Device Name: Sleep Watch®

Classification: Class 2

Device Description:

The Sleep Watch® is a wrist-worn device that monitors activity, temperature, cardiovascular and light exposure, it can be used to analyze sleep quantity and quality, circadian rhythms, evaluate heart health, automatically collect and store data for sleep parameters, heart rate, heart rate variability, and assess activity, intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders based on Actigraphy and Photoplethysmography (PPG) recordings, typically collected during sleep.

The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and circadian rhythms for the use by or on the order of physicians, trained technicians, or other healthcare professionals.

The Sleep Watch System is intended for use on a general-purpose computing platform, it does not issue any alarms.

The Sleep Watch® system consists of:

- The Sleep Watch® built-in with accelerometer, gyroscope, PPG, temperature, and light sensors, as well as BLE and WiFi chips.
- The Sleep Watch® collects raw data from each sensor.
- The Sleep Watch® processes signals with filters and stores raw data in eMMC storage.
- Psychomotor Vigilance Task (PVT)
- An App manages the Sleep Watches
- A web Application Programing Interface (API) to allow authenticated users to upload data collected form Sleep Watch® to AMI Cloud Platform
- A database to store the input, intermedium output, final output and associated data.
- A web-based database API to access the database and get outputs.
- A dashboard, a web-based user interface, to display, retrieve, manage, edit, verify, and summarize Sleep Watch® outputs.
- Proprietary algorithms to analyze actigraphy and PPG raw data.
- A reporting API to generate sleep reports.

The Sleep Watch System is intended for patients in the home environment for passive, noninvasive, data collection of physiological parameters that will later be transmitted to a SaaS platform for remote review by a clinician. The Sleep Watch® device is intended for use in infants and older.

The Sleep Watch System measures and records:

- PPG (Red, Green, Infrared) raw data
- Accelerometer (X, Y, X) and Gyroscope (Vx, Vy, Vz) raw data
- Light (R, G, B) data
- ZCM (Zero Crossing Mode)
- PIM (Proportional Integrating Measure)
- Estimate Sleep and Wake
- PVT test results
- Skin Temperatures
- Heart rate (HR)
- Heart rate variability (HRV)
- Respiration rate (RR)

The Sleep Watch device does not provide physiological alarms.

The Sleep Watch System generates sleep and other parameters for various interval types as per the predicate analysis software ActionW. These interval types include: DOWN (major sleep periods marked manually, automatically or semi-automatically); UP (all full or partial non-DOWN intervals); CUSTOM (separate intervals marked manually or according to an activity or time-based rule); and 24-Hr (daily time-based intervals with a selectable start time); O-O the time from sleep Onset (as defined by the LPS, latency to persistent sleep) to sleep Offset (the end of the last sleep episode in the Down Interval). For each interval type, the user should be able to select for reporting from amongst the following variables that can be calculated with only a Sleep/Wake estimate:

File ID	name of file from which statistics have been generated
Interval Type	See Descriptions below
Activity Mode	ZCM (frequency), TAT (duration), or PIM (intensity) of movement
Start Day	Start Day of Interval
Start Date	Start Date of Interval
Start Time	Start Time of Interval
End Day	End Day of Interval
End Date	End Date of Interval
End Time	End Time of Interval
Midpoint	Midpoint time of interval
Duration	Minutes from start to end of interval
Activity Mean	Mean activity score (counts/epoch)
Activity Median	Median activity score (counts/epoch)
Activity SD	SD of Activity Mean
Wake Minutes	Total minutes scored as Wake
Sleep Minutes	Total minutes scored as Sleep
Percent Sleep	Percent minutes scored Sleep (100*(Sleep minutes)/Duration)
Sleep Efficiency	(100* Sleep Minutes/(O-O Duration))

Sleep Onset Latency	Minutes to the first epoch scored sleep (no duration criteria applied)
Latency to Persistent Sleep	Minutes to start of 1st 20-min block with >= 19 min sleep OR Minutes to the start of the 1st 10-minute block with >= 9 min sleep
Wake after Sleep Onset	Wake min during O-O interval
Acceleration Index	Change in activity rate during interval
Activity Index	% epochs with >0 activity value
Sleep Fragmentation Index	Number of Awakenings / TotalSleepTime (in Minutes) * 100.00
Brief Wake Ratio	Brief Wakes (duration of 1 min or less) / Number of Awakenings (Wake Episodes)
Short Burst Inactivity Index	Number of episodes of zero recorded activity lasting one minute / Number of episodes of zero recorded activity lasting any amount of time * 100.00
Bad Epochs	Total epochs marked as bad
Wake Episodes	number of blocks of contiguous wake epochs
Mean Wake Episode	Mean duration of Wake Episodes (minutes)
Long Wake Episodes	Number of Wake Episodes >= duration in Options: Sleep: Sleep Statistics Criteria text box
Longest Wake Episode	Duration of longest Wake Episode (minutes)
Sleep Episodes	Number of blocks of contiguous sleep epochs
Mean Sleep Episode	Mean duration of Sleep Episodes (minutes)
Long Sleep Episodes	Number of Sleep Episodes >= duration in Options: Sleep: Sleep Statistics Criteria text box
Longest Sleep Episode	Duration of longest Sleep Episode (minutes)
Lowest Light measurement	
Highest Light measurement	
Light measurement mean	
SD of Light Mean Lux	
Minutes above 20 Lux	
Minutes above 500 Lux	
Minutes above 1000 Lux	
Minutes above 10000 Lux	
% of interval above 20 Lux	
% of interval above 500 Lux	
% of interval above 1000 Lux	
% of interval above 10000 Lux	

Additional metrics should be added that take into account the system's eventual ability to do sleep staging. Among these are:

- Light sleep occurrences
- Total Stage Changes (after sleep onset)
- Stage Summary: Latency, Duration, %TST

The Sleep Watch allows for on-wrist and/or in-App rating scales (0 to 10), with experimenter selectable initial value (0,5,10) and/or questionnaires (each limited by the constraints of readability). These features should be on-demand, according to an experimenter selected schedule, or both.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception,
which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction