ZOLL itamar

WatchPAT™ ONE

Operation Manual

Itamar Medical REF OM2196370



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

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*The CE does not apply to the WatchPAT™ONE-M and WatchPAT™ONE E device options.

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.

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NOTE:

• Latest versions of the WatchPAT™ device and Software Operation Manuals are available at:

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

• A printed copy will be provided upon request, at no additional cost, within 7 calendar days.

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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) is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The device is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (REM Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP1 generates a peripheral arterial tone Respiratory Disturbance Index ("pRDI"), Apnea-Hypopnea index ("pAHI"), Central Apnea-Hypopnea index ("pAHIc"), sleep staging identification (pSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The device's pSTAGES and snoring level and body position provide supplemental information to its pRDI/pAHI/pAHIc. The device's pSTAGES and 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. Medical personnel shall instruct the patients (and accompanying individual, if needed) how to attach and use the WatchPAT prior to use.
2. The WP1 system in whole, or in part, may not be modified in any way, and in the event of equipment malfunction all repairs should be conducted by authorized Itamar Medical Ltd. personnel or licensed service agents.
3. Medical personnel shall instruct the patients (and accompanying individual if needed) how to attach and use the WatchPAT prior to use.
4. In any case of serious incident or harm, contact the ZOLL Itamar Help Desk 24/7 at 1-888-748-2627 and report the incident to the appropriate authority of your country.
5. The eligibility of a patient for a WatchPAT study is entirely at the discretion of the physician and is generally based upon the patient's medical status (e.g. injury or physical malformation of fingers, compromised circulation, etc.).
6. The WatchPAT is not indicated for children less than 12 years old or who weigh less than 65 lbs / 30 kg.
7. The AHIc was not clinically assessed for patients who are in high altitudes or for patients using opioids.

8. 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.*

9. The WP1 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 WP1 arrhythmia function is to be used for informational use only as additional information to the sleep indices.

1.3 Precautions

As the WatchPAT Analysis algorithm partially relies on sympathetic activation, the HCP should consider the appropriateness of choosing WatchPAT 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.
   NOTE: WatchPAT is safe to use with pacemaker and does not interfere with its operation.

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.



NOTE:
PAT Respiratory Disturbance Index (pRDI) is indicated for patients 17 years of age or older.

1.5 Data Generated by the WatchPAT

The WatchPAT generates a Respiratory Disturbance index (“pRDI”), Apnea-Hypopnea Index (“pAHI”), Central Apnea-Hypopnea Index ("pAHIc"), percentage of total sleep time with Cheyne-Stokes Respiration pattern (%CSR) and 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 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.

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.

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.

NOTE:
The arrhythmia feature is available only in approved territories.

1.6 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
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
3	Medical Device Software – Software Life Cycle Processes	IEC 62304
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
5	Medical devices. Application of risk management to medical devices	EN ISO 14971
6	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements	ISO 15223-1
7	Medical devices - Information to be supplied by the manufacturer	EN ISO 20417
8	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1
9	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61
10	US: Federal Communication Commission - Radio frequency devices	Federal Code of Regulation (CFR) Title 47, Chapter I, Sub-Chapter A, Part 15
11	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 (does not apply for WatchPAT™ONE-M option)

	STANDARD	IDENTIFICATION
12	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 RSS-Gen RSS-102
13	Japan Radio Law	Law No. 131 of 1950 (does not apply for WatchPAT™ONE E and WatchPAT™ONE-M options)
14	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS Directive 2015/863/EU (RoHS 3)
15	European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)	REACH REGULATION (EC) No 1907/2006

1.7 Conventions Used in this Manual

	**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.

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

1.8 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 the package is damaged, unintentionally opened before use, and/or exposed to environmental conditions outside of those specified, please contact Itamar Medical.
- For environmental conditions during transportation and storage: see Specifications section.
- 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.
- 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.

1.9 Safety Notes

- Handle unit with care.
- 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).
- Do not expose the device to heat, liquids, flammabiles or fire.
- The device should not be used in an oxygen rich environment.
- The device should not be used with flammable anesthetics.
- The device is for single use. Keep it in its packaging until ready for use. Avoid exposure to dust or excessive light.

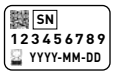
1.10 Symbols Used on the Product Labels

SYMBOL	EXPLANATION
	Follow instructions for use
	Consult instructions for use or consult electronic 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
	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 (does not apply for WatchPAT™ONE-M and WatchPAT™ONE E options)
	Authorized representative in the European Community
HVIN:	The HVIN (Hardware Version Identification Number) identifies hardware specifications of a product version. The HVINs are WatchPAT ONE, WatchPAT ONE E, WatchPAT ONE-M
PMN	The PMN (Product Marketing Name) is the name or model number under which the product will be marketed / offered for sale in Canada. The PMNs are WatchPAT ONE, WatchPAT ONE E, WatchPAT ONE-M
IC:	The ISED (Innovation, Science and Economic Development) Canada certification number (IC). The product certification number is 27705-WATCHPATONE

SYMBOL	EXPLANATION
MD	Medical Device
	Japanese Radio technical conformity mark (does not apply for WatchPAT™ONE E and WatchPAT™ONE-M options)
R	The certification by the Japanese Radio Law. Certification number: 003-210274 (does not apply for WatchPAT™ONE E and WatchPAT™ONE-M options)
5 GHZ band (W52,53) indoor use only (except communicate to high power radio)	Based on the notification of Japanese radio equipment regulation article “49-20.3”, “49-20.4”, and “49-20.5” (N.48 of 2007 MIC, revised June 29, 2018) (does not apply for WatchPAT™ONE E and WatchPAT™ONE-M options)
1	Single patient - multiple use - WatchPATONE-M configuration only - indicates a medical device that may be used multiple times (multiple procedures) on a single patient
UDI	Unique device identifier

The following label is located on the device:



The following label is located on the device packaging:



1.11 Regulatory Agencies Information

The WatchPAT™ONE is cleared by the FDA under K223675, trade name WatchPAT™ONE (WP1).

The product complies with MDR 2017/745 (Medical Device Regulation) requirements and CE approved (does not apply for WatchPAT™ONE-M and WatchPAT™ONE E options).

The product is marked with the CE logo.

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 SpO_2 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 also includes detection of cardiac arrhythmia as additional information to its sleep indices. For further identification of central apnea, the respiratory movement channel generated from the RESBP sensor is used in the zzzPAT algorithm in addition to the other channels. 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 (WPONE/WPONE-M and WPONE E)

NOTE:
The availability of WPONE-M and WPONE E is limited only to some territories.

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.

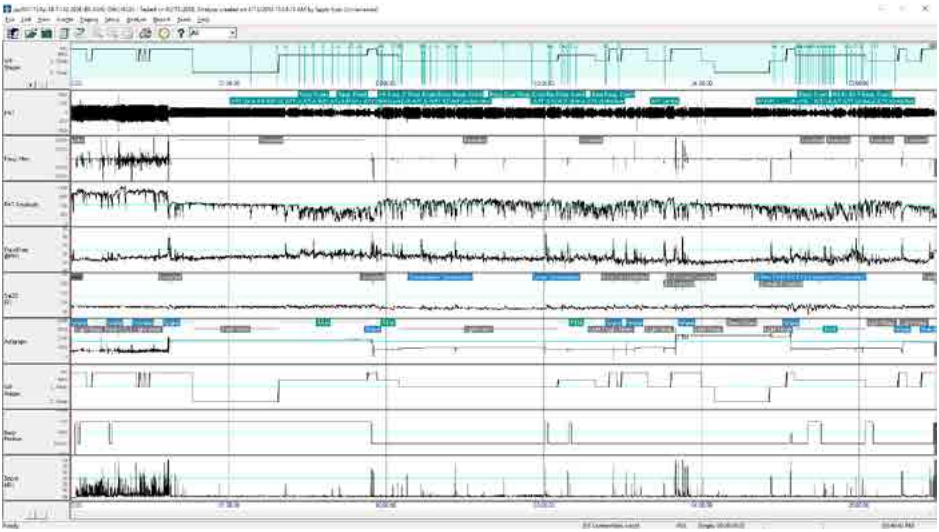


Figure 3 – A zzzPAT Analysis Program typical screen

4. For WPONE-M only

The WPONE-M (multi-night study) is similar to the WPONE configuration, the only difference is having the capability for finger probe replacement in order to support up to 3 nights use by the same patient with the same WPONE-M device. It is up to the physician to send extra kits to the patient for 1-2 extra night tests. The patient should replace the probe, old chest sensor sticker and battery in order to start the 2nd or 3rd night test. The mobile app will guide the patient in the process of preparing for a new test.

Each kit for one extra night study consists of:

- 1 new finger probe for WPONE-M (uPAT probe for WPONE-M)
- 1 chest sensor sticker
- 1 new battery

Each probe needs to be registered in the zzzPAT or CloudPAT™ before it is sent to the patient in the same way the WPONE device is registered by using the 9 digit Serial Number on the probe.

The recording durations depend on the quality of the battery used. It is important to always use good quality battery. Make sure your batteries are compatible with the local standards.

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 3.45mW. 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.



NOTE:

WP1 device does not store any sensitive, confidential, or proprietary data. Additionally, the WP mobile application automatically removes all user data upon uninstallation. Therefore, no special sanitization procedures are required when decommissioning the device or app.

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.



NOTE:
Only qualified personnel should prepare the WatchPAT equipment prior to use.



NOTE:
In case of discomfort or allergic reaction, patient should remove the device from the body.

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 (see 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.



NOTE:
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.

NOTE:
You may need some assistance putting on the WatchPAT device. If needed have someone present to assist you.

3.1.1 Application Installation

Find the WatchPAT™ 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.

NOTE:
It is recommended to not exceed five meters between your mobile phone and the wrist device.

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 a chest sensor, 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.



NOTE:

The uPAT probe connector should not be left exposed. Keep the connector connected to the probe at all times, especially during cleaning. Replace the probe just before performing the Device test.



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



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.

3.3 Test End

In the morning a Stop recording button will be displayed on the Application screen. Press the Stop 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.

If you are using the WPONE-M option, you can reuse the device for the same patient with a new probe, chest sensor sticker and battery for every additional night before disposing, otherwise dispose after first night.

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

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

NOTE:

Insert the battery into the device just before bed time, so it is full when the test starts.

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

Notes/ Conditions for Battery Use:

1. The recording durations depend on the available life time of battery. It is important to insert 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 –

1. Wrist
2. Finger
3. 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.

WARNING

Do not close wrist strap too tightly.



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 (to avoid possibility of strangulation).

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.

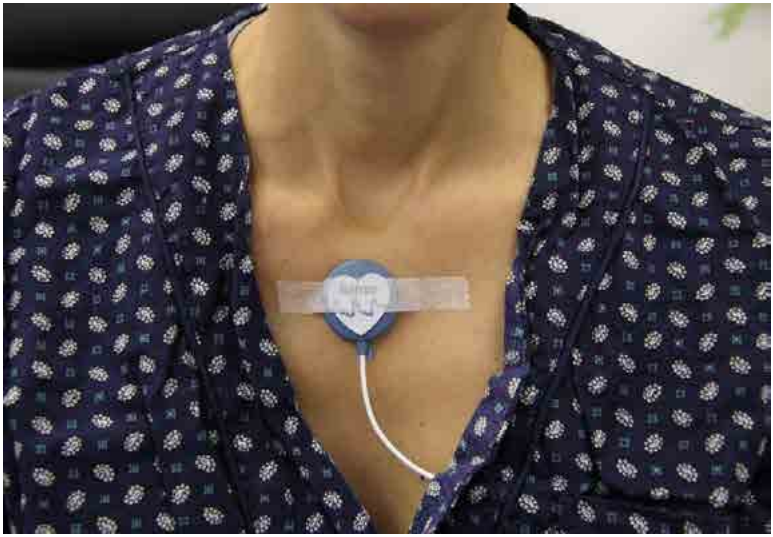


Figure 6 – Chest Sensor placement

3.4.5 Attaching the Finger Probe

Proper Finger Probe placement is critical for good performance.

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.

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



Figure 7 – Placing Finger in the Finger Probe

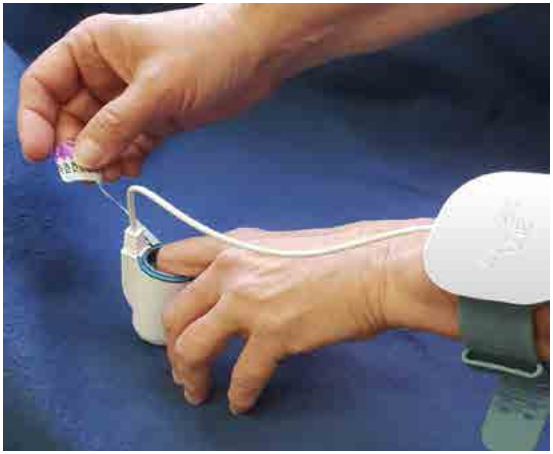


Figure 8 – Removing TOP Tab while pressing against hard surface

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.

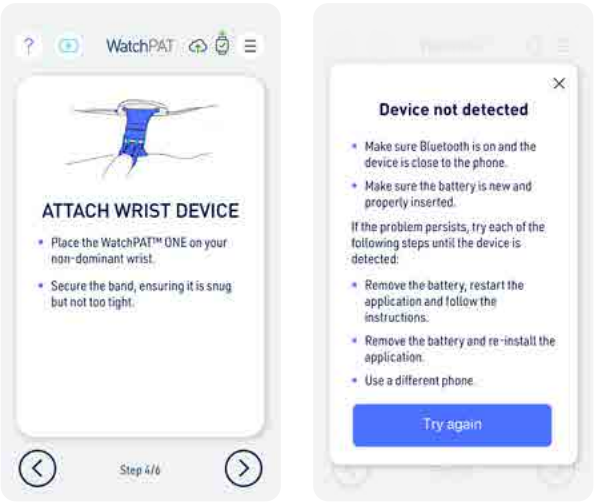


Figure 9 – Application screen samples

A - on left, explanation and step counting, and B - on right, with warning 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 LED will blink either green (if connection with Application has happened) or red (until connection with Application happens). A solid red LED indication means that there is a hardware problem.

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.

1. **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.

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).

A notification will appear in cases in which the WatchPAT ONE device Software needs to be updated. You will be notified to leave the device close to your phone and not to close the application.
The update process takes up to 2-3 minutes.



Figure 10 – Loading Screen

2. **Welcome Screen**

The application will then ask to enter a mobile number, as shown in Figure 11. The patient should use the same mobile number provided to the healthcare provider.



Figure 11 – Welcome screen

3. **Select device Screen**

If the patient chooses not to share the mobile phone, the device type will need to be manually selected (see Figure 12).



Figure 12 – Select a device screen

4. **Let's get started Screen**

After the patient has entered the mobile number or selected WP1 in the device selection screen, the application will display an introductory screen that provides informative details (see Figure 13). The entire process can first be reviewed by using the Quick Guide link 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 14).

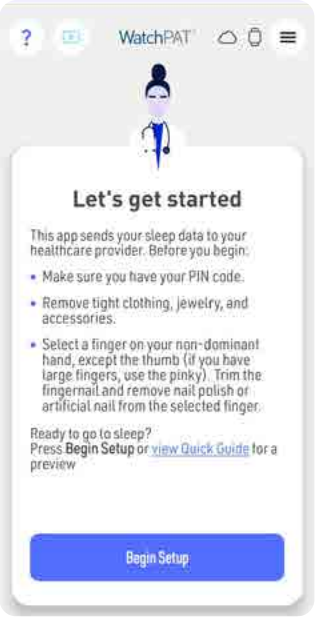


Figure 13 – Let's get started Screen

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 WP application.

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 14 – Battery insertion screen

5. **Preparation Screen**

The Application will next display the Preparation Screen (see Figure 15). This step guides you how to prepare for the study.



Figure 15– Preparation screen

6. **PIN Insertion Screen**

If a mobile phone number was not input in the patient registration phase then a 4 digit PIN code will be required (see Figure 16). The PIN code is generated by the healthcare service provider. The patient's phone must be connected to the Internet during this stage.

This step is required to confirm the patient's identity, to detect if someone else is mistakenly using the product.

If the mobile phone was registered when initiating the device, the 4 last digits of the mobile phone will be automatically used as a PIN code and this screen will be skipped (in case the patient had entered the mobile phone in the welcome screen). In this case the conformation that the device is the one registered to the patient, is automatically performed in the background using the 4 last digit of the patient mobile phone.

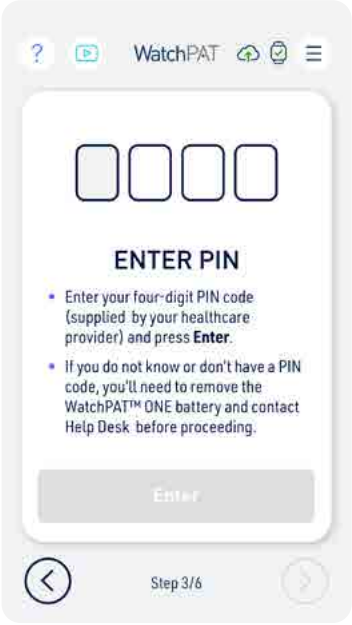


Figure 16 – PIN Screen

7. **Patient Setup Screens**

The Patient Setup screens (see Figure 17) guide the user when applying the device and its sensors.

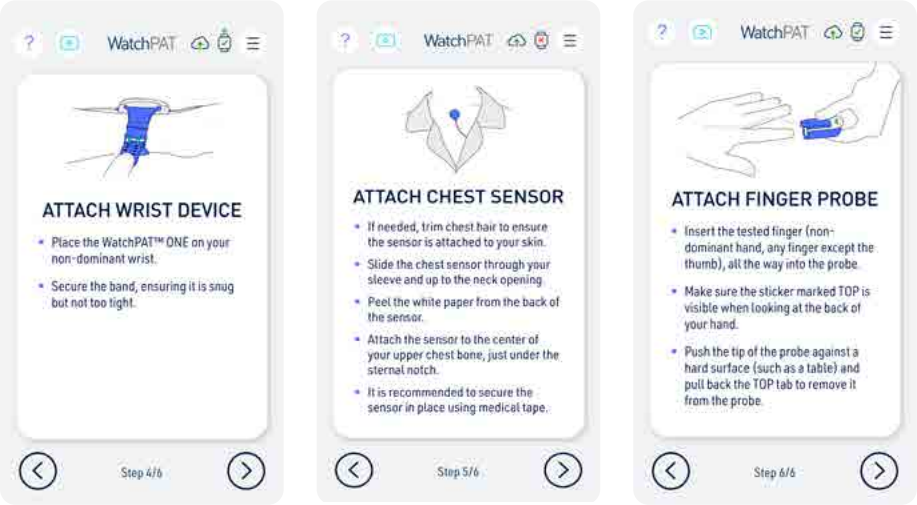


Figure 17 - Patient Setup Screens

Chest sensor screen available only on relevant models.

The test will not begin until the patient's finger is inserted. You will be notified if your finger is not detected and instructed to insert your finger into the probe.

Once you are ready to go to sleep and the device is fully applied, you will be shown a Start recording screen (see Figure 18 – Start recording Screen), followed by a confirmation screen. The confirmation screen reminds you that the probe must be attached, and battery should not be removed. Press "Start recording" button on the Application screen and then “Yes ” on the confirmation screen, to Start recording.

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.



Figure 18 – Start recording Screen

8. **Sleep Test Screen**

The Sleep Test Screen is an active Application screen throughout the study. The screen (see Figure 19) also displays the time that has passed from the start of the study.

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.

NOTE:

The LED at the center of the device cover will blink during the night.

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



Figure 19 – Sleep Test Screen

9. **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 Stop recording button on the Application's screen (see Figure 20), 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 (see Figure 21) 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 20 – Stop recording button

NOTE:
Approximately ten hours after the test start, the WatchPAT device will stop acquiring data. This is normal.



Figure 21 – Application's indication that data is still being offloaded from the device

The completion of the test is indicated with the appearance of the Test Completion screen (see Figure 22 - Left). The LED of the device will constantly blink in green when all the data from the device has been transferred to the Mobile Phone.

The device is a single-use product, so it cannot be used once again. If you have the WatchPAT multi-night option, you can use the device on the same patient for up to 3 nights. 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.

The WatchPAT ONE Green program (available in certain countries), offers you to send the WatchPAT ONE device back to us free of charge for proper disposal. Further information can be found in the WatchPAT ONE app or in Itamar Medical website (See Figure 22 - Right).

NOTE:

The WatchPAT™ONE is Single Use. Re-use of single use products may cause cross contamination, potentially leading to infection and/or patient injury (WPONE-M can be used for up to 3 nights by replacing the finger probe).

1. **For WPONE-M only: Preparation for a New Test**

On the second and third night, connect a new battery to the WPONE-M and restart the application.

The following screen will be displayed after the WELCOME screen.

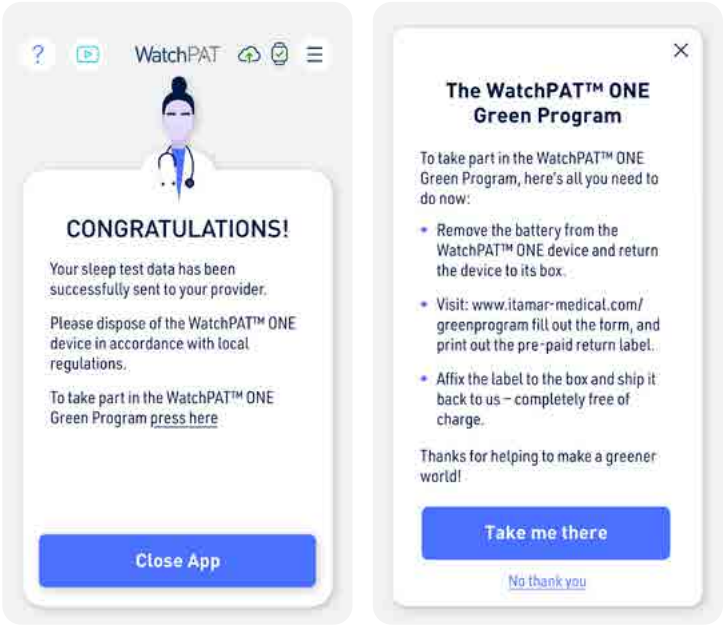


Figure 22 – Test Completion Screen

The "click here" link will show the steps to follow with explanation of how to replace finger probe, chest sensor sticker and battery.



Figure 23 – Preparation For New Test Screen

NOTE:
It is recommended to leave the finger probe connected to the WPONE-M at all times in order to avoid leaving the connector exposed.

Instructions for new study preparation (for 2nd and 3rd night)

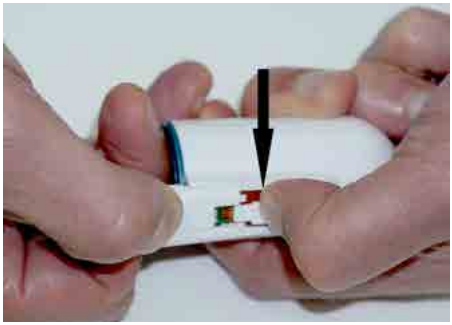


Figure 24 –Finger probe disconnection

1. Remove the used probe by pressing the small tab (clip) marked by the arrow, and then, holding the connector's slider, gently slide it away from the probe. Properly dispose of used probe.



Figure 25 – New Finger probe connection

2. Connect a new probe by inserting the white slider to the probe until the white cover of the probe clicks into its place.



Figure 26 – Chest sensor sticker removal

3. Remove the used chest sensor sticker by pulling the sticker.

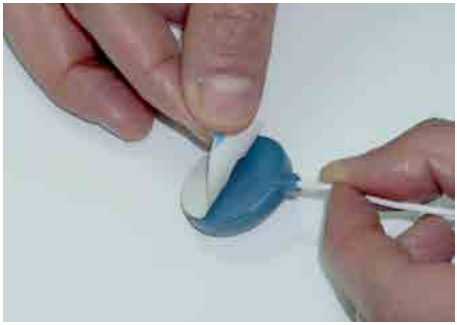


Figure 27 – Chest sensor sticker adhesion

4. Attach a new sticker by peeling off the cover on one side of the sticker.



Figure 28 – Battery removal

5. Remove battery.



Figure 29 – Battery insertion

6. Insert a new disposable AAA battery. The direction of '+' and '–' is illustrated on the battery lid and inside the battery compartment.

NOTE:

If you receive a PHOTO or LED error after you reconnected a new finger probe, that means that the finger probe is not connected properly and you need to:

1. Disconnect and reconnect the probe.
2. Select NEXT.

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 available.	Provide internet access to your phone

Error Message	Possible Reason	Action
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 out, select Forget Device from menu 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.
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	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
The WatchPAT is asking to turn on Bluetooth	The Mobile phone does not have its Bluetooth communication turned ON.	Approve the Application's request of the turning ON the BlueTooth capability.

Error Message	Possible Reason	Action
Connection with WatchPAT ONE 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	Check Bluetooth communication in mobile phone / bring the device closer to the Phone / Put a fresh Alkaline AAA battery in the device
Internet connection not available	Mobile phone has no internet access	Check internet communication in mobile phone
Incorrect PIN, please try again	The PIN used does not match your records	Enter the correct PIN
-Authentication failed or Initialization errors occurred, please fix them and restart application. -Exceed number of PIN retires	A non-valid PIN used at all attempts	The clinic will remind the patient of the correct PIN and they will also reset the retries counter
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
User not registered in system	The device handed to the patient has not been registered	Call physician office
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
WPONE-M only: Device exceeded maximum number of uses. Please dispose	The device has been used already for 3 tests and cannot be used again.	Dispose of the device.

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

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.

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	Pulse rate Amplitude Oximetry	30-150 ± 1bpm 0-0.5V ± 10% A_{RMS} ≤ 3% (in range 70%-100%)
PAT Channel	Bandwidth	0.1-10Hz
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° to 40°C
	Storage	0° to 40°C
	Transport	-20° to 60°C
Humidity	Operating	10% – 93% (non-condensing)
	Storage & Transport	0% – 93% (non-condensing)
Atmospheric pressure	Operating & Storage	10 – 15psi
	Transport	8 – 15psi

Properties		Description
Physical Measurements (Rigid parts)	Main device Dimensions (L x W x H)	Device (Enclosure): 60mm*55mm*18mm
	Weight	Device (Enclosure): 38gr (without battery)
Device transmitter	BLE Version	4.0
	Operating frequency	2.4GHz
	Band Width	250KHz
	Transmitted Power	4dBm
	Operating range	5m indoor
	Antenna type	Printed
	BLE Profile Type	UART
Mobile phone	Operating System	Android 13 minimum iOS 15 minimum
	BLE Version	4.2
	Network	Wi-Fi / Cellular
	Storage Required	>120MB
Expected service life/shelf-life		18 month

NOTE:

Software Bill of Materials for WP1 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.

NOTE:

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

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%.

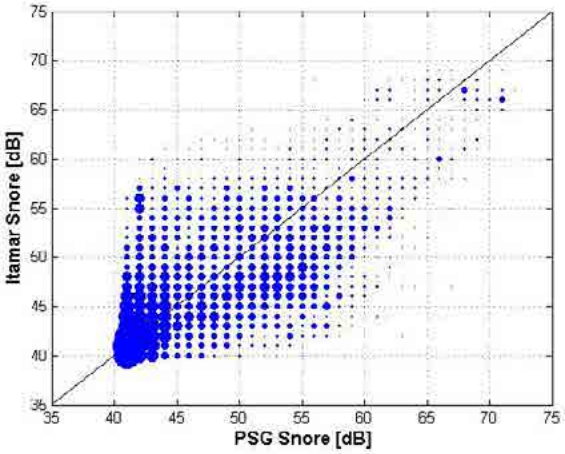
Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059 and 0.8311).

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

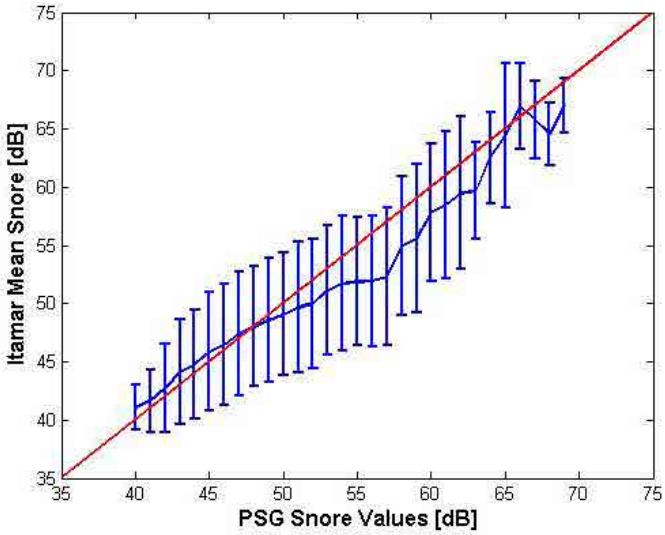


An estimation of the error in each snoring level was calculated by looking at the WatchPAT™ device measurement cut by the results of dB-meter in intervals of 1 dB in the range of above 40dB (below 40 dB was considered not clinically significant being background noise). A high correlation was observed 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
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 ± 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 WP200 with equivalent chest sensor to the one used with the WatchPAT device.

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/license-agreement

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., PO 3579

Caesarea 3088900, Israel

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APPENDIX B: CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

Clinical benefits of the WatchPAT™ONE:

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

Performance characteristics of the device:

Performance characteristics	
AHI	Sensitivity/Specificity: 85%/88.2% (AHI threshold = 15)
AHIc (Central Sleep Apnea)	Sensitivity/Specificity: 71.4%/98.6% (AHIc threshold = 10)
Sleep Stages	Accuracy: 65% Kappa agreement value: 0.462
SpO_2	A_{RMS} SpO_2 70-100%: 2.0
Arrhythmia	AFib total duration in sleep: Sensitivity/specificity (TH=6min) – 84%/95.5% AFib longest event: Sensitivity/specificity (TH=6min) – 83.3%/98.5% PB events/min: Sensitivity/specificity (TH=0.5) – 100%/98.2%

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

Notes:

- Certain types of mobile telecommunication devices may interfere with the WatchPAT.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the 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 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.
- WatchPAT was tested under the least favorable working conditions, meaning the device recorded data while transmitting it to the smartphone via BLE.

TABLE 1 – FROM IEC 60601-1-2:2014, AMD1:2020		
Declaration – Electromagnetic Emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class B	The WP1 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 WP1 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 WP1 or shielding the location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

TABLE 2 - FROM IEC 60601-1-2:2014, AMD1:2020			
Declaration – Electromagnetic Immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	2,4,8kV contact 2, 4, 8,15kV air	2,4,8kV 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	2kV for power supply lines 1kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	1kV line(s) to line(s) 2kV line(s) to earth 2kV Signal input/ output) to earth	Not Applicable	Not Applicable
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 (50/60Hz) 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 - FROM IEC 60601-1-2:2014, AMD1:2020			
Declaration – Electromagnetic Immunity			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0,15MHz – 80MHz 6 Vrms in ISM bands between 0,15MHz and 80MHz 80% AM at 1kHz	3 Vrms 0,15MHz – 80MHz 6 Vrms in ISM bands between 0,15MHz and 80MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the WP1, 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. 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	

Proximity magnetic fields IEC 61000-4-39	8 A/m (30kHz, CW) 65 A/m (134.2kHz, pulse modulation 2.1kHz) 7.5 A/m (13.56MHz, pulse modulation 50kHz)	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 radiofrequency communications equipment (emitters) and the WatchPAT, according to the maximum output power of the equipment, as recommended in the table below.

TABLE 4 - FROM IEC 60601-1-2:2014, AMD1:2020				
Recommended separation distances between portable and mobile RF communications equipment and the WP1				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150kHz to 80MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150kHz to 80MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800MHz to 2,5GHz $d = [\frac{23}{E_1}]\sqrt{P}$
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

IEC 60601-1-2:2014, AMD1:2020				
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment				
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation**	**Immunity Test level (V/m)**
385	380 to 390	TETRA 400	Pulse modulation [b] 18Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	28
870				
930				
1720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217Hz	28
1845				
1970				
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	28
5240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	9
5500				
5785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the WP1 may be reduced to 1m. The 1m 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, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18Hz. While it does not represent actual modulation, it would be worst case.				

IEC 60601-1-2:2014, AMD1:2020		
Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30kHz	CW	8
134,2kHz	Pulse modulation [b] 2.1kHz	65 [c]
13,56MHz	Pulse modulation [b] 50kHz	7.5 [c]
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s., before modulation is applied.		

APPENDIX D: 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.

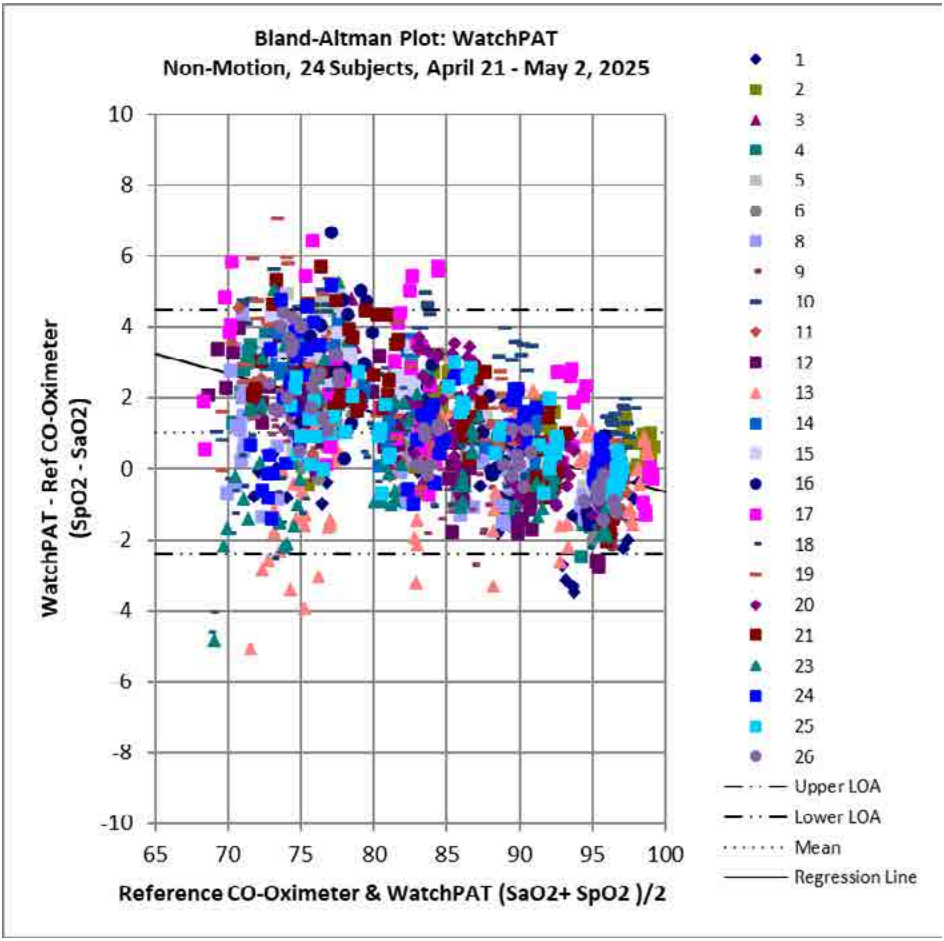
1. Overall, the A_{RMS} is estimated to be 2 for the range 70-100%

2. The next tables show SpO_2 Accuracy results when compared to reference co-oximetry and non-disparate performance:

WatchPAT COMPARISON TO REFERENCE CO-OXIMETRY						
	67--100	70--100	90--100	80--<90	70--<80	67--<70
# pts	1708	1671	534	595	542	37
Bias	1.0	1.0	-0.2	1.0	2.1	3.3
A_{RMS}	2.0	2.0	1.0	1.6	2.8	3.7

NON-DISPARATE PERFORMANCE				
	Decile SaO2	Light (MST 1-3)	Medium (MST 4 -7)	Dark (MST 8-10)
A_{RMS} (Bias)	67-100	2.0 (1.0)	2.3 (1.4)	1.6 (0.7)
	70-100	2.0 (1.0)	2.2 (1.3)	1.6 (0.6)
	90-100	0.9 (-0.3)	1.2 (-0.1)	1.0 (-0.3)
	80-90	1.4 (0.9)	1.8 (1.2)	1.7 (1.0)
	70-80	2.9 (2.1)	3.1 (2.7)	2.1 (1.4)

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



Reference: Bland-Altman Range	67-100%
Linear Regression (Bland Altman)	y = 10.4371 + -0.11094 x
Mean Bias	1.02
# pts	1708

Bland-Altman Results for Multiple Observations Per Individual

Between-Subject Variance ($\sigma\mu^2$)	0.62
Within-Subject Variance (σ^2)	2.45
Upper 95% Limits of Agreement	4.46
Lower 95% Limits of Agreement	-2.41

Source of data

Title:	SpO_2 Accuracy Validation for WatchPAT Oximetry Platform via Reference CO-Oximetry Study ID# PR 2024-598
Date:	24 Jul 2025
Clinical Investigator(s):	Element Materials Technology 80 Health Park Drive, Ste 20 Louisville, CO 80027, USA
Sponsor:	Itamar Medical, Ltd. 9 Halamish St PO 3579, Caesarea 3088900, Israel
Device(s):	Zoll WatchPAT finger probe
Study Date(s):	April 21 – May 2, 2025

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 (SpO_2) that is used with the WatchPAT™ONE device.

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

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 84 patients and the following results were obtained:

- Sensitivity = 71.4%
- Specificity = 98.6%
- Positive predictive value (PPV) = 90.9%
- Negative predictive value (NPV) = 94.5%

In addition, the following statistics was demonstrated:

Area Under the Curve (AUC) = 0.913 of a ROC for a PSG threshold of AHIc = 10

Pearson correlation between AHIc of PSG and WP200U of R=0.80 with a slope of 1.22 and offset of 0.79.

Percentage of total sleep time with CSR pattern (%CSR)

Pearson correlation between %CSR of the WP200U with %CSR of PSG of R=0.84 with a slope of 1.08 and offset of 0.05.

In addition, the overall %CSR agreement between WP200U and PSG (per sec) is 92.11% with Kappa level of agreement of 0.495.

Source of Data

Title: Evaluation of the WP200U compatibility to identify CSA and CSR updated analysis

Date of the Report: April 10, 2018

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

Sponsor: Itamar Medical, Ltd. 9 Halamish St POB 3579, Caesarea 38900 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™ONE device.

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.

	**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.

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.