib) and/or misclassify between premature beats and AFib.

1.2 PRECAUTIONS

The WatchPAT should not be used in the following cases:

1. Use of one of the following medications: alpha blockers, short acting nitrates (less than 3 hours before the study).
2. Permanent pacemaker: atrial pacing or VVI without sinus rhythm.
3. The WatchPAT is not indicated for children who weigh less than 65 lbs / 30 kg.

1.2.1 Additional Precautions for Pediatric Use

The WatchPAT is indicated for use in patients 12 years and above. The following precautions and notes are referring to patients aged 12-17 years.
Precautions:

1. Pediatric patients with severe comorbidities such as Down syndrome, neuromuscular disease, underlying lung disease or obesity hypoventilation should be considered for sleep study in a laboratory polysomnograph (PSG) rather than a home sleep testing (HST).
2. It is recommended that the physician makes sure that the patient and his/her guardian are aware that the use of specific drugs and other substances used to treat ADHD, antidepressants, corticosteroids, anticonvulsants, use of caffeine, nicotine, alcohol and other stimulants might interfere with sleep and affect the sleep study's conditions.

1.3 DATA GENERATED BY WATCHPAT

The WatchPAT generates a PAT respiratory disturbance index (“PRDI”), PAT Apnea-Hypopnea Index (“PAHI”), PAT central Apnea-Hypopnea Index (pAHIc), percentage of total sleep time with Cheyne-Stokes Respiration pattern (%CSR) and PAT sleep staging identification ("PSTAGES"). The WatchPAT respiratory indices and sleep stages are estimates of conventional values and stages identification that are produced by polysomnography (“PSG”). The WatchPAT also generates acoustic decibel detector used for snoring level and body position discrete states from the Chest Sensor. PAHIc is indicated for use in patients 17 years of age and older.
The WatchPAT also includes detection of cardiac arrhythmia (Atrial Fibrillation and Premature Beats) as additional information to its sleep indices.

NOTE:

- The arrhythmia feature is available only in approved territories
- The arrhythmia output flags patients suspected of having arrhythmias thereby aiding the physician to decide if further arrhythmia investigation is needed. The results, together with patient’s anamnesis should be considered when deciding on further investigation

1.4 QUALITY ASSURANCE SYSTEM

The WatchPAT is compliant to the following standards:

	STANDARD	IDENTIFICATION
1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005, AMD1:2012, AMD2: 2020
		ANSI/AAMI ES60601-1:2005/ (R) 2012 and A1:2012, C1:2009/ (R) 2012 and A2:2010/(R) 2012 [Including Amendment 2 (2021)]
		CAN/CSA -C22.2 No.60601-1:08, CAN/CSA -C22.2 No.60601-1 :14 (including amendment 1) + AMD2:2022 (MOD)
2	Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC 60601-1-2:2014, AMD1:2020
3	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	IEC TR 60601-4-2:2016

	STANDARD	IDENTIFICATION
4	Medical Device Software – Software Life Cycle Processes	IEC 62304:2006 + A1:2015
5	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	IEC 60601-1-11:2015, AMD1:2020
6	Degrees of protection provided by enclosures (IP Code) – IP22	IEC 60529 Ed 2.2 + COR2
7	Medical devices - Part 1: Application of usability engineering to medical devices	IEC 62366-1:2015 + AMD1:2020
8	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020
9	Medical devices. Application of risk management to medical devices	EN ISO 14971:2019
10	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	ISO 15223-1:2021

	STANDARD	IDENTIFICATION
11	Graphical symbols for electrical equipment in medical practice	PD IEC/TR 60878: 2022
12	Graphical symbols - Safety colors and safety signs -- Registered safety signs; refer to instruction manual/ booklet	ISO 7010:2019 (M002)
13	Information supplied by the manufacture with medical devices	EN ISO 20417:2021
14	Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10993-1:2020
15	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61:2017, COR1:2018
16	Federal Communication Commission - Radio frequency devices	Federal Code of Regulation (CFR) FCC Part 15, Subpart C, Section 15.247
17	Technical Information Report Risk management of radiofrequency wireless coexistence for medical devices and systems.	AAMI TIR69: 2017 (2020)
18	American National Standard for Evaluation of Wireless Coexistence	ANSI IEEE C63.27-2021

	STANDARD	IDENTIFICATION
19	EU: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	EN 300 328 V2.2.2 (2019)
20	Canada: Digital Transmission Systems (DTSs), Frequency Hopping Systems (FHSs) and Licence-Exempt Local Area Network (LE-LAN) Devices, including: General Requirements for Compliance of Radio Apparatus, Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)	RSS-247 (2017) RSS-Gen (2018) RSS-102 (2015)
21	Commission Regulation (EU) on electronic instructions for use of medical devices	EU 207/2012
22	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS Directive 2015/863/EU (RoHS 3)
23	FDA Quality Systems Regulation (QSR)	21 CFR part 820
24	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2016

1.5 CONVENTIONS

WARNING: Indicates a potentially hazardous situation, which if not avoided could result in injury or death

CAUTION: Indicates that the equipment or environment can be harmed, or data can be corrupted

NOTE: Indicates additional information to help the user obtain optimum performance

TIP: Indicates useful information to simplify steps or procedures

1.5.1 Warnings, Cautions and Notes

- The WatchPAT is powered with one off-the-shelf AAA battery.
- The WatchPAT is portable with continuous operation.
- The WatchPAT parts/components/etc. are defined as Applied Parts BF type, according to IEC 60601-1.
- The WatchPAT should only be transported in its original package. If package is: 1) damaged 2) unintentionally opened before use 3) exposed to environmental conditions outside of those specified please contact Itamar Medical Help Desk.
- For environmental conditions during transportation & storage see Technical Specifications.
- For environmental conditions during operation see Technical Specifications.
- To avoid risk of battery leakage, the WatchPAT device should not be stored for a prolonged period with a battery inserted in the battery compartment.
- Sleep professionals should read the Operation Manual before using the WatchPAT.
- The WatchPAT complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:
  - This device may not cause harmful interference.
  - This device must accept any interference, including interference that may cause undesired operation of the device.
- The WatchPAT device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:
  - This device may not cause interference.
  - This device must accept any interference, including interference that may cause undesired operation of the device.

1.6 SAFETY PRECAUTIONS

WARNING:

- Do not let the device get wet.
- Do not expose the device to heat or flammable liquid or gases.
- Avoid placing food or water on any part of the device.
- In the event of fire use only fire extinguishers approved for use on electrical fires.
- Handle device with care. This device is sensitive to extreme movements and to falling.
- Do not try to introduce any foreign object into the device.
- Do not expose this device to an oxygen rich environment.
- Do not use this device with flammable anesthetics.
- In case of discomfort or allergic reaction, remove the device from your body.
- Avoid strangulation when attaching the chest sensor.

NOTE:

- The chest sensor's safety and effectiveness was not validated on pediatric patients.
- Special attention on training the pediatric patient and/or his accompanying individual on use and placement of the device prior to initiating a sleep study with the WatchPAT device.
- Contact Itamar Medical in the event of a serious incident with the device.

1.7 SYMBOLS USED ON PRODUCT LABELS

The following table displays the product labels symbols and their descriptions:

SYMBOL	EXPLANATION
	Follow instructions for use
	Date of manufacture
1.5V DC ⎓	Battery operating voltage
	Single use, do not re-use
	Temperature limit
	Use-by date
	Medical device manufacturer
REF	Catalogue number
SN	Serial number

SYMBOL	EXPLANATION
IP22	Ingress protection-The device is protected against insertion of fingers and vertically dripping water shall have no harmful effect when the device is tilted at an angle up to 15° from its normal position
	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Type BF applied part
	According to the WEEE Directive 2012/19/EU, all waste electrical and electronic equipment (EEE) should be collected separately and not disposed of with regular household waste. Please dispose this product and all of its parts in a responsible and environmentally friendly way
EC REP	Authorized representative in the European Community
MD	Medical device
	Consult instruction for use or electronic instruction for use
UDI	Unique device identifier

2. INTRODUCTION

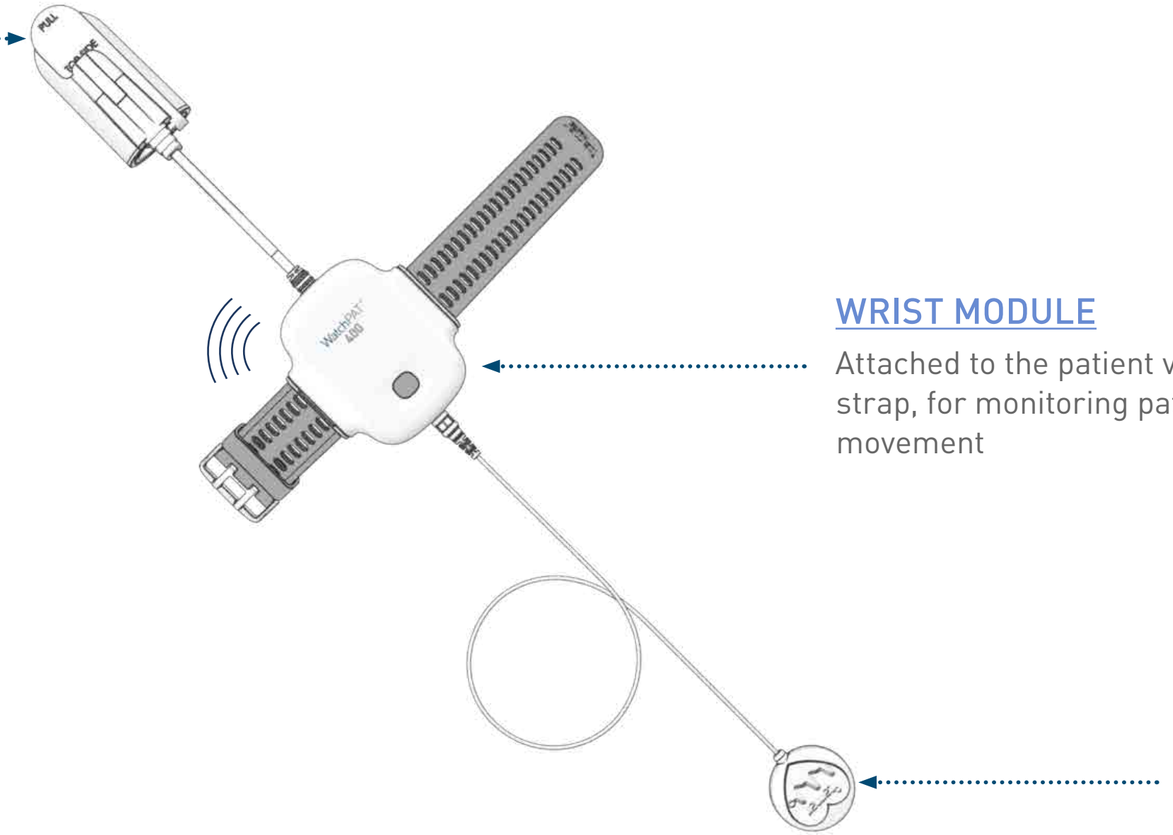
This chapter introduces the WatchPAT400 and includes the following:

2.1 OVERVIEW

The WatchPAT400 is a wearable device that consists of a wrist module, finger probe and chest sensor. The device monitors and records a number of different physiological parameters, this data is then transmitted to the application for analysis.

FINGER PROBE

Connects via a 22cm cable to the wrist module and monitors the heart rate and oxygen saturation



WRIST MODULE

Attached to the patient via a wrist-strap, for monitoring patient movement

APPLICATION

Downloads to your mobile phone and allows the healthcare provider to receive and analyze the recorded data

CHEST SENSOR

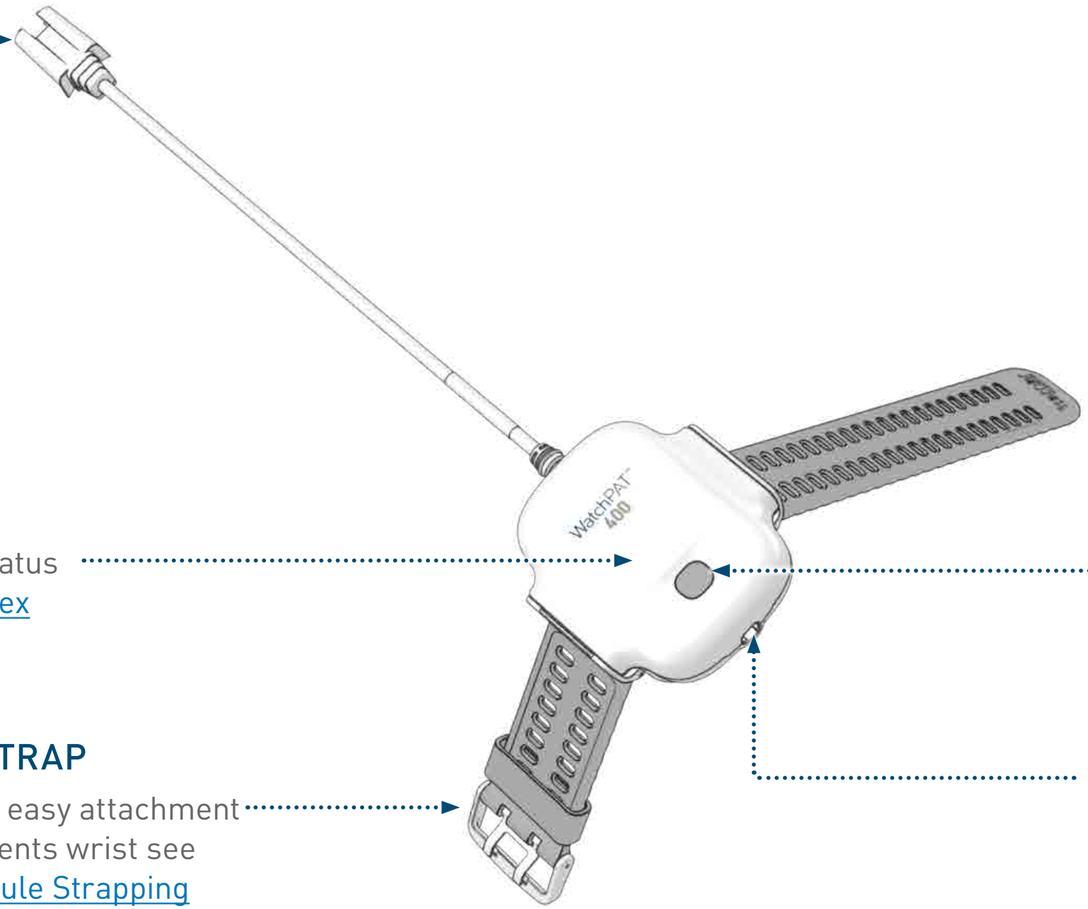
Connects via a 1.2m cable to the wrist module and monitors the snoring and breathing sounds of the patient, as well as patient position and chest movement

2.2 WRIST MODULE DESCRIPTION

The wrist module manages and controls the device and includes the following components:

FINGER PROBE CABLE

Allows for connection to the finger probe see Finger Probe Connection



LED INDICATION

Indicates the device's status see LED Color Code Index

BUTTON

Enables device operation

CHEST SENSOR PORT

Connects to the chest sensor via a cable see Chest Sensor Connection

WRIST STRAP

Allows for easy attachment to the patients wrist see Wrist Module Strapping

2.3 CHEST SENSOR DESCRIPTION

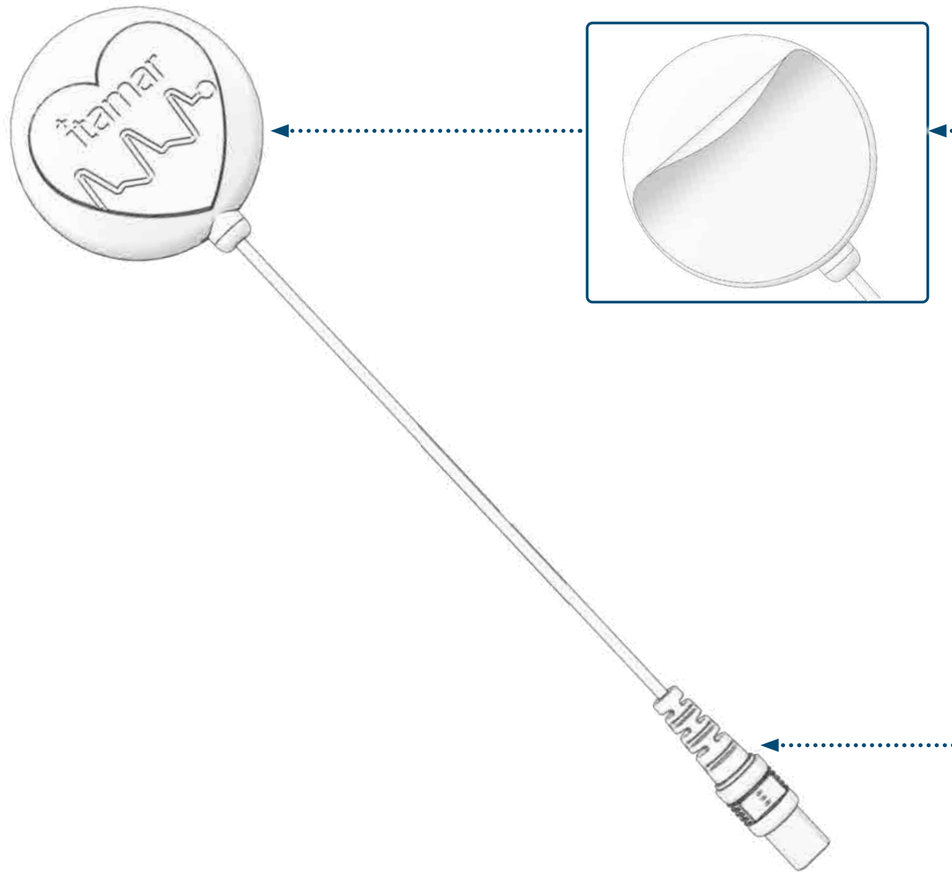
The chest sensor records snoring, body positions and chest movements. It includes the following components:

RESBP SENSOR (INTERNAL)

The RESBP (Respiratory Effort, Snore and Body Position) sensor is an acoustic decibel detector. It uses a very sensitive microphone that records snoring and other sounds in the audio range

3-AXIS ACCELEROMETER SENSOR (INTERNAL)

3-axis accelerometer provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit) and chest movement



REMOVABLE PAPER

Protects the adhesive until the patient is ready to attach the sensor prior to the study see Chest Sensor Placement

CHEST SENSOR CABLE

Allows for connection to the wrist module see Chest Sensor Connection

2.4 FINGER PROBE DESCRIPTION

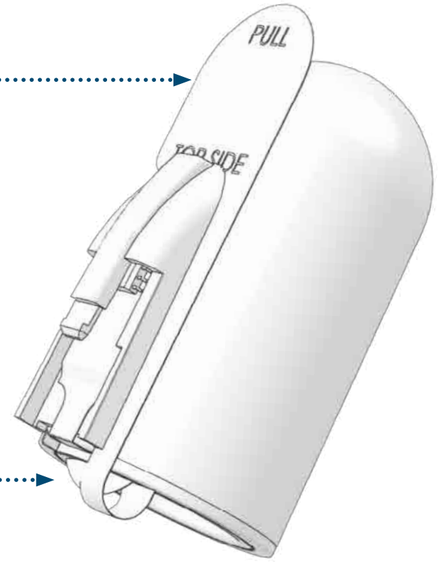
The finger probe measures and records the heart rate and oxygen saturation using a plethysmographic method and includes the following components:

TOP TAB

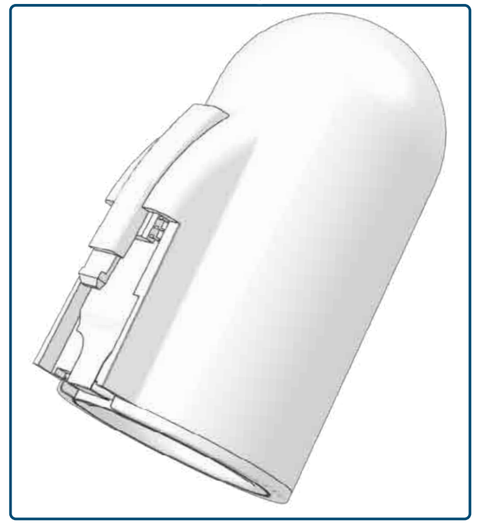
Displays correct orientation see Finger Probe Attachment

WRIST MODULE PORT

Connects to the wrist module via a cable see Finger Probe Connection



Finger probe without top tab



2.5 APP DESCRIPTION

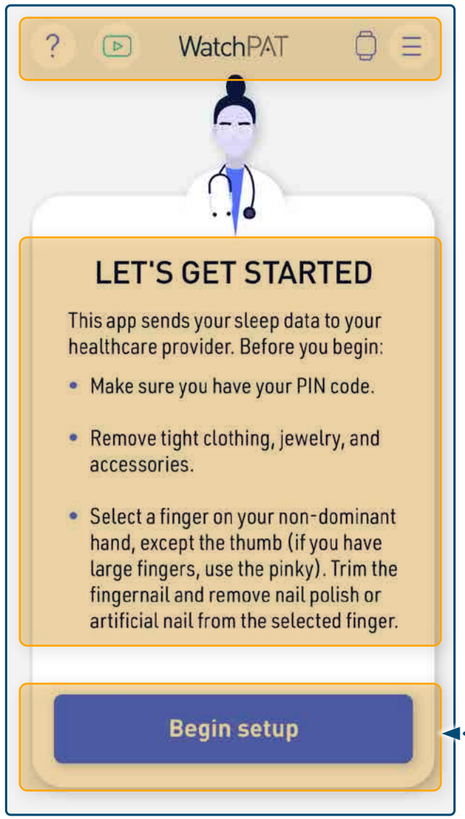
The WatchPAT application downloads to the mobile phone to operate the sleep study. The app records the data and sends it online to be analyzed.
The home screen displays the following:

UPPER TOOL BAR

To access settings and status indications see Upper Tool Bar Description

MAIN SCREEN

Provides information and patient operating instructions



LOWER BUTTONS

Enables navigating to the different screens

NOTE: When using the WatchPAT application, users should follow standard mobile security practices. This includes password-protecting your device, keeping the operating system up-to-date, installing anti-malware software, and avoiding the use of public Wi-Fi networks when accessing the application. These measures help ensure the security of personal data while using the WP400 application

2.5.1 Upper Tool Bar Description

The WatchPAT application's upper tool bar displays the following:

VIDEO LINK

Enables the user to access support videos that offer visual instruction

CLOUD CONNECTION

Indicates the application's connection to the cloud

DEVICE CONNECTION

Indicates the application's connection to the WatchPAT400 device

HELP

Enables the user to access support resources that provide assistance in navigating the application

MENU BAR

Provides access to additional settings

3. PROVIDER OPERATION

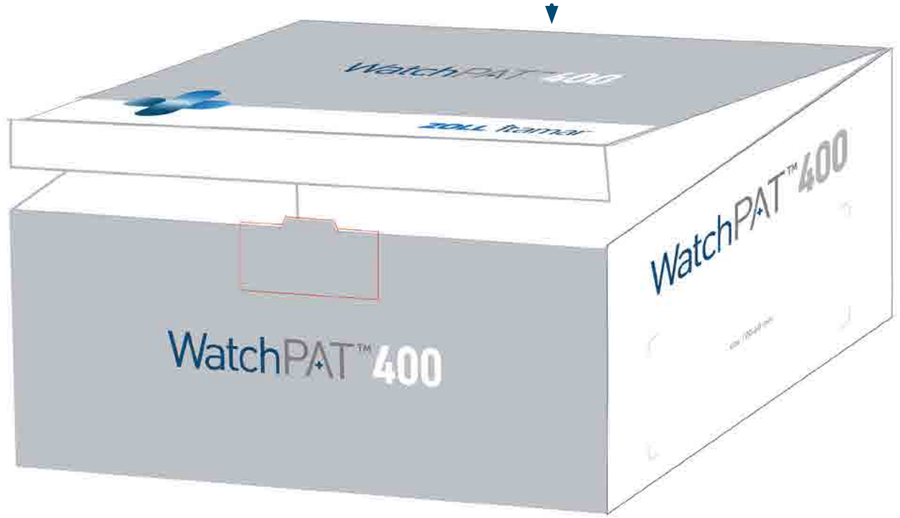
This chapter reviews the tasks for providers associated with operating the WatchPAT400 and includes:

- Unpacking
- Finger Probe Connection
- Device Registration
- Chest Sensor Connection
- Battery Insertion
- Device Self Test via App
- Device Self Test without App
- Cleaning Instructions
- Wrist Module Strap Attachment
- Packaging Kit for Patient
- Receiving KIT from Patient
- Troubleshooting
- Study Reports
- Service

3.1 UNPACKING

Perform the following steps to unpack the WatchPAT400:

1. Open the WatchPAT400 box. The WatchPAT400 case is inside

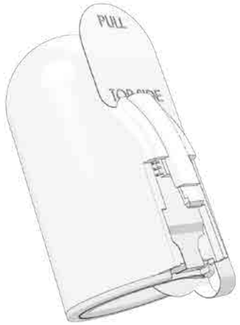


2. Unzip the WatchPAT400 case

3 Verify all parts are present

Finger probe

Refer to Finger Probe Connection for more information



Chest sensor

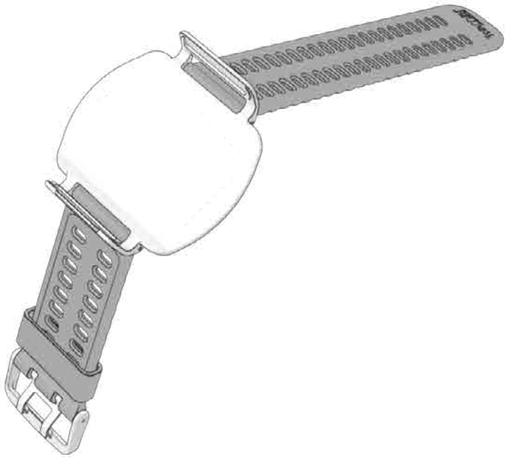
Refer to Chest Sensor Connection for more information

Wrist device

Refer to Wrist Module Description for more information

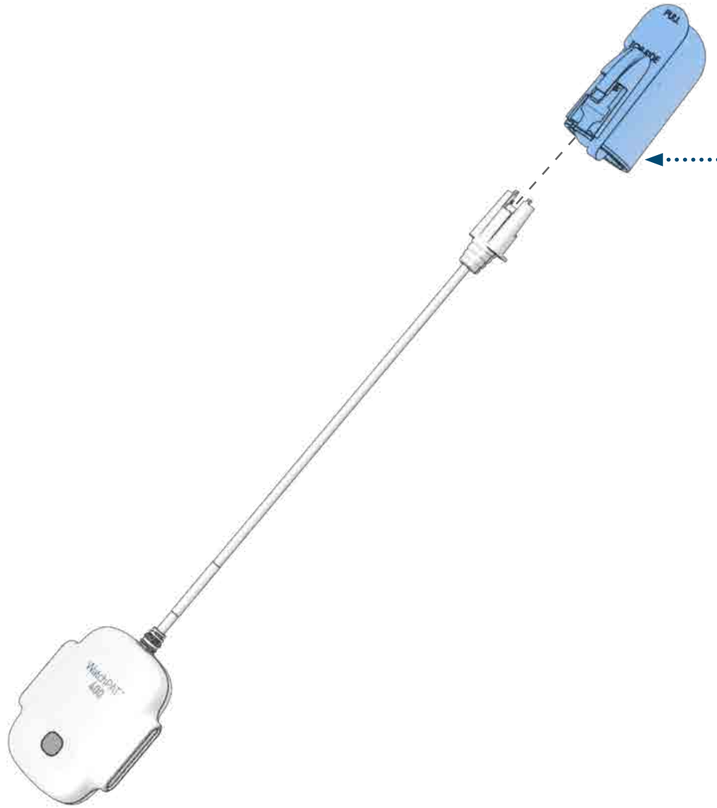
Wrist base

Refer to Wrist Module Strap Attachment for more information



3.2 FINGER PROBE CONNECTION

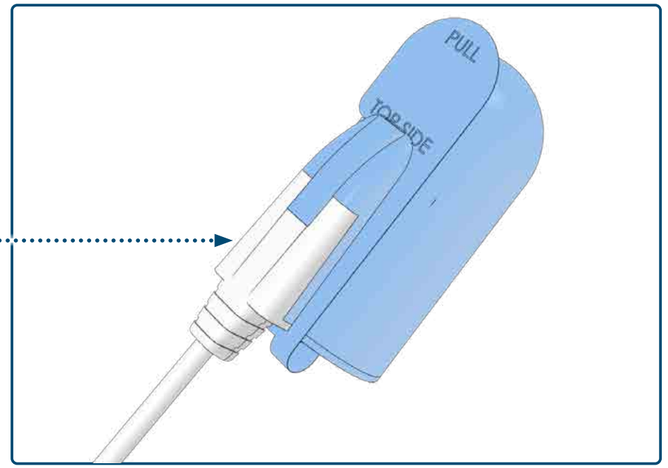
Perform the following steps to connect the finger probe to the wrist device:



1. Connect the finger probe to the finger probe cable

NOTE: The probe is single use. Reuse of probe between patients can lead to cross-contamination, infection, and/or patient injury.

2. Verify the white cover of the probe clicks into place



NOTE: Do not remove the tab

3.3 DEVICE REGISTRATION

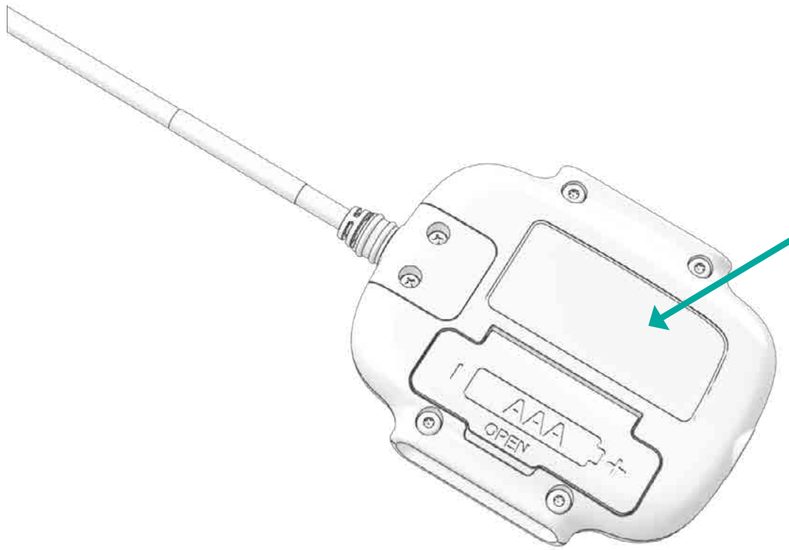
Perform the following steps to register the patient and the device to the zzzPAT software:

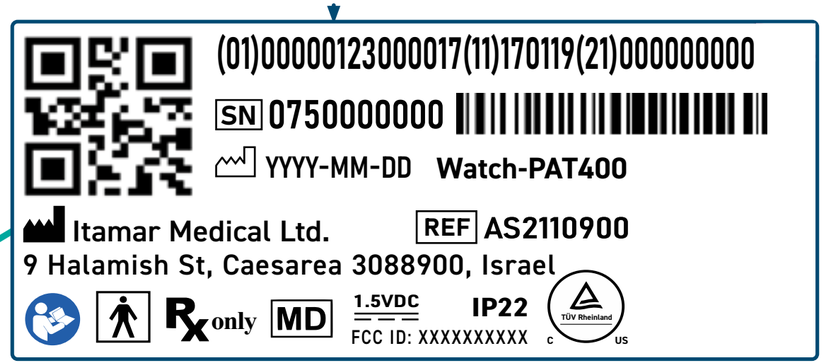
NOTE: Refer to zzzPAT Operation Manual for further instructions

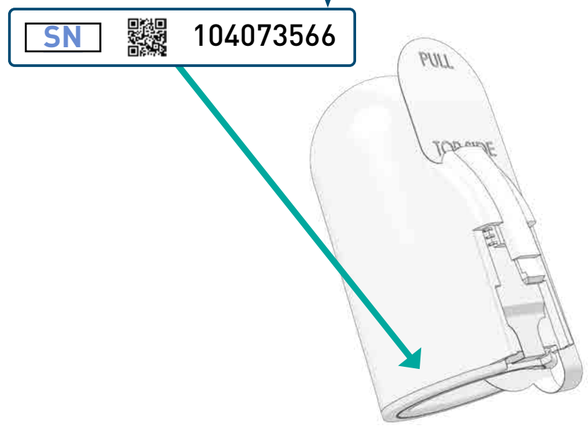
1. Open the **zzzPAT** software

2. Insert or scan the serial number located on the wrist device

3. Insert or scan the serial number located on the finger probe

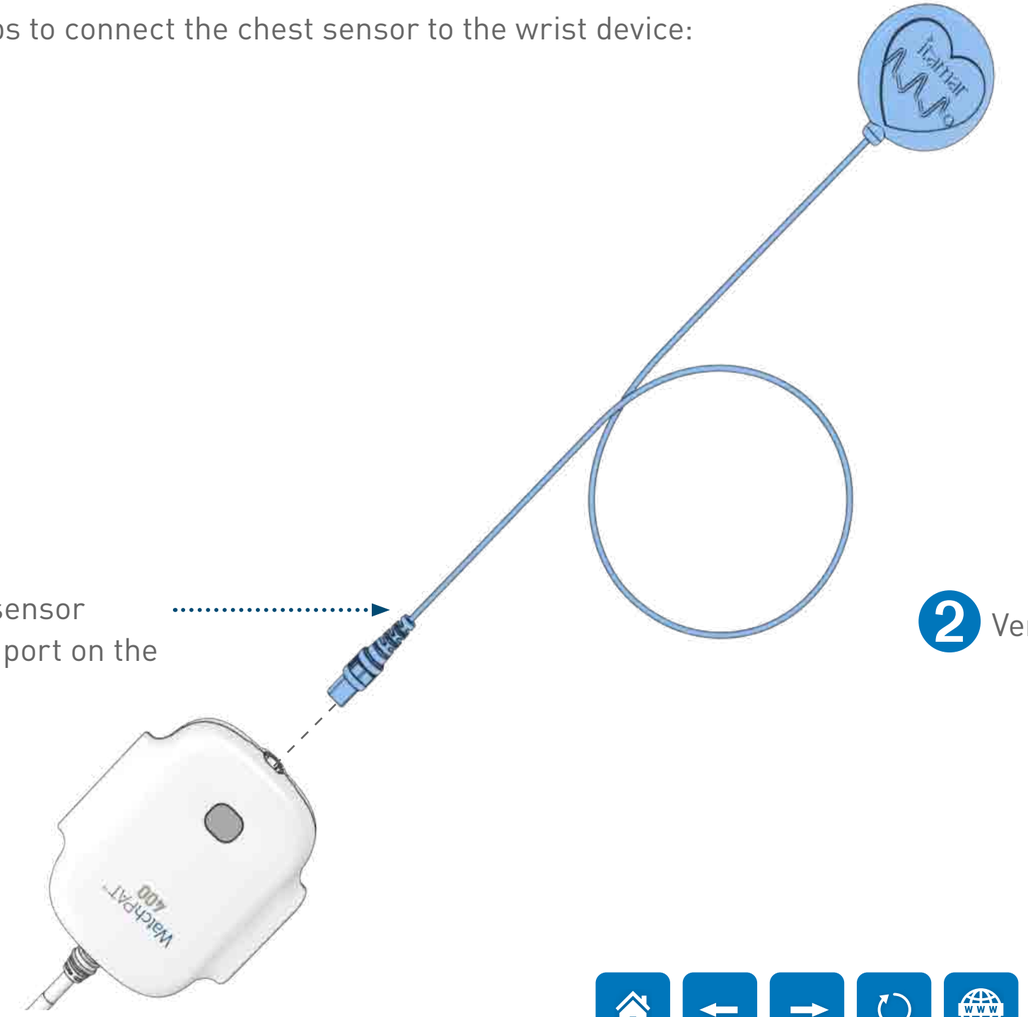






3.4 CHEST SENSOR CONNECTION

Perform the following steps to connect the chest sensor to the wrist device:

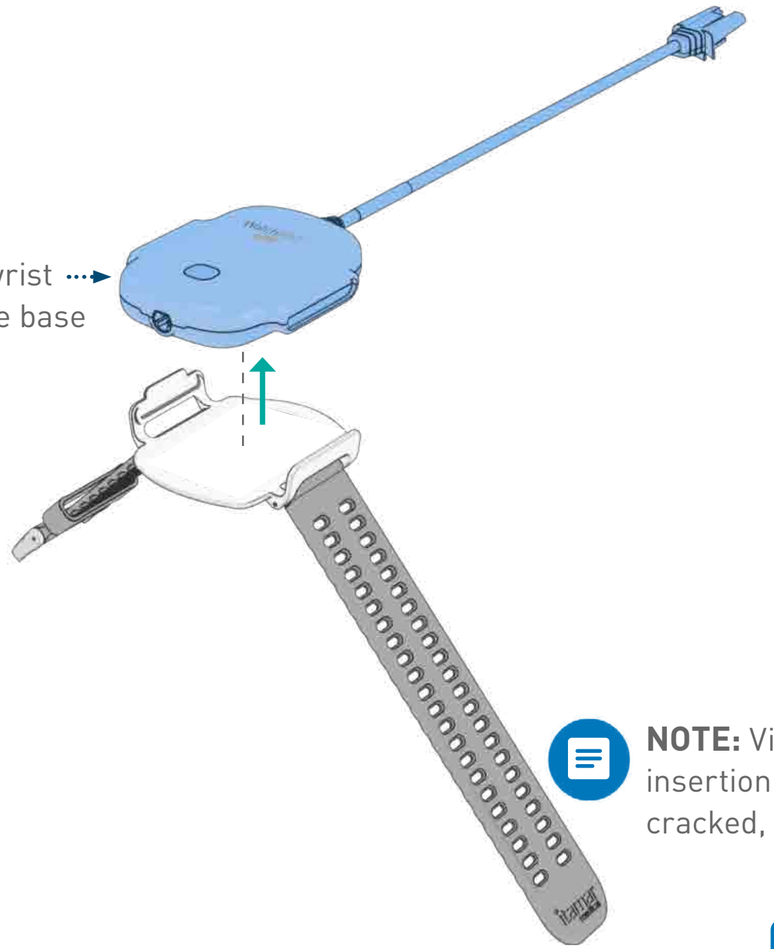


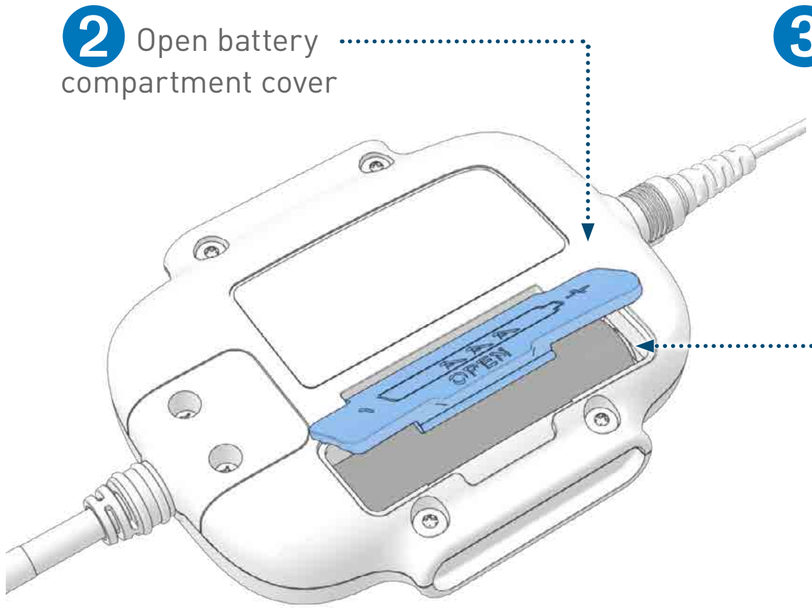
1. Connect the chest sensor cable to the chest sensor port on the wrist device

2. Verify the cable is fully connected

3.5 BATTERY INSERTION

Perform the following four steps to insert or replace the battery in the wrist device:

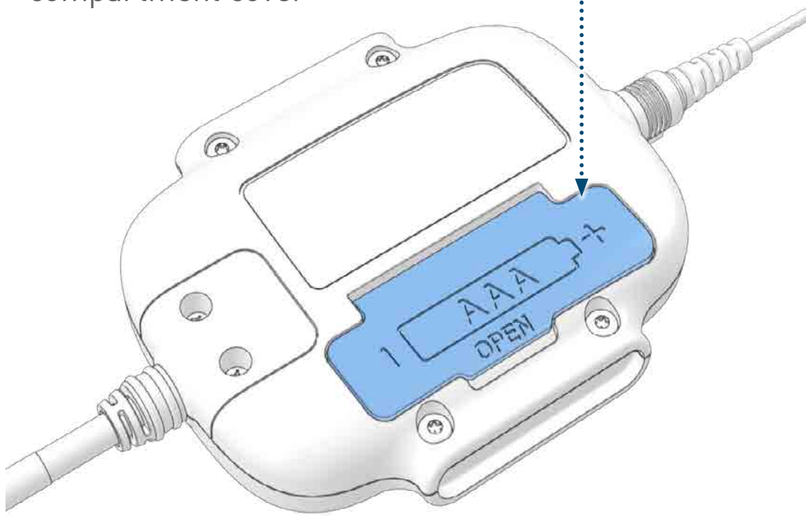




NOTE: Visually inspect the battery before insertion, to ensure it is not swollen, cracked, leaking or has any defect.

NOTE: Align the polarity marking (+ and -) of the battery with the polarity illustrated on the lid and in the battery compartment. Verify that the flat side of the battery is pushed against the spring.

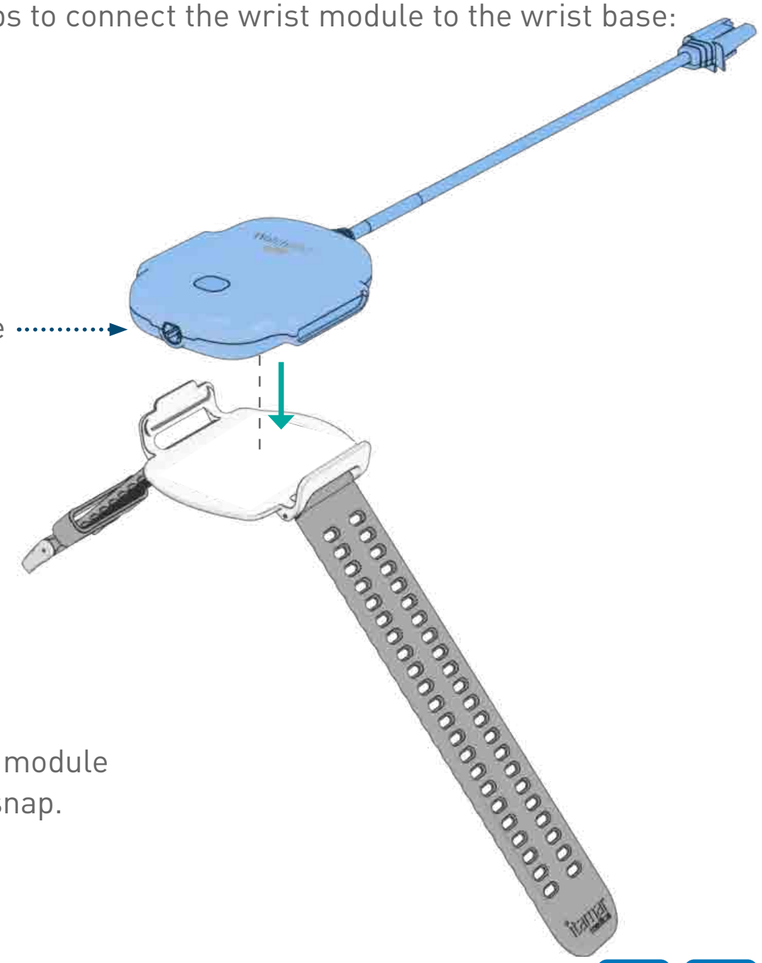
4 Close battery compartment cover



NOTE: Battery should not be stored in the WatchPAT battery compartment, and only be inserted before sending to patient.

3.6 WRIST MODULE STRAP ATTACHMENT

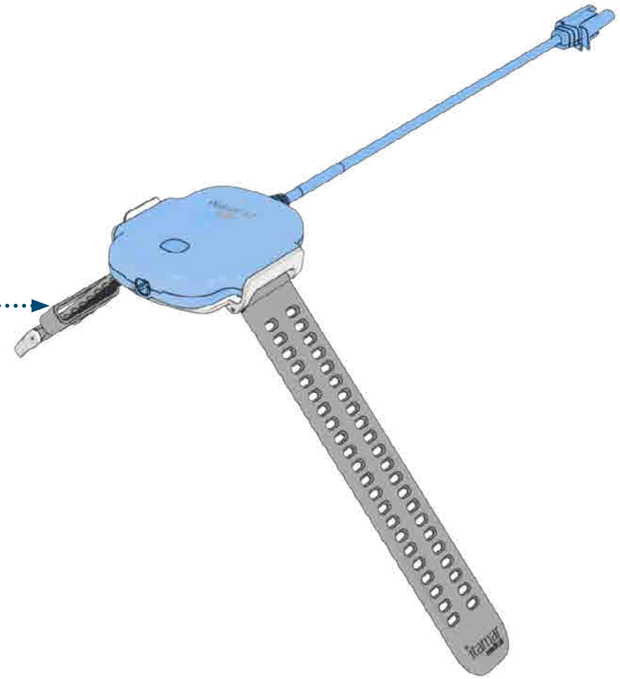
Perform the following steps to connect the wrist module to the wrist base:



1 Insert wrist module into the base

NOTE: The wrist module connects with a snap.

2 Verify device clicks into place



3.7 DEVICE SELF TEST VIA APP

The device must be tested and registered to the patient prior to sending the device.

3.7.1 Installing Application

Perform the following four steps to install the WatchPAT application on your mobile phone:

1. Scan the QR code located on the inner side of the KIT hood

2. Download and install the WatchPAT application

   Allow application to have access to files and locations

3. In 'Welcome page' tap '**Continue without entering a number**'

4. Select the **WatchPAT400** device from device options list

3.7.2 Performing Device Self Test

Perform the following eight steps to complete the self test:

1. Tap the menu bar in the WatchPAT application

2. Tap **Device Testing** to open the Technician mode

3. Tap **Scan device Serial Number** to scan the WatchPAT device's QR code. To enter the SN manually skip to Step 4

4. [Manual Option] Enter the WatchPAT's device serial number manually and tap **Enter**

5 Tap **Start Device Test** to start the device's test

6 Tap **OK** to confirm the device passed the test

NOTE: For test failures and error messages see Test Failures

7 Tap **Yes** to start a device test with another WatchPAT device. Repeat steps 1 - 6 for the next device

NOTE: Tap **No** to go straight to Step 8

8 Tap **Exit Device Testing** to exit the Technician mode of the app

3.7.3 Test Failures

The following table reviews the causes and solutions for the device's application self test failures:

ERROR MESSAGE	CAUSE	ACTION
Low Battery	Battery is too weak or expired	Perform the following steps to replace the battery: 1. Tap **OK** 2. Change the battery see Battery Insertion 3. Restart device self test see Performing Device Self Test
Probe Failure	Fingerprobe is missing or expired	Perform the following steps to attach a new fingerprobe: 1. Tap **OK** 2. Attach a new fingerprobe see Finger Probe Connection 3. Restart device self test see Performing Device Self Test
H/W Failure	Device hardware failure	Contact Itamar Medical Customer Support
Chest Sensor not detected	Chest sensor is missing	Peform the following steps to attach the chest sensor: 1. Tap **OK** 2. Attach the chest sensor see Chest Sensor Connection No need to restart the device self test

3.8 DEVICE SELF TEST WITHOUT APP

Perform the following steps to complete the device self test without the app:

NOTE: The device self LED test is only necessary when performing setup without application.

1. Verify all parts are connected to the device
2. Press the device button for five seconds
3. The LED is green for fifteen seconds to indicate the device is ready

NOTE: Refer to LED Index if error LED is displayed

3.8.1 LED Index

The following table reviews the causes and solutions for any error LEDs when setup is performed without application:

ERROR LED		CAUSE	SOLUTION
Red	Constant	Other errors	Contact Itamar Medical
	Flashing	Battery error	Replace the battery with a fresh Alkaline AAA battery
Yellow	Constant	Finger probe error	Disconnect and reconnect the finger probe see Finger Probe Connection
	Flashing	Device ready to record	Device ready for patient use
		Missing chest sensor	Connect chest sensor to device see Chest Sensor Connection
No Light		Battery depleted, or battery is placed backwards or hardware error	Check the battery. If it is goo and placed properly there is a hardware error. Return device to Itamar Medical

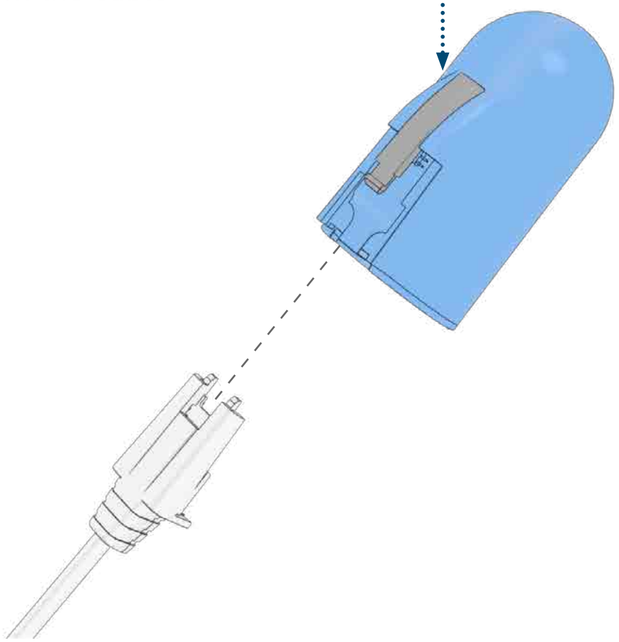
NOTE: Once corrective action is complete, remove the battery, wait for 15 seconds, re-insert the battery and wait for the LED to flash green. Press button for 5 seconds to reinitialize the test

NOTE: Contact the Help Desk as specified on the package or an authorized representative directly, if the problem persists

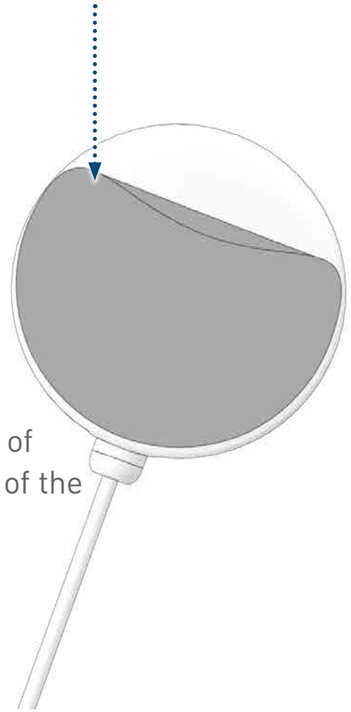
3.9 RECEIVING KIT FROM PATIENT

Perform the following steps upon receiving kit from patient:

1. Remove and dispose of the used finger probe by pressing and holding the small tab to gently slide it away from the cable

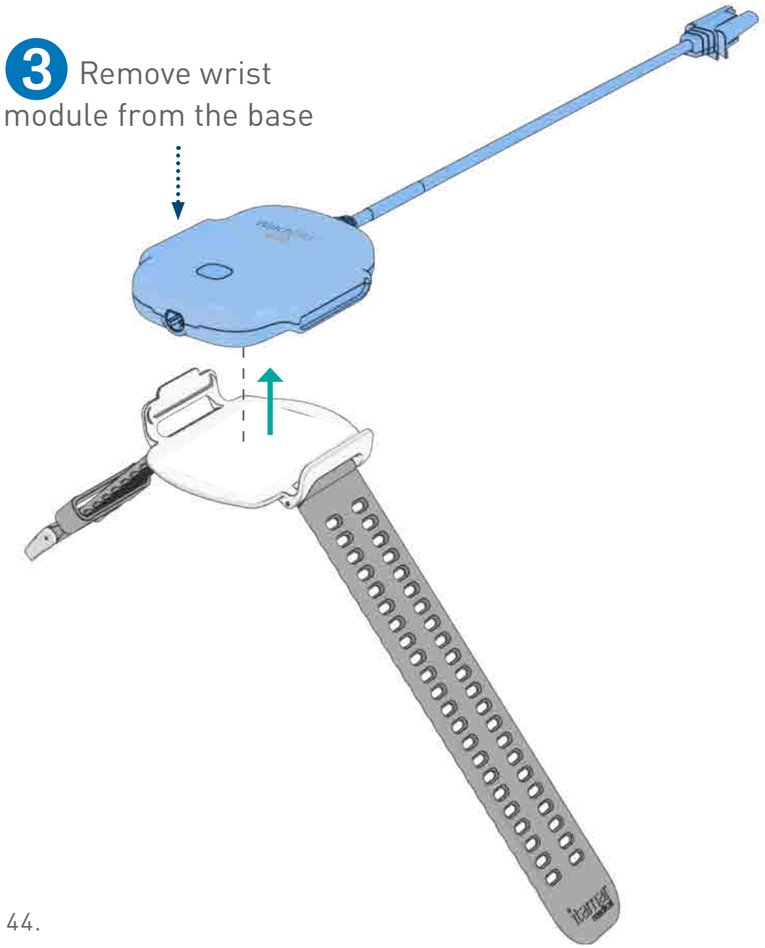


2. Remove and dispose of the used chest sensor adhesive sticker only

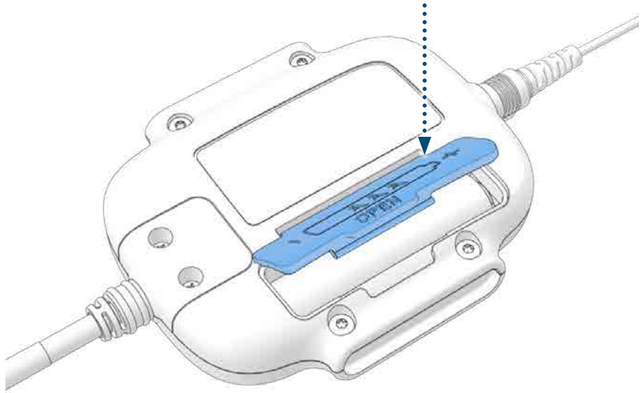


NOTE: Do not dispose of chest sensor. Dispose of the adhesive sticker only

3 Remove wrist module from the base



4 Remove and dispose of the battery by opening the battery compartment



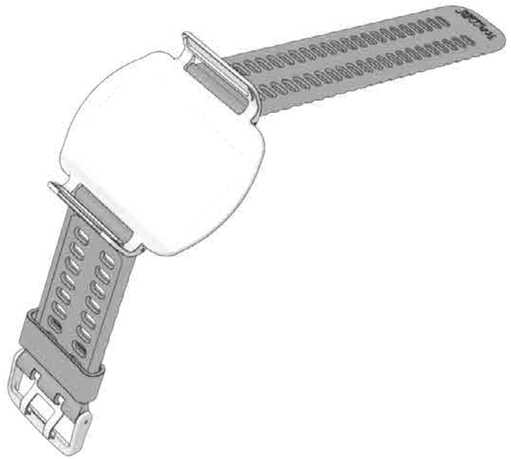
NOTE: Dispose of device components according to local ordinances

NOTE: WP400 device does not store any sensitive, confidential, or proprietary data. Additionally, the WP400 mobile application automatically removes all user data upon uninstallation. Therefore, no special sanitization procedures are required when decommissioning the device or app

3.10 CLEANING INSTRUCTIONS

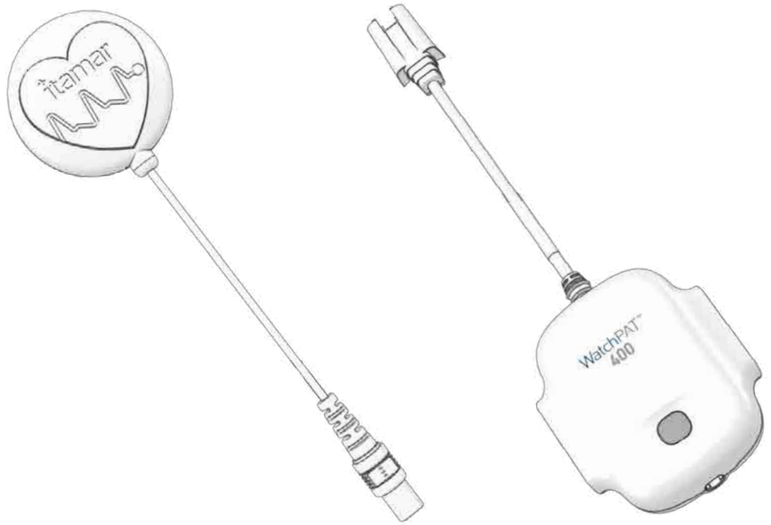
Perform the following steps to clean and disinfect kit after patient use to avoid cross contamination between device uses:

1. Disinfect the wrist base using IPA or any 70% alchol spray



NOTE: Disassemble the wrist module from the wrist device before cleaning.

2. Thoroughly wipe clean the finger probe cable, chest sensor and wrist module using IPA or other 70% alcohol wipes



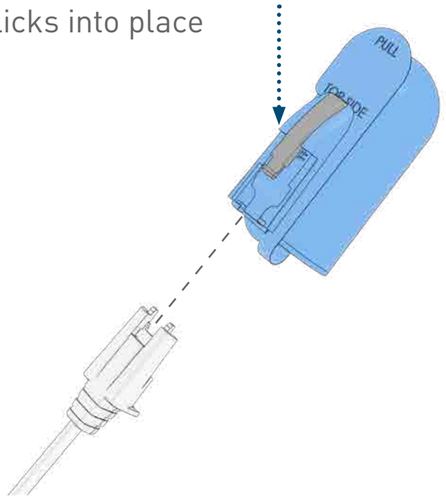
3. Perform a visual inspection of the components and reassemble the wrist module to the wrist base. If necessary, repeat steps 1 and 2

NOTE: It is recommended to wipe clean the WatchPAT case

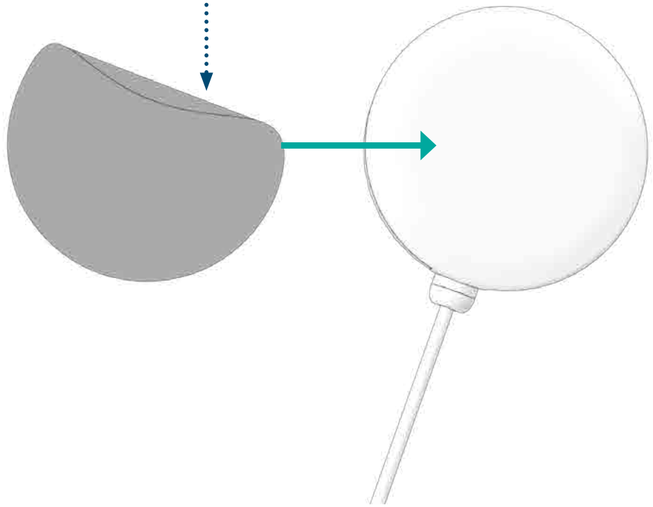
3.11 PACKAGING KIT FOR PATIENT

Perform the following five steps to package kit for patient:

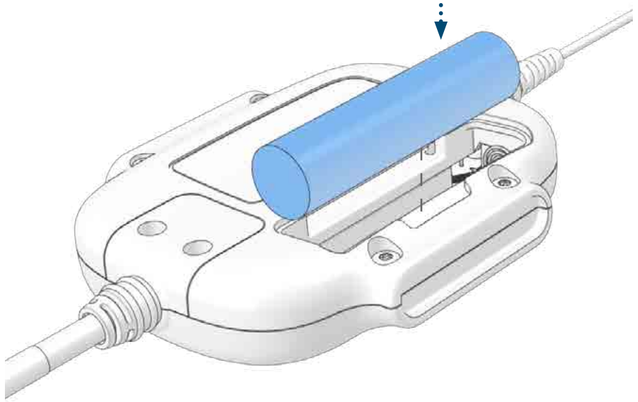
1 Connect a new finger probe by connecting the probe to the finger probe cable until the white cover of the probe clicks into place



2 Attach new sticker to the chest sensor by peeling off the cover on one side of the sticker

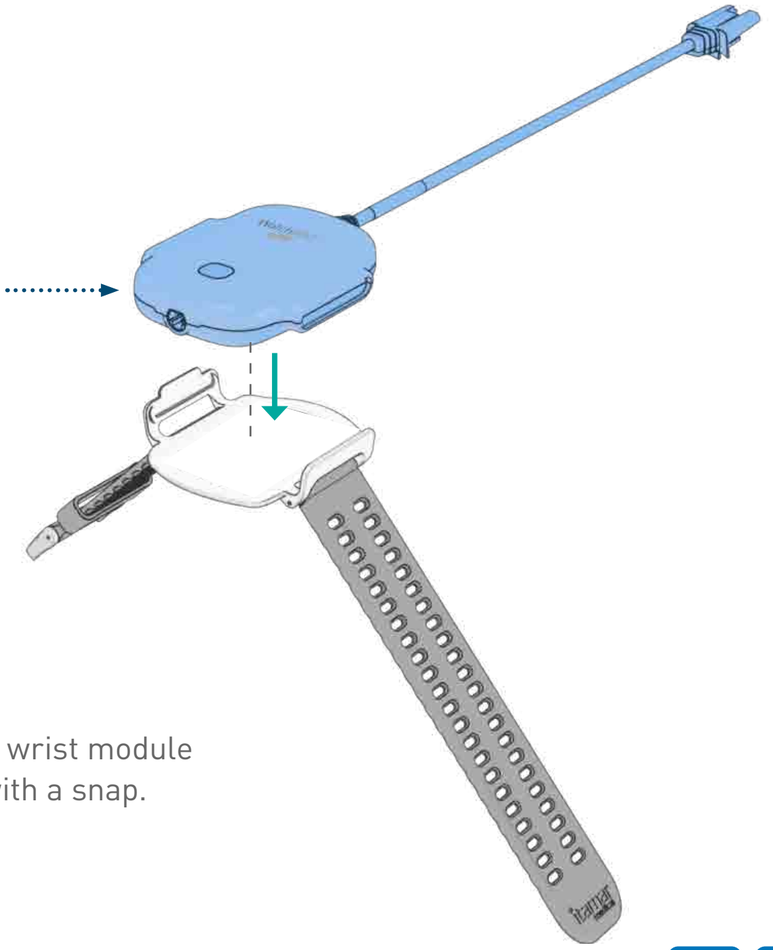


3 Insert new disposable **AAA** battery into the wrist module see Battery Insertion



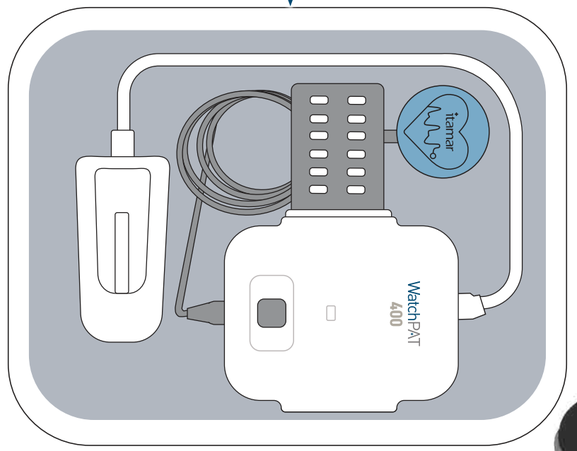
NOTE: If LED error is received after connecting a new finger probe check Troubleshooting

4 Insert wrist module into the base



NOTE: The wrist module connects with a snap.

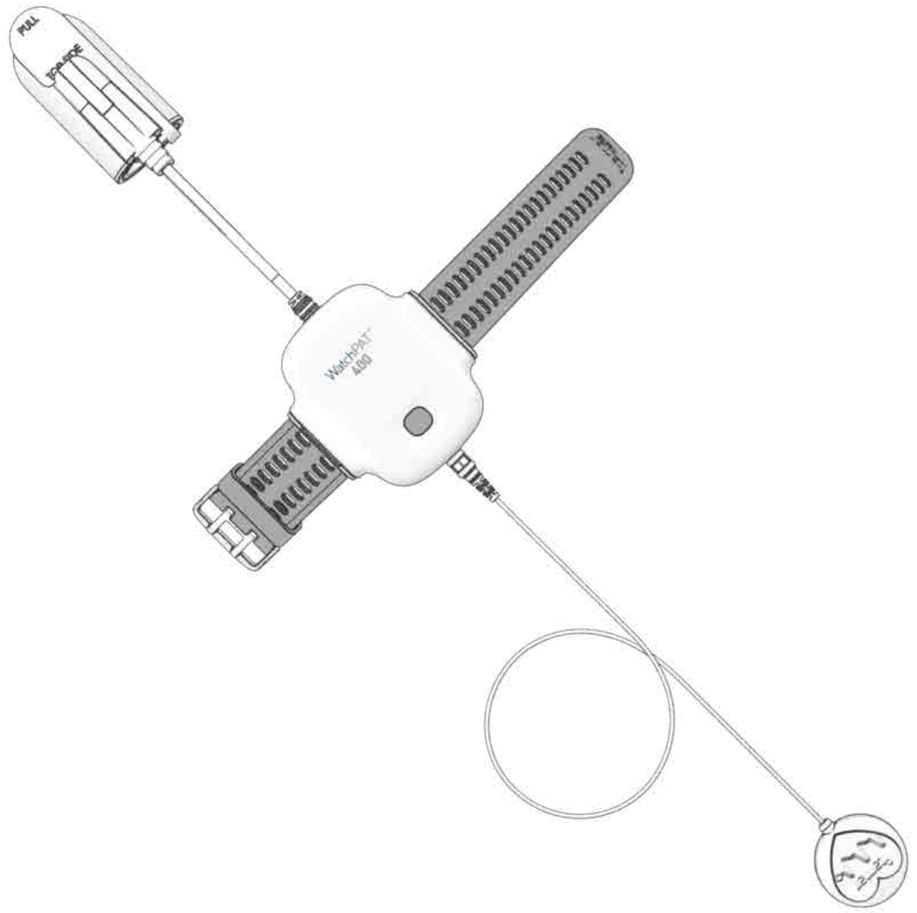
5 Place device with all components into the WatchPAT400 case



3.11.1 Handling

The WatchPAT400 device has been designed and manufactured to meet reliability requirements applicable to medical equipment. Verify the following to ensure maximum durability of operation:

- Store at room temperature, following the conditions on the label, and avoid direct sun light.
- Do not expose the WatchPAT device to extreme temperature or humidity conditions (such as storing in a car or bathroom).
- Use only the designated package for transportation.



3.12 TROUBLESHOOTING

3.12.1 Application Error Messages

The following table includes the actions required for system alarms and error messages displayed on the applicaton's screen:

ERROR MESSAGE	POSSIBLE REASON	ACTION
Device critical errors detected: - Probe LED failure - Probe photo failure	There is a hardware failure in finger probe	Return device to Itamar Medical, and a new one will be shipped in return
Initialization errors occurred: -Chest sensor failure	There is a hardware failure in chest sensor	
Initialization errors occurred: -Device already used	The device has already been in use (when in WELCOME screen)	
Device's critical errors were detected: -Used device	The device has already been in use (when in BATTERY screen)	
Initialization errors occurred: -Insufficient storage space	The application fails to allocate storage on the Mobile phone	Free up to 70MB on the Mobile Phone so the application can operate properly
Communication failure, please try again or the Internet connection is not available	Mobile phone has no internet access	Provide internet access to your phone
Please wait	If this is displayed in battery screen or PIN screen for a long time, it may indicate access to the internet is not available	Provide internet access to your phone

ERROR MESSAGE	POSSIBLE REASON	ACTION
Device is not located Please check if WatchPAT400's LED flashes. If it does, place your phone closer to the device If not: Verify that you placed a new battery and check it is properly positioned	The application cannot find an active device in its proximity	**LED flashing red:** • Bring the device closer to the phone and tap **Next** • Verify Bluetooth is enabled on your phone. • Remove device battery, select **Forget Device** from menu bar and start again • Close other applications that are using bluetooth • If LED still flashing, return device to Itamar Medical **LED not flashing:** • Verify the battery is placed correctly and tap next
Device battery is low or the device's battery is depleted or damaged. Please replace the battery and try again	The device battery has run out of power	Replace the battery with a fresh Alkaline AAA battery
Multiple devices are identified in the surrounding. Please remove battery from all irrelevant devices and try again	The application sees more than one active device	Verify other WatchPAT400 devices in room are turned OFF until after the application successfully establishes communication with the device
The WatchPAT is asking to turn on Bluetooth	Mobile phone does not have its Bluetooth communication turned ON	Approve the application's request of the turning ON the BlueTooth capability
Connection with WatchPAT400 device is lost or the app cannot communicate with the device. Waiting for the communication to resume	Mobile phone Bluetooth communication failures - or -The application cannot find an active device in its proximity - or - No battery in device was found	1. Check Bluetooth communication in mobile phone 2. Bring the device closer to the phone 3. Put a fresh Alkaline AAA battery in the device
Internet connection not available	Mobile phone has no internet access	Check internet communication on mobile phone

ERROR MESSAGE	POSSIBLE REASON	ACTION
Please do not close the application while the data is being uploaded. The data transmission will take several minutes	Some of the data in the device has not been uploaded	Keep the app running and close by to the device until a message that all the data has been transmitted successfully appears
Please plug your phone in a charger	No charger plugged into mobile phone	Plug the phone in to a charger
Attention: The WatchPAT device cannot be communicated. Please bring it closer to the Application	The device is not in proximity or the battery has been extracted	Bring the device closer to the phone or insert the battery

NOTE: If App or device appears to have been impacted by a cyber security issue and could directly impact health and safety, users should report to Itamar Medical customer support.

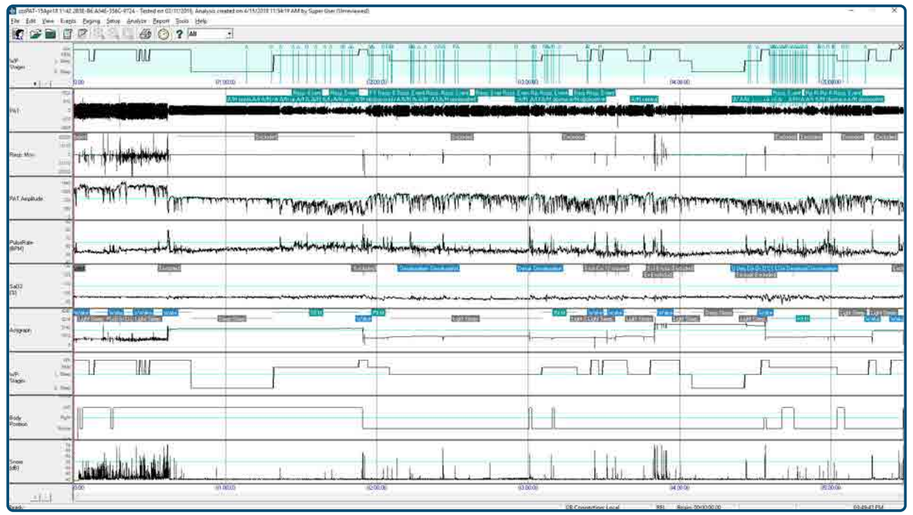
NOTE: Contact Itamar Medical 24/7 Help Desk at 1-888-748-2627, if the problem persists

3.13 STUDY REPORTS

During the sleep study the WatchPAT400 device uploads the recorded data to a web server, informing the clinic of its availability, and referring to its location for data downloading and analysis by the zzzPAT software.
Perform the following steps to review the zzzPAT software:

1. Download the zzzPAT software from https://www.itamar-medical.com/support/upgrades-installation/ onto your laptop

2. Activate the zzzPAT software



3. Download the study data from its location in the web server

3.14 SERVICE

The WatchPAT400 device has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum safety of operation, the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this Manual.
In order to prevent unnecessary failures while patient is using the device, we recommend performing the routine maintenance recommendations as well as the preventive maintenance recommendations as described in this section.

WARNING:

Switch off WatchPAT400 before performing any service or maintenance procedures

CAUTION: Do not use any replacement accessories other than those specified or sold by Itamar Medical

3.14.1 Routine Maintenance Recommendations

The following table reviews when to perform the routine maintenance procedures:

PROCEDURE	RECEIVED KIT FROM PATIENT	BEFORE SENDING KIT TO PATIENT
Clean the device, wrist strap and RESBP sensor	✓	
Inspect device, cable and sensor for possible defects. The product must be serviced if any damage is detected	✓	
Visually inspect the PAT cable's electrical connectors when replacing a probe. The product must be serviced if any damage is detected	✓	
Visually inspect the strap, carrying case and all accessories for possible defects.The product must be replaced if any damage is detected	✓	✓
Perform and pass technician test prior to sending kit to patient		✓
Store product in carrying case while not in use	✓	✓
Replace battery	✓	✓

3.14.2 Preventative Maintenance Recommendations

The following table reviews when to perform the preventative maintenance procedures:

PROCEDURE	AFTER: 200 SLEEP STUDYS OR 1 YEAR OR ERROR MESSAGE IN DEVICE TEST	WHEN DEFECT IS DETECTED OR ERROR MESSAGE IN DEVICE TEST
Replace PAT cable	✓	✓
Replace RESBP sensor if connector is broken or the cable near the connector is peeling off or broken		✓
Replace strap		✓
Replace carrying case		✓

NOTE: Other system parts are not user-serviceable parts. Any maintenance needs that are not listed here should be performed only by qualified service personnel authorized by Itamar Medical Ltd

3.14.3 Replacing Finger Probe Cable

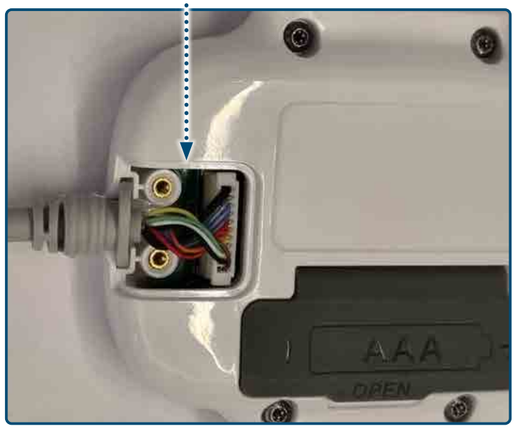
Perform the following five steps to remove and replace the fingerprobe cable:

1. Open lid of the finger probe cable compartment by removing two screws

2. Carefully disconnect the cable from the connector by pulling out the cable

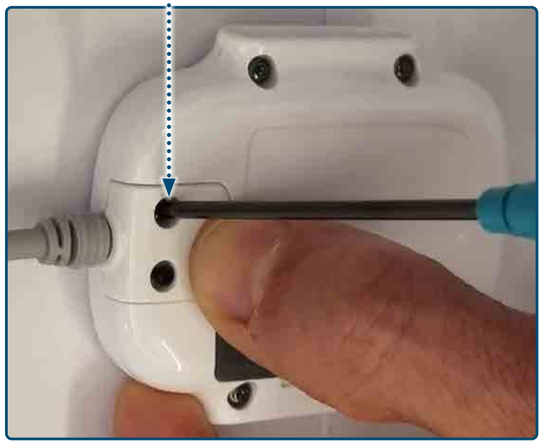
3. Connect a new finger probe cable by gently inserting the connector back into the wrist module until a click is heard.

4 Verify the cable is in place correctly



NOTE: Verify the plastic shoulders of the cable are inserted into the matching cavity on the module before closing the lid

5 Close the lid using two screws



4. PATIENT OPERATION

This chapter reviews the patient tasks associated with operating WatchPAT400 and includes:

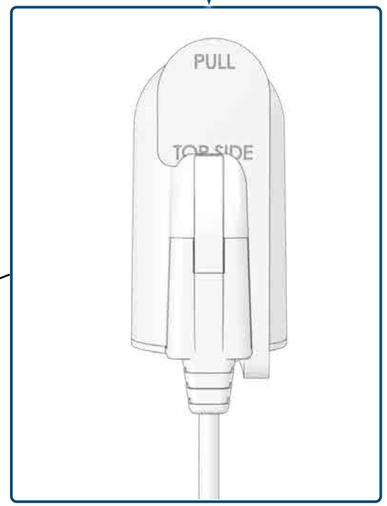
4.1 PATIENT KIT BOX UNPACKING

Perform the following steps to unpack the kit:

1. Unzip the WatchPAT400 case

2. Verify all parts are present and connected

3. Verify tab on finger probe is connected



4.2 APPLICATION INSTALLATION

Perform the following steps to install the WatchPAT application on your mobile phone:

1. Scan the QR code located on the inner side of the KIT hood

2. Download and install the WatchPAT application

NOTE: It is important to perform application installation and setup before unpacking the kit

NOTE: When a new version of the Application is released, it is uploaded by Itamar Medical to the application stores (apple store and google play). In- app notification will be included in the WatchPAT Application to inform the users that a new software version is available for download in the application stores

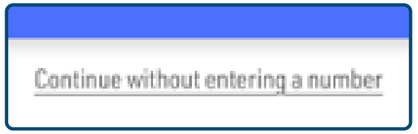
Updates device FW is automatically uploaded to the device when connected with the App

4.3 DEVICE REGISTRATION

The application can be registered with a mobile number or without as follows:

To register the application with your mobile phone number - Enter country code and mobile phone number on the 'Welcome page'.

To register the application without your mobile phone number - Tap **Continue without entering a number** on the 'Welcome page'.



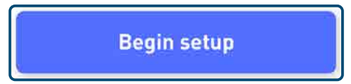
4.4 DEVICE SETUP

Perform the following steps to set up the WatchPAT device on the application:

1. Select the **WatchPAT400** device from the device options list

2. Select your preferred language

3. Read the instructions on the 'let's get started' screen and tap **Begin setup**

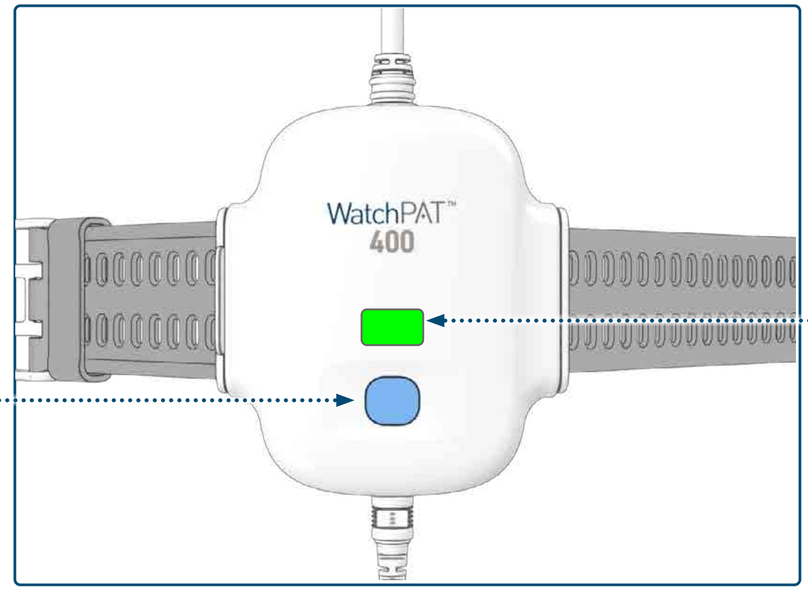


4.5 POWER UP

Perform the following steps to power up the device and run the self test:

1. Power on the device by pressing the ON button on the wrist module for five seconds

2. The LED will flash green for one second to indicate the self-diagnostic tests has started



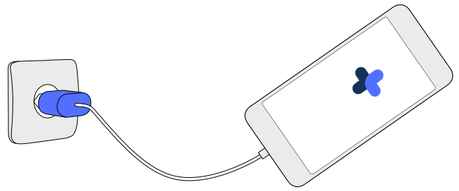
NOTE: Device will turn Off if it does not pair with the application within 5 minutes

4.6 PATIENT PREPARATIONS

Prior to use, the patient should be trained by clinical staff.
Perform the following steps to prepare for the sleep study:

1 Turn off all noise sources, so the room you are sleeping in is as quiet as possible

2 Connect the mobile phone to its charger during the night



3 Tap the ⟩ button on the WatchPAT App when the preparations are complete

4 Enter your four digit PIN code into the WatchPAT app and press '**Enter**'

NOTE: This number is personal and will be supplied by your healthcare provider when the WatchPAT400 device is assigned to you

NOTE:

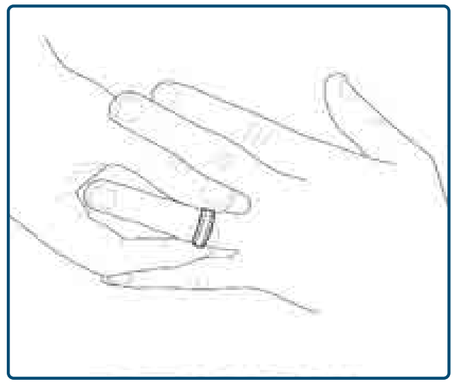
- It is recommended to not exceed five meters between your mobile phone and the wrist device
- It is advised to sleep alone in the room
- The application provides detailed instructions for the patient to follow
- If needed, have someone present to assist putting on the device

CAUTION: Maintain a 5-meter separation distance between the device and any portable RF communications equipment.

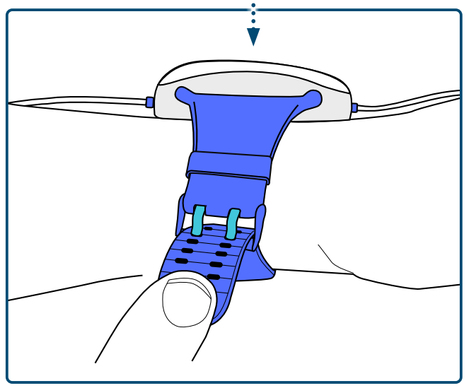
4.7 WRIST MODULE STRAPPING

Perform the following steps to attach the wrist module to your wrist:

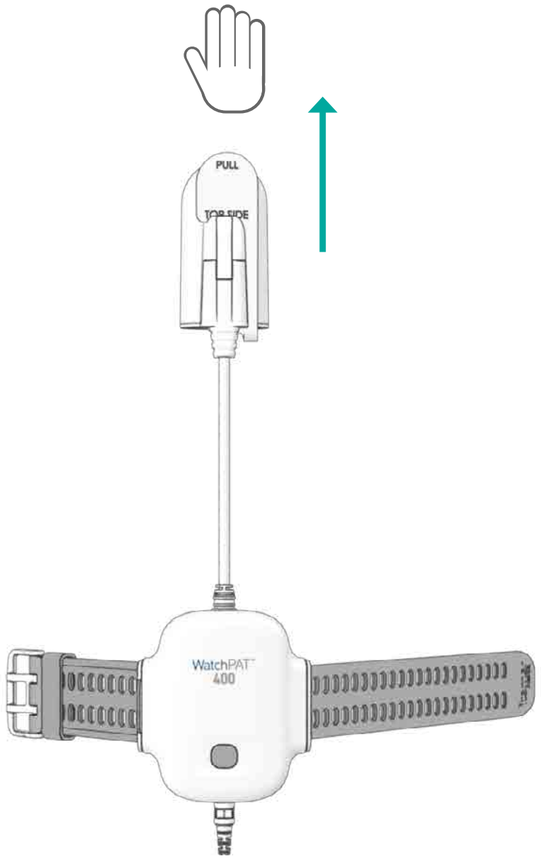
1 Remove tight clothes, rings, watches and other jewelry from your non-dominant hand and wrist



2 Strap the WatchPAT400 device to your non-dominant hand. Do not close wrist strap too tightly



NOTE: Verify the cable that connects to the finger probe points towards the fingers



3 Tap the ⟩ button on the WatchPAT app when the wrist module is attached to your wrist

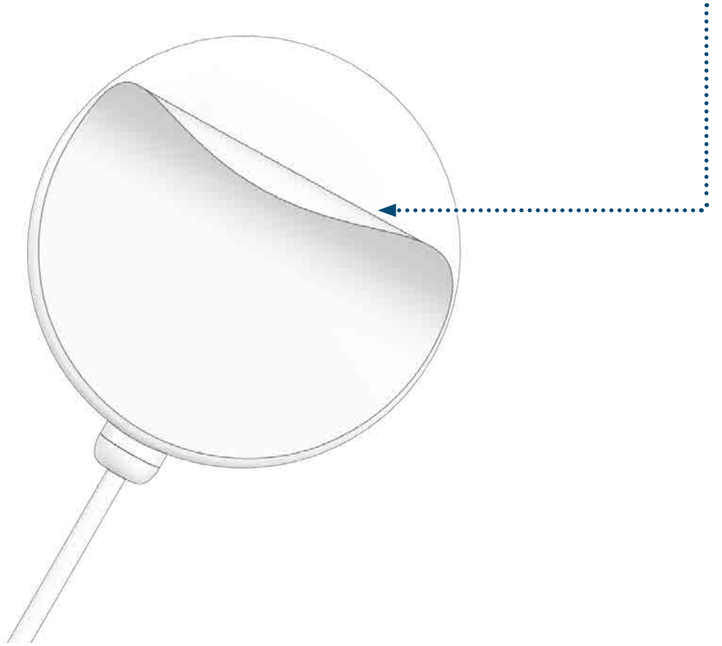
4.8 CHEST SENSOR PLACEMENT

Perform the following seven steps to attach the chest sensor to the chest:

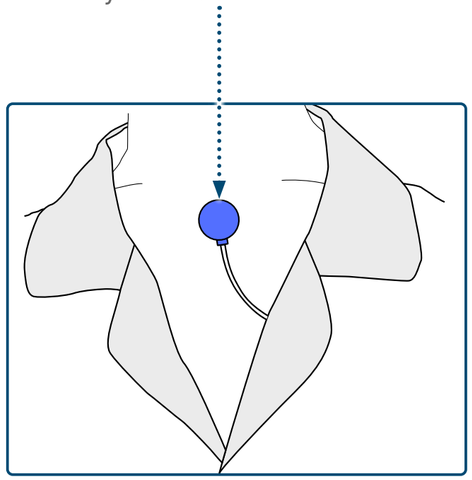
1. Shave chest hair if needed to ensure chest sensor is attached directly to your skin.

2. Thread the chest sensor through the sleeve of your nightshirt, and up to the neck opening

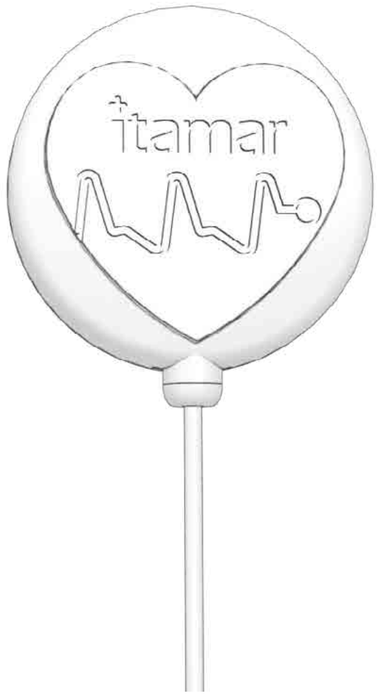
3. Peel the white paper from the back of the chest sensor to reveal the sticker



4 Attach the chest sensor to the center of your upper chest bone, just below the front of your neck



5 Align the main icon to your body, with the cable pointing down



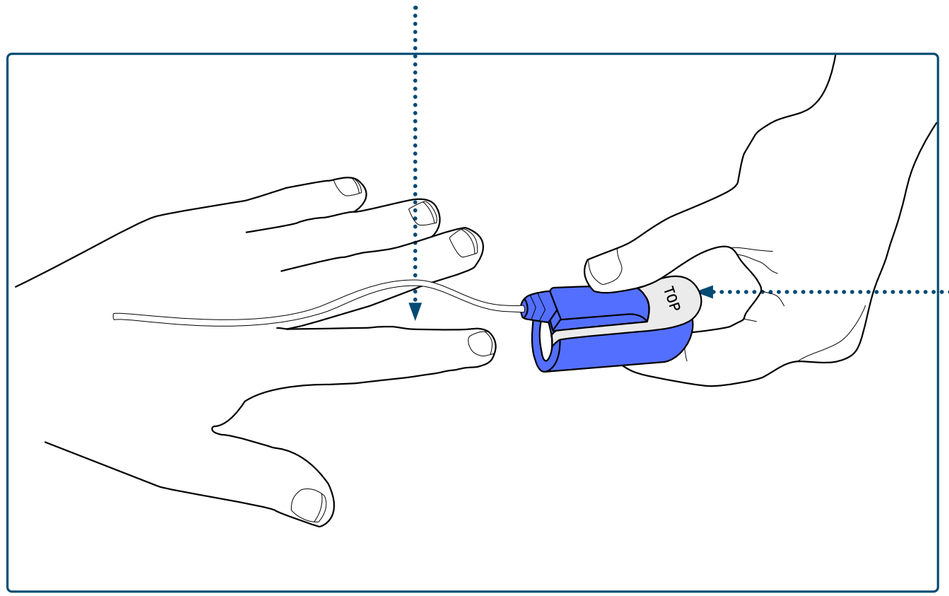
6 If needed, secure the chest sensor in place with medical tape

7 Tap the ⟩ button on the WatchPAT app when the chest sensor is placed on your chest

4.9 FINGER PROBE ATTACHMENT

Proper finger probe placement is critical for good performance. Perform the following six steps to attach the finger probe to your finger:

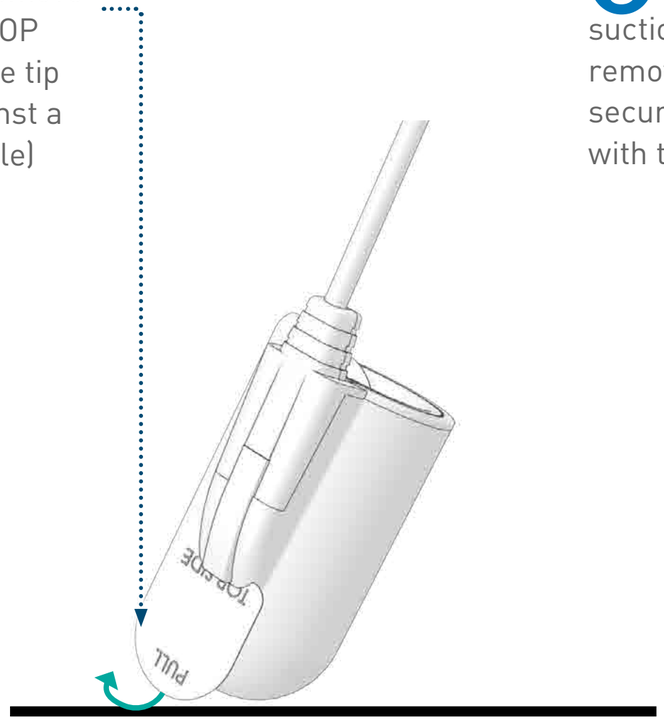
1. Remove nail polish and artificial nails from the study finger and make sure the fingernail is cut short
2. Insert your index finger (or other, if so insructed) gently into the probe until you feel the end
3. Verify that the tab marked **TOP** is on the top of your finger (above your nail)



NOTE: It is recommended that the finger probe be attached to the index finger of your non-dominant hand, but it can be attached on any finger, except the thumb. Patients with large fingers may use their small finger (pinky)

NOTE: The tab on the finger probe should be removed only after the finger is inserted into the probe

4 Gradually remove the tab marked TOP while pressing the tip of the probe against a hard surface (table)



5 You might feel a slight suction once the tab is removed. For small fingers, secure the probe to the finger with tape

NOTE: DO NOT remove the Finger Probe before the night study is terminated. Once the probe is removed it cannot be re-attached

6 Tap the (›) button on the WatchPAT app when the finger probe is attached to your finger

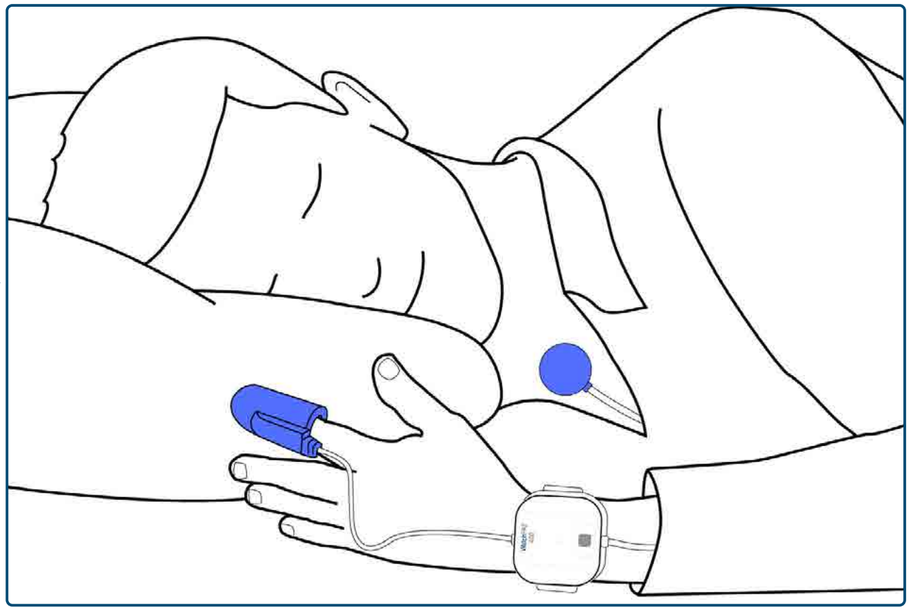
4.10 SLEEP STUDY

This section reviews the steps to perform the sleep study.

4.10.1 Start Study

Perform the following four steps to start the sleep study:

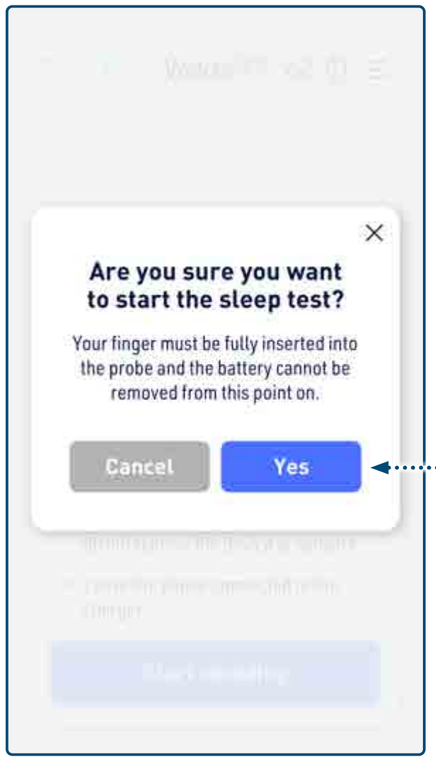
1. Start the home sleep study once all setup activities are completed successfully and you are in bed and ready to go to sleep



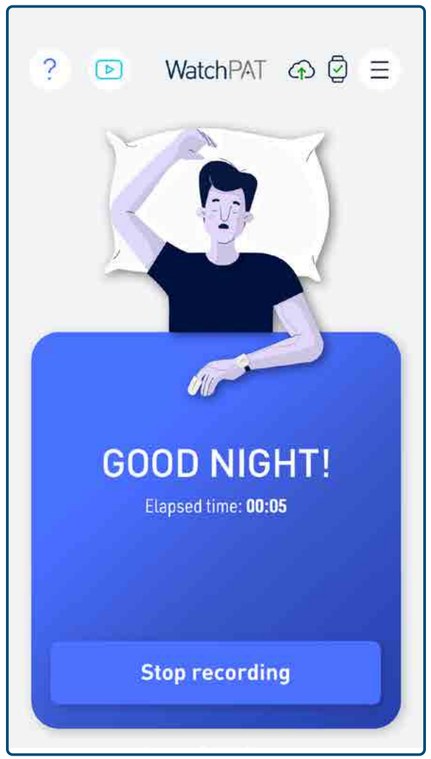
NOTE: If you need to get up during the night, there is no need to carry around the mobile phone. Yet, do not remove the WatchPAT device or sensors

2 Tap **Start recording**

3 Tap **Yes** to start the sleep study



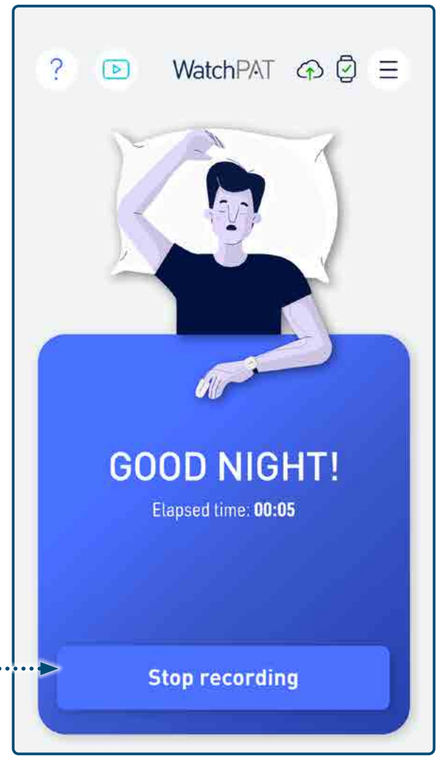
4 The application will now start recording, the patient may go to sleep



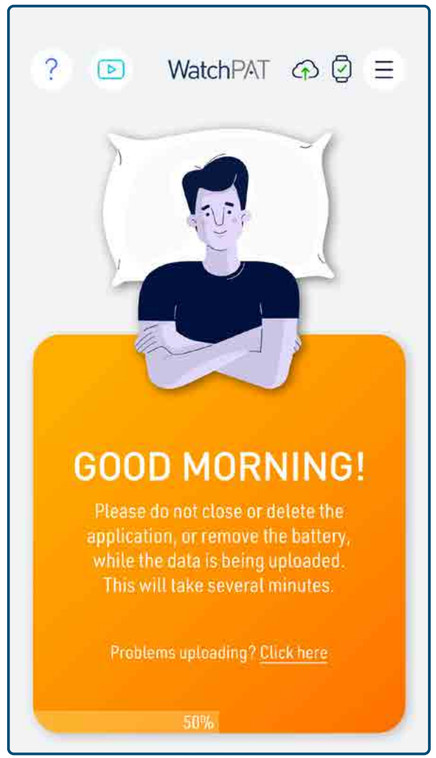
4.10.2 Complete Study Post Sleep

Perform the following steps in the morning to complete the sleep study:

1. Tap the **STOP RECORDING** button to stop the recording



2. Keep the device in proximity to your mobile phone until the application's confirmation that the study is complete



NOTE: If confirmation is not received within 15 minutes refer to Patient Troubleshooting

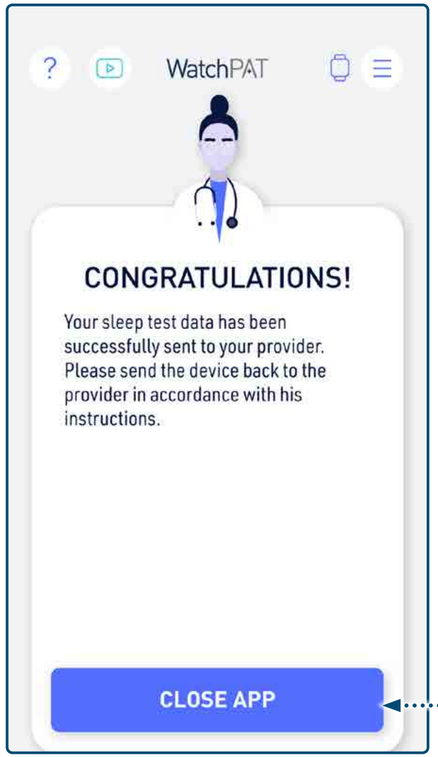
4.10.3 Study Data Upload Information

Perform the following six steps upon completion of the sleep study:

NOTE: Check for network connectivity if there is a delay in uploading the data

NOTE: If continuing with a multi night sleep study refer to Multi Night Sleep Study

1. Remove the device from your wrist, finger and chest



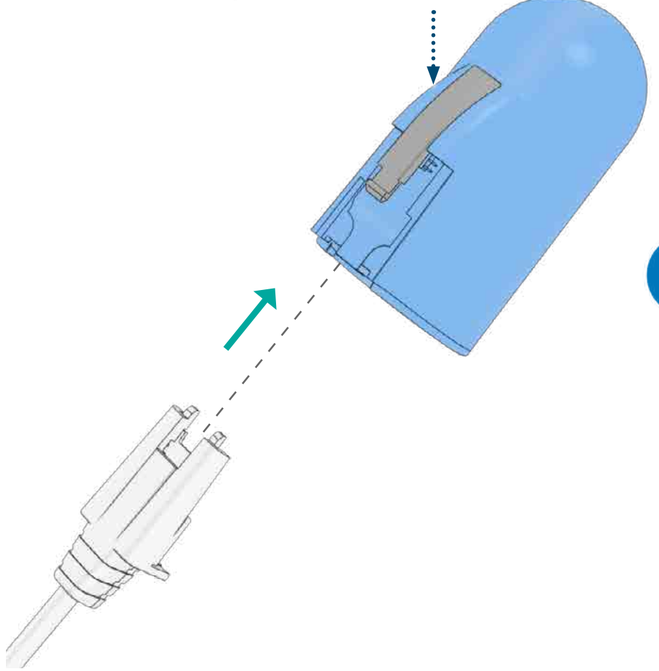
2. The study data continually uploads to the server during the sleep study

3. Tap **Close App** to close the application

4.11 MULTI NIGHT SLEEP STUDY

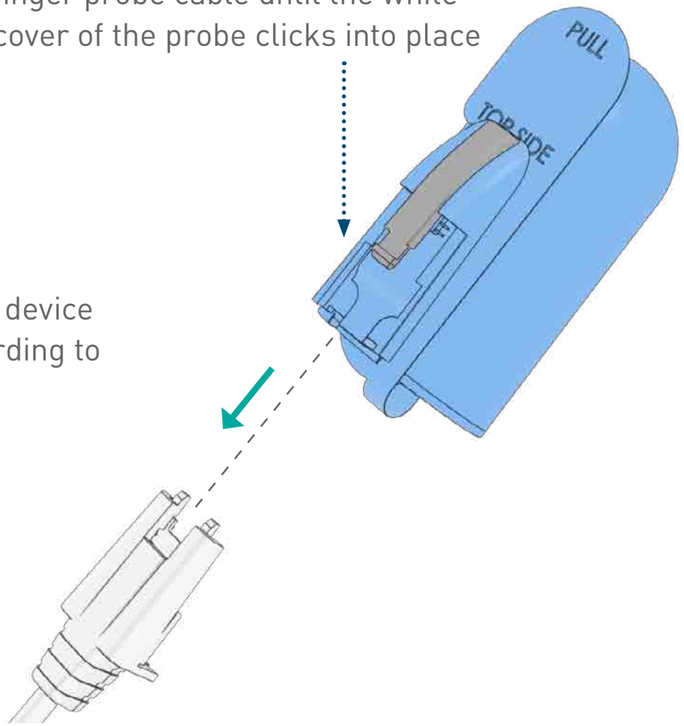
Perform the following steps to prepare the device and application for an optional multi night sleep study:

1. Remove and dispose of the used finger probe by pressing and holding the small tab to gently slide it away from the cable



NOTE: Dispose of device components according to local ordinances

2. Connect a new finger probe by connecting the probe to the finger probe cable until the white cover of the probe clicks into place



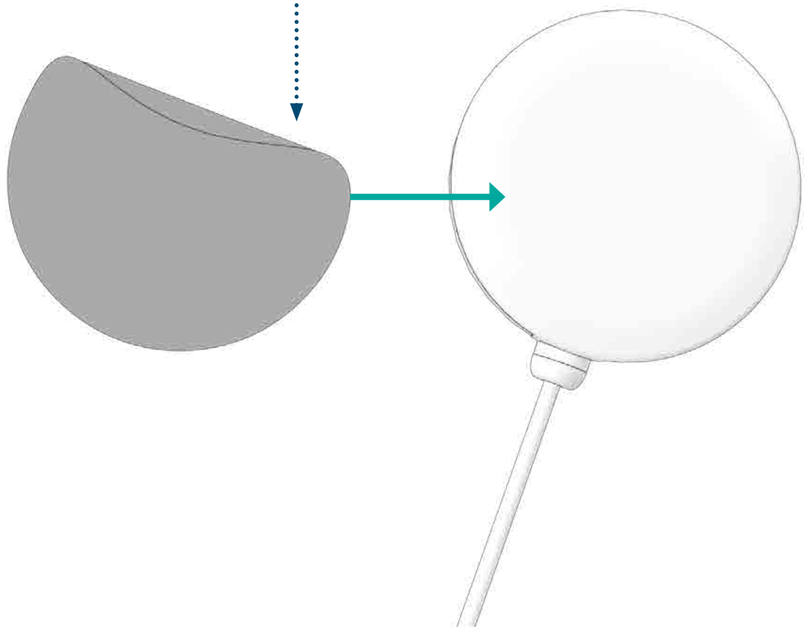
NOTE: Perform the following steps if a photo or LED error is displayed after replacing the finger probe:

- Disconnect and reconnect the finger probe
- Select **NEXT** in the application

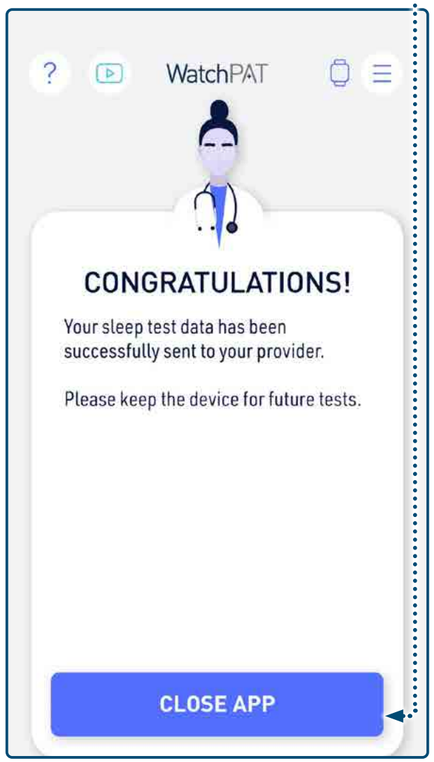
3 Remove and dispose of the used chest sensor adhesive sticker only

NOTE: Do not dispose of chest sensor. Dispose of the adhesive sticker only

4 Attach new sticker to the chest sensor by peeling off the cover on one side of the sticker



5 Tap **Close App** and restart the application

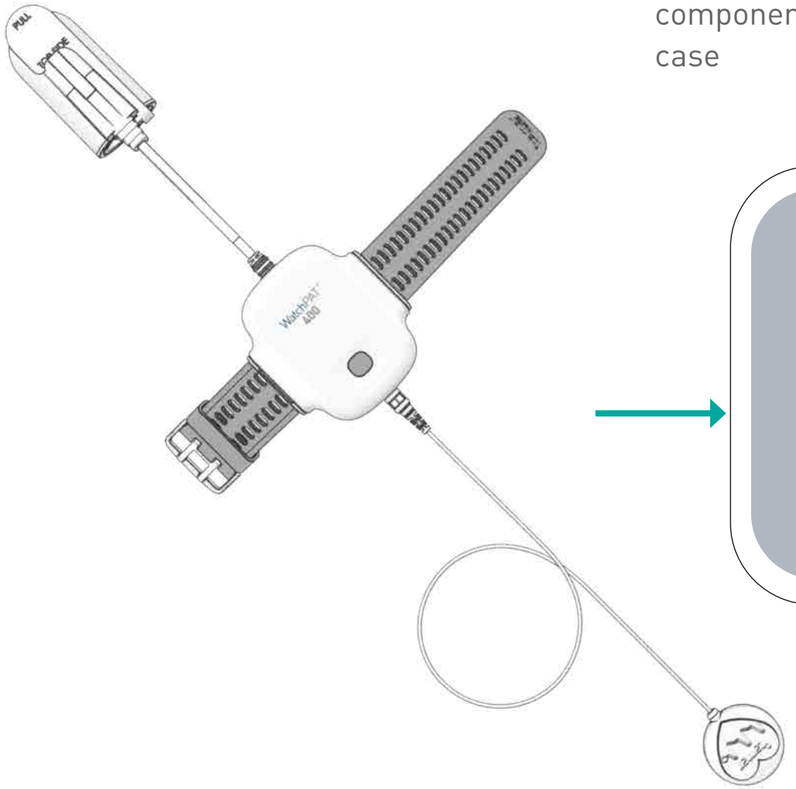


6 Tap **Click here** to replace the chest sensor sticker and finger probe see Multi Night Sleep Study steps 1 -4

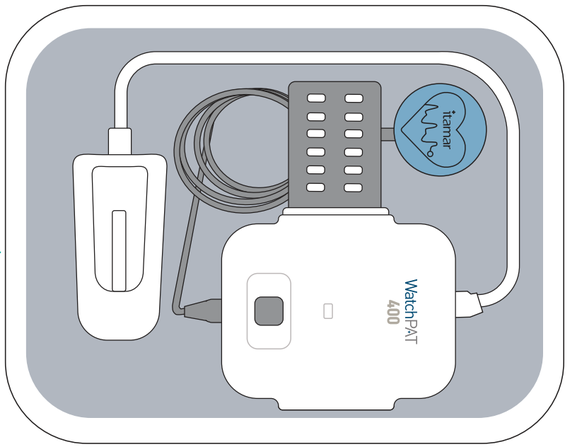
7 Tap the ⟩ button to continue to the preparation screen to begin the sleep study

4.12 KIT RETURN

Upon completion of the sleep study, perform the following steps to send the WatchPAT400 kit back to your healthcare provider:



1 Place device with all components into the WatchPAT400 case



2 Post the case back to your healthcare providor

NOTE: Be in touch with your healthcare providor for their address

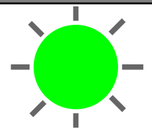
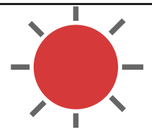
4.13 PATIENT TROUBLESHOOTING

The following table includes the actions required for error messages displayed on the applications screen:

ERROR MESSAGE	POSSIBLE REASON	ACTION
User not registered in system	The device handed to the patient has not been registered	Call provider office
The WatchPAT is asking to turn on Bluetooth	The Mobile phone does not have its Bluetooth communication turned ON	Approve the application's request for turning ON the BlueTooth capability
Internet connection not available	Mobile phone has no internet access	Check internet communication in mobile phone
Exceed number of PIN retires	A non-valid PIN used at all attempts	Call provider office for correct PIN and to reset the retries counter
Please plug your phone in a charger	No charger plugged into a mobile phone	Plug in a charger
Please wait	If this is displayed in battery screen or PIN screen for a long time, it may indicate the access to the internet is not available	Provide internet access to your phone
Please plug your phone in a charger	No charger plugged into a mobile phone	Plug in a charger
Data from WatchPAT400 device finished transferring. Please open the application to upload data to your doctor	The Application could have been suspended by your Phone before completion of the data upload	Open the WatchPAT400 application and follow the guidance provided in its screens
Attention: The WatchPAT device cannot be communicated. Please bring it closer to the application	The device is not in proximity or the battery has been extracted	Bring the device closer to the phone or insert the battery

4.13.1 LED Color Code Index

This section reviews the LED colors and their indications after performing the self test see Power up.

LED COLOR	FLASHING STATUS	INDICATION	ACTION
Green 	Flashing	Connection with application has occured	The sleep study is ready to begin
Red 	Flashing	Waiting for connection to application	Wait a few seconds
Red 	Constant	Hardware problem	Refer to Patient Troubleshooting to resolve the problem

5. TECHNICAL SPECIFICATIONS

This following table includes the technical specifications for WatchPAT400:

PROPERTIES		DESCRIPTION
Recording time		Approx. 10 hours
Channels		PAT, pulse rate, oximetry, actigraphy, In configuration with chest sensor: Snoring, body position, chest movement
Sample resolution		PAT, actigraphy, Snore: 12 bits, oximetry : 1% In configuration with chest sensor: Body position5 discrte states: supine, prone, right, left and sit Chest movements - 12 bits x 3 axis
User interface		Mobile phone: mobile application Device: LED
Accuracy	Pulse rate	30-150 ± 1 bpm
	Amplitude	0-0.5V ± 10%
	Oximetry	Arms ≤ 3% (in range 70%-100%)
PAT channel	Bandwidth	0.1-10 Hz

PROPERTIES		DESCRIPTION
Data storage	Media	NOR SPI Flash
	Capacity	16MB
Power supply	Battery	One OTS 1.5V Alkaline AAA battery
Operating voltage		3.3V
Temperature	Operation	0°C to 40°C
	Storage	0°C to 40°C
	Device storage (w/o probe)	-20°C to 40°C
	Transport	-20°C to 60°C
Humidity	Operating	10% – 93% (non-condensing)
	Storage & transport	0% – 93% (non-condensing)
Atmospheric pressure	Operating & storage	10 – 15 psi
	Transport	8 – 15 psi

PROPERTIES		DESCRIPTION
Physical Measurements (rigid parts)	Main device dimensions (L x W x H)	Device (Enclosure): 60mm*55mm*18mm
	Weight	Device (Enclosure): 38 gr (without battery)
Device transmitter	BLE version	4.2
	Operating frequency	2.4 GHz
	Band width	250 KHz
	Transmitted power	4dBm
	Operating range	5m indoor
	Antenna type	Printed
	BLE profile type	UART
Mobile phone	Operating system	Minimal OS that is supported: Android 10 iOS 15
	BLE version	4.2 or higher
	Network	Wi-Fi / Cellular
	Storage required	>120MB
Wrist module service life		5 years

NOTE: Software Bill of Materials for WP400 is continuously maintained and reviewed by Itamar Medical. Latest version of the SBOM is available in a machine readable format upon demand by contacting Itamar Medical Customer Support

5.1 NETWORK COMMUNICATION AND INTERFACES

This following table includes the communication specifications for WatchPAT400:

	BLUETOOTH LOW ENERGY (BLE)	MOBILE HTTPS PORT 443	DEVICE OPERATIONAL MONITORING INTERFACE (OM) WITH SENSORS
FUNCTIONALITY	Used for secure, short-range wireless communication with compatible mobile devices	Secure data transmission over the internet between the mobile application and cloud services	Interface used to receive data from integrated sensors for monitoring device performance and physiological measurements
DIRECTION	Incoming and outgoing	Outgoing	Incoming
NOTES	BLE is used to establish initial connections with mobile applications and exchange data between the device and the mobile app	All communications are encrypted using HTTPS on port 443 to ensure data privacy and security	The device collects data from internal sensors to monitor its performance and environmental conditions

NOTE: All unused ports on the device are disabled by default to ensure security and prevent unauthorized access

5.2 CHEST SENSOR ACCURACY

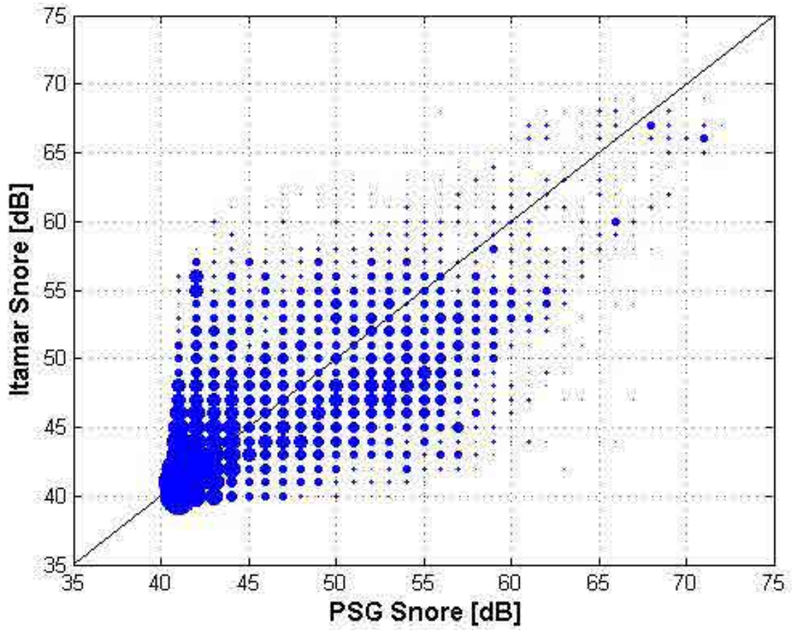
This section, for those using a configuration with a chest sensor, gives statistical performance of the snoring and the body position measurements of the Chest Sensor.

1. **Body Position**

   The body position was compared to the gold standard, manual scoring of the video recording of 31 patients, in 1 minute's epochs (total of 7111 epochs) during sleep. The Agreement between the device and the video recording was 90%. Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059 and 0.8311).

2. **Snoring**

   The snoring level was compared to a gold standard PSG dB-meter placed 1 meter from patient's head. The study included 26 patients, and the analysis was done in 30sec epochs. The correlation coefficient was calculated using Pearson method, assuming a linear relation between the results of the two devices. A statistically significant correlation was calculated between the two devices: r=0.65 p value<0.0001. The table shows a scatter plot of sleep disturbance Index produced by WatchPAT device and dB-meter, with linear regression line.

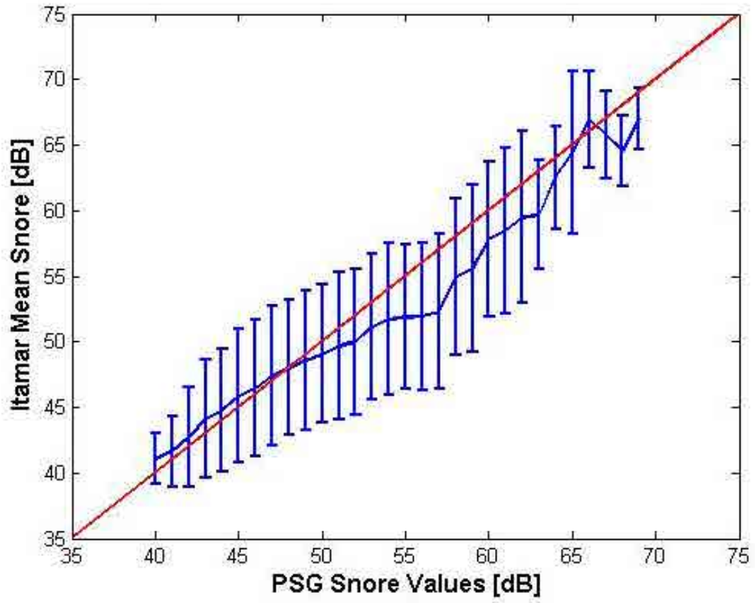


An estimation of the error in each snoring level was calculated by looking at the WatchPAT™ device measurement cut by the results of dB-meter in intervals of 1 dB in the range of above 40dB (below 40 dB was considered not clinically significant being background noise). A high correlation was observed between the results of the two devices for the range of 40-70dB (where sufficient data points were gathered), meaning the resemblance in the results uniformly existed for all the snore levels measured.
The next table presents the statistics of WatchPAT™ device measurements per dB-meter calculation at that range.

PSG DB VALUE	N	MEAN	STD	COEF. OF VARIATION [%]	MIN	MAX	MEDIAN	LOWER 95% CI	UPPER 95% CI
40	2033	41.10	1.89	4.60	40	54	40	41.01	41.18
41	1319	41.61	2.67	6.43	40	54	41	41.47	41.76
42	908	42.68	3.79	8.88	40	62	41	42.44	42.93
43	746	44.12	4.49	10.19	40	58	42	43.80	44.44
44	719	44.75	4.65	10.39	40	65	43	44.41	45.09
45	643	45.90	5.07	11.04	40	59	45	45.51	46.30
46	602	46.45	5.17	11.13	40	59	46	46.04	46.86
47	590	47.39	5.31	11.21	40	66	47	46.96	47.82
48	568	48.03	5.17	10.76	40	61	49	47.60	48.45
49	414	48.56	5.33	10.97	40	64	49	48.05	49.08
50	369	49.07	5.27	10.75	40	61	49	48.53	49.60
51	334	49.68	5.66	11.39	40	63	50	49.07	50.28
52	335	50.00	5.58	11.17	40	64	51	49.39	50.59

PSG DB VALUE	N	MEAN	STD	COEF. OF VARIATION [%]	MIN	MAX	MEDIAN	LOWER 95% CI	UPPER 95% CI
53	311	51.18	5.56	10.86	40	63	51	50.56	51.79
54	253	51.71	5.78	11.19	40	66	52	51.00	52.42
55	209	51.85	5.49	10.59	40	66	52	51.11	52.60
56	182	51.91	5.62	10.82	40	64	52	51.09	52.72
57	129	52.29	5.91	11.30	41	64	52	51.26	53.32
58	95	54.94	5.94	10.82	42	67	55	53.73	56.15
59	66	55.53	6.37	11.47	42	66	55.5	53.97	57.10
60	72	57.82	5.92	10.24	44	66	58	56.43	59.21
61	58	58.48	6.31	10.78	43	68	58.5	56.82	60.14
62	43	59.47	6.56	11.02	46	68	60	57.45	61.48
63	32	59.63	4.15	6.96	50	67	59	58.13	61.12
64	15	62.53	3.93	6.28	56	68	64	60.36	64.71
65	22	64.41	6.21	9.64	49	70	67	61.66	67.16
66	48	66.90	3.66	5.48	59	70	68.5	65.83	67.96
67	42	65.76	3.28	4.99	60	71	67	64.74	66.78
68	27	64.56	2.67	4.13	55	68	65	63.50	65.61
69	6	67	2.37	3.53	64	70	67	64.52	69.48

The results are also presented in the next graph. The figure presents the mean WatchPAT device with SD error bar.



Summary statistics (mean ± SD) of WatchPAT device by dB-meter levels.

NOTE: The snoring and body position safety and effectiveness was validated on adult population only. The clinical study was conducted with the WP200U with equivalent Chest Sensor to the one used with the WatchPAT device.

6. APPENDICES

This chapter includes the following appendices:

6.1 APPENDIX A: LICENSE AGREEMENT

This License Agreement represents the complete and exclusive understanding between you and Itamar Medical. The document can be viewed at https://www.itamar-medical.com/wp-content/uploads/2024/08/U.S.-License-Agreement-082624.pdf Should you have any questions concerning this License Agreement, or if you desire to contact Itamar Medical for any reason, please write to:

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3290 Cumberland Club Drive, Suite 100
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6.2 APPENDIX B: MANUFACTURING DECLARATIONS

ACCORDING TO IEC 60601-1, 60601-1-2 & 60601-4-2

Notes:

- The WatchPAT requires special precautions with regards to electromagnetic compatibility.
- Certain types of mobile telecommunication devices are likely to interfere with the WatchPAT.
- The recommended separation distances in this section must therefore be complied with.
- The WatchPAT must not be used near or on top of another device. If this cannot be avoided, it is necessary - before clinical use - to check the equipment for correct operation under the conditions of use.
- The use of accessories other than those specified or sold by Itamar Medical as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the unit.
- The WatchPAT device does not have essential performance according to IEC 60601-1-2.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the WatchPAT, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The WatchPAT400 was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity performance: performance of medical electrical equipment and medical electric systems.

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic Emissions

- WatchPAT is intended for use in the electromagnetic environment specified in the following tables 1, 2, 4 and 6 below.
- The user must ensure that it is used in such an environment.
- No unexpected behavior was detected during immunity testing and performance was met.

TABLE 1 – DECLARATION - ELECTROMAGNETIC EMISSIONS		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group1 Class B	The WatchPAT400 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.
Harmonic emissions IEC 61000-3-2	Class B	The WatchPAT400 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 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 re-orienting or relocating the [WatchPAT400 or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

TABLE 2 - DECLARATION - ELECTROMAGNETIC IMMUNITY			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV 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 1 kV for input/ output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/ output) to earth	Not Applicable	Not Applicable

TABLE 2 - DECLARATION - ELECTROMAGNETIC IMMUNITY			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

TABLE 3 - DECLARATION - ELECTROMAGENTIC IMMUNITY			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the WatchPAT400], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{23}{E_1}]\sqrt{P}$ 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, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	

TABLE 3 - DECLARATION - ELECTROMAGENTIC IMMUNITY			
Proximity magnetic fields IEC 61000-4-39	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, pulse modulation 2.1 kHz) 7.5 A/m (13.56 MHz, pulse modulation 50 kHz)	Not Applicable	Not Applicable

RECOMMENDED SEPARATION DISTANCES

The WatchPAT is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.
The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (emitters) and the WatchPAT, according to the maximum output power of the equipment, as recommended in the table below.
Precaution: To help prevent adverse events, one should follow the recommended separation distances between RF communications equipment and the WatchPAT.

TABLE 4 - RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE [ME EQUIPMENT OR ME SYSTEM]				
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

TABLE 5 - TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT				
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Immunity Test level (V/m)**
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				

TABLE 5 - TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATIONS EQUIPMENT				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

TABLE 6 - TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO PROXIMITY MAGNETIC FIELDS		
Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation 2.1 kHz	65
13,56 MHz	Pulse modulation 50 kHz	7.5

6.3 APPENDIX C: SPO_2 ACCURACY IN THE WATCHPAT

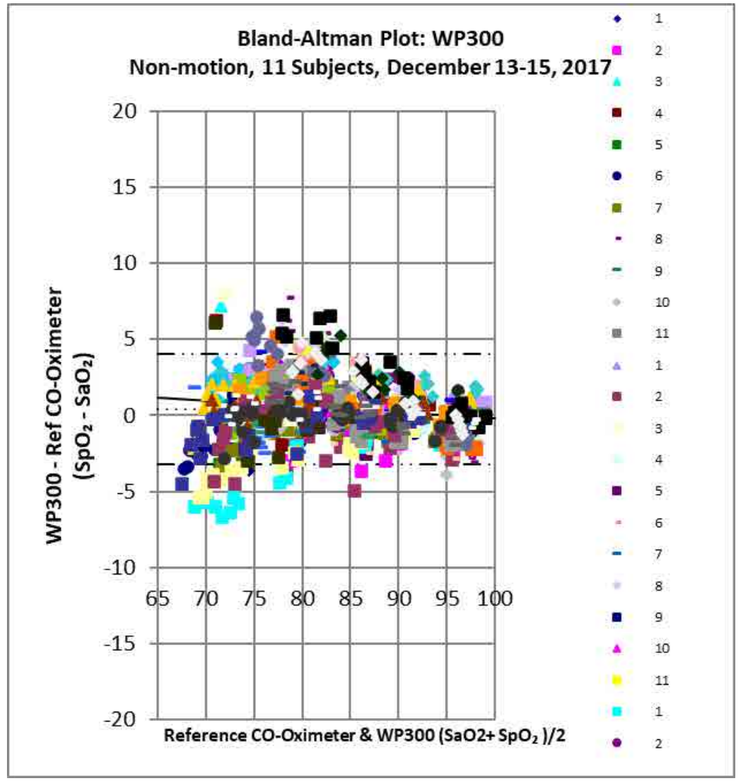
The WatchPAT device uses Itamar Medical Pulse Oximetry system for the measurement of functional oxygen saturation of arterial haemoglobin (SpO_2). This appendix includes information regarding the accuracy of these measurements following a clinical study of Itamar Medical Pulse Oximetry.

1. Overall, the Arms is estimated to be 1.9 for the range 70-100%
2. The next table shows SpO2 Accuracy Results:

COMPARISON TO REFERENCE CO-OXIMETRY					
WatchPAT	* 70- -100	90--100	80--<90	67--<80	A_{RMS} Spec 3% for range of 70-100%
# pts	1350	415	460	475	Pass
Bias	0.4	-0.4	0.6	0.9	
A_{RMS}	1.88	1.10	1.62	2.54	

* Note: The range of 70% to 100% includes reference data down to 67%.

3. The next plot shows the Bland-Altman plot for Itamar-Medical WatchPAT:



Reference: Bland-Altman Range	70-100%
Linear Regression (Bland Altman)	y = 3.7344 + -0.03937 x
Mean Bias	0.41
# pts	1350
Upper 95% Limits of Agreement	4.02
Lower 95% Limits of Agreement	-3.21

Source of data

Title:	WatchPAT Accuracy Validation via Reference CO-Oximetry Study ID# PR 2017-247
Date:	2018-01-23
Clinical Investigator(s):	Clinimark 80 Health Park Drive, Suite 20 Louisville, Colorado 80027, USA
Sponsor:	Itamar Medical, Ltd. 9 Halamish St PO 3579, Caesarea 3088900, Israel
Device(s):	Non-Motion: Itamar Medical WatchPAT Pulse Oximetry
Study Date(s):	December 13-15, 2017

NOTE: The clinical study was conducted with the WP300 with the same Pulse Oximetry System for the measurement of functional oxygen saturation of arterial hemoglobin (SpO2) that is used with the WatchPAT device.

NOTE: A Functional tester cannot be used to assess the accuracy of the internal pulse oximeter.

6.4 APPENDIX D: CENTRAL SLEEP APNEA SYNDROME DETECTION

The efficacy of the WP200U in the detection of AHIc for a threshold of 10 was evaluated in a multi-center study in 72 patients and the following results were obtained:
Sensitivity = 70.6%
Specificity = 87.3%
Positive predictive value (PPV) = 63.2%
Negative predictive value (NPV) = 90.6%
In addition, the following statistics was demonstrated:
Area Under the Curve (AUC) = 0.873 of a ROC for a PSG threshold of AHIc = 10
Pearson correlation between AHIc of PSG and WP200U of R=0.83 with a slope of 0.91 and offset of 0.26.

ADDITIONAL NON-DIAGNOSTIC INFORMATION

The efficacy of the WP200U in the assessment of %CSR (Cheyne Stokes Breathing) pattern was evaluated in a sub-group of 17 patients that were found to have AHIC≥10 by the PSG on a standard 30 seconds epoch-by-epoch comparison .
A total of 10,509 aggregated epochs were derived from these patients and the following results were obtained:
Sensitivity = 51.3%
Specificity = 93.7%
Positive Predictive Value (PPV) = 78.4%
Negative Predictive Value (NPV) = 81.3%
Overall Agreement = 80.7%

Source of Data

Study Title: Diagnosis of Sleep-related Respiratory Disorders in patients suspected of having SDB with and without cardiac disorders
Date of the Report: May 25, 2016
Principal Investigator(s): Prof. Giora Pillar (Carmel Medical Center)
Sponsor: Itamar Medical, Ltd. 9 Halamish St POB 3579, Caesarea 3088900 Israel
Device(s): Watch PAT 200U (WP200U)
Study Period: September 5, 2015 to February 24, 2016
National Clinical Trial (NCT) Numbers: NCT02369705, NCT01570738

NOTE: The AHIc and %CSR were validated in a clinical study using the WP200U device having the same analysis that is used with the WatchPAT device.

6.5 APPENDIX E: FCC COMPLIANCE LETTER

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in residential installations. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio and television reception.
However, there is no guarantee that interference will not occur in a particular installation. If this device does cause such interference, which can be verified by turning the device off and on, the user is encouraged to eliminate the interference by one or more of the following measures:

- Re-orient or re-locate the receiving antenna.
- Increase the distance between the device and the receiver.
- Connect the device to an outlet on a circuit different from the one that supplies power to the receiver.
- Consult the dealer or an experienced radio/TV technician.

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.

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

6.6 APPENDIX F: CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS

Clinical Benefits of the WatchPAT:

1. Ambulatory device for aiding in the diagnosis of sleep disorders in a home setting.
2. Reduces the need of in lab examination.
3. Reduces testing duration.
4. Less cumbersome (less sensors attached to the patient).
5. Calculates sleep apnea indices based on sleep time and not recording time (more accurate).
6. Enable the identification of positional sleep apnea.
7. Reduces logistics - wireless use nature enables immediate results to the physician.

Performance Characteristics of the WatchPAT:

PERFORMANCE CHARACTERISTICS	
AHI	AUC:0.953 (AHI threshold = 15), Linear Regression: r=0.9, p≤0.001 Sensitivity/Specificity: 85%/88.2%
AHIc (Central Sleep Apnea)	AUC: 0.913 (AHIc threshold = 10), Linear Regression: r=0.96, p≤0.001 Sensitivity/Specificity: 71.4/98.6% AND *Linear Regression: r=0.96, p≤0.001 Sensitivity/ Specificity: 100%/100%
Sleep Stages	Accuracy: 65% Kappa agreement value: 0.462 (95% CI: 0.455 to 0.468)
ODI (SpO2)	ARMS SpO2 70-100%: 1.9
Snoring Level	Pearson Correlation r=0.65 p<0.001

PERFORMANCE CHARACTERISTICS	
Body Position	Kappa agreement value 0.8185 (95% CI: 0.8059 to 0.8311) Agreement 90%
Arrhythmia AFib total duration in sleep	Sensitivity/specificity (TH=6 min) – 84%/95.5% AFib longest event: Sensitivity/specificity (TH=6 min) – 83.3%/98.5% PB events/min: Sensitivity/specificity (TH=0.5) – 100%/98.2%

Thank you!

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REF OM2196900 | Rev 1 | Aug-2024