CELESTE+™

Device Profile

Reference Document

Introduction

Celeste+ is a mobile software used to collect symptom data for sleep apnea risk, including severity of daytime sleepiness and personal chronic disease risk factors. Celeste+ also records sleep breathing patterns and sends the sound files to secure servers in the cloud. Celeste+ then analyzes and interprets the sleep breathing results, along with the profile data provided by the individual, to measure and track sleep-related health risks over time.

Celeste+ includes file transfer capabilities that enable transfer of the Celeste+ acoustic recordings and recordings from third-party sleep devices from the patient's mobile device to EnsoSleep PPG. Celeste+ also assists in clinic management by indicating to patients the parameters for a successful completion of studies (as set by their clinic).

Please read this document carefully before using the device. User information can be found in the instructions for use available with the device.

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.

Target Population

Celeste+ is indicated for use in adults 22 years old and above.

Product Requirements

Mobile Device Requirements:

- Android version 10+ or iPhone version 15.5+
- Audio microphone 8kHz or greater

Channels

Audio

- Snore
- Acoustic Flow

Study Scoring

The algorithm processes an overnight audio recording of breathing sounds to find full or partial cessation of breathing. The scoring results should be reviewed and edited as necessary.

The device identifies the following physiological events: eARS (EnsoData Audio Respiratory Score)

See the instructions for use and reference information for the device for more details about the eARS value determination.

Clinical Performance

The device was designed and tested under the following standards and guidelines:

- EN ISO 13485 Third Edition 2016/A11 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes

Sample size (n)	59 (n = 32 AHI >= 15, n = 27 AHI <= 15)
Sensitivity (%)	87.9
Specificity (%)	57.7

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 computing 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.
- The device neither interprets results nor suggests a diagnosis or recommendations for treatment.
- The scoring provided by this device must be reviewed, edited as necessary, and approved by a qualified healthcare professional.
- AASM recommends that polysomnography, rather than home sleep apnea testing be used for the diagnosis of OSA in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.
- AASM recommends that if a single home sleep apnea test is negative, inconclusive, or technically inadequate, polysomnography be performed for the diagnosis of OSA.
- Notify EnsoData and the appropriate government agencies if an adverse event has occurred that is related to use of this product.

EnsoData

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