




WatchPATTM ONE

Operation Manual

Itamar Medical **REF** OM2196370

R_x only Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner

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Note:

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



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

zzzPAT Software Manual is also available on the zzzPAT installation CD and is installed as part of the software installation.

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

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1 GENERAL INFORMATION

This manual is part of the WatchPAT™ONE (hereafter called WatchPAT) system family of products.

1.1 Intended Use / Indications for Use

The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 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). The WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). WatchPAT™ONE is available in two configurations, with and without a chest sensor. The chest sensor provides snoring level, body position and Central Apnea Hypopnea Index ("PAHIc").

The WP1's PSTAGES, snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP1'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.

PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.

1.2 Restrictions for Use

1. The WatchPAT should be used only in accordance with physician's instructions. For precautions see Section 1.3.
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 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.
6. The WatchPAT system in whole, or in part, may not be modified in any way.
7. The WatchPAT is used as an aid for diagnostic purposes only and should not be used for monitoring.
8. Only suitably trained and qualified personnel should be authorized to prepare the WatchPAT equipment prior to use.
9. 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.
10. 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

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11. 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.
 12. 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 Guide section. If necessary, contact our service office to report the incident, and to receive further instructions.
 13. The step by step instructions should be carefully followed when attaching the unit.
 14. The WatchPAT is not indicated for patient with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT device.
 15. The WatchPAT is not indicated for children less than 12 years old.
 16. The AHIC was not clinically assessed for patients who are in high altitudes or for patients using opioids.

1.3 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. Sustained* non-sinus cardiac arrhythmias.
** 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.*
4. The WatchPAT is not indicated for children who weigh less than 65 lbs / 30 kg.

1.4 Additional Precautions specific to pediatric use

The WatchPAT is indicated for use in patients 12 years and above.

The following Precautions and Notes are referring to pediatric 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.

Notes:

- PAT Respiratory Disturbance Index (PRDI) is indicated for patients 17 years of age and above.
- The Chest Sensor 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 (for further details see section 7 and section 8).

1.5 Data Generated by the 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.

PRDI and PAHIC are indicated for patients 17 years of age or greater.

1.6 Quality Assurance System: EN ISO 13485

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 + CORR.1:2006 + CORR.2:2007 + AM1:2012 |
| | | ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 |
| | | CAN/CSA -C22.2 No.60601-1 :08 + amendment 1 |
| 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 |
| 3. | Medical Device Software – Software Life Cycle Processes | IEC 62304:2006 +A1:2015 |
| 4. | 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 |
| | Degrees of protection provided by enclosures (IP Code) | IEC 60529 Ed 2.2 + COR2 |

| | STANDARD | IDENTIFICATION |
|-----|---|--|
| | – IP22 | |
| 5. | Medical devices - Application of usability engineering to medical devices | IEC 62366:2007 + A1:2014 |
| 6. | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | IEC 60601-1-6:2010 + A1:2013 |
| 7. | Medical devices. Application of risk management to medical devices | EN ISO 14971:2012 |
| 8. | Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements | ISO 15223-1:2016 |
| 9. | Graphical symbols for electrical equipment in medical practice | PD IEC/TR 60878: 2015 |
| 10. | Graphical symbols - Safety colors and safety signs -- Registered safety signs; refer to instruction manual/booklet | ISO 7010:2019 (M002) |
| 11. | Information supplied by the manufacture with medical devices | EN 1041:2008 + A1:2013 |
| 12. | Biological evaluation of medical devices - Part 1: Evaluation and testing | ISO 10993-1:2018 |
| 13. | Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment | ISO 80601-2-61:2011 |
| 14. | FDA Quality Systems Regulation (QSR) | 21 CFR part 820 |
| 15. | Medical devices. Quality management systems. Requirements for regulatory purposes | EN ISO 13485:2016 |
| 16. | Federal Communication Commission - Radio frequency devices | Federal Code of Regulation (CFR) Title 47, Chapter I, Sub-Chapter A, Part 15 |
| 17. | Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. | AAMI TIR69: 2017 |
| 18. | American National Standard for Evaluation of Wireless Coexistence | ANSI IEEE C63.27-2017 |
| 19. | Commission Regulation (EU) on electronic instructions for use of medical devices | EU 207/2012 |
| 20. | Medical Device Directive | MDD 93/42 EEC MDD 2007/47/EC |
| 21. | Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment | RoHS Directive 2011/65/EU (RoHS 2) |

1.7 Conventions Used in this Manual

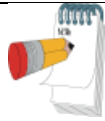
Note: Throughout this document, the references WatchPAT™**ONE**, WP-ONE and WatchPAT are used to refer to the WatchPAT™**ONE** device configurations, unless stated otherwise.



Warnings are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or cause damage/malfunction to the system, resulting in non-recoverable loss of data.



Cautions are used to identify conditions or actions, which could cause interference with data acquisition and/or impair study results.



Notes are used to identify an explanation, or to provide additional information for purposes of clarification.

1.8 Warnings, Cautions and Notes

The WatchPAT is powered with one off-the-shelf AAA battery.

The WatchPAT is portable with continuous operation.

The WatchPAT uses BF patient applied parts.

The WatchPAT should only be transported in its original package.


Environmental conditions during transportation & storage: See Specifications section.

Environmental conditions during operation: See Specifications section.









To avoid risk of battery leakage, the WatchPAT device should not be stored from prolonged period with a battery inserted in the battery compartment.







Sleep professionals (other than patients) using the WatchPAT should read the Operation Manual.

1.9 Safety Precautions

| | |
|---|---|
|  | <p>WARNINGS</p> <p>Do not let the device to get wet.</p> <p>Do not expose the device to heat or flammable liquid or gases</p> <p>Avoid placing food or water on any part of the system.</p> <p>In the event of fire use only fire extinguishers approved for use on electrical fires.</p> <p>Handle unit with care. This unit is sensitive to extreme movements and to falling.</p> <p>Do not try to introduce any foreign object into the unit.</p> |
|---|---|

1.10 Symbols Used on the Product Labels

| Symbol | Explanation |
|---|-----------------------------|
|  | Follow instructions for use |
|  YYYY-MM-DD | Date of manufacture |
| 1.5V DC  | Battery Operating Voltage |
|  | Single use, do not re-use |
|  | Temperature limit |
|  | Use-by date |
|  | Medical device Manufacturer |
|  | Catalogue Number |

| | |
|---|--|
|  | Serial Number |
| 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 |
| FCC ID | A unique identifier assigned to a device registered with the United States Federal Communications Commission. For legal sale of wireless devices in the US, manufacturers must: Have the device evaluated by an independent lab to ensure it conforms to FCC standards. |
|  | 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. |
|  | The product is marked with the CE logo 2797 for BSI |
|  | Authorized representative in the European Community |

1.11 Regulatory Agencies Information

The WatchPAT™ONE is cleared by the FDA under K183559, trade name WatchPAT™ONE (WP1).

The WatchPAT™ONE is a Class IIa medical device according to MDD 93/42/EEC Annex IX rule 10, as amended by 2007/47/EC.

2 OVERVIEW

The WatchPAT is a wearable device, worn on the wrist, that is utilizing a plethysmographic based finger-mounted probe that measures the PAT™ (Peripheral Arterial Tone) signal. The PAT® signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT® signal amplitude.

The Finger Probe also measures RED and IR (Infra-Red) signals, which are used for the measurement of SpO₂ signal.

In the WatchPAT™ONE with a chest sensor, the Snoring, Body Position and the subject's chest movement signals are recorded by the integrated Chest Sensor.

The recorded data is transmitted to an Application on a mobile phone and is then stored on a Web Server.

Following the sleep study, the recordings are automatically downloaded from the Web Server and analyzed in an offline procedure using the proprietary zzzPAT software.

The zzzPAT algorithms use the WatchPAT channels for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). The zzzPAT uses WatchPAT's snoring and body position channels to generate snoring level and body position discrete states.

The software issues comprehensive reports of the study, with statistics and graphic presentation of the results. The night data can be viewed and the automatically detected events can be revised manually.

2.1 System Description

The WatchPAT records the following characteristics:

- PAT[®] Signal
- Oxygen saturation
- Actigraphy (movement)

With the configuration that consists of a Chest Sensor, it also provides -

- Acoustic decibel detector for Snoring evaluation
- Chest movement
- Body Position

The overnight sleep study data is stored in Web Server storage, delivered via the Internet. After the study is recorded, the data is downloaded from the Web Server using the zzzPAT. The zzzPAT software, utilizing automatic algorithms, detects respiratory and other events that occurred during sleep as well as periods of REM, deep sleep, light sleep and wakefulness. The pulse rate signal is derived from the PAT[®] signal and used in the automatic analysis. The software issues a comprehensive detailed report. The data of the home sleep test can be viewed on the PC screen and the automatically detected events can be revised manually.

The WatchPAT device package is comprised of the following items:

1. WatchPAT device that includes:
 - Wrist Device
 - Finger Probe
 - Chest Sensor - In configuration with Chest Sensor
 - Package

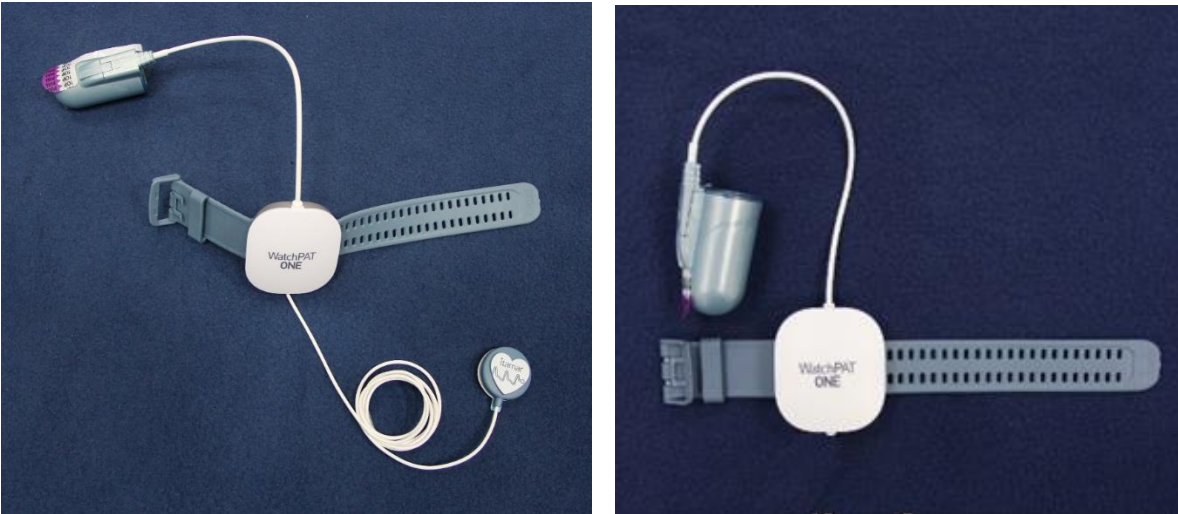


Figure 1 – WatchPAT Device (two configurations)

-
2. The WatchPAT Application is a proprietary mobile application that is available for download from the mobile application stores as marked on the product's package. A typical Application screen is displayed in Figure 2 – Application Screen.

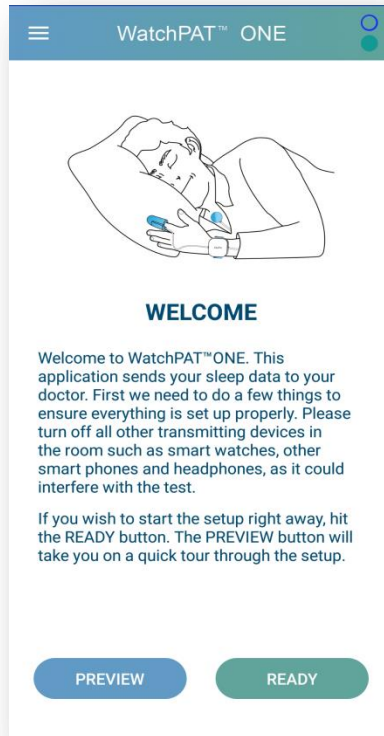


Figure 2 – Application Screen

3. The zzzPAT Analysis tool (see Figure 3) is a proprietary PC software utility used by your physician for initializing the study, retrieving, analyzing and displaying the data. More information is provided by the zzzPAT Software User Manual.

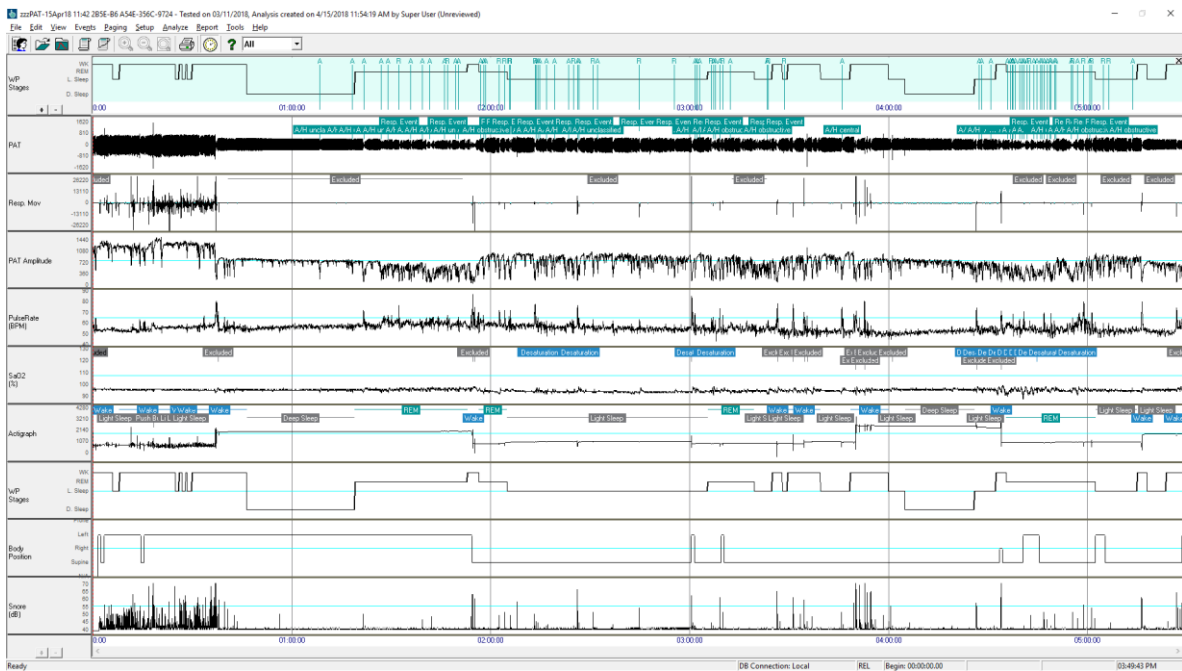


Figure 3 – A zzzPAT Analysis Program typical screen

2.2 Finger Probe Description

The WatchPAT Finger Probe is an electro-opto-pneumatic finger-mounted probe. Its role is to continuously measure the relative state of the vasomotor activity in the distal part of the finger based on a plethysmographic method. The Finger Probe is designed to cover the distal part of the finger with a uniform predetermined pressure field extending to the tip of the finger, at all fingers' sizes. This design prevents venous blood pooling, engorgement and stasis, which inhibits retrograde venous shock wave propagation, and allows partial unloading of arterial wall tension that significantly improves the dynamic range of the measured signal. The optic component of the probe measures the optical density related changes of the arterial blood volume in the digital arteries, associated with each heartbeat. Peripheral arterial constrictions, when present, are shown by attenuation in the PAT signal amplitude, a marker of sympathetic activation.

The Finger Probe also measures the changes in absorbance of the finger at both red and infrared light at peak wavelengths of approximately 660nm and 910nm respectively. The maximum optical output power is 65mW. These measurements are used to calculate the oximetry signal in an offline program according to the pulse oximetry principles.

The Finger probe is an integral part of the WatchPAT™ device and is to be used only with the WatchPAT device.

2.3 Chest Sensor Description

This section is applicable for those using a WatchPAT™ONE configuration that has a chest sensor.

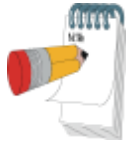
The Chest Sensor consists internally of two sensors: a snore sensor and a chest movement sensor. The Snore Sensor is an acoustic decibel detector. It uses a highly sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a signal that provides a clear, reliable indication of the presence of these sounds.

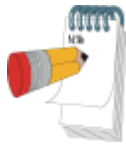
The Chest Sensor uses a 3-axis accelerometer that provides a signal that reflects the movement of the chest, which can be translated both to the patient's sleeping posture (supine, prone, right, left and sit) and to the chest movement signal resulted by the subject's breathing during the night.

3 HOME SLEEP TEST

Before using the WatchPAT the patient should be trained by the clinical staff.

The WatchPAT is suitable for a home sleep test that takes place at typical sleep setup and operated by the patients. The test and its preparation steps are simple and easy to follow. The traits required for the operation of the sleep test do not exceed the ones required to operate other mobile phone applications. Therefore, mobile phone owners that are acquainted with the operation of their phone will be able to perform this test as well.

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>These instructions are designed to help you use the WatchPAT after seeing a demonstration of how to mount the device and its components and correctly operate the WatchPAT device.</p> |
|---|---|

| | |
|--|---|
|  | <p style="text-align: center;">NOTE</p> <p>In the case of pediatric patient, special attention on training the patient and / or his accompanying individual on use and placement of the device prior to initiating a sleep study with the WatchPAT device.</p> |
|--|---|


The home sleep test is comprised of the following three main tasks

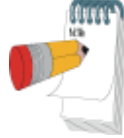
- Test Preparation – before bed time
- Sleep Test – during sleep
- Test End – at wake-up

The Application screens will guide you throughout the process. Before you conduct the home sleep test, you should be acquainted with the full description of the test components, as described in 3.4.

3.1 Test Preparation

For optimal data collection, the preparation steps need to be followed as described. This section describes all possible steps. If a specific step is irrelevant for your situation, this step needs to be skipped.

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>Make sure the room you are sleeping in is as quiet as possible during the night, therefore turn off any possible noise sources. As the device consists of snoring sensor, it is advised to sleep alone in the room.</p> |
|---|---|

| | |
|---|--|
|  | <p style="text-align: center;">NOTE</p> <p>You may need some assistance putting on the WatchPAT device. If needed have someone present to assist you.</p> |
|---|--|


3.1.1 Application Installation

Find the WatchPAT™ONE Application at the mobile application stores and have it installed on your Mobile phone. Follow all instructions that your phone presents during the installation process, until the Application has been successfully installed. It will request access to files, so it can keep the recording files, and access to location because this is a precondition for using the Bluetooth communication.

It is preferred to install the Application in advance so when bed time arrives the Application will be ready to go.

3.1.2 Application Setup

The wrist device that will be applied on your hand will transmit the recorded data to your mobile phone's Application. Place the mobile phone in proximity to the device, so the two can easily communicate. It is strongly recommended to place it in the room you sleep in, not exceeding five meters in between.

| | |
|---|---|
|  | <p style="text-align: center;">WARNING</p> <p>Use your mobile phone vendor recommendation for safe distance location of the phone.</p> |
|---|---|

Note that the Application runs on your mobile phone all night long. To prevent battery depletion during the home sleep test, do connect your phone to its charger during the night.

At bed time, and before running the Application, insert a AAA Alkaline battery into the battery compartment of the WatchPAT device (see Figure 4 – Battery insertion).

Next, run the WatchPAT Application on your Mobile phone and follow its instructions, it will lead you throughout the setup stage and into the test.

During the setup process you will be requested to input a personal identification number (PIN). This number is personal and will be provided to you when the WatchPAT product is assigned to you. It will always be a number that you are familiar with.

3.1.3 Patient Preparation

The best conditions for the sleep test are when potential obstacles are put out of the way. Before applying the WatchPAT, make sure you remove tight clothes, rings, watches and other jewelry from your non-dominant hand and wrist and from your neck and chest. Furthermore, remove nail polish and artificial nails from the test finger and make sure the fingernail is cut short. In case needed and a chest sensor is used, trim chest hair to ensure the chest sensor attached directly to your skin.

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

When using the WatchPAT™ONE with the chest sensor configuration, thread the Chest Sensor through the sleeve of the night shirt and up to the neck opening. Peel the white paper from the back of sensor's sticker. Attach the Chest Sensor to your chest under the sternal notch (to the center of your upper chest bone, just below the front of neck) and align the main icon to your body, cable pointing down. If possible, secure the Chest Sensor in place with medical tape.

Insert your selected finger of your non-dominant hand into the Finger Probe until you feel the tip of the probe. Detach and remove the TOP tab while pressing the tip of the probe against a hard surface.



WARNING

The product should not cause any discomfort or pain. If you experience wrist or arm discomfort, loosen the strap. If the discomfort is not alleviated immediately, call help desk.



NOTE

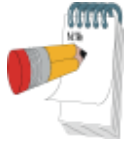
It is recommended that the Finger Probe be attached to the index finger of your non-dominant hand, but it can be attached on any finger, except the thumb. Patients with large fingers may use their small finger (pinky) for the Finger Probe.

Once these steps are completed the device is ready for operation.

3.2 Sleep Test

You can start the home sleep test once all setup activities are completed successfully and you are in bed and ready to go to sleep. The Application will confirm that all the sleep test preconditions have been properly met and a START button will be displayed.


Press the START button and go to sleep. The data is recorded throughout the night and stored in a remote Web Server.

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>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.</p> |
|---|---|

3.3 Test End

In the morning an END RECORDING button will be displayed on the Application screen. Press the END RECORDING button and the recording will stop. At this stage you should take off the device from your arm, finger and chest (if exists). The last of the recording data still needs to be transmitted from the device so keep the device in proximity of the phone and before you close the Application wait for the Application's confirmation of the completion of the test.

Follow the local, state, national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>The battery is most likely still functional after the full night sleep test, so you may consider using it in another appliance, before disposing of it.</p> |
|---|---|

3.4 User Interaction with the WatchPAT

This section describes in detail the interaction of the patient with WatchPAT components. You should get familiar with this section before conducting the home sleep test.

3.4.1 Battery Insertion

The device is powered by a single disposable Alkaline AAA battery. The device starts working once a battery is inserted.

When you are ready for the test, insert the battery into the battery compartment of the device. The compartment is in the bottom part of the device. First open the compartment cover, as shown in Figure 4, and insert the battery.

Note that proper positioning of the battery is essential for operation. When placing the battery in its place, align the polarity marking (+ and -) of the battery with the polarity illustrated on the lid and in the battery compartment. Make sure that the flat side of the battery is pushed against the spring.

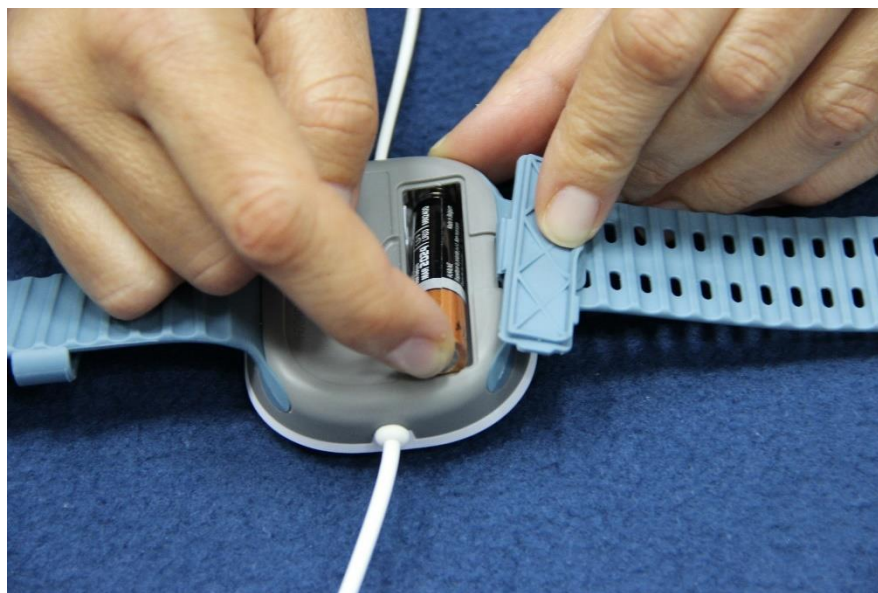



Figure 4 – Battery insertion

| | |
|---|--|
|  | <p style="text-align: center;">NOTE</p> <p>Insert the battery into the device just before bed time, so it is full when the test starts.</p> |
|---|--|

Notes/ Conditions for Battery Use:

1. The recording durations depend on the available life time of battery. It is important to insert place the battery just before usage.
2. The battery will be checked during device self-test, the WatchPAT will notify the patient in case the battery power is low.
3. If battery was improperly inserted or is depleted the WatchPAT will not turn on. In this unlikely situation, the patient should replace the faulty battery with a new AAA Alkaline battery, purchased in a local store.
4. Battery should not be stored in the WatchPAT battery compartment, and only be inserted when the patient is ready for the night test.

3.4.2 Wearing the WatchPAT™ ONE device


The WatchPAT components are to be applied on specific location that will provide the required signals. The sensors should be applied on the –

- a) Wrist
- b) Finger
- c) Chest (if a chest sensor is provided)

3.4.3 Strapping the Wrist Device

The first step would be applying the wrist device. Place the wrist strap on the non-dominant arm and close it snugly but not tightly (see Figure 5). Ensure that the side connected to the Finger Probe is towards the fingers.

You may find it convenient to place the wrist strap with the WatchPAT device facing down on the table and then place the back of the wrist over the wrist strap in order to fasten the straps.

| | |
|---|--|
|  | <p style="text-align: center;">WARNING</p> <p>Do not close wrist strap too tightly.</p> |
|---|--|

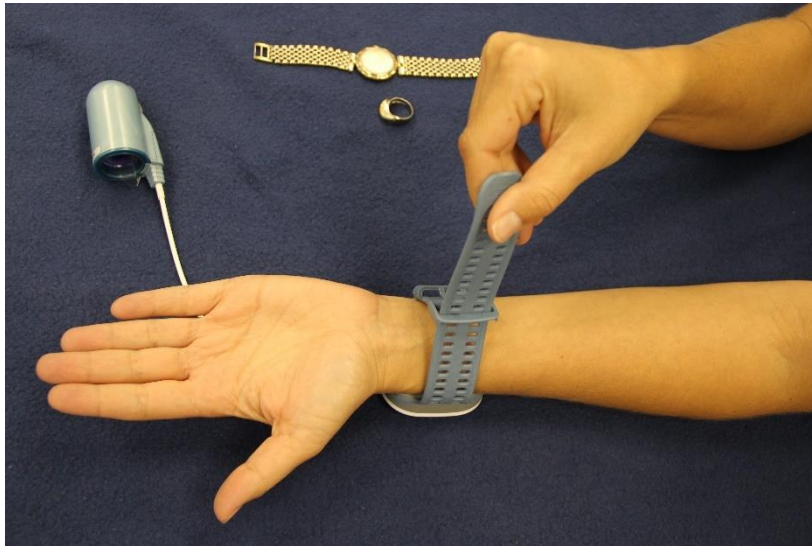


Figure 5 – Strapping the main device

3.4.4 Attaching the Chest Sensor

Next, if you have the configuration with a chest sensor, you should apply it on your chest. First thread the Chest Sensor through the sleeve of your night shirt, up to the neck opening. Peel the white paper from the back of sensor's base to expose the sticker. Attach the Chest Sensor to your chest under the sternal notch (to the center of your upper chest bone, just below the front of neck) and align the main icon to your body, cable pointing down, as shown in Figure 6 – Chest Sensor placement. It is best to trim chest hair if needed to ensure the Chest Sensor attached directly to your skin. You can also secure the Chest Sensor in place with medical tape.



Figure 6 – Chest Sensor placement

3.4.5 Attaching the Finger Probe

Proper Finger Probe placement is critical for good performance.



NOTE

The tab inside the Finger Probe should be removed only **AFTER** the finger is inserted into the probe.

To attach the Finger Probe:

1. Insert your index finger (or other, if so instructed) gently into the probe until you feel the end (see Figure 7).
2. Make sure that the tab marked TOP is on the top of your finger (above your nail).
3. Detach and gradually remove the tab marked TOP slowly and firmly while pressing the tip of probe against a hard surface (table, leg, etc.) until the tab is completely removed from the probe (Figure 8). You might feel a slight suction once the tab is removed. For small fingers secure the probe to the finger with a medical tape.

The Finger Probe is now attached.



Figure 7 – Placing Finger in the Finger Probe

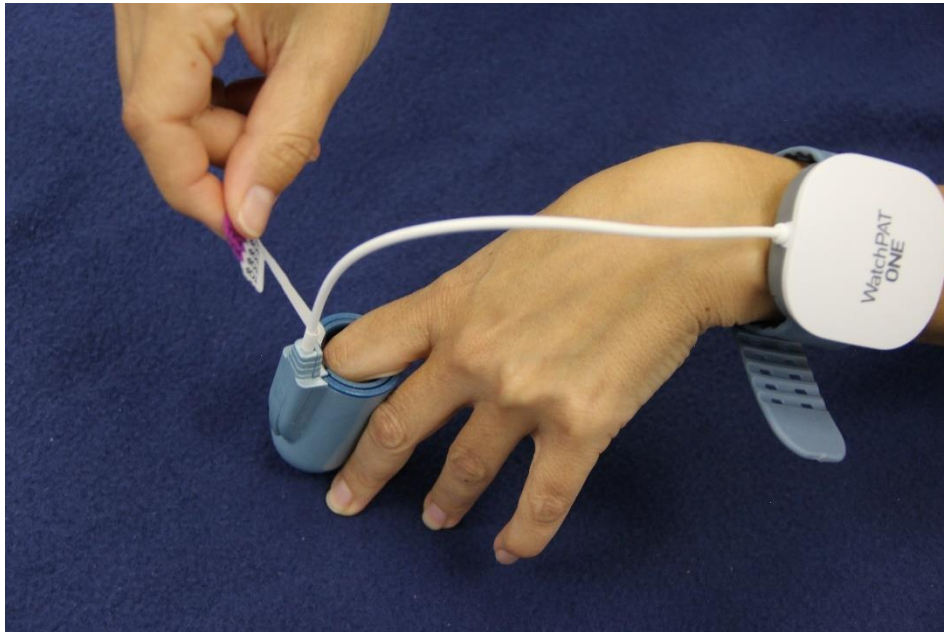


Figure 8 – Removing TOP Tab while pressing against hard surface



NOTE

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

3.4.6 Using the mobile phone Application

The Application is used to route the collected data to its storage location on the Web Server, so an Internet access is required for your mobile phone. The Application consists the product's display and keyboard. It guides the patient through the home sleep test preparation process and other operational activities.

It is also used to keep the patient informed of the progress of the home sleep test.

The display is comprised of several fields, as depicted in Figure 9. The status of your home sleep test and its progress will be reflected by the Mobile Application (see Figure 9 – A). The center of the screen is used to provide description or guidance. It will also be used to warn the patient (see Figure 9 – B) at unlikely situation that require the patient's attention.

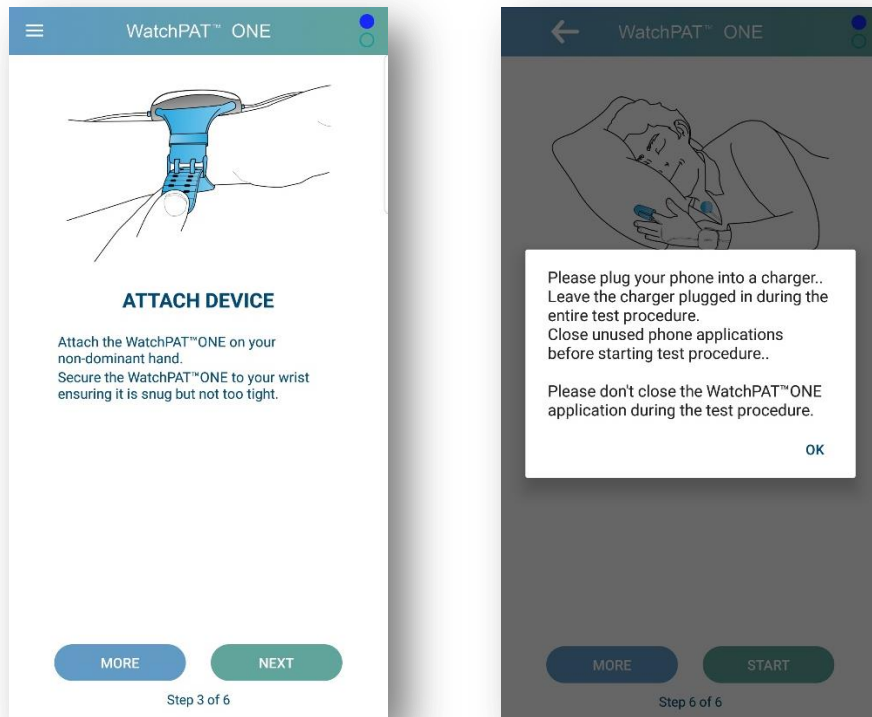
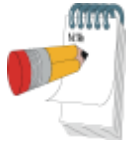


Figure 9 – Application screen samples (A – on left - explanation and step counting, and B – on right, with a warnings messages)

When you (or any accompanying individual if needed) turns on the WatchPAT device, by inserting the battery into the battery compartment, for a few seconds the self-diagnostic test is automatically performed and the LED in the center of the device cover will blink.

If the WatchPAT device passes this self-diagnostic test, the blinking will have either a green color (if connection with Application has happened) or red blinking (until connection with Application happens). A solid red color will indicate that there is a hardware problem.

| | |
|---|--|
|  | <p style="text-align: center;">NOTE</p> <p>During the data recording, the mobile phone turns off the display to conserve battery life. Patient can open the Application at any stage, as done with any other Application on this phone.</p> |
|---|--|

When running the WatchPAT Application, you will be going through a series of screens that will guide you safely through the entire study. The screens that you will be seeing are described hereby–

a. Application Loading Screen

The Application “Loading Screen” is an interim display (see Figure 10). It lets you know that the system is being loaded onto the Mobile phone. This should not take more than a few seconds.

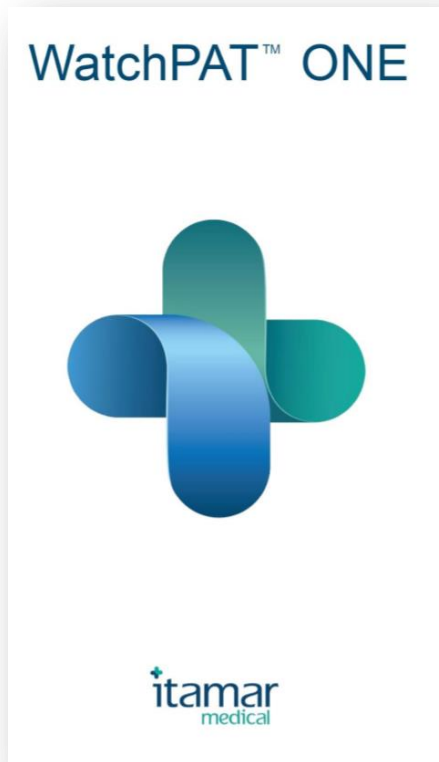


Figure 10 – Loading Screen

At this stage the Application will assure that the phone has the requisites required to run the Application. If any limitations are met, you will be notified. In some cases, you will be able to assist to overcome these blocking factors (e.g. - storage needs to be freed up or a Bluetooth communication needs to be turned ON). In these cases, you will be asked to assist, with guidance being provided. When the installation process requests your permissions to access the media and the location of your phone, it is important that you provide that (press ALLOW).

b. Welcome Screen

The Application will first display an introductory screen that provides informative details (see Figure 11). The entire process can first be reviewed by using the PREVIEW button that is displayed.

The battery can be inserted now into the device's battery compartment. The device should be nearby (in the same room). If the battery is not inserted, the Application will display a request to do so (see Figure 12).

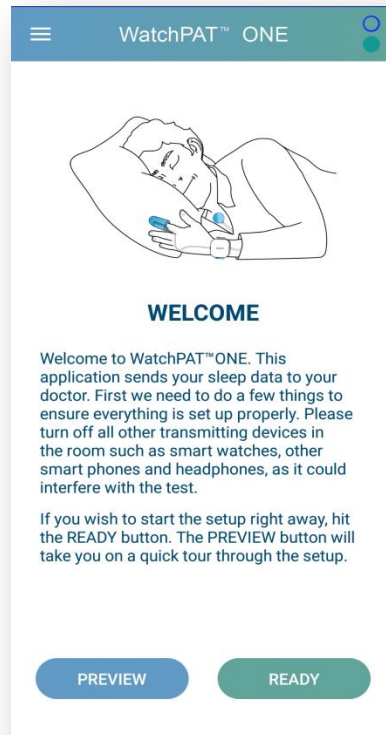


Figure 11 – Welcome screen

If the Application scanning operation failed to detect an active WatchPAT in its proximity, it will indicate that the operation failed. Try to detect the failure root cause and start a new scan. The most common reasons for a failure to detect the device is (a) A battery was not inserted into the device (b) The battery was inserted in the wrong direction (c) The mobile phone is out of reach of the device (not in the same room).

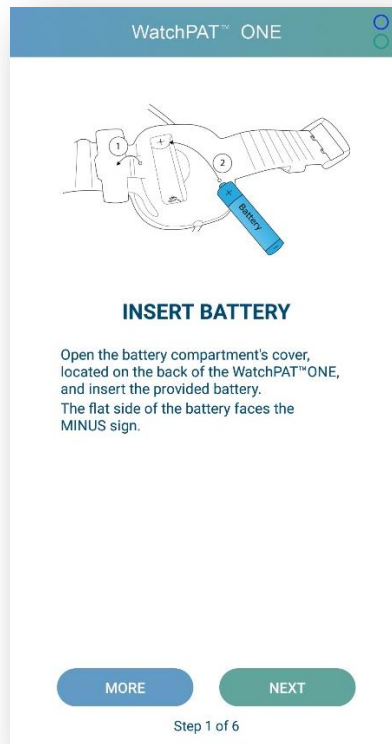


Figure 12 – Battery insertion screen

c. Preparation Screen

The Application will next display the Preparation Screen (see Figure 13). This step guides you how to prepare for the study.

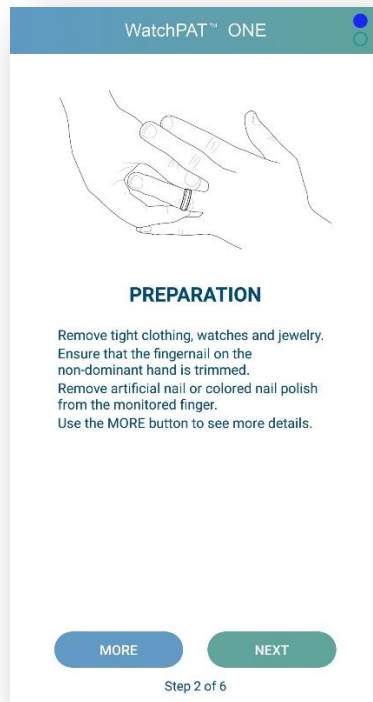


Figure 13 – Preparation screen

d. PIN insertion Screen

When you are prepared, the Application will ask for your PIN (Personal Identification Number) before proceeding (see Figure 14). This step is required to confirm your identity, to detect a mistakenly someone else using this product. Your PIN number is a four-digit number that has been agreed with you when the product was provided to you, and a hint that might help you remember the PIN is displayed. Your phone must have an Internet access at this stage.

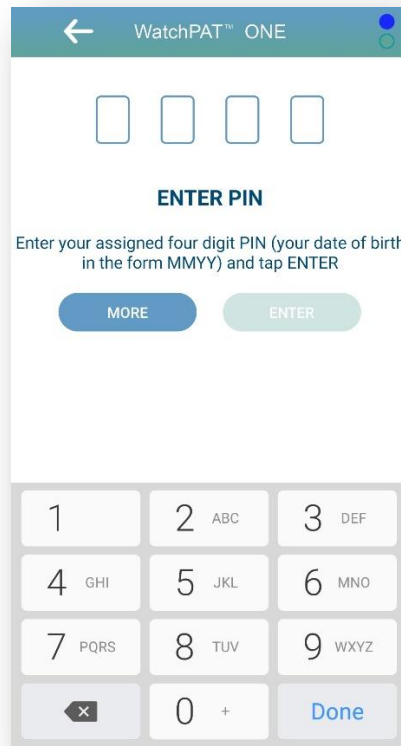


Figure 14 – PIN Screen

e. Patient Setup Screens

The Patient Setup screens (see Figure 15) are used to guide you when applying the device and its sensors.

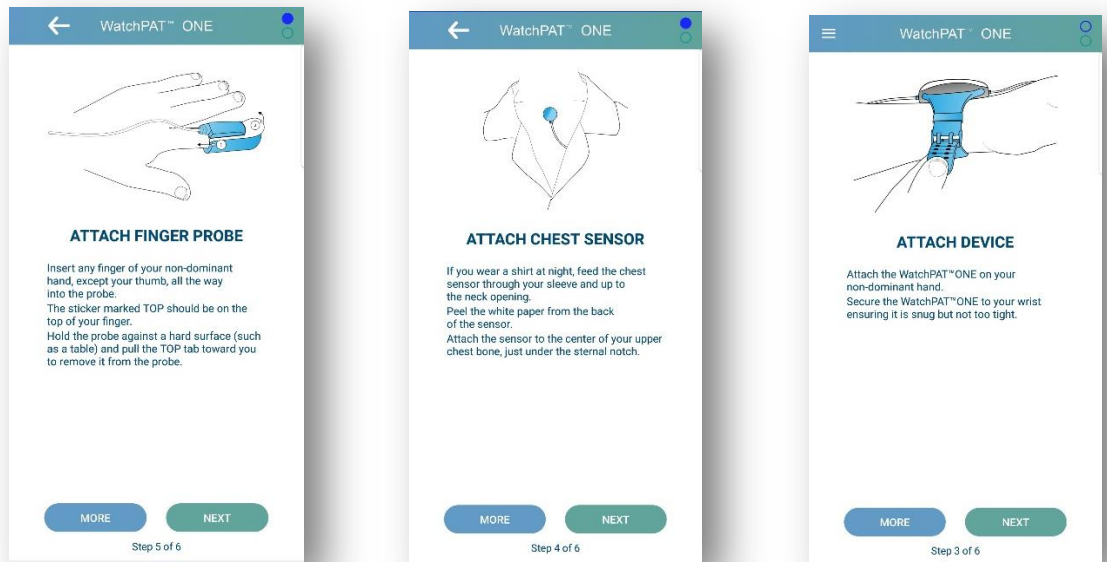


Figure 15 - Patient Setup Screens (chest sensor screen available only on relevant models)

Once you are ready to go to sleep and the device is fully applied, you will be shown a **START RECORDING** screen (see Figure 16 – Start Recording Screen), and you should press the button on the Application screen to get the recording started.

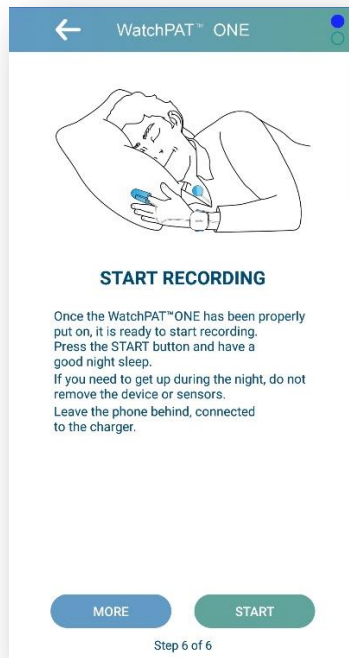


Figure 16 – Start Recording Screen

The Application will instruct the device to start collecting the signals from the sensors, and to transmit them to the Application. The Application will immediately upload the received data to the Web Server, if access to the Internet is available. If Internet is not available, the data will be stored on the Phone and uploaded when access is available.

f. Sleep Test Screen

The Sleep Test Screen is the active Application screen throughout the study. The screen reflects the activity with animated movement of its components (see Figure 17). It also displays the time that has passed since you have pushed the START RECORDING key.

Note that the Application is active the entire night, yet the screen will be dimmed by your Mobile phone whenever you stop interacting with it. You can reopen the screen whenever you desire, just like you would open any of your other Applications that run in the background.

If you wake up in the middle of the night, but plan to keep on sleeping, do not access the Application. If you exit your bed room for some reason, the Application will reestablish the connection with the device once you return, and the sleep test will continue uninterrupted. Yet, do not remove the device and its sensors off your body, as this action will interrupt the test and it will not be possible to resume.

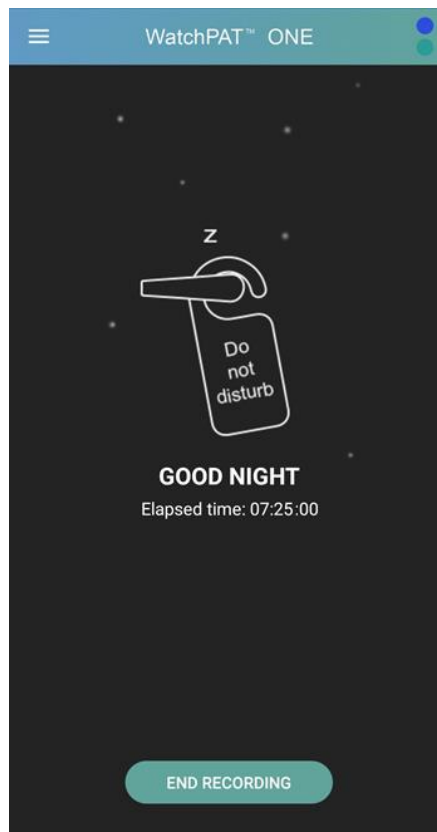



Figure 17 – The animated Sleep Test Screen

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>The LED at the center of the device cover will blink during the night</p> |
|---|---|

When you wake up you should press the END RECORDING button (see Figure 18). This will cease any further data acquisition.

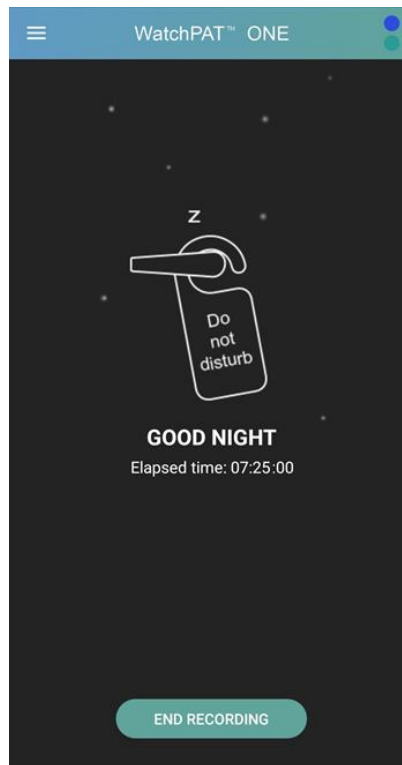


Figure 18 – END RECORDING button

g. Test Completion Screen

The analysis of your sleep data will be based on the data that was collected during your sleep. The data that was collected after you wake up will be ignored. Therefore, there is no need to keep the device on your hand after your sleep is fully over. After you have pressed the END RECORDING button on the Application's screen, you may take off the device, the Finger Probe and Chest Sensor.

If the Application needs more time for offloading the data from the device, it will display a screen (like the ones in Figure 19) asking you to allow some more time for the process to complete. A progress indication will be provided. Please follow the guidance that is provided in the Application's screens and do not close the Application until you are asked to do so.

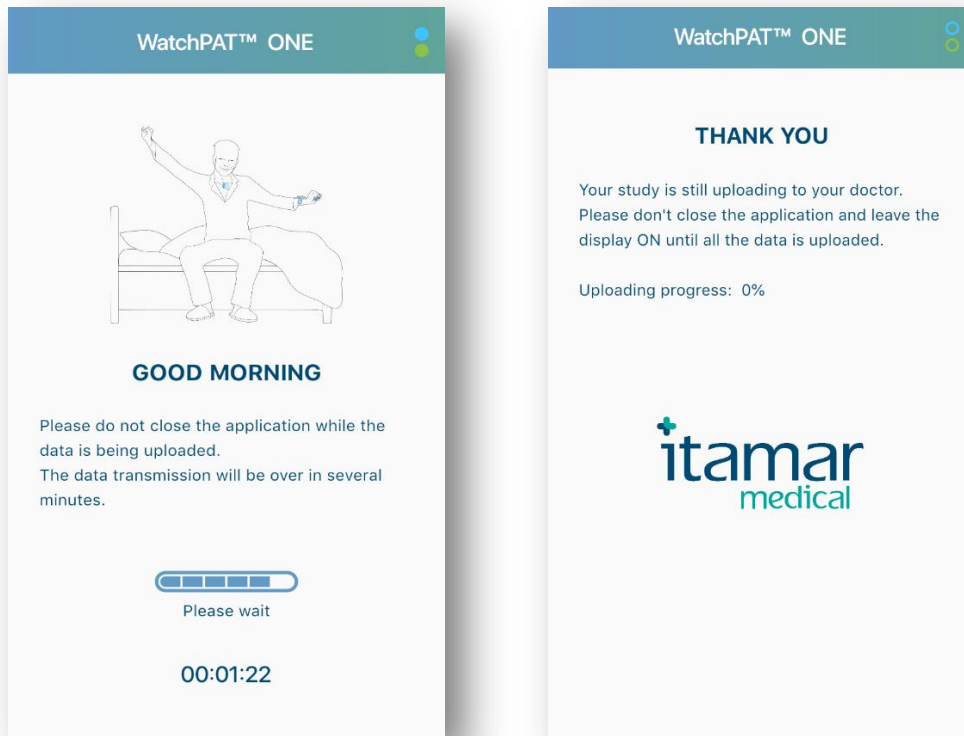


Figure 19 –Application’s indication that data is still being offloaded from the device

| | |
|--|---|
| | <p style="text-align: center;">NOTE</p> <p>Approximately ten hours after the test start, the WatchPAT device will stop acquiring data. This is normal.</p> |
|--|---|

The completion of the test is indicated with the appearance of the Test Completion screen (see Figure 20). The LED of the device will constantly blink in green when all the data from the device has been transferred to the Mobile Phone.

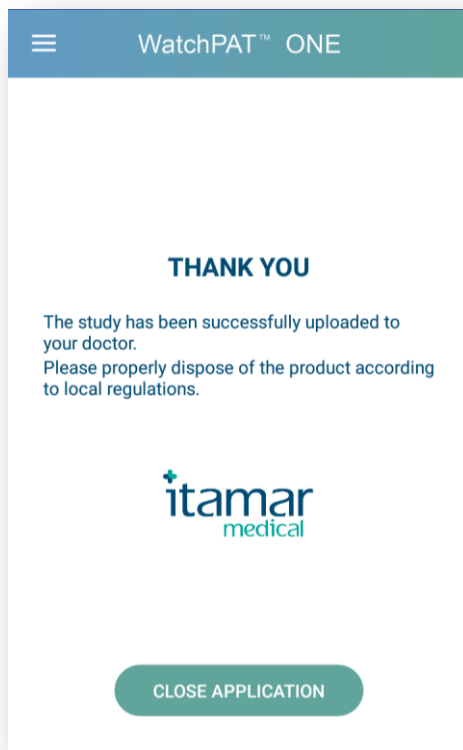


Figure 20 – Test Completion Screen

The device is a single-use product, so it cannot be used once again. Dispose the device and all of its components in a responsible and environmentally friendly way. You should follow the local, state, national governing ordinances and recycling instructions regarding disposal or recycling of the device and its sensors, including batteries.

3.5 Important Notes

Wearing the WatchPAT device should not cause any discomfort or pain. If you experience wrist or arm discomfort, loosen up the wrist strap. If the discomfort is not alleviated immediately, call the service number, provided with the product.

- Do not attempt to disconnect any part of the unit.
- Do not try to introduce any foreign object into the unit.
- If any part appears disconnected or does not resemble the illustrations, call the service number for assistance.
- Do not, under any circumstances, attempt to fix the problem yourself.

If you have any questions about using the machine, before, during or after your at-home recording session, call the service number.

4 DATA DOWNLOAD AND ANALYSIS

During the sleep study the WatchPAT 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.

To analyze the study data activate the zzzPAT software and download the study data from its location in the Web Server.

See the zzzPAT Software User Manual for detailed instructions.

5 PRODUCT HANDLING

This section should be read by the product provider.

The WatchPAT device has been designed and manufactured to meet reliability requirements applicable to medical equipment. To ensure maximum durability of operation, the system should be used and handled in strict compliance with the instructions provided in this Manual.

5.1 Battery

You may consider placing a new AAA Alkaline battery in the package before shipping to patient.

5.2 Handling

Handle with care:

- Use only the designated package for transportation
- 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)

5.3 Storing the WatchPAT device

- The WatchPAT device should be stored in its original package at room temperature and low humidity.
- The battery should not be stored in the WatchPAT battery compartment during shipment.

6 TROUBLESHOOTING GUIDE

6.1 Application Error Messages

If an error occurs or a message is displayed on the Application's screen, you should take the actions specified below. If the problem persists you may contact the Help Desk as specified on the package or an authorized representative directly.

| Error Message | Possible Reason | Action |
|---|---|---|
| Device critical errors were detected: Device errors: -Probe LEDs -Probe photo | There is a hardware failure in finger probe | Return the device to the provider, and a new one will be shipped in return. |
| Initialization errors occurred: Please fix them and restart application: -SBP | There is a hardware failure in chest sensor | Return the device to the provider, and a new one will be shipped in return. |
| Initialization errors occurred, please fix them and restart application. -Device already used | The device has been already in use (when in WELCOME screen) | Return the device to the provider, and a new one will be shipped in return. |
| Device's critical errors were detected. Device errors: -Used device | The device has been already in use (when in BATTERY screen) | Return the device to the provider, and a new one will be shipped in return. |
| Initialization errors occurred, please fix them and restart application. -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 the access to the Internet is not achievable. | Provide internet access to your phone |
| Device is not located. Please check if WatchPAT ONE's LED blinks. 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 | If there is no blinking on the device cover, check if the battery in the device was properly placed and press NEXT. If it is blinking, bring the device closer to the Phone and press NEXT. Check if the Bluetooth is enabled on your device If there is still no connection created, pull the device's battery |

| Error Message | Possible Reason | Action |
|---|---|---|
| | | <p>out and start again. If there is still no connection created, try closing other Applications that use the BLE. If the RED blinking still resumes, there is a problem with the device, and it needs to be returned.</p> |
| <p>Device battery is low or The device's battery is depleted or damaged. Please replace the battery and try again.</p> | <p>The device battery has run out of power</p> | <p>Replace the battery with a fresh Alkaline AAA battery</p> |
| <p>Multiple devices are identified in the surrounding. Please remove battery from all irrelevant devices and try again.</p> | <p>The Application sees more than one active device</p> | <p>You should make sure other WatchPAT ONE devices in room are turned OFF (batteries removed) until after your Application has successfully establishes communication with your device</p> |
| <p>The WatchPAT is asking to turn on Bluetooth</p> | <p>The Mobile phone does not have its Bluetooth communication turned ON.</p> | <p>Approve the Application's request of the turning ON the Blue Tooth capability.</p> |
| <p>Connection with WatchPAT ONE device is lost or The app cannot communicate with the device. Waiting for the communication to resume.</p> | <p>Mobile phone Bluetooth communication failures - or - The Application cannot find an active device in its proximity - or - No battery in device was found</p> | <p>Check Bluetooth communication in mobile phone / bring the device closer to the Phone / Put a fresh Alkaline AAA battery in the device</p> |
| <p>Internet connection not available</p> | <p>Mobile phone has no internet access</p> | <p>Check internet communication in mobile phone</p> |
| <p>Incorrect PIN, please try again</p> | <p>The PIN used does not match your records</p> | <p>Enter the correct PIN</p> |
| <p>Authentication failed or Initialization errors occurred, please fix them and restart application. - Exceed number of PIN retries</p> | <p>A non-valid PIN used at all attempts</p> | <p>The clinic will remind the patient of the correct PIN and they will also reset the retries counter</p> |
| <p>Please do not close the application while the data is being uploaded. The data transmission will take several minutes</p> | <p>Some of the data in the device has not been uploaded.</p> | <p>Keep the APP running and close by to the device until a message that all the data has been transmitted successfully appears</p> |
| <p>User not registered in system</p> | <p>The device handed to the patient has not been</p> | <p>Call physician office</p> |

| Error Message | Possible Reason | Action |
|---|---|--|
| | registered | |
| Please plug your phone in a charger | No charger plugged into a mobile phone | Plug in a charger |
| Data from WatchPAT ONE 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 WatchPAT ONE 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 |

6.2 Device Error Messages

If an error occurs and the LED on the device's cover is blinking, you should take the actions specified below. If the problem persists you may contact Itamar or an authorized representative directly.

| Device LED's status | Possible Reason | Action |
|--|--|--|
| No light | Battery depleted, or battery is placed backward or hardware error. | Check the battery. If it is good and placed properly there is a hardware error. Return device to Itamar. |
| Red LED blinks (every 10 seconds) | The Mobile phone ran out of power | Connect a charger, rerun the Application and keep the device close by until all the stored data has been sent to the Application |
| Red LED blinks (every 10 seconds) | The Mobile phone and the device are not close enough | Make sure the phone and the device are nearby, until all the stored data has been sent to the Application |
| Red LED blinks fast (5 times per second) | There is a hardware failure in the device | Return the device to the provider, and a new one will be shipped in return. |
| Red LED is on | The device battery is running out of power | Replace the battery with a fresh Alkaline AAA battery |

7 SPECIFICATIONS

| 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 Position 5 discrete states: supine, prone, right, left and sit Chest Movements – 12 bits x 3 axis |
| User Interface | | Mobile phone: Mobile Application Device: LED |
| Accuracy | <i>Pulse rate</i> <i>Amplitude</i> <i>Oximetry</i> | 30-150 ± 1 bpm 0-0.5V ± 10% Arms ≤ 3% (in range 70%-100%) |
| PAT Channel | <i>Bandwidth</i> | 0.1-10 Hz |
| Data Storage | <i>Media</i> | NOR SPI Flash |
| | <i>Capacity</i> | 16MB |
| Power Supply | <i>Battery</i> | One OTS 1.5V Alkaline AAA battery |
| Operating Voltage | | 3.3 V |
| Temperature | <i>Operation</i> | 0°C to 40 °C |
| | <i>Storage</i> | 0°C to 40 °C |
| | <i>Transport</i> | -20°C to 60 °C |
| Humidity | <i>Operating</i> | 10% – 93% (non-condensing) |
| | <i>Storage & Transport</i> | 0% – 93% (non-condensing) |
| Atmospheric pressure | <i>Operating & Storage</i> | 10 – 15 psi |
| | <i>Transport</i> | 8 – 15 psi |
| Physical Measurements (Rigid parts) | <i>Main device Dimensions (L x W x H)</i> | Device (Enclosure): 60mm-55mm-18mm |
| | <i>Weight</i> | Device: 38 gr |
| Device transmitter | <i>BLE Version</i> | 4.0 |
| | <i>Operating frequency</i> | 2.4 GHz |
| | <i>Band Width</i> | 250 KHz |
| | <i>Transmitted Power</i> | 4dBm |
| | <i>Operating range</i> | 5m indoor |

| Properties | | Description |
|--------------|------------------|---------------------------------------|
| | Antenna type | Printed |
| | BLE Profile Type | UART |
| Mobile phone | Operating System | Android 5.0 minimum iOS 10 minimum |
| | BLE Version | 4.0 |
| | Network | Wi-Fi / Cellular |
| | Storage Required | >120MB |

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.

I. 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%.

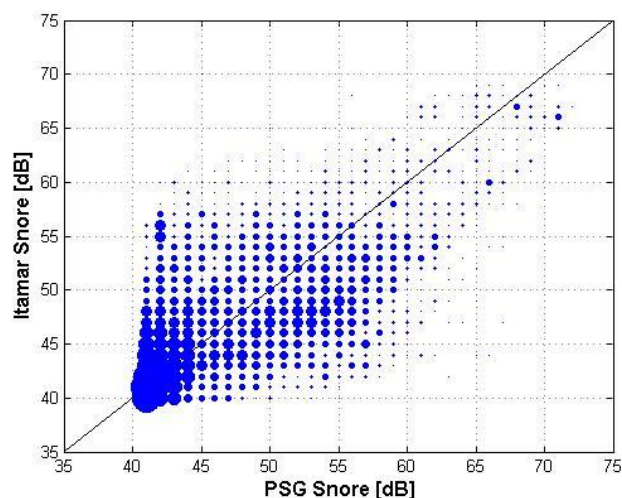
Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059 and 0.8311).

II. 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: $r=0.65$ $p \text{ value} < 0.0001$.

The next figure shows a scatter plot of sleep disturbance Index produced by WatchPAT device and dB-meter, with linear regression line.



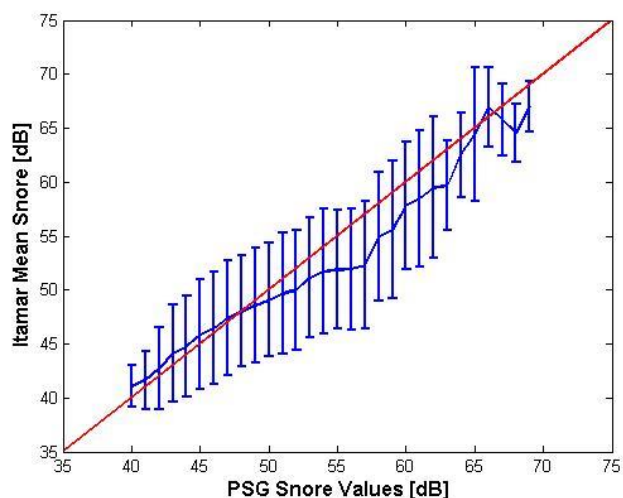
An estimation of the error in each snoring level was calculated by looking at the WatchPAT™ device measurement cut by the results of dB-meter in intervals of 1 dB in the range of above 40dB (below 40 dB was considered not clinically significant being background noise). A high correlation was observed 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 |
| 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 |

| PSG DB Value | N | Mean | Std | Coef. Of Variation [%] | Min | Max | Median | Lower 95% CI | Upper 95% CI |
|--------------|-----|-------|------|------------------------|-----|-----|--------|--------------|--------------|
| 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 figure. The figure presents the mean WatchPAT device with SD error bar.



Summary statistics (mean \pm SD) of WatchPAT device by dB-meter levels

| | |
|---|--|
|  | <p>NOTE</p> <p>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.</p> |
|---|--|

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/terms-and-conditions/>

Should you have any questions concerning this License Agreement, or if you desire to contact Itamar Medical for any reason, please write to:

USA:

Itamar Medical Inc.
3290 Cumberland Club Drive, Suite 100
Atlanta, Georgia 30339, USA
Tel: 1 888 748 2627

Worldwide:

Itamar Medical Ltd.
9 Halamish St., P.O.Box 3579
Caesarea Ind. Park, 3088900, Israel
Tel: +972 4 617 7000

APPENDIX B:

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APPENDIX C: MANUFACTURING DECLARATIONS ACCORDING TO IEC 60601-1 & 60601-1-2

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.

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 – from IEC 60601-1-2:2014 | | |
|---|-------------------|--|
| Guidance and manufacturer's declaration – electromagnetic emissions – WatchPAT | | |
| The WatchPAT is intended for use in the electromagnetic environment specified below; The customer or the user of the WatchPAT should assure that it is used in such an environment. | | |
| Emissions test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The WatchPAT uses RF energy for internal function and for BLE (4dbm) transmissions. 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 WatchPAT 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. |
| Harmonic Emissions IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Not applicable | |

| Table 2 - from IEC 60601-1-2:2014 | | | |
|---|---|--|---|
| Guidance and manufacturer's declaration – electromagnetic immunity – WatchPAT | | | |
| The WatchPAT is intended for use in the electromagnetic environment specified below; The customer or the user of the WatchPAT should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2 Test level | Compliance level | Electromagnetic environment - guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact ± 2 kV, +4 kV, + 8 kV, +15 kV air | Not Applicable ± 2 kV, +4 kV, + 8 kV, +15 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%. 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 public low-voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment. |
| NOTE: UT is the a.c. mains voltage prior to application of the test level. | | | |

| Table 4 - from IEC 60601-1-2:2014 | | | |
|---|---|--|--|
| Guidance and manufacturer's declaration – electromagnetic immunity – WatchPAT | | | |
| The WatchPAT is intended for use in the electromagnetic environment specified below; The customer or the user of the WatchPAT should assure that it is used in such an environment. | | | |
| Immunity test | IEC 60601-1-2 Test level | Compliance level | Electromagnetic environment - guidance |
| Conducted RF IEC 61000-4-6 | 3V 0.15-80 MHz Outside ISM Bands 6V 0.15-80 MHz Inside ISM Bands | Not applicable Not applicable | Portable and mobile RF communications equipment should be used no closer to any part of the WatchPAT , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance |

Table 4 - from IEC 60601-1-2:2014

| | | | |
|--|-------------------------------------|---------------|--|
| <p>Radiated RF IEC 61000-4-3</p> | <p>10 V/m 80 MHz to 2,7 GHz</p> | <p>10 V/m</p> | <p> $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,7 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 equipment marked with the following symbol:  </p> |
| <p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> | | | |
| <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> | | | |
| <p>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 WatchPAT is used exceeds the applicable RF compliance level above, the WatchPAT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WatchPAT.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.</p> | | | |

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 radiofrequency 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 6 - from IEC 60601-1-2:2014 | | | | |
|---|--|---|------------------------|-------------------------|
| Recommended separation distances between portable and mobile RF communications equipment and the WatchPAT | | | | |
| Rated maximum output power of transmitter | Separation distance according to frequency of transmitter (in meters) | | | |
| | Meters [m] | | | |
| | 150kHz to 80MHz outside ISM Bands | 150kHz to 80MHz inside ISM Bands | 80MHz to 800MHz | 800MHz to 2.7GHz |
| Watts [W] | $d = 1.17\sqrt{P}$ | $d = 2\sqrt{P}$ | $d = 1.2\sqrt{P}$ | $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.2 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.63 | 0.37 | 0.73 |
| 1 | 1.17 | 2.0 | 1.17 | 2.3 |
| 10 | 3.7 | 6.32 | 3.7 | 7.3 |
| 100 | 11.7 | 20 | 11.7 | 23 |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> | | | | |

IEC 60601-1-2: 2014 4th Edition

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

| Test Frequency (MHz) | Band ^{a)} (MHz) | Service ^{a)} | Modulation ^{a)} | Maximum Power (W) | Distance (m) | Immunity Test Level (V/m) | Compliance Level (V/m) |
|----------------------|--------------------------|--|---|-------------------|--------------|---------------------------|------------------------|
| 385 | 380-390 | TETRA 400 | Pulse modulation ^{b)} 18Hz | 1.8 | 0.3 | 27 | 27 |
| 450 | 430-470 | GMRS 460 FRS 460 | FM ^{c)} ± 5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 | 28 |
| 710 | 704-787 | LTE Band 13, 17 | Pulse modulation ^{b)} 217 Hz | 0.2 | 0.3 | 9 | 9 |
| 745 | | | | | | | |
| 780 | | | | | | | |
| 810 | 800-960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation ^{b)} 18 Hz | 2 | 0.3 | 28 | 28 |
| 870 | | | | | | | |
| 930 | | | | | | | |
| 1720 | 1700- 1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation ^{b)} 217 Hz | 2 | 0.3 | 28 | 28 |
| 1845 | | | | | | | |
| 1970 | | | | | | | |
| 2450 | 2400- 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation ^{b)} 217 Hz | 2 | 0.3 | 28 | 28 |
| 5240 | 5100- 5800 | WLAN 802.11 a/n | Pulse modulation ^{b)} 217 Hz | 0.2 | 0.3 | 9 | 9 |
| 5500 | | | | | | | |
| 5785 | | | | | | | |

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

^{a)} For some services, only the uplink frequencies are included.

^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal.

^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

APPENDIX D: SPO₂ ACCURACY IN THE WATCHPAT

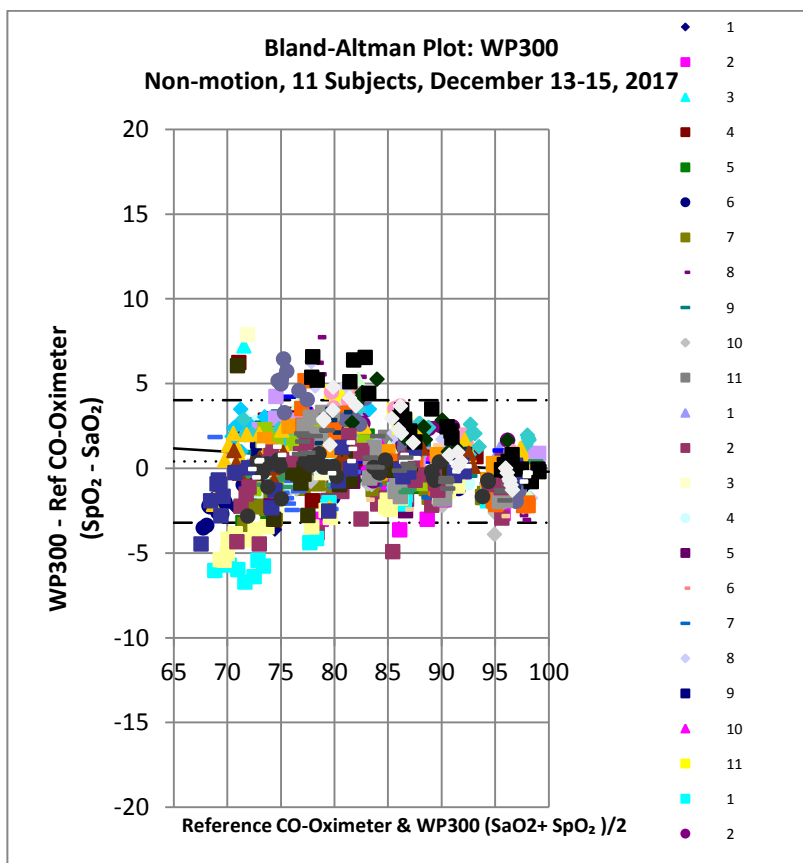
The WatchPAT device uses Itamar Medical Pulse Oximetry system for the measurement of functional oxygen saturation of arterial haemoglobin (SpO₂). This appendix includes information regarding the accuracy of these measurements following a clinical study of Itamar Medical Pulse Oximetry.

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 | ARMS 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

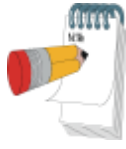
Date: 2018-01-23


Clinical Investigator(s): Clinimark
80 Health Park Drive, Suite 20
Louisville, Colorado 80027, USA

Sponsor: Itamar Medical, Ltd. 9 Halamish St POB 3579, Caesarea
3088900 Israel

Device(s): Non-Motion: Itamar Medical WatchPAT Pulse Oximetry

Study Date(s): December 13-15, 2017

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>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.</p> |
|---|---|

| | |
|---|---|
|  | <p style="text-align: center;">NOTE</p> <p>A Functional tester cannot be used to assess the accuracy of the internal pulse oximeter.</p> |
|---|---|

APPENDIX E: 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 \geq 10 by the PSG on a standard 30 seconds epoch-by-epoch comparison¹. 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

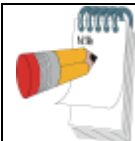
Principal Investigator(s): Prof. Giora Pillar (Carmel Medical Center)

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.


¹ %CSR indication is not cleared by FDA.

APPENDIX F: 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.

| | |
|--|---|
|  | <p>WARNING</p> <p>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.</p> |
|--|---|

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.

A distance of at least 0.5 cm. between the equipment and all persons should be maintained during the operation of the equipment.