Instructions for use

General information

Manufacturer information

Mitral

FUTURE4CARE, 8 Rue Jean Antoine de Baïf, Paris, 75013 France

Contact: support@apneal.ai

Website: https://www.apneal.ai/

CE 2797

MD

Device information

Apneal Pro is a class IIa medical device in accordance with Regulation (EU) 2017/745 (for Medical Device Regulation). The CE marking is placed on the device via the application interface in the '**About**' screen in the settings.

apneal Pro

Table of content

1. Definition and glossary

Term	Definition
AHI	Apnea–Hypopnea Index Average number of apneas and hypopneas during the night per hour of sleep. The AHI is used to quantify the severity of sleep apnea–hypopnea syndrome and is expressed in events per hour of sleep.
Respiratory events	Apneas are defined as complete (≥90%) cessations of airflow lasting at least 10 seconds. Hypopneas are defined, in accordance with the American Academy of Sleep Medicine (AASM) 2023 Scoring Manual, as a ≥30% reduction in airflow lasting at least 10 seconds, associated with either a ≥3% oxygen desaturation or an arousal from sleep..
Obstructive apnea or hypopnea	Sleep-related respiratory events characterized by repeated episodes of complete or partial upper airway obstruction during sleep.
Central apnea or hypopnea	Sleep-related respiratory events characterized by repeated episodes of absent or significantly reduced respiratory effort during sleep, resulting in reduced airflow without upper airway obstruction.
Indeterminate apnea or hypopnea	Sleep-related respiratory events that cannot be clearly classified as obstructive or central due to limited or inconclusive data.
min	Minutes
dB	Decibel: Unit of measurement of sound intensity.
bpm	Beats per minute: Unit of measurement of Heart Rate (HR) Number of heartbeats (or pulses) occurring in one minute.
HR	Heart rate
PSG	Polysomnography

2. Product description

2.1 Intended use

Apneal Pro is a Software as a Medical Device intended for use on a smartphone, designed to measure physical and physiological sleep parameters with the aim of screening and aiding in the diagnosis of Sleep Apnea Hypopnea Syndrome (SAHS) in adult patients with sleep complaints

Apneal is not intended as a replacement for full polysomnography when additional parameters are needed.

2.2 Technical performance and benefit

The clinical performance of the Apneal Pro has been validated and compared to the gold standard polysomnography (PSG) on 432 adult patients.

Apnea-Hypopnea Index (AHI) measured by Apneal presents:

- A Pearson correlation > 85% with the AHI extracted from the PSG
- An average difference with the AHI extracted from the PSG inferior to 5 e/h with a standard deviation of the differences inferior to 10 e/h
- An average of the absolute difference with the AHI extracted from the PSG inferior to 10 e/h with a standard deviation of the differences inferior to 10 e/h
- Sensitivity and specificity for classifying 4 classes of AHI
    - normal (AHI <5)
    - mild (5 ≤ AHI < 15)
    - moderate (15 ≤ AHI <30) and
    - severe (AHI ≥ 30)

According to the following 3 thresholds:

	Sensitivity (Se)	Specificity (Sp)

NOTE: The Apnea-Hypopnea Index (AHI) was scored strictly following the standardized clinical criteria recommended by the AASM 2023 Scoring Manual. It was calculated without any threshold

AHI > 5	> 0,9	> 0,7
AHI > 15	> 0,8	> 0,8
AHI > 30	> 0,75	> 0,9

optimization. No data-driven or machine-learning-based threshold tuning or adjustment was applied. According to the AASM, the AHI is defined as the total number of apneas and hypopneas per hour of sleep.

Total Sleep Time (TST) measured by Apneal presents:

- An average difference with the TST extracted from the polysomnography (PSG) inferior to 11 minutes with a standard deviation of the differences inferior to 55 minutes.
- An average of the absolute difference with the TST extracted from the polysomnography (PSG) inferior to 40 minutes with a standard deviation of the differences inferior to 45 minutes.

Other variables of interest measured by Apneal present the following results:

Body position: The body position detection method demonstrated an overall agreement greater than 0.95 with the PSG video reference across supine, prone and lateral positions.

Snoring detection: The snoring detection method demonstrated a sensitivity greater than 0.90 for identifying snoring events compared to PSG ambient-microphone annotations.

Heart rate: The heart rate method demonstrated a mean absolute difference inferior to 2 beats per minute compared with the electrocardiogram reference, when evaluated over 5-second averaging periods.

Central Apnea Index (CAI): The CAI measured presented an intraclass correlation coefficient greater than 0.90 relative to the PSG CAI.

This device is intended to provide an indirect clinical benefit by:

- Reducing SAHS diagnostic delays and
- Enabling faster referral to a sleep specialist.

2.3 Functional description

The medical device Apneal Pro is composed of three integrated components:

- **The mobile application,** used by patients at home, enables sleep examinations to be performed under natural sleep conditions.
- **Apneal Pro (web application):** designed for healthcare professionals, it supports the interpretation of results, coordination of the care pathway, and patient management.
- **The artificial intelligence module:** analyzes the collected data to measure physical and physiological sleep parameters, detect respiratory events, and provide key indices, including the Apnea-Hypopnea Index (AHI).

The present instruction applies to the **web application only**, which is designed to be used by authorized healthcare professionals (HCPs) to:

- Manage patient care pathways,
- Interpret examination results generated by the Apneal mobile app and AI module,
- Support communication and coordination of care.

Access to Apneal Pro is restricted to healthcare professionals and authorized administrators, as defined by the user roles below.

2.4 Users role

Apneal Pro defines several user roles, each with specific functions and access permissions within the platform.

Access to medical data is strictly limited to **authorized and validated healthcare professionals** according to their role.

2.4.1 Administrator

The administrator manages the organizational structure and user ecosystem of the Apneal Pro platform.

Main functions:

- Manage organizations, contracts, and collaborators

- Create and modify prescriber accounts
- Oversee platform configuration and access control

Access rights:

- Full administrative access (non-clinical)
- No access to patient medical data

2.4.2 Prescriber

The prescriber is a healthcare professional authorized to manage patient examinations within the Apneal Pro system.

Main functions:

- Invite and register patients on the platform
- Assign sleep examinations to patients
- Access and interpret all medical data related to their patients

Access rights:

- Full access to the medical data of assigned patients
- No access to patients managed by other prescribers

2.4.3 Tele-expertise asker (TEA)

The Tele-Expertise asker (TEA) is a healthcare professional seeking a specialist's opinion on a patient case via the Apneal Pro system.

Main functions:

- Access patient records under their responsibility
- Consult medical data and examination results
- Submit and manage tele-expertise requests through the platform

Access rights:

- Access limited to patients for whom a tele-expertise request has been submitted

2.4.4 Specialist

The Specialist is a physician specialized in sleep medicine and part of the Apneal professional network. They respond to tele-expertise requests and interpret clinical data related to SAHS.

Main functions:

- Receive and manage tele-expertise requests
- Access patient data for cases under their medical responsibility
- Contribute to diagnosis support and clinical interpretation
- Manage patient appointments and follow-up

Access rights:

- Access limited to patients under their medical responsibility

2.4.5 Promoter

The Promoter is a representative responsible for overseeing the operational follow-up of patients enrolled under their contract.

Main functions:

- Monitor the overall patient pathway and progress within the Apneal Pro system
- Track the status and follow-up of patients associated with their contract
- Access operational information related to patient management

Access rights:

- Access limited to patients associated with their contract
- No access to patients' medical data or clinical information

3. Safety information

3.1 Contraindications and/or undesirable effects

Contraindication: The use of Apneal Pro is contraindicated in patients with **active implantable medical devices** (e.g., pacemakers, mechanical heart valves, electrical neurostimulators...)

3.2 General precautions and warnings

Please read this section carefully before using the device, ensuring you understand it and can use the device according to the instructions.

Apneal is an **aid** to clinical assessment only. A normal or negative AHI result does not exclude sleep-disordered breathing.

Do not make a definitive diagnosis or start treatment based solely on this result — confirm by polysomnography if clinical suspicion remains.

Limitations of use

The safety and performance of Apneal Dx have not been established under the following conditions or in the following patient populations. Use of the device in these situations is outside the clinically validated conditions of use and may affect the reliability or clinical relevance of the results:

- Patient with thoracic deformities or atypical thoracic movements preventing proper positioning of the phone on the chest
- Patient suffering from neurological disorders causing involuntary or uncontrollable movements
- Patients with moderate or severe valvular disease.
- CPAP therapy titration
- Pregnant women
- Children (<18yo)

If you are unsure about eligibility, do not invite the patient and refer them for a polysomnography (PSG) or to a sleep specialist.

3.3 Reporting incident

Any serious incident that has occurred in relation to this device must be reported to the manufacturer (at support@apneal.ai) and to the competent authority of your Member State.

3.4 Paper version

A paper version of this document is available upon request within 7 days with no additional cost. Please send an email to support@apneal.ai to request it.

4. How to use

4.1 Installation of the software and required configuration

No installation is required. Apnea Pro is a web-based application that can be accessed directly through any compatible internet browser at: https://app.apneal.ai

Browser Compatibility (minimum versions)

- Google Chrome — version 110 or higher
- Mozilla Firefox — version 110 or higher
- Apple Safari — version 15 or higher

Security Recommendations

- Use only secure and up-to-date browsers.
- Always log out and close the session after use.
- Do not access the platform from public or unprotected computers.

4.2 Start-up procedure

4.2.1 Invitations

A practitioner may be granted access to Apneal Pro in two ways:

- By an Apneal Administrator:

The Apneal administrator can invite a doctor to join the platform.

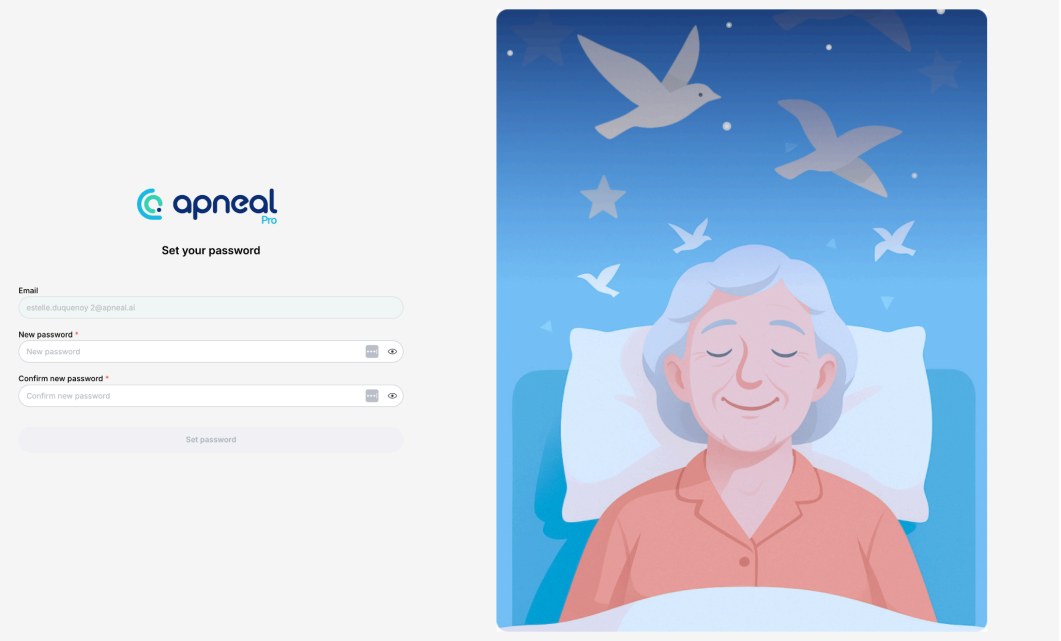
- By an existing Administrator:

An administrator who is already part of the Apneal network may also invite another doctor. In this case, the invited doctor will either be associated with the inviting practitioner or become part of the same organization.

In both cases, the invited doctor receives **an invitation email** containing a direct link to Apneal Pro.

4.2.2 Account finalization

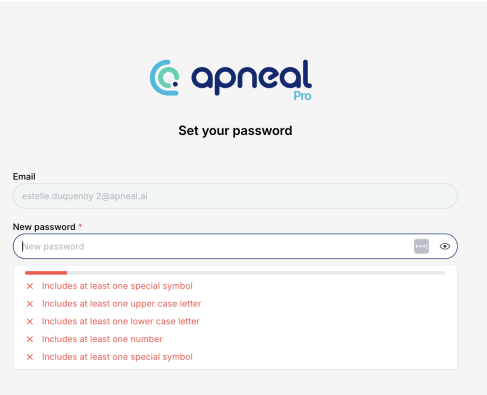
- Open the invitation email you have received and click on the “Finalize my account” link.
- You will be redirected to a page where you can set your password.

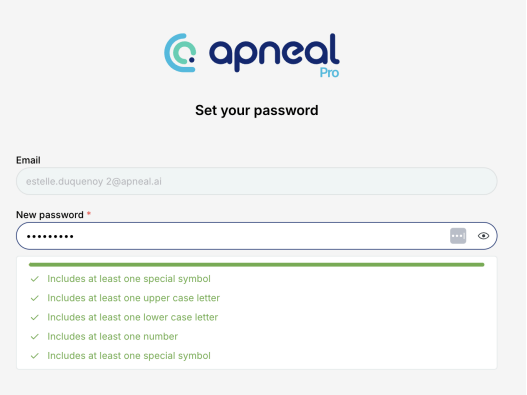


Password requirements:

Your password must include:

- at least one uppercase letter,
- at least one special character (e.g., !, @, #, ?),
- at least one number,
- and be a minimum of 8 characters long.





- Once your password is set, you can access the login page and sign in to your account.

1 Login

If you have already finalized your account, follow these steps to connect:

- Enter the **email address** used to create your account.
- Enter your **password**.
- Click the **“Sign in”** button.

Forgot your password? → A recovery option is available.

2 Verification code (2FA)

A verification code will be sent to the phone number associated with your account.

This code is required to confirm your identity and ensure secure access.

> Your phone number was provided during your initial invitation process.

3 Consent

Before continuing, you must validate the consent screens ‘Privacy policy & Terms of use’.

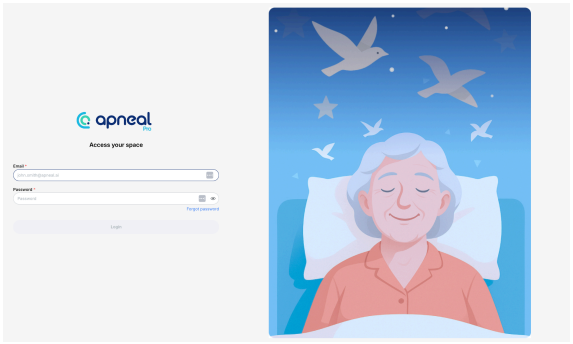
This step is mandatory in order to continue configuring your account.

4 Slider onboarding

Before accessing the main application, you will be guided through a short introduction tour to learn more about Apneal.

- Review the information slides.
- Click “Access Apneal Pro” to proceed.

You can now access the application and start using Apneal Pro.



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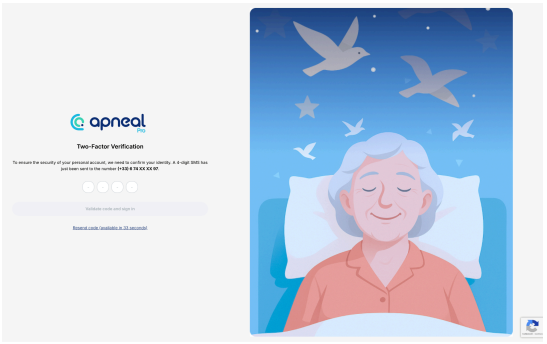

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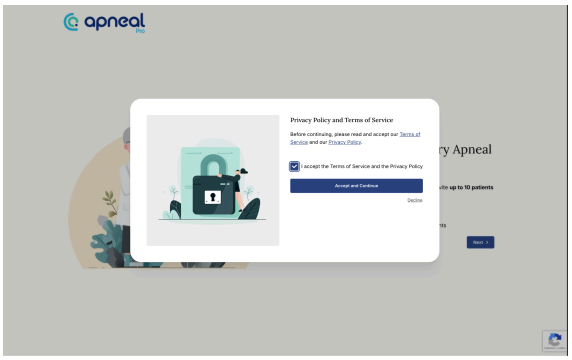

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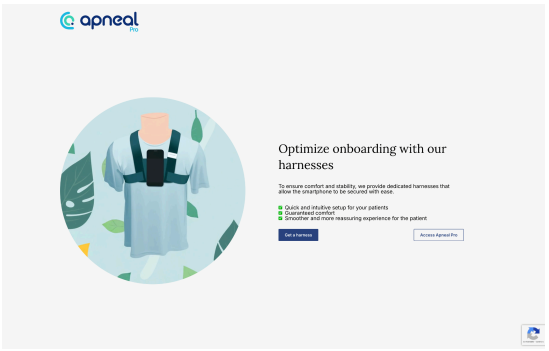

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4.3 Access levels

Apneal Pro includes several functional pages that allow users to manage patients, review nightly reports, and configure system settings.

The application features a dynamic sidebar navigation menu that adapts to each user's role. Depending on their access rights, users may see different menu items, such as Patient List, Patient Profile, Night Reports, Plannification, Patient Tracking, Settings, or Administration.

The table below summarizes the access levels associated with each user role within the application:

Feature/Roles	Administrator	Prescriber	TEA	Specialist	Promoter
Patient list	✗	✓	✓	✓	✗
Patient profile	✗	✓	✓	✓	✗
Night report	✗	✓	✓	✓	✗
Planning	✗	✗	✗	✓	✗
Patient tracking	✗	✗	✗	✗	✓
Settings	✓	✓	✓	✓	✓
Administration	✓	✗	✗	✗	✗

These access controls ensure that each user can only view or modify the information relevant to their responsibilities, maintaining both security and data integrity across the platform.

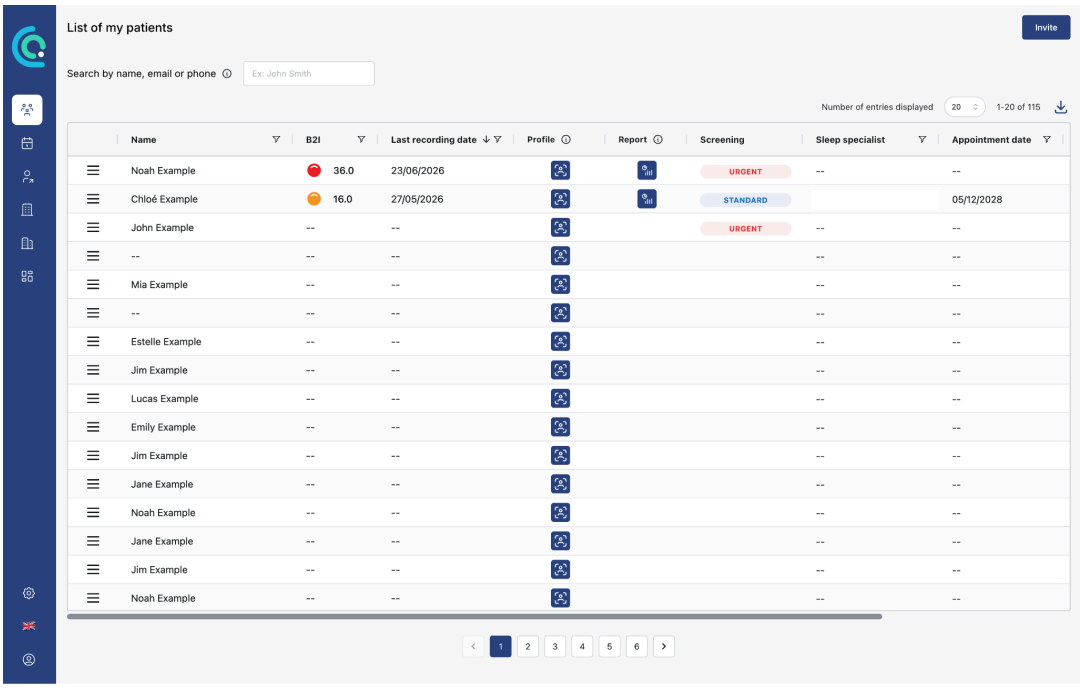
4.4 Patient list

The Patient List page displays all patients associated with the user's account. Each row corresponds to a patient and contains several columns providing key information and shortcuts.

From left to right:

- **Quick** Access Menu – The first column provides shortcuts that allow the user to open the patient's profile page or directly access the night report of the most recent recording.
- **General information** – The following columns display the patient's name.
- **Sleep data** – The next two columns present the Apnea–Hypopnea Index (AHI) and the date of the last recording. If no recording has been performed yet, the symbols "–" are displayed.
- **Profile access** – The next column provides a link to open the detailed Patient Profile page.
- **Night report access** - The next column provides a link to display the latest night report page.
- **Follow-up information** - If the user is authorized to view this information (i.e. the post-night workflow is activated), three additional columns are displayed: the screening (patient categorization after their night), the sleep specialist responsible for the patient's follow-up (or who has already managed their care), and the appointment date.

To facilitate navigation, a search bar is available at the top of the page, enabling users to quickly locate a patient by entering their first or last name.

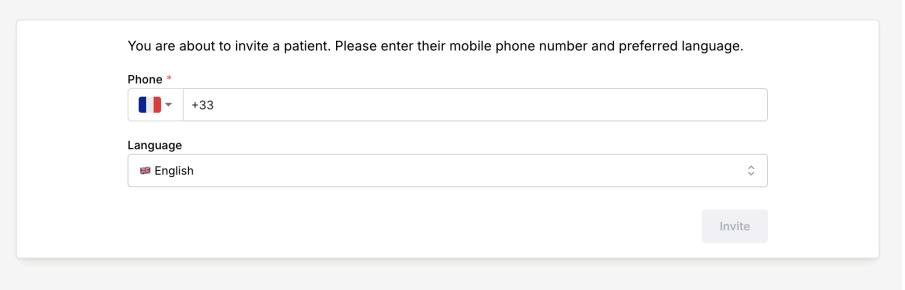


4.4.1 Patient invitation

> *This feature is only available to healthcare professionals with prescribing authority.*

From the patient list page, prescribers can access the patient invitation feature by clicking the “Invite” button located in the top-right corner of the screen.

On the patient invitation page, the prescriber simply enters the patient’s unique identification number and clicks the “Invite” button to send the invitation.



If a patient with the same identification number already exists in the database, the user will be notified, and the invitation will not be processed.

After a successful invitation, the prescriber is automatically redirected to the Patient List page, where the newly invited patient will appear.

4.5 Patient profile

This page can be accessed from the patient list page, either by clicking on “patient profile” from the quick-access menu, or by selecting the profile icon in the “view profile” column.

The patient profile page provides detailed clinical and sleep-related information for each patient.

Once opened, the page includes two main sections (accessible via tabs):

4.5.1 General

This tab is displayed by default.

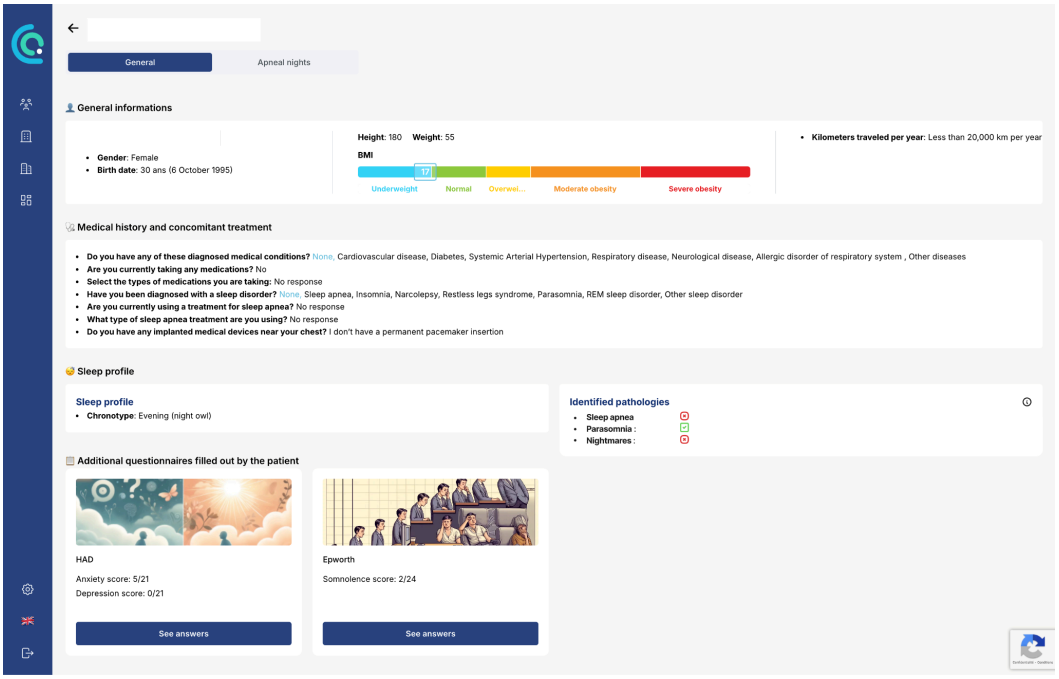
This section summarizes data collected through the onboarding questionnaires and, when available, through additional sleep profiling questionnaires. Its purpose is to provide the prescriber with the patient’s overall clinical context.

If the patient has not yet completed the questionnaires, no data will be displayed.

Otherwise, the page presents several subsections:

- **General Information:** includes basic demographic and lifestyle data such as sex, age, height, weight, BMI, and habits (e.g., driver status).
- **Medical History and Treatment:** displays the patient’s answers to the medical background and treatment questionnaires.
- **Sleep Profile:** summarizes global sleep characteristics (such as chronotype and sleep duration type, e.g., short or long sleeper) and highlights identified sleep disorders (e.g., bruxism, narcolepsy, hypersomnia, etc.).

- **Additional questionnaires:** if the patient has completed additional pathology-specific questionnaires, these can be accessed directly by clicking the “See answers” button.

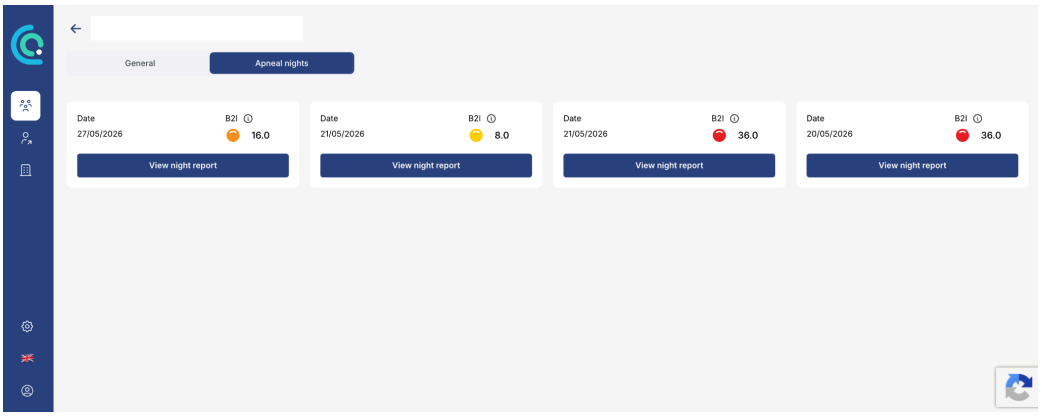


4.5.2 Apneal nights

This tab lists all recorded sleep sessions for the selected patient. Each card represents one recorded night and displays:

- the date of the recording,
- the Apnea–Hypopnea Index (AHI),
- and a color indicator showing the severity level:
  - 🟢 Green: **normal** (AHI < 5)
  - 🟡 Yellow: **mild** (5 ≤ AHI < 15)
  - 🟠 Orange: **moderate** (15 ≤ AHI < 30)
  - 🔴 Red: **severe** (AHI ≥ 30)

A “View report” button is available on each card, allowing direct access to the detailed night report.



4.6 Night report

This page can be accessed:

- From the *patient list* page, by selecting "*View latest night report*" from the quick-access menu;
- From the *patient profile* page, under the Apneal nights tab, by selecting the desired recording and clicking "*View report.*"

Once a patient has recorded a night and the report has been generated, HCPs can review the sleep study results alongside the patient's clinical background.

The application will provide you with an analysis of the signals recorded during sleep, offering information on sleep quality and respiratory events. Key metrics and observations include AHI, body movements, sleep position, heart rate, snoring, micro-awakenings, and others.

The analysis findings are presented in a structured sleep report that gives a detailed overview of the recording, including:

1 General informations

This section summarizes both the patient's identity data and the main parameters recorded during the selected night. It provides a quick overview of the context and key indicators before reviewing the detailed analysis.

- **Recording informations**

This subsection displays general information about the recording session, including:

- Recording date
- Total sleep duration
- Sleep latency (time taken to fall asleep after the start of the recording)
- Effective sleep time (from sleep onset to final awakening, excluding intermediate awakenings)
- Sleep efficiency (ratio of effective sleep time to total recording time)

These metrics give an overview of the patient's sleep continuity and the overall quality of the recording.

- **Patient informations**
  This subsection contains general demographic data about the patient:

  - First name and last name
  - Gender
  - Date of birth
  - Height, weight, and Body Mass Index (BMI)

  This information allows the healthcare professional to correlate the physiological data with the patient's clinical profile.

- **Sleep apnea symptoms observed during sleep**
  This subsection presents an indicator bar showing the patient's AHI for the recorded night. The indicator uses a color scale to represent the severity of sleep apnea symptoms:

  🟢 Green: Normal (AHI < 5)
  🟡 Yellow: Mild (5 ≤ AHI < 15)
  🟠 Orange: Moderate (15 ≤ AHI < 30)
  🔴 Red: Severe (AHI ≥ 30)

- **AHI et snoring per position**
  This subsection details the Apnea–Hypopnea Index (AHI) and the percentage of snoring time according to the patient's body position during sleep:

- Supine
- Prone
- Left side
- Right side

This analysis helps identify positional sleep apnea and snoring patterns related to sleeping posture, which can be clinically relevant for treatment recommendations.

2 Detailed report

This section provides an in-depth analysis of the patient's recorded sleep session. Each subsection includes both summary indicators and visual charts to help interpret the data over time. The graphs display variations in physiological signals and behavioral patterns throughout the night.

A Movements

Chart: This section shows the percentage of body movements detected during the night, calculated over 5-minute time windows. It serves as an indicator of sleep fragmentation and restlessness.

B Positions

Summary: displays the percentage of total time spent in each sleeping position.

Chart: shows automatic detection of body position (supine, prone, lateral) throughout the night and visualizes position changes in real time, allowing analysis of posture variability.

This information helps correlate the occurrence and severity of respiratory instabilities with the patient's sleeping position.

C Respiratory events

Apneas are defined as complete (≥90%) cessations of airflow lasting at least 10 seconds.

Hypopneas are defined, in accordance with the American Academy of Sleep Medicine (AASM) 2023 Scoring Manual, as a ≥30% reduction in airflow lasting at least 10 seconds, associated with either a ≥3% oxygen desaturation or an arousal from sleep.

Summary: displays the duration of the longest instability episode (in seconds) and the percentage of central and obstructive respiratory events detected during the night.

Chart:

- Vertical white bars represent the frequency of respiratory events — taller bars indicate more events at a given moment.
- Red horizontal marks highlight the most significant breathing perturbations observed.

This visualization helps identify when respiratory events occurred and how severe they were during the night.

Central events: Sleep-related respiratory events characterized by a reduction or cessation of airflow without associated respiratory effort, due to a transient loss of central respiratory drive.

They include central apneas (complete absence of airflow and effort for ≥10 seconds) and central hypopneas (≥30% reduction in airflow lasting at least 10 seconds, associated with a ≥3% oxygen desaturation or an arousal, without evidence of increased respiratory effort).

Obstructive events: Sleep-related respiratory events characterized by a reduction or cessation of airflow despite continued or increased respiratory effort, due to a partial or complete obstruction of the upper airway.

They include obstructive apneas (complete cessation of airflow for ≥10 seconds with persistent respiratory effort) and obstructive hypopneas (≥30 % reduction in airflow lasting at least 10 seconds, associated with a ≥3 % oxygen desaturation or an arousal, occurring in the presence of respiratory effort).

D. Heart rate

Summary: displays the average, maximum, and minimum heart rate (in bpm) calculated over 5-minute time windows.

Chart: the line shows the heart rate trend throughout the night.

E. Snoring

Summary: shows the proportion of total sleep time spent snoring, along with the average and maximum snoring intensity (in dB).

Chart: shows the sound level of the recording, expressed in decibels (dB). Snoring trains (continuous sequences of detected snoring, separated from each other by a period of silence or non-characteristic noises) are visible above the curve.

F Sleep stages

Summary: displays the percentage of total time spent awake vs. asleep during the night.

Chart: shows tracking of wakefulness and sleep periods, useful for measuring nighttime fragmentation and sleep latency.

G Signal quality

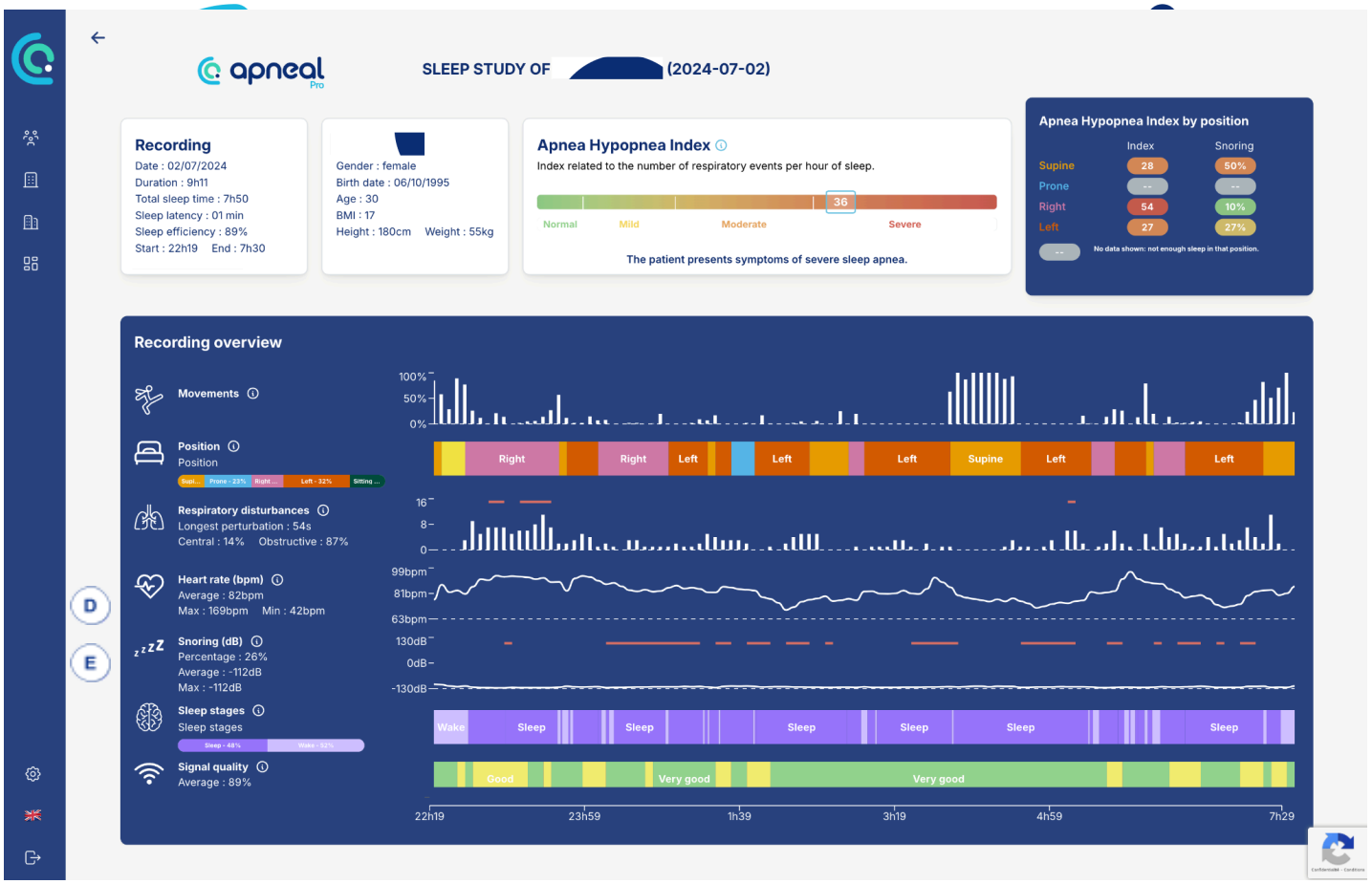
Summary: reliability score calculated every 5 minutes, based on the algorithm's output probabilities. It reflects the consistency of predictions and, indirectly, the quality of the input data.

Chart: shows the quality of the recorded signal throughout the night

- Very good
- Good
- Moderate
- Bad

The **Signal Quality Index** indicates the quality of the acquired physiological signal; analyses and automated classifications derived from periods with **low** index may be unreliable and must be interpreted with caution and, where appropriate, corroborated by clinical judgment or repeat acquisition.

The two buttons located in the upper-left corner, when available, respectively allow the user to respond to or view responses to the PMCF questionnaire (see Section 4.10), and to view the responses to the post-night questionnaire completed by the



patient. The latter provides additional information about how the patient's night unfolded, as reported after the recording.

Warnings

Always cross-check the night results with the patient profile (General tab).

Never make a clinical decision based on a truncated or incomplete report.

A

Always verify that the displayed report corresponds to the correct patient and the correct recording session.

C

If a report is missing, deleted, or inaccessible in the portal, first contact the Apneal support team. If the issue cannot be resolved promptly, repeat the analysis or refer the patient for polysomnography (PSG) or another reference examination.

F

If a report shows signs of modification, falsification, or inconsistency, contact the

Apneal support team. If the integrity of the data cannot be confirmed, discard the report and confirm the results through polysomnography (PSG) or another reference examination.

If there is any inconsistency between the displayed report and the patient's clinical status, do not interpret the data and request confirmation by polysomnography (PSG) or another reference examination.

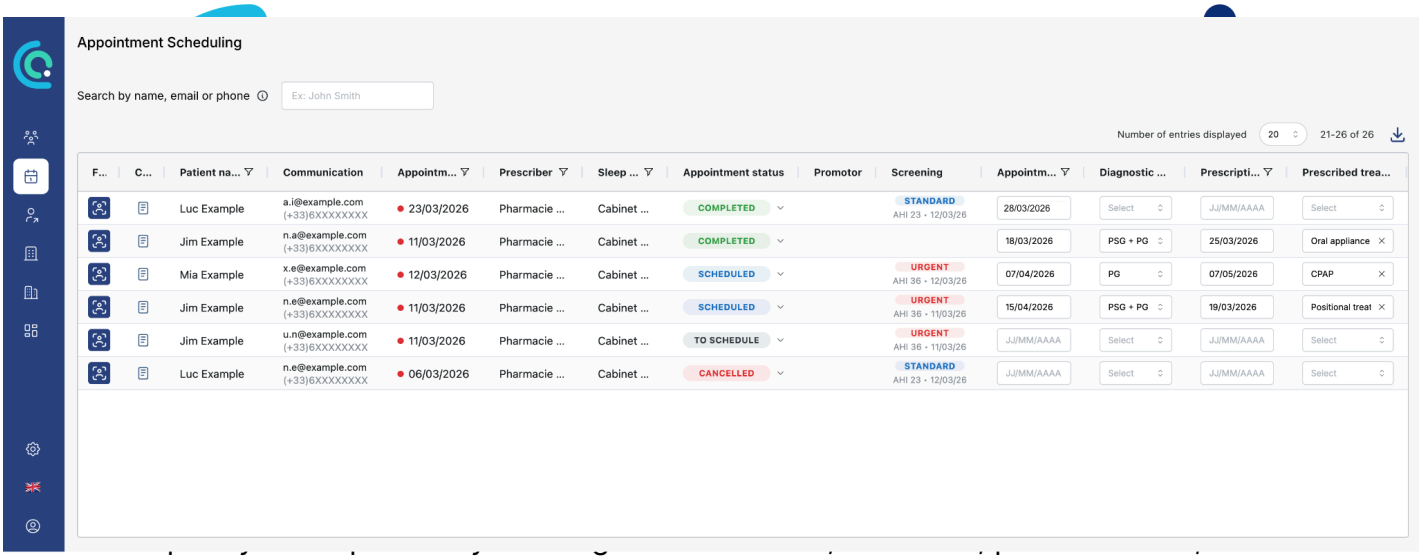
Reports displayed in the portal must not be exported or reused outside the intended application environment. Any unauthorized extraction carries a risk of confidentiality breach (GDPR/HIPAA).

4.7 Planning

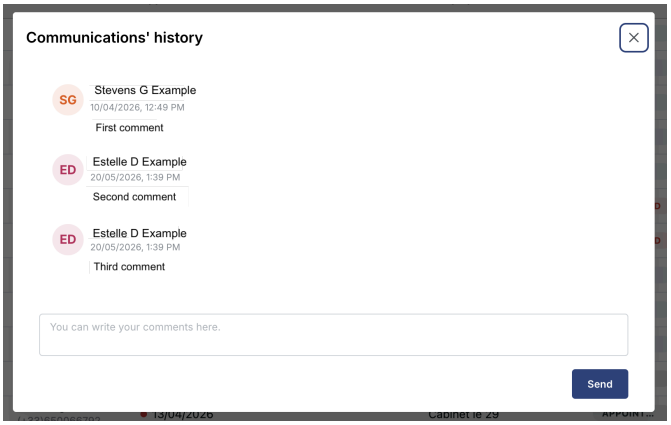
The Planning page displays a list of all appointments for patients associated with the user's account. Each row corresponds to a single appointment and provides key information as well as quick actions.

From left to right:

- **Quick access menu** – The first column provides shortcuts to quickly open the patient's profile page.
- **Comments access** – Opens a modal displaying the full history of comments recorded for the patient.
- **General information** – Displays the patient's name and contact details (phone number and email address).
- **Appointment & patient-related information** – The following columns provide detailed contextual information, including:
    - Proposed appointment date
    - Referring organization (prescriber)
    - Specialist organization responsible for the appointment
    - Appointment status
    - Patient's originating organization (promoter)
    - Night screening data (patient categorization, AHI, and night recording date)
    - Date the appointment took place


Appointment Scheduling
Search by name, email or phone
Ex: John Smith
Number of entries displayed
20
21-26 of 26
F...
C...
Patient na...
Communication
Appointm...
Prescriber
Sleep ...
Appointment status
Promotor
Screening
Appointm...
Diagnostic ...
Prescripti...
Prescribed trea...
Luc Example
a.l@example.com
(+33)6XXXXXXXX
23/03/2026
Pharmacie ...
Cabinet ...
COMPLETED
STANDARD
AHI 23 • 12/03/26
28/03/2026
Select
JJ/MM/AAAA
Select
Jim Example
n.a@example.com
(+33)6XXXXXXXX
11/03/2026
Pharmacie ...
Cabinet ...
COMPLETED
18/03/2026
PSG + PG
25/03/2026
Oral appliance
Mia Example
x.e@example.com
(+33)6XXXXXXXX
12/03/2026
Pharmacie ...
Cabinet ...
SCHEDULED
URGENT
AHI 36 • 12/03/26
07/04/2026
PG
07/05/2026
CPAP
Jim Example
n.e@example.com
(+33)6XXXXXXXX
11/03/2026
Pharmacie ...
Cabinet ...
SCHEDULED
URGENT
AHI 36 • 11/03/26
15/04/2026
PSG + PG
19/03/2026
Positional treat
Jim Example
u.n@example.com
(+33)6XXXXXXXX
11/03/2026
Pharmacie ...
Cabinet ...
TO SCHEDULE
URGENT
AHI 36 • 11/03/26
JJ/MM/AAAA
Select
JJ/MM/AAAA
Select
Luc Example
n.e@example.com
(+33)6XXXXXXXX
06/03/2026
Pharmacie ...
Cabinet ...
CANCELLED
STANDARD
AHI 23 • 12/03/26
JJ/MM/AAAA
Select
JJ/MM/AAAA
Select

address.


Communications' history
SG
Stevens G Example
10/04/2026, 12:49 PM
First comment
ED
Estelle D Example
20/05/2026, 1:39 PM
Second comment
ED
Estelle D Example
20/05/2026, 1:39 PM
Third comment
You can write your comments here.
Send

4.8 Patient tracking

The Patient tracking page provides an overview of the care pathway for all patients associated with the selected contract. It allows promoters to monitor patient progression from invitation to treatment initiation.

At the top of the page, a set of KPI cards summarizes the global activity:

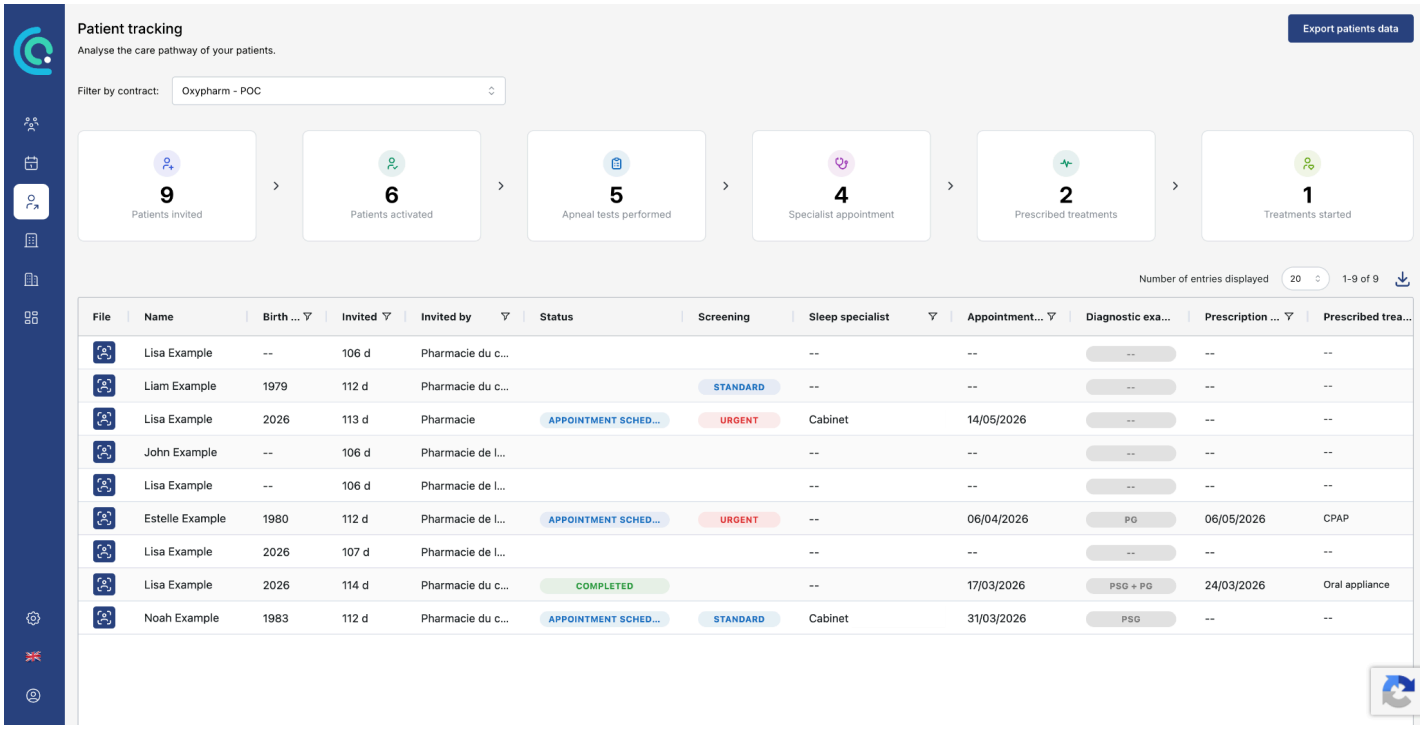
- Patients invited
- Patients activated
- Apnea tests performed
- Specialist appointments scheduled
- Prescribed treatments
- Treatments started

A contract filter is available to switch the scope of displayed patients when the user is associated with multiple contracts.

Each row corresponds to a single patient and displays key information across the care journey, from left to right:

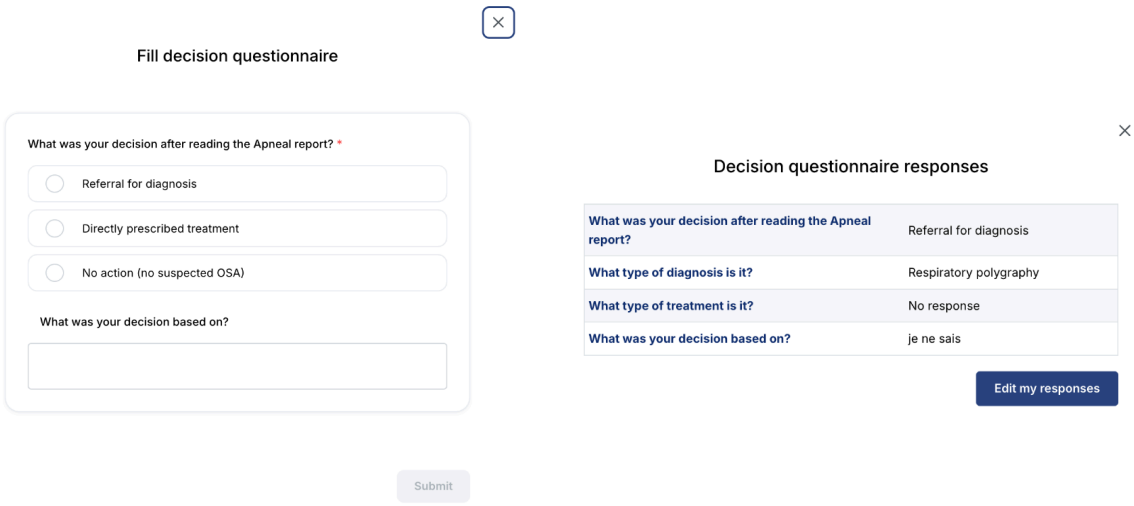
- **Quick access & patient identification**
  - The first two columns, *File* and *Name*, are displayed only when the practitioner also holds a prescriber and/or specialist role, allowing access to full patient data.
  - If not, these are replaced by a single *Identifier* column showing an anonymized patient ID.
- **General Information** & **Invitation tracking** – The next columns display the patient birth year, the date since his invitation, and the name of the inviting organization.
- **Appointment information** – The following columns provide detailed contextual information, including:
  - Appointment status
  - Night screening data (patient categorization)
  - Specialist organization responsible for the appointment
  - Date the appointment took place
  - Type of examination, if applicable
  - Treatment information (prescribed treatment date and type), if a prescription exists

An Export button is available in the top-right corner of the page. It allows users to export the complete patient tracking list, including all available information, as a CSV file.



sleep data.

Update your answers: You can access and edit your responses at any time directly from the Night Report.

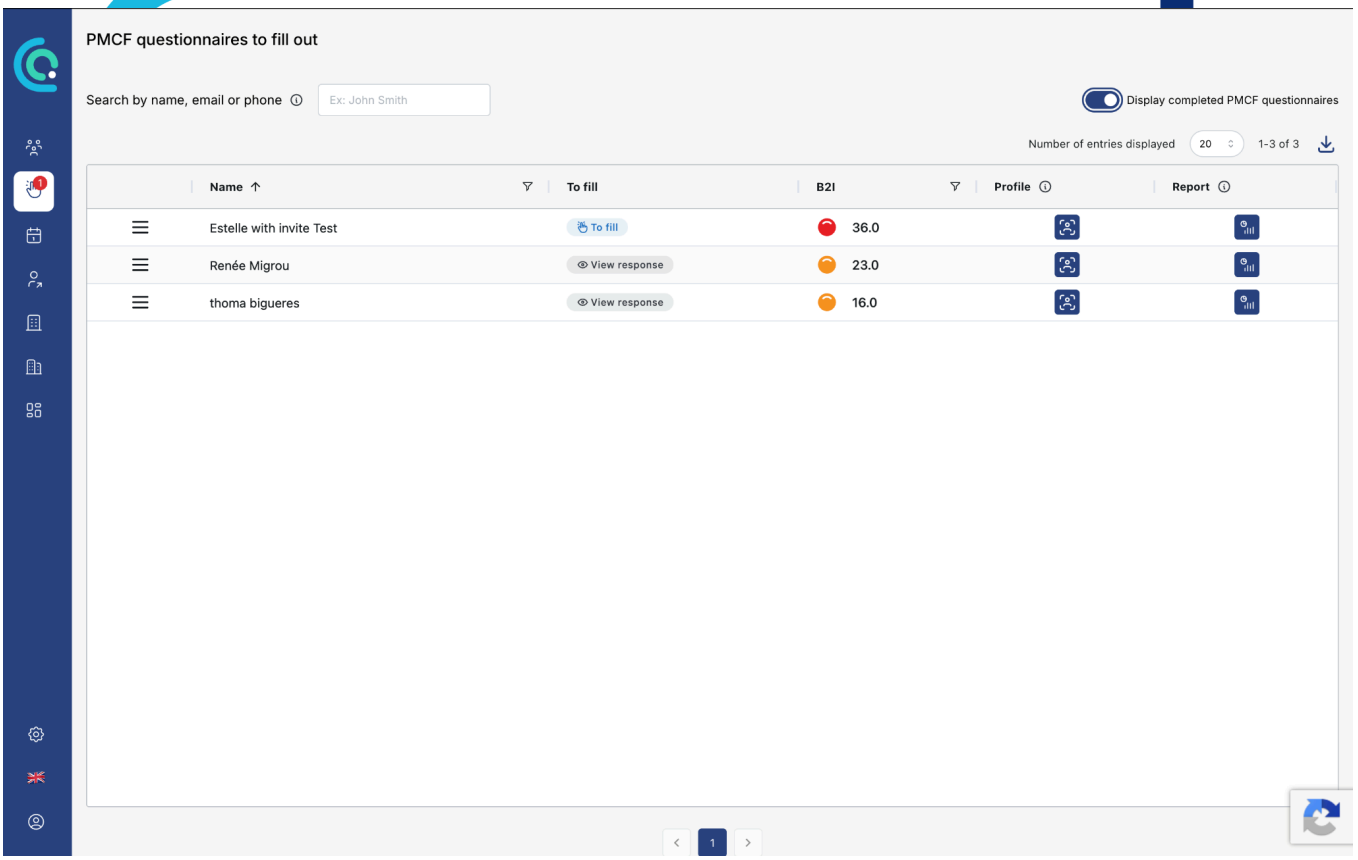


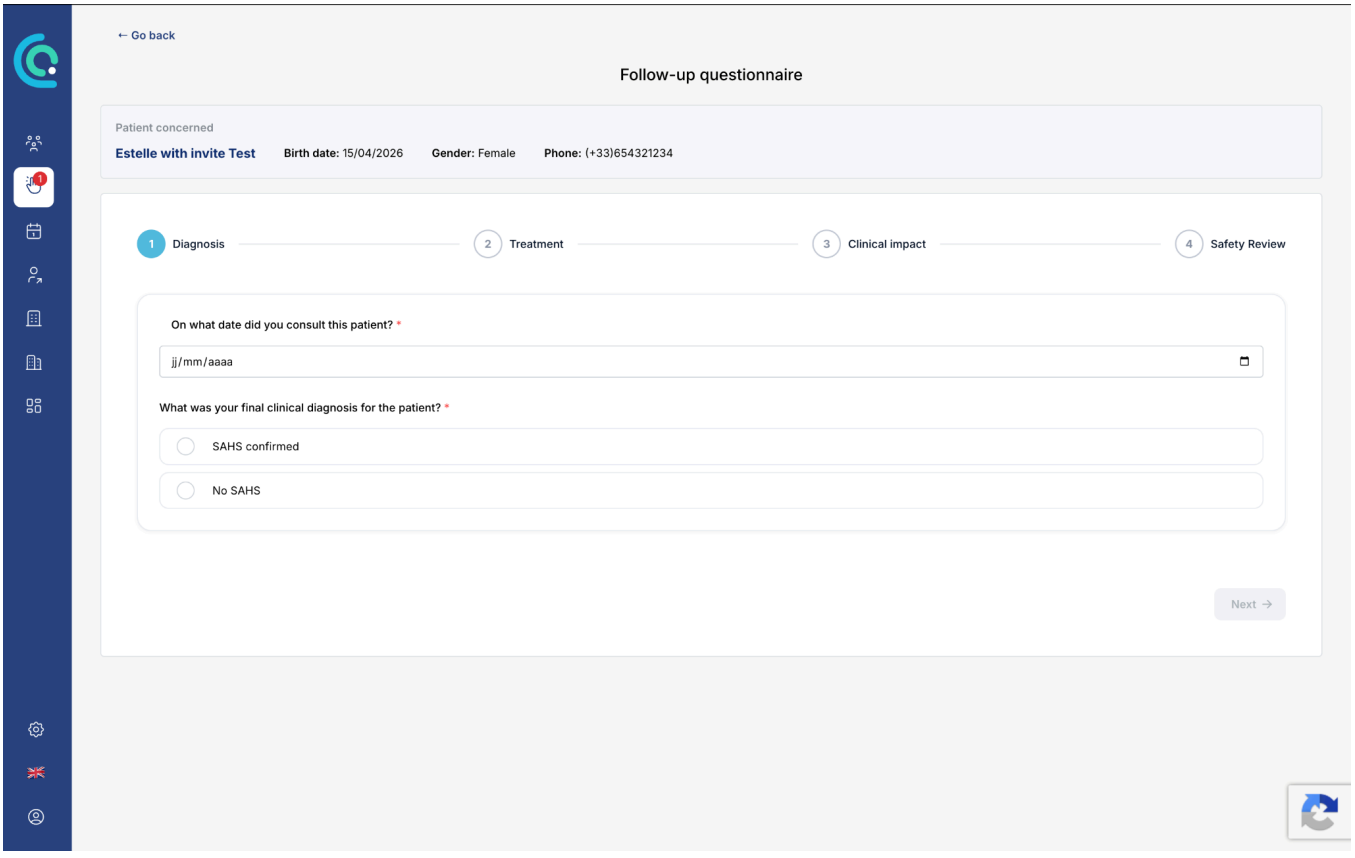
Six month PMCF questionnaire

All follow-up questionnaires assigned to your patients are centralized on the dedicated **PMCF Questionnaires** page. A questionnaire becomes available here approximately six months after a patient's first overnight recording, provided they have consented to data sharing for Post-Market Clinical Follow-up.

- **Complete a new questionnaire:** Locate the eligible patient in the table and click the **"To fill"** button in the Action column.
- **Show completed questionnaires:** By default, completed questionnaires are hidden from your view. To display them, enable the **"Display completed PMCF questionnaires"** toggle located above the table.
- **Review past responses:** Once completed questionnaires are displayed, you can review your answers by clicking the **"View response"** button in the Action column.

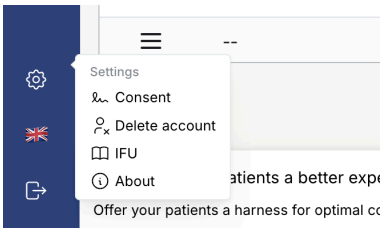
Responses can then be reviewed by clicking the "View response" button in the Action column.


PMCF questionnaires to fill out
Search by name, email or phone
Ex: John Smith
Display completed PMCF questionnaires
Number of entries displayed
20
1-3 of 3
Name
To fill
B2I
Profile
Report
Estelle with invite Test
To fill
36.0
Renée Migrou
View response
23.0
thoma bigueres
View response
16.0
1


← Go back
Follow-up questionnaire
Patient concerned
Estelle with invite Test
Birth date: 15/04/2026
Gender: Female
Phone: (+33)654321234
1 Diagnosis
2 Treatment
3 Clinical impact
4 Safety Review
On what date did you consult this patient? *
jj/mm/aaaa
What was your final clinical diagnosis for the patient? *
SAHS confirmed
No SAHS
Next →

4.10 Settings

Access the application settings by tapping the gear icon located in the bottom navigation bar.



4.9.1 Consent

You can withdraw your consent at any time from there.

> If you withdraw your consent to the *'Privacy policy'* or *'Terms of use'*, you will be automatically logged out. To access the application again, you will need to provide your consent.

4.9.2 Delete account

You can request to delete your account.

> Once confirmed, all your personal data will be permanently removed, and you will no longer have access to the application.

4.9.3 User manual

You can access the user manual by clicking on the "User Guide" option. This allows you to quickly view instructions and learn how to use the app's features.

4.9.4 About

Access the device's legal notices and regulatory labeling.

5. Maintenance

5.1 Technical maintenance recommendations

The web application is regularly updated to correct bugs, enhance performance, and introduce new features.

Updates are deployed automatically and become available to all users without requiring any manual action.

Users are advised to always access the application through the official Apneal web address to ensure they are using the latest and most secure version.

Keeping the application up to date ensures optimal performance, data protection, and continued compliance with regulatory requirements.

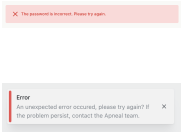
In the event of web portal unavailability (e.g., network outage, server failure, or cybersecurity incident such as a DoS or ransomware attack), do not delay patient management while waiting for the service to be restored. Follow standard clinical procedures and, if necessary, refer the patient for polysomnography (PSG).

5.2 Decommissioning

To deactivate your account and remove associated information, refer to section 4.9.2: *Delete account*. Once your account is decommissioned, it will be deleted, and access to the application will no longer be possible.

For security purposes, user accounts are automatically deactivated following 12 months of continuous inactivity.

6. Troubleshooting and error messages

Icon	Description	Message
	Technical error	This type of error is usually caused by a technical issue. If possible, please try your action again. If the problem persists, please contact the Apneal team.
	Account deletion confirmation request	You will make a request for account deletion. The Apneal team will get back to you to keep you informed. → Delete Your request has been taken into account It will be effective within 14 days → I understand
	Further information	You can find this symbol throughout the application. It allows you to obtain useful additional information.

7. Cybersecurity and data protection

7.1 Overview

This section summarizes the key security capabilities, configuration options, and operational recommendations to maintain a secure operating environment.

7.2. Security capabilities

- **Authentication & Access Control**
  - Each user has a unique, password-protected account.
  - Access to Apneal Pro is strictly role-based, in line with professional responsibilities and legal authorizations.
  - Login sessions automatically expire after a period of inactivity.
- **Logging & Auditing**
  - Security-relevant events (e.g., login, updates ...) are logged for audit and traceability purposes.

7.3 Secure operating environment

Apneal assumes operation on a secure, up-to-date, and well-maintained platform environment.

- Browser Compatibility and minimum versions
  - Google Chrome — version 110 or higher
  - Mozilla Firefox — version 110 or higher
  - Apple Safari — version 15 or higher
- Users must:
  - Keep their device operating system updated with official security patches.
  - Ensure that access to Apneal services occurs within a protected and authorized IT environment.

7.4 Recommended IT security controls

To maintain a high level of cybersecurity and data protection:

- Regularly update the operating system.
- Avoid connecting to public or unsecured Wi-Fi networks.
- Protect access credentials and do not share them.

7.5 Incident handling

Apneal uses secure communication channels for all data exchanges with its backend services.

If the app or service becomes unavailable, behaves unexpectedly, or if a cybersecurity incident is suspected (e.g., unauthorized access, data breach, ransomware, inability to send or view reports, unusual messages, or data loss):

1. Stop using the device immediately if it is safe to do so.
2. Isolate it from networks if possible.
3. Follow your local procedure.
4. Notify Apneal support (support@apneal.ai).

7.6 Data protection

Apneal Pro collects and processes personal health data to provide sleep analysis and diagnostic support.

Data are processed by Mitral as data controller and are protected using appropriate technical and organizational measures.

Apneal complies with GDPR principles, including data minimization, purpose limitation, and secure processing of health data.

7.7 Data disposal

For the data disposal procedure, refer to section 4.7.2: *Delete account*.

8. Symbols

Symbols	Description
	Manufacturer
	Indicates that the product is a medical device
	Signals a medium containing information about a unique device identifier (UDI)
	Catalog reference
	Serial number
	Instruction for Use Consult the user manual.
	Warning: Indicates that special precautions are required when using the device, or that, in the current situation, the user must exercise vigilance or take action to avoid undesirable consequences.
	Important recommendation
	Ce marking indicating the conformity of the device to the European regulatory requirements related to medical devices according to (EU) 2017/745 The number below indicates the Notified Bodies issuing the CE certificate.

9. Expected lifetime and end-of-support policy

9.1 Expected lifetime

The Apneal Pro is designed and validated for an **expected lifetime of two (2) years** from its initial release date.
This expected lifetime assumes that:

- the application is used on operating systems listed as compatible in the latest version of the IFU,
- and the operating system continues to meet the performance requirements defined in the technical specifications.

After the expected lifetime has been reached, the manufacturer **cannot guarantee full performance or continued compatibility** of the software with future operating system versions.

9.2 End-of-support policy

At the end of the expected lifetime or if the software is no longer maintained:

- The manufacturer will cease updates, compatibility testing, and user support.
- Users will be informed in advance through official communication channels (e.g., website).
- Continued use of the application beyond this period is at the user's own risk, as accuracy and performance cannot be assured.

10. Compliance with international standards and regulation

To ensure safety and efficiency, the device has been developed in compliance with the following* standards and regulations

Designation	Name	Applied version
Regulation (EU) 2017/745	Regulation of the European parliament and the council of 5 April 2017 concerning **medical devices (Medical Device Regulation)**	5 April 2017
Regulation (EU) 2021/2226	Rules the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards **electronic instructions for use of medical devices**	14 December 2021
EN ISO 13485	Medical devices – Quality management systems requirements for regulatory purposes (ISO 13485:2016)	2016/A11:2021
EN ISO 14971	Medical devices – Application of risk management to medical devices (ISO 14971:2019)	2019/A11:2021
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015/Amd 1:2020
EN 62304	Medical device software – Software life cycle processes (IEC 62304)	2006/A1:2015
EN 82304-1	Medical device software – General requirements for product safety (IEC 82304-1)	2016
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2021)	2021

** An exhaustive list of standards and collaterals is available on demand.*