

Introduction

Celeste+™ collects sleep data and helps you manage your sleep studies. It transfers recordings from third-party sleep devices and recordings from your microphone to your clinic.

Clinic Phone		Setup Code		Number of Nights	
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Please read this document carefully before recording a sleep study.



Contact your clinic if you have questions.

Before You Start

- Make sure your Android OS is at least version 12, or your iPhone OS is at least version 15.2. Phones no longer supported by the manufacturer may not work.
- Make sure your sleep device battery is charged to at least 60% to record a full night of sleep.
- Make sure your phone has at least 350 MB of storage for the sleep files.
- Plug in your phone. Your recording will end if your phone shuts down.
- If you are recording audio with the microphone, allow Celeste+ to use your microphone.
- The recording stops if you reach the 12-hour time limit.

Record with Audio

Clinics cannot listen to the sounds and voices, they only see the audio signal (like a heartbeat signal).

If you use the microphone:

- put the phone near the bed with the microphone facing you (1-2 feet away),
- things that make noise (like white noise machines) will mask your breathing sounds,
- remove noise and distractions (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).

To turn off the microphone: in your phone settings under the Celeste+ app disable the Microphone option.

Record without Audio

If you are recording without the microphone, keep your phone within 15 feet of your head.

Download and Open Celeste+

Download Celeste+ from the [iOS App Store](#)/[Google Play Store](#).

Apple:



Google:



- The first time you open Celeste+ you must read and accept the terms and conditions.
- If there are changes to Celeste+, it prompts you to update before you can use it.
- Celeste+ prompts you to enable the microphone.
- Allow Bluetooth connections in the phone system settings to link Celeste+ to your sleep device.

Add Your Information

1. Enter the setup code to link your sleep test with the clinic. Only use the code given to you by the clinic.
2. If prompted, enter your personal information. Double check it to make sure it is correct.
3. Tap Finish.

Connect to a Device

1. Put on the sleep device per the manufacturer's instructions.
2. Tap Scan. Celeste+ displays nearby sleep devices.
3. Tap the desired device.
4. Tap Connect.

Repeat the steps above for each device in your order.

If you already connected a sleep device and set up your profile, Celeste+ automatically displays all the devices that are connected and part of your order so you can start recording.

Disconnect or Change the Device

1. Tap the arrow icon next to the sleep device name.
2. Tap Disconnect Device.

Celeste+ will no longer auto-connect.



Start Recording

1. Put on the device(s) when you are ready to go to sleep.
2. Open Celeste+.
3. If necessary, reconnect the primary device.
4. Tap Start Recording.
5. If you are using more than one device, like a body position recorder, scan for the next device.
6. Once the next device is connected, click Start Recording.

IMPORTANT: If you are recording audio, do not hard quit (force close) Celeste+ because the audio recording will not restart when you re-open Celeste+.

End Recording

1. Before you stop the study, make sure you recorded at least the minimum amount of time. The recording timecard turns green when you meet the minimum.
2. To stop the study, tap End Recording.
3. Keep Celeste+ open while your study is sent for analysis. Celeste+ displays errors if there is a problem.

Product Information

UDI: (01)00864458000452(11)260126(10)8.4

Indications for Use: USA/Canada - 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.

Indications for Use: Australia - A Software as a Medical Device (SaMD) that manages data transfer between third-party devices and clinical systems. It analyzes sound recording data from compatible third-party devices for use by healthcare professionals to aid in the diagnosis of sleep, respiratory, and other disorders. It is intended for use by and on order of a healthcare professional.

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+ and that are still actively supported by the mobile device manufacturer.



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.

4. Tap Back to Home to record another night and see a list of successful nights.

View Nights Required

Celeste+ displays the number of nights you must record. If your clinic asks you to record more than one night, you may see the number of nights to record and an end date when you need to finish. Celeste+ displays a list of your recordings. If you have reached the end date and do not have the required number of nights, contact your clinic.

Clear All Data

You can reset Celeste+ and clear all your data on your mobile device. This removes your recordings, devices, and personal data. Tap the settings icon then tap Reset All Data. Recordings already sent to the clinic are not deleted from the clinic system.

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