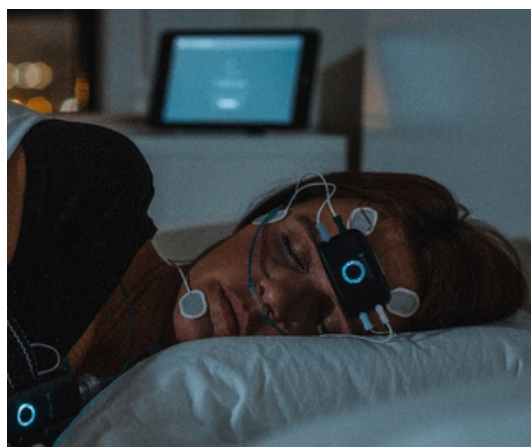


POLYSOMNOGRAPHY & SLEEP EEG IN PHARMACEUTICAL TRIALS

Polysomnography and sleep EEG (PSG) are common diagnostic modalities in clinical practice. However, because of its 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 designed to target sleep.

CEREBRA SLEEP SYSTEM[®]



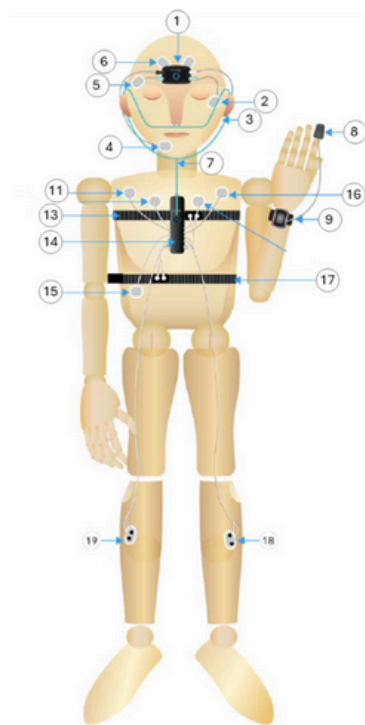
The Cerebra Sleep System is an FDA-cleared (K213007) full Level 2 PSG system that is easy to deploy at trial sites that support inpatient trials. Trial participants can be set up by any clinical tech after 1-2 days of training. Compared to other PSG systems, the system is well tolerated by trial participants.

The Cognition company can provide all equipment and support services on a per-study basis without any up-front costs for the site.

Now, early-phase trial sites can provide advanced PSG biomarker services to pharma clients for any compounds that may affect sleep. These can be drugs to treat; insomnia, hypersomnia, sleep apnea, narcolepsy, and other sleep disorders. They could also be drugs that impair sleep.

FULL LEVEL 2 POLYSOMNOGRAPHY ASSESSMENTS

Some PSG systems only perform EEG recording, but the Cerebra Sleep System performs a comprehensive “Level 2” recording session. This not only includes EEG, it also monitors eye movements (EOG), muscle activity (EMG), heart rate, breathing patterns, snoring, blood oxygen saturation level, and body position. The full Level 2 assessments ensure that drug effects on all relevant physiologic sleep measures can be captured and reported.



MODULE	NO	CHANNEL	EEG ONLY	LEVEL 3	FULL LEVEL 2
HEAD UNIT	1	HEAD UNIT	✓		✓
	2,5	EYE SENSORS	✓		✓
	3	MASTOID SENSOR	✓		✓
	4	CHIN SENSOR	✓		✓
	6	EEG SENSOR	✓		✓
HAND UNIT	8	PULSE SENSOR			✓
	9	SPO2 SENSOR			✓
TABLET	20	AUDIO SENSOR		✓	✓
CHEST UNIT	7	NASAL CANNULA		✓	✓
	11	ECG GROUND		✓	✓
	13	CHEST BELT		✓	✓
	14	CHEST UNIT		✓	✓
	15	STOMACH BIAS SENSOR		✓	✓
	16	LEFT ECG SENSOR		✓	✓
	17	ABDOMEN BELT		✓	✓
	18, 19	LEG SENSORS			✓

OBJECTIVE DIGITAL PSG BIOMARKERS

Polysomnography “biomarkers” provide detailed and objective data on sleep architecture, including the amount of time spent in different sleep stages (e.g., REM, non-REM, deep sleep), sleep onset latency, and the number of awakenings. This is 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.

NOT JUST SLEEP STAGING

The system also collects and reports data for; snoring, pulse, body position, oximetry, and respiration. These biomarkers provide a complete picture of sleep physiology and a drug’s impact on those processes.

AUTOMATED DATA ANALYSIS PIPELINE

Like all COGNISION® products, the 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.

CONCLUSION

The Cerebra Sleep System offers significant benefits in pharmaceutical trials, particularly for CNS-acting drugs, by providing objective, detailed, and early insights into drug effects on sleep architecture.

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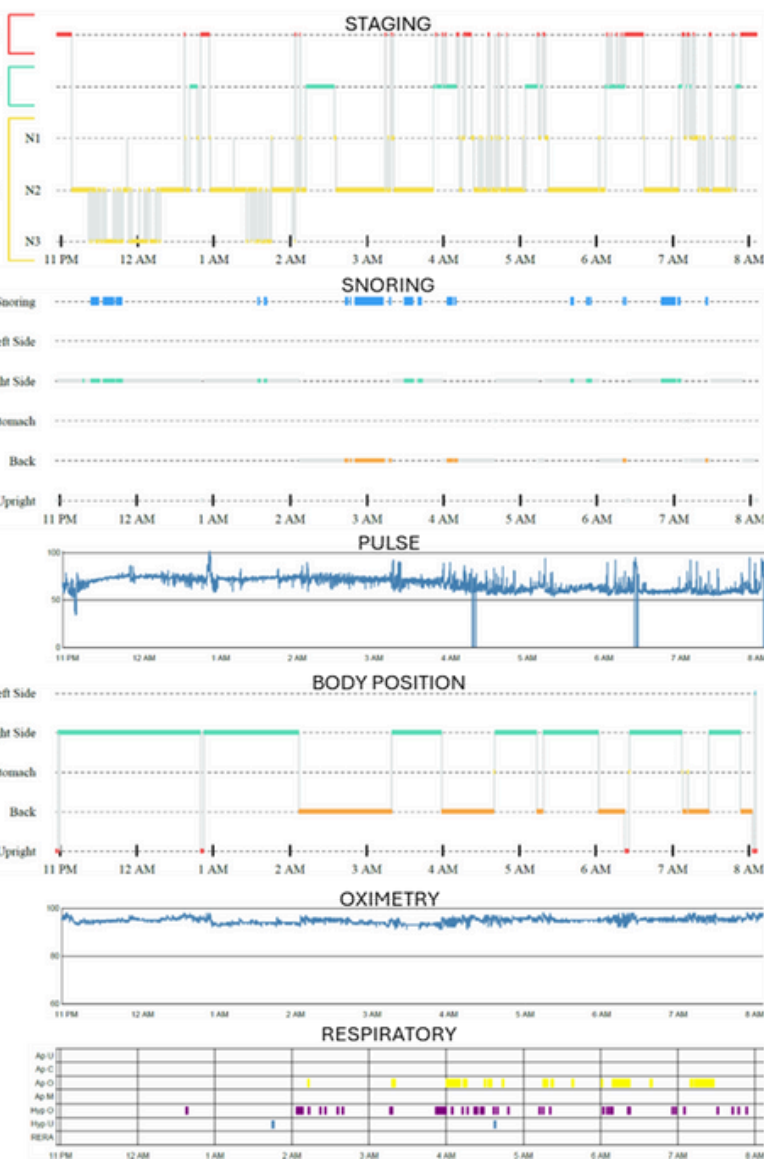
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