The SleepImage System

The SleepImage System is Software as a Medical Device (SaMD) designed to automatically analyze and display Electrocardiogram (ECG) and optionally it analyzes and displays oxygen saturation data (SpO2). This information is intended to assist Healthcare Professionals in evaluating Sleep Disorders. SleepImage is designed to have one unified account for a clinic, hospital, medical/dental practice, or research institution which is created and maintained by an Administrator and utilized by Clinicians.

The SleepImage website is designed to be flexible so that it can be used by small individual practices or clinics, as well as large organizations and researchers. With SleepImage’s Software as a Medical Device you have the ability to scale usage as patient testing demands rise and fall, while only paying for what you need.

SleepImage can successfully analyze evenly-sampled normal sinus rhythm ECG waveforms that meet the recommended minimum data acquisition characteristics outlined in our Website Instructions for Use. Data sources currently include SleepImage M1 Sleep Data Recorder as well as EDF files containing ECG data collected during sleep that are consistent with the acquisition characteristics mentioned above. The data sources list will be updated as additional Recorders and Data File types are identified and allowed by MyCardio. *For devices not sold by SleepImage, an activation fee per device will apply. Contact sales@sleepimage.com for more information.

Two Account Roles

Admin Role

The Admin role is designed for a Practice Manager or Head Administrator in an organization. Admins perform operational functions such as managing Clinician access, adding Patients, uploading sleep studies as well as purchasing supplies and report credits for the account.

Clinician Role

The Clinician role is designed for Clinicians to review, monitor and analyze their Patients’ uploaded sleep studies. Clinicians can add Patients, upload sleep studies and also have the ability to note detailed observations about each sleep study.

Pricing

There are three components to SleepImage: Software Access Report Credits, Electrodes and Recorders.

- **Report Credits:** $14.99 1 SleepImage Report Credit
- **Electrodes:** $29.85 30 Tests (also available in 9 and 90 test quantities)
- **Sleep Data Recorder Kit:** $275.00 Per Kit (includes required cables for testing, and uploading)

Sleep Data Recorders use two 3v 90mAh CR2016 coin cell batteries (two included in each Kit) which should be replaced approximately every five studies. These batteries can be sourced locally at pharmacies & retail stores, or through online retailers.