# Watch-PAT200

## Operation Manual

### Itamar Medical P/N - OM2196300

**Caution**: **Federal (U.S.) law restricts this device to sale by, or on the order of, a physician. Not for pediatric use**.

## 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 Watch-PAT200 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 in Appendix A.

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ISO 9001:2000 and ISO 13485:2003

See appendix B for contact information of the regulatory authorized representative

Record of Revisions

| Revision | Date | Description | Chapter | Pages | Resp. |
|---|---|---|---|---|---|
| 0 | March 2008 | Preliminary | All | All | |
| 1 | June 2008 | Sleep Stages and AHI | All | All | |
| 2 | July 2008 | ISO logo, list of standards, Medes address, pictures | All | All | Bonita |
| 3 | Feb 09 | Updating:<br>Itamar Medical address<br>List of standards<br>Labeling | <br>-, 11<br>1.6<br>1.10.1 | <br>i, 47<br>3<br>7 | Orit |

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# 1. GENERAL INFORMATION

This manual is part of the Watch-PAT200 (WP200) system.

## 1.1. Intended use / Indications for use

The Watch-PAT200 (WP200) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200 is a diagnostic aid for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). The WP200 generates a peripheral arterial tonometry ("PAT") respiratory disturbance index ("PRDI"), apnea-hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WP200's PSTAGES provides supplemental information to its PRDI/PAHI. The WP200's PSTAGES is 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.

The WP200 is not indicated for children less than 17 years old.

## 1.2. Restrictions For Use

- The WP200 should be used only in accordance with physician's instructions. For exclusion criteria see Section 1.3.
- Only qualified medical personnel may authorize the use of the WP200.
- Qualified medical personnel must instruct the patients how to attach and use the WP200 prior to use.
- In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
- 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.
- The WP200 system in whole, or in part, may not be modified in any way.
- The WP200 is used as an aid for diagnostic purposes only, and should not be used for monitoring.
- Only suitably trained and qualified personnel should be authorized to prepare the WP200 equipment prior to use.
- The WP200 Operation Manual should be carefully studied by the authorized operators, and kept where it is easily accessible. Periodic review of the Manual is recommended.

- 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.

- The tracings and calculations provided by the WP200 system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.

- 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, contact our service office to report the incident, and to receive further instructions.

- The step by step instructions for the patient should be carefully followed when attaching the unit to the patient.

### 1.3. Exclusion Criteria

The WP200 should not be used in the following cases:

- Age less than 17 years old.

- Use of one of the following medications: alpha blockers, short acting nitrates (less than 3 hours before the study).

- Permanent pacemaker.

- Sustained non-sinus cardiac arrhythmias.

### 1.4. Data Generated by the Watch-PAT200

The WP200 generates a PAT respiratory disturbance index (PRDI) and its derivative, the PAT Apnea-Hypopnea Index (PAHI) and PAT sleep staging identification (PSTAGES). The PRDI, PAHI and PSTAGES are estimates of conventional RDI and AHI values and REM, Deep Sleep, Light Sleep and Wake stages identification that are produced by polysomnography (PSG).

### 1.5. Equipment Classification

The **WP200** is a Class IIa medical device under MDD 93/42/EEC (1993) Annex IX rule 10.

## 1.6. Quality Assurance System: ISO 9001

The Itamar Medical WP200 is compliant to the following standards.

| | **STANDARD** | **#** |
|---|---|---|
| 1. | Medical electrical equipment- general requirements for safety. | IEC 60601-1 |
| 2. | Medical electrical equipment electromagnetic compatibility | IEC 60601-1-2 |
| 3. | Medical Device Software- Software Life Cycle Processes | IEC 62304 |
| 4. | Quality systems – Model for quality assurance in design, development, production, installation and servicing | ISO 9001 |
| 5. | Quality systems medical devices | ISO 13485 |
| 6. | CMDR - Canadian Medical Device Regulations | SOR/98-282 |
| 7. | Risk Analysis for medical devices | ISO 14971 |
| 8. | Labeling Medical Devices | EN 980 |
| 9. | Medical Device Directive | MDD 93/42 EEC |
| 10. | CSA standard for safety | CSA 22.2 No. 601.1 |
| 11. | UL standard for safety | UL 60601-1 |

## 1.7. CE and CSA Compliance

CE
0473

The WP200 complies with the CE mark according to MDD (Medical Device Directive) and related standards.

The unit is marked with the CE logo and a CE conformity card is included in every shipment.

C US

The WP200 is certified by CSA.

### 1.8. Conventions Used in this Manual

| | |
|---|---|
|  | **Warnings** are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or cause damage/malfunction to the system, resulting in non recoverable loss of data.<br>**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.<br>**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.<br>**Les notes** sont utilisées pour identifier les explications et pour donner des informations supplémentaires dans le but de clarifier. |

#### 1.8.1. Warnings, Cautions and Notes

The WP200 is internally powered from a 4.2 V battery.
The WP200 is portable with continuous operation.
The WP200 uses BF patient applied parts.
The WP200 uses UL listed power supply.
The power supply is used in a non-patient environment only.
The WP200 should only be transported in its original case.
There are no serviceable parts inside the WP200.
Environmental conditions during transportation & storage:

Temperature: -20ºC ~ 40ºC. Recommended temperature for long term storage <21ºC
Relative humidity: 10% ~ 70%
Atmospheric pressure: 940 hPa ~ 1060 hPa

Environmental conditions during operation:

Temperature: 15ºC ~ 30ºC. Recommended temperature 18ºC ~ 25ºC
Relative humidity: 30% ~ 70%
Atmospheric pressure: 940 hPa ~ 1060 hPa

Sleep professionals (other than patients) using the WP200 should read the Operation Manual.

## 1.9. Safety Precautions

**WARNINGS**

Use only the USB charger provided (5V DC, 5W maximum capacity power supply). Only authorized personnel may charge the WP200. Failure to heed this warning may cause permanent damage to the equipment.

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 WP200 MUST be charged ONLY after being removed from the patient!

The WP200 MUST be removed from the patient BEFORE connecting it to a PC!

**The Adult Flex Pulse Oximetry Sensor** may cause skin sensitivity to the patient. Discontinue use of the NONIN double-backed adhesive tape strips or the Hydrogel tape strips if the patient exhibits allergic reactions to the adhesive material.

**AVERTISSEMENTS**

Utiliser seulement un 5V DC, 5W alimentation d'énergie. Seul les techniciens autorisés peuvent charger la montre PAT. Ignorer cet avertissement peut causer des dommages irréparables a l'équipement. Ne pas mouiller l'unité. L'unité est sensible au mouvement extrême est à la chute. L'utiliser avec précaution. Ne pas essayer de brancher ou débrancher une des parties de l'unité.

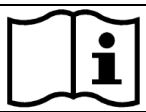
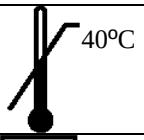
Ne pas introduire un objet étranger a l'intérieur de l'unité.

Le système WP200 **doit** être rechargé **uniquement** après avoir été retiré de la main du patient.

Il est impératif de retirer le système WP200 de la main du patient **avant** de le relier a l'ordinateur pour faire fonctioner les programmes.

L'Oximetre pur adulte '' Flex Pulse'' peut produire des sensibilités dermatologique aux patients.

## 1.10. Symbols used on the WP200 device labels

| | |
|---|---|
|  | **Consult operating instructions** |
|  | **Consult accompanying documents** |
|  | **BF Type** Applied Parts |
|   | **The WP200 is certified by CSA** |
|  0473 | **The WP200 complies with the CE EMC Directives and related standards** |
| 2008  | **Year of manufacture** |
| 3.7V DC ⎓ | **Battery Operating Voltage** |
|  | **Do not re-use** |
|   | **Temperature limitation** |
|  | **Use by** |

### 1.10.1. WP200 labels



## 2. OVERVIEW

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep, 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 OSAS in the adult population.

The WP200 is worn on the wrist and is utilizing a plethysmographic based finger–mounted probe, to measure 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 PAT signal is recorded continuously and stored on an embedded micro SD card, together with data from a built-in pulse-oximetry sensor (mounted on an adjacent finger) and an actigraph (embedded in the WP200). 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 four WP200 channels (PAT, oxygen saturation, pulse rate and actigraphy) for the detection of respiratory events, differentiation between wakefulness and sleep stages such as Deep, Light and REM sleep. 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.

An optional sensor for Snoring and Body Position provides snoring in decibels during sleep and 5 body positions (right, left, prone, supine and sit).

## 2.1. System Description

The WP200 system is comprised of the following items:

- WP200 device that includes:
  - Embedded actigraph
  - Embedded pulse oximeter
  - Embedded CPU and electrical circuit card
  - Embedded micro SD card drive
  - Rechargeable Lithium Ion Battery
  - LCD display
- PAT probe
- PAT probe connection cable
- Pulse oximeter sensor – with single use adhesive pads
- Wrist Strap
- Snore and Body Position sensor - optional
- USB battery charger
- USB cable
- Step-by-Step Reference Guide
- Carrying case


**Figure 1 – Packed Device**

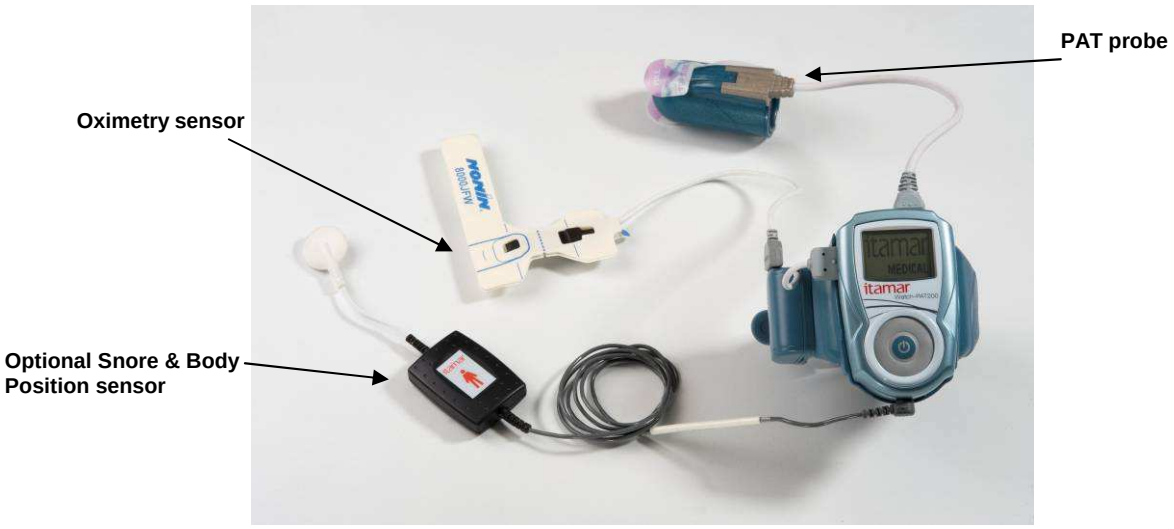



**Figure 2 – Watch-PAT200 Device with all sensors**

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 Operation Manual.

### 2.1.1. User Interaction with the WP200

#### Keys

The WP200 has the following keys (see Figure 3):

- Central On/Enter key to power on the WP200 (the only key visible to the patient)
- Outer ring containing four keys (left, right, up, down) that may be used by the Operator for entering the diagnostic mode and navigating through the diagnostic menu. These keys are hidden from the patient.

#### LCD display

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

- Title: Current operational mode and time
  - PATIENT mode while recording night study
  - DIAGNOSTIC mode while testing device
  - PC HOST while connecting to PC
  - CHARGER mode while connecting to USB Charger
- Info: Specific information depending on operational mode

- Status: Message indicating device status depending on operational mode


**Figure 3 – The Buttons and Display**


**Figure 4 – Service Ports and Peripherals**


**Figure 5 – WP200 Wrist with Oximetry module**

## 2.2. WP200 Function

The WP200 records the following channels:

- PAT Signal
- Oxygen saturation
- Actigraphy (movement)

The overnight sleep study data is stored on an embedded micro SD card in the WP200. After the study is recorded, the data is downloaded from the WP200 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.

## 2.3. Built-In Self-Diagnostic Procedures

### 2.3.1. Operator tests

The WP200 contains a comprehensive built-in self-diagnostic procedure. This procedure is available to the operator and hidden from the patient. The procedure can be accessed it the UP and DOWN keys (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 tests:

- Device Test – tests the WP200 for errors before performing a night study (make sure all probes are connected before initiating this test)

- Oximetry Sensor Test – verifies oximetry sensor is connected and shows average saturation

The Device test is the default test. Once the device test has passed you should also run the oximetry sensor test.

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

To run the self-diagnostic procedure:

- Press the ENTER button (Center key) for 2 seconds till the Itamar medical logo appears on he LCD screen
- Immediately press the **UP + DOWN** keys (see Figure 3) simultaneously for 1 second

The following screen will be displayed:

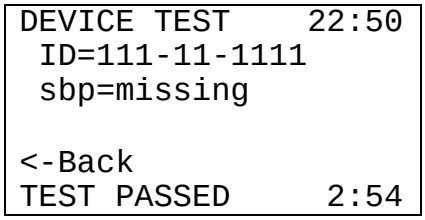
```
DIAGNOSTIC     22:40
2.2140     20-Jul-08
*device test (30001)
 oxi test
 end testing
Select test ↑↓
```

- First line displays title and current time
- Second line displays current embedded S/W version (2.2139) and current date
- Third line displays option for running device test (serial number of device in parenthesis)
- Fourth line displays option for running oximetry sensor test
- Fifth line indicates option for end testing (turn device off). If no test is selected within 3 minutes the WP200 device will automatically shut down
- The Up, Down keys (↑↓) 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.

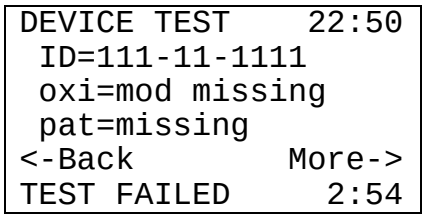
It is recommended that you perform the device and oxi test every time you prepare the WP200 for a night study.

### 2.3.2. 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 messages:

- File error: not loaded, missing – the study file was not loaded or somehow the file was deleted
- Battery error: low – needs charging
- Probe error: used, missing, bad – connect an unused probe
- Oximetry error: module missing - connect oximetry module
- Hardware (H/W) error: error code - contact customer support
- SBP (Snore and Body Position sensor) warning: sensor missing – does not affect PASSED status
- RTC (Real Time Clock) warning: faulty – indicates problem with internal clock but does not affect PASSED status

`More->` indicates that there are more error/warning messages and will be displayed if the Right (`->`) button is pressed.
`<-Back` we move to previous screen.

### 2.3.3. Oximetry test

For the oximetry test make sure the sensor is attached to the finger. At the end of the test the saturation and/or any error message will be displayed:

```
OXI TEST        22:50
SaO2=98%

Attach to finger
<-Back
Testing…
```

```
OXI TEST        22:50
SaO2=N/A
oxi=mod missing
Attach to finger
<-Back
Testing…
```

The possible oximetry error messages are:

- Oximetry error: module or sensor missing - connect oximetry module and sensor.
- SaO2= Not Available (N/A) - attach sensor to finger.

The blood saturation is continuously updated, therefore wait for one minute or so for the saturation to stabilize when testing.
`<-Back` we move to previous screen.

### 2.3.4. Patient test

When the patient turns on the WP200 by pushing the On/Enter key (center button) for about 2 seconds a self-diagnostic test is automatically performed and the following screen is displayed:

```
PATIENT          22:51



Please wait
Testing…
```

If the WP200 passes this self-diagnostic test, the following screen will be displayed

```
PATIENT          22:51

GOOD NIGHT!!!

Time elapsed=9:50
Recording…
```

**Note**
During recording the LCD display turns off to conserve battery life. Any key pressed during Recording will turn on the LCD for 30 seconds.

If the WP200 fails this self-diagnostic test, the following screen will be displayed:

```
PATIENT          22:51
Error=xxxx
Device S/N=xxxxx

Call Help Desk
TEST ABORTED
```

- The error message will be displayed for 1 minute then the WP200 will shut off.

The following are the possible error/warning messages:

xxx1 - battery low

xxx2 – Nonin module/sensor disconnected

xx2x – PAT probe error (used probe)

xx4x – File error (no new file)

xx8x - PAT probe error (bad probe)

x4xx - SBP (Snore and Body Position sensor) missing warning

| | |
|---|---|
|  | **Note**<br>The "x" stands for 0-F value (Hexadecimal code)<br>Error codes are additive, i.e. both PAT probe and File errors will produce error code xx6x. |

# 3. PREPARATION FOR SLEEP STUDY

## 3.1. Charging The Battery

| | |
|---|---|
|  | **Warning**<br><br>For AC charging use only a USB charger having a 5V DC output, with 5W minimum capacity. Using any other charger may cause permanent damage to the WP200 and may jeopardize the operator. |

The battery must be charged every time the WP200 is prepared for use. The battery may be charged through the USB port of a computer, or with the USB charger provided.

To charge the WP200:

1. Disconnect the Oximetry module by disconnecting the Oximetry module connector.
2. Gently slide the WP200 out of the wrist strap until a click is heard and the USB port is exposed. Be careful not to damage the oximetry module connector and cable.
3. Connect the USB port of the WP200 to the USB port of a computer using the USB cable provided or to the USB charger provided (see Figure 6).

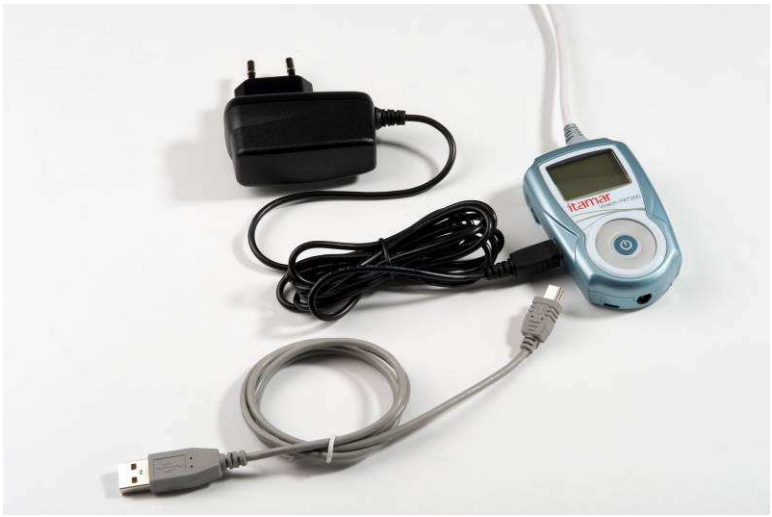
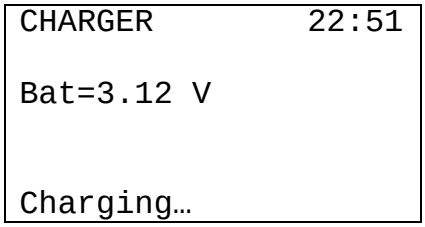


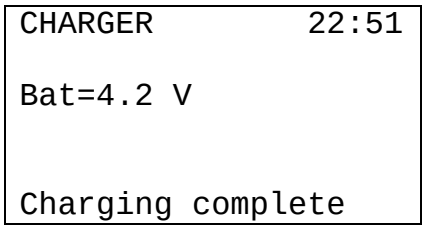
**Figure 6 – Charging the WP200**

4. The LCD will blink slowly and the following screen will be displayed:



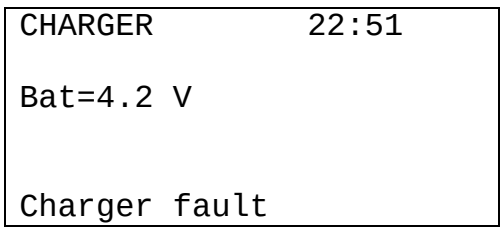

   - The display will show **"CHARGER"** if you are charging with the USB charger or **"PC HOST"** if you are charging with a computer.
   - The current battery voltage is shown.
   - Charge the battery the first time for approximately three hours. Thereafter recharging takes approximately 1-1.5 hours.

5. When charging is complete, the LCD will stop blinking and the following screen will be displayed:




6. Disconnect the charger or communication cable. The WP200 will switch off in 30 seconds.
7. Reseat the WP200 in the wrist strap by gently sliding it back in until a click is heard.
8. Check that the oximetry module connector is properly connected to the WP200.

Should a charging error arise the LCD will blink rapidly and the following screen will be displayed.



### 3.2. Preparing The Oximetry Sensor

Use Nonin 8000JFW Flexiwrap pad and Nonin oximeter as supplied.

**Figure 7 – Oximetry Sensor**

1. If the sensor was previously used, carefully remove the used Flexiwrap pad from the sensor. Remove any remaining adhesive from the sensor – if necessary clean the sensor using isopropyl alcohol.
2. Place the new Flexiwrap pad with the printed side facing down on a flat surface.
3. Partially peel off the paper covering of the pad to expose the adhesive area around the two cut out sections.
4. Place the sensor on the pad with the back facing the sticky side placing the sensor's protrusions into the corresponding cutout sections as shown in Figure 8.
5. Reapply the paper covering of the pad.

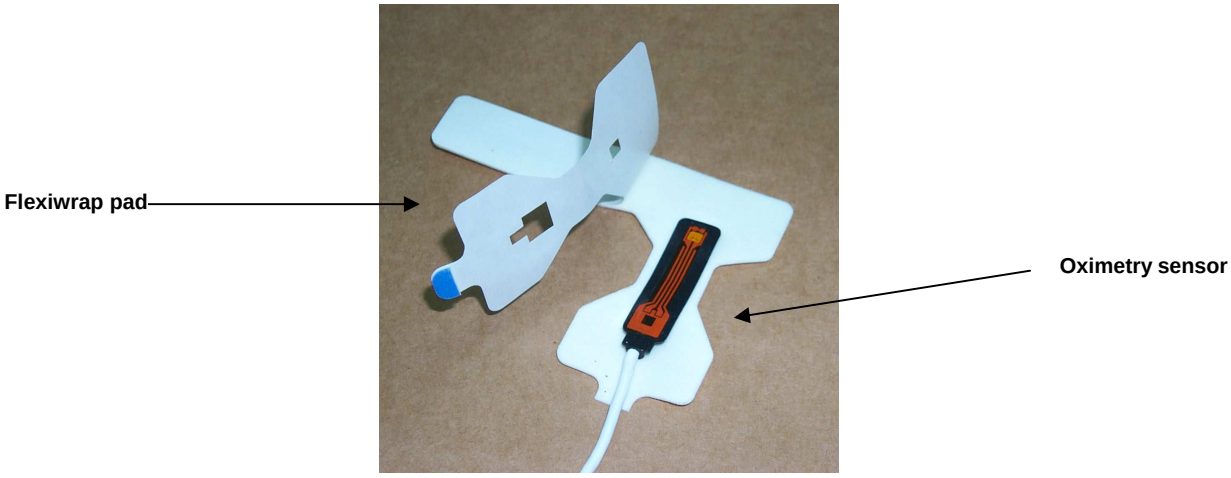



**Figure 8 – Preparing The Nonin 8000JFW Oximetry Sensor**

### 3.3. Preparing the Wrist strap

The wrist strap requires no special preparation other than ensuring its cleanliness. You may clean it if needed. Take care not to allow the oximetry module or connector to get wet (see Figure 5). See section 5.1 for detailed cleaning instructions.

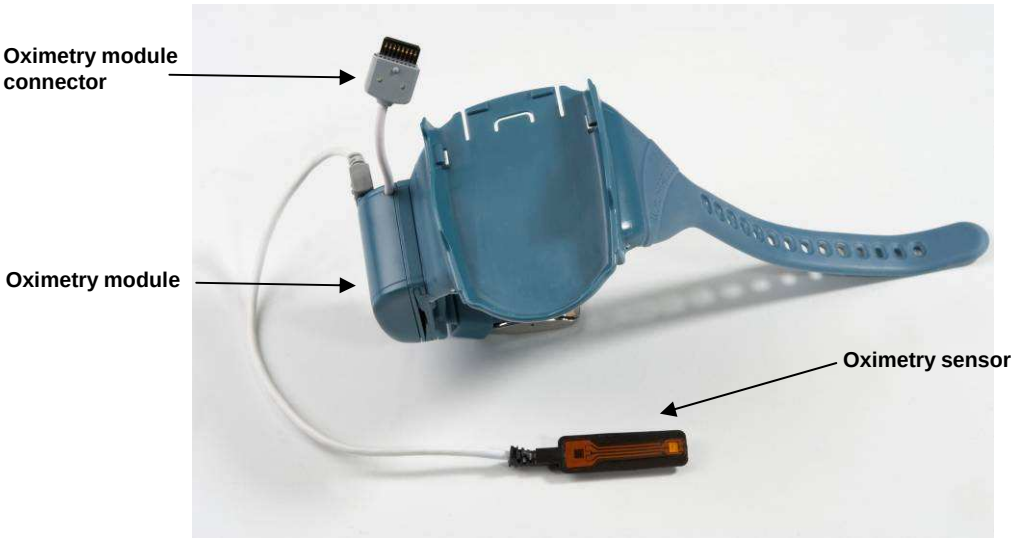



**Figure 9 – Wrist Strap**

#### 3.3.1. Mounting the WP200 on the wrist strap

To mount the WP200 on the wrist strap:

1. Gently slide the WP200 into the wrist strap until a click is heard indicating that it is properly seated.
2. Connect the oximetry module connector (Figure 9) to the oximetry module port on the WP200 (Figure 4).

### 3.4. Replacing the PAT Probe

| | |
|---|---|
|  | **Warning**<br><br>The PAT 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 blue tab (clip) marked by the arrow in Figure 10, and then, holding the gray 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 10 – Disconnecting The Probe**

**Figure 11 – Probe disconnected**

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

| | |
|---|---|
|  | **Note**<br>Take care when inserting the gray slider to insure proper seating in the probe. |

The WP200 is now ready for performance of a sleep study by the patient. (Figure 12)

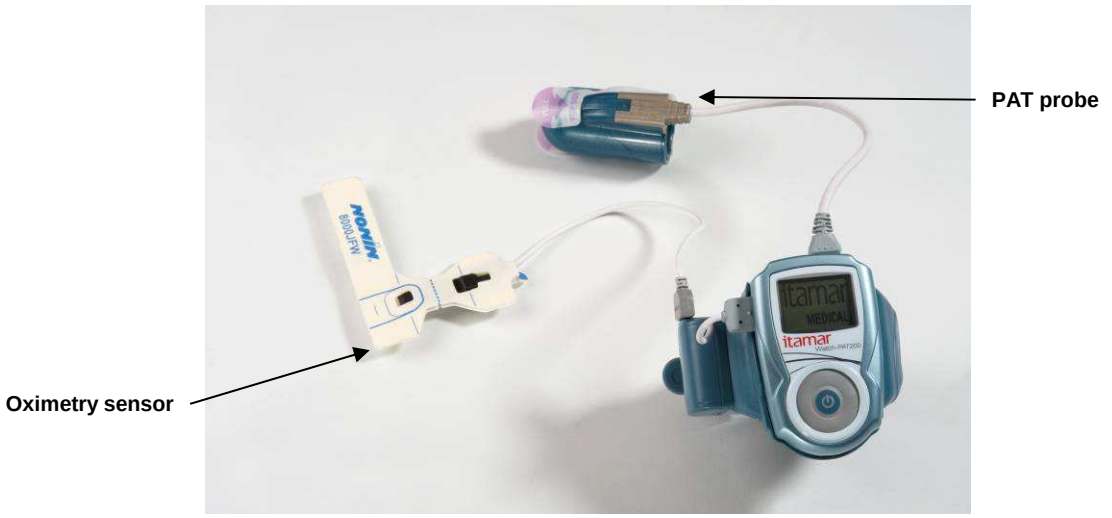



**Figure 12 – WP200 Fully Prepared**

### 3.5. Preparing the WP200 for a New Study

Refer to the zzzPAT Software Manual for preparation of the WP200 for a new study.

### 3.6. Testing The WP200

Run the built-in self-diagnostic facility as described in Section 2.3 above

#### 3.6.1. WP200 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 8.

### 3.7. Packing The Carrying Case

The following items must be placed inside the carrying case, in their respective compartments:

- The WP200 mounted in the Wrist strap with the PAT probe and oximetry sensor attached.
- Body Position and Snore sensor (optional)
- Step-by-Step Reference Guide to the WP200.

| | |
|---|---|
|  | **Note**<br><br>Demonstrating the use of the WP200 to the patient is important for obtaining reliable recordings and improving patient confidence. |

## 4. DATA DOWNLOAD AND ANALYSIS

Following the sleep study the WP200 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 WP200 to the computer (see Figure 4) The WP200 will switch off and then switch on in charging mode.
2. Activate the zzzPAT software to download and analyze the study data.

See the zzzPAT Software User Manual for detailed instructions.

# 5. MAINTENANCE

The WP200 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.

The system contains no user-serviceable parts. It should be maintained and serviced only by qualified service personnel, authorized by Itamar Medical Ltd.

## 5.1. Cleaning

The various components of the WP200 have different cleaning requirements.

- The WP200
- The wrist strap
- The oximetry sensor

### 5.1.1. Cleaning the WP200

There is no need to clean the unit during ordinary operation. Should it become necessary to clean the WP200, proceed as follows:

1. Wipe parts with a clean, dry, lint-free cloth.
2. Clean casing with lint free cloth lightly moistened with 70% alcohol.

| | |
|---|---|
|  | **Warning**<br><br>Clean the WP200 only with the PAT probe attached. |

### 5.1.2. Cleaning the oximetry sensor

The Nonin 8000JFW pulse oximetry sensor has two parts, the single-use adhesive band and the optical sensor with cable and plug. The sensor/cable component is reusable, and should be cleaned as described in section 3.2.

### 5.1.3. Cleaning the Wrist Strap

You may clean the wrist strap with lint free cloth lightly moistened with 70% alcohol.

### 5.1.4. The PAT probe

The PAT probe is designed for a single use only. It may not be cleaned and must be discarded and replaced before each study.

## 5.2. Handling

Handle with care:

- Use only the designated case for transportation
- Store at room temperature, and avoid direct sun light
- Do not expose the WP200 to extreme temperature or humidity conditions (such as storing in a car or bathroom)

## 5.3. Replacing The Oximetry Sensor

Should it become necessary to replace the oximetry sensor, proceed as follows:

1. Carefully disconnect the oximetry sensor from the oximetry module on the wrist strap.

2. Carefully insert the connector of the new oximetry sensor cable to the oximetry sensor port in the oximetry module on the wrist strap (see Figure 13) noting proper alignment (3 round protrusions facing up).


**Figure 13 – Replacing Oximetry Sensor**

### 5.4. Replacing The PAT Probe Cable

To replace the PAT probe cable:

1. Carefully disconnect the PAT probe cable from the WP200.
2. Connect a new PAT probe cable by gently inserting the connector into the WP200, noting proper alignment (3 round protrusions facing up).


**Figure 14 – Replacing the PAT probe**

### 5.5. Replacing The Battery

| | |
|---|---|
|  | **Warning**<br><br>Replace the battery only with an authorized battery provided by Itamar Medical Ltd. |

In the event of a battery error message during the self-diagnostic tests or after charging, it may be necessary to replace the battery.

To replace the battery:

1. Open the battery compartment cover with a Phillips screwdriver.
2. Remove the battery.

3. Gently remove the connector from the connection port.
4. Insert the connector of the new battery into the port. It will slide in easily. Don't force the connector into the port. It may properly be inserted in only one direction.
5. Place the battery and connecting wire into the battery compartment.
6. Close the battery compartment cover and secure with the Phillips screwdriver.


**Figure 15 – Replacing the Battery**

## 5.6. Setting The Time and Date of the WP200

The WP200's Time and Date can be set through the zzzPAT application. Refer to the zzzPAT Software Manual for preparation of the WP200 for a new study.

## 5.7. Storing The WP200

- The WP200 should be stored in its carrying case at room temperature and low humidity.
- In order to preserve battery performance when the WP200 is not in use, store with the battery fully discharged. Before storing the WP200 allow it to deplete the battery charge until it shuts down automatically.

## 6. APPLYING THE WP200

| | |
|---|---|
|  | **Note**<br>These instructions are designed to help the patient use the WP200 **after** seeing a demonstration by trained personnel of how to mount the probes on his/her fingers and correctly operate the WP200. |

The following detailed instructions are summarized in the patient's step-by-step reference guide. They are written as if the reader is the patient using the WP200.

### 6.1. Preparing for use of the WP200

Before using the WP200, review the following notes:

- Remove all rings, watches and jewelry from your non-dominant hand and wrist.
- The probes may be worn on any two fingers of your non-dominant hand. We recommend that the oximetry sensor and PAT probe be attached to the ring and index fingers respectively (Figure 16). The following instructions relate specifically to these fingers. Patients with very large fingers may use their small finger (pinky) for the PAT Probe.
- Ensure that fingernails of fingers that will be monitored are well trimmed, (less than 1mm from nail bed) with no jagged edges. Clip and file nails, if necessary
- Remove artificial fingernails or dark nail polish from the monitored fingers

You may need some assistance putting on the WP200. If needed have someone present to assist you.

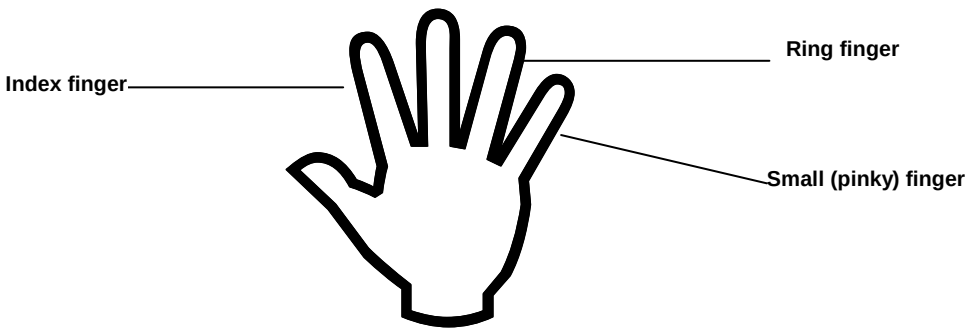



**Figure 16 – Finger Designation**

### 6.2. Applying The WP200

To apply the WP200 to your wrist:

1. Open the carrying case and take out the wrist strap with the WP200 mounted. All parts should already be connected, as illustrated in Figure 12.
2. Ensure that the WP200 is firmly seated in the wrist strap. If not, gently seat the WP200 in the strap by sliding it into its seating position. You will hear a click when the WP200 is properly seated in the strap.
3. Place the wrist strap with the WP200 on the non-dominant arm and close it snugly but not tightly. Ensure that the rounded end is towards the body and the open end towards the fingers. You may find it convenient to place the wrist strap with the WP200 face down on the table and then place the back of the wrist over the wrist strap in order to fasten the straps (Figure 17).
4. At this point both probes are hanging loose (Figure 18).

.

**Figure 17 – Putting On The Wrist strap**

**Figure 18 – Wearing WP200**

## 6.3. Applying The Oximetry Sensor

Now you will attach the oximetry sensor to your ring finger, as was demonstrated to you and is illustrated in the figures below.

### 6.3.1 Applying the Nonin 8000JFW Oximetry Sensor

If you are using the Nonin 8000JFW oximetry sensor proceed as follows:

1. Remove the adhesive strip from the unit (see Figure 19)
2. Position the oximetry sensor on your ring finger with the wire on the bottom side of the finger (see Figure 20) – the finger should reach the centerline marker on the pad
3. Fold the bottom short flaps around your finger (see Figure 20)
4. Fold top flap over the finger and fold the short flap around your finger (see Figure 21)
5. Complete this procedure by wrapping the long flap around the short wrapped flaps (see Figure 22).
6. Ensure that the dotted line of the Flexiwrap pad is properly located, as indicated by the arrow (see Figure 23), and that the two square black protrusions are opposite one another.
7. The oximetry sensor is now attached. When the WP200 is turned on, the sensor will glow red.

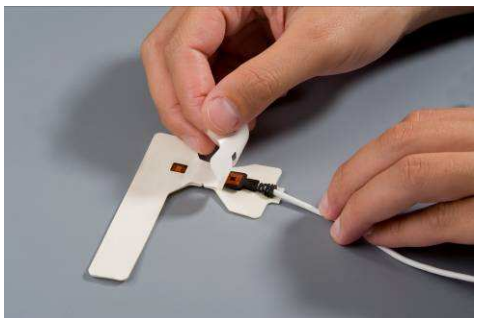


**Figure 19 – Removing Adhesive Cover**

**Figure 20 – Positioning Oximetry On Ring Finger**

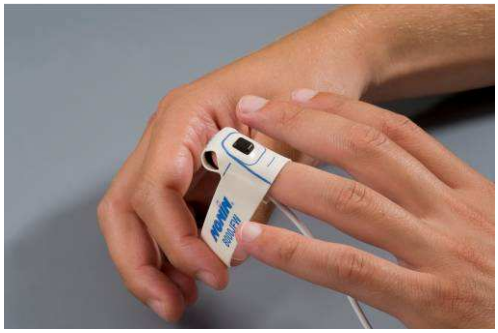


Figure 21 – Fold Top Flap and Short Flap

Figure 22 – Wrap The Long Flap

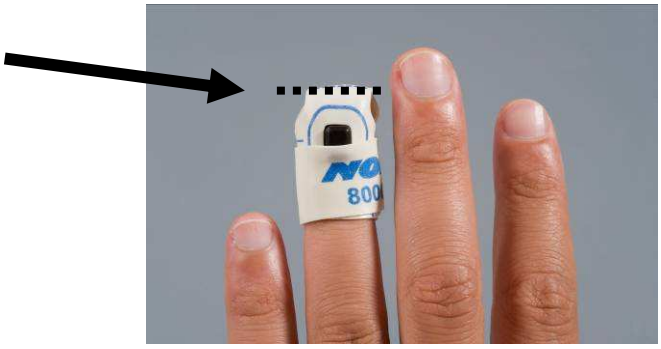


Figure 23 – Flexiwrap Line Indication

### 6.4. Attaching the PAT Probe

Proper probe placement is critical for good performance.

| | |
|---|---|
|  | **Note**<br><br>The tabs inside the probe should be removed only AFTER the finger is inserted into the probe. |

To attach the PAT probe:

1. Insert your index finger (or other if so instructed) gently into the probe until it reaches the end (see Figure 24).
2. Make sure that the paper tab marked TOP is above your nail and the tab marked BOTTOM is below your finger.
3. Detach and pull the tab marked TOP slowly and firmly towards the back of your hand, until completely removed from the probe (Figure 25).

4. Detach and pull on the tab marked BOTTOM slowly and firmly towards the back of your hand, until completely removed (Figure 26). You might feel a slight suction once the tabs are removed.

The PAT probe is now attached (Figure 27).

**Figure 24 – Placing Finger In PAT Probe**

**Figure 25 – Removing TOP Tab**

**Figure 26 – Removing BOTTOM Tab**

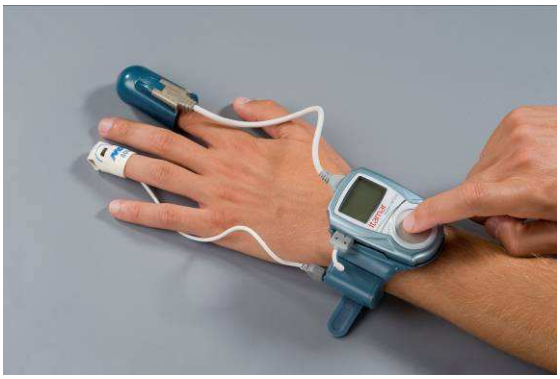


**Figure 27 – Wearing the WP200 – Ready for Sleep**

| | |
|---|---|
|  | **Note**<br>DO NOT remove the PAT probe before the night study is terminated. Once the probe is removed it cannot be re-attached. |

### 6.5. Switching On The WP200

You are now ready to switch on the WP200.

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

```
PATIENT      22:51

GOOD NIGHT!!!


Time elapsed=9:50
Recording…
```

| | |
|---|---|
|  | **Note**<br>To conserve the battery the LCD display will switch off after a few seconds. Pressing any button will restore the display for about 30 seconds. |

### 6.6. When You Wake Up

When you awake, remove the WP200 from your arm as follows:

1. Remove both probes from your fingers.
2. Take off the wrist strap.
3. Place all parts in the carrying case.

| | |
|---|---|
|  | **Note**<br>Pressing the center button does not switch off the WP200. The oximetry sensor red light will remain lit. Approximately ten hours after the WP200 is turned on, it will switch off. This is normal. |

### 6.7. Important Notes

Wearing the WP200 should not cause any discomfort or pain. If you experience wrist or arm discomfort, loosen up the wrist strap. If the discomfort is not alleviated immediately, call the service number.

- Do not attempt to 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 unit to an electrical supply or any other unit, 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.

# 7. PATIENT TRAINING – GUIDELINES

## 7.1. Walk Through The Process Of Using The WP200

- Product introduction – WP200, wrist strap, PAT probe, oximetry sensor
- WP200 and wrist strap attachment
- Probe and sensor attachment
- Switch on
- Ending the study

## 7.2. 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.

## 7.3. Applying The WP200

Use the Demo Kit.

- Demonstrate how to apply the WP200 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 finger nails are closely trimmed
2. **Wearing the Wrist Strap**
   - Should be comfortable, not too tight
3. **Attaching the WP200**
   - Make sure the WP200 is properly mounted on the wrist strap. If it is loose, gently slide it in until you hear a click.
4. **Attaching the oximetry sensor**

- Before PAT probe attachment
- If using the Nonin 8000FJW sensor, demonstrate proper placement of the finger on the Flexiwrap pad – note the position of the fold line, and that the two black square protrusions are opposite each other.
- Folding the flaps of the Flexiwrap pad to secure sensor properly.
- Make sure it is not too tight

5. **Attaching the PAT probe**
   - Insert finger all of the way into the probe
   - Remove the Tabs one by one by pulling slowly and gradually
   - Both tabs must be fully removed
   - The probe is limited to a SINGLE USE. Do not remove probe during the night.

### 7.4. Switching on the WP200

Demonstrate switching on the WP200 by pressing the round center button

- Push button firmly until the LCD display lights up
- The oximetry sensor light will glow red during the entire test

### 7.5. Removing The WP200

- Demonstrate how to remove the WP200 and place it back in the carrying case.
- The oximetry sensor light will keep glowing red.
- The WP200 doesn't switch off – once turned on it will record until the battery is exhausted.

### 7.6. Patient Training

Following your demonstration have the patient attach the demo device by himself.

Verify that the attachment is properly done. Especially monitor carefully attachment of the oximetry sensor.

### 7.7. Review Safety, General And Functional Issues

- Avoid exposing the WP200 to extreme conditions (high temperature, high humidity)

- Provide a telephone number to call in case of questions or problems.

# 8. TROUBLESHOOTING GUIDE

## 8.1. 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 | | |
| Loaded | | |
| Unloaded | File not loaded | Load file |
| Battery error % full | Battery defective or uncharged | Charge battery or replace |
| Probe error | | |
| Used | Probe previously used | Replace probe |
| Missing | Probe absent | Attach probe |
| Oximetry sensor error | | |
| No sensor | Sensor absent | Replace sensor |
| Disconnected | Sensor disconnected | Connect sensor cable to port |
| No communication | Module not connected | Check cable connection |
| Hardware status error code | WP200 defective | Consult Itamar or authorized representative |
| SBP discon | WP200 defective | Consult Itamar or authorized representative |
| RTC faulty | WP200 defective | Consult Itamar or authorized representative |
| Short recording time | Patient removed the WP200 or probe from hand prematurely | Explain proper use to patient |
| | Insufficient battery charge caused early termination of recording | Recharge battery and try again |
| | Damaged WP200 | Contact your authorized sales representative |

## 8.2 Patient Error Messages

If an error message is displayed when the patient powers on the WP200, 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 |
|---|---|---|
| Oximetry sensor light turns off while WP200 is on. | Oximetry sensor plug not fully inserted | Verify that oximetry sensor plug is fully inserted into the WP200 |
| | Faulty oximetry sensor | Check the oximetry sensor probe for damage and replace if necessary |
| Oximetry sensor disconnected | Sensor not properly connected or faulty | Check connection. If problem persists replace sensor |
| WP200 doesn't switch on | ON button not activated | Press the ON button firmly for at least 3 seconds |
| | PAT 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 WP200; check if probe has been previously used and replace with new probe if necessary |
| Hardware code | WP200 failure | Contact Itamar or authorized representative |

## 9. SPECIFICATIONS

**Table 3 – WP200 Specifications**

| **Properties** | | **Description** |
|---|---|---|
| PAT Probe | | Itamar's proprietary probe only |
| Recording Time | | 10 hours (minimum) |
| Oximetry Probe | | Custom Nonin 8000J Flex Sensor |
| Channels | | Measuring 4 signals: PAT, Pulse rate, Oximetry, Actigraphy |
| Sample Resolution | | PAT and Actigraph – 12 bit; oximetry – 1% |
| User Interface | | LCD display |
| Accuracy | *Pulse rate*<br>*Amplitude*<br>*Oximetry* | 30-150 ± 1 bpm<br>0-1V 1%<br>70-100% ± 1% |
| PAT Channel | *Fixed Gain* | 600 |
| | *Fixed Offset* | 1.5 Volts |
| | *Bandwidth* | 0.1-10 Hz |
| Data Storage | *Media* | Micro SD card |
| | *Capacity* | 64 MB (minimum) |
| | *Format type* | Formatted to FAT 32 |
| Power Supply | *Battery* | Proprietary, rechargeable Lithium Ion Battery |
| | *Capacity* | > 500-700 mAh |
| | *Cell Type* | Lithium Ion cell type |
| | *Internal Charger* | Proprietary Lithium Ion battery charger |
| | *External Power Supply* | 5V DC, 5W with USB connector |
| Operating Voltage | | 3.3 V |
| Temperature | *Operation* | Room temperature |
| | *Storage* | 0 – 50 $^0$C |
| Humidity | *Operating & Storage* | 10% – 60% (non-condensing) |
| Dimensions | *L x W x H* | 80 x 50 x 20 mm |
| | *Weight* | 0.13 kg |

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## 8 SEVERABILITY

Should any term or provision of this License Agreement be declared void or unenforceable by any court of competent jurisdiction in any country or countries, such declaration shall have no effect on the remainder of this License Agreement in such country or countries, or on this License Agreement in other countries.

## 9 NO WAIVER

The failure of either party to enforce any rights granted to it hereunder or to take action against the other party in the event of any breach hereunder shall not be deemed a waiver by that party as to subsequent enforcement actions in the event of future breaches.

## 10 GOVERNING LAW AND JURISDICTION

This License Agreement is governed by the laws of the State of New York, excluding its conflict of laws principles. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to any of the transactions contemplated by this License Agreement.

# 11 ENTIRE UNDERSTANDING

This License Agreement represents the complete and exclusive understanding between you and Itamar concerning the license by Itamar to you of Licensed Software and Licensed Products and supersedes all prior agreements and representations between the parties with respect to the subject matter hereof, unless specifically stated otherwise in a writing signed by Itamar and you. This License Agreement may not be amended other than by a written agreement specifically intended for this purpose and signed by Itamar and you.

Note: Should you have any questions concerning this License Agreement, or if you desire to contact Itamar for any reason, please write to: Itamar Medical Ltd., 9 Halamish St., Caesarea, 38900, Israel, Facsimile: +972-4-627 5598, or visit Itamar's web site at www.itamar-medical.com.

# APPENDIX B: REGULATORY REPRESENTATIVE

Itamar Medical's authorized regulatory representative is:

MEDES LIMITED
5 Beaumont Gate, Shenley Hill,
Radlett, Herts WD7 7AR
England
Tel: +423-663-169205
Tel / Fax: + 44 1923859810

# APPENDIX D: DESCRIPTION OF THE WATCH-PAT PROBE

The Watch-PAT 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 Watch-PAT 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 Watch-PAT probe is an integral part of the Watch-PAT device.

APPENDIX E: MANUFACTURING DECLARATION ACCORDING TO IEC 60601-1-2

# Manufacturer Declaration According to IEC 60601-1-2

## Electromagnetic Emissions

| The Model Watch-Pat 200 (WP-200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Watch-Pat 200 (WP-200) should assure that it is used in such an environment. | | |
|---|---|---|
| **Emissions Test** | **Compliance** | **Electromagnetic Environment Guidance** |
| RF Emissions CISPR 11: 2004 + A2: 2006 | Group 1 | The Model Watch-Pat 200 (WP-200) 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. |
| RF Emissions CISPR 11: 2004 + A2: 2006 | Class B | The Model Watch-Pat 200 (WP-200) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

# Manufacturer Declaration According to IEC 60601-1-2

## Electromagnetic Immunity

The Model Watch-Pat 200 (WP-200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Watch-Pat 200 (WP-200) should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ± 6 kV Contact<br>± 8 kV Air | ± 6 kV Contact<br>± 8 kV Air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the Watch-Pat-200 (WP-200), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended Separation Distance**<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>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 metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range [b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio (AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Watch-Pat 200 (WP-200) is used exceeds the applicable RF compliance level above, the Watch-Pat 200 (WP-200) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Watch-Pat 200 (WP-200).

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.