



Step by Step Guide

WatchPAT™ 300

Home Sleep Test

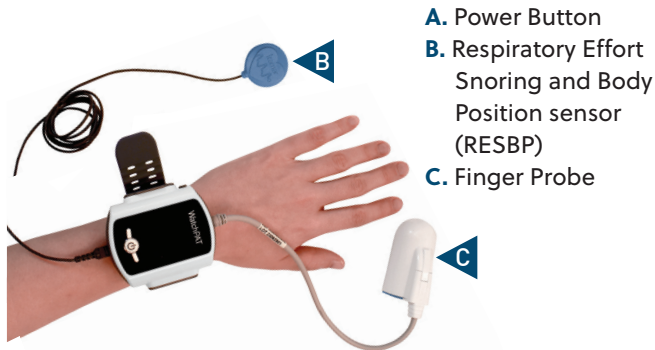


For an instructional video go to:
www.watchpat-howtouse.com

ZOLL itamar®

WatchPAT™ 300 - Step by Step Guide

This guide is to be used after your practitioner has showed you how to use the WatchPAT™ 300 device.



Before applying the WatchPAT™ 300:

- It is recommended to apply the WatchPAT™ 300 device to your non-dominant hand.
- Probe can be worn on any finger, except the thumb. If you have large fingers, the pinky is recommended.
- Before use, remove tight clothes, rings, watches and other jewelry.
- Remove nail polish and artificial nails from the test finger and make sure the fingernail is cut short.

Notes:

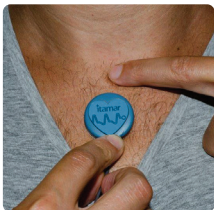
- Once you have turned on the WatchPAT™ 300 device, it cannot be turned off.
- Apply the device and turn it on only when you are ready to sleep.
- Adult supervision may be required to apply the device.
- Images in the demonstrated guide are for the left hand; similar process can be applied for the right hand.

The carrying case contains:

- This reference guide.
- Device with Finger Probe.
- Respiratory Effort Snoring and Body Position sensor (RESBP).



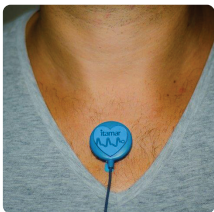
+ Step 1 - Applying the Respiratory Effort Snoring and Body Position sensor (RESBP)



- 1a.** For men: trim thick chest hair, if needed.
- 1b.** Take the RESBP Sensor through the sleeve of your night shirt up to the neck opening.



- 1c.** Peel the white paper from the back of the sensor.



- 1d.** Attach the sensor to the center of your upper chest bone, just under the sternal notch. Make sure the image on the RESBP sensor is upward facing.



- 1e.** Secure the RESBP sensor with additional medical tape.

+ Step 2 - Applying the WatchPAT™ 300 Device



- 2a.** Strap the device to your non-dominant hand.
- 2b.** Close wrist strap (not too tightly).

+ Step 3 - Applying the Finger Probe

- 3a.** Probe can be worn on any finger, except the thumb. If you have large fingers, the pinky is recommended.



- 3b.** Insert the finger into the probe until you feel the bend. The sticker marked TOP should be on the top of your finger (Above the nail).



- 3c.** Press the tip of the probe against a hard surface (i.e. table, leg).
- 3d.** Pull and remove the TOP tab completely out of the probe.

+ Step 4 - Turning ON the Device

Note: The device should only be turned on when you are ready to go to sleep.



- 4a.** Press firmly on the Power button until the display lights up. Next screen "Please wait Testing..." After a few seconds "GOOD NIGHT!!!" ✓ message will appear. The display will turn OFF after a short period. You are now ready to go to sleep.
- 4b.** In the case there is a problem, "TEST ABORTED" ✗ will appear, call Help Desk.
- 4c.** In the case your finger is not inside the probe, an error appears instructing you to insert the finger. Wait till the device turns off, insert finger and try again.

+ Step 5 - During the night



- Anytime you press on the button, the display will light up for a minute.
- If you need to get up during the night, do not remove the device or sensors.
- Do not press any buttons if you need to get up during the night.
- If using the bathroom, do not get the WatchPAT™ 300 wet.
- The WatchPAT™ 300 should not cause any discomfort or pain. Should you encounter unbearable discomfort, remove the device and call the help desk.

+ Step 6 - Next Morning

When you wake up:

- 6a.** Device will turn off automatically. There is no OFF button.
- 6b.** Remove the finger probe and the RESBP sensor
- 6c.** Take off from your wrist.
- 6d.** Insert all parts back into the carrying case.

Important Notes

- 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 other device, machine or computer.
- Do not use WatchPAT™300 near or on top of another device.
- Do not, under any circumstances, attempt to fix a problem by yourself.
- The finger probe is for a single use. In case used probe is connected an error message will appear. Please be aware that utilizing used probe can cause cross contamination, potentially leading to infection and/or patient injury.
- In any case of serious incident or harm, contact the ZOLL Itamar™ Help Desk and report the incident to the competent authority of your country.
- 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 ZOLL Itamar™ Help Desk.
- Before using the WatchPAT™300 the patient should be trained by the clinical staff.
- For professional user manual see <https://www.itamar-medical.com/support/manuals>.

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/PAHlc. The WP300's PSTAGES, snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

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

Restrictions for Use

1. The WatchPAT™ 300 should be used only in accordance with a physician's instructions.
2. 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.
3. The WatchPAT™ 300 is used as an aid for diagnostic purposes only and should not be used for monitoring.
4. 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.
5. The "Step-by-Step Reference Guide" for the patient should be carefully followed when attaching the unit to the patient.
6. The WatchPAT™ 300 is not indicated for patient with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT™ 300 device.
7. The WatchPAT™ 300 is not indicated for children less than 12 years old.

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.

Additional Precautions specific to pediatric use

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.

Specifications:

Properties	Description	
Recording Time	Approx. 10 hours	
Channels	PAT, Pulse rate, Oximetry, Actigraphy; In configuration with Respiratory Effort Snoring and Body Position sensor: Snoring, Body Position (5 discrete states: supine, prone, right, left and sit), Chest Movement	
Temperature	Operation	0°C to 40°C
	Storage	0°C to 40°C
Humidity	Operating	10% - 93% (non-condensing)
	Storage	0% - 93% (non-condensing)
Atmospheric pressure	Operating & Storage	10 - 15 psi

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 Table:

Performance characteristics	
AHI	AUC:0.953 (AHI threshold = 15), Linear Regression: $r=0.9$, $p<0.001$ Sensitivity/Specificity: 85%/88.2%
AHlc (Central Sleep Apnea)	AUC: 0.913 (AHlc 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%

If you have any questions or in
the event that the system does
not operate properly,
contact ZOLL Itamar™ Help Desk at:

 1-888-748-2627 

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Caution: US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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