

OBJECTIVE DIGITAL PSG BIOMARKERS

Polysomnography biomarkers provide quantifiable data on sleep architecture, sleep continuity, spectral and microstructure features, respiratory and movement, and physiologic safety measures.

These data can be particularly valuable when assessing the impact of drugs on sleep, especially for compounds intended to treat insomnia, depression, or other CNS conditions.

Drugs that target neurotransmitters like GABA, serotonin, or histamine can also profoundly affect sleep cycles and increase sleep fragmentation, and PSG offers a way to precisely measure these effects.

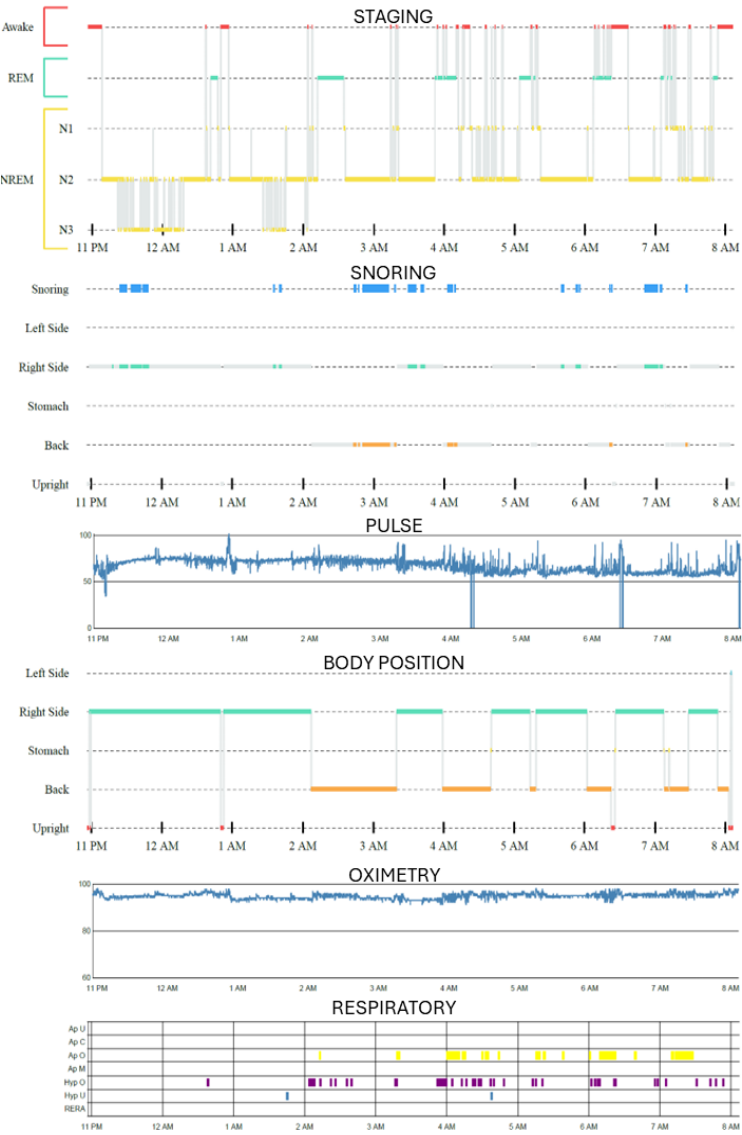
AUTOMATED DATA ANALYSIS PIPELINE

Like all COGNISION® products, these PSG biomarkers are the result of a fully automated data analysis pipeline and are available to the sponsor or CRO within hours of the sleep session.

COGNISION SERVICES

Cognition’s clinicians, scientists, and technologists stay continuously up-to-speed with the PSG industry to ensure that our offerings provide the best value proposition to the pharmaceutical industry. These activities include involvement with the ISCTM Sleep Working Group which is an industry partnership of leading experts who review, evaluate, and advise pharmaceutical companies on the most effective PSG biomarkers and technologies.

Cognition can provide a complete range of PSG services that offer significant benefits in pharmaceutical trials, particularly for CNS-acting drugs, by providing objective, detailed, and early insights into drug effects on sleep architecture.



COGNISION PSG CLINICAL TRIAL SERVICES	
Fit-for-Purpose PSG Devices	All devices are FDA cleared and AASM approved. They are wireless and are designed for simplified application and automatically transmit study data to Cognition’s web-base database.
Drug/Indication-Specific Biomarker Selection	Cognition’s scientists can provide recommendations for selecting specific PSG biomarkers that are best fit for the particular drug mechanism of action or for use with specific clinical indications.
Study Design and Operations Consulting	Pharma clients can leverage Cognition’s experience and expertise during the early trial design phase as well as during detailed operational planning. This can include protocol design, site selection, power calculations, and analytical methods.
Site Qualification	Before any PSG trial is initiated, Cognition staff will perform site qualification to ensure the site has the necessary facilities and staff to perform successful trials.
Site Staff Training	Any clinical technician can be trained to perform high-quality PSG studies. Cognition will train and certify techs to setup and monitor the studies and will provide training certifications upon successful completion of the training.
Quality Monitoring	Cognition performs near-realtime quality reviews of all PSG studies to ensure data quality and reliability. Quality metrics are captured for all studies in the COGNISION® database.
Data Management & Transfer	Cognition manages the complex raw data, metadata, and biomarker data within a proprietary, web-based clinical trial management system (CTMS). All trial data can then be exposed to or shared with other stakeholders who have the appropriate user rights. Formal data transfers can be performed which meet the specifications of a Data Transfer Agreement (DTA).
Data & Statistical Analysis	All raw PSG test data can be automatically scored, biomarkers extracted, and statistical comparisons can be performed using the COGNISION® Pharmaco-Statistics Dashboard. This can provide near-realtime statistical results before, or soon after database lock.
Scientific Interpretation	Cognition has experts in clinical care, pharmacology, and sleep medicine all available to provide appropriate scientific interpretations of the data collected in PSG trials.
Study Reporting	At the end of any contracted trial, Cognition will prepare a trial report that will provide additional information related to the PSG studies that were performed.

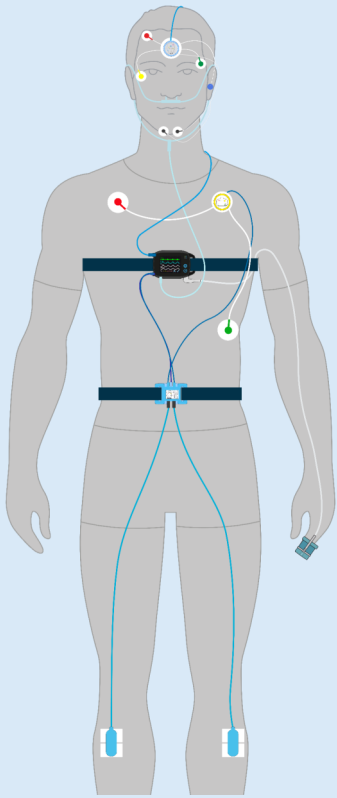


PSG & Sleep EEG

POLYSOMNOGRAPHY & SLEEP EEG IN PHARMACEUTICAL TRIALS

Polysomnography and sleep EEG (PSG) are common diagnostic modalities in clinical practice. However, because of their complexity, requirements for special expertise, and high cost, PSG biomarkers have found only limited use in pharmaceutical trials, especially with CNS compounds that are not intended to target sleep.

Now, Cognition has enabled all early-phase trial sites to provide advanced PSG biomarker services to pharma clients for any compounds which may affect sleep. These can be drugs to treat insomnia, hypersomnia, sleep apnea, narcolepsy, and other sleep disorders. Or they may be drugs that impair sleep and may present a risk to patients.



FIT-FOR-PURPOSE DEVICE CONFIGURATIONS				
	PSG-1 Full Level 1 w/Camera	PSG-2 Full Level 2	PSG-3 Respiration, Airflow, Oxygen Saturation	PSG-4 Simplified Home Testing
Biomarker				
EEG (Brain Activity)	✓	✓	✗	✓
EOG (Eye Movement)	✓	✓	✗	✓
EMG (Chin Muscle Activity)	✓	✓	✗	✓
Oxygen Saturation (SpO ₂)	✓	✓	✓	✓
Respiration (Chest & Abdomen)	✓	✓	✓	✗
Airflow	✓	✓	✓	✗
Body Position	✓	✓	✗	✓
Head Movement	✓	✓	✗	✓
Snoring Sounds	✓	✓	✗	✓
ECG/Heart Rate	✓	✓	✗	✗
Leg Movement	✓	✓	✗	✗
Video	✓			

FULL-SERVICE PSG PROVIDER

- Cognition provides all necessary hardware, training, support, data management, analytical and scientific services to enable full Level 2 PSG studies.
- Trial participants can be setup by any clinical tech after 1-2 days of training.
- Compared to other PSG systems, Cognition’s devices are well tolerated by trial participants leading to more accurate sleep data with lower patient burden.
- All devices have been clinically validated to ensure consistent and robust PSG results.
- All data is automatically uploaded to the web; and 3) all data is analyzed through an automated data analysis pipeline to minimize variation and ensure reproducibility.

PRACTICAL AT-HOME CLINICAL TRIALS

Cognition can also provide simplified, clinically validate hardware that can be applied by a study participant or participant’s partner at their home. These devices facilitate decentralized clinical trials (DCT) while still capturing the most important physiologic measures.

SOMNOtouch PSG+

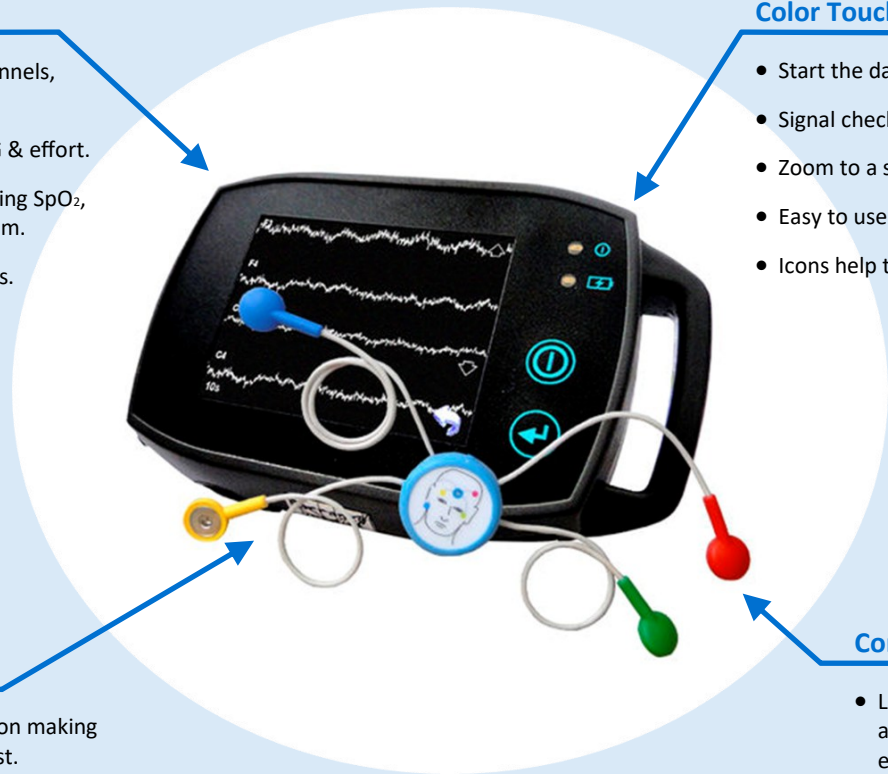
FULL LEVEL 1 AND 2 PSG RECORDING

The **SOMNOtouch™ PSG+** combines the comfort, function and power of much larger sleep diagnostic devices in a small perfectly formed size. At only 2.3 oz and 3.3 x 2.2 x 0.7 inches it is one of the lightest yet powerful touch screen ambulatory/stationary polysomnography devices on the market today.

The recording and display module is the brain for all physiologic signals including; EEG, EOG, EMG, SpO₂, Respiration, Air-flow, Body Position, Head Movement, Snoring Sounds, ECG, Leg Movement, and Video. This easy-to-use device supports full Level 1 and 2 recording and then uploads the data to the cloud for automated analysis and quantification of various sleep parameters.

PSG Recording

- Headbox with up to 25 channels, including; EEG, EOG, EMG.
- Combi sensor for PLM, ECG & effort.
- 11 Internal channels including SpO₂, pulse rate, & plethysmogram.
- Easy-to-use snap electrodes.



Color Touch Screen

- Start the data recording on the device.
- Signal check on the screen.
- Zoom to a selectable time base.
- Easy to use interface.
- Icons help to easily identify attached sensors.

Intelligent Connect

- Automatic sensor recognition making montages a thing of the past.

Continuous Impedance Check

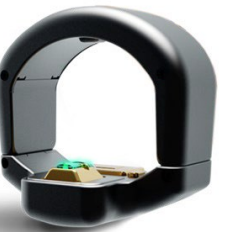
- Lower noise, higher signal quality and easy confirmation of proper electrode hook-up.

HomeSleepTest REM+

SLEEP EEG, OXYGEN SATURATION, AND ACTIGRAPHY AT HOME

With the **HomeSleepTest REM+** and the **O₂Fellow Smart Ring** patients can undergo a complete PSG assessment, including EEG, EMG, oxygen saturation, and actigraphy, in a familiar environment without the need for an overnight stay in a laboratory. The forehead module is lightweight, wireless, and uses simple adhesive patches for EEG/EMG. The actigraphy measures are collected via a sensor enabled smart ring.

At the end of the sleep session, the data is automatically uploaded to the cloud for automated analysis and quantification of various sleep parameters.



HomeSleepTest REM+

- Up to 36 hrs. recording duration.
- 256 Hz sampling rate.
- 2 hrs. charging time.
- Continuous impedance check.
- Wi-Fi data upload to cloud.

O2Fellow Smart Ring

- 3 sizes for optimal fit.
- 11 hrs. duration, 2 hr charge time.
- Data transfer via Bluetooth

Docking Station

- Multi-port docking station with fast recharging.
- Fast data transfer (Approx. 90s for a PSG).
- Virtual docking station to display device status on PC.



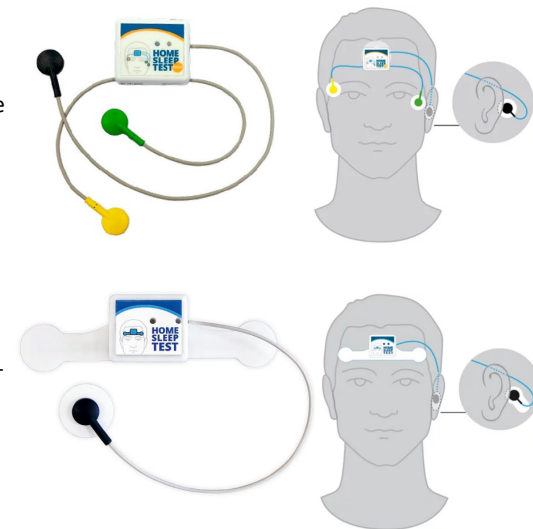
Online Video Recording

- Easy setup of video camera.
- Bluetooth transceiver.
- Cloud storage



Electrode Options

- Standard Snap Electrodes which support the AASM-compliant positioning of the EOG electrodes to improve recording of horizontal and vertical eye movements.
- Convenient Patch Electrode which can be easily applied by the participant at home and ensures reliable recording of the EOG and EEG channels.



Tablet

- An app guides the participant from the simple application through to the start of the measurement in a few easy steps.
- The HST module sends data to the tablet via Bluetooth.
- After the recording is complete the data is automatically uploaded to a secure cloud.

