Health Technology Review	
Technology Ref.:	HTA22062
Technology Name:	WATCH PAT ONE, DEVICE
Approvals by International Bodies:	**510(k) FDA**
Company name:	**FIRST CURE DRUG STORE - SOLE PROPRIETORSHIP L.L.C.**
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Short Description of the Technology:	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). The WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WatchPAT™ONE chest sensor provides snoring level, body position and Central Apnea Hypopnea Index ("PAHIc"). The WP1's PSTAGES, snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. 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. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older. The WatchPAT is a wearable device, worn on the wrist, that is utilizing 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 Finger Probe also measures RED and IR (Infra-Red) signals, which are used for the measurement of SpO2 signal. In the WatchPAT™ONE with a chest sensor, the Snoring, Body Position and the subject's chest movement signals are recorded by the integrated Chest Sensor. The recorded data is transmitted to an application on a mobile phone and is then stored on a Web Server. Following the sleep study, the recordings are automatically downloaded and analysed in an offline procedure using the proprietary zzzPAT software. The zzzPAT algorithms use the WatchPAT channels for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). zzzPAT uses WatchPAT's snoring and body position channels to generate snoring level and body position discrete states. The software issues comprehensive reports of the study, with statistics and graphic presentation

	of the results. The night data can be viewed and the automatically detected events can be revised manually. The WatchPAT™ONE is a fully disposable unit.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

WatchPat is an innovative diagnostic Home Sleep Apnea Test (HSAT) that utilizes the peripheral arterial tone signal. The WP1 device consists of the following: (1)unified finger PAT probe that was used in WP300 to measure the PAT and oximeter signals; (2)Actigraph which provides a signal that is used to determine periods of sleep/wake based on the motion of the wrist; (3)electronics, except for an antenna added in the WP1's PCB to support BLE communication; (4)chest sensor (RESBP) to measure snoring level, body position and chest movements; and (5) zzzPAT Software and algorithm to analyze the data. The device measures up to 7 channels (PAT® signal, heart rate, oximetry, actigraphy, body position, snoring, and chest motion) via sensors on the wrist, chest and finger. It is a typically used to assess obstructive sleep Apnea, a common sleep disorder characterized by interrupted breathing during sleep. The WatchPAT ONE generates report & transmits data to a licensed physician who reviews the information to diagnose patient condition. The technology used in U.S., Japan, and some European countries.

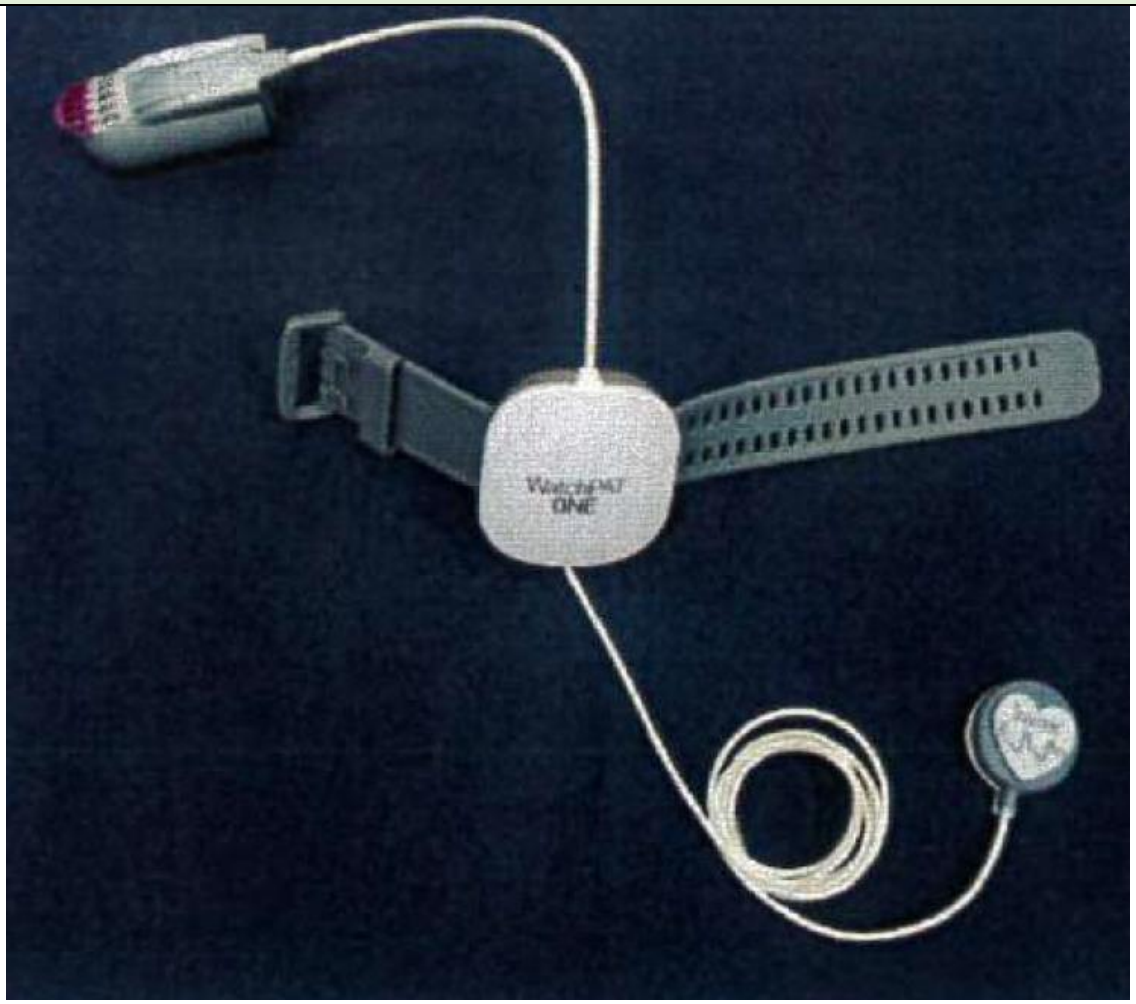
Advantages	Disadvantages
The device is FDA approved and CE marked; it measures biological signals to help identify sleep Apnea ; The WatchPAT ONE uses three sensors to monitor and record seven metrics that doctors use to diagnose Sleep Apnea.	A home test does not capture the same amount of data as an in-lab test (less accurate).
There are no safety concerns or risks on the patients nor healthcare professional; no evidence of device recalls or safety alerts.	Inconclusive results may require an in-lab sleep study, negating the cost-effectiveness.
Accessibility and affordability; WatchPAT ONE can be a more convenient and less expensive . It is an option for people who are reluctant to participate in a lab-based sleep study & provide a conv low-cost alternative in some cases.	Many home sleep test devices are designed to beep when a sensor falls off, or something is amiss with the equipment. If an error occurs throughout the night, the beeping can wake the patient causing more interrupts and inaccurate readings.
The WatchPAT One generates a report that helps to take a look at the patient's sleep architecture, getting an understanding of how Apnea is disrupting their sleep.	Home sleep tests do not rule out sleep Apnea. In fact, HSTs are not necessarily meant to detect the presence of sleep Apnea but aim to diagnose the severity of the disorder. If it is a mild to moderate OSA, it might also be referred for a PSG in the office to capture more sensitive Apnea events.
The WatchPAT One is one-time use, it is a fully disposable and not used from patient to patient.	User error may cause the test to be less accurate than claimed.

We recommend an **approval of using this technology** with the following conditions:

1. Approval on the use of "WATCH PAT ONE" as Home Sleep Apnoea Test under the supervision of the healthcare professional taking into consideration the device limitation.
2. The technology is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder nor prescribing treatment.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "WATCH PAT ONE, DEVICE"

- **Population/ Intended User**;
  - Patient with Sleep Apnea/ patients suspected to have sleep related breathing disorders.
- **To be prescribed by**:
  - By Healthcare Professionals.
- **Clinical Setting:**
  - NA
- **Condition of use:**
  - As per the device manual
- **Exclusion criteria:**
  - WATCH PAT ONE can be used only for the screening/diagnosis of moderate to severe OSA without other comorbidities like cardiovascular disease, stroke, or other conflicting medical issues.