WatchPAT™ ONE

Operation Manual

Itamar Medical REF OM2196370

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

DISCLAIMER

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

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EN ISO 13485:2012 and ISO 13485:2003 / CMDCAS
See "0Appendix B: Regulatory representative" for contact information of the regulatory authorized representative

Record of Editions

Edition	Date	Description	Chapter	Pages	Resp.
1	May 2018	Initial	All	All	Itay
2					
3					

Note:

- Latest version of the WatchPAT® System Operation Manual is available at:
  http://www.itamar-medical.com/Support/Downloads.html
- 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.

Table of Contents

List of Figures

1 GENERAL INFORMATION

This manual is part of the WatchPAT®ONE (hereafter called WatchPAT) system.

1.1 Intended Use / Indications for Use

The WatchPAT device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WatchPAT is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WatchPAT generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WatchPAT's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WatchPAT'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. The WatchPAT should be used only in accordance with physician's instructions. For exclusion criteria 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. 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.
9. 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.

10. The step by step instructions should be carefully followed when attaching the unit.
11. The WatchPAT is not indicated for patient with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT device.
12. The WatchPAT is not indicated for children less than 12 years old.

1.3 Exclusion Criteria

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.
3. Sustained non-sinus cardiac arrhythmias.
4. The WatchPAT is not indicated for children who weigh less than 65 lbs.

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 ADHA, 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 optional 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	#
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
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) – IP22	IEC 60529 Ed 2.2 + COR2
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.	Symbols for use in the labelling of medical devices	EN 980:2008
10.	Graphical symbols for electrical equipment in medical practice	PD IEC/TR 60878: 2015

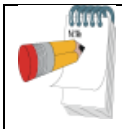
	STANDARD	#
11.	Graphical symbols - Safety colors and safety signs -- Registered safety signs; refer to instruction manual/ booklet	ISO 7010:2011 (M002)
12.	Information supplied by the manufacture with medical devices	EN 1041:2008 + A1:2013
13.	Biological evaluation of medical devices - Part 1: Evaluation and testing	ISO 10993-1:2009
14.	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61:2011
15.	FDA Quality Systems Regulation (QSR)	21 CFR part 820
16.	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485:2012
17.	Medical devices - Quality management systems - Requirements for regulatory purposes (Health Canada)	CAN/CSA-ISO 13485:2003
18.	Canadian Medical Devices Regulation	SOR/98-282
19.	Federal Communication Commission	Federal Code of Regulation (CFR) Title 47, Chapter I, Sub-Chapter A, Part 15

1.7 NRTL Compliance

TBD

1.8 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.

	**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.

1.9 Warnings, Cautions and Notes

The WatchPAT is powered with one off-the-shelf AAA battery.
The WatchPAT is portable with continuous operation.
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.
Sleep professionals (other than patients) using the WatchPAT should read the Operation Manual.

1.10 Safety Precautions

WARNINGS

Do not let the device to get wet.

Avoid placing food or water on any part of the system.

In the event of fire use only fire extinguishers approved for use on electrical fires.

Handle unit with care. This unit is sensitive to extreme movements and to falling.

Do not attempt to connect or disconnect any part of the unit.

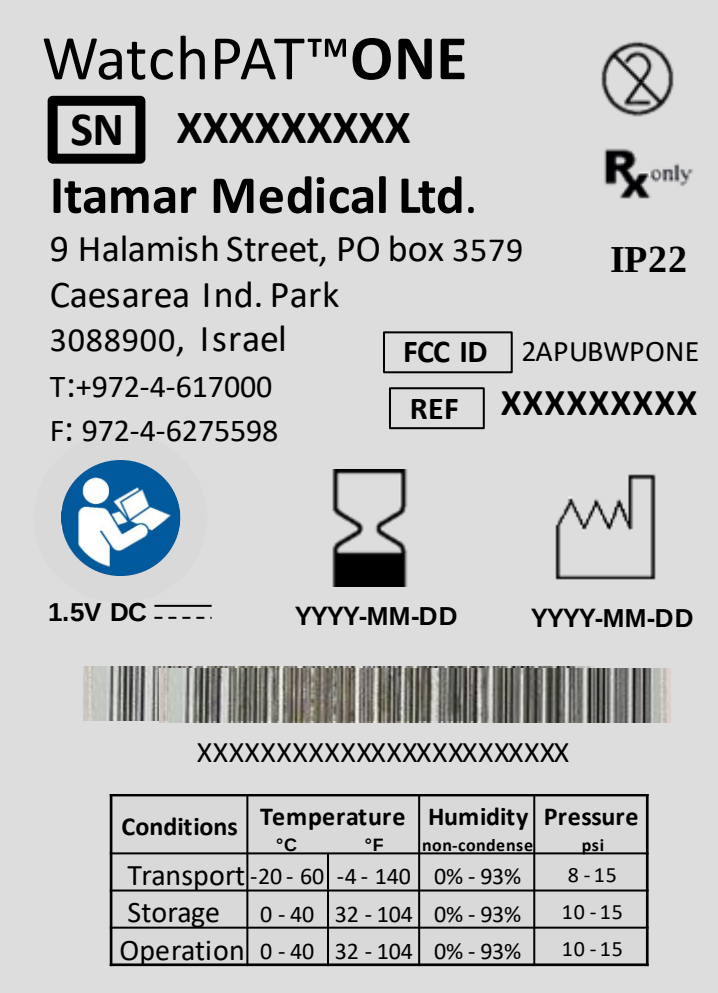
Do not try to introduce any foreign object into the unit.

1.11 Symbols Used on the Product Labels

	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
REF	Catalogue Number
SN	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
Rx only	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.

1.12 WatchPAT Device Labels

The following label is located on the device's package.



Conditions	Temperature °C	Temperature °F	Humidity non-condense	Pressure psi
Transport	-20 - 60	-4 - 140	0% - 93%	8 - 15
Storage	0 - 40	32 - 104	0% - 93%	10 - 15
Operation	0 - 40	32 - 104	0% - 93%	10 - 15

1.13 FDA information

TBD

2 OVERVIEW

Sleep apnea syndrome is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. Obstructive sleep apnea is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep with the presence of breathing effort, while Central Sleep apnea is characterized by no respiratory effort. Both conditions often lead to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is usually based on the apnea-hypopnea index (AHI – the number of Apneas, and Hypopneas per hour of sleep) and / or the Respiratory Disturbance Index (RDI) which is AHI plus Respiratory Effort Related Arousals (RERA), along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of sleep apnea in the adult population.

The WatchPAT is worn on the wrist and 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) channels, which are used for the measurement of SpO_2 signal.

The PAT® and SpO_2 signals are recorded continuously and stored on a remote server, together with data from a built-in actigraph (embedded in the WatchPAT). Snoring, Body Position and the subject's chest movement signals are recorded bythe integrated Chest Sensor. The recorded data is transmitted to an Application on a mobile phoneand 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)
- Acoustic
- 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
- Step-by-Step Reference Guide
- Package
- Battery (optional)

Figure 1 – Packed Device

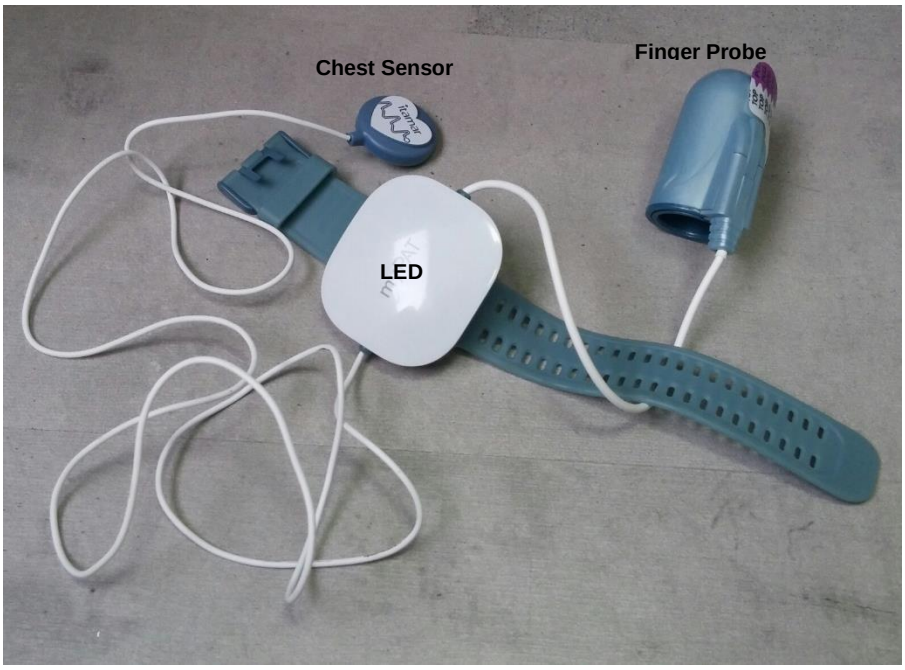


Figure 2 – WatchPAT Device with Sensors

2. The WatchPAT Application is a proprietary mobile application that is available for download on the App Stores. A typical Application screen is displayed in Figure 3 – Application Screen.

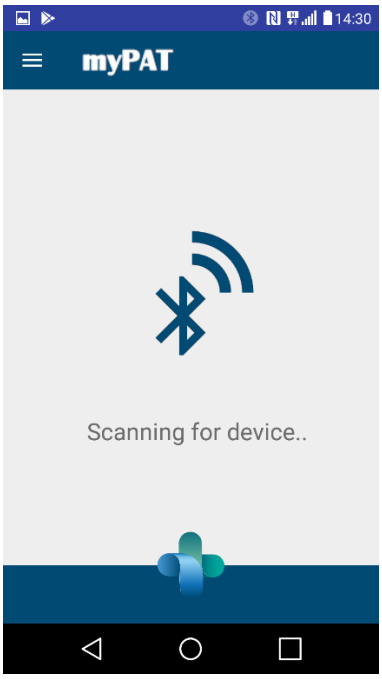


Figure 3 – Application Screen

3. The zzzPAT Analysis Program (see Figure 4) 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 Operation Manual.

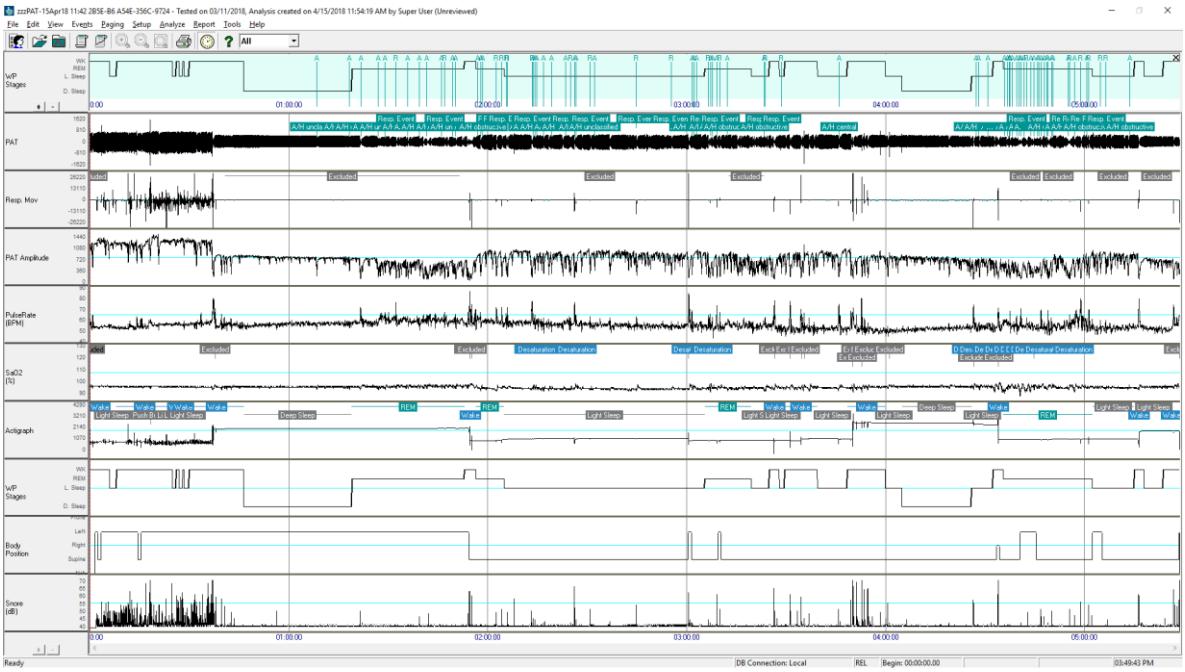


Figure 4 – A zzzPAT Analysis Program typical screen

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. These measurements are used to calculate the oximetry signal in an offline program according to the pulse oximetry principles.

2.3 Chest Sensor Description

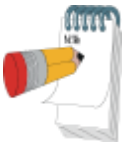
The Chest Sensor consists internally of two sensors: a snore sensor and a chest movement sensor. The Snore Sensor is an acoustic decibel detector. It uses a highly sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a signal that provides a clear, reliable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

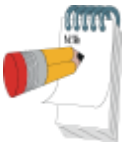
The Chest Sensor uses a 3-axis accelerometer that provides a signal that reflects the movement of the chest, which can be translated both to the patient's sleeping posture (supine, prone, right, left and sit) and to the chest movement signal resulted by the subject's breathing during the night.

3 HOME SLEEP TEST

Before using the WatchPAT®ONE you should read this chapter.

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 does 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** 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.

	**NOTE** 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.

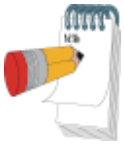
The home sleep test is comprised of the following three main tasks

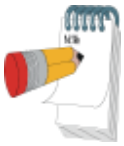
- Test Preparation – before bed time
- Sleep Test – during sleep
- Test End – at wake-up

The Application screens will guide you throughout the process. Alternatively, the Quick Reference can also be followed. 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, in which cases these need to be skipped.

	**NOTE** Make sure the room you are sleeping in is as quiet as possible during the night, 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®ONE Application on the Google Play Store and have it installed on your Mobile phone. Follow all instructions that your phone during the installation process, until the Application has been successfully installed.

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 mounted 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.

	**WARNING** Use your mobile phone vendor recommendation for safe distance location of the phone.

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 an AAA Alkaline battery into the battery compartment of the WatchPAT device (see Figure 5 – 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. In will always be a number that you are familiar with.

3.1.3 Patient Preparation

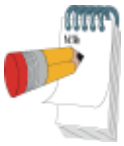
The best conditions for the sleep test are when potential obstacles are put out of the way. Make sure you remove tight clothes, rings, watches and other jewelry from your non-dominant hand and wrist and from your neck and chest. Furthermore, ensure that the finger nail of the finger that will be monitored is well trimmed, (less than 1mm from nail bed) with no jagged edges. Clip and file nail, if necessary. Remove artificial fingernail or colored nail polish from the monitored finger.

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

Thread the Chest Sensor through the sleeve of the night shirt and up to the neck opening. Peel the white paper on back of sensor's sticker. Attach the Chest Sensor to your chest under the sternal notch (align the main icon to your body). If needed, trim or shave chest hair. If possible, secure the Chest Sensor in place with medical tape.

Insert your index 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. Patients with large fingers may use their small finger (pinky) for the Finger Probe.

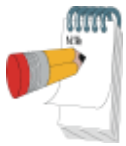
Once these steps are completed the device is ready for operation.

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.

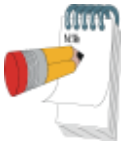
Press the START button and go to sleep. The data is recorded throughout the night and stored in a remote Web Server.

	**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 TEST button will be displayed on the Application screen. Press the STOP TEST button and the recording will stop. At this stage you should take off the device from your arm, finger and chest. The last of the recording data still needs to be transmitted from the device so 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.

	**NOTE** 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.

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.

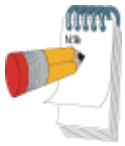
3.4.1 Battery Insertion

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 5, 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 5 – Battery insertion

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

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 Mounting the WatchPAT®ONE device

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

a) Wrist
b) Finger
c) Chest

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 6). 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.

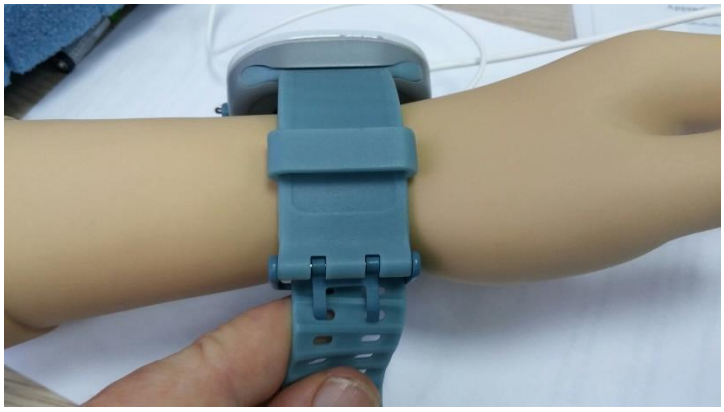


Figure 6 – Strapping the main device

3.4.4 Attaching the Chest Sensor

Next you should apply the Chest Sensor 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 7 – 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.

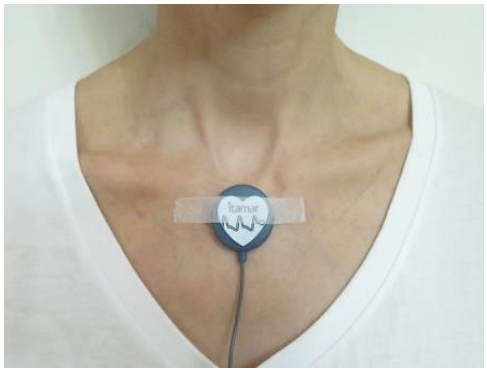
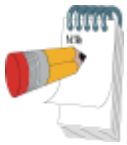


Figure 7 – Chest Sensor placement

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 8).
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 9**Error! Reference source not found.**). 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.

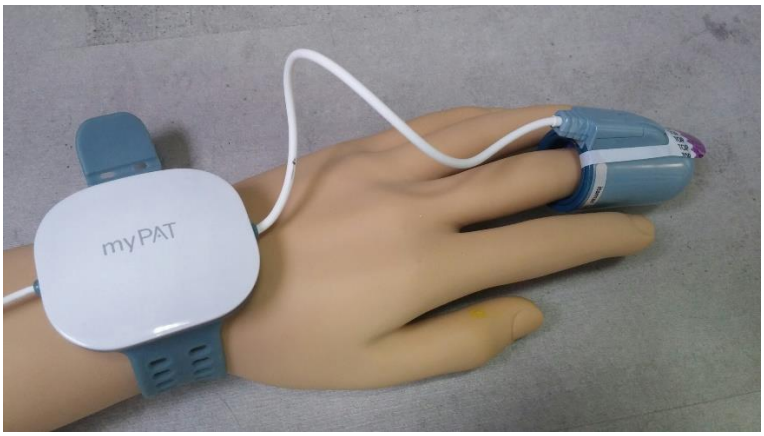


Figure 8 – Placing Finger in the Finger Probe

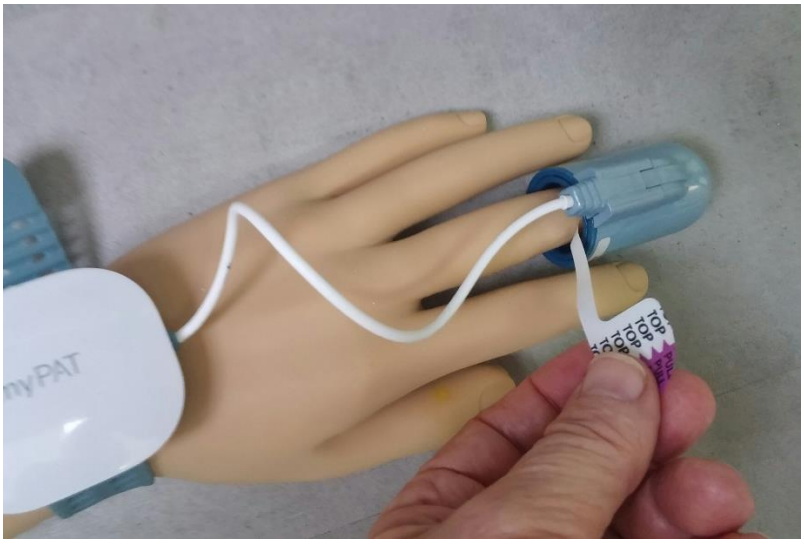
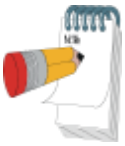


Figure 9 – Removing TOP Tab while pressing against hard surface

	**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. The Application is 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 10 . You can understand the status of your home sleep test by reading the status line (see Figure 10 – A). The center of the screen is used to provide description or guidance. It will also be used to warn the patient (see Figure 10 – B) at unlikely situation that require the patient's attention.

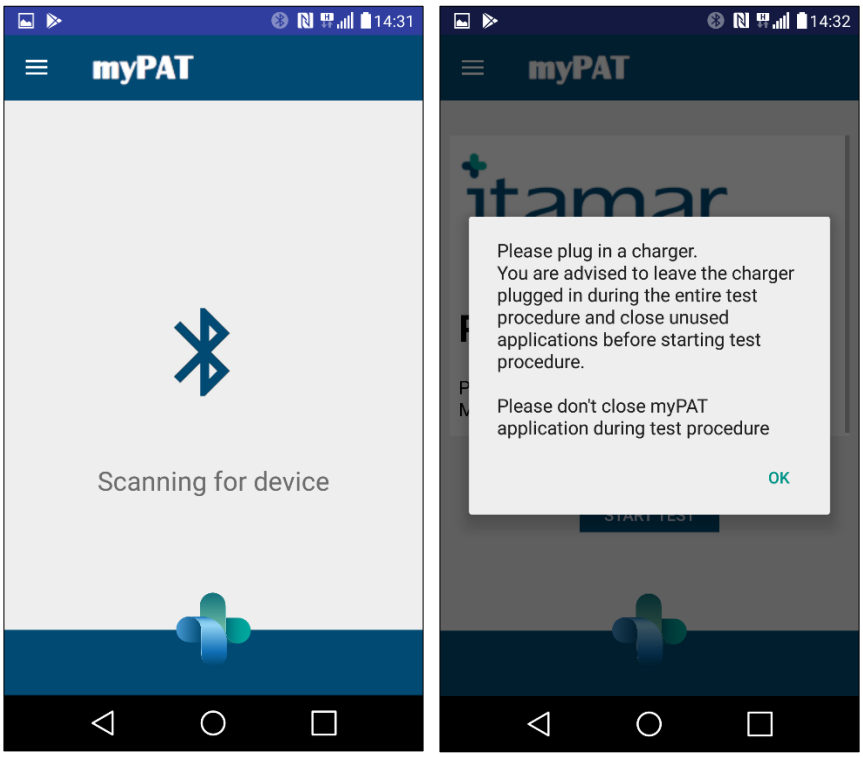
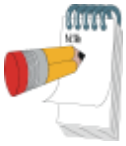


Figure 10 – Application screen samples (A – on left - with Status line, and B – on right, with a warnings messages)

When the patient (and 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 under the device cover will blink.
If the WatchPAT device passes this self-diagnostic test, the blinking will have either a green color or green combined with red.

	**NOTE** 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.

If the WatchPAT device fails this self-diagnostic test the device's cover LED will blink in RED, and if possible, a message will be displayed by the Application.
When running the WatchPAT Application, you will be going through the following screens –

a. Application Loading Screen
The Application "Loading Screen" is an interim display (see Figure 11). It lets you know that the system is being loaded onto the Mobile phone. This should not take more than a few seconds.

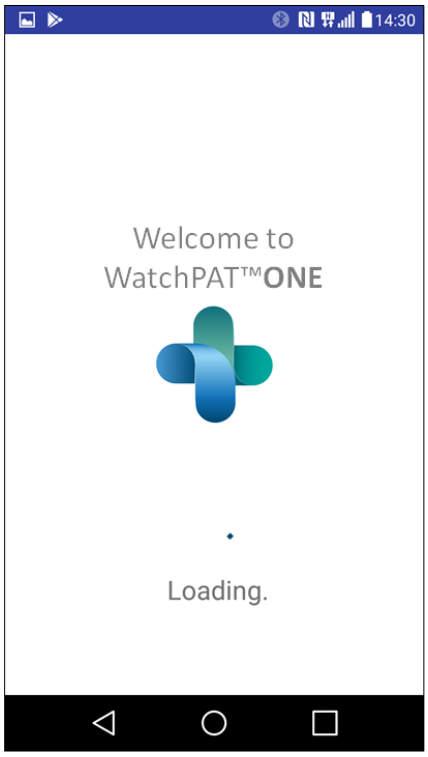


Figure 11 – Loading Screen

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 Blue Tooth communication needs to be turned ON). In these cases, you will be asked to assist, with guidance being provided.

b. Synchronization Screen
The Application will first try to establish a communication channel with the device (see Figure 12). The battery should be inserted by now in the device, and the device should be nearby (in the same room). Once the connection has been established, the Application will change its Status line to 'Connected'.

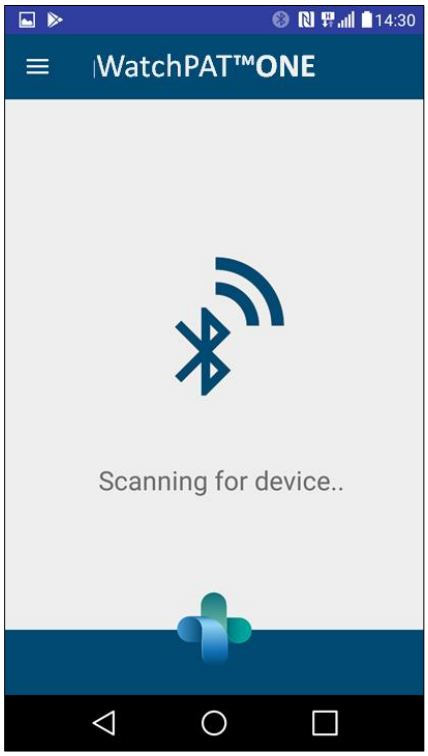


Figure 12 – Scanning device screen

If the Application scanning operation failed to detect an active WatchPAT in its proximity, it will indicate that the operation failed (see Figure 13). Try to detect the failure root cause and select the SCAN AGAIN button to start a new scan. The most common reasons for a failure to detect the device is (a) A battery was no 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).

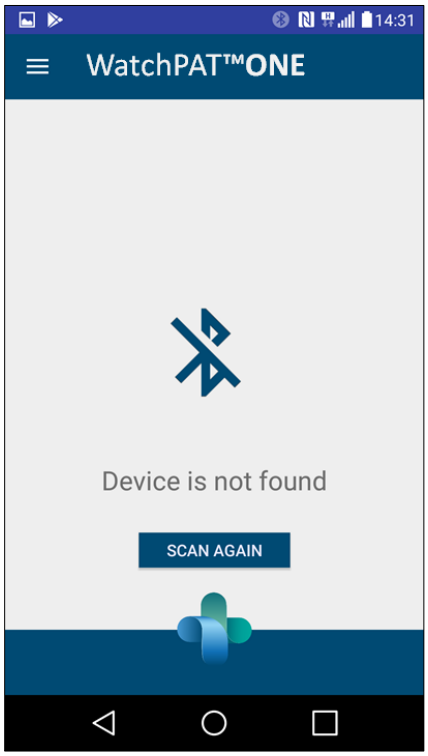


Figure 13 – A failed scanning screen

c. PIN insertion Screen

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.

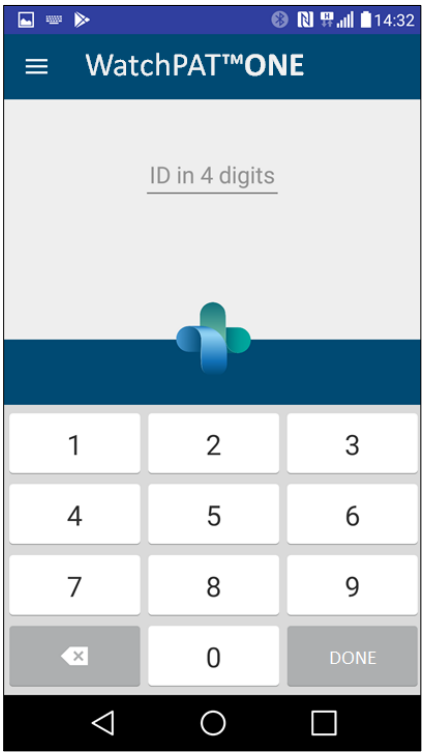


Figure 14 – PIN Screen

d. Patient Setup Screen

The Patient Setup_screen (see Figure 15) is used to guide you with applying the device and its sensors, as described in the User Manual or the Quick Reference and that you are ready to start the test.

Once you are ready to go to sleep and the device is fully applied, you can press the START button on the Application screen.

The Application will instruct the device to start collecting the signals from the sensors, and to transmit these 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.

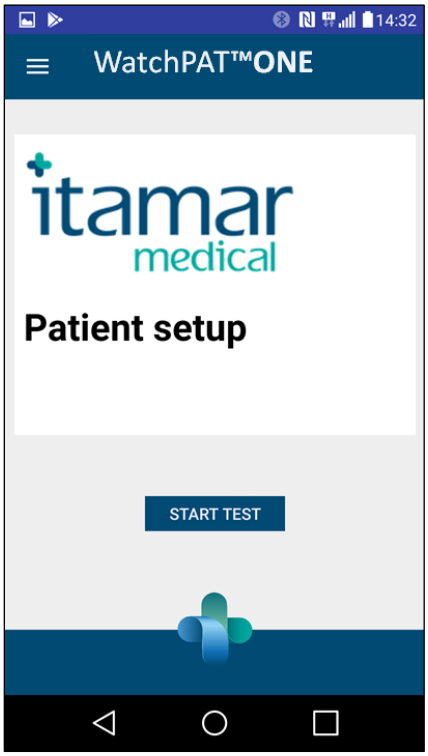


Figure 15 – Patient Setup Screen

e. Sleep Test Screen

The Sleep Test Screen displays the data transmissions status (see Figure 16). The communication between the device and the Application is represented by the Mobile phone icon (left icon). The label 'Connected' below the icon states that communication has been established. The blinking transmission waves indicate that data is being received from the device.

The communication status between the Application and the Web Server is represented by the Cloud icon (see Figure 16). The label 'Connected' underneath the icon states that the communication channel has been established. When connected, a check mark will be displayed in the cloud.

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 and return, the Application will reestablish the connection with the device and the sleep test will

continue uninterrupted. Yet, do not remove the device and its sensors, as this action will interrupt the test and it will not be possible to resume.

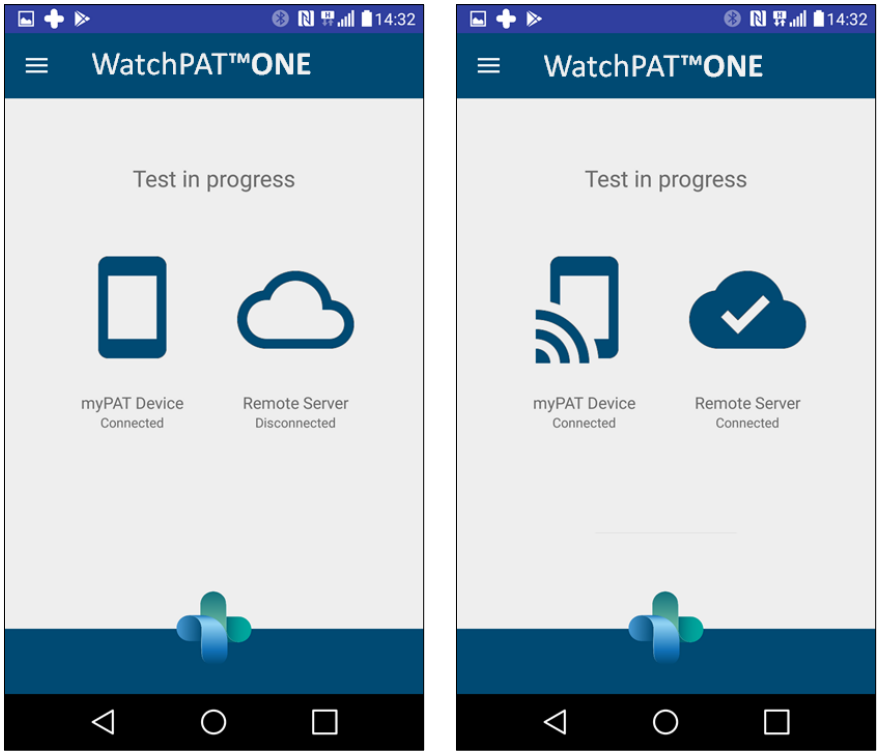
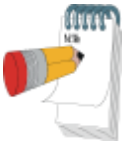
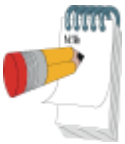


Figure 16 – Sleep Test Screens, at various connection statuses

	**NOTE** The LED under the device cover will blink during the night

	**NOTE** The Remote Server ‘‘Disconnected’ status is a valid status and should not alert you. The Application can upload the data later, whenever reception is available.

When you wake up you are requested to press the STOP TEST button (see Figure 17). This will cease any further data acquisition.

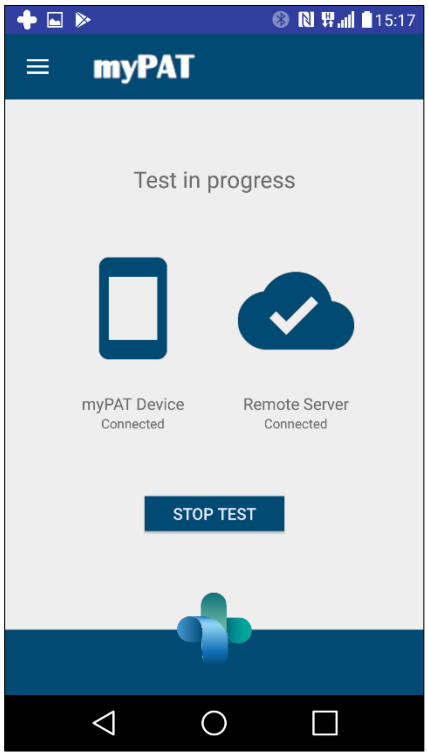
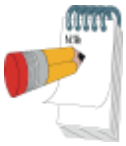


Figure 17 – STOP TEST button

f. 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 TEST button on the Application screen, you may take off the device, the Finger Probe and Chest Sensor:



NOTE

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

Allow the phone Application to keep on running until a message appears in the status line indicating that all the data has been transmitted successfully (see Figure 18).
Do note that "Test is completed" message doesn't indicate that all data was transmitted to the server.

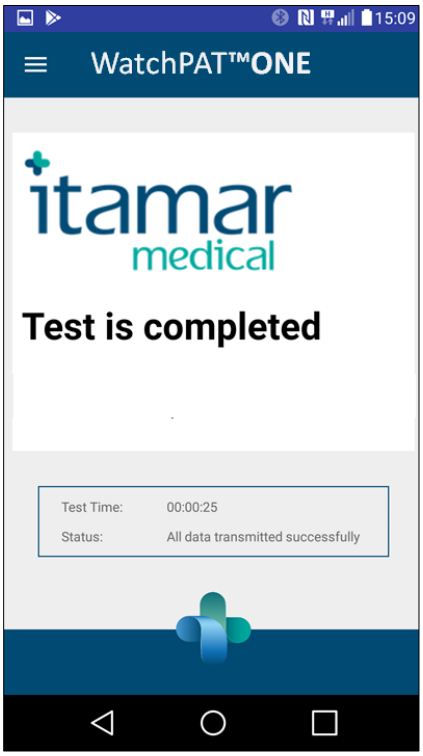


Figure 18 – Test Completion Screen

The device is a single-use product, so it cannot be used any more. 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 it 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.

- 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

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 Itamar or an authorized representative directly.

Error	Reason	Action
HW failure	There is a hardware failure in the device.	Return the device to the provider, and a new one will be shipped in return.
Device not valid	The device has been already in use	Return the device to the provider, and a new one will be shipped in return.
Running out of power	The device battery has run out of power	Replace the battery with a fresh Alkaline AAA battery
Connection establishment failure	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 SCAN AGAIN. Next, If it is blinking, bring the device closer to the Phone and press SCAN AGAIN. If the RED blinking resumes after SCAN AGAIN button was pressed, there is a problem with the device and it needs to be returned.
Connection establishment failure	The Application sees more than one active device	You should make sure other devices in room are turned OFF until after your Application has successfully establishes communication with your device
Connection failure	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
Data transmission failure	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
Connection establishment failure	The Mobile phone does not have its Blue Tooth communication turned ON.	Approve the Application's request of the turning ON the Blue Tooth capability.
PIN Mismatch	The PIN used does not match your records	Enter the correct PIN

Error	Reason	Action
Data completeness failure	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
Not enough storage	The Application fails to allocate storage on the Mobile phone	Free up the request amount of storage on the Mobile phone

7 SPECIFICATIONS

Properties		Description
Recording Time		Approx. 10 hours
Channels		PAT, Oximetry, Actigraphy, Snoring, Chest Movement
Sample Resolution		PAT, Actigraphy, Snore, Chest Offset: 12 bits Oximetry: 1% Body Position 5 discrete states: supine, prone, right, left and sit
User Interface		Mobile phone: Android Application Device: LED
Accuracy	*Pulse rate* *Amplitude* *Oximetry*	30-150 ± 1 bpm 0-0.5V ± 10% Arms ≤ 3% (in range 70%-100%)
PAT Channel	*Bandwidth*	0.1-10 Hz
Data Storage	*Media*	NOR SPI Flash
	Capacity	16MB
Power Supply	*Battery*	One OTS 1.5V Alkaline AAA battery
Operating Voltage		3.3 V
Temperature	*Operation*	0^0C to 40 ^{0}C
	Storage	0^0C to 40 ^{0}C
	Transport	-20^0C to 60 ^{0}C
Humidity	*Operating*	10% – 93% (non-condensing)
	Storage & Transport	0% – 93% (non-condensing)
Atmospheric pressure	*Operating & Storage*	10 – 15 psi
	Transport	8 – 15 psi
Physical Measurements *(Rigid parts)*	*Dimensions (L x W x H)*	Device (Enclosure): 60mm*55mm*18mm Finger Probe: 30mm*40mm*74mm Chest Sensor: 15mm*15mm*10mm
	Weight	Device: 38 gr Finger Probe: 20 gr Chest Sensor: 8 gr
Device transmitter	*BLE Version*	*4.0*
	Operating frequency	*2.4 GHz*
	Band Width	*250 KHz*
	Transmitted Power	*4dBm*

Properties		Description
	Operating range	*5m indoor*
	Antenna type	Printed
	BLE Profile Type	UART
Mobile phone	Make	LG, Samsung
	Operating System	Android 5.0 minimum
	BLE Version	4.0
	Free Storage Required	>100MB

Chest Sensor Accuracy

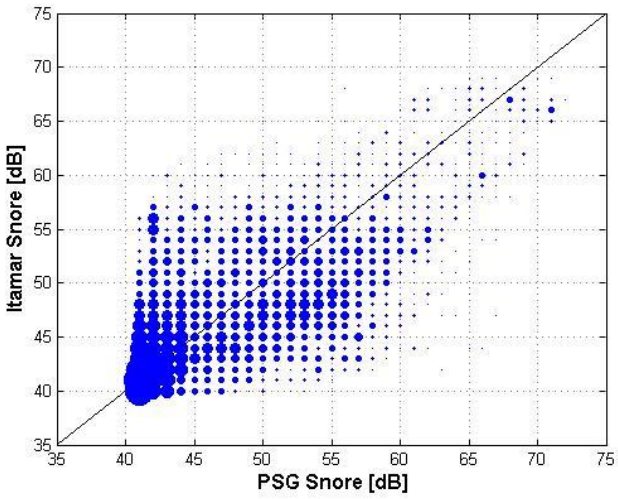
This section gives statistical performance of the snoring and the body position measurements of the Chest Sensor.

I. Body Position

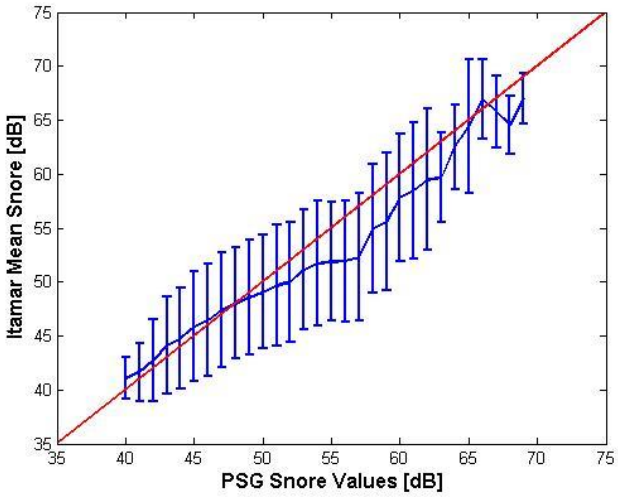
The body position was compared to the gold standard, manual scoring of the video recording of 31 patients, in 1 minute's epochs (total of 7111 epochs) during sleep.
The Agreement between the device and the video recording was 90%.
Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059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

II. Snoring

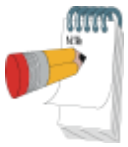
The snoring level was compared to a gold standard PSG dB-meter placed 1 meter from patient's head. The study included 26 patients, and the analysis was done in 30sec epochs.
The correlation coefficient was calculated using Pearson method, assuming a linear relation between the results of the two devices. A statistically significant correlation was calculated between the two devices: $r=0.65$ p 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.



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 the same Chest Sensor that is 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 www.itamar-medical.com/Support/Downloads.html .

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: REGULATORY REPRESENTATIVE

TBD

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.

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.

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**
			Portable and mobile RF communications equipment should be used no closer to any part of the **WatchPAT** , including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance**
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	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 M Hz t o 800 MHz $d = 2.3\sqrt{P}$ 800 MHz t o 2,7 GHz where P i s the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer and d i s the recommended separation Distance in meters (m). Field strengths from fixed R F 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: 

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

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

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**.

b
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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 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]		
Watts [W]	**150kHz to 80MHz** outside ISM Bands $d = 1.17\sqrt{P}$	**150kHz to 80MHz inside ISM Bands** $d = 2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.7GHz** $d = 2.3\sqrt{P}$
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
	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. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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: SPO_2 ACCURACY IN THE WATCHPAT

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

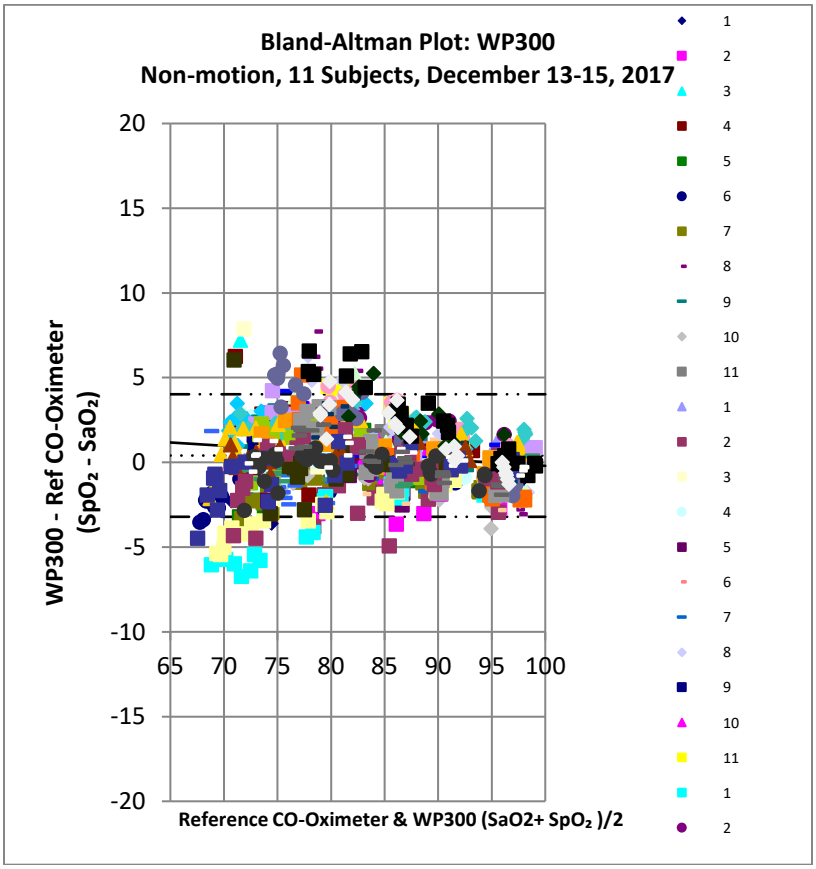
1. Overall, the Arms is estimated to be 1.9 for the range 70-100%

2. The next table shows SpO_2 Accuracy Results:

Comparison to Reference CO-Oximetry					
WatchPAT	* 70—100	90--100	80--<90	67--<80	A_{RMS} Spec 3% for range of 70-100%
# pts	1350	415	460	475	**Pass**
Bias	0.4	-0.4	0.6	0.9	
A_{RMS}	1.88	1.10	1.62	2.54	

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

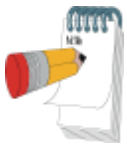
3. The next plot shows the Bland-Altman plot for Itamar-Medical WatchPAT :



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

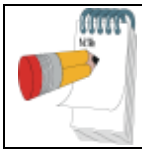
Source of data

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



NOTE

The clinical study was conducted with the WP300 with the same Pulse Oximetry System for the measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) that is used with the WatchPAT 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 72 patients and the following results were obtained:

- Sensitivity = 70.6%
- Specificity = 87.3%
- Positive predictive value (PPV) = 63.2%
- Negative predictive value (NPV) = 90.6%

In addition, the following statistics was demonstrated:
Area Under the Curve (AUC) = 0.873 of a ROC for a PSG threshold of AHIc = 10
Pearson correlation between AHIc of PSG and WP200U of R=0.83 with a slope of 0.91 and offset of 0.26

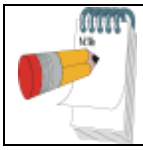
ADDITIONAL NON-DIAGNOSTIC INFORMATION

The efficacy of the WP200U in the assessment of %CSR (Cheyne Stokes Breathing) pattern was evaluated in a sub-group of 17 patients that were found to have AHIC≥10 by the PSG on a standard 30 seconds epoch-by-epoch comparison[1]. 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 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 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.

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.

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