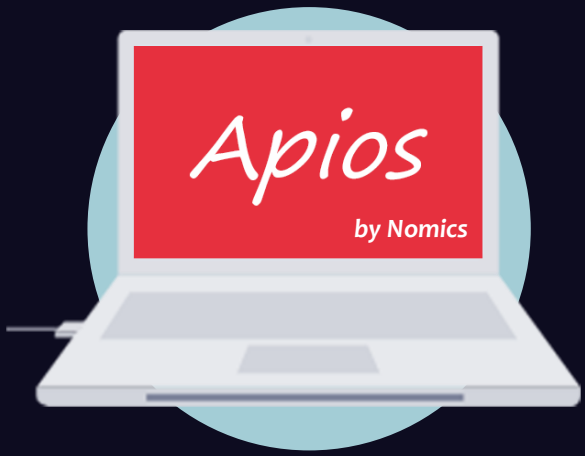

User Guide Apios

NS500 - Apios

Nomics®

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Nomics Unique Registration Number (SRN): BE-MF-000004514

MDR certificate number: 784332

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Table of contents

DEFINITIONS AND ABBREVIATIONS

Abbreviation	Signification
OSA	Obstructive Sleep Apnea Syndrome
CPAP	Continuous Positive Airway Pressure
SRBD	Sleep-Related Breathing Disorders
AASM	American Association of Sleep Medicine
AHI	Apnea–Hypopnea Index
RDI	Respiratory Disturbance Index
REI	Respiratory Event Index
RERA	Respiratory Effort-Related Arousal
OSAHS	Obstructive Sleep Apnea–Hypopnea Syndrome

THE APIOS SYSTEM

THE APIOS SYSTEM

The Apios system is designed as an advanced clinical decision support tool to inform and assist qualified healthcare professionals in evaluating and managing sleep-disordered breathing (SDB) in combination with sleep recordings obtained using Nomics portable sleep recorders (NS113 Somnolter, NS121 Brizzy, NS126 Brizzy+) and associated sensors.

NS500 Apios serves as the main system, which is the subject of this user manual. Sleep recorders function as accessories designed to work within the system. These sleep recorders must be used with specific sensors, each selected according to the intended recording configuration. As these sensors are intrinsically necessary for the proper functioning of the sleep recorders and contribute directly to the generation of data analyzed by Apios, they are also considered accessories of the Apios software.

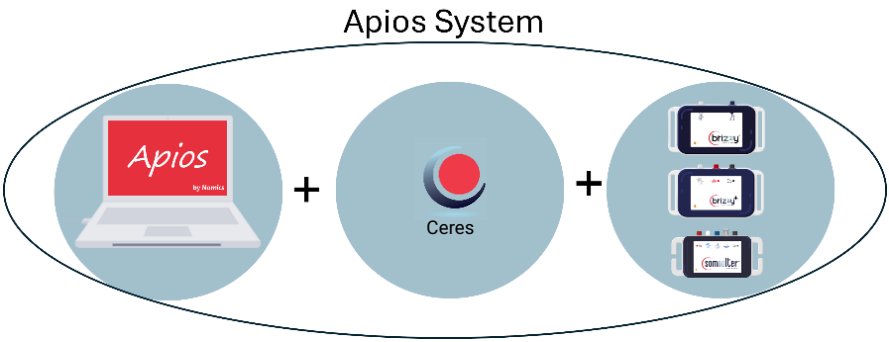


Figure 1: Apios System Description

Software Apios

NS500 Apios is a standalone software program. NS500 Apios can only analyze compatible sleep recorders that have been uploaded to the Nomics database using the CERES software (Windows/Mac).

The NS500 Apios software is accompanied by the following accessories:

1. Ceres

CERES is a software non-medical, compatible Windows/Mac, developed and made available by Nomics, designed to:

- Configure NS121 Brizzy, NS126 Brizzy+, and NS113 Somnolter sleep recorders before starting a recording
- Transfer a recording stored in a sleep recorder's memory to the Apios cloud database. Ceres is the only way to transfer data acquired by the sleep recorder to NS500 Apios. To do this, you need to use the NS921 USB cable supplied by Nomics, which is also considered an accessory.

It is the physician's responsibility to configure a sleep recorder and upload recordings to the web database. The patient does not have access to CERES.

2. Sleep recorders NS121 Brizzy/NS126 Brizzy+/NS113 Somnolter

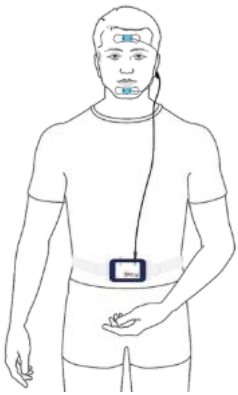
The NS121 Brizzy, NS126 Brizzy+, and NS113 Somnolter sleep recorders (as well as the various appropriate sensors) are the three compatible accessories that generate compatible recordings that can be analyzed by NS500 Apios. Sleep recorders do not officially offer clinical functions; they synchronously record various physiological parameters during the night so that NS500 Apios can analyze them. Sleep recorders do not provide any information about these physiological parameters to the patient (user). A sleep recorder may be provided to a patient by their treating physician.

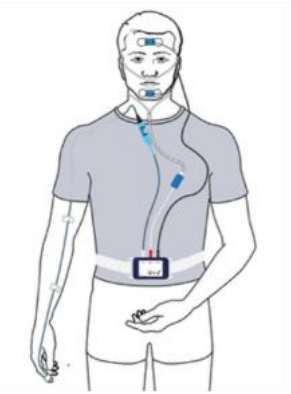
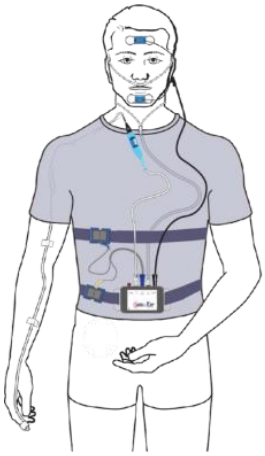
3. Sensors used with the sleep recorders

Each sleep recorder must be used with a specific set of sensors, selected according to the intended recording configuration.

These sensors are essential for the sleep recorders to function properly. They directly contribute to the quality and accuracy of the signals subsequently processed by NS500 Apios.

Note that the NS405 Distance Sensor (Jawac) must be used with the NS910 JawaGrips to attach the probes to the forehead and chin. The NS910 JawaGrips (adhesive supports for NS405) are also part of the Apios System accessories.

Sleep recorder model	Connections and placement	Sensors
 **NS121 - Brizzy**		• NS405 Distance Sensor (JAWAC®) • Body position (Sensor built into the sleep recorder that measures body position) • Optionally, NS922 ECG Module, can be used

 **NS126 – Brizzy+**		• NS405 Distance Sensor (JAWAC®) • NS962 Flow Sensor • NS920 XPOD Module • Body position (Sensor built into the sleep recorder that measures body position) • Optionally, NS965 ECG Auxiliary Sensor, can be used
 **NS113 - Somnolter**		• NS405 Distance Sensor (JAWAC®) • NS920 XPOD Module • NS918-N Inductive Interface Cable (Chest and abdominal belts) • NS918-B Inductive Interface Cable (Chest and abdominal belts) • Body position (Sensor built into the sleep recorder that measures body position) • NS960 Pneumotachograph (Pneumotachograph module for CPAP monitoring) • TA-001/80 — Adapter for CPAP Titration • Optionally, NS965 ECG Auxiliary Sensor, can be used

Below, you will find a list of all NS500 Apios accessories manufactured and distributed by Nomics:

Reference	Product Name	Function
NS113	Somnolter	Recorder
NS126	Brizzy+	Recorder
NS121	Brizzy	Recorder
NS920	XPOD Module	Sensor
NS922	ECG Module	Sensor
NS965	ECG Auxiliary Sensor for Somnolter	Sensor
NS405	Distance Sensor	Sensor
NS910	JawaGrips	Adhesive
NS918-N	Inductive Interface Cable	Sensor
NS918-B	Inductive Interface Cable	Sensor
NS921	USB Cable	Cable

NS960	Pneumotachograph	Sensor
NS962	Flow Sensor	Sensor
N/A	Ceres	Software
NS900	Device fastening belt	Fastening
NS904	Transport bag for Somnolter	Transportation
NS924	Transport bag for Brizzy/Brizzy+	Transportation
NS814	Fin for attaching to Brizzy Casing	Spare
NS816	Fin for attaching to Somnolter Casing	Spare
SF-A-022	*Flow Sensor/Adult	Sensor
TA-001/80	*CPAP Adapter including PVC tube, Luer-Lock, 80 cm (31")	Sensor
9010NX	*Reusable Inductive Effort Belt – Nox Compatible	Sensor
8000SS or 8000SM	*Soft Sensor, Reusable, Small, 1 M	Sensor
	*Soft Sensor, Reusable, Medium, 1 M	Sensor
15805-2 or NC-002c	*2-Ft Adult Nasal Pressure Monitoring Cannula	Sensor
	*Nasal Pressure monitoring Cannula (adult) 0,6m tube, male luer connector	Sensor
15804-2 or NC-022	*2-Ft Pediatric Nasal Pressure Monitoring Cannula	Sensor
	*Nasal Pressure monitoring Cannula (pediatric) 0,4m tube, male luer connector	Sensor
NS896 or NS-UK896	*USB Charger	Charging
	*USB Charger UK	Charging

* Products distributed by Nomics

INDICATIONS OF USE AND INTENDED USE

NS500 Apios is intended to receive, process, and analyse physiological and clinical data acquired from user inputs, compatible sleep recorders via first-party accessory software. From the raw data, it automatically detects and classifies respiratory events, calculates resulting clinical indices, and generates signals and structured reports for clinician review. The Apios Platform is intended for use by qualified healthcare professionals to inform the risk assessment, diagnosis, severity assessment, and treatment follow-up of patients with suspected or confirmed sleep-disordered breathing. The software does not autonomously establish a diagnosis or treatment decision, as the final interpretation must be made by a clinician.

TARGET USERS

NS500 Apios is intended to be used by healthcare professionals authorised under applicable regulation to either assess, diagnose or manage sleep-disordered breathing.

TARGET PATIENTS

Apios is intended for the analysis of ambulatory sleep examinations performed on patients in defined clinical populations, when used and interpreted by a qualified healthcare professional.

To reflect the different clinical situations in which an ambulatory sleep examination may be indicated, the use of Apios is structured into clinical workflows. These workflows are used to describe, for each target population:
- the clinical objective pursued,
- the type of recording performed (where applicable),
- and the associated limitations of use.

The selection of the appropriate workflow, the type of recording, and the patient's eligibility for an ambulatory sleep examination remain the responsibility of the healthcare professional. Apios supports the analysis and interpretation of available data and does not replace clinical judgement.

WORKFLOW 1: PRE-TEST – TRIAGE AND TEST SELECTION

The Pre-test workflow is intended for patients undergoing an initial clinical assessment prior to an ambulatory sleep examination. It structures the collection and review of clinical information to help the clinician determine whether an ambulatory sleep examination is appropriate. No recording device is required.

Target population:
Adults or children in whom obstructive sleep apnoea is suspected.

This workflow is not intended for:

- the general population without symptoms or risk factors,
- populations for which the selected triage questionnaire has not been validated.

WORKFLOW 2: CASE FINDING

The Case Finding workflow is intended for patients aged 3 years and older with suspected sleep-disordered breathing, with initial identification based on an examination performed with **Brizzy** (NS121, Type IV recorder).

Target population:
Adults and children aged 3 years and older with suspected OSA, for whom a Type IV examination is clinically appropriate in a screening context.

This workflow is not intended for:

- children under 3 years of age.
- paediatric patients presenting a "congenital phenotype" (also described as "Type 3 TROS"), characterised by craniofacial anomalies, neuromuscular disorders, or genetic syndromes predisposing to OSA, including in particular: Down syndrome (Trisomy 21), Pierre Robin sequence, cerebral palsy, muscular dystrophies, Prader-Willi syndrome.
- patients with significant cardiopulmonary disease, respiratory muscle weakness or high risk of hypoventilation (including awake hypoventilation), history of stroke, or chronic opioid therapy.
- patients with known or suspected severe insomnia or other significant sleep disorders.
- and, more generally, any patient for whom relevant clinical practice guidelines advise against screening using a Type IV sleep study.

WORKFLOW 3: ADULT DIAGNOSIS

The Adult Diagnosis workflow is intended for adult patients referred for a diagnostic ambulatory sleep examination, when a Type III recording is clinically appropriate. Compatible recorders include NS113 Somnolter and NS126 Brizzy+, and are used at a minimum with NS920 Oximeter, NS405 JAWAC® Distance Sensor, and NS962 Flow Sensor.

Target population:
Adults with suspected OSA for whom a Type III examination is clinically appropriate for diagnostic purposes.

This workflow is not intended for:

- patients with significant cardiopulmonary disease, potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation, high risk of sleep-related hypoventilation, history of stroke, or chronic opioid therapy.
- patients with known or suspected severe insomnia, or other significant sleep disorders likely to interfere with the interpretation of a Type III examination.

- and, more generally, any patient for whom comorbidities or clinical presentation justifies the performance of in-laboratory polysomnography, in accordance with applicable clinical guidelines.

WORKFLOW 4: PAEDIATRIC DIAGNOSIS

The Paediatric Diagnosis workflow is intended for paediatric patients aged 3 years and older referred for a diagnostic ambulatory sleep examination, when a Type III recording is clinically appropriate. Compatible recorders are NS113 Somnolter and NS126 Brizzy+, used at a minimum with NS920 Oximeter, NS405 Distance Sensor JAWAC®, and NS962 Flow Sensor.

Target population:
Children aged ≥ 3 years with suspected OSA for whom a Type III examination is clinically appropriate for diagnostic purposes.

This workflow is not intended for:
- patients under 3 years of age.
- patients for whom applicable paediatric clinical guidelines recommend full in-laboratory polysomnography as the standard diagnostic approach.
- patients presenting a congenital clinical profile characterised by craniofacial anomalies, neuromuscular disorders, or genetic syndromes likely to affect airway structure or respiratory function, including in particular:
    - Trisomy 21,
    - Pierre Robin sequence,
    - cerebral palsy,
    - muscular dystrophies,
    - Prader-Willi syndrome.

WORKFLOW 5: CPAP THERAPEUTIC FOLLOW-UP

The Therapeutic Follow-up workflow is intended to evaluate the effectiveness of standard continuous positive airway pressure (CPAP) therapy, based on recordings obtained with NS113 Somnolter or NS126 Brizzy+, and is used at a minimum with either the TA-001/80 CPAP Titration Adapter or the NS960 Pneumotachograph Module for CPAP monitoring.

Target population:
Adult patients treated with standard CPAP, for whom ambulatory follow-up is clinically appropriate.

This workflow is not intended for:
- patients treated with non-invasive positive airway pressure modalities other than CPAP, including Volume Assured Pressure Support (VAPS) or Adaptive Servo-Ventilation (ASV).
- paediatric patients.
- and, more generally, any patient for whom applicable clinical practice guidelines advise against monitoring CPAP efficacy or compliance using a Type III ambulatory sleep study.

APIOS SYSTEM CLINICAL BENEFITS

The clinical benefits come from the Apios system (Apios and the sleep recorders) and relates to the improve diagnostic accuracy, workflow efficiency, and access to care through:

- Accurate detection and classification of adult SDB severity to enable timely diagnosis and treatment.
- Reliable detection and classification of paediatric SDB for early clinical intervention.
- Accurate estimation of Total Sleep Time (TST) via mandibular movement (Jawac) signal, improving AHI accuracy and diagnostic reliability.

- Supports screening of SDB in adults and children.
- Higher accuracy of detection and classification of adult SDB severity due to jawac-estimated micro-arousal in AHIvar2.
- Supports CPAP management by identifying the determinants of unintentional leaks.
- Standardised automated scoring reduces inter-scorer variability.
- Digitalised pathway reduces the time to report.
- Improved patient triage through validated digital version of validated questionnaires.
- Earlier diagnosis allows timely initiation of therapy, reducing prolonged exposure to untreated OSA and its consequences.
- Integration of diagnostic and follow-up workflows within a single platform reduces fragmented care.
- Public Health benefit: Scalable, efficient diagnostics reduce backlog and burden of undiagnosed OSA.
- Ambulatory studies are less intrusive and more tolerable for most patients, increasing adherence and reach.
- Improved diagnostic accuracy in ambulatory sleep studies thanks to exhaustive measure of respiratory events, specifically those related to micro-arousal.

APIOS SYSTEM LIMITATIONS, CONTRA-INDICATIONS, PRECAUTIONS AND WARNINGS

LIMITATIONS

- The sleep recorders are not intended for real-time monitoring of sleep apnea or for life support.
- The sleep recorders are not intended for use on children under 3 years of age.
- Ambulatory physiological sleep recorders that acquire input signals processed by the Apios platform serve as accessories to it. Currently validated compatible monitors are NS121 Brizzy, NS126 Brizzy+, and NS113 Somnolter, all manufactured by Nomics.
- For all conditions of use, precautions, and contraindications relating to Apios accessories, please refer to the dedicated user manuals.
- The NS500 Apios platform provides a link to the list of known bugs. This information can be found on the NS500 Apios label (known issues). For more information, refer to the "UPDATE NOTES" section.

CONTRA-INDICATIONS

NS500 Apios is not intended to analyze the following patient records:

1. General exclusions from the population

The Apios system is not intended for patients who require laboratory polysomnography (PSG) for accurate assessment, including patients with significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular disease, hypoventilation while awake, or a high risk of sleep-related hypoventilation, a history of stroke or chronic opioid use, or patients with or suspected of having severe insomnia or other significant sleep disorders.

2. Specific exclusions for children

For pediatric protocols, the Apios system is not intended for patients with congenital phenotypes predisposing them to obstructive sleep apnea (OSA) and requiring a complete PSG, including Down syndrome, Pierre Robin sequence, cerebral palsy, muscular dystrophies, and Prader-Willi syndrome.

3. Exclusions related to therapeutic monitoring

The Apios system is intended for patients treated with non-continuous positive pressure devices, including volume-assisted positive pressure (VAPS) and adaptive servo-ventilation (ASV) devices.

PRECAUTIONS

- It is the doctor's responsibility to check and correct the results obtained by Apios, with the help of a specialist, if necessary, before drawing up the report.
- The use of NOMICS sleep monitoring systems may not be appropriate if, in the opinion of the responsible physician, the patient is not eligible for a home sleep study given their general state of health.
- Do not use a defective sleep recorder or accessories. Contact your distributor or Nomics for a replacement, if necessary.

WARNINGS

- Sleep recorders must not be used in a magnetic resonance imaging (MRI) scanner.
- Sleep recorders are not defibrillator-proof.
- Sleep recorders must not be used near devices that emit strong electromagnetic interference.

INSTALLATION / CONFIGURATION

SPECIAL TRAINING OR QUALIFICATIONS OF THE USER

This platform has been specifically designed for healthcare professionals and requires no prior training to use. However, a presentation is offered to new users to help them familiarize themselves with the system.

NS500 APIOS PLATFORM FEATURES

NS500 Apios is a Class IIa medical device developed by Nomics. The product is certified as compliant with the Medical Device Regulation 2017/745 MDR.

NS500 Apios is designed to ensure stable performance and compliance with regulatory requirements for a period of 5 years from its last update, provided it is used in accordance with the conditions described in this manual.

Description of regulatory symbols:

	Catalogue number | ISO 15223-1
	Unique device identifier | ISO 15223-1
	CE marking indicating compliance with the Medical Device Regulation in the European Union (MDR 2017/745) | ISO 15223-1 The notified body responsible for conformity assessment is BSI, listed under number 2797 in the NANDO database.
	Refer to operating instructions | ISO 15223-1
	Country of manufacture. This symbol is accompanied by the software release date. | ISO 15223-1
	Manufacturer | ISO 15223-1

	Used-by-date (date after which the medical device should no longer be used) | ISO 15223-1
	Medical Device | ISO 15223-1
 	General danger (used in the user manual) | ISO 7010 Warning / Caution (used in the user manual and on the label) | ISO 15223-1
	General obligation | ISO 7010

Description of symbols used on Apios:

	Symbol related to legal and compliance matters (general). Symbol appearing on the label to certify compliance (Terms of Use, Cookie Policy, and Privacy Policy).
	Blue symbol: safety communication. Additional information. This icon is usually a button that you can click on. You can always view the general details.
	Red symbol with a number inside: Warning. The number inside the triangle indicates the number of warnings (used on the platform). The details of the warnings must be checked.
	Red symbol with clock: Warning, the recording sent is too short and cannot be used.
	Red symbol with caution: Warning (used on the platform). The details of the warnings must be checked.
	The circle surrounding the signal validity number illustrates this validity. Lorsque l'arc de cercle est vert, la validité est bonne. • When the arc of the circle is green, the validity is good. • When the arc of the circle is orange, the validity is average. • When the arc of the circle is red, the validity is poor and the result should be interpreted accordingly.
	Erreur affichée dans le cas où aucun résultat n'a pu être généré, pour cause de données invalides.

REQUIRED CONFIGURATION AND HANDLING CONDITIONS

To install and use Ceres:

- Windows 10 or 11 / macOs minimum Ventura 13.3 (22E252)
- 1 USB port
- Internet access and ability to download the installation file

To use Apios:

- Chrome (147.0.7727.50), Safari (17), Firefox (149.0) or Edge (146.0.3856.97)
- Accès à internet et à l'URL www.dashboard.nomicscare.com

Using an unvalidated or outdated browser may cause navigation errors. You should not use Apios if your browser is unvalidated or outdated.

ACCOUNT ACTIVATION

When you are registered on the platform by a Nomics operator, you will receive an invitation to connect and a temporary password to activate your account. This information is sent to you by email. Simply accept the invitation and enter the temporary password provided.

Once your account is activated, you will be invited to set up at least one passkey. It is strongly recommended to set up multiple passkeys. The accepted methods for registering passkeys are:

- Password manager
- Web browser
- Mobile phone
- Microsoft/Apple account
- FIDO2 security key

Note that some features are only available to users with access to advanced analysis. This access is managed by your distributor.

Please note that in certain specific cases managed by Nomics, it is possible to log in using two-factor authentication (password and app) instead of a passkey. In this case, you must install an authentication app. The most common ones are:

- Microsoft Authenticator
- Google Authenticator
- Authy
- 1Password
- LastPass Authenticator

Apios will then display a QR code, which you will need to scan using the authentication app. Once you have done this, the app will give you a 6-digit code that you will need to enter on the platform.

Each time you log in, simply enter your password, open the app, and enter the code provided by the app.

INSTALLATION OF CERES SOFTWARE

The Apios platform is used in combination with the Ceres software, which is installed on your computer. To do this, you need to:

- Check that the computer meets the minimum configuration given above,
- Switch on the computer. Close all active applications before installing the software,
- Download the installation file from your profile,
- You will then be informed of all the installation stages by the installation utility. Depending on your computer's configuration, installation may take several minutes,
- Once the installation is complete, open the Ceres software and check that it is working properly. To do this, connect your sleep recorder to the computer and check that Ceres recognises it.

DIFFERENTS USAGE FLOWS

NS500 Apios software can be used in different ways, each corresponding to a specific clinical workflow. There are 5 different clinical workflows, use the accessories according to the workflow that best fits the needs of your examination.

ID	Definition	Required accessories
Dx-Adult	This clinical flow is intended for the diagnosis of sleep-disordered breathing (SDB) in adults.	NS126 Brizzy+ or NS113 Somnolter and their sensors (see dedicated section "THE APIOS SYSTEM")
Dx-Ped	This clinical flow is intended for the diagnosis of sleep-disordered breathing (SDB) in children.	NS126 Brizzy+ or NS113 Somnolter and their sensors (see dedicated section "THE APIOS SYSTEM")
Screening	This clinical flow concerns the screening of sleep-disordered breathing (SDB) in children and adults.	NS121 Brizzy and its sensors (see dedicated section "THE APIOS SYSTEM")
Pre-Test	This clinical flow uses validated digital questionnaires to assess the likelihood that a patient has obstructive sleep apnea (OSA) before a sleep study is performed.	/
CPAP	This clinical flow is designed for patients who have already been diagnosed with OSA in order to monitor the effectiveness of their CPAP treatment through direct assessment of the patient under CPAP.	NS126 Brizzy+ or NS113 Somnolter and their sensors (see dedicated section "THE APIOS SYSTEM")

NS500 APIOS AND THE RECORDER (CERES)

MAKING A RECORD

NS500 Apios is part of the NOMICS sleep monitoring system. Depending on the clinical flow concerned, it must be used in combination with the NS113 Somnolter, NS121 Brizzy, or NS126 Brizzy+ sleep recorders. This section therefore applies to DX-Adult, DX-Child, Screening, and CPAP flows.

Two recording modes are offered: the "programmed" mode and the "automatic" mode, in order to provide greater flexibility in managing recordings.

“Automatic” mode:

This is the sleep monitor default mode.

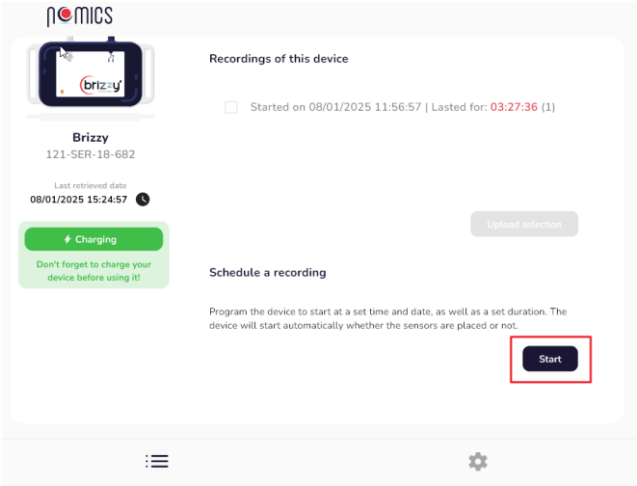
To start recording, simply connect the Jawac mandibular lowering sensor (NS405 Distance Sensor) to the sleep recorder. When the indicator light turns on, the sleep recorder is ready for use. Throughout the recording period, the indicator light will flash (green if the Jawac (NS405 Distance Sensor) is correctly positioned).

To stop recording, simply disconnect the mandibular lowering sensor. The indicator light will stop flashing and the recorder will return to standby mode. The data can then be downloaded to a computer using the supplied NS921 USB cable (see "Send a record" section).

“Programmed” mode:

In this mode, the sleep recorder must be programmed by the user using the Ceres software. Recording will start automatically at the specified date and time and will continue for the set duration. Recording occurs regardless of whether the sensors are connected. At the end of the recording, the sleep recorder switches off automatically and returns to automatic mode by default.

- Open the Ceres software,
- Connect the sleep recorder to the computer using the NS921 USB cable provided,
- Click on “Start”, in the “Schedule a recording” section,



- Select the desired date and time for the start of recording,
- Select the recording duration,
- Depending on your sleep recorder version, you can also select any auxiliary sensors to be used,
- Confirm recording programming.

Note: Recording stops automatically when the battery charge level becomes too low for the sleep recorder to function properly. Always ensure that the battery has sufficient charge when you start recording.

USING THE SOFTWARE

PATIENT FILE MANAGEMENT

ACCESS TO THE WEB PLATFORM

To access Apios, simply open the browser of your choice (see “Required configuration” section) and go to: https://dashboard.nomicscare.com.

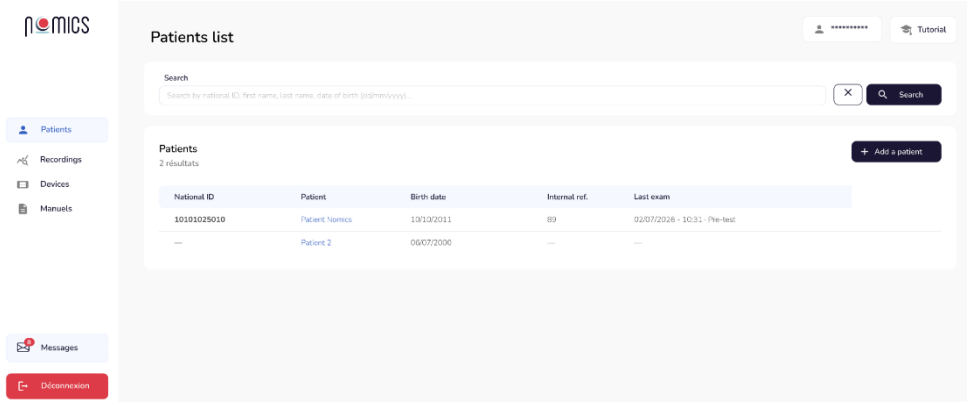
You then simply need to log in:

To that end, Nomics is strengthening its security and will progressively integrate the use of passkeys to log in. This feature is available on Apios starting from version V6.15.0.

You will be contacted directly to make this change.

As long as you have not been contacted, you can continue to log in using your email address and password.

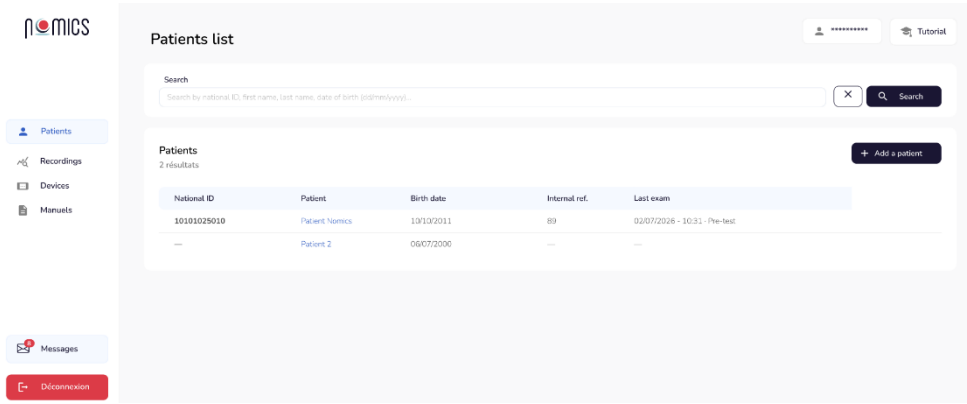
Once the process of setting up passkeys has been completed (with Nomics' assistance), you will be able to log in using your email address and the passkey(s) you have configured.



PATIENT FILE

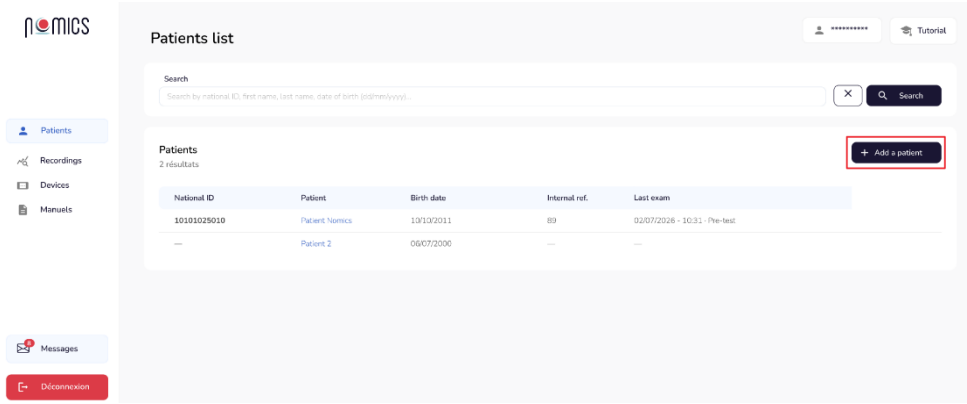
NS500 Apios is organized into patient records. All patients can be found on the “Patients” page, accessible from the left-hand menu.

You can search for a patient by last name, first name, ID, or date of birth. Use the dedicated search bar.



ADD A NEW PATIENT

From your patient list, you can add a new patient. To do so, simply click the corresponding button. You will then need to fill in the fields related to your patient. Please note that fields marked with an asterisk are required.



To avoid any risk of duplicate patient records, please be careful not to make any mistakes when entering the national ID number. In addition, you must enter this number twice.

FLOW DX-ADULT, DX-PED, SCREENING, CPAP

SEND A RECORD

The sleep recorder stores data in internal memory until it is connected to a computer. Once connected to a computer, the memory becomes erasable, i.e. when the next recording is started, the entire memory will be erased beforehand to free up memory space for the new data to be recorded.

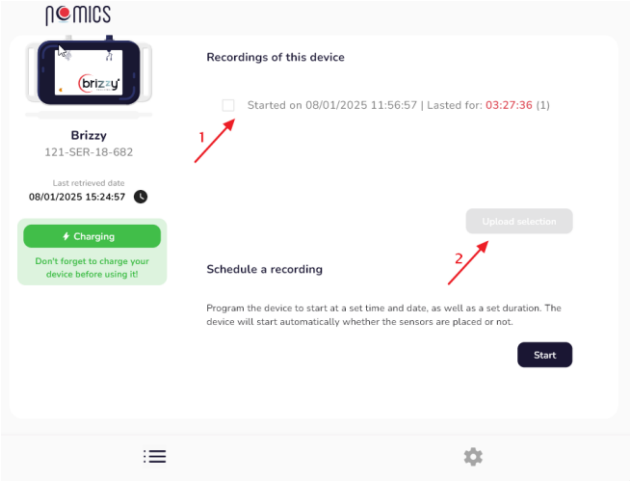
To avoid any risk of data loss, we recommend that you always send a recording as soon as it has been made.

To send the data recorded on the sleep recorder to the web platform, simply:

- Open the Ceres software,
- Connect the sleep recorder to the computer using the NS921 USB Cable supplied by Nomics,

Some operations are performed via the USB cable specially developed by Nomics to connect the sleep recorder to the PC. For safety reasons, it is strictly forbidden to connect the sleep recorders to a computer while the patient is wearing the device. Do not give the USB cable to the patient with the sleep recorder.

- Select the record and click on "Upload selection",
- Wait until the upload is complete, then disconnect the sleep recorder and close Ceres.



PAIRING WITH A PATIENT

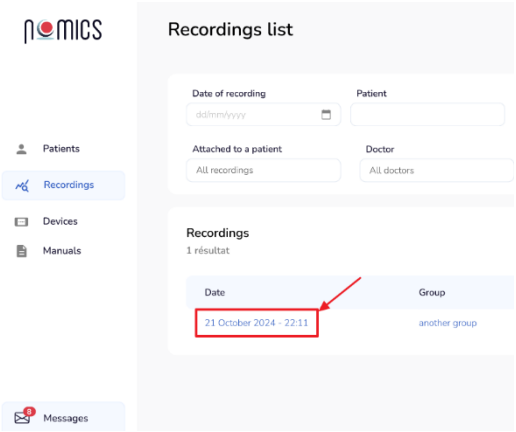
Once the recording has been sent, you'll need to go to Apios and link it to your patient. To do this, go to your list of recordings (from the left-hand menu) and sort it to display only the recordings that haven't yet been linked to a patient. Then click the "Link to a patient" button on the desired analysis and select your patient.

Note that you can create a new patient at this step. Simply click “New patient.”

If an error occurs while linking to a patient, contact Nomics.

PATIENT INFORMATION

To access a sleep study, simply click on its date. You will then need to review and complete the information about your patient for that sleep study.



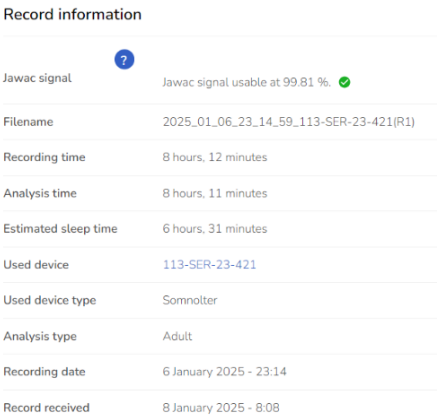
Note: don't forget to select the type of analysis between adult and child.

The following rule applies:

- Under 16 years of age, select child
- Over 18 years of age, select adult
- Between 16 and 18 years of age: assess your patient's body size and musculature

RECORD SUMMARY

The second step provides a quick overview of the recording. Information includes the date, time and duration of the recording, the sleep recorder used, and the type of analysis performed. Additionally, the Jawac signal's usability percentage confirms whether the recording was successful. If usability falls below 70%, a warning is displayed to alert the healthcare professional. In such cases, it may be useful to understand how the patient's night went.



A warning is also displayed when the estimated sleep time is less than 4 hours.

At this stage, if the recording lasts less than 5 minutes, an explicit error will be displayed, and the recording will not be analyzed.

ADVANCED ANALYSIS OF SIGNALS

This section is only for users with access to advanced signal analysis.

SIGNALS

The different signals displayed depend on the accessories and configuration used.

- Jawac: mandibular lowering (in mm). The Jawac signal (Jaw Activity) is derived from measurements taken by the mandibular lowering sensor. The "0 mm" level is the reference level corresponding to complete closure of the mouth. The signal falls when the mandible is lowered and rises when the mandible is raised. This signal is obtained using the NS405 Distance Sensor (Jawac) sensor, which is compatible with all three sleep recorders.
- Nasal flow: nasal flow (dimensionless). This parameter is measured by the flow sensor and gives an indication of respiratory flow, via the nasal cannula.
  This signal is obtained using the NS962 Flow Sensor, which is compatible with the NS126 Brizzy+ sleep recorder. This sensor is directly integrated into the sleep recorder.
- Nasal vibration: signal derived from nasal flow (dimensionless).
- Respiratory movements: the respiratory movements of the thorax and abdomen of two inductive straps or the respiratory movement obtained from the sleep recorder's internal accelerometer.
- SpO2: oxygen saturation of haemoglobin (in %). SpO2 is measured by pulse oximetry.
  This signal is obtained using the NS920 XPOD Module, which is compatible with all three sleep recorders.
- Pulse rate: pulse rate (in bpm for "beats per minute"). Pulse rate is measured by pulse oximetry.
  This signal is obtained using the NS920 XPOD Module, which is compatible with all three sleep recorders.
- Plethy pulse: the plethysmographic wave (dimensionless). Plethy Pulse is derived from pulse oximetry.
  This signal is obtained using the NS920 XPOD Module, which is compatible with all three sleep recorders.
- Position: the position of the body (dimensionless):
  1. Standing
  2. Prone: lying on the stomach
  3. Left: lying on the left side
  4. Right: lying on the right side

5. Supine: lying on the back

This signal is obtained from the internal accelerometer of the sleep recorders.

- Jawac effort: component of the JAWAC signal which highlights respiratory effort.
  This signal is obtained using the NS405 Distance Sensor (Jawac) sensor, which is compatible with all three sleep recorders.
- RIP Abd: Abdominal respiratory inductance plethysmography, dimensionless.
  This signal is obtained using the NS918 Inductive Interface Cable (plethysmography), compatible with the NS113 Somnolter sleep recorder.
- RIP Chest: Thoracic respiratory inductance plethysmography, dimensionless.
  This signal is obtained using the NS918 Inductive Interface Cable (plethysmography), compatible with the NS113 Somnolter sleep recorder.
- RIP Sum: sum of RIP Abd and RIP Chest signals.
  This signal is obtained using the NS918 Inductive Interface Cable (plethysmography), compatible with the NS113 Somnolter sleep recorder.
- RIP Phase: signal derived from RIP Abd and RIP Chest signals, representing the phase shift between thoracic and abdominal movements.
  This signal is obtained using the NS918 Inductive Interface Cable (plethysmography), compatible with the NS113 Somnolter sleep recorder.

As part of the CPAP flow (which requires the use of the NS960 Pneumotachograph module), the following signals will be displayed:

- Tidal volume: expressed in liters, represents the volume of air that enters and leaves the lungs with each breath
- Mask pressure: air pressure delivered by the CPAP, expressed in cmH2O.
- Global leak: total leaks (in l/min) measured by the NS960 Pneumotachograph module.
- NI Leak: unintentional leaks (in l/min). These correspond to global leaks minus intentional leaks. Intentional leaks are specific to the mask used.

The display of these signals can be configured as follows:

In step 4 "Signal analysis", simply click on the "Signals" button.

A list of all the signals then appears. You can show or hide each signal. You can also arrange the order in which the signals appear.

Warning: when you click on "Save selection as default", this will save the current configuration as the base configuration. This means that every recording with the same signals will be displayed according to this configuration.

Note that it is also possible to define several signal display preference profiles.

If you do not click on "Save selection as default", the changes will only apply to the current analysis.

Note: In some cases, the Jawac signal needs to be refocused. This is the case when the analysis begins with a period of wakefulness and the graph finds its zero point in this reference value.

In this case, simply:

1. Correctly redefine the start and end of the analysis if necessary.
2. Manually move the horizontal line of the Jawac zero point to re-centre it on the signal.

This can only be done when the Jawac is defined as the navigation signal.

NAVIGATION SIGNALS

The navigation signal, located at the very top, allows you to view the entire analysis and move around. Right-click on the navigation signal to move to the desired location and view all the signals selected during that period.

Click the horizontal double arrow to the left of the signal to view the entire signal.

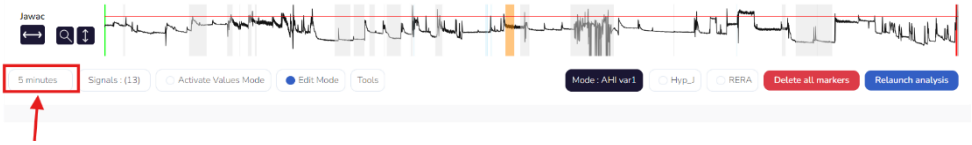
An orange zone represents the signal display area.

It is also possible to move around the navigation signal using the → and ← arrows on the keyboard, or the scroll wheel of the mouse. The displacement will always be ¼ of the display window.

To move the view by ½ a screen, use the CTRL + → and CTRL + ← combinations shortcuts.
To scroll through an entire display window, use the Shift + → and Shift + ←combination shortcuts.

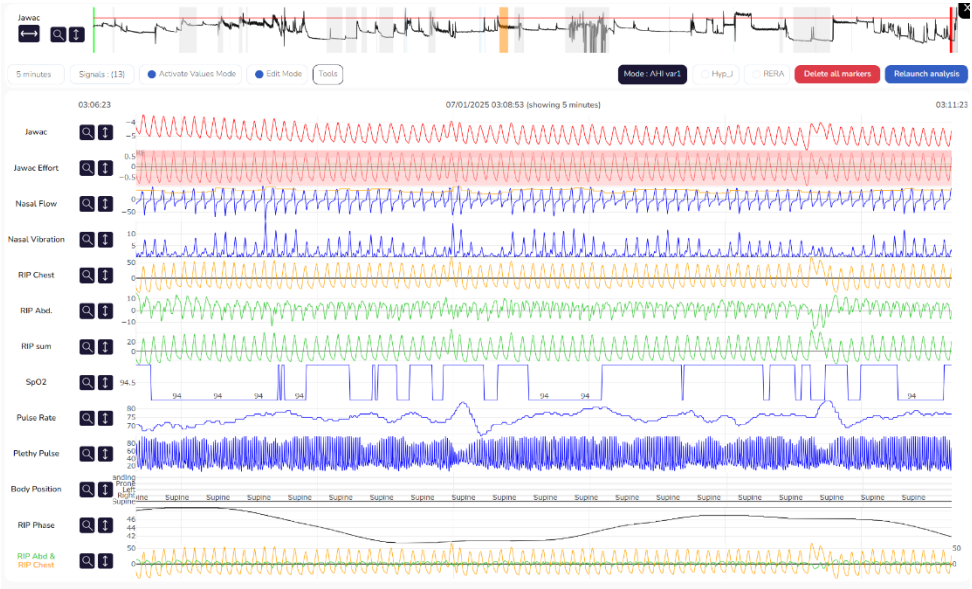
The display window can be changed by clicking on the corresponding button.

Another way to navigate the signal is by using the horizontal scroll bar at the bottom of the screen.



VALUE MODE

By clicking on the corresponding button, the value mode shows the exact value of each of the signals at a given time.



ZOOM OPTIONS

For each signal, you can activate or deactivate the automatic zoom. Each time you move over the navigation signal, the automatic zoom will adapt so that the entire signal is visible and centred in the display window. As a result, the scale of the signal in question is not fixed.

Once the automatic zoom has been deactivated, you can zoom in on the signal manually. To do this, select the zoom icon on the left of the signal. Once selected, the icon turns light blue.

When the icon is selected, simply use the scroll wheel of the mouse to adjust the zoom level. This can also be done using the keyboard shortcuts shift/+ and shift/-.

Note: You can change the vertical space allocated to each signal in the same way as for zooming but using the stretch icon to the right of the zoom icon.

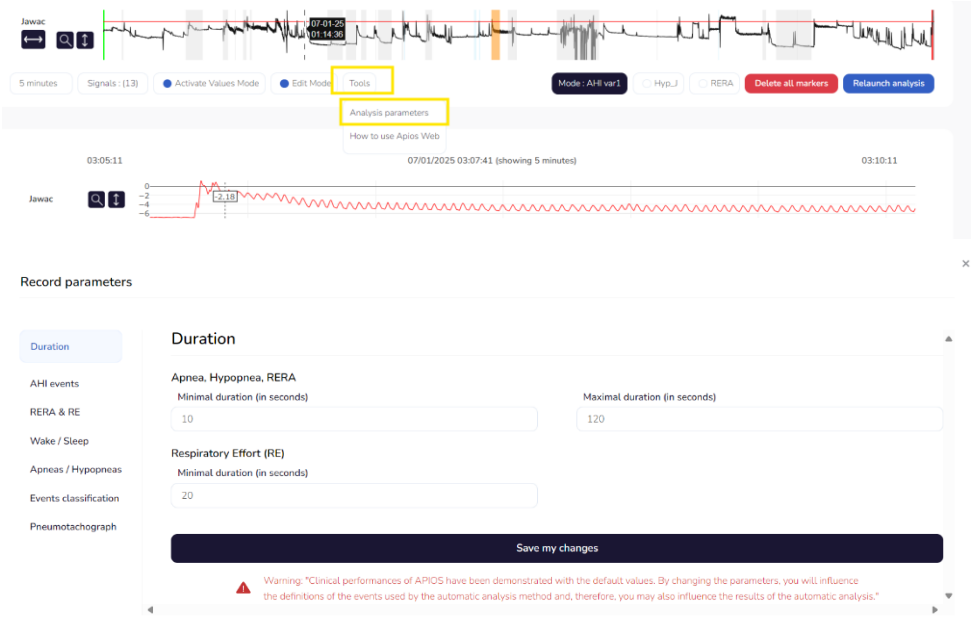
When automatic zoom is deactivated, moving the navigation signal will have no impact on the scale of the signals concerned.

DISPLACEMENT SIGNAL

When "Edit" mode is deactivated (see "Manual marking" section), it is possible to enter each signal and move it vertically for optimal viewing.

The results of the automatic data analysis constitute a proposal for the assessment of sleep-disordered breathing. However, automatic analysis cannot replace a doctor's judgement, and it is therefore the operator's responsibility to assess the results and seek specialist advice if necessary.

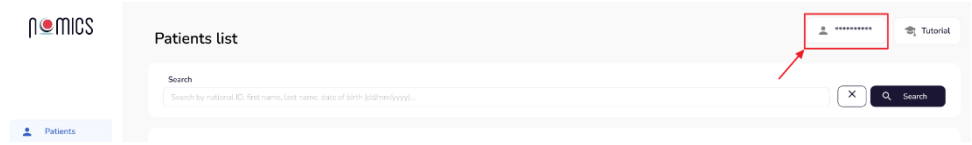
Some automatic analysis parameters can be modified. To do this, simply click on Tools → Analysis parameters.



The user can therefore influence the event definitions and algorithmic principles used by the analysis method, and consequently, the results of the automatic analysis. If you would like more details about the algorithmic principles behind the analysis, please refer to the dedicated document: "D-Apios Algorithmic Principles_EN".

Note that modifying parameters within an analysis will only impact that specific analysis.

If you wish to change the default automatic scan settings, simply go to your profile and change your scan settings. Once done, the automatic analysis will always apply these settings.



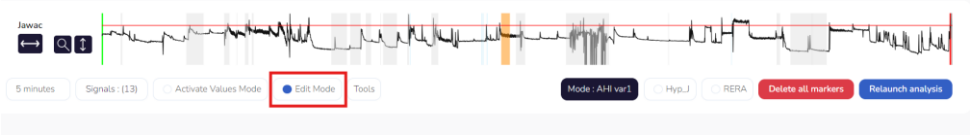
Each time a recording is received, the automatic analysis will automatically start. If you change any parameters, the automatic analysis will always be restarted.

Please note that this feature is only available to users with advanced access. This section is intended for these users only.

The results of the automatic analysis can be modified manually by the user. The user can also choose to carry out the analysis of the recording entirely manually.

The various actions that can be carried out manually are listed and detailed in the following table.

It is important to note that some modifications can be made when Edit mode is activated, while others require this mode to be deactivated. To do this, simply tick the corresponding box, or use the 'e' key on your keyboard.



Manual signal analysis	
Set/move the start and end of analysis terminals	Move the green bar (for the start) / red bar (for the end) to the desired position on the navigation signal.
Add a marking	This action requires Edit mode to be activated. Delimit the area to be marked by clicking on the signal and dragging the cursor. A list of possible markings will then appear. Assign a marking type to this zone by selecting the desired type or pressing the corresponding keyboard key (see below).
Delete a marking	This action requires activation of Edit mode. Place the cursor on the upper part of the marking concerned. Right-click and select "Delete" at the bottom of the list that appears.
Modify the position of a marker	This action requires activation of Edit mode. Place the cursor in the centre of the marker concerned. Click and hold, then move the marker to the required location.
Modifying the duration of a marker	This action requires activation of Edit mode. Place the cursor on one of the ends of the marking concerned. Click and hold, then move the end of the marking.
Modify the type of marking	This action requires activation of Edit mode. Place the cursor on the upper part of the marking concerned. Right-click and choose the type of marking from the list that appears or by pressing the corresponding keyboard key (see below). Please note that certain types of marking only apply to certain signals. Desaturation, for example, can only appear on the SpO2 signal.

Any manual modification of the markings following the generation of an analysis report will render this report obsolete. The software automatically detects this state of affairs and launches the report generation again (see below) to integrate the manual modifications into the calculation of the results given in the results.

ANALYSIS REPORT

Record

To help you understand the results displayed, tooltips are provided for each block.

The analysis report shows the results of the analysis in figures and graphs.

The report is generated automatically following automatic data analysis. The report reflects the recording and the markings (whether manual or automatic) that have been applied to the signals.

If changes are made to the markings after the report has been generated, the report will be updated automatically.

Severity indicators

The analysis report provides several severity indicators, referred to as "AHI Var1," "AHI Var2," "RDI," and "RDI." They differ as follows:

AHI var1

• Index that groups together events measured by most polygraphs.

• Counts central and desaturating apneas and hypopneas.

• Tends to underestimate severity.

AHI var2

• Index that corresponds to the AASM definition of AHI.

• Counts central and desaturating apneas and hypopneas and adds Jawac hypopneas.

• Closest value to what polysomnography would have calculated, and therefore the best diagnostic index

RDI

• Index that corresponds to the AASM definition of RDI

• Counts all respiratory events, including RERAs

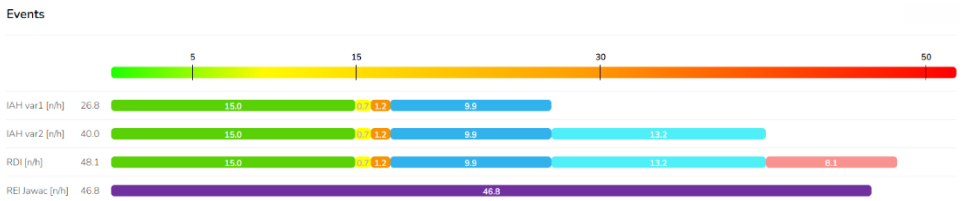
• Additional index, useful for the granularity of sleep-disordered breathing, but not for the diagnosis of OSAHS.

REI

• Index that groups together respiratory disturbances detected on the Jawac signal only.

• Well correlated with the RDI

• Additional, non-diagnostic index that depends on a single signal.

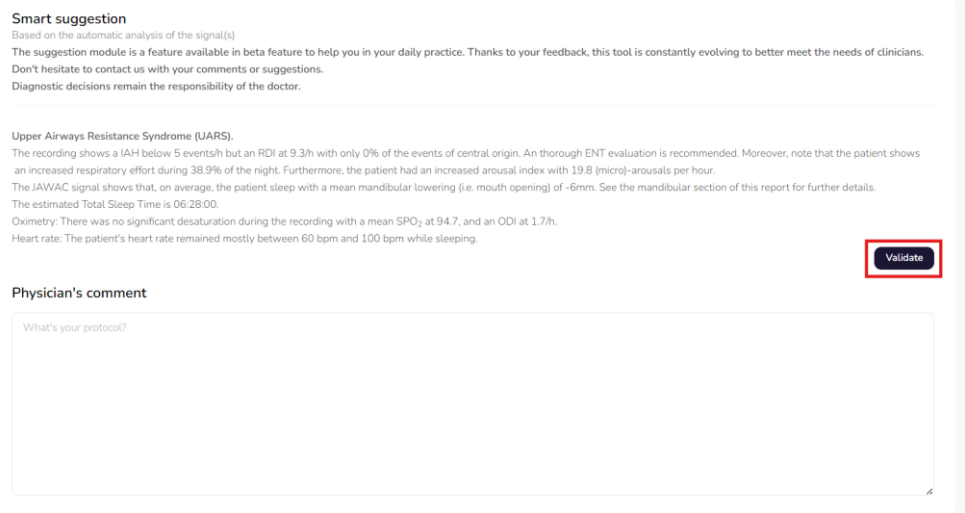


In the “Key Values” section, the AHI Var2 is used by default and is also used for smart conclusions. However, you can choose the reference index you want to use by changing your settings.

Your contact details and/or logo can be automatically inserted at the top of the analysis report (see the "Customisation" section below).

It is also possible to add your conclusions at the end of the report. To do this, you can use the smart suggestion which is generated automatically on the basis of the results. It should be noted that the suggestion does not take into account non-breathing sleep disorders and that it is not a diagnosis, because it's the doctor's responsibility to make the diagnosis.

If the doctor or person responsible for the analysis agrees with the smart suggestion, it can be validated by clicking on the corresponding button. This action copies the smart suggestion and pastes it into the space reserved for the doctor/responsible for the analysis. The latter is then free to modify or add to it.

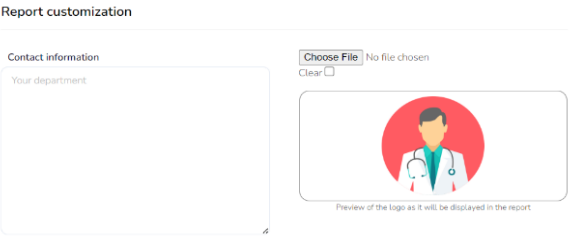


CUSTOMISATION

All the customisation options are available via your profile. Simply click on your name in the top right-hand corner of the screen.

ADD A HEADER TO THE PDF REPORT

If you would like your contact details to be displayed on the PDF reports you download from Apios, simply enter them in the report customisation field.



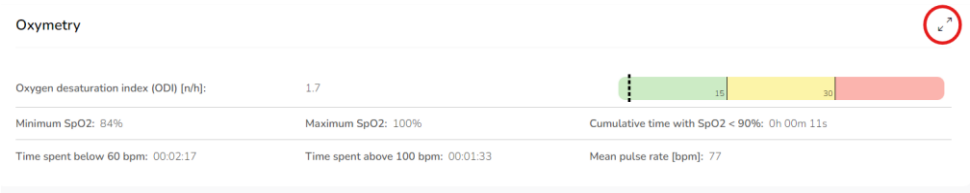
Note: This customization also applies to pre-test reports.

CUSTOMISE THE RESULTS PAGE DISPLAY

Certain blocks of information on the results page can be displayed in 2 different configurations:

- Reduced mode: only essential information is displayed.
- Extended mode: all detailed information is displayed.

It is always possible to switch from one mode to the other using the double arrow in the top right-hand corner of the block.



In your profile, you can define the default display mode for each of these blocks.

*This feature is only available to NS126 Brizzy+ or NS113 Somnolter users.

ANALYSIS PARAMETERS

Within your profile, you can define your default analysis parameters. These are the settings that will be taken into account when each of your recordings is automatically analysed.

ADD SCREENSHOTS OF SIGNALS

This section is only for users with access to advanced signal analysis.

In the signal analysis, and when you are in full-screen mode, click on Tools → Screenshot to record the signals. You can take up to two screenshots. These will automatically appear on the results page as well as in the PDF report.

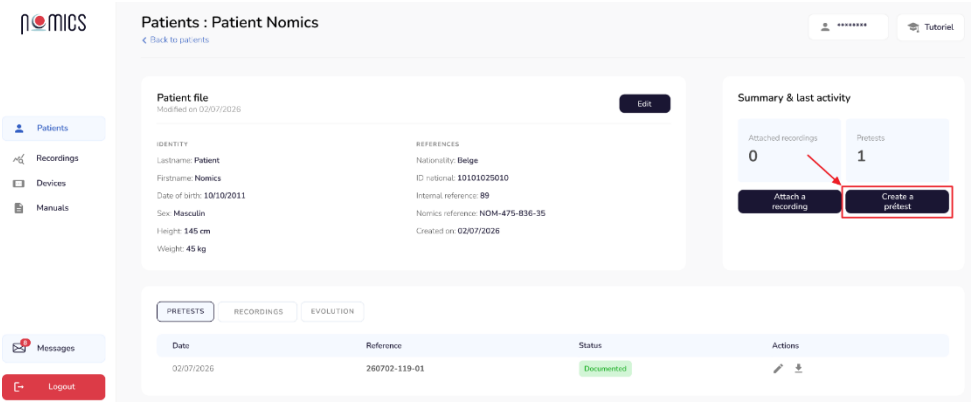
PRE-TEST WORKFLOW

This section is intended only for users who have access to the pre-test.

CREATING A NEW PRE-TEST

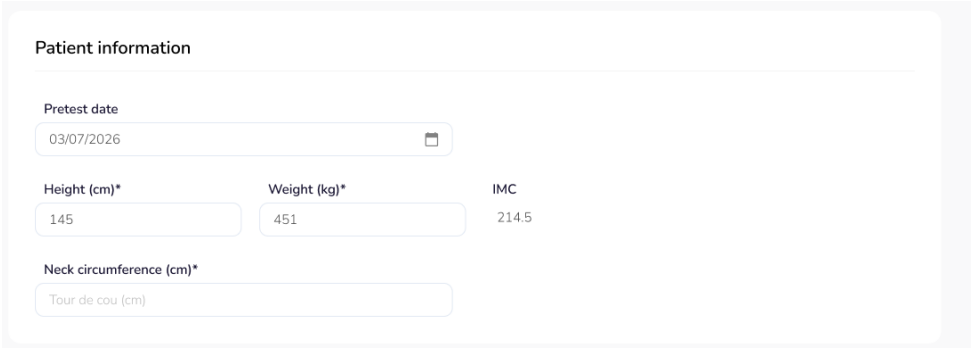
To create a new pre-test for a patient, you must first create the patient's file (see the relevant section).

Then, simply create a new pre-test from the patient's file.



PATIENT INFORMATION ENCODING

First, you need to verify or complete the information about your patient as part of this pre-test.



ANWERS TO THE QUESTIONNAIRES

Then simply answer the questionnaires provided. Some questions are addressed directly to healthcare professionals, while others should be asked to the patient.

RESULTS

The results (score calculations and interpretation for each questionnaire) are then calculated automatically and made available.

Your contact details and/or logo can be automatically inserted at the top of the analysis report (see the “Customization” section below).

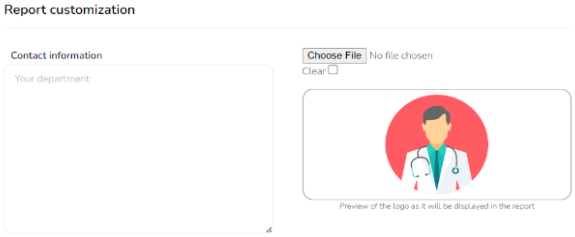
It is also possible to add your conclusions at the end of the report. To do this, you can use the smart suggestion that is automatically generated based on the results.

If the physician or person responsible for the analysis agrees with the smart suggestion, it can be validated by clicking on the corresponding button. This action copies the smart suggestion and pastes it into the space reserved for the physician/person responsible for the analysis. The latter is then free to modify or complete it.

CUSTOMISATION

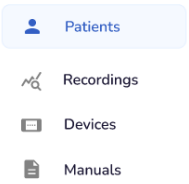
All possible customizations can be made via your profile. To do so, simply click on your name in the upper right corner of the screen.

If you want your contact details to be displayed on the PDF reports you download from Apios, simply enter them in the report customization section.



ACCESS TO MANUALS

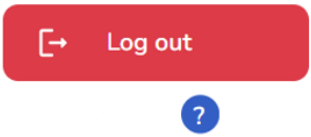
All user manuals, placement instructions and useful documents can be viewed and downloaded (in PDF format) from the dedicated area. To do this, click on the manual button in the left-hand menu. It is also available from the “Apios About” page.



If you are unable to download the eIFU and require a PDF version, please contact Nomics Customer Service.

UPDATE NOTES

All information about the NS500 Apios version is available on the “About” page. To access it, click on the question mark to the right of the version number in the left-hand menu.



On the “About” page, you will find:

- A link to the list of release notes.

For each update, you will find an explanation of what's new.

- A link to the list of known issues (bugs).

For each known bug, you will find an explanation and an alternative solution, if available.

IT SECURITY MEASURES AND PROTECTION AGAINST UNAUTHORIZED ACCESS

- The data transmission between your computer, the platform and the sleep recorders (NS121 Brizzy, NS126 Brizzy+ et NS113 Somnolter) uses a proprietary protocol that reduces the risk of a fraudulent software to falsify data. There are no parameters that could be modified by a fraudulent software to alter the way data is processed by the sleep recorders.
- Do not use public connections. When you connect to a public Wi-Fi network (airport, train station or café), a hacker can take advantage of poorly encrypted Wi-Fi to intercept your data. Since you need to exchange personal and patient data, use only private or corporate networks with strong password protection.
- Adopting a rigorous password policy and using strong authentication will help you protect your personal and patient data as much as possible. Passwords must be individual, difficult to guess and secret.
- Antivirus and anti-malware software is one of the most widely adopted security tools. Antivirus and anti-malware solutions help detect viruses and other fraudulent code that could steal, modify, or damage your sensitive data. That's why we strongly recommend you adopt one. Reliable protection against viruses and malware requires constant vigilance to keep these tools up to date (update regularly).
- APIOS allow you to collect a lot of information about your patients. Review everything to determine which data is essential and which is redundant. Don't transmit anything you don't need for the analysis. Don't forget that you have an obligation to protect all sensitive and private data. In addition, you must ensure that you do not collect information that NOMICS doesn’t need. Please refer to the sleep recorders user manuals for further information (NS121 Brizzy, NS126 Brizzy+ and NS113 Somnolter).
- Protecting your patients' data means controlling who can access it. You must limit access to those who need it to carry out their tasks. It's very important not to share your access to APIOS platform.
- Sometimes, it's the little things that can make your APIOS data platform harder to hack. In addition to not clicking on integrated links on emails from unknown senders, get into the habit of turning off unattended devices and computers, especially at night. It's also important to log out of the APIOS platform after each visit, and don’t leave your session open.
- Nomics is committed to processing personal data in accordance with the General Data Protection Regulation (GDPR). For more information, please see the privacy policy, available on Apios.

SLEEP RECORDER MANAGEMENT

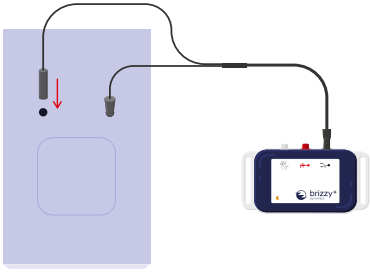
CALIBRATING THE SLEEP RECORDER

Before using the recorder for the first time, its parameters must be adjusted to best match the mandibular lowering sensor connected to it. Failure to calibrate will result in invalid data.

It is not necessary to calibrate the sleep recorder each time it is used. The system will warn you if recalibration is required. However, the sleep recorder must be recalibrated if a different mandibular lowering sensor is associated with it. To calibrate, connect your sleep recorder to the computer using the NS921 USB Cable supplied, open Ceres and click on "Calibrate my device". Then follow the instructions on the screen. Once started, the operation takes about 20 seconds. The green indicator light flashes rapidly during calibration.

Each time a new mandibular lowering sensor is associated with the sleep recorder, the sleep recorder must be recalibrated.

Throughout calibration, the probes must be kept pressed into the holes in the calibration tool.



When calibrating, make sure that the calibration tool is at least 20cm (8") away from any metal object and any other electronic device (e.g. computer). Pay particular attention to the material (possibly metal) of which the table on which the calibration tool is placed is made.

TROUBLESHOOTING

In the event of an apparently erroneous result which could have an impact on your patient's care, please contact your local distributor or Nomics Technical Service.

For any other questions or technical problems related to the use of NS500 Apios, please contact Nomics. Nomics is responsible for commissioning and maintaining the platform. Any serious incident involving the Apios system, and its accessories or consumables must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is located, in order to ensure regulatory compliance and protect patient safety.

In case of technical problems, the technical service may ask you a remote access to your computer. The technician will guide you to provide him with the identification code and password.

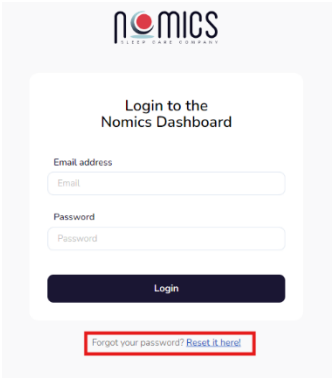
Contact details of technical services:
Technical Services
Nomics S.A.
4, rue des Chasseurs Ardennais
4031 Angleur (BELGIUM)
Tel : +32 (0)4 372 93 42
support@nomicscare.com

PASSWORD LOST/FORGOTTEN

In case you are still using an email and password system to log in:

If you have lost or forgotten your password, simply click on the button shown below. An email will be sent to you in order to reset your password.

You can also change your password at any time. To do this, go to your profile and click on "Change my password".



In case you use an e-mail address and passkeys to log in:

If you are unable to log in using your passkeys, use your recovery password to authenticate yourself. You will then receive a verification code via email. Use this code to generate new passkeys and then log in.

You can change your password at any time by going to your profile.

If you use two-factor authentication (using a password and an app) to log in:

- If you have forgotten your password, you can reset it by clicking on forgot password. Then follow the instructions you receive by email.
- If you are unable to use the authentication app, please contact Nomics so that you can reconfigure your settings.

CHANGE OF E-MAIL ADDRESS

All your personal details can be changed by clicking on your name at the top right of the web page.

PASSKEY MANAGEMENT

If you are using passkeys, you can manage them in your profile by clicking on your name at the top right of the web page.

You can:

- Delete a passkey you no longer use or no longer have access.
- Add a new passkey.

PERFORMANCE INDEX

The indices calculated and validated by the Apios system to assist you with your medical care are listed in the following table, along with their respective performance levels. Please note that these performance levels take into account the measurements taken by the sleep recorders and the calculations performed by the NS500 Apios software.

The other information included in the analysis report is provided for informational purposes only and no performance is claimed for it.

* The performance of the ODI and McGill scores are calculated in the same way, as the calculations are derived from the same single signal.

Index	Performance
REI	Sensitivity at the 15/h threshold: 83.3% Specificity at the 15/h threshold: 70%
AHI Var1	Sensitivity at the 15/h threshold: 66.7% Specificity at the 15/h threshold: 97.5%
AHI Var 2	Sensitivity at the 15/h threshold: 80.6% Specificity at the 15/h threshold: 97.5%
RDI	Sensitivity at the 5/h threshold: 90.8% Specificity at the 5/h threshold: 63.6% Sensitivity at the 15/h threshold: 88.1% Specificity at the 15/h threshold: 91.2%
Supine AHI	Sensitivity at threshold of 15/h: 90.6% Specificity at threshold of 15/h: 97.5%
Respiratory effort	Correlation: 0.85
Sleep fragmentation (Arousal index)	Correlation: 0.85
Total sleep time	Correlation: 0.83
Percentage of central events	Correlation: 0.48
McGill Score	Correlation: 0.92*
ODI	Correlation: 0.92*

Nomics reserves the right to make, at any time and with no prior notice, changes or improvements to this document and/or to the product, accessories and/or software this document describes.

NOMICS' Jawac sensor technology is covered by an international patent.

For further information, please contact:
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CE 2797