WatchPAT™ 300

Operation Manual

Itamar Medical REF OM2196381

℞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™ 300 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/lmages/licensewp.pdf.

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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, as well as any pending US patent applications and corresponding patents and/or applications filed in other countries.

CE
2797

EN ISO 13485:2016
See appendix D for contact information of the regulatory authorized representative

Record of Editions

Edition	Date	Description	Chapter	Pages
1 (OM2196380)	September 2017	Initial	All	All
2 (OM2196380)	Oct 2017	Added labels	1.13	9
3 (OM2196380)	Feb 2018	Change photos Update Note Update standard list Update device label Remove note re self-diagnostic test from zzzPAT SW Update 'patient test' messages Remove noting primary/secondary from battery type Update maintenance and cleaning Minor updates to the language in patient training Update device dimensions Update regulatory EU representative Update: manufacturing declaration according to IEC 60601-1 & 60601-1-2 63 Update SpO2 accuracy in the WP300 Add note re AHIc and CSR	All 1.7 1.13 2.4.1, 3.7 2.4.3 3.1.1 6 7, 8 10 Appendix D Appendix F Appendix G Appendix H	All ii 4 9 16, 23 19 20 31 37, 41 46 63 61 66 69
4	Sep 2018	Change photos	All	All
5	Feb 2019	Update sec Exclusion criteria Update list of standards Update NRTL certified body - TUV Update symbols Adding clarification Update Operator tests Adding RESBP Update text Update zzzPAT info Adding zzzPAT Hardware Requirements section Update Spare parts list	1.3 1.7 1.8 1.12 2.1 2.4.1 6 7 App A App I App G	2 4 5 8 11 15-16 30 34 47 66 67
6	Sep 2019	Update Standards Updating Device Label Update Tamper-Proof Bracelet instructions Updating Specification table - dimensions Update EU REP address	1.7 1.13 4.2 10 App D	4 9 27-28 46 55
7	Feb 2020	Add restriction for AHIc Changed from Exclusion Criteria to Precautions Change Precautions wording for arrhythmias	1.2 1.3 1.3	2 2 2
8	Sep 2022	CE compliance – MDR update Add MD Symbol Standards update Updated Sticker with MD Symbol Change WP300 and WatchPAT as WatchPAT™ 300 for consistency Changed copyright note Address consistency Modify slightly the discomfort note	1.6, 1.7 1.12 1.7 1.13 All Appendix C 7.6	3, 5 8 4-5 9 Cover page I, 55 41
9	Jan 2023	Copyright year Add Arrhythmia SW feature	 1.2, 1.3, 1.5 2	Cover page 2, 3 11
10	Oct 2024	Merge OM2196380 into OM2196381 in order to create a single OM version in English, and updating images Updates to comply with: MDR Arrythmia for approved territories New editions for Safety IEC60601-1 (2020) and EMC IEC 60601-1-2 (2020) standards. eIFU (update URL for WP300 OM) Updating list of standards Add URL for zzzPAT S/W (instead of the reference to zzzPAT CD) Removing RESBP warranty Correcting bracelet	All	All

NOTE:

- Latest version of the WatchPAT™ 300 Operation Manual and zzzPAT Software Manual are available at:
  
  https://www.itamar-medical.com/support/manuals
- zzzPAT Software Manual is installed as part of the software installation.
- Latest Software is available at:
  
  https://www.itamar-medical.com/support/upgrades-installation/
- Printed Manual/s will be provided within 7 calendar days if requested at no additional cost.

Table of Contents

List of Figures

List of Tables

1 GENERAL INFORMATION

This manual is part of the WatchPAT™ 300 system.

1.1 Intended Use / Indications for Use

The WatchPAT™ 300 (WP300) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP300 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 WP300 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 WP300's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP300'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™ 300 should be used only in accordance with physician's instructions. For precautions see Section 1.3.
2. Only qualified medical personnel may authorize the use of the WatchPAT™ 300 .
3. Qualified medical personnel must instruct the patients (and accompanying individual if needed) how to attach and use the WatchPAT™ 300 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™ 300 system in whole, or in part, may not be modified in any way.
7. The WatchPAT™ 300 is used as an aid for diagnostic purposes only, and should not be used for monitoring.
8. Only suitably trained and qualified personnel should be authorized to prepare the WatchPAT™ 300 equipment prior to use.
9. The WatchPAT™ 300 Operation Manual should be carefully studied by the authorized operators, and kept where it is easily accessible. Periodic review of the Manual is recommended.
10. Itamar Medical Ltd. makes no representation whatsoever, that the act of reading the Manual renders the reader qualified to operate, test or calibrate the system.

11. The tracings and calculations provided by the WatchPAT™ 300 system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
12. In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this Manual, the operator should refer to the Troubleshooting section. If necessary or in any case of serious incident or harm, contact the Itamar™ Medical Help Desk and report the incident to the competent authority of your country.
13. The "Step-by-Step Reference Guide" for the patient should be carefully followed when attaching the unit to the patient.
14. The WatchPAT™ 300 is not indicated for patient with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT™ 300 device.
15. The WatchPAT™ 300 is not indicated for children less than 12 years old.
16. The AHIc was not clinically assessed for patients who are in high altitudes or for patients using opioids.
17. 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™ 300'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.*
18. The WatchPAT™ 300 is not intended to be used as a diagnostic device for any cardiac arrhythmia and is not intended to replace traditional methods of diagnosis of cardiac arrhythmia. The WatchPAT™ 300 arrhythmia function is to be used for informational use only as additional information to the sleep indices.
    The arrhythmia output flags patients suspected of having arrhythmias thereby aiding the physician to decide if further arrhythmia investigation is needed.
    a. 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.
    b. The absence of arrhythmia flagging in the sleep report does not rule out any arrhythmia
    c. In some patients, in particular those with a high density of premature beats or AFib, the device may under-detect arrhythmic events (both premature beats and AFib) and/or misclassify between premature beats and AFib.

1.3 Precautions

The WatchPAT™ 300 should not be used in the following cases:

1. Use of one of the following medications: alpha blockers, short acting nitrates (less than 3 hours before the study).
2. Permanent pacemaker: atrial pacing or VVI without sinus rhythm.
3. The WatchPAT™ 300 is not indicated for children who weigh less than 65 lbs / 30 kg.

1.4 Additional Precautions specific to pediatric use

The WatchPAT™ 300 is indicated for use in patients 12 years and above.
The following Precautions and Notes are referring to pediatric aged 12-17 years.
Precautions:

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

Notes:

1. PAT Respiratory Disturbance Index (PRDI) is indicated for patients 17 years of age or greater
2. The snoring and body position safety and effectiveness was not validated on pediatric patients
3. 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™ 300 device (for further details see section 7 and section 8)

1.5 Data Generated by the WatchPAT™ 300

The WatchPAT™ 300 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™ 300 respiratory indices and sleep stages are estimates of conventional values and stages identification that are produced by polysomnography (“PSG”). The WatchPAT™ 300 also generates optional acoustic decibel detector used for snoring level and body position discrete states from an external integrated snoring and body position (SBP/RESBP) sensor. The WatchPAT™ 300 also includes detection of cardiac arrhythmia (Atrial Fibrillation and Premature Beats) as additional information to its sleep indices.
PRDI and PAHIc are indicated for patients 17 years of age or greater.

	**Note** The arrhythmia feature is available only in approved territories.

	**Note** The arrhythmia output flags patients suspected of having arrhythmias thereby aiding the physician to decide if further arrhythmia investigation is needed. The results, together with patient's anamnesis should be considered when deciding on further investigation.

1.6 Life Time

The lifetime of the WP300 should be differentiated by its main components life time. The electronic components do not have expiration date and therefore the only components that can deteriorate are the mechanical parts.
Expected usage conditions for the device (Life time determining):

- Environment:
  - Ambient temperature: 0°C÷40°C
  - Room condition
- Duty cycle:
  - 10 hours working duration
  - 200 days per year

Based on the above, the estimated Life Time definition for the device is 5 years.

1.7 Quality Assurance System: EN ISO 13485

The Itamar Medical WatchPAT™ 300 is compliant to the following standards.

	STANDARD	#
1.	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1
		ANSI/AAMI ES60601-1
		CAN/CSA – C22.2 No.60601-1
2.	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	IEC 60601-1-2

	STANDARD	#
3.	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
	Degrees of protection provided by enclosures (IP Code) – IP22	IEC 60529
4.	Medical Device Software – Software Life Cycle Processes	IEC 62304
5.	Medical devices — Part 1: Application of usability engineering to medical devices	IEC 62366-1
6.	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	IEC 60601-1-6
7.	Medical devices. Application of risk management to medical devices	EN ISO 14971
8.	Medical devices. Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements	ISO 15223-1
9.	Graphical symbols for electrical equipment in medical practice	PD IEC/TR 60878
10.	Graphical symbols - Safety colours and safety signs - Registered safety signs	ISO 7010
11.	Medical devices - Information to be supplied by the manufacturer	EN ISO 20417
12.	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	ISO 10993-1
13.	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61
14.	FDA Quality Systems Regulation (QSR)	21 CFR part 820
15.	Medical devices. Quality management systems. Requirements for regulatory purposes	EN ISO 13485
16.	Commission Regulation (EU) on electronic instructions for use of medical devices	EU 2021/2226
17.	General Data Protection Regulation (GDPR)	EU 2016/679
18.	Medical Device Regulation	MDR 2017/745

	STANDARD	#
19.	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	RoHS Directive 2015/862/EU (RoHS 3)
20.	Registration, Evaluation, Authorisation and Restriction of Chemicals Directive	REACH Directive (EC) 1907/2006
21.	Australian Regulatory Guidelines for Medical Devices	ARGMD
22.	CMDR - Canadian Medical Device Regulations	SOR/98-282
23.	Japanese Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics	MHLW MO 169

1.8 CE and TÜV RHEINLAND Compliance

The product complies with MDR 2017/745 (Medical Device Regulation) requirements and CE approved.

The product is marked with the CE logo.

The product is certified by TÜV RHEINLAND.

1.9 Conventions Used in this Manual

Note: Throughout this document, the references WatchPAT™, WatchPAT™ 300, and WP300 device are used to refer to the WatchPAT™ 300 device.
Note: Throughout this document, the reference Snore & Body Position sensor is referring to both SBP sensor and RESBP sensor unless specified otherwise.
Note: Central+ is a WatchPAT™ 300 module that enables identification of central apnea. Central+ functionality can be achieved when using the WatchPAT™ 300 with the RESBP sensor and compatible software.

	**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. **Les avertissements** sont utilises pour identifier les conditions ou les actions qui- si elles sont ignorées- peuvent porter atteinte à la sécurité des patients ou causer des dommages au système et résulter à une perte irréversible des données.

	**Cautions** are used to identify conditions or actions, which could cause interference with data acquisition and/or impair study results. **Les précautions** sont utilisées affin d'identifier les conditions ou les actions qui peuvent interférer avec le ramassage de données et provoquer des résultats équivoque.

	**Notes** are used to identify an explanation, or to provide additional information for purposes of clarification. **Les notes** sont utilisées pour identifier les explications et pour donner des informations supplémentaires dans le but de clarifier.

1.10 Warnings, Cautions and Notes

The WatchPAT™ 300 is powered with one off-the-shelf AAA battery.
The WatchPAT™ 300 is portable with continuous operation.
The WatchPAT™ 300 parts/components/etc. are defined as Applied Parts BF type, according to IEC 60601-1.
The WatchPAT™ 300 device may be used in a home or clinical setting. The device is not intended for use in an Oxygen Rich Environment (home use oxygen supplement is generally not considered an Oxygen Rich Environment) or with flammable anesthetics.
The WatchPAT™ 300 should only be transported in its original case.
There are no serviceable parts inside the WatchPAT™ 300 except for cables.
Environmental conditions during transportation & storage: See Specifications section.
Environmental conditions during operation: See Specifications section.
To avoid risk of battery leakage, the WatchPAT™ 300 device should not be stored from prolonged period with a battery inserted in the battery compartment.
Sleep professionals (other than patients) using the WatchPAT™ 300 should read the Operation Manual.

1.11 Safety Precautions

WARNINGS

Do not let the unit 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.

The WatchPAT™ 300 MUST be removed from the patient BEFORE connecting it to a PC!

AVERTISSEMENTS

Ne pas mouiller l'unité.

Éloigner le dispositif de toute source d'eau ou nourriture.

En cas d'incendie, utiliser uniquement des extincteurs homologués pour l'utilisation en cas d'un incendie dû à une source électrique.

Manier avec précaution. L'unité est fragile : éviter les mouvements soudains et chute.

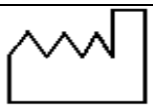
Ne pas tenter de brancher ou débrancher une des parties de l'unité.

Ne pas introduire un corps étranger a l'intérieur de l'unité.

Le système WatchPAT™ 300 **doit** être rechargé **uniquement** après avoir été détaché de la main du patient.

Il est impératif de détacher le système WatchPAT™ 300 de la main du patient **avant** de le relier à l'ordinateur.

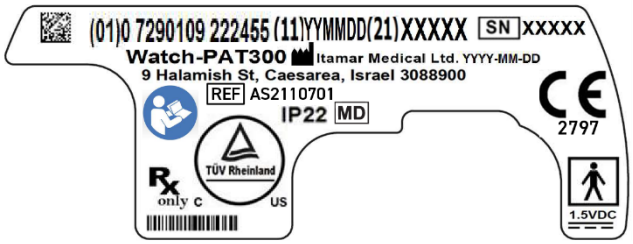
1.12 Symbols Used on the Product Labels

	Follow instructions for use
	Consult instructions for use or consult electronic instructions for use
	Type BF applied part
	The product is certified by TÜV RHEINLAND
	The product is marked with the CE logo 2797 for BSI
	Medical device
	Date of manufacture
	Battery Operating Voltage
	Single use, do not re-use
	Temperature limit
	Use-by date
	Medical device Manufacturer
	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
EC REP	Authorized representative in the European Community
Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	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.

1.13 WatchPAT™ 300 Device Labels

The following label is located on the back side of the device



1.14 FDA information

The WatchPAT™ 300 is cleared by the FDA under K180775, trade name Watch-PAT300 (WP300).

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™ 300 is worn on the wrist and utilizes 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 same probe measures RED and IR channels used for the measurement of SpO2 signal. The PAT® and SpO2 signals are recorded continuously and stored on an embedded flash memory, together with data from a built-in actigraph (monitor for human rest/activity cycles, embedded in the WatchPAT™ 300). Snoring and Body Position signals are generated from the SBP/RESBP integrated sensor (optional). The Respiratory Effort Snoring and Body Position sensor records the subject's chest movement signal in addition to the snoring and body position signals that are included with the SBP sensor.
RESBP is also available in a configuration that supports connection of Thermal Airflow sensor, for more information see Appendix K (this configuration is applicable in the EU only).
Following the sleep study, the recordings are automatically downloaded and analyzed in an offline procedure using the proprietary zzzPAT software.

The zzzPAT algorithms use the WatchPAT™ 300 channels for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). 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 also includes detection of cardiac arrhythmia as additional information to its sleep indices. The zzzPAT uses WatchPAT™ 300 's snoring and body position channels to generate snoring level and body position discrete states. The use of SBP/RESBP is optional and according to physician preference.

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

2.1 System Description

The WatchPAT™ 300 system is comprised of the following items:

- WatchPAT™ 300 device that includes:
  - Embedded actigraph
  - Embedded CPU and electrical circuit card
  - Embedded flash memory
  - AAA Battery
  - OLED display
- Unified PAT and Pulse Oximeter Probe (uPAT probe) (includes oximetry)
- uPAT probe connection cable
- Wrist Strap
- Snore and Body Position sensor (SBP/RESBP) – optional
- Cable for Tamper-Proof Bracelet and Tamper-Proof Bracelet – optional
- USB cable
- Step-by-Step Reference Guide (to be used in conjunction with Section 7)
- Quick Reference Cards (to be used in conjunction with Section 8)
- Carrying case

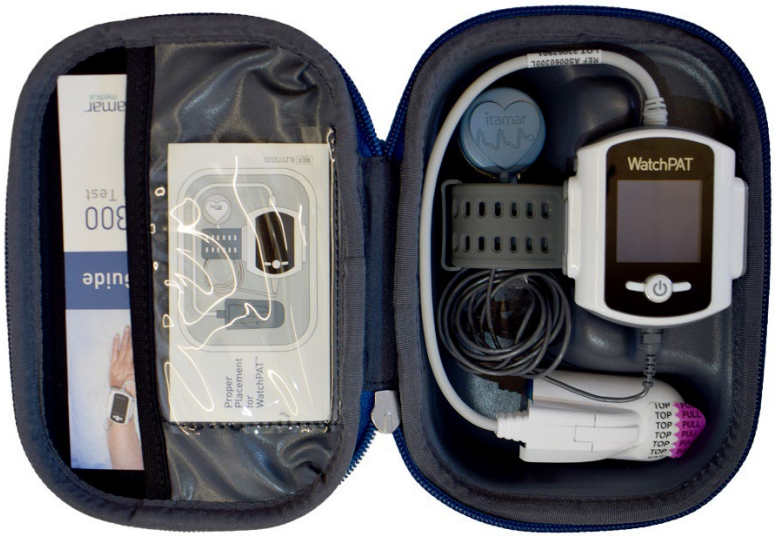


Figure 1 – Packed Device

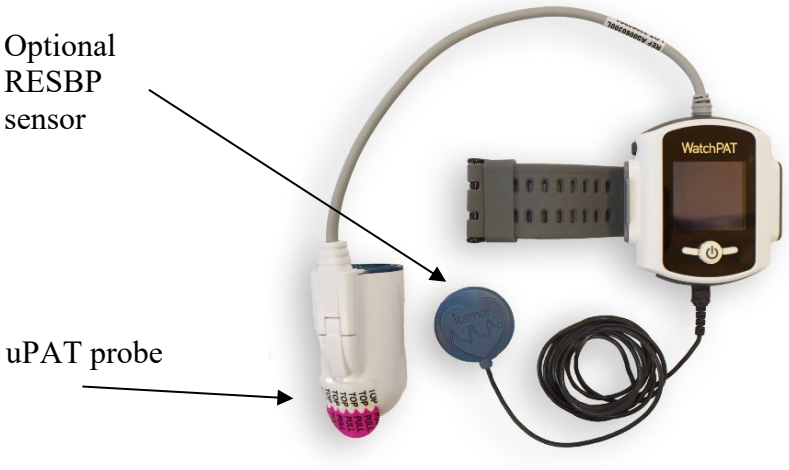


Figure 2 – WatchPAT™ 300 Device with Sensors

An additional item required for the operation of the system is the zzzPAT kit. zzzPAT is a proprietary PC software for initializing the study, retrieving, analyzing and displaying the data. For more information, refer to the zzzPAT Software Manual.

2.2 User Interaction with the WatchPAT™ 300 Device Keys

The WatchPAT™ 300 has the following keys (see Figure 3):

- Central On/Enter key to power on the WatchPAT™ 300
- Horizontal buttons (left and right) that may be used by the Operator for entering the diagnostic mode and navigating through the diagnostic menu. These buttons are hidden from the patient.

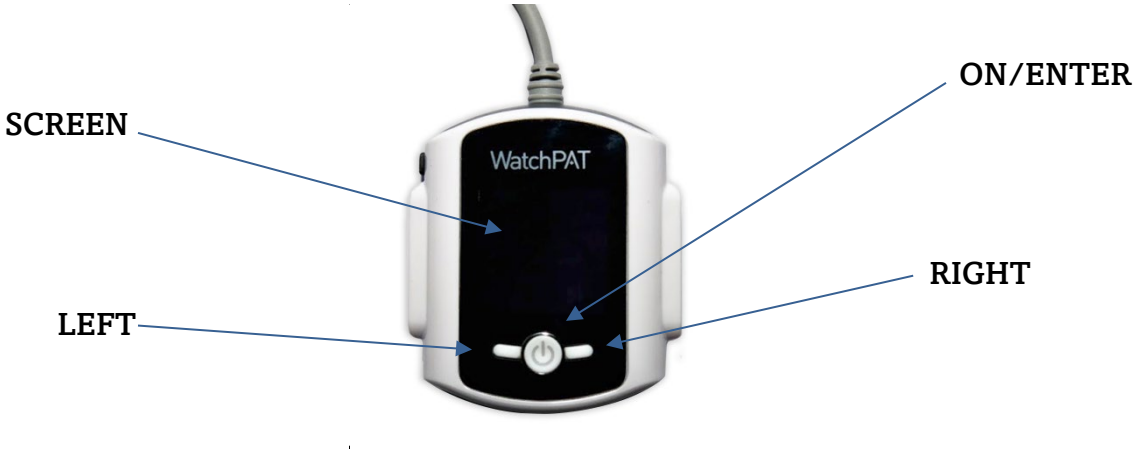


Figure 3 – The Buttons and Display

Display

The display is used for reading status and error messages. The display is divided to three sections: Title, Info and Status.

- Title (first line): Current operational mode and time
  - PATIENT mode while recording night study
  - DIAGNOSTIC mode while testing device
  - PC HOST while connecting to PC
- Info (2nd-7th line): Specific information depending on operational mode
- Status (last line): Message indicating device status depending on operational mode

Service Ports and Peripherals

The WatchPAT™ 300 device has 4 ports that are used for sensor connections, a battery compartment with a cover for battery replacement and a cable connector compartment with a cover for uPAT cable servicing. (see Figure 4).

- The bracelet port is used for connecting the tamper-proof bracelet which is covered by a lid.
- Internal uPAT probe port is used for connecting the uPAT probe. The port's compartment can be accessed through a lid in order to replace the cable.
- A port for connecting the optional Snore & Body Position sensor.
- The USB port is used for connecting to the PC to initialize the device and download the recording.
- Battery compartment, covered by a lid.

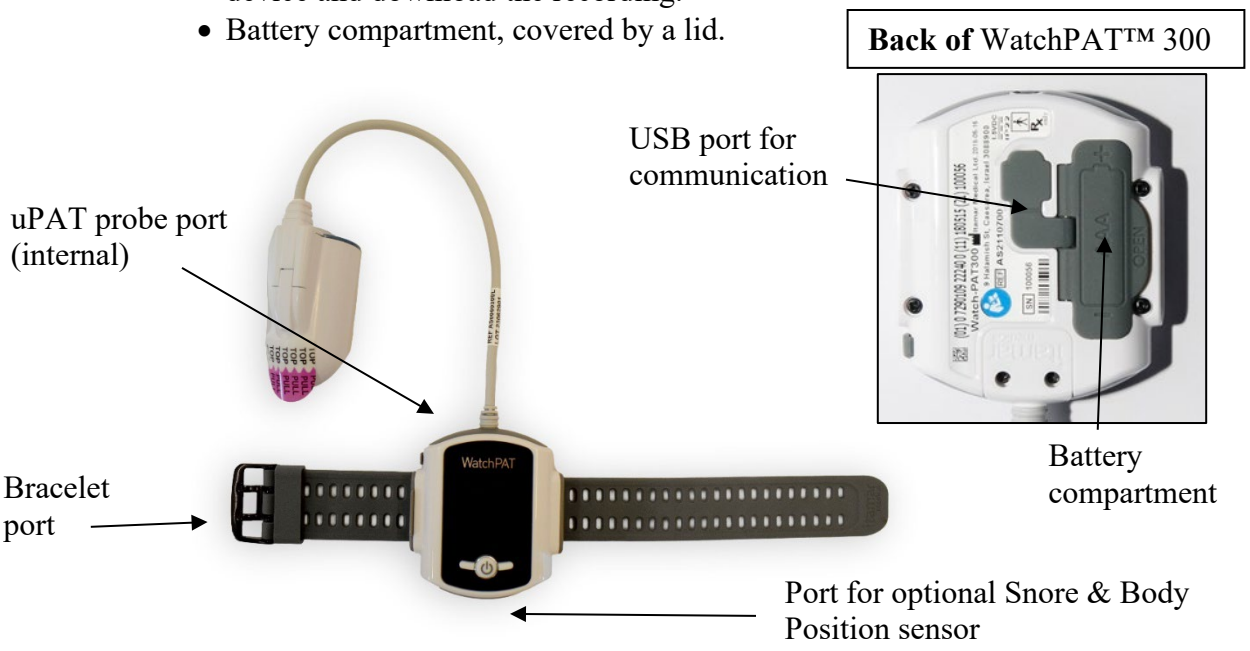


Figure 4 – Service Ports and Peripherals

2.3 WatchPAT™ 300 Device Function

The WatchPAT™ 300 records the following channels:

- PAT® Signal
- Oxygen saturation
- Actigraphy (movement)
- Acoustic decibel detector for Snoring evaluation (optional)
- Body Position (optional)
- Chest movement signal (optional)
- Available in EU only:

  Nasal Air Flow (optional), for more information see Appendix K

The overnight sleep study data is stored on an embedded flash memory in the WatchPAT™ 300 device. After the study is recorded, the data is downloaded from the WatchPAT™ 300 device through the USB cable using the zzzPAT software. 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 comprehensive detailed reports of the study. The whole night data can be viewed on the PC screen and the automatically detected events can be revised manually.

An optional tamper-proof patient identification function is available using a custom bracelet whose presence during the night verifies that the identified patient is indeed the one sleeping with the device (see Tamper-Proof Testing with WatchPAT™ 300 Device section).

The patient normally sleeps only one night with the WatchPAT™ 300 device unless an optional multi-night option is selected which enables an up to 3 nights study with the same device (see Multi-night study section).

2.4 Built-In Self-Diagnostic Procedures

2.4.1 Operator Tests

The WatchPAT™ 300 contains a comprehensive built-in self-diagnostic procedure. This procedure is available to the operator. The procedure can be accessed if the right and left buttons (see Figure 3) are pressed simultaneously after the device is powered ON (during the first 30 seconds only after the device is powered ON). The procedure performs the following test:

- Device Test – tests the WatchPAT™ 300 for errors before performing a night study (make sure all sensors are connected before initiating this test)

	**Note** In all times, the current time is shown in the upper right hand corner of the display.

To run the self-diagnostic procedure:

- Press the ENTER button (round center key) for 2 seconds till the power up screen appears on the screen
- Immediately press the **RIGHT+LEFT** buttons only (see Figure 3) simultaneously for 1 second

The following screen will be displayed:

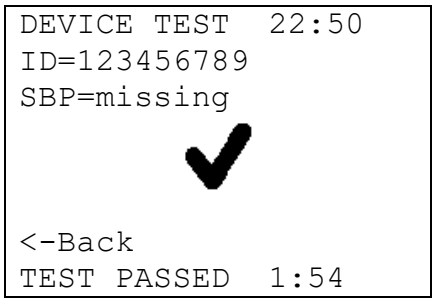
```
DIAGNOSTIC   22:40
4.0.0000 20-May-18
ID=123456789
  * device xxxxxx
    set language
    set battery
    end testing
Select test ->
```

- First line displays title and current time
- Second line displays current embedded S/W version and current date
- Third line displays patient ID
- Fourth line displays option for running device test (serial number of device)
- Fifth line for setting the language
- Sixth line for setting the battery type
- Seventh line for exiting the testing mode and turning device off. If no test is selected within 3 minutes the WatchPAT™ 300 device will automatically shut down
- The right and left buttons will navigate between the lines.
- An asterisk will indicate current selection. When moving the keys, the asterisk will move to indicate the current selection. Press the central Enter key to make the desired selection.

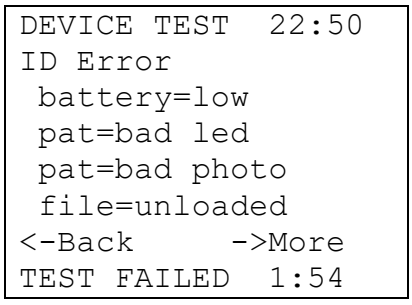
It is recommended that you perform the Device test every time you prepare the WatchPAT™ 300 for a night study.

2.4.2 Device Test

At the completion of the device test, a **TEST PASSED** indicates that the device is ready for the night study.



At the completion of the device test, a **TEST FAILED** indicates a problem that should be taken care of before the device is released for a night study.



The following are the possible error, warning or information messages:

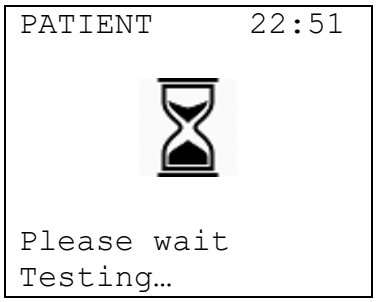
- File error: not loaded, missing – the study file was not loaded or somehow the file was deleted
- File error: used x/3 x=1..3 – only when multi-night option is selected
- Battery error: low – needs replacement of battery
- Probe error: used, missing, bad – connect an unused probe
- Hardware (H/W) error: error code - contact customer support
- SBP/RESBP (Snore and Body Position sensor) warning: sensor missing – does not affect PASSED status
- RTC (Real Time Clock) error: faulty – indicates problem with internal clock and need to set the clock (through the software)
- Bracelet error: missing – the study file was chosen with the bracelet option but the bracelet is not connected during the device test
- Information messages:
    - multi-night=on - when a multi night study is required
    - bracelet=on - when a study with tamper-proof patient identification bracelet is required

`More->` indicates that there are more error/warning messages and will be displayed if the Right (`->`) button is pressed.

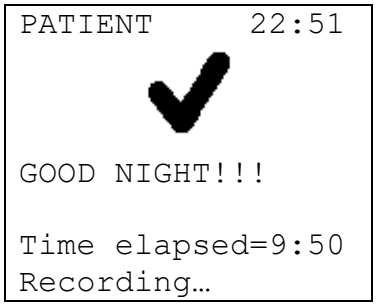
`<-Back` will move to the previous screen if the Left (`<-`) button is pressed.

2.4.3 Patient Test

When the patient (and accompanying individual if needed) turns on the WatchPAT™ 300 device by pushing the On/Enter key (round center button) for about 2 seconds a self-diagnostic test is automatically performed and the following screen is displayed:

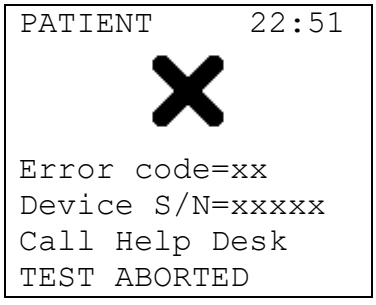


If the WatchPAT™ 300 device passes this self-diagnostic test, the following screen will be displayed:



Note During recording the display turns off to conserve battery life. Pressing the On/Enter key (center button) during recording will turn on the display for a few seconds.

If the WatchPAT™ 300 device fails this self-diagnostic test, the following screen will be displayed:



- The error message will be displayed for 1 minute and then the WatchPAT™ 300 device will shut off.
- If this is a study with the tamper-proof bracelet and the wrong bracelet is connected the "wrong bracelet" error message appears.
- If this is study with the tamper-proof bracelet and the bracelet is not connected the "connect bracelet" error message appears in order to remind the patient to connect the bracelet.

The following are the possible error/warning messages:

xxx1 - battery low

xx2x – uPAT probe error

xx4x – File error

xx8x - uPAT probe error (bad led)

x1xx - uPAT probe error (bad photo)

x4xx – SBP/RESBP missing warning

xxx8 – Actigraph error

x2xx – RTC error

x8xx – Bracelet error

1xxx – file not init

Note The "x" stands for 0-F value (Hexadecimal code)

Error codes are additive, i.e. both uPAT probe and File errors will produce error code xx6x.

3 PREPARATION FOR SLEEP STUDY

3.1 Inserting the Battery

To insert the battery to the WatchPAT™ 300 device:

1. Remove the WatchPAT™ 300 device out of the wrist strap by unsnapping the left side of the WatchPAT™ 300 strap (the one with higher edge).
2. Open the battery compartment on the back of the device (see Figure 5) and remove the battery from the device (if there is one).
3. Insert a new disposable (or fully charged rechargeable) AAA battery in the compartment. The direction of '+' and '–'is illustrated on the battery lid and inside the compartment.
4. Close the battery compartment.
5. Reseat the WatchPAT™ 300 device on the wrist strap by inserting gently first the right side of the device into the strap and then the other side until a click is heard.

3.1.1 Battery information

The WatchPAT™ 300 is powered by one off-the-shelf AAA battery. The battery can be alkaline or rechargeable NiMH. Use a new or fully charged battery for each study.

Notes/ Conditions for Battery Use:

1. 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. Rechargeable battery (NiMH, minimum 700 mAh) should be charged before each recording. Use only UL 1642 or UL2054 and IEC 62133 compatible battery.
3. Alkaline battery should be replaced after each recording.
4. The battery will be checked during device test. The WatchPAT™ 300 will notify you in case the battery power is low.
5. If battery was improperly inserted or depleted the WatchPAT™ 300 will not turn on.
6. When recording multiple nights the patient might be required to change the battery after each night.
7. To avoid risk of leakage, battery should not be stored in the WatchPAT™ 300 for a prolonged period of time.

Battery	One OTS 1.5V Alkaline AAA battery **OR** One OTS rechargeable AAA 1.2V NiMH battery
Capacity	> 700 mAh
Cell Type	Alkaline **OR** Nickel-metal hydride battery rechargeable (NiMH)

Figure 5 – Battery Compartment

3.2 Preparing the Snore and Body Position Sensor

Attach the small round double sided adhesive sticker to the Snore and Body Position sensor on the back side (front side has an image), by peeling off the cover on one side of the sticker.
For more details see Appendix A: WatchPAT™ Integrated snoring + Body Positioning Sensor Operating Instructions (SBP/RESBP)

3.3 Preparing the Wrist Strap

The wrist strap requires no special preparation other than ensuring its cleanliness. You may clean it if needed. See section 6.1 for detailed cleaning instructions.

3.4 Mounting the WatchPAT™ 300 on the Wrist Strap

To mount the WatchPAT™ 300 device on the wrist strap:

Gently insert the WatchPAT™ 300 on the wrist strap by inserting first the right side of the device into the strap and then the other side until a click is heard indicating that it is properly seated.

3.5 Replacing the uPAT Probe

	**Warning** The uPAT probe connector is very sensitive and therefore should never 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.

Remove a used probe by pressing the small tab (clip) marked by the arrow in Figure 6, and then, holding the connector's slider, gently slide it away from the probe – do not pull the slider off by pulling the cord, as it may damage the wiring. Properly dispose of used probes.

Figure 6 – Disconnecting the Probe

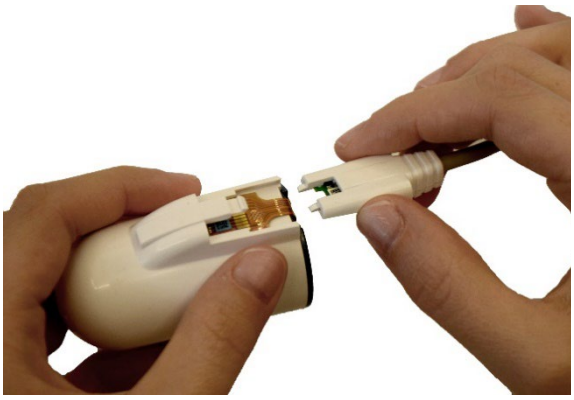


Figure 7 – Probe Disconnected

Connect a new probe by inserting the blue slider to the probe until the blue tab of the probe clicks into its place.

	**Note** Take care when inserting the blue slider to insure proper seating in the probe.

Figure 8 – WatchPAT™ 300 Fully Prepared

3.6 Preparing the WatchPAT™ 300 Device for a New Study

Refer to the zzzPAT Software Manual for preparation of the WatchPAT™ 300 for a new study.

3.7 Testing the WatchPAT™ 300 Device

Run the built-in self-diagnostic facility as described in Section 2.4 above.
The WatchPAT™ 300 device is now ready for performance of a sleep study by the patient (Figure 8).

3.8 WatchPAT™ 300 Self-diagnostic Test Results and Trouble-shooting

Should any of the self-diagnostic tests fail or report error messages refer to the trouble-shooting guide in Section 9.

3.9 Packing the Carrying Case

The following items must be placed inside the carrying case, in their respective compartments (see Figure 1 – Packed Device):

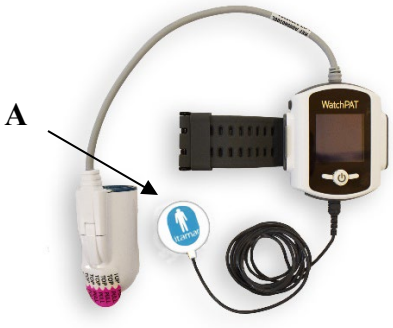
- The WatchPAT™ 300 device mounted in the Wrist strap with the uPAT probe attached.
- Step-by-Step Reference Guide to the WatchPAT™ 300 device.
- Body Position and Snore sensor (optional)
- Cable for bracelet (optional for patient identification)
- For multi-night only: extra uPAT probes and batteries.

	**Note** Demonstrating the use of the WatchPAT™ 300 device to the patient (and accompanying individual if needed) is important for obtaining reliable recordings and improving patient confidence.

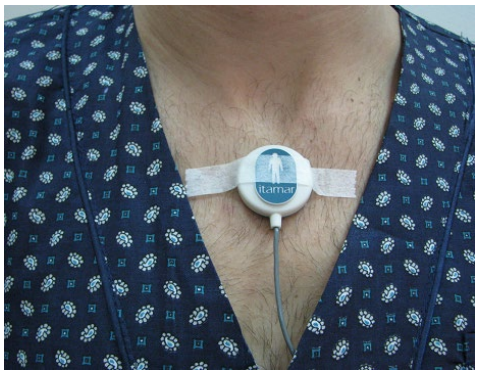
4 OPTIONAL FUNCTIONS

4.1 Using the integrated Snore & Body Position Sensor

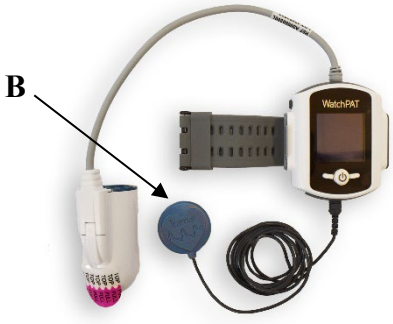
The integrated sensor consists internally of two sensors: a snore sensor and a body position sensor.



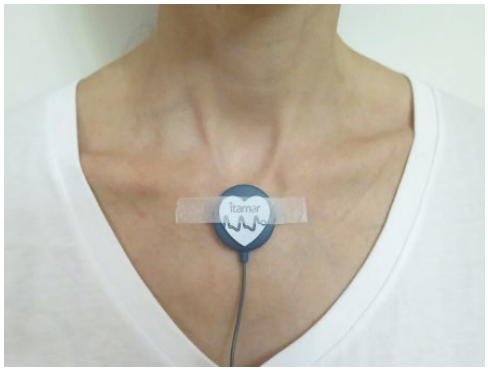
A - Integrated SBP sensor



SBP Sensor Attachment



B - Integrated RESBP sensor



RESBP Sensor Attachment

The integrated sensor is powered by the WatchPAT™ 300 device and does not require a battery. It is automatically activated by the WatchPAT™ 300 device when plugged into the Snore & Body position port.

The **snore sensor** is an acoustic decibel detector. It uses a very sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a small analog voltage that provides a clear, reliable indication of the presence of these sounds.

The **body position** sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).

For RESBP only: The **chest movement signal** uses the same 3-axis accelerometer to provide raw chest movement signal data for measuring subject's breathing during the night.

See Appendix A: WatchPAT™ Integrated snoring + Body Positioning Sensor Operating Instructions (SBP/RESBP).

RESBP is also available in a configuration that supports connection of Thermal Airflow sensor, for more information see Appendix K.

4.2 Tamper-Proof Testing with WatchPAT™ 300 Device

The WatchPAT™ 300 device Tamper-Proof bracelet is an add-on accessory used to authenticate the patient doing a sleep study and assure the study is recorded from the right person.

The bracelet is a single use small plastic band designed to be worn around the wrist of the hand. It contains an electronic circuit that signals to the WatchPAT™ 300 device the integrity of the bracelet and a unique identification. During the night the bracelet is connected to the WatchPAT™ 300 device using a small cable (see Figure 9).

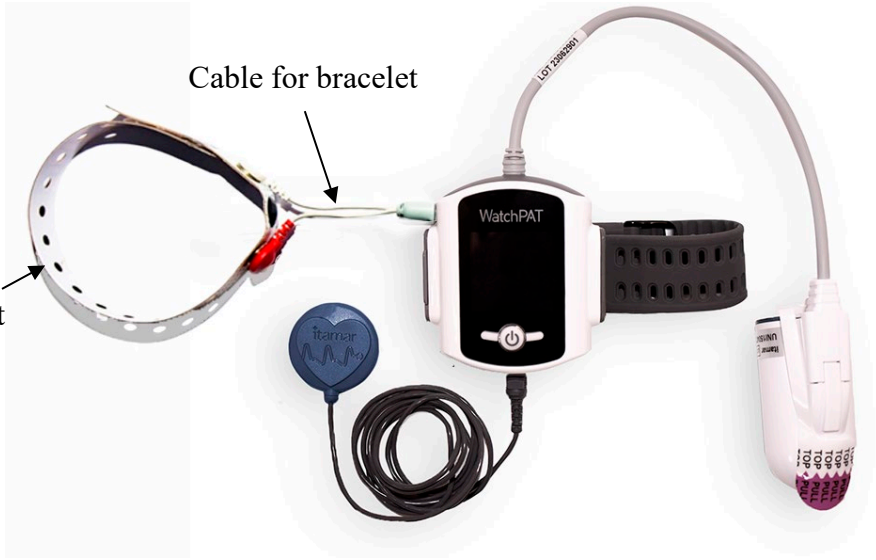


Figure 9 – WatchPAT™ Device with Tamper-Proof Bracelet

Before the device is given to the patient for home sleep study, the technician identifies the patient and secures the bracelet to the patient's wrist by a tamper-proof connector that ensures the bracelet will not be removed without cutting the Bracelet.

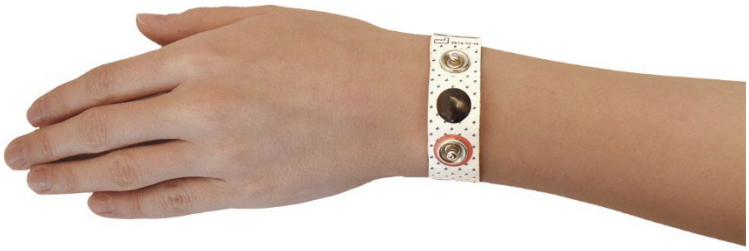


Figure 10 – Bracelet on Patient's Hand

When preparing the WatchPAT™ 300 device for a sleep study, the technician pairs the Tamper-Proof Bracelet and the device and registers the bracelet's unique ID in the WatchPAT™ 300 device (see Appendix B: Tamper-proof testing with).

The patient can wear the Bracelet for several days, continuing normal day-to-day activity until he is ready to record his sleep study. Before starting the recording, the patient will need to connect the Bracelet, via the bracelet's cable 2 connectors, to the WatchPAT™ 300 device. The device will not start without connection to the paired Bracelet.

Figure 11 – WatchPAT™ 300 Device with Cable for Bracelet

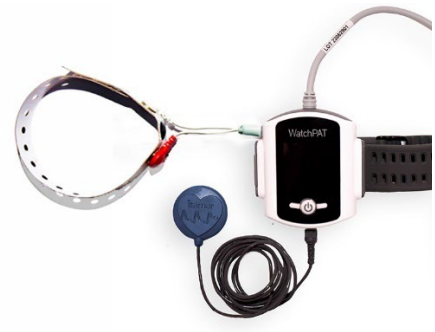


Figure 12 – WatchPAT™ 300 Device with Bracelet

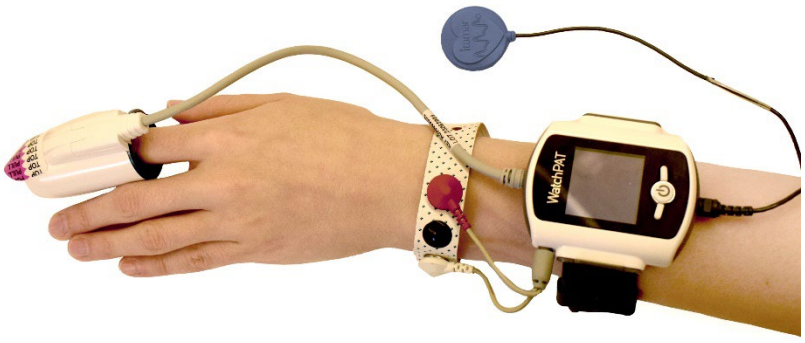


Figure 13 – Bracelet and WatchPAT™ 300 Device on a Patient's Hand

During the recording the device will periodically check the Bracelet connectivity. If the connection to the Bracelet will be lost for the time exceeding a predefined limit a warning will appear on the sleep report that the patient removed the bracelet and the time.
After the recording is completed the patient can cut the Bracelet and return it with the device for study analysis.

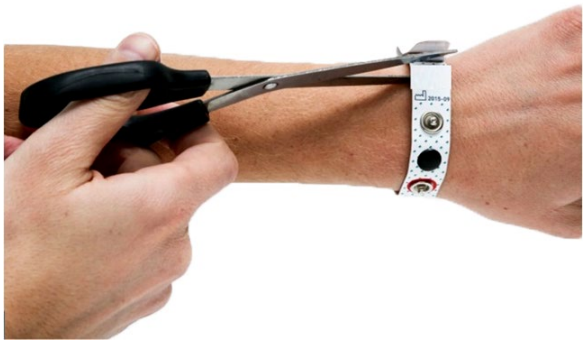


Figure 14 – Cut the Bracelet

4.3 Multi-night study

A patient study may be defined as multi-night study and the patient can sleep up to 3 nights with the same WatchPAT™ 300 device. The multi-night option may be selected during New Study function (see zzzPAT Software Manual).

If a 2 or 3 night multi-night option is selected the patient must replace the uPAT probe and replace the battery between nights. Extra uPAT probes and batteries must be added to the WatchPAT™ 300 device case.

In case of multi-night study all of the patient studies will be loaded automatically to the zzzPAT during the upload (see zzzPAT Software Manual).

Figure 15 – Case for 2 Night Multi-night Study

5 DATA DOWNLOAD AND ANALYSIS

Following the sleep study the WatchPAT™ 300 device is returned to the referring sleep clinic for data downloading and analysis by the zzzPAT software.

To download and analyze the study data:

1. Connect the USB port of the WatchPAT™ 300 device to the computer (see Figure 4). The WatchPAT™ 300 device will switch off.
2. Activate the zzzPAT software to download and analyze the study data.

See the zzzPAT Software Manual for detailed instructions.

6 MAINTENANCE

The WatchPAT™ 300 device has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum safety of operation, the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this Manual.

In order to prevent unnecessary failures while patient is using the device, we recommend performing the routine maintenance recommendations as well as the preventive maintenance recommendations as described in this section.

Routine maintenance recommendations

a) Cleaning the device, wrist strap and SBP/RESBP sensor.
b) Device should be inspected for possible defects, in the device, cables and sensors. The product must be serviced on any case of damage.
c) PAT cable's electrical connectors should be visually inspected while replacing a probe. The product should be serviced in case any damage to the connector is found.
d) The following items should be visually inspected and replaced if found damaged: strap, carrying case and all accessories.
e) Complete technician test must be done and passed with no errors prior to handing the product to a patient.
f) The product should be stored in its carrying case while not in use.

Preventive maintenance recommendations

a) Battery – replace battery before each sleep study. Remove battery from the WatchPAT™ 300 device if the device is not used for prolonged time.
b) PAT Cable – replace the PAT cable after 200 sleep studies, after 1 year or when it is found broken on any of its components.
c) SBP/RESBP Sensor – replace if its connector is broken, if the cable near the connector is peeling off or if it is found broken on any of its components.

See sections 6.1,6.2, 6.3 and 6.4 bellow for detailed instruction on Cleaning and replacing the uPAT cable and the battery respectively.

Following is a summary table with routine and preventive maintenance recommendations:

Routine maintenance recommendations:

	Scenario	
Routine maintenance action	Back from sleep study	Before handing to patient
Cleaning	X	
Replace battery	X	X
Check cable connections	X	
Check carrying case	X	X
Check strap	X	X
Perform technician test		X

Preventive maintenance recommendations:

	Scenario	
Routine maintenance action	Lesser of: 200 studies, 1 year, error message in device test	When a defect is found or upon error message
Replace PAT Cable	X	X
Replace SBP / RESBP Sensor		X
Replace Strap		X
Replace Carrying Case		X

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

6.1 Cleaning

The various components of the WatchPAT™ 300 device have different cleaning requirements:

- The WatchPAT™ 300 device
- The wrist strap
- The Snore & Body Position sensor (SBP/RESBP)

6.1.1 Cleaning the WatchPAT™ 300 Device

In order to clean the WatchPAT™ 300 device and Carrying Case proceed as follows:

- Wipe parts with a clean, lint-free cloth lightly moistened with 70% ethyl alcohol or isopropyl alcohol (IPA).

Warning Clean the WatchPAT™ 300 device only with the uPAT probe attached.

6.1.2 Cleaning the Wrist Strap

You may clean the wrist strap with lint free cloth lightly moistened with 70% ethyl alcohol or isopropyl alcohol (IPA).

In order to disinfect the wrist strap by immersing into disinfecting liquid follow the steps:

- Remove WatchPAT™ 300 device from wrist strap
- Immerse wrist strap in 70% ethyl alcohol or isopropyl alcohol (IPA)

6.1.3 The Snore & Body Position Sensor

Using 70% ethyl alcohol, thoroughly clean both sensor and cable.

6.1.4 Single Use Products

The single use products are not required to be cleaned and must be discarded and replaced before each study.

The single use products are:

- uPAT probe
- Tamper-Proof Bracelet
- SBP/RESBP adhesive sticker

Warning Re-use of single use products can cause cross contamination, potentially leading to infection and/or patient injury.

6.2 Handling

Handle with care:

- Use only the designated case for transportation
- Store at room temperature, and avoid direct sun light
- Do not expose the WatchPAT™ 300 device to extreme temperature or humidity conditions (such as storing in a car or bathroom)

	**Note** In the event the WatchPAT™ 300 package being damaged, and/or exposed to environmental conditions outside of those specified please contact Itamar Medical.

6.3 Replacing the uPAT Probe Cable

To replace the uPAT probe cable:

1. Open lid of the uPAT cable compartment by removing the 2 screws

Figure 16 – uPAT Probe Cable with Screw

2. Carefully disconnect the uPAT probe cable from the connector by pulling out the cable.
3. Connect a new uPAT probe cable by gently inserting the connector back into the WatchPAT™ 300 device until a click is heard. Make sure the plastic shoulders of the cable are inserted into the matching cavity on the device before you close the lid.
4. Make sure you secure back the screws on the plastic lid.

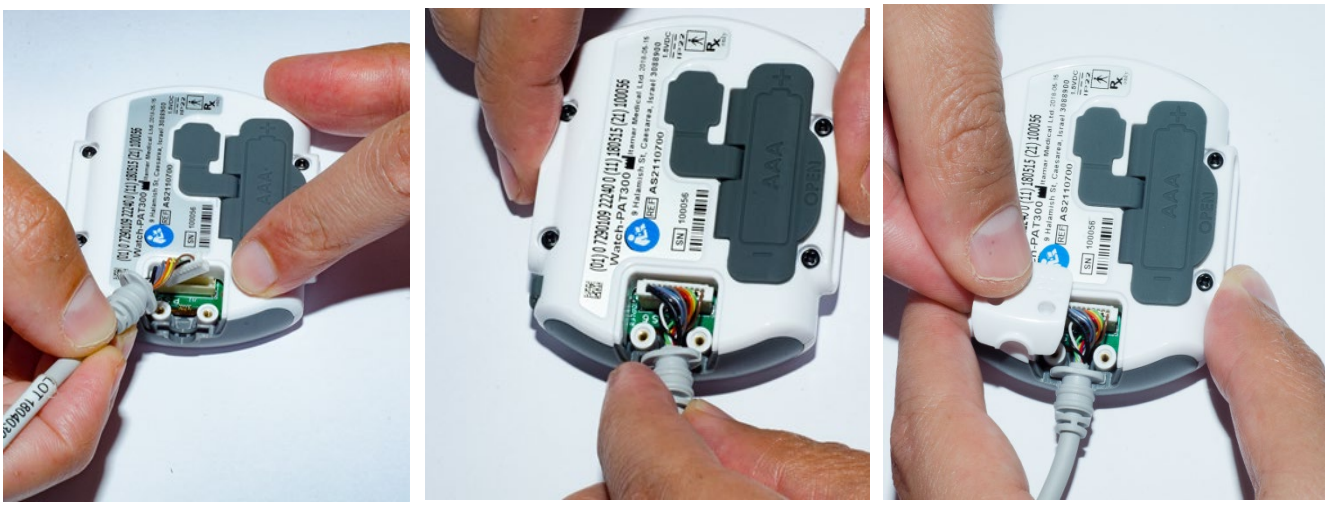


Figure 17 – Replacing the uPAT Probe

	**Warning** Use only the original screws that belong to the WatchPAT™ 300 device. Using different screws could harm the device.

6.4 Setting the Time and Date of the WatchPAT™ 300 device

The WatchPAT™ 300 device Time and Date can be set through the zzzPAT application. Refer to the zzzPAT Software Manual for preparation of the WatchPAT™ 300 device for a new study.

6.5 Storing the WatchPAT™ 300 device

- The WatchPAT™ 300 device should be stored in its carrying case at room temperature and low humidity.
- To avoid risk of leakage, battery should not be stored in the WatchPAT™ 300 for a prolonged period of time.

7 APPLYING THE WATCHPAT™ 300 DEVICE

	**Note** These instructions are designed to help the patient use the WatchPAT™ 300 **after** seeing a demonstration by trained personnel of how to mount the probes on his/her fingers and correctly operate the WatchPAT™ 300 device.

	**Note** In the case of pediatric patient, special attention on training the patient and/or his/her accompanying individual on use and placement of the device prior to initiating a sleep study with the WatchPAT™ 300 device.

The following detailed instructions are written as if the reader is the patient using the WatchPAT™ 300 device.

7.1 Preparing for Use of the WatchPAT™ 300 Device

Before using the WatchPAT™ 300, review the following notes:

- Remove tight clothing, rings, watches and jewelry from your non-dominant hand and wrist and from your neck and chest.
- We recommend that the uPAT probe be attached to the index finger of your non-dominant hand (Figure 18). The following instructions relate specifically to this finger. Patients with large fingers may use their small finger (pinky) for the uPAT Probe.
- Ensure that fingernail of finger that will be monitored are well trimmed, (less than 1mm from nail bed) with no jagged edges. Clip and file nail, if necessary.
- Remove artificial fingernail or dark nail polish from the monitored finger.
- If you are using the SBP/RESBP sensor, trim chest hair if needed to ensure the sensor attached directly to your skin.
- You may need some assistance putting on the WatchPAT™ 300 device. If needed have someone present to assist you.
- Make sure the room you are sleeping in is as quiet as possible during the night, turn off any possible noise sources. When using the Snore & Body Position sensor it is advised to sleep alone in the room.
- Apply the device and turn it on only when you are ready to sleep.

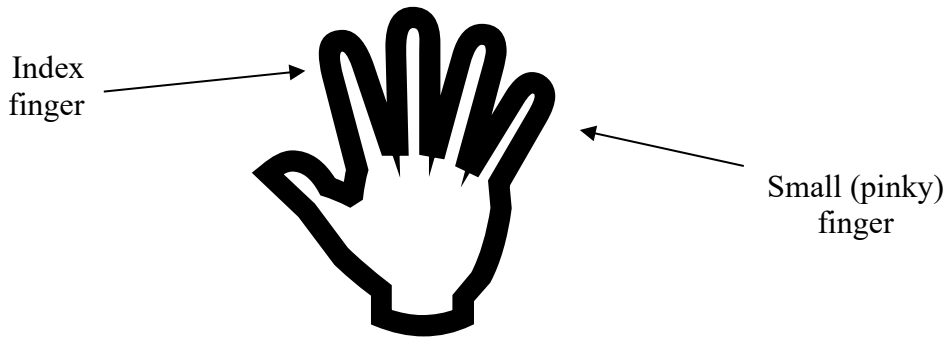


Figure 18 – Finger Designation

7.2 Applying the WatchPAT™ 300 Device

To apply the WatchPAT™ 300 device to your wrist:

1. Open the carrying case and take out the wrist strap with the WatchPAT™ 300 device mounted. All parts should already be connected, as illustrated in Figure 8.
2. Mount the device on the wrist strap according to the orientation depicted on the bracket (display and buttons).

Figure 19 – WatchPAT™ 300 Wrist Strap

3. Ensure that the WatchPAT™ 300 device is firmly seated in the wrist strap. If not, gently seat the WatchPAT™ 300 device in the strap by inserting first the right side and then pressing on the left side of the device as illustrated in Figure 20 (You will hear a click when the device is properly seated in the strap).

Figure 20 – Seating device on wrist strap

4. Place the wrist strap with the WatchPAT™ 300 device on the non-dominant arm and close it snugly but not tightly. Ensure that the end connected to the finger probe towards the fingers. You may find it convenient to place the wrist strap with the WatchPAT™ 300 device face down on the table and then place the back of the wrist over the wrist strap in order to fasten the straps (Figure 21).

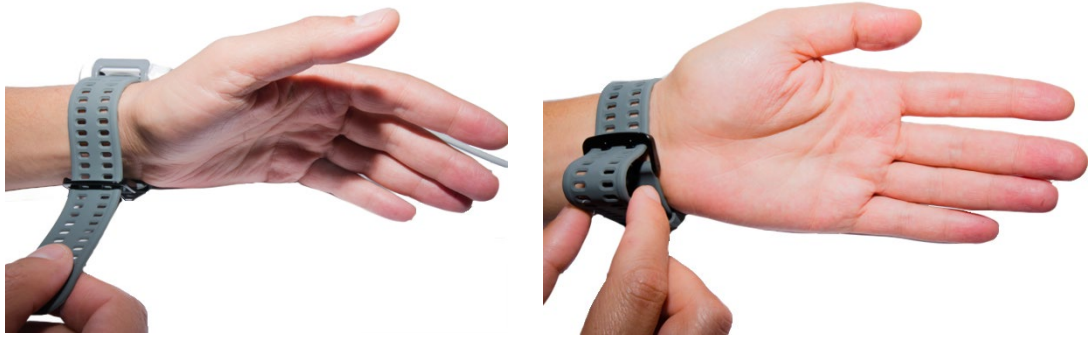


Figure 21 - Putting On the Wrist Strap

5. At this point the uPAT probe is hanging loose.

7.3 Attaching the uPAT Probe

Proper probe placement is critical for good performance.

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

To attach the uPAT probe:

1. Insert your index finger (or other if so instructed) gently into the probe until you feel the end (see Figure 22 –).
2. Make sure that the sticker 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 (WatchPAT™ 300 case, table, leg, etc.) until the tab is completely removed from the probe (Figure 23). 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 uPAT probe is now attached (Figure 24).

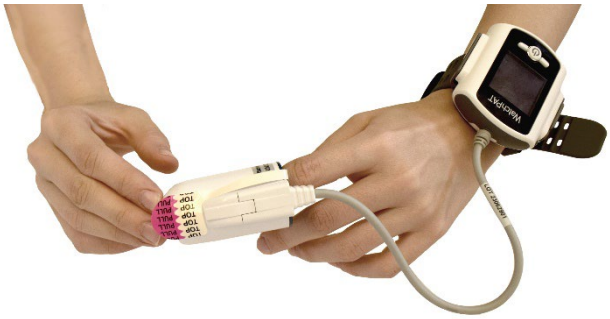


Figure 22 – Placing Finger In uPAT Probe

Figure 23 – Removing TOP Tab

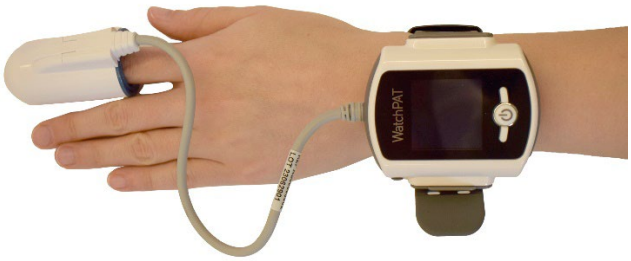


Figure 24 – Wearing the WatchPAT™ 300 – Ready for Sleep

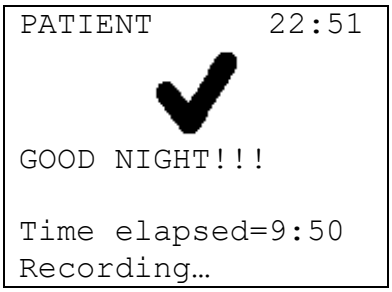
	Note DO NOT remove the uPAT probe before the night study is terminated. Once the probe is removed it cannot be re-attached.

	Note If the Snore & Body position sensor is included in the WatchPAT™ 300 device case see Appendix A: WatchPAT™ Integrated snoring + Body Positioning Sensor Operating Instructions (SBP/RESBP).

7.4 Switching On the WatchPAT™ 300 device

You are now ready to switch on the WatchPAT™ 300 device.

Just before you lie down to go to sleep, firmly press the ON/Enter round button (Figure 3) until the display lights up. After a short delay the screen will display "Good Night! Recording…"



	**Note** To conserve the battery the display will turn off after a few seconds. Pressing the button will restore the display for few seconds.

7.5 When You Wake Up

When you awake, remove the WatchPAT™ 300 device from your arm as follows:

1. Remove the finger probe and the Snoring and Body Position sensor.
2. Take off the wrist strap.
3. Insert all parts back into the carrying case.

	**Note** Pressing the round center button does not switch off the WatchPAT™ 300 device. There is no OFF button. Approximately ten hours after the WatchPAT™ 300 device is turned on, it will switch off. This is normal.

7.6 Important Notes

The WatchPAT™ 300 should not cause any discomfort or pain. Should you encounter unbearable discomfort, remove the device and call your healthcare professional and/or the Itamar™ Medical Help Desk at: 1-888-748-2627.

- Do not attempt to connect or disconnect any part of the unit.
- Do not try to introduce any foreign object into the unit.
- Do not try to connect the WatchPAT™ 300 to an electrical supply or any other device, machine or computer.
- 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.

8 PATIENT TRAINING – GUIDELINES

Instruct the patients (and accompanying individual if needed) how to attach and use the WatchPAT™ 300 prior to use.

	**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™ 300 device.

8.1 Walk Through the Process of Using the WatchPAT™ 300 device

- Product introduction – WatchPAT™ 300 device, wrist strap, uPAT probe
- WatchPAT™ 300 device and wrist strap attachment
- Probe and sensor attachment
- Switch on
- Ending the study

8.2 Product Introduction

- Open the Demo-case and introduce the 'Quick guide step-by-step' instruction manual.
- Introduce each component by its name and identify it as in the figures in the manual.

8.3 Applying the WatchPAT™ 300 device

Use the Demo Kit.

- Demonstrate how to apply the WatchPAT™ 300 device on your wrist while following the 'step by step' guidelines and referring to the relevant figures.
- Demonstrate the following:

1. **Hand Preparation**
   - Remove rings, watches and jewelry from hand
   - Remove fingernail polish and artificial nails
   - Make sure selected finger nail is closely trimmed
2. **Attaching the Snore & Body Position Sensor (optional)**
   - The sensor is attached to the patient's chest right under the sternal notch. The sternal notch is the little U shape where the collar bones meet at the top of the breast bone.

- If needed, trim chest hair to ensure the sensor attached directly to your skin.
- To position the sensor attach it with the image standing up (cable pointing down) after peeling off the round adhesive sticker and pressing against the skin.
- Make sure the sensor is tight against the skin.
- Secure the snoring sensor in place with medical tape.

3. **Wearing the Wrist Strap**
   - Should be comfortable, not too tight.
4. **Attaching the WatchPAT™ 300 Device**
   - Make sure the WatchPAT™ 300 device is properly mounted on the wrist strap. If it is loose, gently insert it in until you hear a click.
5. **Attaching the uPAT Probe**
   - Insert finger all of the way into the probe
   - Press tip of probe against a hard surface (WatchPAT™ 300 device case, table, leg, etc.) while removing tab in order to keep the finger from moving inside the probe
   - For small fingers secure the probe to the finger with a medical tape.
   - The probe is limited to a SINGLE USE. Do not remove probe during the night.

8.4 Switching on the WatchPAT™ 300 Device

- Demonstrate switching on the WatchPAT™ 300 device by pressing the round center button
- Push button firmly until the display lights up

8.5 Removing the WatchPAT™ 300 Device

- Demonstrate how to remove the WatchPAT™ 300 device and place it back in the carrying case.
- The WatchPAT™ 300 device doesn't switch off – once turned on it will record until the battery is exhausted.

8.6 Patient Training

- Following your demonstration have the patient attach the demo device by himself or with the assistance of accompanying individual if needed.
- Verify that the attachment is properly done.

8.7 Review Safety, General and Functional Issues

- Avoid exposing the WatchPAT™ 300 device to extreme conditions (high temperature, high humidity)
- Provide a telephone number to call in case of questions or problems.

9 TROUBLESHOOTING GUIDE

9.1 Operator Error Messages

If an error message is displayed while performing the self-diagnostic tests, take the actions specified below. If the problem persists contact Itamar or an authorized representative.

Table 1– Operator Troubleshooting

Error	Possible Reason	Action
File error		
Not loaded	Study not initialized for new patient	Connect device to PC and perform New Study in zzzPAT
Battery error % full	Battery defective or uncharged	Replace battery
Device does not turn ON	Battery low, defective or not properly inserted	Replace battery or insert battery properly
Probe error		
Used	Probe previously used	Replace probe
Missing	Probe absent	Attach probe
Bad	Probe is defective	Replace probe
Hardware status error code	WatchPAT™ 300 device defective	Consult Itamar or authorized representative
SBP/RESBP disconnected even if it is connected	WatchPAT™ 300 device or SBP/RESBP sensor defective	Consult Itamar or authorized representative
RTC faulty	WatchPAT™ 300 device defective	Consult Itamar or authorized representative
The display does not power up while connecting to PC or device cannot communicate with zzzPAT.	Depleted battery may prevent device from powering up.	Disconnect from PC, remove the battery from device and reconnect to PC.
Short recording time	Patient removed the WatchPAT™ 300 or probe from hand prematurely	Explain proper use to patient
	Insufficient battery charge caused early termination of recording	Replace battery or Recharge rechargeable battery and try again
	Damaged WatchPAT™ 300 device	Contact your authorized sales representative

9.2 Patient Error Messages

If an error message is displayed when the patient powers on the WatchPAT™ 300 device, the patient should take the actions specified below. If the problem persists the patient may contact Itamar or an authorized representative directly.

Table 2 – Patient Troubleshooting

Error	Possible Reason	Action
WatchPAT™ 300 device doesn't switch on	ON button not activated	Press the ON button firmly for at least 3 seconds
	uPAT probe not connected	Ensure probe is connected and try again
Probe disconnected	Probe may not be connected, or may be a used probe	Check connection of probe to cable and cable to the WatchPAT™ 300 device; check if probe has been previously used and replace with new probe if necessary
Hardware code	WatchPAT™ 300 device failure	Contact Itamar or authorized representative

10 SPECIFICATIONS

Table 3 – WatchPAT™ 300 Specifications

Properties		Description
uPAT Probe		Itamar's proprietary probe. Measures PAT and Oximetry.
Recording Time		Approx. 10 hours
Channels		Measuring 4-8 signals: PAT, Pulse rate, Oximetry, Actigraphy, Snoring (optional), Body Position (optional), Chest Movement (optional), Airflow in EU only (optional).
Sample Resolution		PAT and Actigraphy – 12 bit, oximetry – 1% Snoring – 12 bit, Chest Movements – 12bit x 3 axes, Body Position – 5 discrete states Air flow - 10 bit (EU only - optional)
User Interface		OLED display
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	128 MB (minimum)
Power Supply	*Battery*	One OTS 1.5V Alkaline AAA battery **OR** One OTS rechargeable AAA 1.2V NiMH battery
Operating Voltage		3.3 V
Temperature	*Operation*	0^0C to 40 ^{0}C
	Storage (Device)	-20^0C to 40 ^{0}C
	Storage (Probe)	0^0C to 40 ^{0}C
	Transport (Device & Probe)	-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
Dimensions	*L x W x H*	69mm*59mm*17mm
	Weight	98 gr (excluding uPAT probe weight of 20 gr)

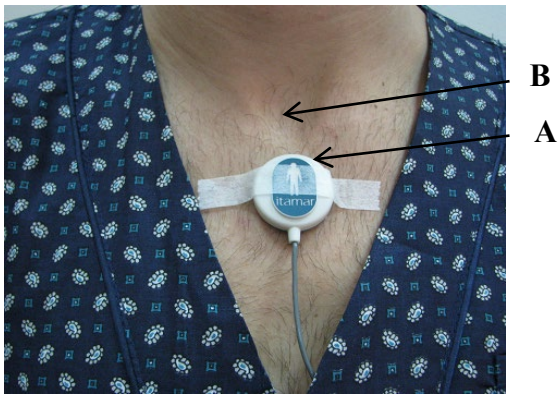
APPENDIX A: **WatchPAT™ Integrated snoring + Body Positioning Sensor Operating Instructions (SBP/RESBP)**

RESBP/SBP must be used with zzzPAT v 5.0.74.4 and above and is to be used only with the WatchPAT™ 300 or WP200U devices.

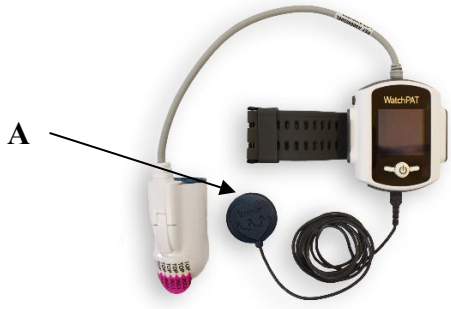
Description

The integrated sensor consists internally of two sensors: a snore sensor and a body position sensor.

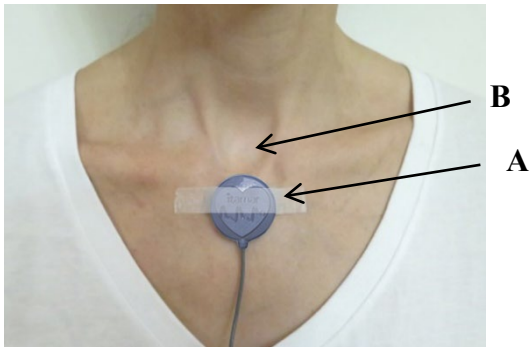
A - Integrated SBP sensor



A – SBP Sensor attachment
B - Sternal notch



A - Integrated RESBP sensor



A-RESBP Sensor Attachment
B-Sternal notch

The integrated sensor is powered by the WatchPAT™ device and does not require a battery. It is automatically activated by the WatchPAT™ when plugged into the Snore & Body position port.

The **snore sensor** is an acoustic decibel detector. It uses a very sensitive microphone that responds to snoring and other sounds in the audio range and converts them to a small analog voltage that provides a clear, reliable indication of the presence of these sounds.

The **body position** sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).

For RESBP only: The **chest movement signal** uses the same 3-axis accelerometer to provide raw chest movement signal data for measuring subject's breathing during the night.

Indications of use

The integrated Snoring & Body position sensor is an accessory of the WatchPAT™ home care device for use with patients suspected to have sleep related breathing disorders. The integrated sensor monitors the snoring level, which aids in the evaluation of the severity of sleep related breathing disorders, and the body position which aids in the evaluation of the type of sleep related breathing disorders. The integrated Snoring & Body position sensor also provides raw chest movement signal data to measure the subjects breathing during the night.

Preparing the sensor

- Attach the round double sided adhesive sticker to the blue side of the sensor.

Applying the sensor

Make sure the room you are sleeping in is as quiet as possible during the night, turn off any possible noise sources. When using the SBP/RESBP it is advised to sleep alone in the room.

- The sensor is attached on the patient's chest right under the sternal notch. The sternal notch is the little U shape where the collar bones meet at the top of the breast bone.
- If needed, trim chest hair to ensure the sensor attached directly to your skin.
- To position the sensor attach it with the image standing up (cable pointing down), after peeling off the round adhesive sticker and pressing against the skin.
- Make sure the sensor is tight against the skin.
- Secure the sensor in place with medical tape.

Cleaning the sensor

Using 70% ethyl alcohol, thoroughly clean both sensor and cable.

SPECIFICATIONS		
Snoring Sensor Technology	Sensitive microphone	
Body Position and Chest Movement (for RESBP only) Sensor Technology	3-axis Accelerometer	
Signal Amplitude	0-3.3 V	
Connector Type	1 mm medical safety connector plug from Plastics1 *Wire Length:* 3.2 foot (100 cm)	
Physical Size	1.3 inch diameter (32 mm diameter)	
Weight	12 gr	
Temperature	*Operation*	0 to 40 ^{0}C
	Storage	-20 to 40 ^{0}C
	Transport	-20 to 60 ^{0}C
Humidity	*Operating, Storage & Transport*	0% – 93% (non-condensing)
Atmospheric pressure	*Operating, & Storage* *Transport*	10 – 15 psi 8 – 15 psi

Snoring and Body Position Accuracy

This section gives statistical performance measure for Itamar SBP sensor, when used with the WatchPAT™ device.

I. Body Position

The body position measured by the WatchPAT™ device with Itamar SBP sensor 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%.

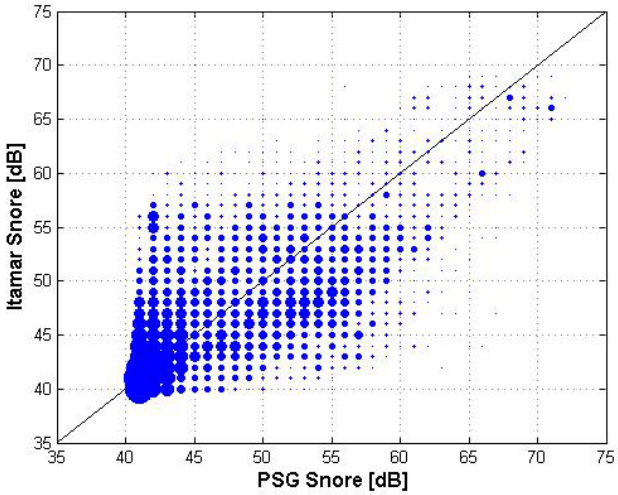
Simple Kappa agreement value was 0.8185 (95% confidence level of 0.8059 and 0.8311).

II. Snoring

The snoring level measured by the WatchPAT™ device with Itamar SBP sensor 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.

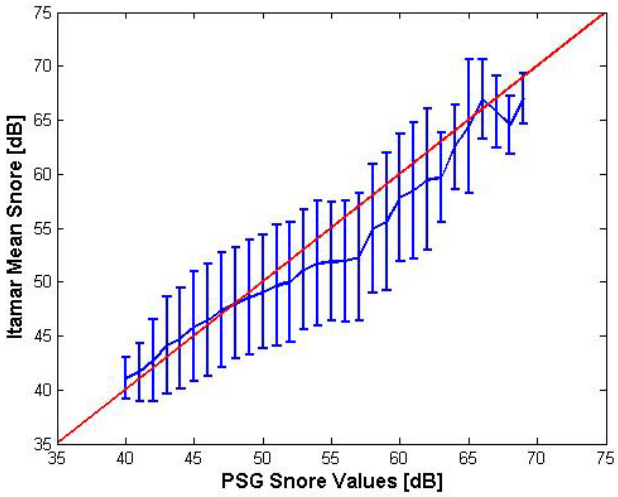


An estimation of the error in each snoring level was calculated by looking at the WatchPAT™ device measurement cut by the results of dB-meter in intervals of 1 dB in the range of above 40dB (below 40 dB was considered not clinically significant being background noise). A high correlation was observed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

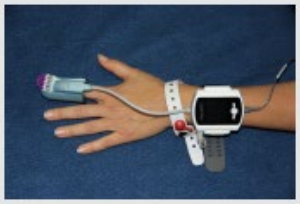


Summary statistics (mean ± SD) of WatchPATdevice by dB-meter levels

	**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 SBP sensor that is used with the WatchPAT™ 300 device.

APPENDIX B: Tamper-proof testing with WatchPAT™ 300

	WatchPAT™ 300	Action	Comment
Important Note	Important Note	This short guide will instruct a WatchPAT trained operator on how to perform Tamper-Proof testing with the WatchPAT. For complete WatchPAT training and instructions please refer to the WatchPAT user manual and to the zzzPAT user manual.	• Make sure the zzzPAT version is: 4.4.64 or higher • Make sure the WatchPAT embedded software version is: 3.2217 or higher • Make sure you enable the "Tamper-Proof Testing" option from the zzzPAT "Setup" menu > "General Settings"
Study Preparation	1 New Study on zzzPAT	While preparing the new study on the zzzPAT [refer to the user manual for detailed instructions], check the box "Study with Tamper-Proof Testing" at the bottom of the "New Study" screen. Note: Once you enable this option you MUST use a bracelet for the night study. The WatchPAT will NOT function without a bracelet connected to it.	
Bracelet Preparation	2 Bracelet	Select a Tamper-Proof Bracelet for the study.	
Bracelet Preparation	3 Connecting the Cable to the WatchPAT	Connect the gray cable with the red and white snap buttons to the WatchPAT socket.	
Bracelet Preparation	4 Connecting the Bracelet	Connect the red and white snap buttons to the red and white snaps on the bracelet respectively.	

	WatchPAT™ 300	Action	Comment
Bracelet Preparation	5 Pairing WatchPAT with Bracelet: Site-Diagnostic Test	Make sure the bracelet is connected before starting the test. Perform the standard site diagnostic test ("device test" as described in the user manual). After test is completed, disconnect the bracelet from the WatchPAT and store it in the WatchPAT case. **Note:** Once the "device test" is successfuly done with the bracelet connected - the specific bracelet must be used for the following night recording.	
Patient Preparation	6 Placing Bracelet on Patient	• Make sure you have all 3 parts: bracelet and two white plastic clips. Place the bracelet upside down on a flat surface (white side facing up). 1. Insert the white plastic clip into the two separated holes (flat side facing up). 2. Wrap the bracelet around the wrist of the non-dominant arm (tested arm) of the patient. 3. Insert the white plastic clips into the holes. Make sure it is snug but not too tight. 4. If there is some loose strap left, fold it and re-insert it into the holes. DO NOT CUT LOOSE STRAP – CUTTING IT WILL RENDER THE BRACELET UNUSABLE 5. Secure the bracelet by placing the second white plastic clip on-top of the first. Make sure it is secured tightly.	
Patient Guidance	7 Explain to Patient	• The patient may choose to perform the study during any night of the week. • The patient may shower with the bracelet. • Instruct patient to turn on the WatchPAT only after it is connected to the bracelet. • THE BRACELET SHOULD NOT BE REMOVED UNTIL THE NIGHT STUDY IS COMPLETED. Removing the bracelet before or during the night will cause the device to shut down. • In the morning,instruct the patient to cut the bracelet along the dotted line by using small scissors and to put it in the WatchPAT case along with all the other parts (DO NOT THROW THE BRACELET AWAY). Do not try to connect ANY other device to the bracelet.	

APPENDIX C: 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/lmages/licensewp.pdf

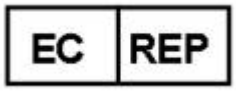
Should you have any questions concerning this License Agreement, or if you desire to contact Itamar Medical for any reason, please write to:

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 Street, PO 3579
Caesarea 3088900, Israel
Tel: +972 4 617 7000

APPENDIX D: REGULATORY REPRESENTATIVE

Itamar Medical's authorized regulatory representative is:



Arazy Group GmbH

The Squaire 12, Am Flughafen,
60549 Frankfurt am Main,
Germany

APPENDIX E: DESCRIPTION OF THE WATCHPAT™ 300 uPAT PROBE

The WatchPAT™ uPAT probe is an 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 uPAT probe is designed to cover the distal part of the finger with a uniform pressure field extending to the tip of the finger. 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 uPAT probe also measures the changes in absorbance of the finger at both red and infrared light at peak wavelengths of 660nm and 910nm respectively. The maximum optical output power is 65mW. These measurements are used to calculate the oximetry signal in an offline program according to the pulse oximetry principles.
The uPAT probe is an integral part of the WatchPAT™ device and is to be used only with the WatchPAT™ 300 or WP200U devices.

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

Notes

• The WatchPAT™ 300 (WP300) requires special precautions with regard to electromagnetic compatibility.
• It must be installed and prepared for use as described in section 3 - Preparation for Sleep Study.
• Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the WatchPAT™ 300 .
• The recommended separation distances in this section must therefore be complied with.
• The WatchPAT™ 300 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.
• To ensure "Isolation means" disconnect the power supply.
• The WP300 has no Essential Performance. Loss or degradation of any of its functions poses no unacceptable risk. It incorporates no alarm system nor possesses the ability to detect alarm conditions. SpO2 values are measured during the sleep study and analyzed at a later stage.

Electromagnetic Compatibility

Electromagnetic Emissions

• WatchPAT™ 300 is intended for use in the electromagnetic environment specified in the following tables below.
• The user and/or installer of the unit must ensure that it is used in such an environment.

Table 4 - 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 **WP300**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 **WP300** 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 **WP300** or shielding the location.
Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Complies	

Table 5 - 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	2,4,8 kV contact 2, 4, 8, 15kV air	2,4,8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 6 - 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 Radiated RF IEC 61000-4-3	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz 10V/m, 80MHz to 2.7GHz, 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the **WP300**, 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: 
Proximity magnetic fields IEC 61000-4-39	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, pulse modulation 2.1 kHz) 7.5 A/m (13.56 MHz, pulse modulation 50 kHz)	Not Applicable	Not Applicable

Recommended Separation Distances

The WatchPAT™ 300 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™ 300, according to the maximum output power of the equipment, as recommended in the table below.

Table 7 - from IEC 60601-1-2:2014, AMD1:2020				
Recommended separation distances between portable and mobile RF communications equipment and the WP300				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

Table 8 - 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] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	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] 217 Hz	28
1845				
1970				
2450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5500				
5785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the **WP300** 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, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

Table 9 - Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz	CW	8
134,2 kHz	Pulse modulation [b] 2.1 kHz	65 [c]
13,56 MHz	Pulse modulation [b] 50 kHz	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 G: SPO2 ACCURACY IN THE WATCHPAT™ 300

The WatchPAT™ 300 device uses Itamar Medical Pulse Oximetry system for the measurement of functional oxygen saturation of arterial haemoglobin (SpO2). This appendix includes information regarding the accuracy of these measurements following a clinical study of Itamar Medical Pulse Oximetry.

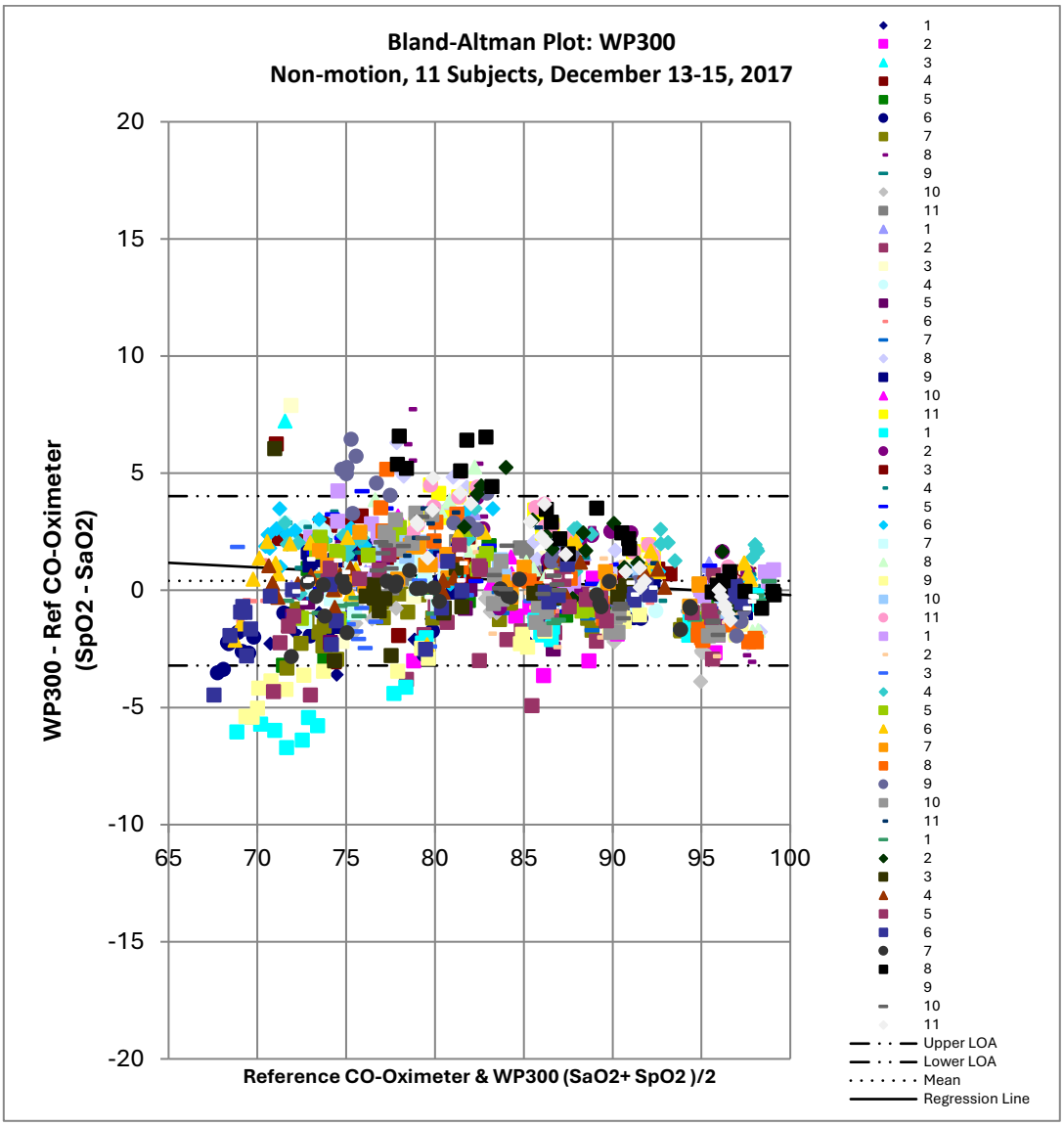
1. Overall, the Arms is estimated to be 1.9 for the range 70-100%

2. The next table shows SpO2 Accuracy Results:

Comparison to Reference CO-Oximetry					
WP300	* 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™ 300:



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:	WP300 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 WatchPAT300 Pulse Oximetry
Study Date(s):	December 13-15, 2017

	**Note** A Functional tester cannot be used to assess the accuracy of the internal pulse oximeter.

APPENDIX H: WP200U EFFECTIVENESS IN DETECTING AHIc AND %CSR

AHIC:

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 an 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.

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

The following statistics were demonstrated:

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™ 300 device.

APPENDIX I: ZZZPAT HARDWARE REQUIREMENTS

Hardware configuration:

Computer Pentium 4 3GHz or higher
1 available USB port
XGA screen resolution (minimum 1024 x 768 pixels)
RAM 1GB or higher

Disk space requirements:

- **Standalone installation**
  - 10GB minimum / 60GB recommended disk space on Files folder and at least 1.2GB on boot drive
- **Shared installation**
  - SQL DB drive – 1.2GB if using our default MS SQL Express installation and enough for 1 year worth of studies (500 KB / study).
  - Shared Files folder for raw data signal files - enough for 1 year worth of studies (30 MB / study).

Operating System:

Windows Server 2008 Service Pack 1 and above
Windows 7 with Service Pack 1
Windows 8
Windows 10

APPENDIX J: SPARE PARTS LIST

The following items can be ordered and purchased individually:

- uPAT probe (a box of 12 uPAT probes)
- uPAT probe connection cable
- Wrist Strap
- Snore and Body Position sensor (SBP/RESBP)
- Adhesive for Snore and Body Position sensor (a package of 12 units)
- Cable for Tamper-Proof Bracelet
- Tamper-Proof Bracelet (a box of 24 bracelets)
- USB cable
- Step-by-Step Reference Guide WatchPAT™ 300
- Quick Reference Cards WatchPAT™ 300
- Carrying case

APPENDIX K: **WatchPAT™ Integrated snoring + Body Positioning Sensor Operating Instructions (RESBP) - configuration that supports connection of Thermal Airflow sensor (APPLICABLE IN THE EU ONLY).**

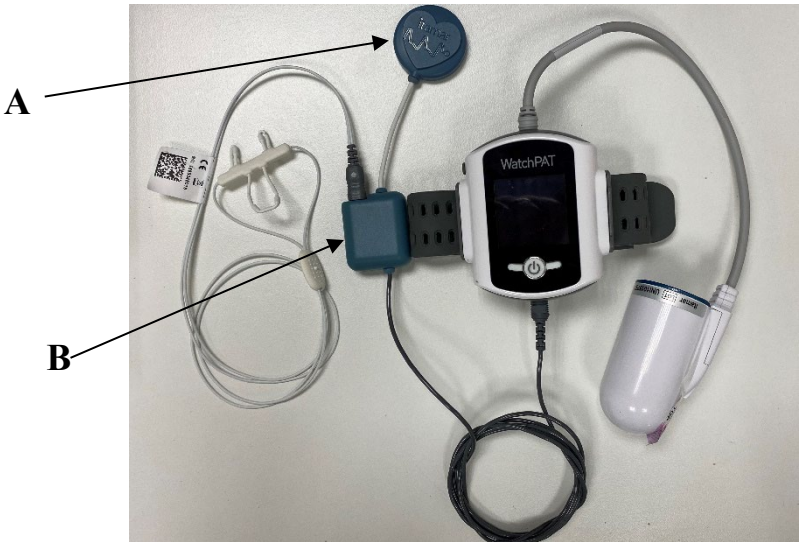
RESBP configuration that supports connection of Thermal Airflow sensor must be used with zzzPAT v 5.2.79 and above.

An optional Nasal Air Flow (NAF) is generated when using the Nasal Air Flow Interface Module (NAF-IM) that allows connection of both RESBP and off-the-shelf Thermal Airflow sensor to the WP300.

Description

The RESBP configuration that supports connection of Thermal Airflow sensor consists of:

- A snoring and body position sensor
- A module that supports connection of off-the-shelf Thermal Airflow sensor.



A – RESBP Sensor
B – Interface (NAF-IM) to connect Thermal Airflow sensor

The RESBP sensor is powered by the WatchPAT™ device and does not require a battery. It is automatically activated by the WatchPAT™ when plugged into the Snore & Body position port.

The **snore sensor** is an acoustic decibel detector.
The **body position** sensor uses a 3-axis accelerometer that provides a signal directly proportional to the patient's sleeping posture (supine, prone, right, left and sit).

The **chest movement signal** uses the same 3-axis accelerometer to provide raw chest movement signal data for measuring subject's breathing during the night.

The module that supports connection of Thermal Airflow sensor is only used to transmit data from RESBP (see Appendix A) and Thermal Airflow sensor to the WatchPAT™ device.

Supported Thermal Airflow sensor

- Off the shelf S.L.P Airflow Thermistor 20 inch REF 1467.

Indications of use

The RESBP is an accessory of the WatchPAT™ home care device for use with patients suspected to have sleep related breathing disorders. The module that supports connection of Thermal Airflow sensor (NAF-IM) transmits data from RESBP and Thermal Airflow sensor to the WatchPAT™ device, which aids in the evaluation of the severity and the type of sleep related breathing disorders.

Preparing the RESBP configuration that supports connection of Thermal Airflow sensor

- Attach the double sided rectangular adhesive sticker to the rear side of the NAF-IM module.
- See Appendix A for RESBP preparation instructions.

Applying the RESBP configuration that supports connection of Thermal Airflow sensor

See illustrated Patient Step by Step guidance for detailed description

Cleaning the RESBP configuration that supports connection of Thermal Airflow sensor

Using 70% ethyl alcohol, thoroughly clean sensor, cables and interface module.

Preventive maintenance recommendations

Replace RESBP if any of the connectors is broken, if the cable near the connector is peeling off or if any of its components is broken.

Operator Error Messages

Error	Possible Reason	Action
NAF missing	RESBP configuration that supports connection of Thermal Airflow sensor is connected to WP300 but Thermal Airflow sensor is disconnected from interface module.	1. Check if Thermal Airflow sensor is connected properly. 2. Try to connect another Thermal Airflow sensor.

SPECIFICATIONS		
Signal Amplitude	0-3.3 V	
Connector Type	1 mm medical safety connector plug from Plastics1 *Wire Length:* 3.9 foot (120 cm)	
Physical Size (Only NAF-IM)	Width: 27.1 mm Length: 33.2 mm Height: 13.5 mm	
Weight	21 gr	
Temperature	*Operation*	0 to 40 ^{0}C
	Storage	-20 to 40 ^{0}C
	Transport	-20 to 60 ^{0}C
Humidity	*Operating, Storage & Transport*	0% – 93% (non-condensing)
Atmospheric pressure	*Operating, & Storage*	10 – 15 psi
	Transport	8 – 15 psi

Snoring and Body Position Accuracy

See Appendix A for RESBP preparation instructions.

APPENDIX L: CLINICAL BENEFITS AND PERFORMANCE CHARACTERISTICS OF THE DEVICE

Clinical benefits of the WatchPAT™ 300:

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

Performance characteristics of the device:

Performance characteristics	
AHI	AUC:0.953 (AHI threshold = 15), Linear Regression: r=0.9, p≤0.001 Sensitivity/Specificity: 85%/88.2%
AHIc (Central Sleep Apnea)	AUC: 0.913 (AHIc threshold = 10), Linear Regression: r=0.96, p≤0.001 Sensitivity/Specificity: 71.4/98.6% AND Linear Regression: r=0.96, p≤0.001, Sensitivity/Specificity: 100%/100%
Sleep Stages	Accuracy: 65%, Kappa agreement value: 0.462 (95% CI: 0.455 to 0.468)
ODI (SpO2)	ARMS SpO2 70-100%: 1.9
Snoring Level	Pearson Correlation r=0.65 p<0.001
Body Position	Kappa agreement value 0.8185 (95% CI: 0.8059 to 0.8311), Agreement 90%

Arrhythmia	AFib total duration in sleep: Sensitivity/specificity (TH=6 min) – 84%/95.5% AFib longest event: Sensitivity/specificity (TH=6 min) – 83.3%/98.5% PB events/min: Sensitivity/specificity (TH=0.5) – 100%/98.2%