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Universitätsklinik für Hals-, Nasen- und Ohrenkrankheiten, Kopf- und Halschirurgie
Direktor und Chefarzt:
Prof. Dr. med. Marco Caversaccio

Night-to-Night Variability of Novel Physiological Parameters in Home Sleep Apnea Testing

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Research legislation:	Ordinance on human research except for Clinical trials (HRO) [1].
Type of Research Project:	Research project involving human subjects
Risk Categorisation:	A
Project leader:	Dr. med. Samuel Tschopp Oberarzt Inselspital University Hospital and University Bern Freiburgstrasse 20, 3010 Bern, Switzerland samuel.tschopp@insel.ch, 031 632 29 41

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PROTOCOL SIGNATURE FORM

Project Title	Night-to-Night Variability of Novel Physiological Parameters in Home Sleep Apnea Testing

The project leader has approved the protocol version ***1 (dated 01.02.2026)*** and confirms hereby to conduct the project according to the protocol, the Swiss legal requirements[1, 2], current version of the World Medical Association Declaration of Helsinki [3] and the principles and procedures for integrity in scientific research involving human beings.

The project leader has received the ICF and considers it appropriate for use.

Project leader:

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GLOSSARY OF ABBREVATIONS

BASEC	*Business Administration System for Ethical Committees*
CRF	*Case report form*
FOPH	*Federal Office of Public Health*
HRA	*Human Research Act*
HRO	*Ordinance on Human*
ICC	*Intraclass correlation coefficient*
OSA	*Obstructive sleep apnea*
PROM	*Patient-reported outcome measures*
VAS	*Visual analog scale from 0 to 10 points (all visual analog scales will include 0, so patients can indicate the absence of a symptom)*

1 BACKGROUND AND PROJECT RATIONALE

Obstructive sleep apnea (OSA) is usually diagnosed from a single night of home sleep apnea testing using the apnea-hypopnea index (AHI). However, the AHI varies substantially from night to night, undermining diagnostic accuracy,[4–7] and shows only modest correlation with symptoms.[8, 9] This variability further limits its usefulness for predicting cardiovascular and other complications.[10] Besides the traditional AHI, more robust physiological markers are needed.

Several emerging physiological metrics - hypoxic burden[11–14], ventilatory burden[15, 16], heart rate variability[13], autonomic arousals, and the pulse wave amplitude drop index[17] – capture the physiological impact of OSA more comprehensively and demonstrate stronger associations with cardiovascular risk. Despite this promise, their night-to-night variability has not been studied.

A systematic evaluation of both established and novel OSA metrics across nights is essential to identify reliable, stable parameters suitable for clinical routine. This improves diagnostic precision beyond what traditional metrics can provide, enhances patient selection, reduces costs and patient harm, and may improve treatment outcomes.

This research project is classified as **Category A** according to Art. 7 of the Human Research Ordinance (HRO). The study exclusively involves **non-invasive sleep measurements** using validated devices also used in routine clinical practice, along with the collection of associated personal health data. No invasive procedures, biological sampling, or interventions exceeding routine clinical assessments are performed. The planned measures, therefore, **entail only minimal risks and burdens** for participants, comparable to standard, non-invasive diagnostic procedures. Accordingly, the overall risk of the project is minimal and fully consistent with formal classification as a **Category A** research project.

2 PROJECT OBJECTIVES AND DESIGN

2.1 Hypothesis and primary objective

We aim to quantify the night-to-night variability in established and novel OSA metrics, identify factors driving this variability, and determine which measures most closely correlate with patient-reported symptoms.

2.2 Primary and secondary endpoints

Building on our previous work[4, 5] on night-to-night variability in home sleep apnea testing, this project aims to examine novel physiological OSA parameters:

1. Quantify the variability and measurement uncertainty of both established and novel sleep parameters across multiple nights.
2. Identify factors that influence variability, including alcohol intake, respiratory infection, subjective sleep quality, and psychological aspects.
3. Assess the association between sleep parameters and patient-reported outcome measures (PROMs).
4. Develop evidence-based recommendations to optimize sleep testing in clinical practice.

The comprehensive list of collected data, primary and secondary endpoints, and the statistical analysis plan are provided in *Section 4: Statistics and Methodology, and Appendix 2.*

2.3 Project design

This project is designed as a single-center, cross-sectional study.

Participants representing the full spectrum of sleep disordered breathing, from healthy controls and primary snorers to patients with severe OSA, will undergo repeated home sleep apnea tests and symptom questionnaires. Respiratory polygraphy will be performed over four consecutive nights, and a wearable oxygen sensor will be used over ten consecutive nights, starting in parallel.

Further methodological details are provided in *Sections 3, 4, and 7*.

2.4 Patient and public involvement

Patients will be involved as active contributors by completing standardized questionnaires on symptoms and their experience with the sleep measurements. Their feedback will be used to evaluate the perceived burden, acceptability, and relevance of the measurement procedures and outcomes. This patient-reported input will directly inform the interpretation of study results, but patients are not involved in the study design, protocol development, or data analysis.

3 PROJECT POPULATION AND PROJECT PROCEDURES

3.1 Project population, inclusion and exclusion criteria

Participants with suspected or diagnosed sleep-disordered breathing of any severity will be recruited at Inselspital University Hospital und University Bern.

No selection or stratification based on sex, gender, or any other patient characteristics is applied during recruitment. Participants are included consecutively based on the clinical indication for home sleep apnea testing, irrespective of sex or gender. Any resulting imbalance reflects the underlying clinical population and does not compromise the scientific validity of the study, as analyses will account for sex and gender as covariates and report their effects transparently.

*For an overview, refer to **Appendix 2: Screening Checklist**.*

Inclusion criteria:

- Patients with suspected or diagnosed sleep-disordered breathing, irrespective of disease severity, as defined by the indications for home sleep apnea testing in the German guidelines [18]
- No active treatment during sleep recordings or within preceding two weeks (e.g., mandibular advancement devices, positive airway pressure therapy)
- Written informed consent obtained

Suspected sleep-disordered breathing is defined according to the indications for home sleep apnea testing as specified in the German guidelines (S3-Leitlinie Nicht erholsamer Schlaf/Schlafstörungen - Schlafbezogene Atmungsstörungen [18]) and is assumed if one or more of the following symptoms are present:

- Witnessed nocturnal apnoeas (reported by the bed partner)
- Loud, irregular snoring
- Excessive daytime sleepiness
- Obesity
- Hypertension and cardiac arrhythmias

- Reduced libido and erectile dysfunction
- Restless sleep
- Morning fatigue, diffuse, dull headaches, dry mouth
- Non-specific psychological symptoms, including reduced energy, decline in performance, personality changes, and cognitive impairment

Exclusion criteria:

- Age <18 years
- Known or suspected neurological sleep disorder (e.g., narcolepsy, parasomnia)
- Known or suspected psychiatric sleep disorder
- Known or suspected central and complex sleep apnea
- Participants who are unable to perform sleep measurements reliably
- Insufficient knowledge of the project language (German)
- Inability to give consent
- Shift workers (with shift work <2 weeks before testing)

The sample size was calculated to be 192 patients (*see Section 4: Statistics and Methodology*).

3.2 Recruitment, screening and informed consent procedure

For a tabular view, see Appendix 1

Screening and recruitment:

Participants will be recruited at Inselspital Bern, University Hospital, Department of Otorhinolaryngology, Head and Neck Surgery. Recruitment will be conducted through consecutive, ongoing enrollment of eligible patients in routine clinical practice by the project investigators, including patients with suspected or established OSA diagnosis of all severities (*see **Appendix 2 Screening Checklist***).

If potential participants are interested in participating, they will be screened based on clinical history to assess inclusion and exclusion criteria (*see **Appendix 2: Screening Checklist***). No screening procedures beyond a patient history (standard care) will be performed before informed consent is obtained.

Recruitment is designed to ensure inclusion across the full spectrum of OSA severity, with no restriction on age beyond adulthood, sex, or gender. Efforts will be made to achieve an appropriate balance of sex and gender by recruiting consecutively from the clinical population.

No advertisement or flyer-based recruitment will be used.

Informed consent procedure:

The project leader (or her/his designee) explains to each participant the nature of the research project, its purpose, the procedures involved, the expected duration, the potential risks and any discomfort it may entail. Each participant is informed that the participation in the research project is voluntary and that he/she may withdraw from the research project at any time and that withdrawal of consent will not affect his/her subsequent medical assistance and treatment. The

participants are informed that he/she can ask any question. Enough time is given to the participant.

All participants are given an information document and a consent form describing the research project. The formal consent of a participant, using the approved consent form, is obtained before the participant is enrolled in the research project.

The participant should read, understand, and voluntarily agree before signing and dating the informed consent form, and is given a copy of the signed document. The consent form is signed and dated by the participant and the project leader (or her/his designee). The signed consent form is retained as part of the investigation records.

All study-specific procedures, including repeated home sleep apnea testing and wearable oxygen monitoring, will only be initiated after written informed consent has been obtained. Participants will receive comprehensive oral and written study information, be given adequate time for consideration, and have the opportunity to ask questions before consent.

3.3 Project procedures

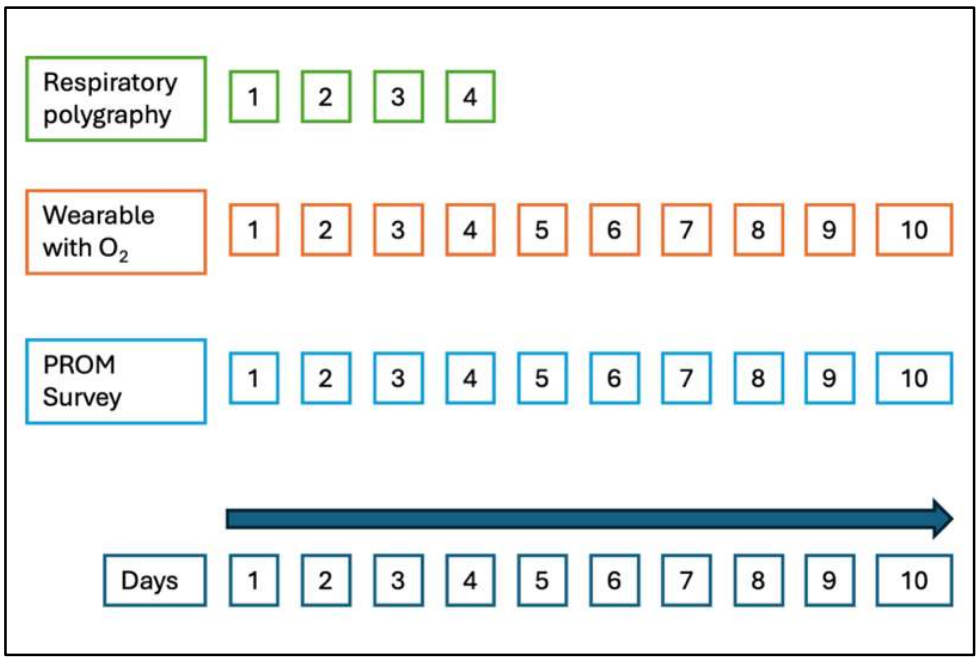
After inclusion and informed consent, participants will complete symptom questionnaires and undergo an upper airway examination as part of standard clinical care (see ***Appendix 2***).

Participants will receive sleep-testing devices. Sleep will be recorded prospectively using respiratory polygraphy over four consecutive nights and a wearable oxygen sensor over ten consecutive nights, starting in parallel.

Home sleep apnea testing devices:

- Respiratory polygraphy (e.g., SOMNOmedics SOMNOtouchTM resp or similar device)
- Wearable oxygen sensor (e.g., SOMNOmedics OtwoFellow or similar device)

Schedule of Sleep Measurements and Patient-Reported Outcome Measures Survey:



For feasibility, full respiratory polygraphy will be limited to four nights. The remaining six nights will be recorded using only the oxygen sensor to capture extended variability in oxygenation, heart rate, and pulse wave amplitude drops, without airway flow or body position measurements.

Each morning, participants will complete a brief survey on subjective sleep quality and report factors that may influence variability, including alcohol and caffeine intake, nicotine use, respiratory infections, allergy symptoms, and psychological aspects. Participants may choose to complete the questionnaire electronically via a personalized link (REDCap®) or on paper.

After completing all recordings, participants will personally return the devices and, if applicable, the paper-based questionnaires to the Department of Otolaryngology, Head and Neck Surgery, for data retrieval and analysis.

Sleep recording will be analyzed and data entered by the project leader or his/her designee. All data will be recorded in a REDCap® database, supported and hosted by the Department of Clinical Research. A comprehensive list of all collected data is given in ***Appendix 2***.

3.4 Withdrawal and discontinuation

Participants may be withdrawn from the study at any time. Upon withdrawal of informed consent, the participant will be excluded by the project leader for non-compliance with study procedures or intercurrent conditions meeting exclusion criteria (e.g., newly identified central sleep apnea). There are no study-related medical reasons mandating discontinuation, as all procedures are non-invasive.

In the event of a premature withdrawal, no further study-specific procedures will be performed. Already completed recordings and questionnaires may be retained and analyzed unless the participant explicitly withdraws consent for data use. No final examination is required, as all measurements are conducted at home and are observational.

All collected data are coded using a unique study identification number. Upon withdrawal of consent, all directly identifiable data (name, address, date of birth) will be deleted, and the code key linking the study ID to the participant will be destroyed, rendering the dataset effectively anonymised. After deletion of the code key, re-identification would only be possible with disproportionate effort. No biological material is stored.

Given the longitudinal nature of the project, drop-outs are expected. All available data will be analyzed using appropriate statistical methods for incomplete repeated-measures data (see *Section 4.2)*.

4 STATISTICS AND METHODOLOGY

The study will be registered on clinicaltrials.gov upon receiving Ethics approval.

4.1 Statistical analysis plan

The final statistical analysis will be performed in consultation with the Clinical Trial Unit Bern.

4.1.1 Endpoints

Primary endpoint

The **primary endpoint** is to estimate the **night-to-night variability of established and novel OSA metrics** obtained from **repeated home sleep measurements**.

Variability statistics will be calculated for the following metrics:

- Apnea-hypopnea index (events per hour of sleep)
- Oxygen desaturation index (events per hour of sleep)

- Hypoxic burden (minute x percent per hour of sleep)
- Ventilatory burden (calculated according to Parekh et al.[16])
- Heart rate variability (calculated according to heart rate variability: standards of measurement guidelines [19])
- Pulse wave amplitude drops (events per hour [17, 20])

Secondary endpoints

Identification of factors contributing to and explaining variability

Each influencing factor will be evaluated on its potential to explain the observed variability in the objective physiological parameters listed above. Each factor will be included individually as a fixed effect in the mixed-effects model and tested for significance.

The following factors will be analyzed:

- Age (years)
- Body mass index (kg(m2)
- Gender
- Upper airway anatomy (tonsil size)
- Mean OSA severity over all nights (of the respective parameter)
- Sleep position (supine time as a percent of sleep time)
- Alcohol consumption (number of drinks)
- Caffeine intake (number of cups)
- Nicotine use (number of packages)
- Sleep Medication (free text)
- Subjective sleep quality (visual analog scale, VAS, 0 to 10 points)
- Snoring intensity (VAS, 0 to 10 points)
- Daytime sleepiness on a VAS *of the subsequent day* (0 to 10 points)
- Daytime sleepiness on the Epworth Sleepiness Scale *of the subsequent day* [21] (0 to 24 points)
- Respiratory symptoms such as infection (VAS, 0 to 10 points)
- Allergy symptoms (VAS, 0 to 10 points and free text)

Association between physiological parameters from sleep testing and PROMs

Associations between physiological metrics and PROMs will be assessed using mixed-effects models, analogously to the analysis of influencing factors above and correlation analysis (Spearman's rank coefficient).

Patient-reported symptoms for correlation analyses:

- Sleep quality on a VAS (0 to 10 points)
- Snoring intensity on a VAS (0 to 10 points)
- Daytime sleepiness on a VAS (0 to 10 points)
- Epworth Sleepiness Scale (0 to 24 points) [21]

4.1.2 Statistical Methods

4.1.2.1 General statistical methods

- Analyses are primarily estimation-focused.
- Hypothesis-based analyses (e.g., comparison of variability of different metrics) will be conducted using two-sided tests with a significance level of α = 0.05.
- Variability and reliability measures will be reported with 95% confidence intervals.
- Descriptive statistics will be used to summarize participant characteristics and sleep parameters. Continuous variables will be reported as means (standard deviation) or medians (interquartile range), as appropriate.
- To account for multiple testing, p-values and confidence intervals will be adjusted within each endpoint family using a false discovery rate approach (Benjamini–Hochberg). The primary endpoints, which is estimation-focused, will not be subject to multiplicity adjustment.
- For reproducible analysis, all statistical analyses will be performed in R (R Foundation for Statistical Computing, Vienna, Austria Analytic code will be version-controlled and archived to ensure transparency and full reproducibility.

4.1.2.2 Variability Assessment

Variability assessment will be conducted analogously to our previously established methodology, developed in consultation with the Clinical Trial Unit Bern,[5] and extended based on the analytical approach described by Frauchiger et al.[22]:

Linear mixed-effects models

Analyses will primarily use **linear mixed-effects models** for each outcome variable to account for repeated measurements within participants. A random intercept for participant will be included to model within-subject correlation.

$$Y_{ij} = \beta_0 + u_i + \varepsilon_{ij}$$

where Y_{ij} is the measurement for participant *i* on night *j*. β_0 is the fixed intercept. u_i represents the random effect for between-subject variability and ε_{ij} represents within-subject variability.

Where relevant, fixed effects will be added to explore potential influencing factors of variability, such as number of nights, age, sex body mass index, alcohol intake and sleep position).

Absolute within-subject deviation

The **mean absolute deviation (MAD)** between each individual measurement and the participant-specific mean across all measurements will be reported.

For each participant *i* with n_i repeated measurements x_{ij} *(j = 1, …, n_i)),* the participant-specific mean was calculated as

$$\bar{x_i} = \frac{1}{n_i}\sum_{j=1}^{n_i} x_{ij}$$

The mean absolute deviation (MAD) from the participant-specific mean will then be computed as

$$\mathrm{MAD_i} = \frac{1}{n_i}\sum_{j=1}^{n_i} \left| x_{ij} - \bar{x_i} \right|$$

The distribution of MAD across participants will be summarized using the mean and standard deviation.

Relative within-subject deviation

The **mean relative absolute deviation (MRAD)** expresses the within-participant deviation relative to the participant-specific mean and will be calculated as

$$\mathrm{MRAD_i} = \frac{1}{n_i}\sum_{j=1}^{n_i}\frac{|x_{ij} - \bar{x_i}|}{\bar{x_i}} \times 100$$

The distribution of MRAD across participants will be summarized using the mean and standard deviation.

Intraclass correlation coefficient

The **intraclass correlation coefficient (ICC)** with 95% confidence intervals will be calculated to assess the night-to-night reliability of sleep apnea metrics. ICC estimates will be interpreted in accordance with the guidelines proposed by Koo and Li.[23]

$$ICC = \frac{\sigma^2_{\mathrm{Between}}}{\sigma^2_{\mathrm{Between}} + \sigma^2_{\mathrm{Within}}}$$

The estimated variances of the residual and random intercept will be derived from the mixed-effects model and used as $\sigma^2_{\mathrm{Within}}$ and $\sigma^2_{\mathrm{Between}}$ respectively.

Coefficient of variation (CV, %) [24]

The coefficient of variation (CV) is a measure of relative variability and expresses the spread of measurements relative to their mean, allowing comparison of variability across different scales or units.

$$CV = \frac{\sqrt{\sigma^2_{\mathrm{Within}}}}{\beta_0} \cdot 100\%$$

The intercept and residual standard deviation from the linear mixed-effects model will be used as the mean and SD in the shown formula of CV%.

Coefficient of repeatability (CR) [25, 26]

The CR represents the value below which the absolute difference between two measurements from the same subject is expected to lie for 95% of pairs, assuming normality and no systematic change.

$$CR = 1.96 \cdot \sqrt{2\,\sigma^2_{\mathrm{Within}}}$$

The standard deviation of differences will be estimated using a linear mixed-effects model with participant-level random intercepts to account for within-subject clustering. Where applicable, correlation between successive measurements will be modeled using an autoregressive covariance structure.

4.1.2.3 Sex and gender analyses

Sex and gender differences will be explored using stratified analyses and interaction terms in mixed-effects models where sample size permits. These analyses are exploratory:

- Descriptive summaries by sex/gender group.
- Interaction terms (metric × sex/gender) in mixed-effects models for variability determinants and PROM associations.
- All estimates will be stratified by sex/gender where sample size permits.

4.1.2.4 Sensitivity analyses

Planned sensitivity checks include:

- Excluding nights with self-reported acute respiratory infection or allergy flare.
- Per-protocol subset that includes only participants who completed all 4 polygraphy nights and, separately, all 10 oxygen measurement nights.
- Alternative metric definitions where applicable (e.g., different desaturation thresholds/event definitions if available from device outputs).
- Robust regression/transformation for strongly skewed metrics.

4.1.2.5 Interim analyses

No interim analyses are planned. This study is observational and minimal risk, with estimation as the primary aim.

4.1.3 Visualization

Several predefined visualizations will be plotted:

1. All sleep measurements of a metric (y-axis) are plotted for each patient (x-axis), ordered by the mean of each patient. The mean will be indicated, and all measurements of a patient will be connected.
2. All sleep measurements for a metric (y-axis) are plotted chronologically across nights (x-axis), centered on each patient's mean across all measurements. All measurements of a patient are connected.
3. The cumulative mean of a metric per patient as nights accrue, expressed as deviation from the overall mean, to demonstrate the stabilization of an estimated metric with increasing numbers of measurements.

An example of the proposed figures can be found in Tschopp et al. 2024 [5]

4.1.4 Statistical software

All analyses will be conducted using **R** version 4.5.2 or later (R Foundation for Statistical Computing, Vienna, Austria). Data cleaning and summarization will be performed using base R functions and packages from the tidyverse. Linear mixed-effects models will be fitted using the lme4 package. Visualizations will be generated with ggplot2, with additional extensions applied as required.

Additionally, MATLAB (The MathWorks Inc., Natick, Massachusetts) may be used for signal processing, such as the calculation of ventilatory burden [15, 16], heart rate variability [13, 19], pulse wave amplitude drops [17, 20].

4.2 Sample Size Calculation

In our previous study[4], the intraclass correlation coefficient for the AHI was 0.76 (95% CI 0.65-0.87). Assuming a confidence level of 95%, a confidence interval width of 0.1, and assuming similar variability for other sleep parameters, a sample size of 160 participants is required to assess variability over four nights reliably.[27]

Assuming a 20% dropout rate, a **total of 192 patients will be enrolled** to achieve a sample size of 160.

4.3 Handling of missing data

Given the longitudinal nature of the project, dropouts are expected. To compensate, we increased the sample size, assuming a 20% dropout rate, to achieve an adequately powered sample size.

For participants who discontinue measurements, all available data will be analyzed. Mixed-effects models inherently accommodate unbalanced repeated measures under a missing-at-random assumption. Missingness patterns will be summarized (number of nights and variables). Sensitivity analyses will be performed to assess robustness.

5 REGULATORY ASPECTS AND SAFETY

5.1 Local regulations / Declaration of Helsinki

This research project will be conducted in accordance with the protocol, the Declaration of Helsinki [3], the Human Research Act (HRA) and the Human Research Ordinance (HRO) [1] as well as other locally relevant regulations. The project leader acknowledges his responsibilities as both the project leader and the Sponsor.

5.2 Notification of safety and protective measures (HRA Art. 15, HRO Art. 20)

If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay.

The project leader is promptly notified (within 24 hours) if immediate safety and protective measures must be taken during the conduct of the research project. The Ethics Committee will be notified via BASEC of these measures and of the circumstances necessitating them within 7 days.

5.3 Serious events (HRO Art. 21)

If a serious event occurs, the research project will be interrupted and the Ethics Committee notified on the circumstances via BASEC within 7 days according to HRO Art. 21[1].

The project leader reports to the ethics committee on the connection between the event and the collection of health-related personal data. At the same time, the project leader submits proposals concerning the next steps to be taken.

Any new relevant information and the outcome to the original Serious Event is reported to the ethics committee via BASEC.

5.4 Procedure for investigations involving radiation sources

Our project does not involve radiation sources.

5.5 Amendments

Substantial changes to the project set-up, the protocol and relevant project documents will be submitted to the Ethics Committee for approval according to HRO Art. 18 before

[1] A serious event is defined as any adverse event where it cannot be excluded, that the event is attributable to the sampling of biological material or the collection of health-related personal data, and which:
a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;

b. results in permanent or significant incapacity or disability; or

c. is life-threatening or results in death.

implementation. Exceptions are measures that have to be taken immediately in order to protect the participants.

The following are considered to be substantial changes:

a. changes affecting the participants' safety and health, or their rights and obligations;

b. changes to the protocol which concern the objectives of the research project;

c. a change of research site or conducting the research project at an additional site; or

d. a change of project leader or Sponsor.

5.6 End of project

Upon project completion or discontinuation, the Ethics Committee is notified within 90 days. The completion of the research project is defined by the last collection of health-related personal data.

If the sleep testing data collected as part of the study are relevant for future patient treatment, they will be stored in the hospital system (EPIC Systems) of the Inselspital Bern, along with a patient's regular medical data.

After completion of data collection, all data will be checked for completeness and consistency before final analysis. Directly identifiable personal data (e.g., name, date of birth, contact details) will be deleted as soon as they are no longer required for project conduct. The key linking participant identifiers to study IDs will be stored separately and securely on password-protected hospital computers. The association of the data with a specific person can only be re-established with disproportionate effort.

No biological material is collected or stored as part of this project.

5.7 Insurance

In the event of project-related damage or injuries, the liability of the institution Inselspital University Hospital and University Bern provides compensation.

6 FURTHER ASPECTS

6.1 Overall ethical considerations

This project addresses a clinically relevant and well-defined knowledge gap regarding the night-to-night variability of established and novel physiological parameters in obstructive sleep apnea. OSA is a common disease, globally affecting an estimated 936 million people.[28] Therefore, the results are expected to have high scientific and social value by improving diagnostic accuracy, informing evidence-based testing strategies, and supporting more individualized patient management. The findings may benefit future patients by reducing misclassification, unnecessary treatment, and healthcare costs.

The study design is justified by the research question and relies exclusively on non-invasive, routinely used home sleep testing devices and brief questionnaires. The burden for participants is low and mainly consists of wearing validated sleep monitoring devices and completing short daily questionnaires. No interventions beyond multiple non-invasive tests using the same devices as for standard clinical practice are performed.

Participation is entirely voluntary. Written informed consent is obtained before any study-specific procedures, and participants may withdraw at any time without consequences for their medical care. The right to information is ensured, and participants may request feedback on their individual results and the overall study conclusions, if desired.

Surplus information and incidental findings may arise from sleep recordings (e.g., previously unrecognized severe sleep apnea or relevant oxygen desaturations). Clinically relevant incidental findings will be handled in accordance with the Swiss Ethics Guidelines and communicated to the participant by a qualified physician, with appropriate recommendations for further clinical evaluation, where indicated.

No biological material and no genetic data are collected. Data protection and confidentiality are ensured throughout the project. Overall, there is a fair and appropriate balance between the minimal burden and risks for participants and the anticipated scientific and societal benefit of the study.

6.2 Risk-Benefit Assessment

This project poses minimal risks to participants. All procedures are non-invasive and based on validated home sleep apnea testing devices that are routinely used in clinical practice. Potential burdens are limited to mild, transient discomfort from wearing the devices during sleep and the time required to complete short daily questionnaires. No medical interventions, invasive procedures, or biological sampling are performed.

Risks related to data protection are minimized through strict coding of data, restricted access to authorized medical personnel only, secure storage on institutional servers (REDCap® Database hosted by the Clinical Research Department of the University of Bern and hospital computers of the Inselspital Bern), and separation of identifying information from research data, as detailed in *Sections 5.6 and 7.*

Participants will receive multiple nights of validated sleep measurements at no cost. This exceeds standard clinical practice and may provide a more robust assessment of their sleep-disordered breathing. While participation is not primarily intended to provide therapeutic benefit, participants gain a better insight into their disease, which better informs clinical decision-making.

The primary benefit of the project lies in its expected contribution to improved understanding of night-to-night variability in established and novel OSA metrics, which may lead to more reliable diagnostics, better patient stratification, and optimized treatment decisions for future patients.

Overall, the minimal risks and burdens for participants are justified by the substantial anticipated scientific and societal benefit of the project.

7 QUALITY CONTROL AND DATA PROTECTION

7.1 Quality measures

Quality assurance is ensured through standardized study procedures as outlined *in Sections 3 and 4*. All measurements are performed using validated sleep testing devices also used in routine clinical practice. All project personnel involved in recruitment, device handling, and data collection are appropriately trained in study procedures, data protection, and Good Clinical Practice principles relevant to observational research.

Data are entered into a secure REDCap® database hosted by the Clinical Research Department of the University of Bern with predefined fields and range checks to ensure data integrity and traceability (see ***Appendix 2*** for a complete data dictionary of the database). Regular plausibility checks and consistency reviews will be performed to identify missing or implausible values. Any data corrections will be documented.

For quality assurance the Ethics Committee may visit the research sites. Direct access to the source data and all project related files and documents must be granted on such occasions.

The project leader has appropriate knowledge and skills in the areas of data security and data protection or can ensure compliance by calling in appropriate expertise (Art. 4 HRO).

7.2 Data recording and source data

Study data are recorded in a secure electronic case report form (eCRF) using REDCap, hosted by the Department of Clinical Research. Data are entered directly from source documents or device outputs into the database, which provides controlled access, user-specific permissions, and an audit trail. All data will be input into predefined fields with range checks to ensure data integrity. A list of all collected data points is provided in ***Appendix 2.***

Source data include sleep device recordings, electronically or paper-based participant questionnaires. Analysis of sleep testing and data collection will be exclusively performed on password-protected hospital computers.

7.3 Confidentiality and coding

Project data will be handled with uttermost discretion and is only accessible to authorized personnel who require the data to fulfil their duties within the scope of the research project. On the CRFs and other project specific documents, participants are only identified by a unique participant number. Coding is done using a method based on the current state of the art that must be based on the current state of the art (Art. 26 HRO).

Directly identifying information is stored separately from research data on a secure, access-restricted hospital computer. Access to coded data is limited to authorized study personnel only. Re-identification is only possible via a securely stored code key, ensuring confidentiality in accordance with the Human Research Ordinance. The key is retained as described *in Section 7.4.*

7.4 Retention and destruction of project data and biological material

The project leader retains all the research project data for a period of at least ten years after the completion or early termination of the research project.

All project data and essential study documents will be securely archived on the computers of the Inselspital University Hospital. Paper-based records for patients who prefer non-electronic surveys will be stored at the Department of Otorhinolaryngology, Head and Neck Surgery, University Clinic of the Inselspital Bern, until completion of the study. Thereafter, all physical documents will be digitized and destroyed. Digital scans will be kept on hospital computers. All electronic data will be stored on protected institutional servers with restricted access.
No biological material is collected.

8 FUNDING / PUBLICATION / DECLARATION OF INTEREST

This study will be conducted using the institutional resources of Inselspital, University Hospital, Bern. Additional funding is being sought through peer-reviewed, competitive funding mechanisms.

Device distributors (e.g., SOMNOmedics Schweiz AG, Switzerland) will be approached solely to request price reductions for study-related equipment. No financial contributions or other benefits influencing the conduct of the study will be accepted.

All funding sources, if obtained, will have no role in the study design, data collection, analysis, interpretation, or publication decisions. The investigators declare that they have no financial or personal conflicts of interest related to this project.

The investigators commit to publishing the study results in peer-reviewed scientific journals irrespective of the direction, strength, or statistical significance of the findings. De-identified data may be shared upon reasonable request in accordance with applicable data protection regulations.

If sex- and gender-related effects are observed, these will be explicitly analyzed and reported in the final study report. If analyses reveal no sex- or gender-specific effects, this absence will also be transparently reported.

9 REFERENCES

1. Ordinance on Human Research with the Exception of Clinical trials (HRO)

2. Human Research Act (HRA)

3. Declaration of Helsinki

4. Tschopp S, Wimmer W, Caversaccio M, Borner U, Tschopp K (2021) Night-to-night variability in obstructive sleep apnea using peripheral arterial tonometry: a case for multiple night testing. Journal of Clinical Sleep Medicine jcsm.9300, jcsm.9300. https://doi.org/10.5664/jcsm.9300

5. Tschopp S, Borner U, Caversaccio M, Tschopp K (2024) Long-term night-to-night variability of sleep-disordered breathing using a radar-based home sleep apnea test: a prospective cohort study. Journal of Clinical Sleep Medicine jcsm.11070. https://doi.org/10.5664/jcsm.11070

6. Lechat B, Naik G, Reynolds A, Aishah A, Scott H, Loffler KA, Vakulin A, Escourrou P, McEvoy RD, Adams RJ, Catcheside PG, Eckert DJ (2022) Multinight Prevalence, Variability, and Diagnostic Misclassification of Obstructive Sleep Apnea. Am J Respir Crit Care Med 205:563–569. https://doi.org/10.1164/rccm.202107-1761OC

7. Roeder M, Kohler M (2020) It's Time for Multiple Sleep Night Testing in OSA. Chest 158:33–34. https://doi.org/10.1016/j.chest.2020.02.024

8. Ulander M, Hedner J, Stillberg G, Sunnergren O, Grote L (2022) Correlates of excessive daytime sleepiness in obstructive sleep apnea: Results from the nationwide SESAR cohort including 34,684 patients. Journal of Sleep Research 31:e13690. https://doi.org/10.1111/jsr.13690

9. Kainulainen S, Töyräs J, Oksenberg A, Korkalainen H, Sefa S, Kulkas A, Leppänen T (2019) Severity of Desaturations Reflects OSA-Related Daytime Sleepiness Better Than AHI. Journal of Clinical Sleep Medicine 15:1135–1142. https://doi.org/10.5664/jcsm.7806

10. Kendzerska T, Gershon AS, Hawker G, Leung RS, Tomlinson G (2014) Obstructive Sleep Apnea and Risk of Cardiovascular Events and All-Cause Mortality: A Decade-Long Historical Cohort Study. PLoS Med 11:e1001599. https://doi.org/10.1371/journal.pmed.1001599

11. Azarbarzin A, Sands SA, Stone KL, Taranto-Montemurro L, Messineo L, Terrill PI, Ancoli-Israel S, Ensrud K, Purcell S, White DP, Redline S, Wellman A (2019) The hypoxic burden of sleep apnoea predicts cardiovascular disease-related mortality: the Osteoporotic Fractures in Men Study and the Sleep Heart Health Study. European Heart Journal 40:1149–1157. https://doi.org/10.1093/eurheartj/ehy624

12. Trzepizur W, Blanchard M, Ganem T, Balusson F, Feuilloy M, Girault J-M, Meslier N, Oger E, Paris A, Pigeanne T, Racineux J-L, Sabil A, Gervès-Pinquié C, Gagnadoux F (2022) Sleep Apnea–Specific Hypoxic Burden, Symptom Subtypes, and Risk of Cardiovascular Events and All-Cause Mortality. Am J Respir Crit Care Med 205:108–117. https://doi.org/10.1164/rccm.202105-1274OC

13. Blanchard M, Gervès-Pinquié C, Feuilloy M, Le Vaillant M, Trzepizur W, Meslier N, Goupil F, Pigeanne T, Balusson F, Oger E, Sabil A, Girault J-M, Gagnadoux F (2021) Hypoxic burden and heart rate variability predict stroke incidence in sleep apnoea. Eur Respir J 57:2004022. https://doi.org/10.1183/13993003.04022-2020

14. Esmaeili N, Labarca G, Hu W-H, Vena D, Messineo L, Gell L, Hajipour M, Taranto-Montemurro L, Sands SA, Redline S, Wellman A, Sehhati M, Azarbarzin A (2023) Hypoxic Burden Based on Automatically Identified Desaturations Is Associated with Adverse Health Outcomes. Annals ATS 20:1633–1641. https://doi.org/10.1513/AnnalsATS.202303-248OC

15. Parekh A, Kam K, Wickramaratne S, Tolbert TM, Varga A, Osorio R, Andersen M, De Godoy LBM, Palombini LO, Tufik S, Ayappa I, Rapoport DM (2023) Ventilatory Burden as a Measure of Obstructive Sleep Apnea Severity Is Predictive of Cardiovascular and All-Cause Mortality. Am J Respir Crit Care Med 208:1216–1226. https://doi.org/10.1164/rccm.202301-0109OC

16. Parekh A, Tolbert TM, Mooney AM, Ramos-Cejudo J, Osorio RS, Treml M, Herkenrath S-D, Randerath WJ, Ayappa I, Rapoport DM (2021) Endotyping Sleep Apnea One Breath at a Time: An Automated Approach for Separating Obstructive from Central Sleep-disordered Breathing. Am J Respir Crit Care Med 204:1452–1462. https://doi.org/10.1164/rccm.202011-4055OC

17. Solelhac G, Sánchez-de-la-Torre M, Blanchard M, Berger M, Hirotsu C, Imler T, Sánchez-de-la-Torre A, Haba-Rubio J, Marchi NA, Bayon V, Bailly S, Goupil F, Waeber A, Heiniger G, Pigeanne T, Gracia-Lavedan E, Zapater A, Abad J, Ordax E, Masdeu MJ, Cabriada-Nuño V, Egea C, Van Den Broecke S, Vollenweider P, Marques-Vidal P, Vaucher J, Bernardi G, Betta M, Siclari F, Barbé F, Gagnadoux F, Heinzer R (2023) Pulse Wave Amplitude Drops Index: A Biomarker of Cardiovascular Risk in Obstructive Sleep Apnea. Am J Respir Crit Care Med 207:1620–1632. https://doi.org/10.1164/rccm.202206-1223OC

18. Stuck BA, Arzt M, Fietze I, Galetke W, Hein H, Heiser C, Herkenrath SD, Hofauer B, Maurer JT, Mayer G, Orth M, Penzel T, Randerath W, Sommer JU, Steffen A, Wiater A (2020) Teil-Aktualisierung S3-Leitlinie Schlafbezogene Atmungsstörungen bei Erwachsenen: AWMF-Registernummer 063-001 – Deutsche Gesellschaft für Schlafforschung und Schlafmedizin (DGSM). Somnologie 24:176–208. https://doi.org/10.1007/s11818-020-00257-6

19. (1996) Heart rate variability: standards of measurement, physiological interpretation and clinical use. Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology. Circulation 93:1043–1065

20. Betta M, Handjaras G, Ricciardi E, Pietrini P, Haba-Rubio J, Siclari F, Heinzer R, Bernardi G (2020) Quantifying peripheral sympathetic activations during sleep by means of an automatic method for pulse wave amplitude drop detection. Sleep Medicine 69:220–232. https://doi.org/10.1016/j.sleep.2019.12.030

21. Johns MW (1991) A New Method for Measuring Daytime Sleepiness: The Epworth Sleepiness Scale. Sleep 14:540–545. https://doi.org/10.1093/sleep/14.6.540

22. Frauchiger BS, Ramsey KA, Usemann J, Kieninger E, Casaulta C, Sirtes D, Yammine S, Spycher B, Moeller A, Latzin P (2023) Variability of clinically measured lung clearance index in children with cystic fibrosis. Pediatric Pulmonology 58:197–205. https://doi.org/10.1002/ppul.26180

23. Koo TK, Li MY (2016) A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med 15:155–163. https://doi.org/10.1016/j.jcm.2016.02.012

24. Bland JM, Altman DG (1996) Statistics Notes: Measurement error proportional to the mean. BMJ 313:106. https://doi.org/10.1136/bmj.313.7049.106

25. Bland JM, Altman DG (1996) Statistics notes: Measurement error. BMJ 312:1654. https://doi.org/10.1136/bmj.312.7047.1654

26. Vaz S, Falkmer T, Passmore AE, Parsons R, Andreou P (2013) The Case for Using the Repeatability Coefficient When Calculating Test–Retest Reliability. PLoS ONE 8:e73990. https://doi.org/10.1371/journal.pone.0073990

27. Bonett DG (2002) Sample size requirements for estimating intraclass correlations with desired precision. Statistics in Medicine 21:1331–1335. https://doi.org/10.1002/sim.1108

28. Benjafield AV, Ayas NT, Eastwood PR, Heinzer R, Ip MSM, Morrell MJ, Nunez CM, Patel SR, Penzel T, Pépin J-L, Peppard PE, Sinha S, Tufik S, Valentine K, Malhotra A (2019) Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. The Lancet Respiratory Medicine 7:687–698. https://doi.org/10.1016/S2213-2600(19)30198-5

29. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ (1989) The Pittsburgh sleep quality index: A new instrument for psychiatric practice and research. Psychiatry Research 28:193–213. https://doi.org/10.1016/0165-1781(89)90047-4

30. Hoddes E, Zarcone V, Smythe H, Phillips R, Dement WC (1973) Quantification of Sleepiness: A New Approach. Psychophysiology 10:431–436. https://doi.org/10.1111/j.1469-8986.1973.tb00801.x

31. Valko PO, Bassetti CL, Bloch KE, Held U, Baumann CR (2008) Validation of the Fatigue Severity Scale in a Swiss Cohort. Sleep 31:1601–1607. https://doi.org/10.1093/sleep/31.11.1601

32. Bastien C (2001) Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep Medicine 2:297–307. https://doi.org/10.1016/S1389-9457(00)00065-4

33. Hershfeld JJ (1979) Edward H. Angle and the malocclusion of the teeth. Bull Hist Dent 27:79–84

34. Friedman M, Ibrahim H, Bass L (2002) Clinical Staging for Sleep-Disordered Breathing. Otolaryngol Head Neck Surg 127:13–21. https://doi.org/10.1067/mhn.2002.126477

35. Brodsky L (1989) Modern Assessment of Tonsils and Adenoids. Pediatric Clinics of North America 36:1551–1569. https://doi.org/10.1016/S0031-3955(16)36806-7

36. Li S, Wu D, Jie Q, Bao J, Shi H (2014) Lingua–epiglottis position predicts glossopharyngeal obstruction in patients with obstructive sleep apnea hypopnea syndrome. Eur Arch Otorhinolaryngol 271:2737–2743. https://doi.org/10.1007/s00405-014-3033-3

Appendix 1: Schedule of Assessments for each participant

Time (days)	**>-1**	**0**	**1-10**	**>10**
Visit	Information	Screening	Home Sleep Testing	Discussion of Results
Oral and written Information	**+**			
Written consent		**+**		
Check inclusion-/ exclusion criteria		**+**		
Medical history		**+**		
Participant characteristics		**+**		
Measurements			**+**	
Questionnaires		**+**	**+**	
Discussion of results *(if desired by the participant)*				**(+)**

Appendix 2: Collected Data

Screening Checklist (prior to informed consent)

Inclusion criteria:

- Patients with suspected or diagnosed sleep-disordered breathing, irrespective of disease severity, as defined by the indications for home sleep apnea testing in the German guidelines [18]
- No active treatment during sleep recordings or within preceding two weeks (e.g., mandibular advancement devices, positive airway pressure therapy)
- Written informed consent obtained

Suspected sleep-disordered breathing is defined according to the indications for home sleep apnea testing as specified in the German guidelines (S3-Leitlinie Nicht erholsamer Schlaf/Schlafstörungen - Schlafbezogene Atmungsstörungen [18]) and is assumed if one or more of the following symptoms are present:

- Witnessed nocturnal apnoeas (reported by the bed partner)
- Loud, irregular snoring
- Excessive daytime sleepiness
- Obesity
- Hypertension and cardiac arrhythmias
- Reduced libido and erectile dysfunction
- Restless sleep
- Morning fatigue, diffuse, dull headaches, dry mouth
- Non-specific psychological symptoms, including reduced energy, decline in performance, personality changes, and cognitive impairment

Exclusion criteria:

- Age <18 years (selection: yes/no)
- Known or suspected neurological sleep disorder (selection: yes/no)
- Known or suspected psychiatric sleep disorder (selection: yes/no)
- Known or suspected central and complex sleep apnea (selection: yes/no)
- Participants who are unable to perform sleep measurements reliably (selection: yes/no)
- Insufficient knowledge of the project language (German; selection: yes/no)
- Inability to give consent (selection: yes/no)
- Shift workers (with shift work <2 weeks before testing; selection: yes/no)

Inclusion as a calculated field (in REDCap®): A participant is included only if all inclusion criteria are met and none of the exclusion criteria apply; otherwise, the participant is excluded.

Personal information (Consent)

- Name (text)
- Date of Birth (date)
- Date of inclusion (date)

- Signature of participant
- Date of signature (date)
- Signature of investigator

Medical History

- Age (years, range: 0 to 150)
- Gender (selection: male, female, other)
- Previous therapies (continuous positive airway pressure, mandibular advancement device, positional trainer, hypoglossal nerve stimulation, free text; selection)
- Previous operations (selection: tonsillectomy, nasal surgery, free text)
- Preexisting health conditions
    - Chronic obstructive pulmonary disease (selection: yes/no)
    - Asthma (selection: yes/no)
    - Hypertension (selection: yes/no)
    - Heart insufficiency (selection: yes/no)
    - Heart arrhythmia or arterial fibrillation (selection: yes/no)
    - Myocardial infarction (selection: yes/no)
    - Hypertension (selection: yes/no)
    - Diabetes (selection: yes/no)
    - Endocrine disorder (selection: yes/no, if yes: specify)
    - Other disease (free text)
- Pregnancy (Yes/No, and if Yes: gestational age in months)
- Symptoms
    - Witnessed apneas (selection: yes/no)
    - Impaired nasal breathing (selection: yes/no)
    - Bruxism (selection: yes/no)
- Subjective sleep quality *in the last month* (VAS points; numeric, range: 0 to 10)
- Snoring intensity *in the last month* (VAS points; numeric, range: 0 to 10)
- Daytime sleepiness *in the last month* (VAS points; numeric, range: 0 to 10)
- Epworth Sleepiness Scale *in the last month* (integer, range: 0-24 points) [21]
- Pittsburgh Sleep Quality Index *in the last month* (integer, range: 0-21 points) [29]
- Stanford Sleepiness Scale (SSS) *in the last month* (integer, range: 0-49 points) [30]
- Fatigue Severity Scale (FSS) *in the last month* (integer, range: 0-63 points) [31]
- Insomnia Severity Index *in the last month* (integer, range: 0-28 points) [32]

Patient characteristics

- Weight (kg: numeric, range: 0 to 250)
- Height (cm; numeric, range: 0 to 250)
- Neck circumference (cm; numeric, range: 0 to 100)
- Septal deviation (selection: yes/no)
- Turbinate hyperplasia (selection: yes/no)
- Mouth opening (selection: normal, impaired)
- Dental Status (selection: healthy/restored, caries, partially dentale, edentulous)
- Biss (Angle classification; selection; type 1, type 2a, type 2b, or type 3) [33]
- Signs of bruxism (selection: yes/no)
- Tongue position (Friedman staging; integer, range: 1 to 4) [34]
- Uvula (selection: normal, long, wide, long and wide)
- Webbing (selection: normal, mild, moderate, severe)
- Distance of palate to pharynx (selection: <5mm, 5-10mm >10mm)
- Tonsil size (Brodsky grading; integer, range: 0 to 4) [35]
- Tongue base hyperplasia (selection: normal, mild, moderate, severe)

- Lingua-Epiglottis position (according to Li; selection: type 1, type 2, type 3) [36]
- Epiglottis form (selection: normal, omega-shaped, retroflected

Sleep Testing

- Date (date; range: from 1.3.2026 and later)
- Recording time (minutes; numeric, range: 0 to 1200)
- Sleep time (minutes; numeric, range: 0 to 720)
- Apnea-hypopnea index (events per hour of sleep; numeric, range: 0 to 120)
- Apnea index (events per hour of sleep; numeric, range: 0 to 100)
- Hypopnea index (events per hour of sleep; numeric, range: 0 to 100)
- Apnea-hypopnea index *supine* (events per hour of sleep; numeric, range: 0 to 120)
- Apnea index *supine* (events per hour of sleep; numeric, range: 0 to 100)
- Hypopnea index *supine* (events per hour of sleep; numeric, range: 0 to 100)
- Apnea-hypopnea index *non-supine* (events per hour of sleep; numeric, range: 0 to 120)
- Apnea index *non-supine* (events per hour of sleep; numeric, range: 0 to 100)
- Hypopnea index *non-supine* (events per hour of sleep; numeric, range: 0 to 100)
- Central apnea-hypopnea index (events per hour of sleep; numeric, range: 0 to 120)
- Oxygen desaturation index (events per hour of sleep; numeric, range: 0 to 120)
- Oxygen desaturation index *supine* (events per hour of sleep; numeric, range: 0 to 120)
- Oxygen desaturation index *non-supine* (events per hour of sleep; numeric, range: 0 to 120)
- Mean Oxygen saturation (%; numeric, range: 50 to 100)
- Time below 90% oxygen saturation (% of sleep time; numeric, range: 0 to 100)
- Time below 88% oxygen saturation (% of sleep time; numeric, range: 0 to 100)
- Time below 85% oxygen saturation (% of sleep time; numeric, range: 0 to 100)
- Time below 80% oxygen saturation (% of sleep time; numeric, range: 0 to 100)
- Hypoxic burden (minute x percent per hour of sleep; numeric, range: 0 to 200)
- Mean heart rate (beats per minute; numeric, range: 20 to 120)
- Time in *supine* position ((% of sleep time; numeric, range: 0 to 100)
- Time in *non-supine* position ((% of sleep time; numeric, range: 0 to 100)

Advanced indices

- Ventilatory burden (calculated according to Parekh et al.[16])
- Pulse wave amplitude drops (events per hour [17, 20]; numeric, range: 0 to 100)
- Heart rate variability (calculated according to heart rate variability: standards of measurement guidelines [19], ms; numeric, range: 0 to 200)

Patient-reported outcome measures (PROM)

- Subjective sleep quality on a visual analog scale (points; numeric, range: 0 to 10)
- Snoring intensity on a visual analog scale (points; numeric, range: 0 to 10)
- Daytime sleepiness on a VAS (points; numeric, range: 0 to 10)
- Daytime sleepiness on the Epworth Sleepiness Scale [21] (points; integer, range: 0 to 24)
- Alcohol intake (number of drinks; integer, range: 0 to 20)
- Caffeine intake (number of cups; integer, range: 0 to 20)
- Nicotine use (number of packages; integer, range: 0 to 10)
- Sleep medication (type and amount, free text)
- Respiratory symptoms such as infection (VAS points; numeric, range: 0 to 10, and free text)
- Allergy symptoms (VAS points; numeric, range: 0 to 10, and free text)