

WatchPAT™ ONE

Disposable Home Sleep Apnea Test

WatchPAT™ ONE Green Program

To take part in the WatchPAT™ ONE Green Program*, here's all you need to do once you've completed your sleep test:

1. Remove the battery from the WatchPAT™ ONE device and return the device to its box.
2. Visit: www.itamar-medical.com/greenprogram fill out the form, and print out the pre-paid return label.
3. Affix the label to the box and ship it back to us - completely free of charge.

Thanks for helping to make a greener world!

*WatchPAT™ ONE Green Program is available in certain countries.

⚠ Important Notes:

- The WatchPAT™ ONE is Single Use. Re-use of single use products may cause cross contamination, potentially leading to infection and/or patient injury.
- 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.
- 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, under any circumstances, attempt to fix a problem by yourself.
- The WatchPAT™ ONE 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.
- Visually inspect the battery before insertion, to ensure it is not swollen, cracked, leaking or has other defect.
- Before using the WatchPAT™ ONE the patient should be trained by the clinical staff.



For step-by-step video instruction please visit watchpatone-howtouse.com





If you have any questions or in the event that the system does not operate properly, contact Itamar™ Medical Help Desk at: **1-888-748-2627**

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Step by Step Instructions Guide

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Download on the App Store

Scan the QR code to download the WatchPAT™ Application



GET IT ON Google play



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WatchPAT™ONE | Step by Step Instructions Guide | Disposable Home Sleep Apnea Test

This guide will take you step by step and show you how to correctly use the WatchPAT™ONE Home Sleep Apnea Test.

Before applying WatchPAT™ONE:

- ✦ Make sure you have internet access, your phone, WatchPAT™ONE device, and PIN code (only if supplied by your healthcare provider).
- ✦ Remove tight clothing, jewelry and accessories.
- ✦ Select a finger on your non-dominant hand, except the thumb (if you have large fingers, use the pinky).
- ✦ Trim the fingernail and remove any nail polish or artificial nail from the selected finger.

Note: Use only Alkaline AAA battery.


Do not insert the battery until you are ready to go to bed.

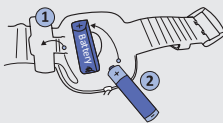
1. Take out the WatchPAT™ONE from the box. Download the WatchPAT™ application to your phone (available on App Store and Google Play Store).

2. Open the WatchPAT™ app and allow all permissions requested. These permissions are necessary to conduct the sleep test. If requested, enter your mobile number in order to begin. You may click the quick guide link for a tour of the app demonstrating how to set up the WatchPAT™ONE device.

Press "Begin Setup" button when ready.


Begin setup

3. Insert the battery into the WatchPAT™ONE device. Press  when done.




4. Preparation:


- Make sure your phone stays plugged in overnight and is not in flight mode.
- Turn off any unnecessary electronic devices in the room.
- Make sure your phone is located no more than 15 feet/5 meters from the WatchPAT™ONE device.
- At least 6 hours of data recording is required.

5. If required, enter the 4-digit PIN code provided by your physician's office or provider, and press .



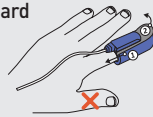
6. Put the WatchPAT™ONE device on your non-dominant hand. Ensure it is not too tight and not too loose. Press  when done.



7. If your WatchPAT™ONE device includes a chest sensor:
 - If needed, trim chest hair to ensure the sensor is attached directly to your skin.
 - Slide the chest sensor through your sleeve and up to the neck opening.
 - Peel the white paper from the back of the sensor.
 - Attach the sensor to the center of your upper chest bone, just under the sternal notch.
 - It is recommended to secure the sensor in place using medical tape. Press  when done.



8. Insert the tested finger all the way into the probe. Make sure the sticker marked TOP is visible when looking at the back of your hand. Push the tip of the probe against a hard surface (such as a table) and slowly pull back the TOP tab to remove it from the probe.



9. Click the "Start recording" button to begin your sleep study. Make sure to leave your phone connected to the charger. You may use your phone as usual however do not close the application.

Start recording

10. In the morning, press the "Stop Recording" button and wait for WatchPAT™ONE device to complete the data transmission. After completing the data transmission you will receive a congratulations message. Once received press "Close App".

Stop recording

Close App

11. Remove the chest sensor, probe and WatchPAT™ONE device. Dispose of the WatchPAT™ONE device in accordance with local regulations.

Intended Use / Indications for Use:

The WatchPAT™ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 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 WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHlc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHlc. The WP1'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™ONE 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™ONE 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™ONE 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 instructions should be carefully followed when attaching the unit.
6. The WatchPAT™ONE is not indicated for patient with injuries, deformities or abnormalities that may prevent proper application of the WatchPAT™ONE device.
7. The WatchPAT™ONE is not indicated for children less than 12 years old.

Precautions

The WatchPAT™ONE 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™ONE 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.

WARNING:

- Do not use WatchPAT™ONE near or on top of another device.
- Do not place portable RF communications equipment (such as monitors, tablets and cellphones) closer than 30 cm (12 inches) from any of WatchPAT™ONE parts since it could cause degradation of the device performance.

NOTE: For Professional Use Manual, see <https://www.itamar-medical.com/support/manuals>

Specifications:

Properties	Description	
Recording Time	Approx. 10 hours	
Channels	PAT, Pulse rate, Oximetry, Actigraphy; In configuration with Chest 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
Mobile phone	Operation system	Android 6.0 minimum, iOS 12 minimum
	BLE Version	4.0
	Network	Wi-Fi/Cellular

Clinical benefits of the WatchPAT™ONE:

1. Ambulatory device for aiding in the diagnosis of sleep disorders in a home setting.
2. Reduces the need of in lab examination.
3. 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.
7. Reduces logistics – wireless and single use nature enable immediate results to the physician.

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%

* additional small dataset