# WatchPAT™ Indications for Use & Exclusion Criteria

## Intended Use / Indications for Use

The WatchPAT™200U (WP200U) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200U 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 WP200U generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position (SBP) sensor.
The WP200U's PSTAGES and SBP provide supplemental information to its PRDI/PAHI. The WP200U's PSTAGES and SBP 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. The WatchPAT™200U device is not indicated for children less than 12 years old.

## Exclusion Criteria

The WatchPAT™200 device 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).**

Additional info: Patients on these medications should have a 3 hour washout period prior to their sleep study, regardless of the medications' half life times.
A widely used clinical study by Zou D *et al*[1] demonstrated that clinical use of the WatchPAT device was accurate and reliable, even for patients treated with clinical dosage of Doxazosin (a commonly used a-blocker used for high blood pressure and benign prostatic hyperplasia (BPH) treatment).
Accumulated experience with hundreds of thousands of WP tested patients further supports the accuracy of WatchPAT.
The same washout can be assumed for alpha agonists, to which the exclusion criteria are not applied.

**2. Permanent pacemaker: atrial pacing or VVI without sinus rhythm.**
Additional info: For patients whose pacing is based on sinus node rhythm the WP ability to accurately diagnose sleep apnea and additional indices will unlikely to be impacted.
In other patients with "on demand" pacemakers, paced time periods will be excluded from the test analysis (using automated algorithm or manually), sufficient non paced time will generate a valid sleep report.
Only patients with permanent pacing should avoid use of the WatchPAT, as their study data may be invalid.

**3. Sustained* non-sinus cardiac arrhythmias.**
* In cases of patient having accumulative time of regular R-R intervals of less than 1.5 hours, the WatchPAT™200U system will not have sufficient valid PAT® signal as required to generate a sleep report

Additional info: WP algorithms may automatically exclude certain invalid time periods from the test analysis, in order to generate a valid sleep report. in particular, the WP algorithms will exclude periods in which the heart rate changes drastically from one beat to the next.
Most A-fib related episodes of changes in beat-to-beat rate are small enough to be reliably included in the test analysis.
A recent study validated that the presence of AF did not cause significant non-valid PAT signal and that the WatchPAT can work accurately in patients with Afib.

**4. THE WP200U IS NOT INDICATED FOR CHILDREN WHO WEIGH LESS THAN 65 LBS.**

## Restrictions and Precautions (highlights)

1. The WatchPAT is a prescription device. Federal (U.S.) law restricts this device to sales by, or on the order of, a licensed healthcare practitioner.
2. PAT Respiratory Disturbance Index (PRDI) is indicated for patients 17 years of age or greater

**For full list of restriction and precautions, please refer to the WatchPAT operation manual.**


[1] Zou D, Grote L, Peker Y, Lindblad U, Hedner J. Validation a portable monitoring device for sleep apnea diagnosis in a population based cohort using synchronized home polysomnography. *Sleep*. 2006;29(3):367-374

REF MM219870