sunrise

Clinical Compendium

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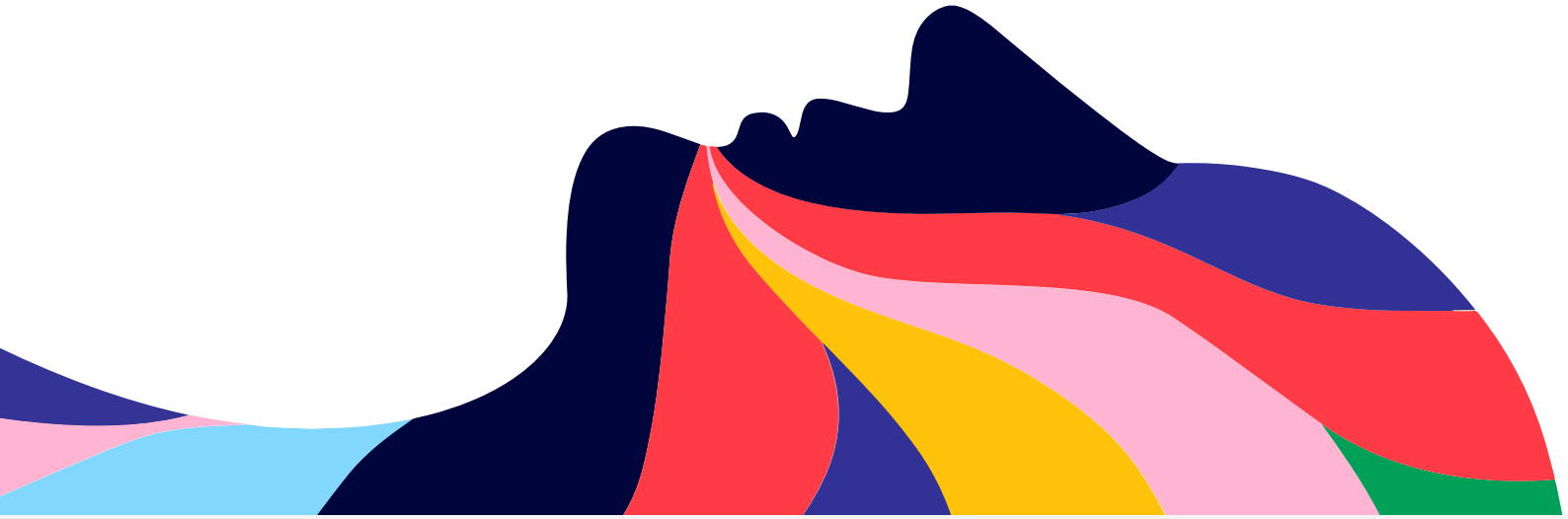


A - Overview of Technical Features

01. The Sunrise Home Sleep Apnea Test

The Sunrise device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders[1]. The Sunrise digital solution consists of the sensor, smartphone application and the software (that analyzes data from the sensor).

During sleep, the Sunrise sensor placed on the patient's chin records mandibular movement (MM) via its embedded inertial measurement unit that encodes the linear acceleration and rotational rate of the mandible.

MM is reflecting both the respiratory drive and variations in upper airway resistances typically occurring during abnormal respiratory events. MM has been established as a surrogate bio-signal for the detection of breathing effort during sleep (Martinot et al., 2015, 2017b, 2020).

Analysis of the MM signal has enabled the identification of specific breathing patterns associated with sleep-disordered breathing (Senny et al., 2008; Maury et al., 2013, 2014; Martinot et al., 2017a). MM analysis has also been shown to differentiate between sleep and wake states, allowing for the identification of total sleep time, which is crucial in the calculation of accurate sleep-disordered breathing indices (Senny et al., 2009, 2012; Maury et al., 2014).

Upon completion of the test, MM data and the data associated with user registered in the Sunrise smartphone app, is transferred via wireless connection (WiFi or mobile data) to the cloud where the Sunrise software, using a dedicated machine learning algorithm, analyzes the data and generates a detailed report. The report is available through the Sunrise platform for the Health Care Professional (HCP)[2] to review and manually edit if necessary.

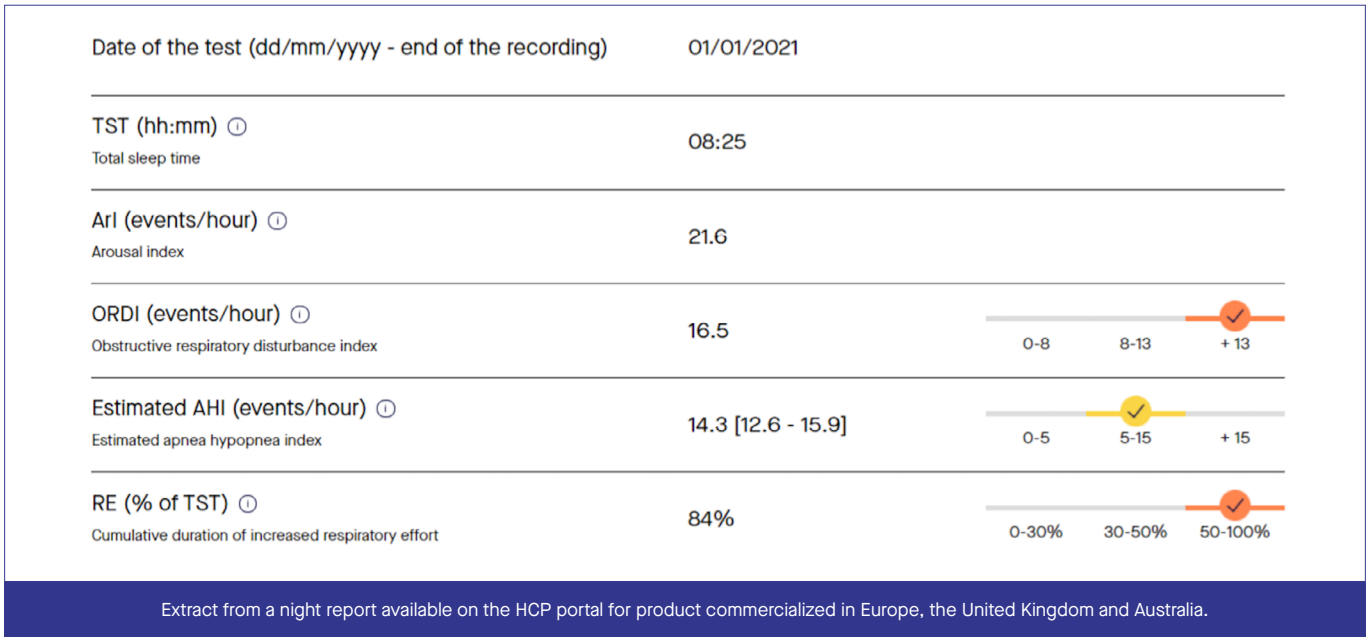
1. For product commercialized in Europe, the United Kingdom and Australia, Sunrise is also intended for children (from 3 to 18 years old) with suspicions of OSA or habitual snoring.

2. For product commercialized in Europe, the United Kingdom and Australia, the report is also available through the Sunrise mobile application for the user.

A - Overview of Technical Features

Currently, the Sunrise software provides the following information in the generated report:

- Sleep structure information: Total Sleep Time (TST), sleep onset latency, wake time after sleep onset, sleep efficiency, arousal index
- Position: position changes per hour, sleep time in supine and sleep time in non-supine
- OSA severity in a categorical format: non-OSA, mild-OSA, moderate-OSA, severe-OSA[3]
- Obstructive Respiratory Disturbance Index (ORDI)[4]
- ORDI in supine, non-supine, REM and NREM[4]
- Apnea-Hypopnea Index (AHI) estimated by using regression models[4]
- Respiratory effort (defined as percentage of TST with breathing difficulties)[4]
- Respiratory Effort Related Arousal (RERA) index defined as sequence of breaths characterized by increased respiratory effort leading to an arousal from sleep[4]
- Awakening index[4]
- Rhythmic Masticatory Muscle Activity index (RMMA) index characterizing sleep bruxism[4]
- Sleep stages (i.e., light non-REM N1+N2, deep non-REM N3 and REM sleep stages)[4]



Extract from a night report available on the HCP portal for product commercialized in Europe, the United Kingdom and Australia.

3 Information available only for product commercialized in the USA.
4 Information available only for product commercialized in Europe, the United Kingdom and Australia.

02. Machine Learning Algorithm Development

The machine learning models consist of ensemble tree-based algorithms such as the Random Forest (for respiratory effort and arousals detection) or the Extreme Gradient Boosting (for sleep stages scoring). The algorithm development was performed as follows:

1. The development and training of the algorithm were based on independent samples of 100 patients for the recognition of respiratory disturbance events and 800 patients for the recognition of sleep stages. Each patient underwent an overnight in-lab PSG with simultaneous mandibular movement (MM) recording using Sunrise. For each patient, the PSG was manually and independently scored by two sleep experts that were blinded to the study protocol and hypothesis. All sleep stages were visually scored according to the American Academy of Sleep Medicine (AASM) rules. The EEG arousals and sleep-related respiratory events were scored in accordance with the criteria established by the AASM Manual for Scoring Sleep and Associated Events as recommended by the International Classification of Sleep Disorders – Third Edition (ICSD-3) for OSA diagnosis.

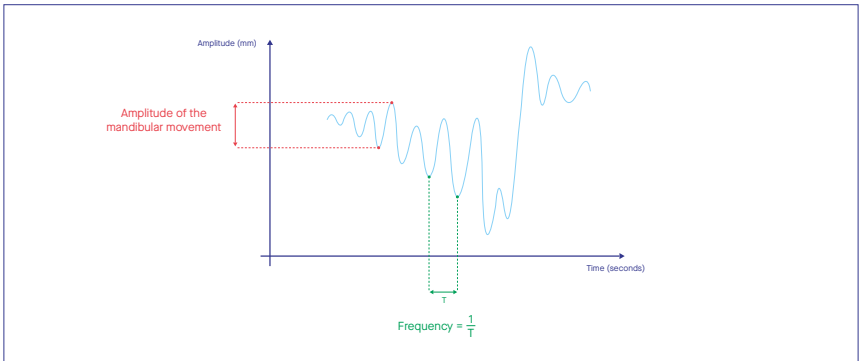
2. Based on the PSG scoring, target labels, i.e., wake, light non-REM (N1+N2), deep non-REM (N3), and REM, were assigned for each PSG epoch of 30 seconds for sleep stage scoring. N1 and N2 stages were combined to reach the best compromise between clinical relevance and best model performances. Similarly, one of the 4 target labels, i.e., wake, quiet sleep, respiratory effort, and arousal was assigned for each PSG epoch of 10 seconds. All labels were assigned only when the two independent scorers unanimously agreed on the scoring of the considered fragment. Ambiguous fragments were labelled as artifacts and excluded from training data.

3. At the same time, relevant features consisting of a combination between sensor axes, processing modes (e.g., filters with low, high, and respiratory frequency bands) and statistical functions were extracted from the corresponding raw MM signal sequences and were used as input data for the algorithm training. A true label was assigned to each 30- and 10-second signal sequences based on the reviewed PSG scoring.

4. The PSG-labelled MM fragments were then fed to the algorithm, cross-checking all available features to best classify/predict each 30- and 10-second fragment based solely on MM signals. The algorithm applied a classification on every 30- and 10-second epoch: it tested whether the processed MM signals could be classified as wake movements, and classified “sleep” fragments into respiratory effort, arousal, or quiet sleep. Basically, sleep was detected when MM occurred at the breathing frequency. During light sleep (N2), the amplitude of MM reaches several tenths of a millimeter and varies slightly. The movements during quiet respiration and light sleep are repeated at a frequency ranging between 0.15 and 0.60 Hz depending on the central drive output. Deepening of sleep (N3) increases the upper airway’s resistance, and this is reflected by an increase in the amplitude of movement, which is also more stable than during N2. REM sleep is easily identified by irregular frequencies and changing amplitudes in MM that are on average smaller than non-REM sleep amplitudes. To identify wake, the algorithm tested whether MM signals were fast, irregular, and nonpredictable (Senny et al., 2009; Senny et al., 2012) whereas quiet sleep is characterized by smooth MM oscillations at the breathing frequency. For the identification of arousal movements, the algorithm detected brisk MM of large amplitude, indicating abrupt closure of the mouth characteristic of arousals (Martinot et al., 2017a).

5 Apneas were defined as a complete cessation of airflow ≥ 10 s and classified as obstructive, central, or mixed according to the presence or the absence of respiratory effort. Hypopneas were scored using the AASM- recommended hypopnoea definition, requiring at least a 30% decrement in airflow lasting 10 s or longer and associated with a decrease of at least 3% in oxygen saturation as measured by pulse oximetry, or an arousal (Berry et al., 2012, 2017).

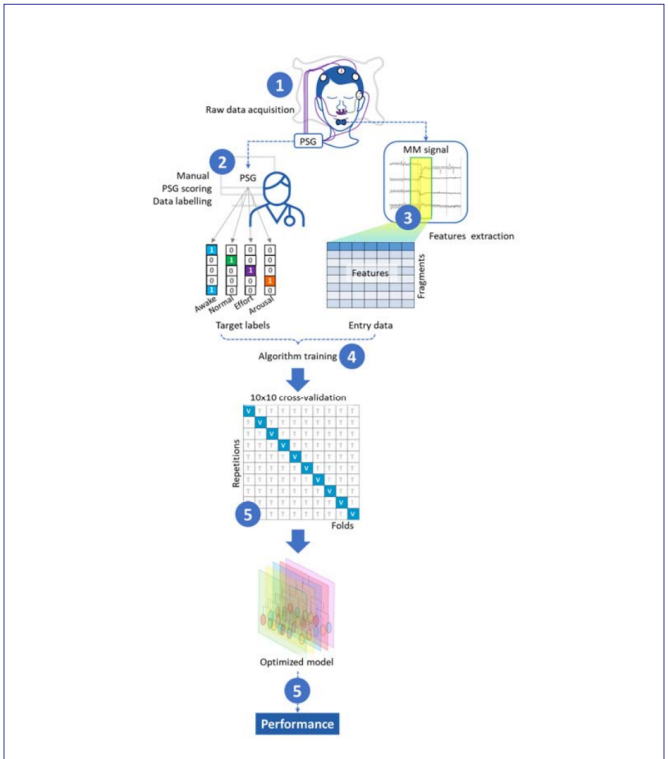
Respiratory effort was identified through oscillating MM at the breathing frequency (Martinot et al., 2017b). The Sunrise algorithm identified respiratory disturbances as a period of respiratory effort ended by an arousal or an awakening.



Mandibular movements during an obstructive apnea.

5. The parameters of the algorithm were optimized through a repeated 10-fold cross-validation procedure. The original data was randomly partitioned into 10 equally sized blocks. A single subsample was used as the validation data for testing the algorithm, and the remaining 9 subsamples were used as training data. The cross-validation process was repeated 10 times to ensure that each subsample was used only once as testing data.

The algorithm of the commercialized product is locked/frozen, meaning that any updates or modifications must be submitted for approval by the appropriate authorities before implementation. After development and training, the next step consisted of validating the algorithm on independent sets of patients. Results of validation studies have been published in peer-reviewed publications summarized in Section B.



Technical details on the Sunrise algorithm development phase.

B - Clinical Validation

01. OSA Diagnosis in Adults (against in-lab PSG)

Assessment of Mandibular Movement Monitoring With Machine Learning Analysis for the Diagnosis of Obstructive Sleep Apnea

Pépin JL, et al. JAMA Netw Open. 2020;3(1):e1919657

Read the article →

Objective

To evaluate whether mandibular movement (MM) monitoring during sleep coupled with an automated analysis by machine learning is appropriate for OSA diagnosis.

Methods

- Patients underwent overnight in-laboratory polysomnography (PSG) and simultaneous MM recordings using Sunrise.
- PSG data was manually and independently scored by 2 sleep experts in accordance with the recommended criteria established by the American Academy of Sleep Medicine (AASM).
- Development of the algorithm with a training set of 100 patients.
- Validation of the algorithm with a separate set of 376 patients.
- Agreement analysis assessed by Bland-Altman plot comparing PSG-ORDI and Sunrise-ORDI, and Receiver Operating Characteristic (ROC) curve analysis to evaluate the clinical performance of Sunrise-ORDI in detecting PSG-defined OSA at 5 events/h and 15 events/h.

Results

- A reliable agreement was found between the PSG-ORDI and the Sunrise-ORDI in patients without OSA (n = 46; mean difference, 1.31; 95% CI, −1.05 to 3.66 events/h) and in patients with OSA with a PSG-ORDI of at least 5 events/h with symptoms (n = 107; mean difference, −0.69; 95% CI, −3.77 to 2.38 events/h). A Sunrise-ORDI underestimation of −11.74 (95% CI, −20.83 to −2.67) events/h in patients with OSA with a PSG-ORDI of at least 15 events/h was detected and corrected by optimization of diagnostic thresholds.
- Sunrise-ORDI had accuracy of 0.92 (95% CI, 0.90-0.94) and 0.88 (95% CI, 0.86-0.90) as well as post-test probabilities of 0.99 (95% CI, 0.99-0.99) and 0.89 (95% CI, 0.88-0.91) at PSG-ORDI of at least 5 and at least 15 events/h, respectively, corresponding to positive likelihood ratios of 14.86 (95% CI, 9.86-30.12) and 5.63 (95% CI, 4.92-7.27), respectively.

Conclusion

The Sunrise automated analysis of MM patterns provided an accurate estimation of ORDI obtained during in-lab PSG in a large cohort of patients with and without OSA. This new approach provides a suitable and convenient home-based alternative to the sleep center setting and serve as a stand-alone tool for automated assessment of OSA.

Key Takeaways

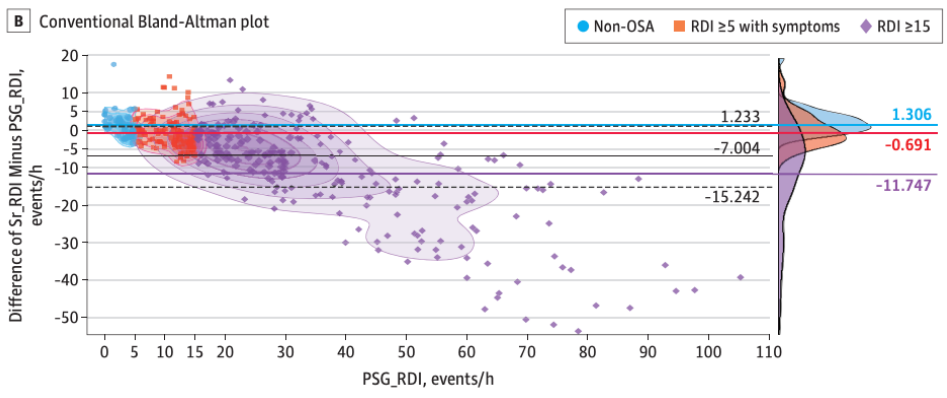
Automatic analysis of MM patterns provides reliable performance in ORDI calculation.

Variable	Value (95% CI)	
	PSG-RDI ≥5 Events/h	PSG-RDI ≥15 Events/h
Sr-RDI cutoff	7.63	12.65
Youden index	0.84	0.76
AUC	0.95 (0.92-0.96)	0.93 (0.90-0.93)
Balanced accuracy	0.92 (0.90-0.94)	0.88 (0.86-0.90)
Sensitivity	0.91 (0.89-0.92)	0.92 (0.90-0.94)
Specificity	0.94 (0.91-0.97)	0.84 (0.81-0.87)
False-positive rate	0.06 (0.03-0.09)	0.16 (0.13-0.19)
False-negative rate	0.09 (0.08-0.11)	0.08 (0.06-0.10)
Positive likelihood ratio	14.86 (9.86-30.12)	5.63 (4.92-7.27)
Negative likelihood ratio	0.10 (0.08-0.12)	0.10 (0.07-0.12)
Positive predictive value	0.99 (0.99-0.99)	0.89 (0.88-0.91)
Negative predictive value	0.59 (0.55-0.63)	0.88 (0.85-0.91)
F1 score	0.95 (0.94-0.97)	0.91 (0.89-0.92)

Abbreviations: AUC, area under the curve; PSG-RDI, polysomnography-derived respiratory disturbance index; Sr-RDI, Sunrise system RDI.

[a] Optimal cutoff points were assessed at the highest value of the Youden index (sensitivity plus specificity minus 1). The F1 score is the harmonic mean between precision and recall. The 95% CIs were obtained by bootstrapping.

Performance of the Sr-RDI to Detect Patients With PSG-RDI at the Diagnostic Levels Reported in the Third Edition of the International Classification of Sleep Disorders.



The reference method of overnight in-laboratory polysomnography (PSG) is shown on the x-axis. A, Kernel density estimation plot shows the distribution of PSG-derived RDI (PSG-RDI) (discontinued trace) vs the Sunrise system RDI (Sr-RDI) (continuous trace) in the 3 clinical groups. B, Conventional Bland-Altman plot shows the disagreement between PSG-RDI and Sr-RDI (y-axis) as a function of PSG-RDI (x-axis), with individual cases stratified into 3 clinical groups. The horizontal lines indicate the mean difference in the whole sample and within each group. The 2 dashed lines indicate the lower and upper levels (mean, ±1.96 SD) of the disagreement in the whole sample. Bidimensional kernel density estimation plots are superposed to show the distribution of the disagreement as a function of PSG-RDI. The distribution of the disagreement between the 2 methods, stratified by group, is shown on the right.

Evaluation of the Agreement Between the 2 Methods of Respiratory Disturbance Index (RDI) Measurement for Obstructive Sleep Apnea (OSA) Diagnosis.

02. OSA Diagnosis in Adults (against in-home PSG)

Diagnosis of Sleep Apnea Using a Mandibular Monitor and Machine Learning Analysis: One-Night Agreement Compared to in-Home Polysomnography

Kelly JL, et al. Front. Neurosci. 2022 16: 726880.

Read the article →

Objective

To evaluate the use of Sunrise using MM for the diagnosis of OSA in real world conditions.

Methods

- 40 patients underwent single overnight in-home PSG and simultaneous MM recordings using Sunrise.
- PSG recordings were manually and independently scored by 2 expert sleep centers (Imperial College London and Grenoble Alpes University Hospital) in accordance with the recommended criteria established by the AASM.
- Agreement between PSG and Sunrise assessed using interclass correlation coefficient and Bland-Altman plot comparing PSG-ORDI and Sunrise-ORDI. ROC curves were constructed to optimize the diagnostic performance of Sunrise at different PSG-ORDI thresholds (5, 15, and 30 events/hour).

Results

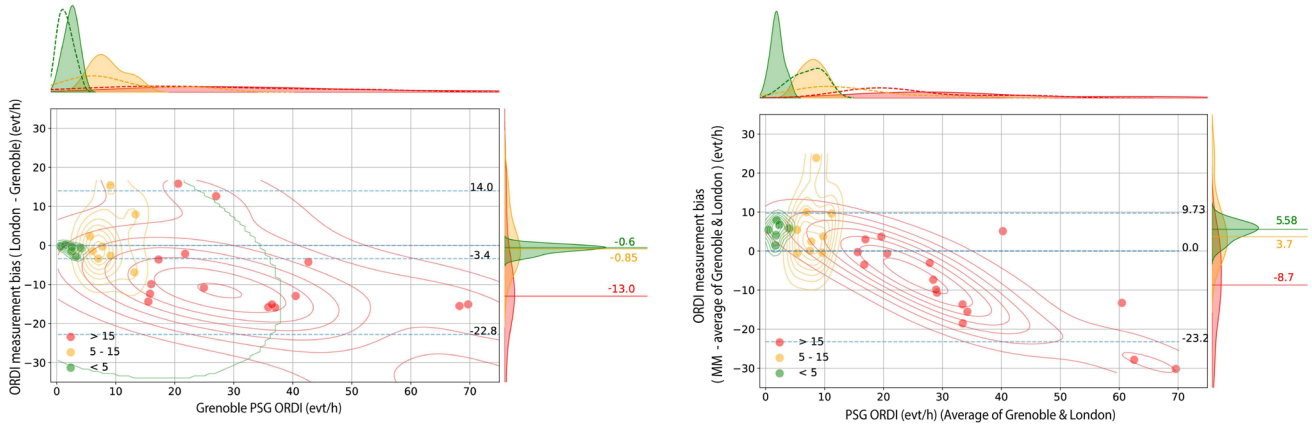
- Good agreement was observed between Sunrise-ORDI and PSG-ORDI with a median bias of 0.00 (95% CI −23.25 to + 9.73) events/h.
- Sunrise-ORDI had accuracy of 94%, 88%, and 87% as well as positive predictive values of 100%, 80%, and 95% at PSG-ORDI of at least 5, 15 and 30 events/h, respectively.

Conclusion

MM with machine learning analysis had good agreement with manually scored PSG recorded in the patients' own home.

Key Takeaways

- The diagnosis of OSA, using Sunrise, is comparable to manually scored in-home PSG.
- Agreement in ORDI, between Sunrise and in-home PSG, is similar to the agreement between by the two expert centers



- Left: Bland-Altman analysis for London PSG-ORDI versus Grenoble PSG-ORDI. Bland-Altman plot shows the disagreement between average PSG-ORDI (London) and PSG-ORDI (Grenoble) (y axis) as a function of Grenoble PSG-ORDI (x axis), with individual cases stratified into three clinical groups.
- Right: Bland-Altman analysis for MM-ORDI versus average PSG-ORDI. Bland-Altman plot shows the disagreement between average PSG-ORDI and MM-ORDI (y axis) as a function of the average PSG ORDI (x axis), with individual cases stratified into three clinical groups.

Bidimensional kernel density estimation plots are superimposed to show the joint distribution of measurement bias within each subgroup. The blue horizontal lines indicate the median, lower and upper bound (5th and 95th centiles) of the measurement bias in the whole sample. The distribution of the disagreement between the two methods, stratified by group, is shown on the right, with three horizontal lines indicating the median bias within each group. MM: mandibular movement; ORDI: obstructive respiratory disturbance index; PSG: polysomnography.

03. OSA Diagnosis in Pediatrics (against in-lab PSG)

Clinical Validation of a Mandibular Movement Signal Based System for the Diagnosis of Pediatric Sleep Apnea

Martinot JB, et al. Pediatric Pulmonology. 2021;1–10.

Read the article →

Objective

To assess the diagnostic capabilities of Sunrise in a population of pediatric patients referred for suspicion of OSA in comparison with in-lab PSG findings.

Methods

- 140 patients aged 3 to 17 years old underwent overnight in-laboratory PSG and simultaneous MM recordings using Sunrise.
- PSG data was manually and independently scored by 2 sleep experts in accordance with the recommended criteria established by the AASM.
- Agreement between PSG and Sunrise assessed by the Bland-Altman plot comparing PSG-ORDI and Sunrise-ORDI. The diagnostic performance of the Sunrise ORDI was determined via ROC curves evaluating the device sensitivity and specificity at PSG OAHI ≥ 1 (mild OSA), 5 (moderate OSA) and 15 events/h (severe OSA).

Results

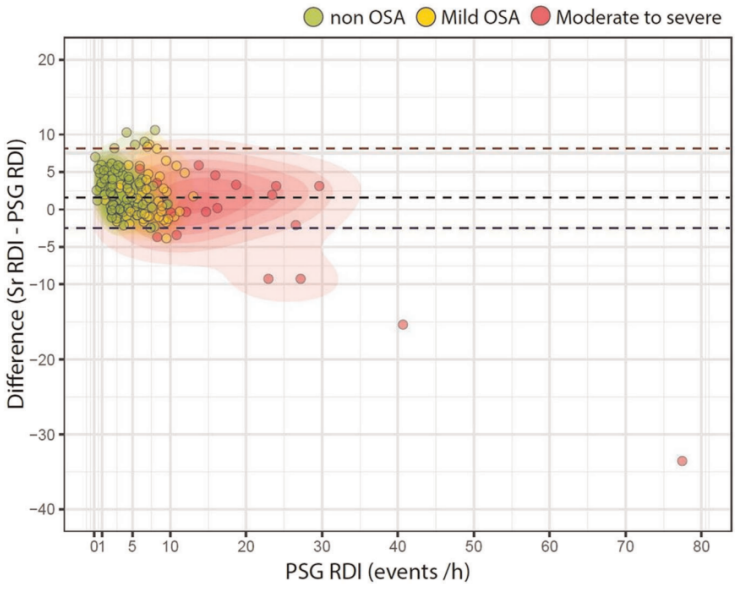
- A median difference of 1.57 events/h, 95% confidence interval: −2.49 to 8.11 was found between the Sunrise-ORDI and PSG-ORDI.
- The Sunrise-ORDI allowed for detection of patients with a PSG-OAHI ≥ 1, 5 and 10 events/h with accuracy levels of 68%, 85% and 94%, respectively. The Sunrise-ORDI diagnostic rules allowed to detect mild OSA with a good sensitivity (82%), to detect moderate OSA with a balanced sensitivity (90%) and specificity (80%), and to detect severe OSA with an excellent performance (sensitivity of 100% and specificity of 88%).

Conclusion

MM automated analysis shows significant promise to diagnose moderate-to-severe pediatric OSA.

Key Takeaways

The Sunrise machine-learning approach based on MM analysis provides a suitable and convenient home-based alternative for the assessment of pediatric OSA.



Bland–Altman plot between PSG_RDI and Sr_RDI as a function of PSG_RDI, with patients divided into three groups: (1) non-OSA (green), (2) mild OSA (PSG_OAHI ≥ 1; yellow), and (3) moderate-to-severe OSA (PSG_OAHI ≥ 5; red). The horizontal and the dashed lines indicate the median, the 5th and the 95th centiles of the disagreement in the whole sample, respectively. OSA, obstructive sleep apnea; PSG_OAHI, obstructive apnea/hypopnea index during polysomnography; PSG_RDI, respiratory disturbances hourly index during polysomnography; Sr_RDI, Sunrise-derived obstructive respiratory disturbance index.

Performance metrics (median and CI)	PSG_AHI≥1		PSG_AHI≥5		PSG_AHI≥10	
Best cut-off	5.75		9.61		13.07	
Sensitivity	0.82	0.78–0.86	0.90	0.87–0.93	1.00	1.00–1.00
Specificity	0.53	0.48–0.59	0.80	0.76–0.84	0.88	0.84–0.91
FPR (false positive rate)	0.18	0.22–0.14	0.10	0.13–0.07	0.00	0.00–0.00
FNR (false negative rate)	0.47	0.52–0.41	0.20	0.24–0.16	0.12	0.09–0.16
PPV (positive predictive value)	0.64	0.59–0.68	0.82	0.78–0.86	0.89	0.86–0.92
NPV (negative predictive value)	0.75	0.70–0.80	0.89	0.85–0.92	1.00	1.00–1.00
F1	0.72	0.68–0.75	0.86	0.83–0.88	0.94	0.93–0.96
BAC	0.68	0.65–0.71	0.85	0.82–0.88	0.94	0.92–0.96
LR + (positive likelihood ratio)	1.76	1.57–2.01	4.52	3.70–5.71	8.28	6.39–11.33
LR-(negative likelihood ratio)	0.33	0.26–0.42	0.12	0.09–0.17	0.00	0.00–0.00
ROC–AUC (area under the ROC curve)	0.751	0.68–0.82	0.90	0.82–0.96	0.98	0.95–1.00

Note: Optimal cutoff points were determined at the highest value of Youden's J index (sensitivity + specificity − 1). The 95% CIs were determined by bootstrapping.

Abbreviations: OSA, obstructive sleep apnea; PSG_AHI, apnea/hypopnea index during polysomnography; PSG_OAHI, obstructive apnea/hypopnea index during polysomnography; PSG_RDI, respiratory disturbances hourly index during polysomnography; ROC, receiver operating characteristic; Sr_RDI, Sunrise-derived obstructive respiratory disturbance index.

Diagnostic performance of Sr_RDI to detect PSG_OAHI at the diagnostic cutoff values for detecting pediatric OSA.

04. Sleep Staging in Adults

Machine Learning–based Sleep Staging in Patients with Sleep Apnea Using a Single Mandibular Movement Signal

Le-Dong NN, et al. Am J Respir Crit Care Med. 2021 Nov 15;204(10):1227-1231.

Read the article →

Objective

To develop, train, and then validate an artificial intelligence algorithm to stage sleep using a single sensor detecting mandibular movements.

Methods

- Patients underwent overnight in-laboratory PSG and simultaneous MM recordings using Sunrise.
- PSG data was manually and independently scored by 2 sleep experts in accordance with the recommended criteria established by the AASM.
- Development of the algorithm with a training set of 800 patients.
- Validation of the algorithm with a separate set of 226 patients.
- Quantitative agreement analysis between Sunrise and PSG was estimated using a linear mixed model by a two-way intraclass correlation coefficient (ICC) (A, 1) (95% CI) for total sleep time, wake time, light NREM, deep NREM, and REM sleep stages. Sunrise performance for each target sleep stage was determined via ROC curves evaluating sensitivity and specificity.

Results

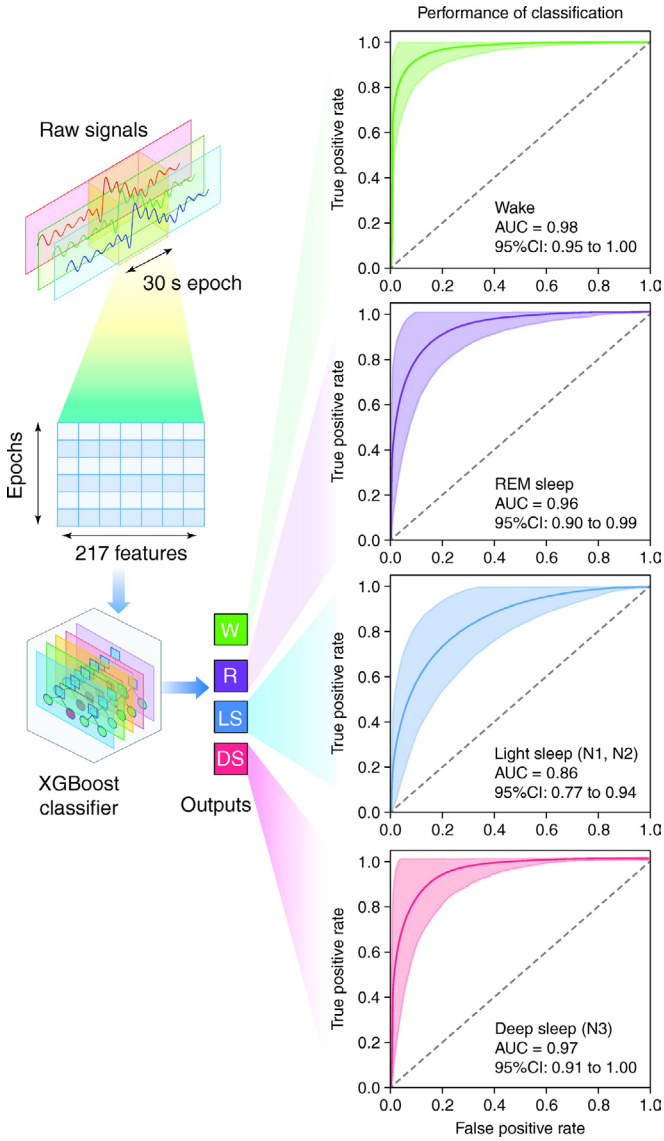
- Sleep epochs classification with substantial qualitative agreement with manual PSG scorers (Kappa = 0.71 and accuracy = 78.3%).
- Quantitative agreement between Sunrise and PSG using a linear mixed model by a two-way ICC (A, 1) (95% CI) was 0.94 (0.93–0.96) for total sleep time, 0.90 (0.88–0.92) for wake time, 0.70 (0.63–0.76) for light NREM, 0.66 (0.58–0.73) for deep NREM, and 0.65 (0.56–0.72) for REM sleep stage. Mean (95%CI) measurement bias for total sleep time, wake time, light NREM, deep NREM and REM sleep stages were -13.0 (-52.9 to +19.0), +3.8 (-6.8 to +16.8), -14.9 (-31.1 to +1.8), +6.5 (-6.0 to +21.2) and +8.4 (-21.3 to +2.4), in min for total sleep time and in % of total sleep time for others.
- Wakefulness was clearly discriminated from sleep states with a sensitivity of 88% and a specificity of 94%. Moreover, the algorithm performed well in detecting REM sleep (sensitivity 83%, specificity 89%) and deep sleep (sensitivity 84%, specificity 90%). Only light NREM sleep was slightly less well detected (sensitivity 60%, specificity 88%).

Conclusion

The MM signal acquired from Sunrise identifies sleep stages with good agreement with in-lab PSG.

Key Takeaways

The mandibular movement signal acquired from a compact inertial measurement device is suitable for automated sleep staging in adults presenting a broad spectrum of OSA severity.



Stagewise receiver operating characteristics (ROC) curve analysis. This consisted of extracting prediction scores for each target stage (wake, light sleep, deep sleep, and REM sleep) and for each patient, then estimating the false and true positive rates of a binary one- versus-rest classification rule to establish the ROC curve. The 95% CIs of the area under the curve (AUC) and smoothing effect were obtained from empirical data (without using any resampling). The diagonal dashed line serves as a reference and shows the performance if sleep staging had been made randomly. The algorithm performed well in detecting REM sleep with a ROC–AUC of 0.96 (0.90–0.99) and non-REM deep sleep with a ROC–AUC of 0.97 (0.91–0.99). Only light non-REM sleep was slightly less well detected with an ROC–AUC of 0.86 (0.77–0.94). CI = confidence interval; DS = deep sleep; LS = light sleep; R = REM sleep; W = wake.

05. Sleep Bruxism in Adults

Artificial Intelligence Analysis of Mandibular Movements Enables Accurate Detection of Phasic Sleep Bruxism in OSA Patients: A Pilot Study

Martinot JB, et al. Nat Sci Sleep. 2021; 13: 1449–1459.

Read the article →

Objective

To identify stereotypical MM in patients with sleep bruxism (SBx) and to automate the detection of rhythmic masticatory muscle activity (RMMA) using artificial intelligence (AI).

Methods

- Patients underwent overnight in-laboratory PSG with bilateral masseter surface EMG and simultaneous MM recordings using Sunrise.
- PSG data was manually and independently scored by 2 sleep experts in accordance with the recommended criteria established by the AASM. SBx was diagnosed based on the criteria defined in the ICSD-3 and the recent version of the AASM manual for the scoring of sleep. All episodes of RMMA related to other masticatory muscle activity like chewing, swallowing or facial scratching, or grimacing are discarded from the training set after audio/video examination during PSG.
- Development of the algorithm with a training set of 39 patients.
- Validation of the algorithm with a separate set of 28 patients.
- Epoch-by-epoch agreement evaluation conducted using a confusion matrix, overall agreement metrics (Cohen's Kappa coefficient and balanced accuracy), and class wise performance analysis, using precision, recall, F1 score and receiver operating characteristic area under the curve (ROC AUC). The Bland-Altman plot was used for quantitative agreement analysis.

Results

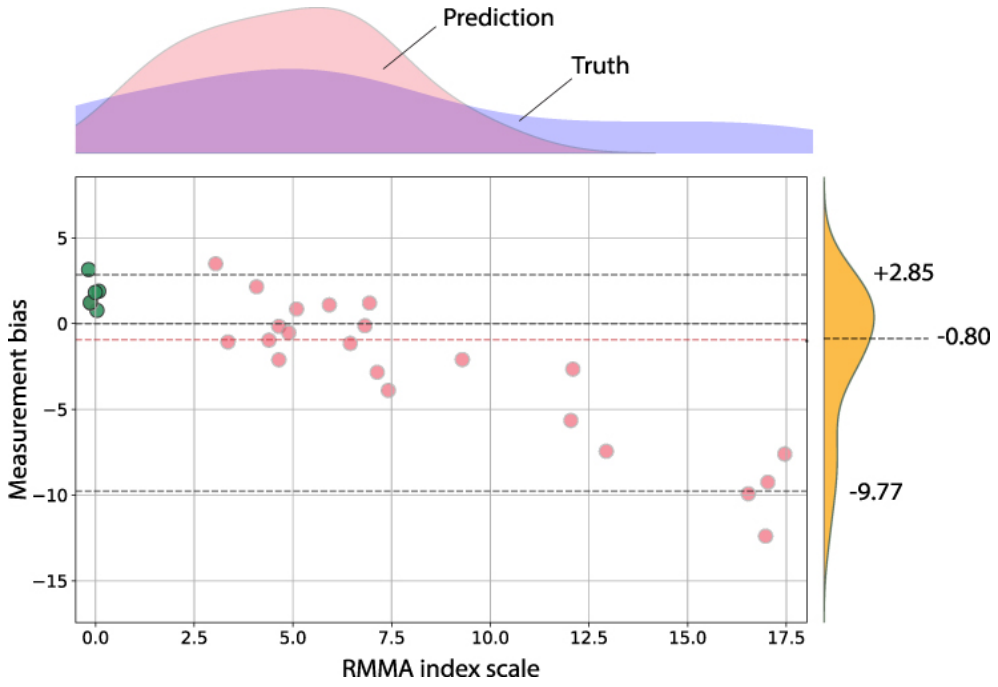
- Very good epoch-by-epoch agreement (Kappa = 0.80) and accuracy of 86.6% for the MM events when using RMMA standards.
- RMMA episodes detected with a sensitivity of 84.3%. Class-wise ROC curve analysis confirmed the well-balanced performance of the classifier for RMMA (ROC area under the curve: 0.98, 95% confidence interval [CI] 0.97–0.99).
- Good agreement between the MM analytic model and manual EMG signal scoring of RMMA with a median bias of −0.80 events/h (95% CI −9.77 to 2.85).

Conclusion

The MM signal acquired from Sunrise identifies SBx with very good agreement compared to in-lab PSG.

Key Takeaways

SBx can be reliably identified, quantified, and characterized with MM when subjected to automated analysis supported by AI technology.



Agreement between MJM analytic model and manual EMG signal scoring of RMMA. Bland-Altman plot evaluating measurement bias of rhythmic masticatory muscle activity (RMMA) index in the 28 subjects of the validation study. The median dash line corresponds to a negative bias 0.8 unit of RMMA index. Upper and lower dashed lines correspond to 95% confidence interval, +2.85 and −9.77 RMMA index. The dots in green represent the 6 true negative subjects.

06. Esophageal Pressure in Adults

Mandibular Movements are a Reliable Noninvasive Alternative to Esophageal Pressure for Measuring Respiratory Effort in Patients with Sleep Apnea Syndrome

Pépin JL, et al. Nat Sci Sleep. 2022; 14: 635–644.

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Objective

To assess whether Sunrise is a reliable surrogate of esophageal pressure (PES) in patients with suspected OSA.

Methods

- Patients underwent overnight in-laboratory PSG with PES measurement and simultaneous MM recordings using Sunrise.
- PSG data was manually and independently scored by 2 sleep experts in accordance with the recommended criteria established by the AASM.
- A total of 8,042 signal sequences were extracted from the PES and MM recordings from 38 patients.
- Evaluation of the similarity and linear correlation between PES and MM was done using the longest common subsequence (LCSS) algorithm and Pearson's coefficient; description of signal amplitudes; estimation of the marginal effect for crossing from normal breathing (NB) to a respiratory disturbance for a given change in MM signal using a mixed linear regression.

Results

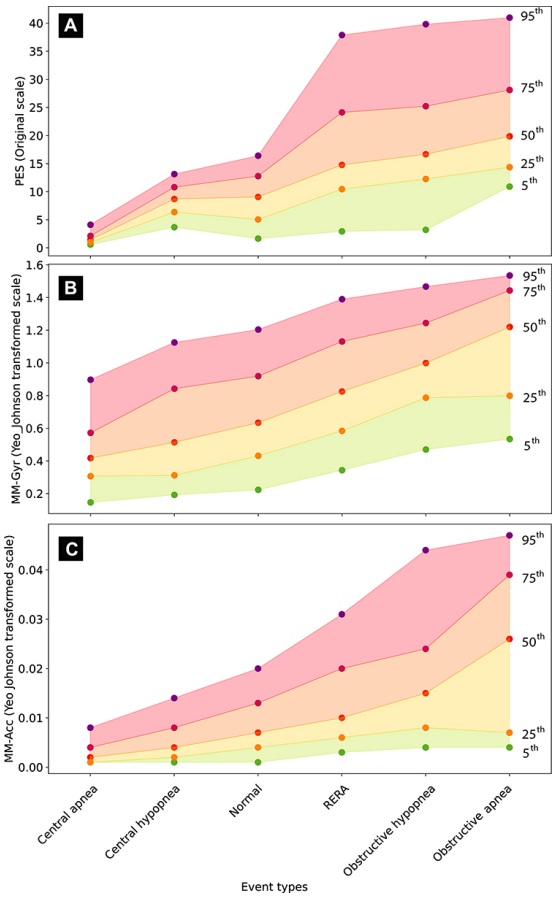
- MM showed a high level of synchronization with concurrent PES signals. Distribution of MM amplitude differed significantly between event types: median (95% confidence interval) values of 0.60 (0.16–2.43) for central apneas, 0.83 (0.23–4.71) for central hypopneas, 1.93 (0.46–12.43) for mixed apneas, 3.23 (0.72–18.09) for obstructive hypopneas, and 6.42 (0.88–26.81) for obstructive apneas.
- Mixed regression indicated that crossing from NB to central events would decrease MM signal amplitude by −1.23 (central hypopneas) and −2.04 (central apneas) units, while obstructive events would increase MM amplitude by +3.27 (obstructive hypopneas) and +6.79 (obstructive apneas) units (all $p<10-6$).

Conclusion

- In OSA patients, MM signals facilitated the measurement of specific levels of respiratory effort associated with obstructive, central or mixed apneas and/or hypopneas.
- A high degree of similarity was observed with the PES gold-standard signal and recorded MM.

Key Takeaways

MM signals are a highly reliable non-invasive alternative to esophageal pressure for measuring respiratory effort in patients with OSA.



Distribution of esophageal pressure (PES; A), gyroscope mandibular jaw movement (MM-Gyr; B) and accelerometer mandibular jaw movement (MM-Acc; C) signal amplitudes during normal breathing and different respiratory disturbances. Each panel on the graph shows the change in distribution of signal amplitudes across normal breathing and the scored respiratory disturbances. Within each event type, the distribution of signal amplitude is summarized in five centiles (95th, 75th, 50th, 25th and 5th, purple, dark red, red, orange, and green points, respectively). The PES signal was evaluated in original scale (mmHg), but the MM-Gyr and MM-Acc amplitudes were transformed using the Yeo-Johnson method to optimize the visual effect. The order of event types on the x-axis was established by sorting the median signal amplitude values.

Abbreviation: RERA, respiratory effort-related arousals.

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