

belun[®]
shed light on your sleep



The World's First AI-Enabled Medical Wearable Ring

HOME SLEEP TEST

GUIDE FOR HEALTHCARE PROFESSIONALS

belun[®]ring



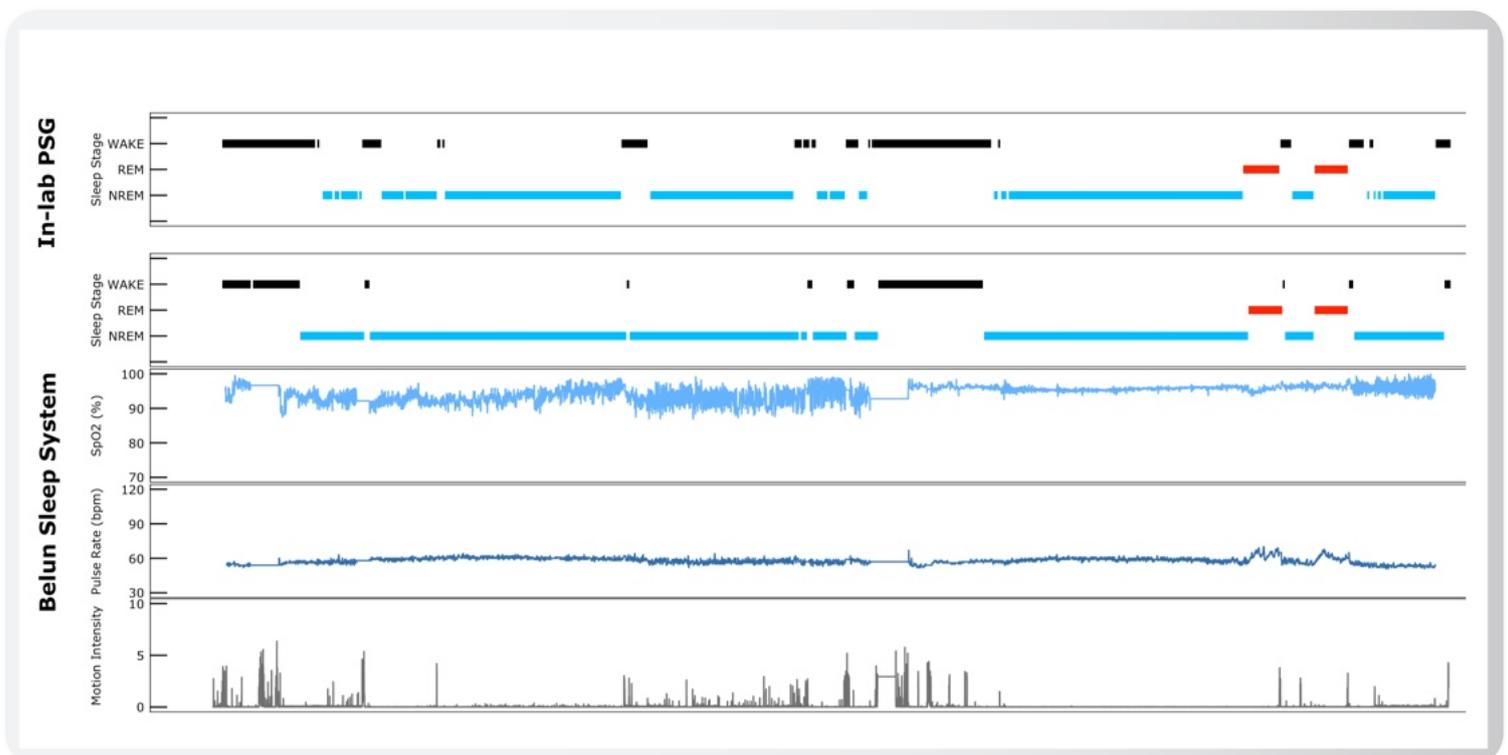
◆ Complete Sleep Architecture

The Belun Sleep System BLS-100 provides clinically validated sleep stages: Wake, NREM and REM sleep using Artificial Intelligence.¹⁻³

The complete sleep architecture provides information on sleep quality including time in bed (TIB), total recording time (TRT), total sleep time (TST), sleep efficiency, sleep latency, wake duration, wake counts, wake after sleep onset (WASO), REM duration, REM percentage in TST, NREM duration, and NREM percentage in TST.

In addition, BLS-100 is able to estimate sleep apnea and hypopnea events related to REM and NREM sleep stages. REM AHI and NREM AHI are essential to clinicians in terms of understanding phenotypes of OSA diagnosis and therapy.

Sleep Stages From BLS-100 Vs PSG-EEG Channel



Understanding The Belun Sleep Study

Belun Sleep Analysis Report

The best research tool with piles of physiological parameters for long-term studies

Test Information

Start Time	2024-08-29 00:41	
End Time	2024-08-29 07:04	
Time Zone	UTC+08:00	
Time in Bed (TIB)	383.0	mins

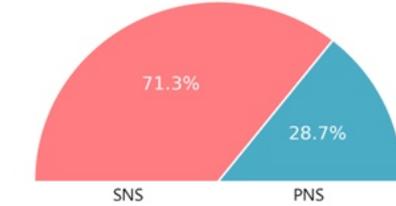
Sleep Summary

bAHI3	41.9	bAHI4	27.4	/hr	0-5
Min. SpO ₂	≤ 70	%	90-100		
SpO ₂ ≤ 90%	13.8	mins	--		
Sleep Efficiency	94.5	%	85-100		
Total Sleep Time (TST)	346.5	mins	420+		
Mean Pulse Rate	67.7	bpm	40-100		
Arrhythmia Ratio	0.1	%	0-5		

Sleep Apnea Severity Scale



ANS Balance



Hypopneas in bAHI3 are scored using AASM 1A criteria (Hypopneas with ≥ 3% oxygen desaturation or arousal)
Hypopneas in bAHI4 are scored using AASM 1B criteria (Hypopneas with ≥ 4% oxygen desaturation)

Sleep Statistics

Start Time	2024-08-29 00:41 (UTC+08:00)	Wake	Duration	20.0	mins
End Time	2024-08-29 07:04 (UTC+08:00)		Counts	13	
Time in Bed (TIB)	383.0 mins		WASO	8.5	mins
Total Recording Time (TRT)	366.5 mins	REM	Duration	175.5	mins
Total Sleep Time (TST)	346.5 mins		% in TST	50.6	%
Sleep Efficiency (TST/TRT)	94.5 %	NREM	Duration	171.0	mins
Sleep Latency	7.5 mins		% in TST	49.4	%

WASO - Wake After Sleep Onset

Respiratory Statistics

	TST	REM	NREM	
bAHI3	41.9	51.6	31.9	/hr
bAHI4	27.4	36.9	17.5	/hr

Oxygen Desaturation Statistics

	TIB	TST	REM	NREM	
ODI3	22.1	22.5	26.7	18.2	/hr
ODI4	14.0	14.0	16.4	11.6	/hr

Hypopneas in bAHI3 are scored using AASM 1A criteria (Hypopneas with ≥ 3% oxygen desaturation or arousal)
Hypopneas in bAHI4 are scored using AASM 1B criteria (Hypopneas with ≥ 4% oxygen desaturation)

ODI3 is calculated using ≥ 3% oxygen desaturation
ODI4 is calculated using ≥ 4% oxygen desaturation

SpO₂ Statistics

SpO ₂		≤ 90%	≤ 89%	≤ 88%	≤ 80%			
Max.	99.0	%	Duration	13.8	9.8	6.7	0.9	mins
Mean	94.5	%	% in TST	3.6	2.6	1.7	0.2	%
Min.	≤ 70	%	Hypoxic Burden	49.3				% min / hr

Pulse Rate Statistics

Max.	104.0	bpm
Mean	67.7	bpm
Min.	50.0	bpm

Cardiovascular Statistics

SDNN	65.0	ms	nLF	71.3	%
RMSSD	37.7	ms	nHF	28.7	%
pNN50	13.7	%	Arrhythmia Ratio	0.1	%

- Sleep Statistics
- Arrhythmia Ratio
- Sleep Apnea Severity Scale
- Autonomic Nervous System Balance
- Respiratory Statistics
- Oxygen Saturation Statistics
- SpO₂ Statistics
- Pulse Rate Statistics
- Sleep Stages
- Pulse Rate Statistics
- Cardiovascular Statistics



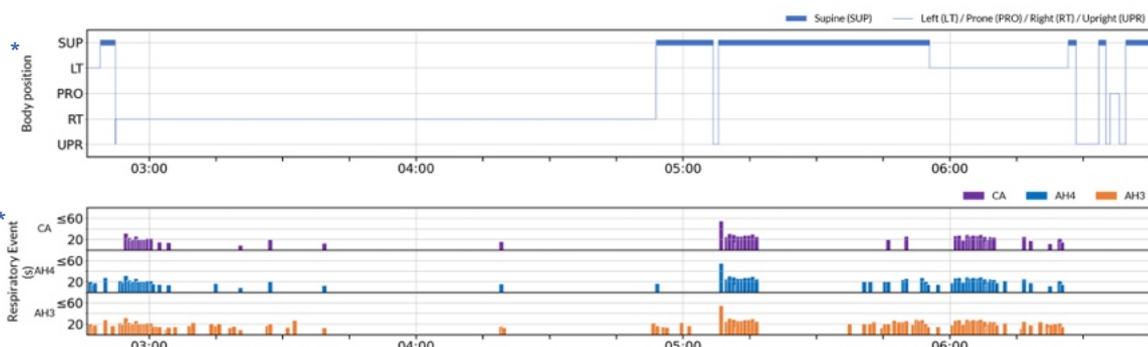
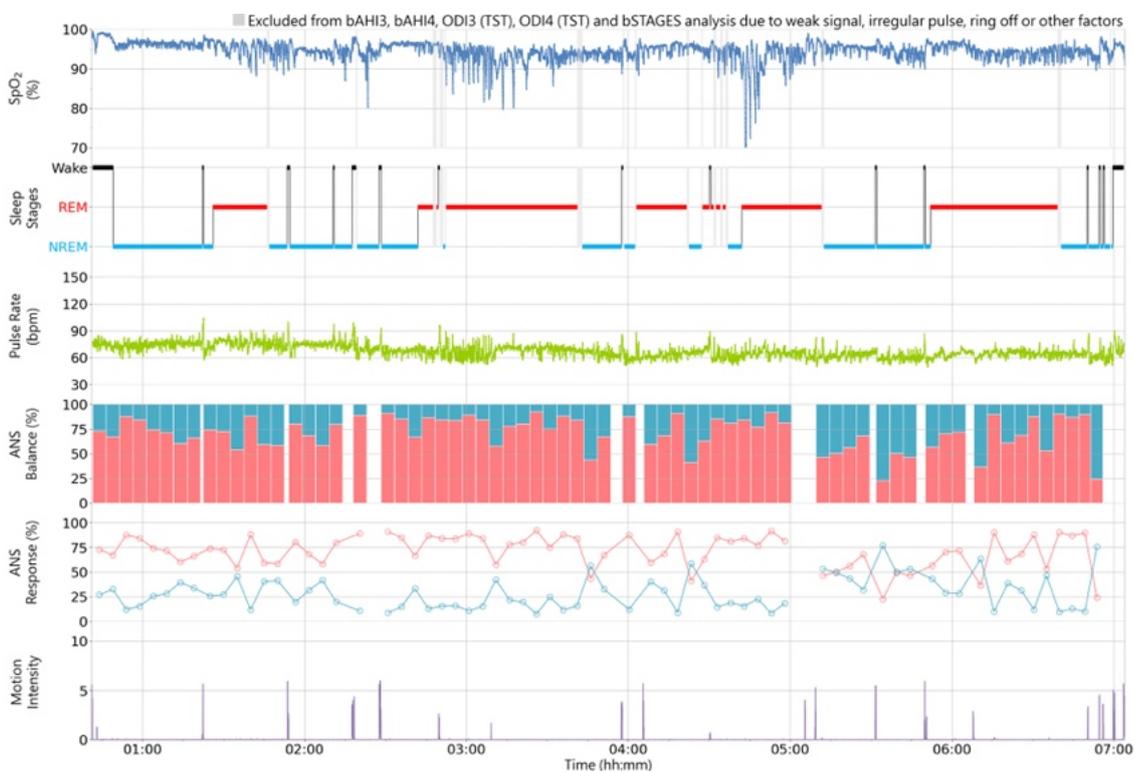
Understanding The Belun Sleep Study

Belun Sleep Analysis Report

The best research tool with piles of physiological parameters for long-term studies

The graphical capture of entire assessment period:

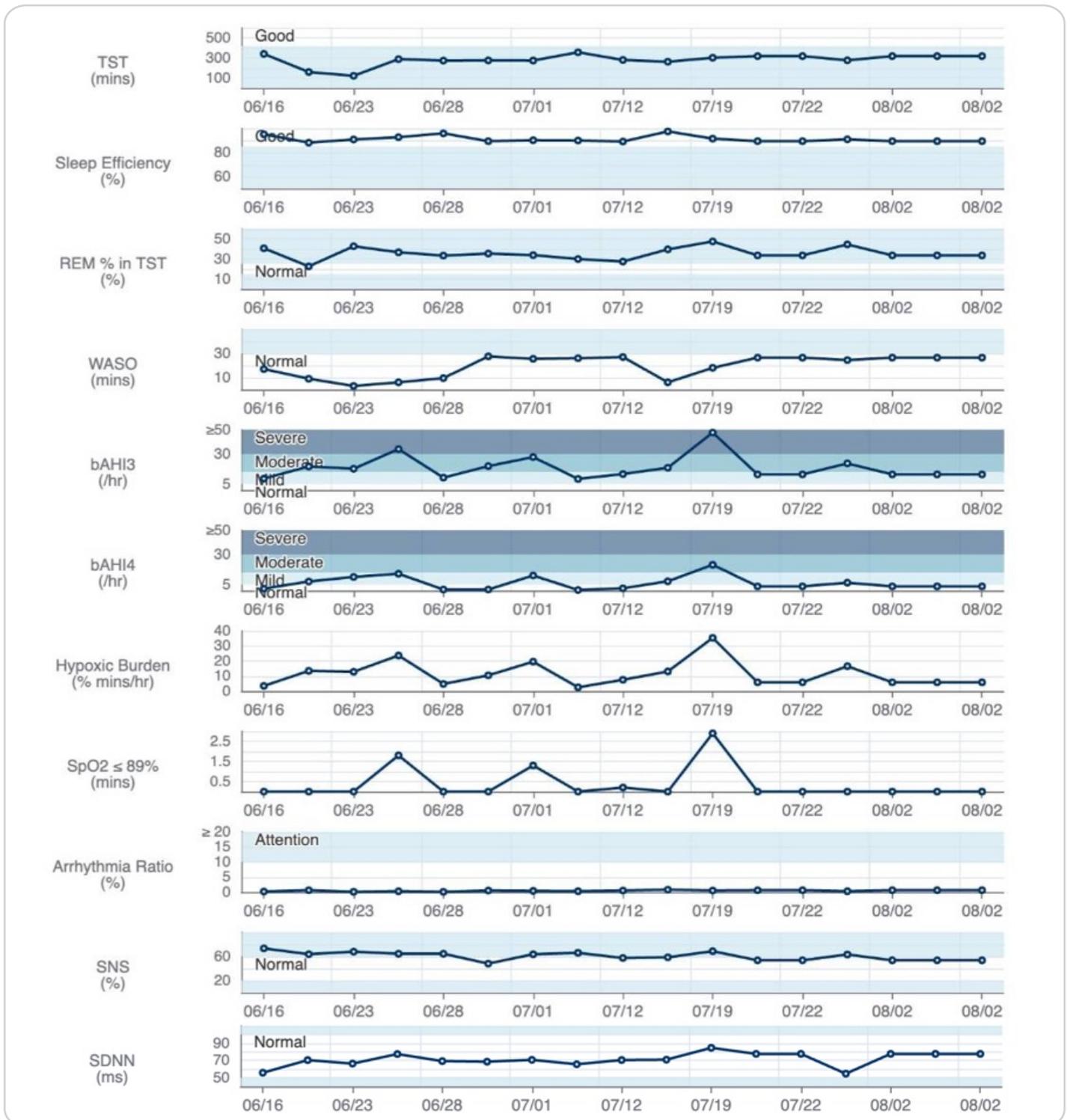
- SpO2
- Sleep Stages
- Sleep Metrics
- Heart Rate Variability Metrics
- Motion Intensity



*For central sleep apnea flagging and body position, please contact us: info@beluntech.com

Understanding The Importance Of Multiple-night Analyses

With comfort from our wearable medical device, the patient is able to perform home sleep test at ease. Apart from reducing the technical difficulties and expensive cost by in-lab polysomnography, the Belun Sleep System enables multiple-night analyses without limitation of measurement period.* This provides greater accuracy by minimizing the first-night effect and averaging night-to-night variability which is less feasible with in-lab polysomnography. Moreover, comprehensive trends on key sleep parameters, autonomic nervous system responses and OSA severity are analysed throughout the measurement period.



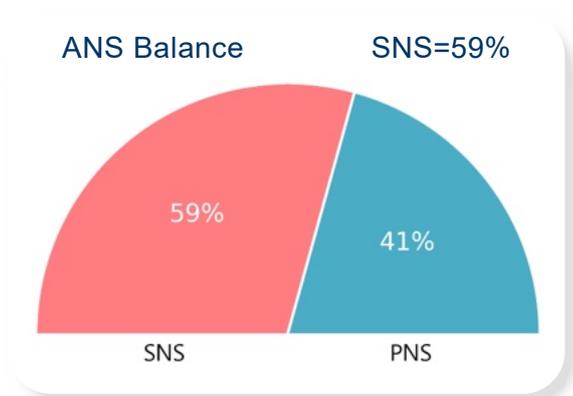
* Continuous measurement can be achieved upon regular upload of sleep data in every 14 days.



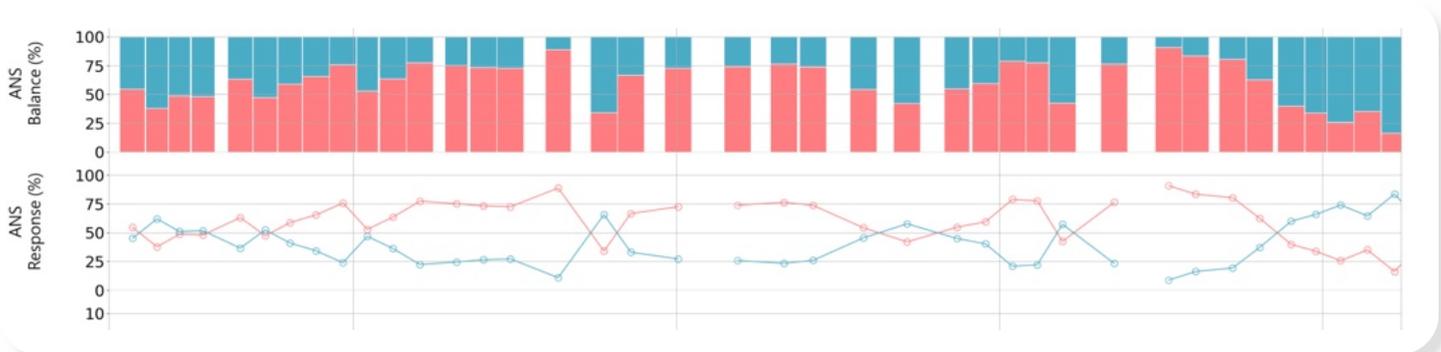
Understanding The Autonomic Nervous System Response

The autonomic nervous system (ANS) is comprised of parasympathetic and sympathetic pathways. Heart rate and blood pressure are modulated on a beat-to-beat basis by balance between these two pathways. Heart rate variability (HRV), surrogate marker of ANS, is characterized as the variability of beat-to-beat intervals of the heart and typically measured using RR intervals. Fluctuations of RR intervals are mediated by sympathetic and vagal efferent activity and can be affected by physiological, pathological, physical, and psychological activity.⁴

When sleep is disturbed, impaired autonomic function can result in sympathetic predominance and blunted parasympathetic activity.⁴ Heightened sympathetic activity is linked to an increase risk of cardiovascular events of up to 46%,⁵ hypertension⁶ and OSA.⁷⁻⁹ The use of HRV analyses has provided a glimpse into cardiac autonomic control across sleep stages, monitoring of OSA progression and treatment response.



Our study demonstrated that the HRV derived from BLS-100 could serve as surrogates for the ones derived from PSG-ECG signals.¹⁰



◆ Home Sleep Testing Made Simple

Belun Sleep System BLS-100 is FDA 510(k) cleared for home sleep apnea test. It allows your patients to conduct sleep tests comfortably.

- FDA 510(k) cleared for both device and AI software
- Clinically validated in U.S. ¹⁻³ and Asian ¹¹ populations
- Accurate and reliable
- Re-usable, without one-off consumable part
- Simple and easy to use
- Small and light-weighted
- Cableless design, negligible sleep disturbance



◆ Simple, Accurate, Re-usable And Cost-effective

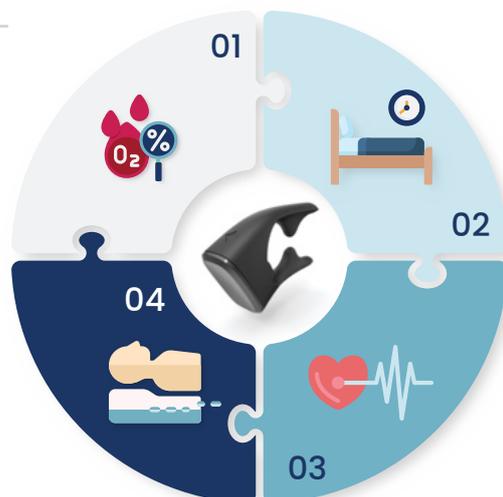
Belun® Ring enables you to evaluate your sleep quality at ease. The following parameters are recorded and provided:

VITAL SIGNS

- Blood Oxygen Saturation
- Pulse Rate

ACTIGRAPHY

- Movement



SLEEP HEALTH

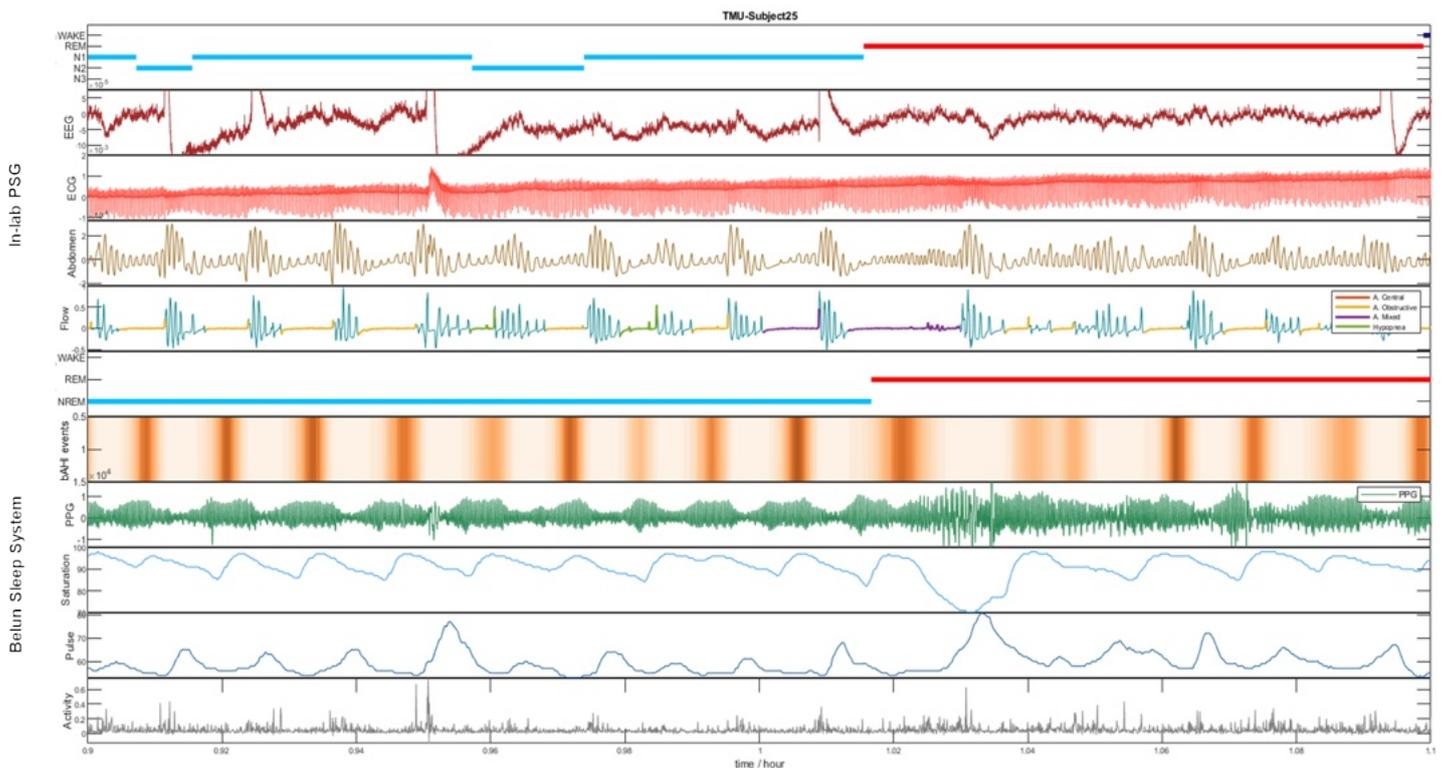
- Sleep Stages
- Apnea Hypopnea Index

AUTONOMIC NERVOUS SYSTEM RESPONSE

- Sympathetic Nervous System Response
- Parasympathetic Nervous System Response

◆ PPG Signal Explained

Belun® Ring BLR-100X, an FDA 510(k) cleared Class II reflectance pulse oximeter, acquires users' photoplethysmography (PPG). The clean PPG signals at a high sample rate (200 Hz) deliver physiological information on oxygen saturation, pulse rate, and heart rate variability (HRV). Our cutting-edge algorithms, Belun Sleep System BLS-100, capture intricate patterns of these signals and accurately estimate AHI and categorize sleep stages. Several clinical trials have validated its robust generalizability in patients even with co-morbidities..^{2,3,11}



◆ BELUN® RING – From Suspected OSA to Diagnosis



belun® | Shed Light on Your Sleep

References:

1. Gu W, Leung L, Kwok KC, Wu IC, Folz RJ, Chiang AA. Belun Ring Platform: a novel home sleep apnea testing system for assessment of obstructive sleep apnea. *Journal of Clinical Sleep Medicine*. 2020;16(9):1611-1617.
2. Yeh E, Wong E, Tsai CW, et al. Detection of obstructive sleep apnea using Belun Sleep Platform wearable with neural network-based algorithm and its combined use with STOP-Bang questionnaire. *PLoS ONE*. 2022;16(10):e0258040.
3. Strumphf Z, Gu W, Tsai CW, et al. Belun Ring (Belun Sleep System BLS-100): Deep Learning-Facilitated Wearables Enables OSA Detection, Apnea Severity Categorization, and Sleep Stage Classification in Patients Suspected of OSA. *Sleep Health*. (Accepted on March 2023)
4. Ucak S, et al. Heart rate variability and obstructive sleep apnea: Current perspectives and novel technologies. *J Sleep Res*. 2021;30(4).
5. Fang SC, Wu YL, Tsai PS. Heart Rate Variability and Risk of All-Cause Death and Cardiovascular Events in Patients With Cardiovascular Disease: A Meta-Analysis of Cohort Studies. *Biol Res Nurs*. 2020;22(1):45-56.
6. Guzzetti S, Piccaluga E, Casati R, et al. Sympathetic predominance in essential hypertension: a study employing spectral analysis of heart rate variability. *J Hypertens*. 1988;6(9):711-717.
7. Aydin M, et al. Cardiac autonomic activity in obstructive sleep apnea: time-dependent and spectral analysis of heart rate variability using 24-hour Holter electrocardiograms. *Tex Heart Inst J*. 2004;31(2):132-136.
8. Aytemir K, Deniz A, Yavuz B, et al. Increased myocardial vulnerability and autonomic nervous system imbalance in obstructive sleep apnea syndrome. *Respir Med*. 2007;101(6):1277-1282.
9. Xie J, et al. Correlation Analysis between Obstructive Sleep Apnea Syndrome (OSAS) and Heart Rate Variability. *Iran J Public Health*. 2017;46(11):1502-1511.
10. Tsai CW, Gu W, Yeh E, et al. Correlation of pulse rate variability (PRV) and heart rate variability (HRV) metrics during sleep in subjects suspected of OSA. *SLEEP 2023* (Accepted as Poster Presentation)
11. Ou YH, Ong J, Thant AT, et al. The Belun sleep platform to diagnose obstructive sleep apnea in patients with hypertension and high cardiovascular risk. *J Hypertens*. 2023;41(6):1011-1017.