



# CELESTE+™

# Patients

Instructions for Use

# Introduction

Celeste+ is a mobile application used to collect sleep data. It transfers recordings from third-party sleep devices to EnsoSleep PPG. It can also record audio of your sleep. Celeste+ analyzes the audio and sends the analysis to EnsoSleep PPG.

Celeste+ helps you manage your sleep studies by showing you how many nights you need to record.

Celeste+ is for iPhone and Android phones.



*Please read this document carefully before using the device.*

## Before You Start

- Update your phone if you are not at or above Android version 10 or iOS version 15.5.
- Make sure your sleep device (for example, a ring or watch) is charged: a device with a low battery may not be able to complete a full sleep session. It should be charged to at least 60% battery to successfully record a full night of sleep.
- Make sure you have at least 350 MB of storage on your phone. Your sleep recording will not start if you do not have enough storage. If your phone runs out of space, the recording stops and it is considered a failed study.
- We recommend you plug in your phone. Bluetooth connectivity and data transfer can rapidly use your battery power. Your sleep recording will not complete if your phone shuts down.
- If you are recording with the microphone, give permission to Celeste+ to use the microphone.
- If you are recording with the microphone, keep your phone 1-2 feet from your head.
- If you are recording without the microphone, keep your phone within 15 feet of your sleep recording device throughout the recording.
- The application automatically stops recording if you reach the 12-hour maximum session time.

# Setup

## Download and Open the App

Go to the [iOS App Store](#)/[Google Play Store](#) and download the Celeste+ app.

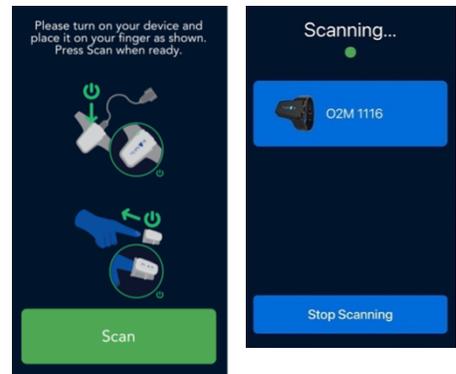
- The first time you open the app you must read and accept the terms and conditions.
- If asked, allow Bluetooth connections in the phone system settings to link the app to your sleep device.

## Connect to a Device

If you previously connected a sleep device and set up your profile, the app automatically attempts to connect so you can start recording (see Start Recording).

You must connect to a sleep device. As the device connects it stores the serial number of the device so the clinic can match the device to your recording.

1. Put on the recording device per the manufacturer's instructions.
2. Tap Scan. The app scans for and displays nearby sleep devices.
3. Tap the desired device.
4. Choose if you want to allow access to your mobile device's microphone to record breathing audio. The audio is analyzed as part of the sleep study. The actual voices and noises recorded are not available, only the audio signal (like a heartbeat signal) and breathing events can be viewed by clinicians.
5. Tap Connect. The app will show that it is connecting to the device.



If you choose to allow audio recording, to get the best recording:

- put the phone (your mobile device) near the bed with microphone facing you (1-2 feet away),
- remove noise and distractions (it is best if you sleep alone and turn off things that make noise), and
- make sure to charge your phone while recording (audio recording may use a lot of power).

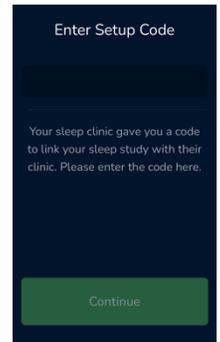
## Disconnect or Change the Device

1. Tap the arrow icon next to the sleep device name.
2. Tap Disconnect Device. If the app was automatically connecting to it, it will no longer auto-connect.
3. To connect another device, tap the sleep device that you want to connect.
4. Follow the instructions under **Connect to a Device**.

## Enter Your Profile

Next, enter the setup code and your personal information.

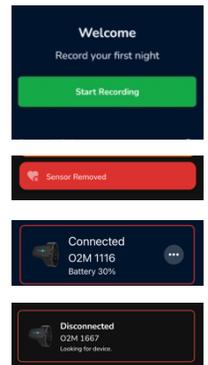
1. Enter the setup code. It is a 5 to 12-digit code from your provider to associate your sleep test with the clinic.
2. If instructed, enter your personal information. Personal information may include first name, last name, date of birth, and phone number. Double check for accuracy.
3. Tap Continue.
4. If instructed, enter your sex, height, and weight.
5. Tap Finish.



## Recording

### Start Recording

1. Put on the device when you are ready to go to sleep.
2. If required, reconnect the device. Follow the instructions under **Connect to a Device**.
3. In the app tap Record Now.
4. If you see any of the below messages, see the information under **Before You Start**.
  - Sensor Removed
  - Low battery – shown by a red border around device Connected
  - Disconnected

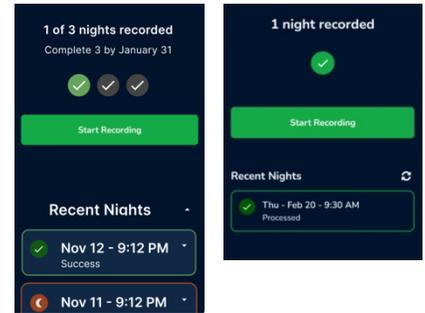


### End Recording

1. Before concluding the study, ensure that the minimum recording time has been met. The recording timecard turns green when you meet the minimum recording time.
2. When you are ready to stop the study, tap End Recording.
3. Keep the app open while your study is processed. A message appears that your sleep recording has been processed, or you need to record another night. Successfully processed nights are sent to your clinic for analysis.
4. Tap Back to Home to record another night and see a list of successfully processed nights.

## View Number of Nights Required

When you open the app, you may see the number of required nights at the top of the screen. If your clinic asks you to record for more than one night, you may see a date by when you need to finish. As you finish recordings, the app may tell you how many more nights you need to record and when all the nights are recorded. If you already have recorded nights, when you open the app, a list of recent nights appears at the bottom of the screen.



## Clear All Data

You can reset the app and clear all your data. This removes recorded nights, devices, and your information from the app. Tap the settings icon then tap Reset All Data. Recorded nights already sent to the clinic are not deleted.

## Frequently Asked Questions

You can access troubleshooting tips by clicking the (?) icon in the upper left corner of the app. If you cannot find the answer to your question, please contact the clinic that directed you to use the app.



## Product Information

### Indications for Use

Celeste+ is indicated to record a patient's respiratory pattern during sleep for the purpose of prescreening patients for obstructive sleep apnea (OSA) syndrome. The device is designed for use in home-screening of adults with suspected possible sleep breathing disorders. Results are used to assist the healthcare professional in determining the need for further diagnosis and evaluation.

The system is not intended as a substitute for full polysomnography when additional parameters such as sleep stages, limb movements, or EEG activity are required.

### Contraindications

The sound recording feature is not intended for use in children or adolescents.

### Safety - Warnings and Cautions



Celeste+ is a prescription device used under supervision of a physician in the United States and in the other countries in which it is cleared for use.



Only use mobile devices that have been validated for use with Celeste+.



When recording sound, best results are obtained by conducting tests in a quiet environment. Minimize noise by sleeping alone and turning off other sources of noise (e.g., music, television, radio). Excessive noise may negatively impact device performance.



Sleep breathing can change with age, weight gain or loss, stress levels, sleeping posture, eating & drinking habits, and with the onset or progression of some medical conditions.



It is possible for the audio recording to include other uses of the microphone or provide audio input such as phone calls, video chats, or applications that use or play sounds. While using Celeste+ it is recommended that you use mobile device settings that limit interruptions and do not use functions or other applications that involve audio.

**Revision History**

Version	Publication Date	Description
0031-A	April 2025	Original issuance.

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Manufactured by:  
 EnsoData, Inc.  
 10 E Doty Street, Suite 449  
 Madison, WI USA 53703  
 Phone: 608-889-3676 (ENSO)  
 Email: support@ensodata.com

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