

# Hypnos: innovative solution for telemonitoring of insomnia

Medical Informatics Project

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## Abstract

Hypnos is a telemedicine application designed to support the daily monitoring and clinical management of patients affected by insomnia, a highly prevalent sleep disorder characterized by difficulties in initiating or maintaining sleep and often associated with reduced sleep quality. With an estimated one-third of the global population affected at some point in life, insomnia represents a significant public health challenge, frequently co-occurring with conditions such as anxiety, depression, cardiovascular disease, and diabetes. The Hypnos system aims to provide an integrated and user-friendly platform for both patients and clinicians, offering essential tools to improve remote care and reduce healthcare workload. The application enables the collection and sharing of physiological data, including heart rate (HR), blood oxygen saturation  $(SpO_2)$ , movement index, and sleep cycle analysis, through wearable devices. In addition, it includes structured daily sleep questionnaires, a secure space for clinical notes, and a complete appointment scheduling system.

This report details the design and development of Hypnos, covering its system architecture, functionalities, and future directions. The goal is to deliver a robust digital health solution that enhances insomnia management through continuous monitoring, improved communication, and data-driven support for clinical decision-making.

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## 1 Context Analysis

Sleep is a universal function of living species, comprising one-third of human life. Poor or insufficient sleep has been associated with a wide variety of dysfunction in most body systems, including endocrine, metabolic, higher cortical function, and neurological disorders [2]. Disorders of sleep can manifest as complaints of either insufficient sleep, excessive amount of perceived sleep, or abnormal movements during sleep.

Research says that early 1 in 2 people experience sleep disturbances during their lifetime with a potential harmful impact on well-being and physical and mental health [3]. The International Classification of Sleep Disorders distinguishes the following 6 categories: insomnia, sleep-related breathing disorders, central hypersomnia, circadian rhythm disorders, parasomnia, and sleep-related motor disorders. For example, insomnia is characterized by complaints about the duration and quality of sleep, difficulty falling asleep, nocturnal awakenings, early awakening, or nonrecuperative sleep. Sleep and mental health are highly related, with many mental health problems also associated with sleeping disorders. Traditionally, sleeping disorders have been viewed because of mental health disorders, but evidence also suggests that sleeping disorders can contribute to the development of new mental health problems.

### 1.1. Insomnia

More than one-third of adults experience transient insomnia at some point in their lives. The diagnosis of insomnia is made when the patient reports dissatisfaction with sleep (sleep onset or sleep-maintenance insomnia) as well as other daytime symptoms (e.g., sleepiness impaired attention, mood disturbances) for at least 3 nights per week and lasts for more than 3 months [7].

Although several insomnia subtypes have been delineated (eg, idiopathic, psychophysiological, and paradoxical), diagnosis and treatment are similar. Recent research has indicated that the classification of insomnia has evolved, with previous diagnoses lacking reliability and validity, prompting current systems like the DSM-5-TR and ICSD-3

to 'lump' different phenotypes into a single diagnosis, often comorbid with other health conditions [5]. The precise pathophysiological mechanisms underlying insomnia have not yet been fully identified, but neurobiological and psychological models have been proposed. Contributing factors include behavioral, cognitive, emotional, and genetic factors. These are often conceptually classified into predisposing, precipitating, and perpetuating factors.

Available treatments for insomnia include pharmacological and nonpharmacological therapies. Treatment should consider other comorbidities that lead to sleep disruption, including other primary sleep disorders (e.g., sleep apnea and periodic limb movement in sleep). Initial counselling and education about good sleep practices is usually helpful, and often sufficient to reduce insomnia symptoms. Good sleep habits include: keeping regular wake times (and explaining that duration of wakefulness and circadian rhythms both affect sleep onset); limiting time in bed to sleep time; use of bed for sleep/intimacy only; avoid afternoon caffeine and limit alcohol intake; and avoiding daytime napping (otherwise these should be very brief, less than 30 minutes, and taken in the early afternoon at latest).

## 1.2. Traditional sleep monitoring: polysomnography

Normal and pathological sleep can be explored either subjectively, that is, by asking the subject, or objectively, using sensors. To date, polysomnography (PSG) [6] remains the gold standard for objectively assessing sleep characteristics. The polysomnography plots a hypnogram, integrating data from several sensors: an electroencephalogram (EEG), an electromyogram (EMG), an electrooculogram (EOG), thoracic movement (from belts on the chest and abdomen), airflow measures, oximetry, and an electrocardiogram (ECG). The sleep stages are scored according to standard visual criteria based on the EEG, EOG, and EMG sensors [1]. The assessment must be carried out under controlled conditions in the laboratory for 8 to 12 hours. An automated hypnogram analysis is possible, but still requires manual integration of data. Successful recording of the PSG over the course of the recording and the analysis of the results must be carried out by a clinician with expertise in sleep pathologies and brain disorders. Although PSG is considered the gold standard, it is an examination with limitations: it can be cumbersome for the patient, is not very accessible, and is not conducted in ecological conditions.

## 1.3. Innovative sleep monitoring: wearable devices

Wearable devices have introduced significant innovations in the field of home sleep monitoring. Unlike traditional polysomnography (PSG), which is limited to clinical settings and short-term assessments, wearables allow for continuous, long-term tracking of sleep-in real-world environments. These devices are typically lightweight, non-invasive, and userfriendly, making them suitable for home use and enhancing patient comfort and adherence. One of the key advancements is the ability of wearables to transmit data remotely through mobile apps and cloud platforms. This enables real-time access for clinicians, supporting remote monitoring and integration into telemedicine. Additionally, wearables promote self-monitoring, giving users personalized feedback that can encourage healthier sleep habits. Although their accuracy in detecting sleep stages may not yet match that of PSG [2], wearables offer a scalable alternative for monitoring general sleep patterns across diverse populations. By combining sleep data with other health metrics like heart rate and movement, wearables support a more holistic approach to understanding and improving sleep health. Among a variety of wearable devices that are nowadays used for sleep monitoring, a smart ring has been chosen for this project. Unlike other common devices, such as smart watches or wristbands, that all share the feature of being noninvasive, the one device that we propose stands out for its comfort while wearing it, which ensures the analysis to be completely unbiased. The smart ring is equipped with sensors that measure sleep-related signals, such as heart rate, blood oxygen saturation  $(SpO_2)$ levels), duration of sleep stages, and hand movements. All data are then transmitted to the patient's smartphone via a Bluetooth link, so as to be stored in the system database.



Figure 1.1: Example of smart ring

## 1.4. Our solution: "Hypnos"

Based on the findings collected to date, we propose Hypnos, an integrated digital solution designed to support clinicians in the monitoring and management of sleep disorders, with a particular focus on insomnia. Hypnos aims to enhance clinical decision-making through continuous, at-home monitoring using a wearable device. The smart ring measures key

physiological parameters such as heart rate (HR), blood oxygen saturation ( $SpO_2$ ) and the number of sleep cycles. The device synchronizes with the patient's smartphone, transmitting data to the application via Bluetooth.

The wearable will be provided by the clinic and retrieved at the end of the monitoring phase. Each night, the application will prompt the patient to activate "sleep mode," initiating data collection. Upon waking, the app gathers the recorded data, prompts the patient to complete a brief questionnaire about their sleep quality, and generates a comprehensive report. Patients may also submit additional information through a dedicated "Notes" section. Usability is a critical factor for the success of these devices [4] and the integration of user feedback, such as through these questionnaires, plays a key role in ensuring that the system meets patient needs and expectations.

A key strength and the true innovation of Hypnos lies in its ability to combine objective data from the wearable device with subjective insights collected through daily sleep questionnaires. This integration of both measurable physiological parameters and the patient's personal perception of sleep, which are equally important in the diagnosis and treatment of insomnia, enables a more holistic and effective clinical evaluation.

Clinicians can access the system via a desktop interface, where, with the patient's consent, they can view all collected data and reports. This remote monitoring capability enables clinicians to make informed decisions regarding treatment adjustments, such as prescribing or modifying medications or recommending further diagnostic tests. Additionally, the application allows specialists to assign targeted questionnaires, offer personalized guidance, and communicate recommendations directly to the patient.

Hypnos also includes scheduling features for managing and booking appointments, streamlining interactions between patients and providers. The system is thought to be for individuals within the working-age population (15–70 years), who are capable of consistently wearing the device without any external support. The patient is required to own a smartphone to be able to use Hypnos' integrated system.

By combining real-time data collection and subjective sleep-related information with clinician oversight, Hypnos represents a promising tool for improving the ecological and clinical management of sleep disorders.



Figure 1.2: Logo of Hypnos Monitoring System

## 1.5. Assumptions and disclaimer

In the current design and implementation of our system, several key assumptions have been established to ensure correct usage and consistent functionality within the intended clinical setting.

- 1. Relevant and prolonged symptoms. We assume that the patient has already experienced clear, clinically significant, and persistent symptoms prior to using the application. Nevertheless, the Hypnos system is intended solely for monitoring and follow-up and is not designed for diagnostic use. While the system incorporates an internal algorithm for data analysis and sleep scoring, its outputs are not to be considered medical diagnoses, but rather clinical decision-support tools. For these reasons, the formal diagnosis is assumed to be established by the specialist during the initial clinical evaluation.
- 2. Clinic-Provided Device and Onboarding. It is also assumed that the wearable device is provided by the clinic, and that the initial setup of the patient's profile is conducted during the first in-clinic visit. As the system functions as a certified medical tool, this approach ensures that all onboarding procedures are fully supervised and controlled by the medical staff. The clinician remains responsible for patient management throughout the entire usage period.
- 3. <u>Single-Clinic Ecosystem</u>. For the sake of simplicity and to reduce development complexity in this initial version, the system assumes that all doctors belong to the same clinical institution. This constraint allows for centralized data access and simplified

user management, while future iterations may consider broader multi-clinic support.

4. <u>Patient-Owned Smartphone</u>. Lastly, we assume that each patient owns and regularly uses a personal smartphone. This is essential for accessing the mobile application, completing daily questionnaires, receiving notifications, and synchronizing data from the wearable device.

These assumptions define the boundaries of the system's operational context and are crucial for its effective and secure use in a controlled clinical environment.

Note on Implementation Status: all the diagrams, together with the full description of our system functionalities we are presenting below, illustrate the comprehensive design and intended workflow. Functionalities marked with a special symbol (\*) are integral to the project's original concept but are <u>not</u> available in the current software release. These features are part of our official development roadmap and are scheduled for implementation in future updates.

## 2 Textual Description

### 2.1. Actors

<u>Patient</u>: is the individual who presents with symptoms of insomnia and visits the private clinic for diagnosis. They have been prescribed a telemonitoring system to continuously track sleep patterns and related physiological parameters, which enables the specialist to evaluate the effectiveness of the treatments in real time and stay consistently informed about the patient's health status.

<u>Sleep specialist</u>: is the healthcare professional (either a pulmonologist or a neurologist) responsible for supervising the patient's sleep monitoring process. During the first in-clinic visit, the Sleep Specialist provides the patient with a wearable device for home-based monitoring and assists in setting up the whole system (pairing the device with their smartphone and signing into the app). Throughout the telemonitoring period, the specialist remotely accesses and analyzes physiological data and reviews sleep reports (periodically generated by the associated app) to track the patient's sleep quality over time. Based on the progression of the condition, the specialist may adjust the therapy plan, prescribe or modify medications, and schedule follow-up visits or additional diagnostic tests as needed.

<u>Wearable device (smart ring)</u>: the device, provided by the private clinic and worn by the patient, measures all useful parameters such as sleeping time, sleep movements, respiratory rate, heart rate variability, and pulse oximetry. The collected data are automatically transmitted via Bluetooth to the application each time the patient opens the app, allowing for further processing and clinical monitoring.

<u>App (application)</u>: is the central interface of the telemonitoring system, connecting all the actors and facilitating seamless data flow. It generates sleep trend reports by combining objective data collected from the wearable device with subjective information gathered through daily sleep quality questionnaires prompted to the user, enables the scheduling of medical appointments and examinations, and supports the upload of prescriptions, referrals, and notes—both from healthcare providers and from patients.

<u>Smartphone</u>: is the device where the application is installed. It is connected to the wearable device via Bluetooth, and each time it synchronizes, it enables the storage of the data collected by it. It allows fast access to the telemonitoring system.

<u>IT Support</u>: provides technical assistance to users and ensures the correct functioning of the system. Responsible for resolving software or connectivity issues, managing data security, and supporting device integration with the app.

## 2.2. Log in

The following textual descriptions describe the two processes followed by the two possible types of users of our telemonitoring system, through the application: the "Patient" and the sleep specialist, which from now on we will call "Doctor".

#### Title

The "Patient" logs into the app

#### Pre-condition

The patient is already registered in the system as "Patient" by the doctor; the patient is already registered on the app with "name", "surname" and "password"; the patient has already performed the first access to the app in the clinic

#### Post-condition

The "Patient" accesses the app

#### Main success scenario

- 1. The app displays the initial log-in screen
- 2. The "Patient" selects the button for "Patient" users
- 3. The "Patient" enters their credentials
- 4. The "Patient" presses the "Log in" button
- 5. The app verifies the provided data
- 6. The app authorizes access to the "Patient"
- 7. The app displays the homepage for "Patient" interface

#### Alternative scenario

5a. The provided password is invalid

- 5a.1. The app displays a credentials error message
- 5a.2. The app prompts the patient to re-enter the password
- 5a.3. The "Patient" enters the password again
- 5a.4. The app verifies the password
  - 5a.4a.1. The provided password is invalid less than 3 times
  - 5a.4a.2. The app displays a password error message

```
5a.4a.3. Return to AS 4a.2.
5a.4b.1. The password is wrong the fourth time (*)
5a.4b.2. The app sends an email to rescue the password (*)
5a.5. Return to MSS 5 (*)
```

The sleep specialist who works at the clinic must log into in the system, by entering their own information, the first time they access it.

#### Title

The "Doctor" registers into the app

#### Pre-condition

The "Doctor" works in the private clinic

#### Post-condition

The "Doctor" is registered in the system

#### Main success scenario

- 1. The user selects the "New Doctor?" button from the login screen
- 2. The system displays the "Add New Doctor" window
- 3. The "Doctor" enters the personal details required
- 4. The "Doctor" enters a valid password
- 5. The "Doctor" clicks the "Add Doctor" button
- 6. The system verifies the correctness of the input data
- 7. The system stores the new doctor in the database

#### Alternative scenario

- 6a. One or more required fields are empty or incorrectly formatted
  - 6a.1. The app displays an error message
  - 6a.2. The "Doctor" corrects the invalid fields
  - 6a.3. Return to MSS 6

After completing the registration, the sleep specialist will be able to log in to the app through a "Log In" screen window like the one used by patients. The process of Log in of the "Doctor" is identical to the one of the patient.

### 2.3. Doctor

The following textual description outlines the standard workflow followed during the patient's first in-clinic visit for suspected insomnia at the clinic. It details the steps performed by the Doctor, from the initial anamnesis and diagnostic process to the delivery to

the patient of a wearable monitoring device in conjunction with Hypnos system. Details the step-by-step interaction between the patient, specialist, and application—from creating a patient profile and prescribing diagnostic exams, to guiding the patient through app setup and device connection. The goal is to ensure the patient is fully prepared and informed to begin remote monitoring of their sleep condition and the configuration of his profile on the system. The scenario includes the collection of relevant medical information, behavioral recommendations, and potential alternative paths in case of technical or clinical exceptions.

#### Title

First visit and device delivery

#### **Pre-condition**

The patient is experiencing symptoms of insomnia; the patient decides to visit the clinic to seek medical evaluation and treatment; the doctor works at the private clinic; the doctor is already registered on Hypnos app

#### Post-condition

The doctor prescribes home monitoring to the patient and provides them with the monitoring device; the patient starts monitoring their sleep using the device and the Hypnos app

#### Main success scenario

- 1. The patient enters the clinic
- 2. The doctor logs into the system
- 3. The patient reports their symptoms to the doctor
- 4. The doctor opens "Patients" section
- 5. The doctor creates the patient's profile
- 6. The doctor carries out a complete medical history (anamnesis) (\*)
- 7. The doctor interviews the patient about their sleep habits and lifestyle
- 8. The doctor records the patient's responses in the app (\*)
- 9. The doctor performs further examinations
- 10. The doctor enters the results of these analyses into the app (\*)
- 11. The doctor evaluates the results
- 12. The doctor establishes a diagnosis of insomnia
- 13. The doctor updates the patient's condition in their profile (\*)
- 14. The doctor suggests home monitoring of the insomnia condition using a wearable device and the Hypnos application
- 15. The patient confirms that they can manage the monitoring process and accepts the treatment

- 16. The doctor provides the wearable device (ring) to the patient
- 17. The patient downloads Hypnos app on their smartphone
- 18. The doctor gives the patient the credentials to access Hypnos
- 19. The patient logs into the app for the first time under the doctor's supervision
- 20. The doctor pairs the device with the patient's profile in the app via Bluetooth (\*)
- 21. The doctor provides information regarding the monitoring process
- 22. The patient wears the ring

#### Alternative scenario

- 10a. An error in the exam upload occurs (\*)
  - 10a.1 The app displays an error message
  - 10a.2 The doctor contacts app support
  - 10a.3 The doctor fills the support form
  - 10a.4 Return to MSS 11
- 11a. The results are alarming, so the doctor suggests additional diagnostic tests
  - 11a.1. The doctor schedules a polysomnography test
  - 11a.2. The doctor enters the appointment in the "Calendar" section of the app
  - 11a.3. Return to MSS 12
- 14a. The doctor decides not to proceed with home monitoring, as the patient's condition does not present clinically significant alterations
  - 14a.1. The doctor sets an appointment for a follow-up visit
  - 14a.2. End of MSS
- 20a. The device doesn't connect to the phone
  - 20a.1. The app displays an error message (\*)
  - 20a.2. The doctor contacts IT support
  - 20a.3. The doctor fills the support form
  - 20a.4. The doctor provides another device to the patient
  - 20a.5. Return to MSS 21

This textual description outlines the typical workflow of the remote check of the telemonitoring in which the doctor follows to systematically review and update a patient's sleep records within the digital system. It begins with accessing the patient's profile to thoroughly examine recorded sleep data and clinical information. The doctor then proceeds to document personalized behavioral recommendations aimed at improving the patient's sleep hygiene, which are entered in the "Notes" section of the application. Additionally, the doctor may manage medical prescriptions by selecting, creating, and updating prescriptions as necessary to support the patient's treatment plan.

#### Title

Remote weekly check

#### **Pre-condition**

The doctor has access to the system, where he can monitor the sleep reports generated by Hypnos; the patient wears the ring every night and every morning fills in the questionnaires proposed by the app

#### Post-condition

The doctor has reviewed the patient's sleep records and updated notes and prescriptions

#### Main success scenario

- 1. The doctor logs into the system
- 2. The doctor opens the "Patients" section
- 3. The doctor selects the patient of interest
- 4. The doctor examines the sleep records
- 5. The doctor enters in the "Notes" section
- 6. The doctor selects "Add notes"
- 7. The doctor inserts guidance on behavioral adjustments to improve the patient's sleep hygiene in the "Note content"
- 8. The doctor clicks on "Save changes" to save the content
- 9. The doctor opens "Prescriptions" section
- 10. The doctor clicks on "Add Prescription"
- 11. The doctor selects the kind of prescription desired
- 12. The doctor inserts comments on the prescription in the section "Contents"
- 13. The doctor clicks on "Add" button to save the prescription

#### Alternative scenario

- 8a. The doctor realizes that they have made an error in the content of the notes
  - 8a.1 The doctor selects the note of interest
  - 8a.2 The doctor clicks on "Edit Note"
  - 8a.3 The doctor corrects the error
  - 8a.4 The doctor Return to MSS 8
- 8b. The doctor realizes that they have given an incorrect indication
  - 8b.1. The doctor selects the note of interest
  - 8b.2. The app deletes the notes
  - 8b.3. Return to MSS 9
- 13a. The doctor realizes that they have made an error in the content of the prescription
  - 13a.1. The doctor selects the prescription of interest
  - 13a.2. The doctor clicks on "Edit Prescription"

- 13a.3. The doctor corrects the error
- 131.4. The doctor returns to MSS 13
- 13b. The doctor realizes that they have given an incorrect prescription
  - 13b.1. The doctor selects the prescription of interest
  - 13b.2. The app deletes the prescription
  - 13b.3. End of MSS

The following textual description concerns specifically scheduling of the doctor's availability by selecting appropriate dates and defining specific time slots in the integrated calendar of Hypnos system.

#### Title

Scheduling Doctor's Availability in the Hypnos System

#### Pre-condition

The doctor works in the clinics; the doctor is already registered in the system

#### Post-condition

The doctor's availability is successfully recorded in the system calendar, allowing patients to book appointments within the specified time slots

#### Main success scenario

- 1. The doctor logs into the system
- 2. The doctor enters in the "Calendar" section
- 3. The doctor selects an available date on the calendar
- 4. The doctor clicks on "Add Slot"
- 5. The doctor specifies the start and end times of their availability for that day

#### 2.4. Patient

This textual description describes the process of patient sleep monitoring through the use of a wearable device (ring) paired and synchronized with the Hypnos application, which is installed on the patient's mobile phone. The objective is to enable patients to track their sleep patterns, document their sleep quality, and communicate relevant information to their healthcare providers. Upon receiving the wearable from a specialist, the patient is guided through a series of interactions with the app to ensure accurate data collection and effective monitoring. The application not only facilitates sleep tracking but also supports user feedback through daily questionnaires and personal notes, as well as access to specialist observations.

#### Title

Patient sleep monitoring

#### Pre-condition

The user is a registered patient of the clinic; the patient has been provided the wearable device from the doctor; the patient has already been registered by the doctor in the system; the patient wears the ring every night; the ring is paired with the app installed on the patient's smartphone

#### Post-condition

Personal sleep data are recorded; sleep reports are generated and uploaded to the system, where the doctor can examine them remotely

#### Main success scenario

- 1. The patient wears the ring before going to bed
- 2. The patients start the sleep monitoring phase
- 3. The patient wakes up and stops the sleep monitoring phase
- 4. The patient logs in to the app
- 5. The patient connects the wearable and the app via Bluetooth (\*)
- 6. The app downloads sleep data from the ring (\*)
- 7. The patient enters the "Questionnaires" section
- 8. The patient fills out daily questionnaires about their sleep quality
- 9. The patient submits the daily questionnaire
- 10. The app registers the data of the device and of the questionnaire
- 11. The app processes the information together
- 12. The app generates a sleep score with the information gathered
- 13. The app displays the score on the "Sleep Records" section
- 14. The patient opens "Notes" section
- 15. The patient checks the "Doctor's Notes"
- 16. The patient writes down daily notes about sleep sessions and personal opinions about the treatment in the "Your Notes" section
- 17. The patient submits the note by clicking on "Add Note"
- 18. The patient opens the "Prescriptions" section
- 19. The patient checks if the doctor has uploaded new prescriptions
- 20. The patient closes the app

#### Alternative scenario

- 5a. Synchronization between the wearable and the app fails (\*)
  - 5a.1. The app displays an error message: "Synchronization failed"
  - 5a.2. The patient re-attempts to connect the wearable via Bluetooth

```
5a.3. Connection successfully established
```

5a.4. Return to MSS 6

5a.3a.1 The connection fails again

5a.3a.2. The app displays an error message: "Synchronization failed"

5a.3a.3. The patient opens the "Support" section in the app

5a.3a.4. The patient fills out and submits the IT Support Request Form

5a.5. End of MSS

9a. The patient doesn't fill out the questionnaire

9a.1. App sends notification to fill questionnaire (\*)

9a.2. The patient fulfills the questionnaire

9a.3. Return to MSS 4

9a.2a.1 The patient does not fill out the questionnaire in 5 minutes

9a.2a.2. Return to AS 9a.1

16a. The patient doesn't need to add personal notes

16a.1. Return to MSS 18

17a. Mistake in the note

17a.1. The patient notices an error in the note written

17a.2. The patient clicks on the "Edit Note" button

17a.3. The patient modifies the note

17a.4. The patient submits the note by clicking "Save Note"

17a.5. Return to MSS 18

17b. Wrong note

17b.1. The patient sends a note by mistake

17b.2. The patient clicks on the "Delete" button of the note

17b.3. The app displays a confirmation pop-up

17b.4. The patient selects "Yes" option

17b.5. The App deletes the note

17b.6. Return to MSS 18

The following textual description specifically concerns the patient's ability to book a visit to the clinic with their doctor by reviewing their available time slots on the Hypnos system and selecting the one that best suits their needs.

#### Title

Patient visit Booking via Hypnos System

#### Pre-condition

The patient must already be registered on the app, which must be installed on their smartphone. The doctor must have previously entered into the system the days and time slots in which they are available for appointments

#### Post-condition

The appointment between the patient and the doctor is successfully scheduled and registered in the system. Both the patient and the doctor receive a confirmation of the booking

#### Main success scenario

- 1. The patient logs into the system
- 2. The patient opens the "Appointments" section
- 3. The patient selects an available date on the calendar
- 4. The patient selects a suitable time slot
- 5. The patient clicks on "Book Appointment" to reserve the spot
- 6. The system updates the selected slot status to "Booked"
- 7. The system stores the booking in the patient's calendar
- 8. The patient receives a confirmation message

#### Alternative scenario

- 3a. No available slots for the selected date
  - 3a.1. The system displays a message: "No available time slots for this date"
  - 3a.2. The patient selects a different date
  - 3a.3. The date presents available slots
  - 3a.4. Return to MSS 4
    - 3a.3a.1. The new date does not present available spots
    - 3a.3a.2. Return to AS 3a.2.
    - 3a.3b.1. The patient decides to contact the doctor
    - 3a.3b.2. The patient opens the "Doctor" section
    - 3a.3b.3. The patient clicks on "Contact Doctor"
    - 3a.3b.4. The patient asks the doctor for new available slots
    - 3a.3b.5. The doctor receives the request and adds new available slots in the system
    - 3a.3b6. The patient receives a notification that new slots are available
    - 3a.3b.7. Return to MSS 3

## 2.5. IT Support (\*)

The IT support carries out its normal routine of activities aimed at ensuring that the application works correctly and meets the user's needs, checking the notifications received and contacting the user who needs it, if necessary. Please note that this functionality

has not yet been implemented due to time constraints; therefore, it is currently missing from the available system. In fact, the IT support interface itself has not yet been developed. However, it represents the next step in our implementation workflow, thus its corresponding textual description has already been designed.

#### Title

Routine check of the application

#### Pre-condition

The IT support does a routine check of the application to see if everything is working as expected, to upload some new documentation, and to respond to eventual requests from users

#### Post-condition

The IT support sends feedback to the system's developer

#### Main success scenario

- 1. The IT support logs into the app
- 2. The IT supports checks if there are updates needed by the app documentation (FAQ, quick guidelines, user manuals)
- 3. No documentation update is required
- 4. The IT support checks the users' feedback
- 5. The IT support checks the app requests
- 6. No system issues are detected
- 7. The IT support checks the user requests
- 8. No new user help requests
- 9. The IT support checks if there are any changes to do in users access and authorization
- 10. There are no changes to do
- 11. The IT support sends feedback to the software's developer

#### Alternative scenario

- 4a. Documentation update is required
  - 4a.1. The IT Support updates and uploads the new documentation
  - 4a.2. Return to MSS 6
- 6a. System issue is detected
- 6a.1. The application has sent a notification to the IT support regarding the technical issue
  - 6a.2. The IT support addresses the system issue
  - 6a.3 Return to MSS 7
- 8a. User help request is found
  - 8a.1. The IT support checks the compiled forms

8a.2. The IT support decides how to contact the users via the appropriate channels (mail, phone number, or live chat)

8a.3 Return to MSS 9

10a. A user access request is pending

10a.1. The IT Support updates the user's access and authorizations as required

10a.2 Return to MSS 11

# 3 Use Case Diagrams

## 3.1. Patient

The patient is the main actor and actively interacts with the sleep monitoring application to support the remote management of their sleep disorder (insomnia). After registering on the app by entering personal information, the patient can download daily sleep reports generated by the app based on data collected from the wearable device and can complete questionnaires automatically generated by the system. The application allows the patient to receive and send notifications, for example, when scheduling a medical visit. In addition, the patient has access to newly prescribed therapies and medications, as entered by the doctor.

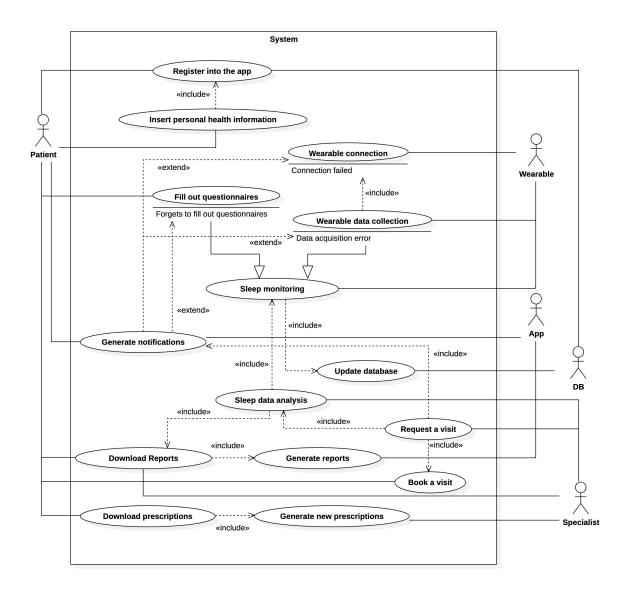


Figure 3.1: Patient - use case diagram

### 3.2. Doctor

The Doctor is a generalized actor representing any kind of Sleep Specialist, such as neurologist or pulmonologist. As the main actor in the clinical workflow, the Doctor is responsible for initiating and managing the patient's telemonitoring program for insomnia. Following the initial clinical evaluation, if the Doctor determines that the patient would benefit from remote monitoring, they provide the patient with a wearable device and activate the telemonitoring process through the application. The Doctor then oversees the patient's progress by reviewing the sleep reports automatically generated by the system. Based on the insights gained from these reports, the Doctor can modify the ongo-

ing therapy, prescribe new medications, and schedule follow-up visits or diagnostic tests. The Doctor plays a central role in adapting the treatment plan over time, ensuring that clinical decisions are guided by up-to-date, real-world data collected from the patient.

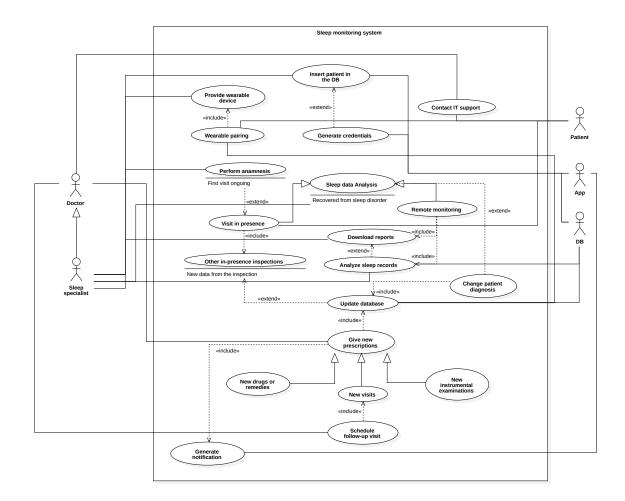


Figure 3.2: Doctor - use case diagram

## 3.3. IT Support

The IT Support is the main actor responsible for managing the technical aspects of the sleep monitoring system. Their role involves providing technical assistance to users, developing user guides and support documentation, analyzing users' feedback to improve usability and communicating directly with the software developers to report issues or suggest enhancements.

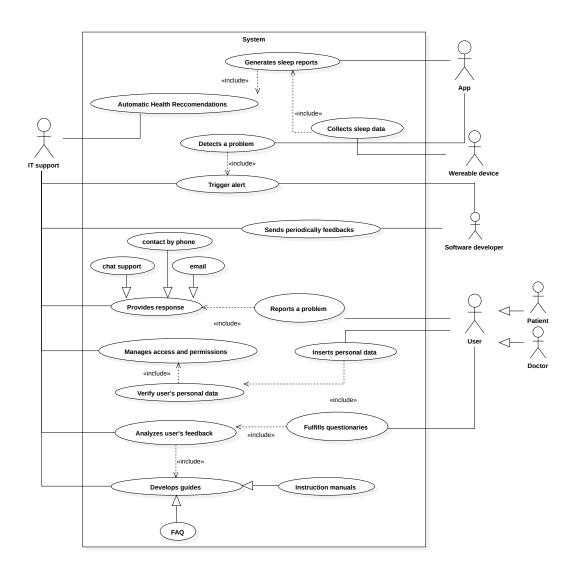


Figure 3.3: IT support - use case diagram

# 4 Activity Diagrams

## 4.1. Log in

The log-in procedure is divided into two possible paths, according to the role of the user. In particular, the user can either be a patient or what we call "doctor" (a general term for any kind of sleep specialist). Patients are expected to use the telemonitoring system via a smartphone and are asked to download the system's application. This will be then paired to the wearable device, previously provided by the general practitioner. The application prompts the patient to insert their credentials (email and password). After three consecutive incorrect password attempts, the application will send an email to assist with recovering the correct password (\*), regardless of the user type. Once the login is successful, the application redirects to the homepage, allowing users to perform their individual activities.

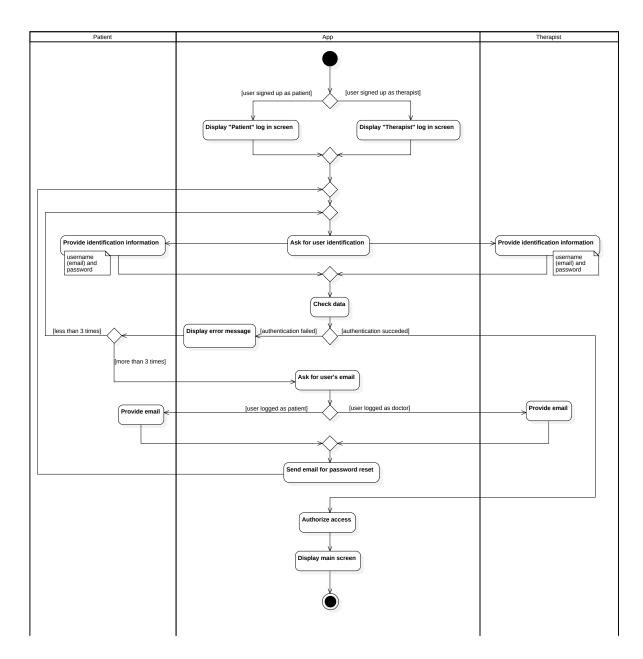


Figure 4.1: Login Activity Diagram

### 4.2. First visit to the clinic

During the patient's first visit to the clinic, the doctor will create their profile and initiate the home monitoring program, as the patient has already been diagnosed with insomnia and meets the criteria for starting the remote follow-up. The specialist will provide the patient with the wearable device and explain how to use it. The patient will be instructed to download the dedicated app, log in, and connect it to the device, which will automatically start syncing data. In case of technical difficulties during setup or pairing,

IT support will be available to assist. Once the system is properly configured, the home monitoring process will begin immediately.

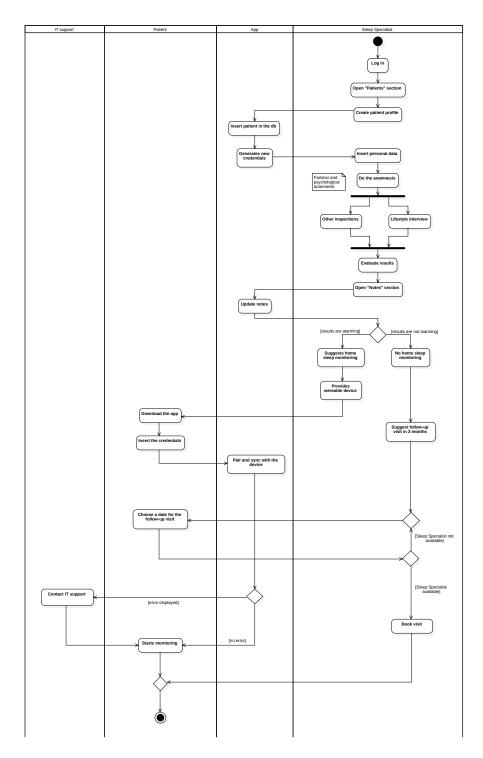


Figure 4.2: First in-clinic visit activity diagram

## 4.3. Remote Sleep Monitoring

This diagram shows the activities of the specialist while remotely checking the patient's data. The specialist plays a crucial role in our analysis, being the actor who is in charge of telemonitoring the patient, making use of the app-generated reports. Upon logging in, the doctor can analyze the patient's reports in order to assess if values are considered risky. If so, the doctor may request the scheduling of an instrumental examination in case thresholds are exceeded for three consecutive months. Otherwise, the doctor asks the patient to fill out questionnaires about sleep habits. The specialist evaluates the therapy and based on reports' values, he may decide to modify the previous one. In such cases, doctors may add new sleep hygiene suggestions or upload new drug prescriptions. All the changes are saved and notified to the patient via the app.

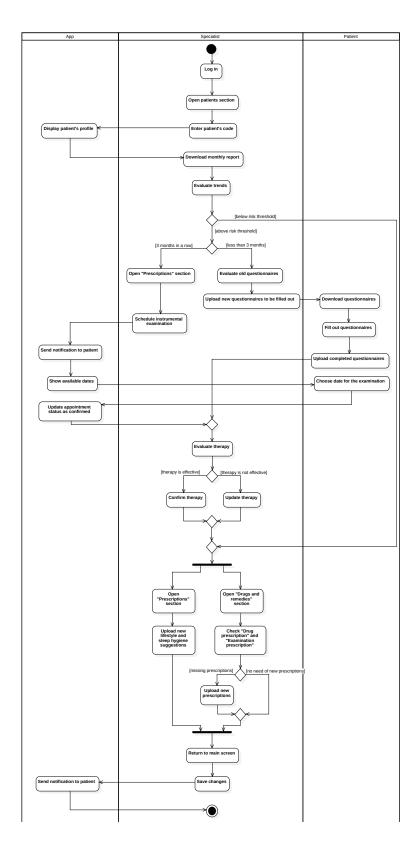


Figure 4.3: Remote Sleep Monitoring activity diagram

## 4.4. Data Uploading

This section describes the data upload process during sleep monitoring, including how errors are handled. Every night, before going to sleep, the patient receives a notification from the app prompting them to begin the monitoring session (\*). At that point, they activate sleep mode and proceed with their night's rest. In the morning, the patient is asked to complete a questionnaire about their sleep experience. Their responses are then saved to the database. If an error occurs during this process, the app will display an error message, allowing the patient to contact IT support for assistance. The app collects both monitoring data and questionnaire responses to generate a daily report for the Sleep Technician. In the final step, the patient has the option to add personal notes before saving and logging out of the app.

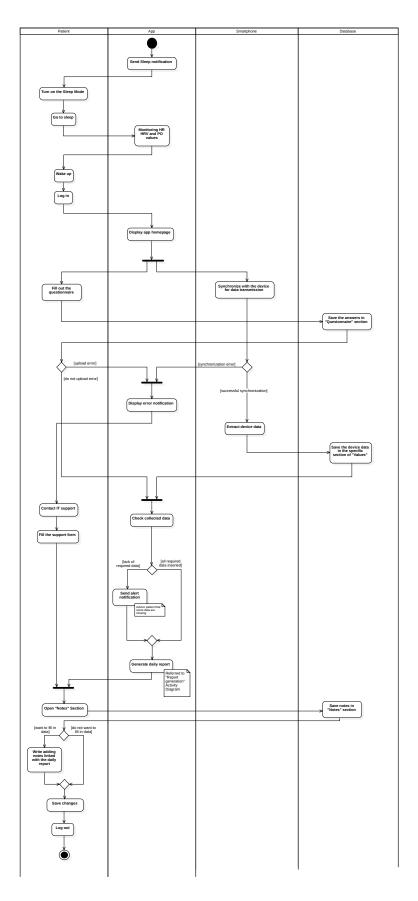


Figure 4.4: Data Uploading activity diagram

## 4.5. Visit booking

This activity diagram describes the procedure for booking a medical visit through the application. The process starts when the patient logs into the system and navigates to the calendar section of the app. If there are available time slots, the patient can directly select the most suitable one and confirm the booking. In cases where no slots are available, the patient has the option to contact the doctor via the app (\*). The specialist receives a notification, logs into the system, and adds new time slots, which are then stored in the database and made accessible to the patient. Once a new appointment is selected and confirmed by the patient, the application automatically sends a confirmation notification to both the patient and the doctor, completing the booking process.

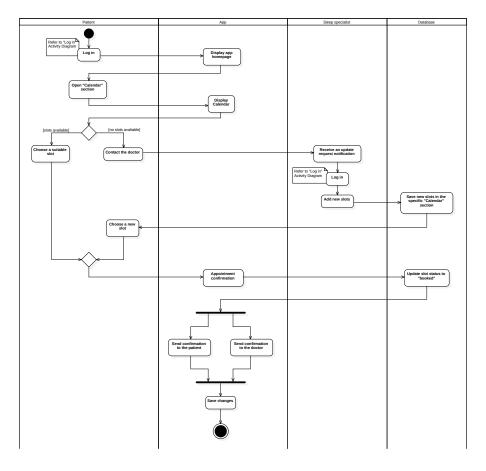


Figure 4.5: Visit booking activity diagram

### 4.6. Final Visit

The Final Visit activity diagram outlines the process for concluding therapy when a patient has shown a positive response to treatment. This visit takes place during the

follow-up period, during which the patient has continued to be monitored. However, if symptoms have reappeared, the Doctor may decide to extend the therapy. The process begins with an interview. If the patient's condition has worsened or not improved, the doctor may initiate a new treatment plan, adjust prescriptions, consult with other specialists, and schedule a new follow-up visit. If the response is positive, the Doctor proceeds with the Therapy Conclusion process. At this stage, the application disconnects the monitoring device, which the patient returns to the clinic. The doctor then confirms that the device has been received. Once confirmed, the app initiates a countdown that will eventually lead to the deletion of the patient's data (\*). The patient's profile is suspended (\*), and a Termination Report is displayed for the specialist to complete, officially closing the course of therapy.

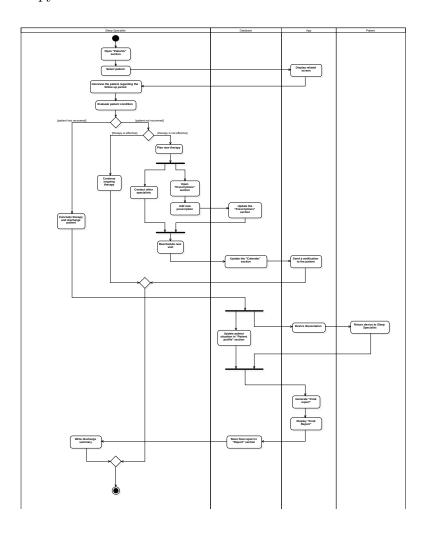


Figure 4.6: Final Visit activity diagram

## 4.7. IT Support (\*)

The IT support activity diagram is linked to all the tasks performed by the application support team. Specifically, the support team primarily monitors for necessary updates and checks if any user has submitted a support request. If updates are required, they proceed with renewing the app documentation. Additionally, if a user requires further assistance, the support team can reach out via email, live chat, or phone call to resolve the issue. Lastly the support team provides feedback to the software developers regarding the application's functionality.

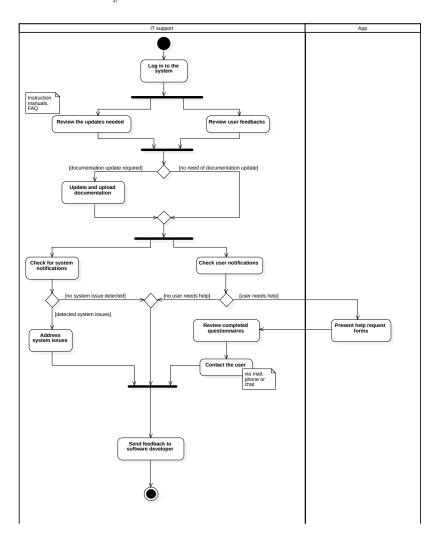


Figure 4.7: IT support activity diagram

## 5 Class Diagram

The class diagram describes the static architecture of the developed system, highlighting the principal entities involved and the relationships among them. The main actors of the system represent the users interacting with the application and the data generated during its use. The primary actors are the Patient and the Sleep Specialist, supported by the IT Technician for technical interventions. All users access the App via standard authentication methods such as email-password login. Each Patient is associated with a unique identifier and personal data such as name, date of birth, and contact information. Patients can autonomously fill in Questionnaires, visualize their Sleep Records, and review the Prescriptions and Notes written by the therapist. Additionally, patients can check available AppointmentSlots and confirm visits, which are stored in their Appointment list along with the appointment status. The Sleep Specialist is responsible for monitoring the patient's sleep and behavioral data. They can access both Sleep Records and Questionnaires filled by the patients, write and edit Notes, prescribe different forms of Prescriptions, ranging from drug treatments to behavioral and instrumental examinations, and propose or confirm Appointments. Sleep Specialists are uniquely identified and specialized according to their therapeutic domain. The App acts as the main interface for all users, managing access, notifications, error handling, and alerts. The Alert system is designed to send reminders for key actions such as data upload, medication intake, or bedtime routines. Alerts are parameterized by type, time, and date. Users authentications are tracked through the Log in class, which associates access events to users and timestamps. This enables accountability and traceability across the system. The Appointment class associates a specific time slot (defined in the AppointmentSlot class) with a patient and a doctor. Each appointment maintains its current Status, which can be either confirmed or canceled, and contains optional additional notes. Sleep Records, collected via Wearable Devices, include raw physiological data such as heart rate, HRV,  $SpO_2$  levels, and sleep duration. These records are analyzed through methods that compute derived metrics such as sleep efficiency, quality, and cycles. The Wearable Device class is responsible for collecting this data. Questionnaires are structured forms that patients fill out regularly. They consist of a set of questions, answers, and a computed

5 Class Diagram 34

score. The results contribute to the ongoing assessment of the patient's well-being and treatment progression. Prescriptions can be of different types: Drug Prescriptions, which include dosage and frequency, Remedies Prescriptions, and Instrumental Examinations that can be booked such as Polysomnography. The IT Technician class handles technical support and system maintenance. The technician can review the Support Forum for user-generated requests, check for application updates, and communicate with users or developers if needed. Lastly, textual content such as Therapist Notes and Patient Notes allows both parties to exchange feedback and document therapeutic evolution.

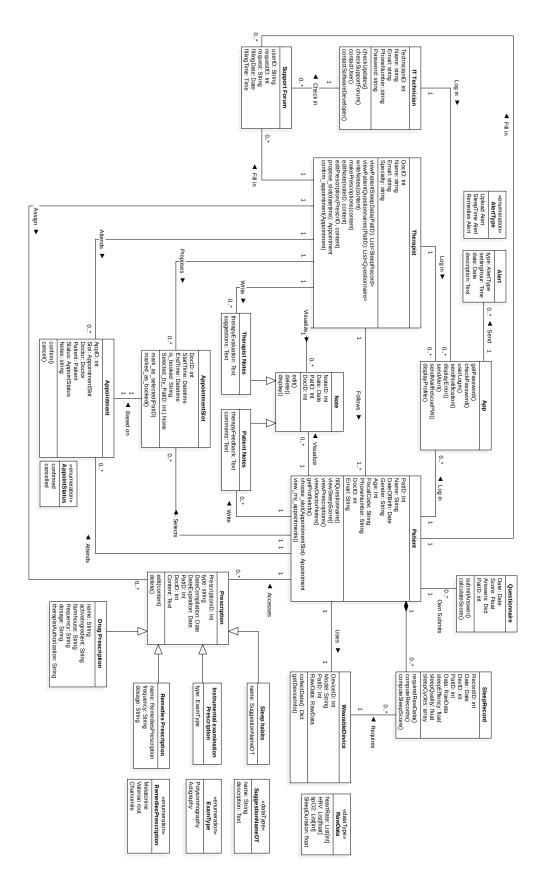


Figure 5.1: Class Diagram

At the core of the model lies the Patients entity, which contains essential biographical information such as name, date of birth, gender, telephone contact, age, and a reference to the treating physician via the DocID field. Each patient is uniquely identified via PatID. The Sleep Specialist is described in the entity Therapist, which includes name, email, specialization, and DocID as the primary key. This entity is linked to several others through relationships that allow it to track clinical activity in a structured way. The Prescriptions entity manages the prescriptions from the Sleep Specialist to each of its patients, linking PatID and DocID, and including details such as the type of prescription and its contents. Notes represent observations made by the Sleep Specialist and the patient. They include a date and a content allowing for the recording of insights or reflections in a more natural and descriptive manner. It is uniquely identified with an ID and contains the keys of both the doctor and the patient. Appointments contain information about doctor-patient appointments and any notes, refers to AppointmentSlot that contains the appointment data and allows for its management. Both entities have a reference to both the Sleep Specialist and the patient involved. The sleep monitoring component is supported by two entities: SleepRecords, which records parameters such as HR, SpO2, and number of sleep cycles; and WearableDevice, which associates wearable devices with patients through a device identifier (DevID). Finally, the Questionnaires entity collects responses to questionnaires filled out by patients, it has date as its primary key and associates each response with a specific patient and physician.

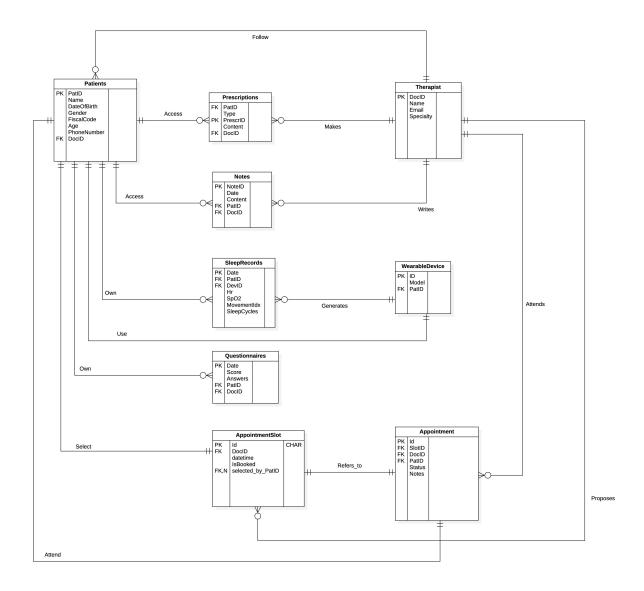


Figure 6.1: ER Diagram

## 6.1. From ER Diagram to Database Relational Schema

This section describes the process followed to convert the Entity-Relationship (ER) diagram of the sleep monitoring system into a relational schema suitable for implementation in a relational database. The ER diagram models the main entities and interactions of the system, including therapists, patients, wearable devices, prescriptions, medical notes, sleep data, questionnaires, and appointments. The goal of this translation is to preserve all relevant information and relationships in a normalized tabular form that can be directly implemented in SQL.

The translation process from an ER diagram to a relational schema involves the following

#### key steps:

1. <u>Entity Mapping</u>: Each entity in the ER diagram is mapped to a relational table. All simple attributes become columns, and the primary key of the entity becomes the primary key of the table.

- 2. <u>Relationship Mapping</u>: Relationships between entities are translated into foreign keys. The placement of the foreign key depends on the cardinality of the relationship.
- 3. Weak Entities and Composite Keys: Entities with composite or dependent keys are modeled using compound primary keys or surrogate keys as appropriate.
- 4. <u>Attributes of Relationships</u>: If a relationship has its own attributes, it is usually transformed into a separate table.

This approach ensures data consistency, referential integrity, and normalization of the relational schema.

Each of the following entities has been converted into a relational table:

- Therapist: Contains information about each doctor, including name, email, and specialty.
- <u>Patients</u>: Represents users monitored in the system. Each patient is associated with a therapist via a foreign key.
- <u>Prescriptions</u>: Records prescribed treatments, associated with both a patient and the issuing therapist.
- Notes: Medical notes written by therapists, linked to both patient and therapist.
- <u>WearableDevice</u>: A device worn by a patient, uniquely identified and associated to a patient.
- <u>SleepRecords</u>: Data collected by wearable devices, including physiological metrics and sleep patterns.
- Questionnaires: Answers and scores submitted by patients, optionally evaluated by a therapist.
- <u>AppointmentSlot</u>: Time slots proposed by therapists, optionally selected by patients.
- <u>Appointment</u>: Represents an actual appointment confirmed based on a slot, including patient, therapist, and appointment metadata.

Each table includes a primary key (either simple or composite), and the relationships are enforced using foreign key constraints.

Below are the main relationships in the ER diagram and how they have been mapped:

- Patients Therapist: Each patient is followed by one therapist. A foreign key DocID in the Patients table references Therapist.
- Prescriptions Patients and Therapist: Each prescription is written by one therapist and assigned to one patient. Foreign keys DocID and PatID in Prescriptions implement this.
- Notes Patients and Therapist: Similar to prescriptions, notes are linked to both the patient and the therapist who wrote them.
- SleepRecords WearableDevice and Patients: Sleep records are generated by a device worn by a patient. The table includes foreign keys DevID (device) and PatID (patient).
- WearableDevice Patients: Each device is assigned to one patient, modeled via a foreign key in WearableDevice.
- Questionnaires Patients and Therapist: A patient fills in a questionnaire, and a therapist may evaluate it. Composite key (Date, PatID) is used, and foreign keys reference both Patients and Therapist.
- AppointmentSlot Therapist and Patients: Slots are offered by a therapist, and may be selected by a patient. The selected\_by\_PatID field is a nullable foreign key.
- Appointment AppointmentSlot, Patients, and Therapist: This represents a confirmed appointment and references the slot, the patient, and the therapist.

All relationships have been mapped using the minimum number of tables, avoiding redundancy and ensuring that foreign keys enforce the original structure of the ER diagram.

Here is a summary of all resulting relations with primary and foreign keys:

- Therapist(DocID%, Name, Email, Specialty)
- Patients(PatID%, Name, DateOfBirth, Gender, FiscalCode, Age, PhoneNumber, DocID  $\rightarrow$  Therapist)

• Prescriptions (PrescrID%, PatID  $\rightarrow$  Patients, DocID  $\rightarrow$  Therapist, Type, Content, Date)

- Notes(NoteID\%, Date, Content, PatID  $\rightarrow$  Patients, DocID  $\rightarrow$  Therapist)
- WearableDevice(DevID\%, Model, PatID  $\rightarrow$  Patients)
- SleepRecords(RecID%, Date, PatID → Patients, DevID → WearableDevice, HR, HRV, SpO2, MovementIdx, SleepCycles)
- Questionnaires(Date%, PatID%  $\rightarrow$  Patients, DocID  $\rightarrow$  Therapist, Score, Answers) (Primary Key: Date, PatID)
- AppointmentSlot(ID%, DocID → Therapist, datetime, isBooked, selected\_by\_PatID
   → Patients)
- Appointment(ID%, SlotID  $\rightarrow$  AppointmentSlot, DocID  $\rightarrow$  Therapist, PatID  $\rightarrow$  Patients, Status, Notes)

The use of foreign keys guarantees referential integrity, ensuring that all relations remain consistent and valid throughout the system's operation.

# 7 Future Developments

Hypnos has the mission to simplify the telemonitoring of sleep disorders such as insomnia, and our goal is to progressively develop the application to include all the features that are not yet available in the current release. In particular, future efforts will focus on enabling direct communication between the app and the wearable device, defining possible API requests to retrieve daily sleep monitoring data, improving the notification system, and expanding both the patient and doctor profiles to include information such as patient anamnesis and current diagnosis.

As part of the application's long-term vision, we intend to extend its capabilities to support the monitoring and analysis of other sleep disorders beyond insomnia, including sleep apnea, restless leg syndrome, and narcolepsy. By incorporating new data processing algorithms and leveraging additional sensors and data collected from the wearable device, the app will be able to offer a more complete and clinically meaningful picture of the patient's sleep health. This will support healthcare professionals in providing personalized treatments and developing a deeper understanding of the interplay between various sleep conditions.

Data privacy will remain a central concern in all future developments. Upcoming versions of the app will implement advanced encryption standards, secure user authentication systems, and data anonymization procedures to ensure that patient information is handled with the highest level of confidentiality. Compliance with data protection regulations such as the GDPR will be a core requirement for maintaining the trust of users and healthcare institutions. In addition, regular security audits and software updates will be conducted to anticipate emerging cybersecurity threats and preserve the integrity of user data.

In the future, the app could also be integrated with broader telemedicine platforms, including patient portals, electronic health record systems, and teleconsultation services. This integration will allow for seamless sharing of sleep-related data with healthcare providers, promoting a more holistic and data-informed approach to care. Access to real-time sleep metrics will enhance the quality of remote consultations and allow clinicians to make more accurate and timely decisions during virtual appointments.

To improve user experience and support, a real-time chat system could be introduced, allowing patients to directly contact technical support whenever issues arise. This will be especially useful for resolving problems related to device pairing, data synchronization, or navigating the app interface. This feature could help build trust among users towards the application, particularly those who may be less familiar with digital technologies.

Artificial intelligence is also intended to play a central role in the app's evolution. Through machine learning algorithms, the app will be capable of identifying patterns and trends in the user's sleep data, enabling predictive insights and recommendations.

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