Introduction to SleepImage®

Medical grade measurement of objective sleep quality and sleep pathology

SleepImage is FDA cleared Medical Software that accurately and objectively measures sleep quality, sleep duration and sleep pathology based on single-lead electrocardiogram (ECG) recordings.

SleepImage has been extensively researched and widely published in many peer-reviewed clinical papers over the last 15 years. It is a cost-effective and user-friendly patented technology that can be broadly used in clinical practices. SleepImage identifies Cardiopulmonary Coupling (CPC), the synchronization of heart rate variability and breathing activity, Cyclic Variation of Heart Rate (CVHR), a known cardiovascular reaction to paused breathing and actigraphy that can help identify positional sleep disorders.

SleepImage has the only FDA cleared measure of sleep quality based on sleep stability, sleep fragmentation, sleep duration, and sleep pathology which is displayed as the Sleep Quality Index (SQI). Using SleepImage in clinical practice is intuitive for both clinicians and patients, similar to the routine measurement of blood pressure, heart rate, weight and temperature. SleepImage has medically-actionable sleep metrics, driven by objective physiological biomarkers and is cleared to evaluate sleep disorders to inform or drive clinical management (aid diagnostic decisions).

SleepImage provides:

» An FDA cleared objective unit of measure for sleep, the Sleep Quality Index (SQI) summarizes sleep quality, sleep quantity and sleep pathology on a scale of 0–100.

» A decision-assist tool to aid clinical decision making to evaluate the type and severity of sleep disorders.

» Interactive graphs where the user can focus on any part of the sleep study, turn frequency displays on and off to examine only on one sleep state at a time and cut out segments with poor signal quality.

» A detailed overview of raw data including ECG, Heart Rate, Respiration, Actigraphy, Heart Rate Variability and Snoring can be individually analyzed across the entire sleep study in step intervals between 10 sec and 4 min.

Clinical benefits:

» An objective and accurate measure of sleep quality, the Sleep Quality Index (SQI).

» An objective and accurate indicator of sleep breathing disorders, the Sleep Apnea Indicator (SAI).

» Phenotypes sleep breathing disorders between obstructive vs. non-obstructive (central) types.

» Dynamically track sleep quality, sleep quantity and sleep pathology over time to help determine therapy efficacy

» Identify patients at risk for comorbid diseases

» Operator-independent output to use in combination with detailed patient history in evaluating the effect of treating sleep pathology to manage comorbid disorders.

How does SleepImage work?

The SleepImage system works on a secure cloud-based website where the data is uploaded, automatically analyzed and presented with a "decision-assist" tool to aid clinical decisions.

What is CPC?

CPC is an algorithm that uses mathematical analysis to determine the synchronization between modulations of heart rate variability and respiration. A list of published peer-reviewed clinical papers is available at www.sleepimage.com/research.

SleepImage data presentation

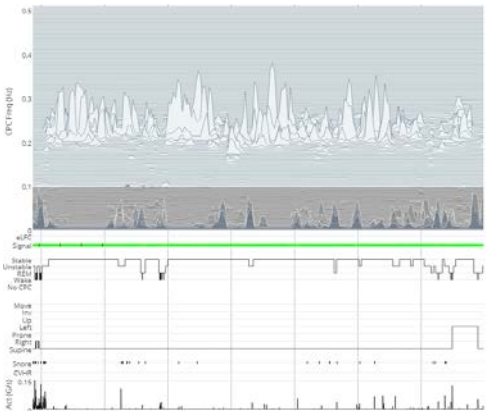
The SleepImage report is designed for ease of use in clinical settings. An overview of sleep results are displayed: sleep quality, sleep duration and an auto generated visual marker of sleep pathology for the evaluation of the presence, nature and severity of a sleep disorder. This decision-assist feature is not a diagnosis of a sleep disorder.

Good sleep

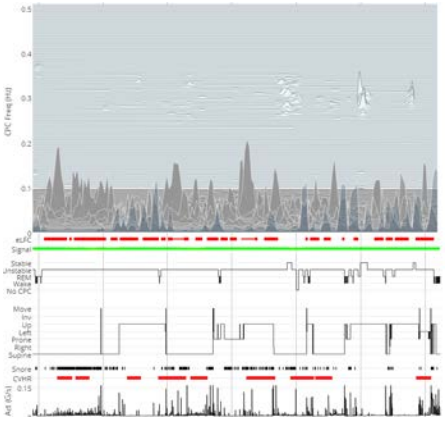
Poor sleep

Additionally, there is graphical presentation of the coupling of heart rate variability and respiration called a sleep spectrogram. In the frontal-view spectrograms, time (hours) is on the horizontal axis, and frequency (Hz) is on the vertical axis. When both data streams are in-phase (coupled), peaks are generated. The graph presents stable sleep as white peaks in the higher frequency range, while unstable sleep is presented as gray peaks in the lower frequency range. REM sleep and Wake are presented in the lowest frequency range as dark gray peaks.

Good sleep

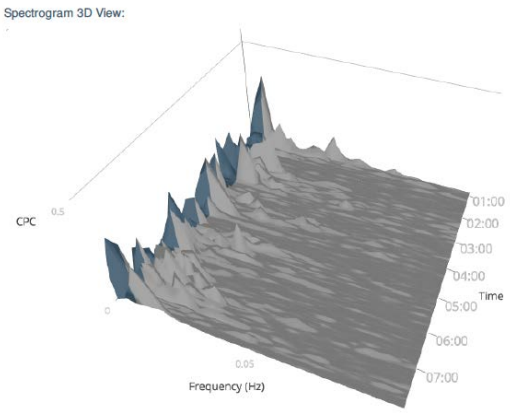


Poor sleep

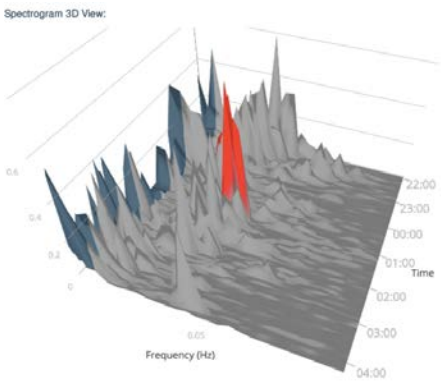


The SleepImage system also offers a 3D view of the spectrogram to phenotype obstructive, central, and complex sleep apnea. Strong chemo reflex modulation of breathing during sleep imposes a repeated metronomic pattern of oscillations in numerous signals. This metronomic pattern, displayed as red peaks, is defined as elevated narrow-band low-frequency coupling (e-LFC$_{nb}$) and is associated with periods of central sleep apnea.

Good sleep



Poor sleep



For Further Information

For further information about SleepImage and CPC technology, visit **www.sleepimage.com**