



SleepImage User Manual

Instructions for Use

SleepImage® System Version 2.28



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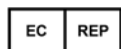


The SleepImage System is a
Medical Device

MyCardio® SleepImage Website

These instructions are available in an electronic format, as a PDF document, on www.sleepimage.com and inside the HELP tab of the SleepImage System website. At the time of publication these instructions are available in the primary languages of the markets where the SleepImage System is currently available. These instructions for use are updated periodically, identified by a sequential revision number.

	Manufacturer	MyCardio LLC 3200 E Cherry Creek South Drive, Suite 540, Denver, CO 80209, USA support@sleepimage.com www.sleepimage.com
	Instructions for Use	Please read the SleepImage User Manual carefully and periodically as it is updated from time to time. Current Version: D-6.00285-4 Rev.4 Issued on June 2 nd , 2026 An electronic version of the current IFU for the cloud-based SleepImage System is available at www.sleepimage.com . Printed copy will be provided upon request within 7 calendar days at no additional cost. Please contact support@sleepimage.com .
	Medical Device	This product is a Medical Device.
	Prescription Use Only	FDA-cleared K182618 Federal law restricts sales of this device as “by or on the order of a licensed healthcare practitioner”.
	Unique Device Identifier	The FDA Unique Device Identifier (UDI) is *+B315SLEEPIMAGESYSTEM0/\$\$72.28D*
	CE Mark	The CE mark is a declaration that the SleepImage System is in compliance with the EU Medical Device Regulation (EU 2017/745).



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Trademarks

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U.S. TM Reg. 4,348,943

U.S. TM Reg. 7,560,885

U.S. TM Reg. 7,560,886

U.S. TM Reg. 7,741,204

U.S. TM 98/806,487

Patent Marking

SleepImage (MyCardio LLC) is a provider of medical systems and services intended to establish sleep quality, evaluate sleep disorders and aid in diagnosis and management of sleep disorder breathing.

The technology in SleepImage systems and services is covered by patents owned and/or licensed in the United States and/or in other countries. This marking is intended to serve as notice under 35 U.S.C. § 287(a).

The following patents apply to SleepImage systems and services, including but not limited to the SleepImage System:

U.S. Patent Number(s): 7,324,845; 7,734,334; 8,401,626; 8,403,848; 12,144,592; 12,257,067. Other patent(s) pending.

Australian Patent Number(s): 2006269263, 2019345287. Other patent(s) pending.

Canadian Patent Number(s): 2566193; 2619617. Other patent(s) pending.

Chinese Patent Number(s): ZL 201980049494.3, ZL 201980071633.2, ZL 202080079952.0. Other patent(s) pending.

European Patent Number(s): 1765156, 1906817, 3809957. Validated in France, Germany, Italy, Spain, United Kingdom. Other patent(s) pending.

Japanese Patent Number(s): 5005539; 5005687; 7253047; 7455815, 7799604. Other patent(s) pending.

Other Patents Pending:

WO2019246234A1; WO2020061014A1; WO2021055943A1; WO2007008706A1; WO2005115230A1

Cyber Security

The protection of information is a shared responsibility of SleepImage and each User. SleepImage requests that Users also take steps to protect the secrecy and privacy of their information, including all passwords and user credentials used to access the SleepImage System. Users need to take reasonable care of their own environment (personal computer). Users should install, maintain, and keep current with software updates, security patches, and malware (antivirus) detection on a regular basis within their own environment (on their own PCs). Users should avoid public networks and should utilize strong passwords, avoid “hardcoded” passwords or common words and passwords which are the same for each device and vulnerable to public disclosure.

SleepImage System Software Version Release History (UK)

Version Numbers:	Release Date:
Version 2.25	February 2025
Version 2.26	June 2025
Version 2.27	September 2025
Version 2.28	November 2025

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Introduction

This document refers to users of the SleepImage System as “Admin,” “Clinician,” and “Interpreting Clinician,” with reference to certain access levels and more generally as “User” or “Users.” Additionally, the document refers to licensed Healthcare Practitioners as “Clinician” and “Clinicians” and individuals under their care as “Patient” and “Patients”. Before using the SleepImage System, please read this manual carefully, paying particular attention to the Cautions and Warnings.

Indications for Use

The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays, and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents, and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

The SleepImage System displays the results of these analyses as graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality, and sleep pathology. The SleepImage System is intended for use on a general-purpose computing platform, it is not a monitor and does not issue any alarms.

Cautions, Warnings

The SleepImage System is intended to assist qualified healthcare professionals to evaluate sleep disorders. The sAHI is intended to aid in diagnosis and management of sleep disordered breathing. The SleepImage Report is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional. Any interpretation of the data to diagnose a medical condition is the sole responsibility of the treating healthcare professional. SleepImage is not responsible for any such use of information reported from the SleepImage System, patient reports or the data therein.

Serious Incident / Serious Adverse Event

If a serious incident or serious adverse event occurs involving the SleepImage System software, immediately contact MyCardio, the Competent Authority of the Member State in which the user and/or patient is established, or the appropriate authorized representative listed above.

A serious adverse event means any adverse event that led to: (a) death, (b) serious deterioration of the health of the subject, that resulted in any of the following: (i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalization or prolongation of patient hospitalization, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease, or (c) fetal distress, fetal death or a congenital physical or mental impairment or birth defect.

Intended Patient Group

The SleepImage Software System is intended to be used for children, adolescents, and adults.

Product Support

The SleepImage System is a cloud-based prescription Software as a Medical Device (SaMD), accessed using a general-purpose computing platform connected to the Internet, using common browsers such as: Chrome, Edge, Firefox, and Safari. The SleepImage System is supported and maintained on an ongoing basis with regular updates and no planned retirement or discontinuation. Updates to the cloud-based software are version controlled as displayed by the current version number on the sign in page to the SleepImage System at <https://clinical.sleepimage.co.uk/login>. All Users will always use the most recent version as the software resides exclusively in the cloud with no requirements for any software to be downloaded onto the user's local computer. Instructions for Use reflecting the current version are in the Help tab of the Users' account. Any changes to this policy to maintain and support the SleepImage System will be announced no less than 6 months in advance of such changes. Accessing historical records in the SleepImage System may be subject to additional charges. The SleepImage System is not an electronic medical record system; it is the Users' responsibility to keep a record of uploaded sleep studies in their medical records.

Customer Support Policy

MyCardio's support for the privacy of our customers and their patients begins with a minimization-based approach to customer and patient data. When requesting support for using the SleepImage System, we would ask that the customer:

- Identify their SleepImage Account by name or email (do not share passwords),
- Clearly describe how our support team can provide assistance,
- Do not submit any Personally Identifiable Information (PII) for patients to our support team, and instead only use the SleepImage System-generated Patient ID,
- Do not submit any patient records, test results, or reports to our support team (the team can access reports and accounts securely), and
- Avoid submitting any Protected Health Information (PHI).

Quality Management System

The MyCardio Quality Management System is compliant to the following standards, directives, regulations, and guidance documents:

1.	Medical Devices: Quality Management Systems. Requirements for Regulatory Purposes	EN ISO 13485:2016
2.	Medical Devices: Application of Risk Management	EN ISO 14971:2019
3.	Medical Devices: Software Life Cycle Processes	EN 62304:2006+A1:2015
4.	Medical Devices: Application of Usability Engineering	EN 62366-1:2015+A1:2020
5.	Medical Devices: Symbols to be used with medical device labels, labelling and information to be supplied. General Requirements	EN ISO 15223-1:2016
6.	FDA Quality Systems Regulation (QSR)	21 CFR part 820
7.	Medical Device Regulation	MDR 2017/745
8.	Medical Devices: Guidance Document on Qualification and Classification of Stand Alone Software used in Healthcare within the Regulatory Framework of Medical Devices	MEDDEV 2.1/6: July 2016
9.	Medical Devices: Guidance Document on Classification of Medical Devices	MEDDEV 2.4/1 Rev. 9: June 2010
10.	Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC	MEDDEV 2.7/1 Rev. 4: June 2016
11.	Commission Regulation (EU) on Electronic Instructions for Use of Medical Devices	EU 207/2012
12.	International Medical Device Regulators Forum (IMDRF). Software as a Medical Device (SaMD): Application of Quality Management System	IMDRF/SaMD WG/N23 Final: October 2, 2015

SleepImage System Website Navigation Menu

Admin Users have the following Tabs available to navigate the SleepImage System:

Patients: Patient List	Clinicians: Clinician List	Profile: Edit / Save Account Name Admin Name	Settings: Change Password Interpretation Templates	Help: Instructions for Use Document Links FAQ	Sign Out
----------------------------------	--------------------------------------	--	--	---	-----------------

Clinician Users have the following Tabs available to navigate the SleepImage System:

Patients: Patient List	Profile: Edit / Save Account Name Admin Name	Settings: Change Username & Password Interpretation Templates	Help: Instructions for Use Document Links	Sign Out
----------------------------------	--	---	--	-----------------

The SleepImage System

The SleepImage System is a Health Insurance Portability and Accountability Act (HIPAA) compliant, cloud-based Software as a Medical Device (SaMD) hosted on the Amazon Web Services (AWS) cloud. The web address is <https://clinical.sleepimage.co.uk>, which can be accessed using commonly used browsers such as Chrome, Edge, Firefox, and Safari. The SleepImage System has three user roles: [Administrator](#), [Clinician](#), and [Interpreting Clinician](#).

Data Input

The SleepImage System SaMD is based on analyzing digital documents containing electrocardiogram (ECG)-; plethysmogram (PLETH)- and oxygen saturation (SpO₂)- signals from electrocardiogram (ECG) and/or photoplethysmogram (PPG) sensors to aid diagnosis of SDB. The software analysis is defined by data acquisition characteristics as shown in the table below:

Sensor	ECG	PPG	
Signal	ECG	PLETH	SpO ₂
Sampling Rate	100 Hz	75 Hz	1 Hz
Digital Resolution	8 bit	8 bit	n/a
Measurement Range	n/a	n/a	0 – 100%
Accuracy Range (70-100%)	n/a	n/a	+/- 3 digits

Data Sources

Data collection and submissions must be provided via a Bluetooth connection using a Bluetooth-compatible Data Source paired with the SleepImage Mobile App. For a good User experience, MyCardio has identified the following hardware devices to have data acquisition characteristics and file formats meeting the SleepImage System requirements:

ECG

- EDF files containing ECG data collected during sleep that are consistent with the acquisition characteristics mentioned above.

PPG

- SleepImage PO2
- SleepImage PO4
- SleepImage PO6
- EDF files containing PLETH data collected during sleep that are consistent with the acquisition characteristics mentioned above.

The above list of hardware devices is provided for informational purposes only and is correct at the time of issue. Data Sources may be referred to collectively as “Recorder” or “Recorders” or “Data Source” and “Data File” or “Data Files.” The Data Source list will be updated as additional data sources are identified and allowed by MyCardio. If your data source is not listed or does not meet the above acquisition characteristics, please email: support@sleepimage.com.

Please use the “STORE” link as described in the “SleepImage Store” chapter below to purchase recording devices that are sold by SleepImage.

Icons used in The SleepImage System

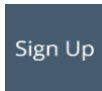
	Add Patients, Clinicians, or Interpretation Template
	Remove Patients or Interpretation Template
	Edit Patients, Clinicians or Interpretation Template
	View Individual Patient's Studies
	Assign Clinicians to Patients
	Share Patient with another SleepImage account
	Clinician's Note has been published by someone else
	Clinician's Note has been published by you
	Read this Website IFU Document in full to learn how to use the SleepImage website. Read SleepImage Mobile App IFU (Android and iOS) to learn how to use the Recorders. Read Introduction to SleepImage in full to learn how to use the information SleepImage presents.

SleepImage User Roles

There are two standard user roles, Admin Role and Clinician Role, and a specialized user role 'Interpreting Clinician Role'. Read all Instructions for Use before using the SleepImage System.

Admin Role

The Admin Role is created by Signing Up for a SleepImage Account.



A unique, valid email address is required to Sign Up for an Account. This email address becomes the Admin Username, and it is the main contact email for the Account.



For sales inquiries, please contact sales@sleepimage.com

Each Account can have only one Administrator Role that can perform the following tasks:

	Add Patients or Clinicians.
	Remove Patients
	Edit Clinicians
	View Individual Patient's Studies
	Assign Clinicians to Patients
	Share Patient with another SleepImage account
	Create Interpretation Templates for the account

Clinician Role

Clinicians are added by the Admin Role who assigns them a Username and Password.

Each Account can have multiple Clinician Roles who can perform the following tasks:

	Add Patients or Interpretation Templates
	Remove Patients or Interpretation Templates
	Edit Patients or Interpretation Templates
	View Individual Patient's Studies
	Share Patient with another SleepImage account

Interpreting Clinician Role

The Interpreting Clinician Role is intended for users who perform interpretations through the SleepImage System but are not affiliated with a specific account or clinic. Interpreting Clinicians will receive interpretation requests for a specific study via email and can use a link in the email to access the study to be interpreted. An interpreting clinician's access to a study is date-restricted, with the expiration date set by the interpretation requestor.

Interpreting Clinician Roles are created the first time an [Interpretation Request](#) is sent by a customer to an interpreting clinician's email. The Interpreting Clinician Role is not associated with a specific account, so the email used for an Interpreting Clinician cannot be one already used in the SleepImage System for another account.

While viewing a study, Interpreting Clinicians will be able to perform the same actions as a Clinician user viewing the study, including manual scoring, adding clinician notes, and downloading a local copy of the report. Interpreting Clinicians also have access to any Interpretation Templates defined by the Customer Admin.

Account Sign Up

SleepImage Accounts are for licensed healthcare practitioners only. Signing Up for an Account creates an Admin Role. There is only **one** Admin Role per Account. An Internet connection, a [supported browser](#) and a unique, valid email address is required to Sign Up for an Account to start using the SleepImage System. The email address used to Sign Up for an Account becomes the default Username for the Admin Sign In

1. Go to www.SleepImage.com and scroll down and click the [Sign Up](#) button.
2. Fill out all the required fields, and any optional fields if they are relevant.
3. Please read the [Terms of Use Agreement](#) and [Privacy Policy](#) before you check the checkboxes "I have read and agree to the Terms of Use Agreement" and "I have read and agree to the Privacy Policy".
4. Click  to submit the form.
5. Please allow 1-2 business days before your account will be ready for use.
6. A member of the SleepImage team will notify you when you can sign in using your email address and temporary password.
7. When you sign in for the first time, please make sure to change your password under Settings.

Account Settings and Security

SleepImage recommends all users enable 2FA for their SleepImage System access. To enable 2FA, sign in to SleepImage System [HERE](#) and go to the Settings screen. Click Edit Account Settings.

In the Account Settings portal, click the pencil icon, located to the right of the email address to change your password. Complete the password change by toggling the switch and then entering your current password and new password. To add or remove two-factor authentication methods, click “Manage two-factor”.

On this screen (below), you can add or remove two-factor authentication methods. SleepImage supports 2 types of two-factor authentication: App and SMS.

Note that two-factor authentication via email is only available to users who had set it up before the release of SleepImage System version 2.25 and is no longer allowed for new enrollments.

Authenticator App:

Scan the QR Code or enter the secret in your authenticator app. Your authenticator app should then display a verification code. Enter this code in the “Verification code” field in the Account Settings portal and click Enable.

SMS:

Enter your phone number and click “Send a one-time code”. You will receive a text message (SMS) with a verification code. Enter the code in the “Verification code” field and click Enable.

Enable two-factor

Select a method *

Authenticator app

Open your authentication app and add your account by scanning the QR code to the right or by manually entering the Base32 encoded secret **CNVLZRQ6IWRQTEWQMVC73BR**.

Once you have completed the first step, enter the code from your authenticator app in the verification code field below.

Verification code *

Enable

English

Go back

User Language Selection

The SleepImage System may be used in multiple languages. Users may set their language preferences from the Profile tab at the top of the page.

Administrator Profile

Home

Demo Clinic

democlinic@sleepimage.com

Profile

Demo

User

Admin Middle Initial (optional)

Language

A English (U.S.)

Enter Country or Time Zone name to set the Time Zone for your location

Location

America/Denver

The selected language will be used as the default for all email notifications and other areas of the system that request a language preference. The selected language will also determine the names of fields used in Patient Notes, but the note content may be written in any other language. SleepImage System does not automatically translate any user-supplied content, like interpretation templates or notes left by clinicians.

When logging out of the system, the last-logged-in user's language preferences will be retained until another user logs in.

SleepImage Store

Access the SleepImage online **Store**, using the Admin Username (email) to purchase the Products & Services. The online store is online available to customers within the United States and Canada.

For customers located in the United Kingdom, please contact sales@sleepimage.com for sales inquiries.

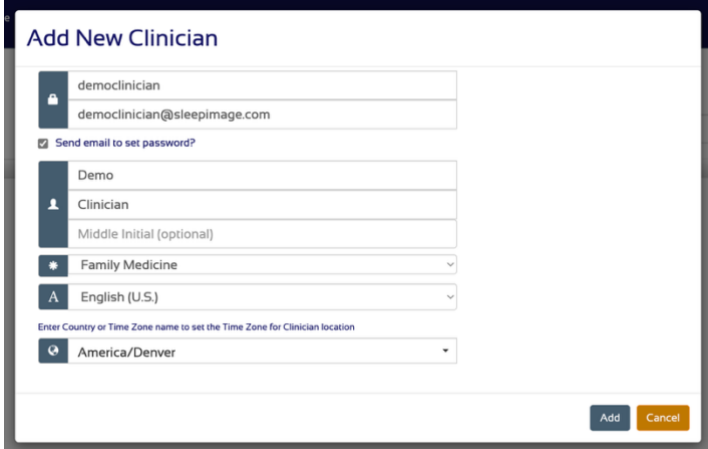
SleepImage User Tasks

Adding & Editing Clinicians

Only the Admin Role can Add Clinicians. Clinicians who have been added, can Edit their own Profile.

Add a Clinician

To add a Clinician, click the Plus icon. An Add New Clinician window will appear. Enter the Clinician's information. If you want to set the password yourself, uncheck the box for "Send email to set password?". Otherwise, the system will send an invitation to the user with a link to set their password. When you're done, click Add.

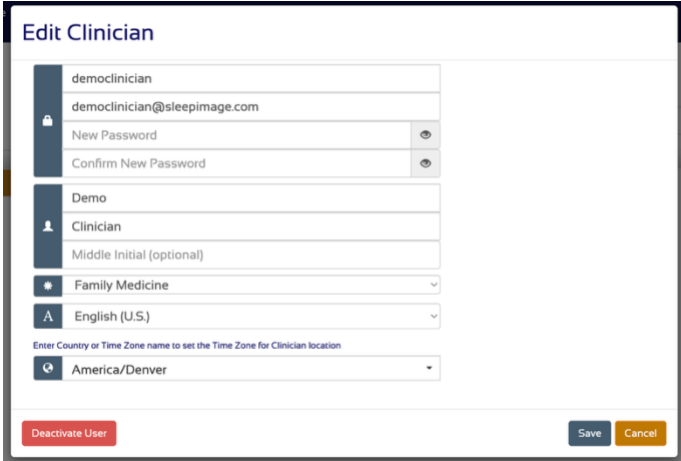


The "Add New Clinician" form contains the following fields and options:

- Username: democlinician
- Email: democlinician@sleepimage.com
- ☒ Send email to set password?
- First Name: Demo
- Role: Clinician
- Middle Initial (optional):
- Specialty: Family Medicine (dropdown)
- Language: English (U.S.) (dropdown)
- Time Zone: America/Denver (dropdown, with label "Enter Country or Time Zone name to set the Time Zone for Clinician location")
- Buttons: Add, Cancel

Edit a Clinician

To Edit a Clinician's information, select the Clinician's name, then click the edit icon. Modify the Clinician's information as necessary. When you're done, click Save. To block access for the user, click Deactivate User. This will prevent them from being able to sign in and access your account.



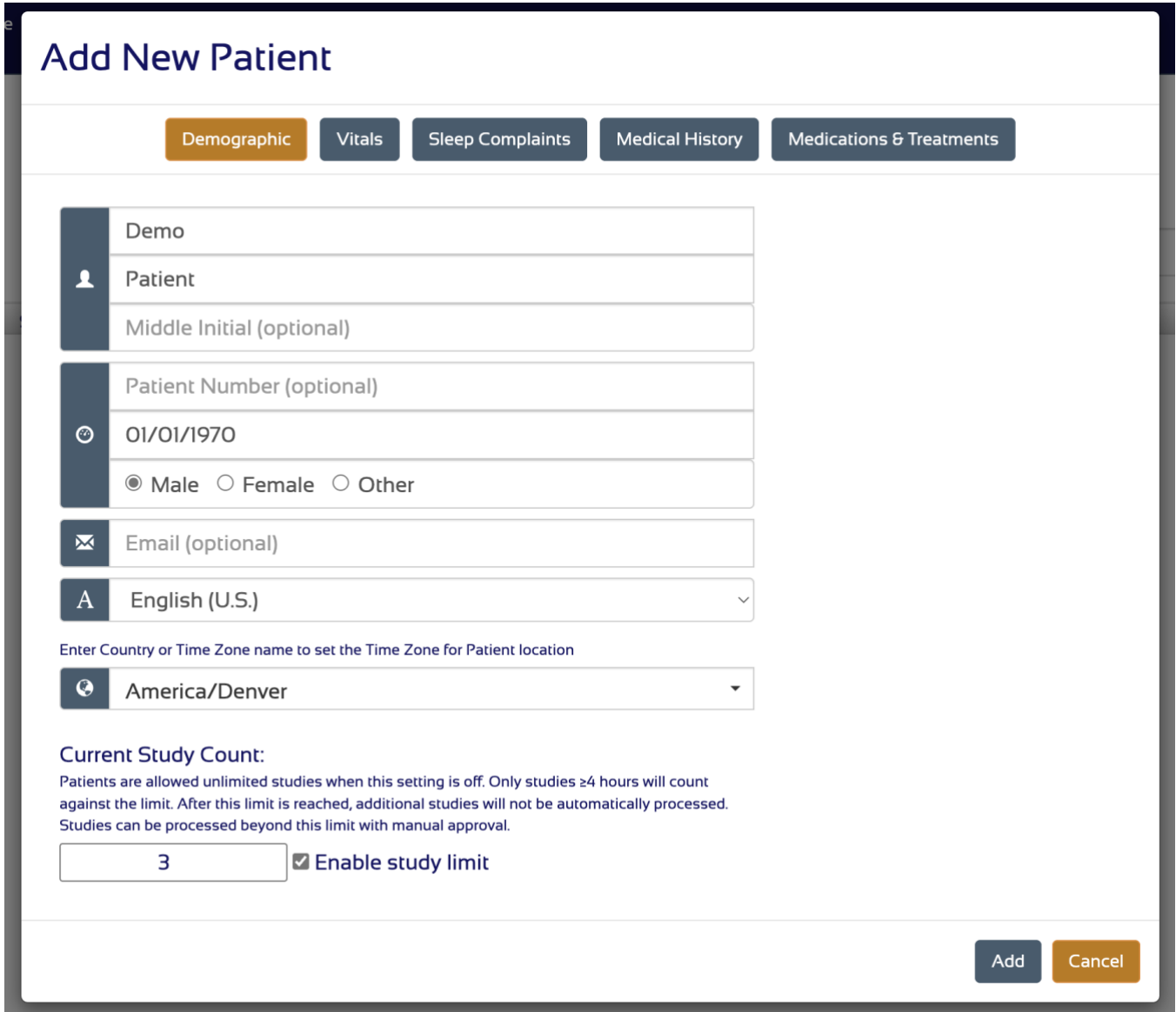
The "Edit Clinician" form contains the following fields and options:

- Username: democlinician
- Email: democlinician@sleepimage.com
- New Password: (password field)
- Confirm New Password: (password field)
- First Name: Demo
- Role: Clinician
- Middle Initial (optional):
- Specialty: Family Medicine (dropdown)
- Language: English (U.S.) (dropdown)
- Time Zone: America/Denver (dropdown, with label "Enter Country or Time Zone name to set the Time Zone for Clinician location")
- Buttons: Deactivate User, Save, Cancel

Adding, Editing & Removing Patients

Add a Patient

To add a Patient, click the Plus icon. An Add New Patient window will appear. Enter Patient information and click Add. If email address is entered, their Patient ID & SleepImage Mobile App download instructions are emailed to the Patient. The Patient Language is used to determine the language in which the Welcome Email is sent.



Add New Patient

Demographic

Vitals

Sleep Complaints

Medical History

Medications & Treatments

Demo



Patient

Middle Initial (optional)

Patient Number (optional)



01/01/1970

☒ Male ☐ Female ☐ Other



Email (optional)



English (U.S.)

Enter Country or Time Zone name to set the Time Zone for Patient location



America/Denver

Current Study Count:

Patients are allowed unlimited studies when this setting is off. Only studies ≥ 4 hours will count against the limit. After this limit is reached, additional studies will not be automatically processed. Studies can be processed beyond this limit with manual approval.

3

☒ Enable study limit

Add

Cancel

When adding a patient, Patient Medical Data may be added. Patient Medical Data is optional. Information entered in these fields will pre-populated in the clinician notes in the patient's studies. This information can be reviewed and edited before publishing a note.

A Study Limit can be established when creating a patient. This study limit can be set for each patient.

The Current Study Count and Study Limit Tool

The Current Study Count is the total number of studies ≥ 4 hours in duration that have been processed for the patient. The value will be blank when adding a new patient.

The Study Limit Tool can be used to limit the number of studies ≥ 4 hrs in duration that are automatically processed for a patient. By default, the study limit is set to unlimited. To enable a Study Limit, check the 'Enable study limit' option on the 'Demographic' tab in the patient's profile and enter a desired limit in the box.

Current Study Count:

Patients are allowed unlimited studies when this setting is off. Only studies ≥ 4 hours will count against the limit. After this limit is reached, additional studies will not be automatically processed. Studies can be processed beyond this limit with manual approval.

☒ Enable study limit

Add Cancel

When the Current Study Count is equal to or greater than the Study Limit, any new studies uploaded by that patient will be automatically marked as 'Pending'. Accepting a 'Pending' study for a patient will process that study, but will not update the patient's study limit, so any future studies will also be placed as 'Pending'.

Edit a Patient

To Edit a Patient's information, select the Patient's name on the Patient List screen, then click edit icon. Enter Patient's Information and Save.

Edit Patient

Demographic

Vitals

Sleep Complaints

Medical History

Medications & Treatments

Demo

Patient

Middle Initial (optional)

Patient Number (optional)

01/01/1970

☒ Male

☐ Female

☐ Other

Email (optional)

English (U.S.)

Enter Country or Time Zone name to set the Time Zone for Patient location

America/Denver

Current Study Count:

Patients are allowed unlimited studies when this setting is off. Only studies ≥ 4 hours will count against the limit. After this limit is reached, additional studies will not be automatically processed. Studies can be processed beyond this limit with manual approval.

☒ Enable study limit

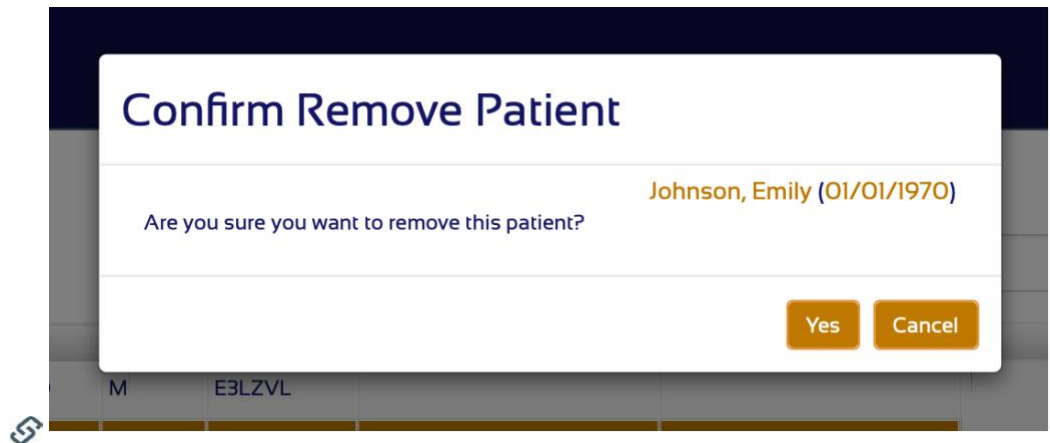
Save

Cancel

Patient information can also be edited directly from the Study Overview and Study Details screens by clicking the edit icon at the top of the screen, next to the patient's name.

Remove a Patient

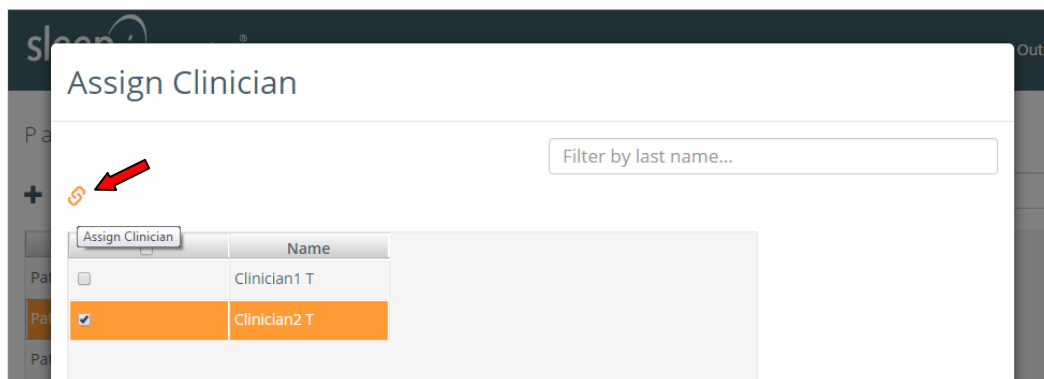
To remove a Patient, select the Patient's name, then click the minus icon. Confirm by selecting "Yes". **Removing a Patient is a permanent action. All studies for the patient will be permanently removed.** Credits used to upload or view their study data will be forfeited.



Assign Clinicians to Patients

Only the Admin Role can Assign Clinicians to Patients. Patients created by a Clinician are automatically assigned to that Clinician.

To Assign a Clinician to a Patient, select a Patient from the Patient List and click the Link icon. Check the box next to the Clinician(s) Name(s) to assign the selected Clinician(s) to this Patient. Click the Link icon  to Save.



To unassign a Clinician: uncheck the box next to the Clinician name. Click the Link icon  to save.

Allow All Clinicians to View All Patients

The Admin Role can set the Account to allow all Clinicians to view all Patients. Use the “Settings” Tab to enable this feature. To remove this Site-Wide setting, simply uncheck the box.

Account Settings

Account settings have been moved
To manage your password and 2FA settings please click on the button below.

[Edit Account Settings](#)

Automatic Patient Sharing

[Update](#)

Site-Wide Settings

These settings will affect all your users

☐ **Allow Clinicians to view all patients.**

When this feature is turned *on*, clinicians are able to view all the patients entered into your account and access their study data.
When this feature is *off*, you assign which clinicians are allowed to view which patients.

Authorized Connection

☒ **SleepImage API**

Share a Patient



Patients can be shared with other SleepImage System users for clinical collaboration such as having a patient’s reports reviewed by a sleep specialist. The original creator of the patient profile is referred to as the “Owner”. The collaborator is the “Recipient”. Only Owners can initiate sharing a patient. Recipients cannot share patients with other SleepImage users.

Before sharing a patient:

1. Contact the intended recipient.
2. Verify that they are a licensed healthcare professional with a SleepImage Account.
3. Verify the email address on the recipient’s SleepImage Account.
4. Confirm that they are willing to review the patient’s test results.

It is each SleepImage user’s responsibility to adhere to all applicable laws, rules, and regulations before sharing a patient.

To share a patient, highlight the patient’s name in the Patient List and click  in the toolbar.

Share Patient

Patient: **Johnson, Emily**
Patient ID: **HQQEY3**

[+](#) [x](#)

Filter by Clinic name...

☐ **Clinic Name** ☐ Clinic Id ☐ Clinic Email

[Close](#)

In the Share Patient screen, enter the email address of the recipient, click the  button, then click Yes to confirm. The language for the notification can also be selected in this dialog box.

Share Patient

Are you sure you want to share patient YSN2PP with Test Share (test@sleepimage.com)?

A

English (U.S.)

▼

Yes

Cancel

If the email address is not found, an “Account Not Found” error message will generate. Please contact the intended recipient to verify the email address in the Profile tab of their account.

Once confirmed, the Recipient’s Account Name will be visible in the Shared column of the Patient List. If a patient has been shared with more than one Sleepimage User, a “...” will be displayed after the Clinic Name of the first Recipient.

Patient List

Role: Admin | 2.23 Testing Clin

Download all studies (CSV)

+ -

Filter by Name...

Name	Last Study	Studies >4hrs / T...	Study Limit	Patient Number	DOB	Gender	Patient Id	Shared	NOTES
Green, Michael	Pending	1 / 1	2		01/01/1970	M	E3LZVL		
Johnson, Emily	08/10/2024	2 / 3	3		01/01/1970	F	NQQEY3		
Smith, John	04/06/2024	3 / 3			01/01/1970	M	U4SXYS	 Sleepimage Test Account...	 Sleepimage Test Account

An Email Notification is sent to both the Patient Owner and the Recipient when a patient is shared.

To Revoke Sharing, highlight the patient’s name in the Patient List and click  in the toolbar. Check the box next to a Recipients name and click the  button.

If you are the Recipient, you can revoke sharing by first highlighting the patients name in the Patient List and then clicking the  button in the toolbar. You will be presented with a dialogue box for confirmation. Click “Revoke” to revoke the sharing and remove the patient from your Patient List.

Please note that Recipients cannot:

- Edit demographic data in a patient’s profile
- Delete a patient
- Delete a patient’s study
- Share a patient (string sharing)
- Accept/Reject pending sleep studies

Automatic Patient Sharing

NOTE: Users should establish a relationship with the intended recipient prior to sharing a patient!

The account admin can configure the account to automatically share all patients that are added to the account with another SleepImage System account. This feature saves time for customers who, for example, share all patients with a sleep specialist for interpretation or for multi-disciplinary care.

You must be logged in as an [Administrator](#) to configure Automatic Patient Sharing. To enable Automatic Patient Sharing, go to the Settings screen, enter the email address for the intended recipient and click the 'Update' button.

Automatic Patient Sharing

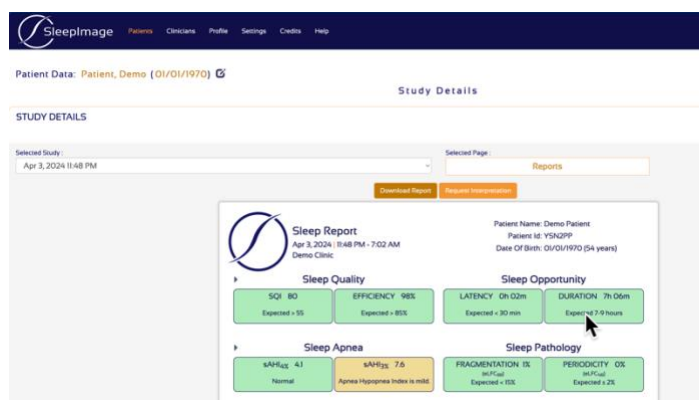


Update

To remove the auto sharing, (1) delete the email address in the email field and (2) click the "Update" button. **Note:** this will not remove sharing on a per patient level. For information on how to remove a patient share, please see the "Share an Individual Patient" section above.

Request Interpretation

The Admin and Clinician roles can use the Request Interpretation feature to send a single study to an Interpreting Clinician instead of using the Share Patient feature. This feature allows the Interpreting Clinician to receive the particular study that has been selected for interpretation for a patient instead of the patient's entire list of studies.



Warning!

Using this feature will grant the recipient access to all the data for a single study. Users should verify that the email address being used is for the intended recipient and that it is an email address accessible to a single person, i.e., not a distribution list.

To request an interpretation, click the 'Request Interpretation' button, then enter the recipient's email address and choose an expiration date in the popup window. Expiration date must be at least one day in the future. Additionally, the interpretation request email can be sent in another language, if the recipient prefers another language.

Request Interpretation

Please enter the recipients email address below.
Please make sure the email address is correct.







Send Cancel

Important!

It is recommended to choose an expiration date such that the access period is as short as possible.

NOTE: the email used by the interpreting clinician cannot be one already associated with an account! It must be either a new email or one that is already associated with an Interpreting Clinician role.

Once you have entered a verified email address and chosen an expiration date, click send. The recipient will receive an email with a link to access the study where they can perform all necessary operations including manual scoring, recalculation and publish clinician notes (interpretation).

Upload a Study

Patient Data is uploaded using the SleepImage Mobile App. Please refer to the [SleepImage Mobile App Instructions](#), available in the Help section of your SleepImage account for further information.

SleepImage Users that have selected the “Monthly Subscription” data plans do not have to Accept or Reject each study, as all studies will be automatically processed at the time of upload and be visible for viewing and interpretation. If a report is uploaded when a subscription is inactive (0 Reports Remaining or past Renewal Date), that report and any subsequent reports for that patient will appear as ‘Pending’. When your subscription is active once more, [Accept or Reject](#) the Pending study to continue standard report generation for that patient.

Studies may also appear as Pending if the patient’s Study Limit has been reached. These Pending studies can also be accepted or rejected while your subscription is active.

Manage Interpretation Templates

Interpretation Templates are a tool that allows users to define templates, which can be used to prepopulate the Impressions and Recommendations Sections when publishing a [Clinician Note](#). Prepopulated text entered in a Clinician Note can be revised by the Clinician before the note is published.

If a template is added by an Administrator, it will be visible to all Clinicians in the account, as well as Interpreting Clinicians that are interpreting for patients in the account.

Clinicians can add, edit and remove their own interpretation templates. These templates will only be visible to the Clinician that created the template.

Adding, Removing, and Editing Interpretation Templates

- Navigate to the Settings screen and then click the corresponding icon at the top of Interpretation Templates section.
- Add a new Interpretation Template
-  Remove an Interpretation Template
-  Edit an existing Interpretation Template

Fields Within an Interpretation Template

- **Template Name** – This field is the Name of the Template and is only shown to users within the Clinical Portal
- **Template Type** – This field determines if the Interpretation Template will be available for use within either the ‘Impression’ field or the ‘Recommendation’ field in the Clinician Note Form.
- **Status**– This field is used to determine whether the Interpretation Template is available to be used in the Clinician Note Form. Templates can either be marked with the status of ‘Active’ or ‘Inactive’ where ‘Inactive’ marked templates will not be available for use within the Clinician Note Form.
- **Private Note**– This field can be used to add additional context for users of the Clinical Portal regarding the Interpretation Template. The contents are only visible in the Interpretation Template Section on the Settings Screen.
- **Template Content**– This field contains the text that will be populated into the Clinician Note Form when the Interpretation Template is selected.

NOTE: Interpretation Templates that were created by an Administrator cannot be edited or deleted by a Clinician.

Add template

Date: Sep 18, 2024

Template name:

Template type:

Status:

Private note:

Template content:

Save Cancel

After adding a template, it can be edited or removed.

Edit template

Date: Sep 3, 2024

Template name: Admin - Example Impression

Template type: Impression

Status: Active

Private note: This template is an example.

Template content: Based on the review of the patient's sleep study report, the findings are indicative of moderate obstructive sleep apnea (OSA). The patient exhibited frequent apneas and hypopneas, particularly during REM sleep, with significant oxygen desaturation events. The overall apnea-hypopnea index (AHI) was elevated, confirming the diagnosis of OSA.

Save Cancel

Confirm Remove Template

Are you sure you want to remove this template?

Admin - Example Impression (09/03/2024)

Yes No

Review Patient Studies

Study (Report) Generation

When a patient uploads a recording, the recording is processed and a report is automatically generated if the patient's Study Limit has not been reached and

- the account has an active subscription or
- the study is generated through a non-subscription method, such as a study included with a recorder.

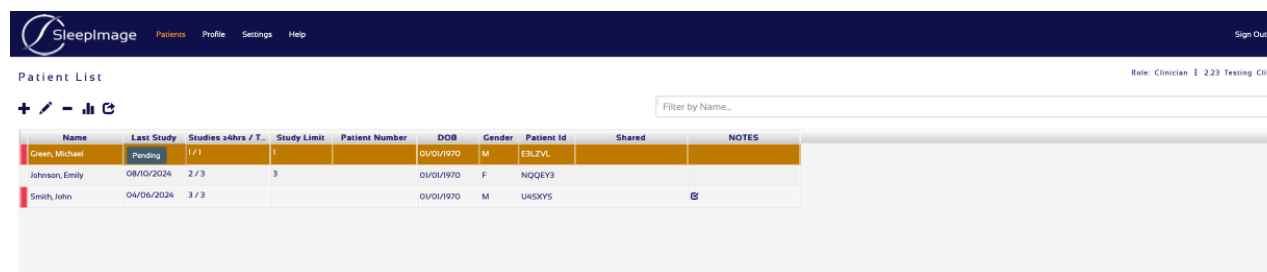
Studies with durations of 4 hours or longer are:

- counted towards the maximum number of reports for each respective subscription plan, and
- counted towards a patient's Study Limit, if applicable.

Studies that are less than 30 minutes long may not appear in the SleepImage portal due to technical limitations.

Go to [Table of Contents](#)

The subscription status is displayed below the menu banner in the clinical portal, along with the Role (of the signed in user) and Clinic Name as shown below.



The screenshot shows the SleepImage clinical portal interface. At the top is a dark blue navigation bar with the SleepImage logo and links for Patients, Profile, Settings, and Help. A 'Sign Out' link is in the top right. Below the navigation bar, the page title is 'Patient List' and the user role/clinic is 'Role: Clinician | 2.23 Testing Clinic'. A search bar labeled 'Filter by Name...' is present. Below the search bar is a table with the following data:

Name	Last Study	Studies x4hrs / T.	Study Limit	Patient Number	DOB	Gender	Patient Id	Shared	NOTES
Green, Michael	Pending	1 / 1	1		01/01/1970	M	ELZVL		
Johnson, Emily	08/10/2024	2 / 3	3		01/01/1970	F	NQQLY3		
Smith, John	04/06/2024	3 / 3			01/01/1970	M	UASXYS		6

Studies will appear with a 'Pending' button if:

- the Renewal Date for the account's subscription has passed,
- the Reports Remaining for the account's subscription is 0, or
- the patient's Study Count is greater than or equal to their Study Limit.

Users with an inactive subscription (0 Reports Remaining or past Renewal Date) will have to renew their subscription before generating the reports. Refer to the [SleepImage Store section](#) for more information on how to manage your subscription.

Users with an active subscription may click the Pending button to open the Upload Studies window. The pending study will be listed with a Status indicator of 'Success' or 'Insufficient Data'.

Success indicates that total recording duration is over 4 hours. Please note that the sleep period may be shorter and that SleepImage categorizes studies with reference to expected values based on at least a 4-hour long sleep period with color-coded output values.

Insufficient Data indicates that the total recording time is less than 4 hours and may be of limited clinical value.

Users can select to Accept or Reject the study. Accepting the study will generate the pending report, while Rejecting the study will delete the file permanently. Studies with a status of 'Insufficient Data' are the same as a study with a Duration of '<4 hours' and can be Accepted for no charge. Refer to 'Study Duration' in the [Patient Overview Page section](#) for more information.

Upload Studies

Last upload Sep 17, 2024 9:48 AM was successful.

V223 Testing, Verification (01/01/1970)

Upload By: V223 Testing

Processing is complete.

Select a checkbox next to each study to either Accept or Reject the study for report generation.

- Each Accepted study will generate a Report to the Patient's Profile.
- Each Rejected study will not generate a Report and is not added to the Patient's Profile.

Once a selection is made for each study, click Confirm to continue, or Cancel to delay selection and close the window.

Accept	Reject	Start Date Time	Duration (HH:MM)	Status
☐	☐	04/04/2024 01:01:34 AM	11:42	Success

1 studies have been uploaded.

- 0 are being accepted for report generation.
- 0 are being rejected.

Confirm

Cancel

Once a pending study has been accepted/rejected, or any conditions that prevented report generation are resolved, subsequent reports for that particular patient will resume automatic report generation while the subscription is active and the patient's Study Limit (if applicable) has not been reached. Reports will remain in Pending until manually released, even if the conditions sending the study to Pending have been resolved.

CSV Account Download

You can download a single CSV containing all reports in your account, where each row is an individual report.

To initiate a CSV Account Download, go to your Patient tab and click the "Download all studies (CSV)" button, in the top right-hand corner of the screen. From there, the System will prompt you to enter the date range for the applicable data that you wish to download, then click 'OK' to download the CSV file.

[Patients](#)
[Clinicians](#)
[Profile](#)
[Settings](#)
[Credits](#)
[Help](#)

[Sign Out](#)
[Store](#)

Patient List

Role: Admin | SleepImage Test Account

Download all studies (CSV)

+

✎

-

📊

🔄

Filter by Name...

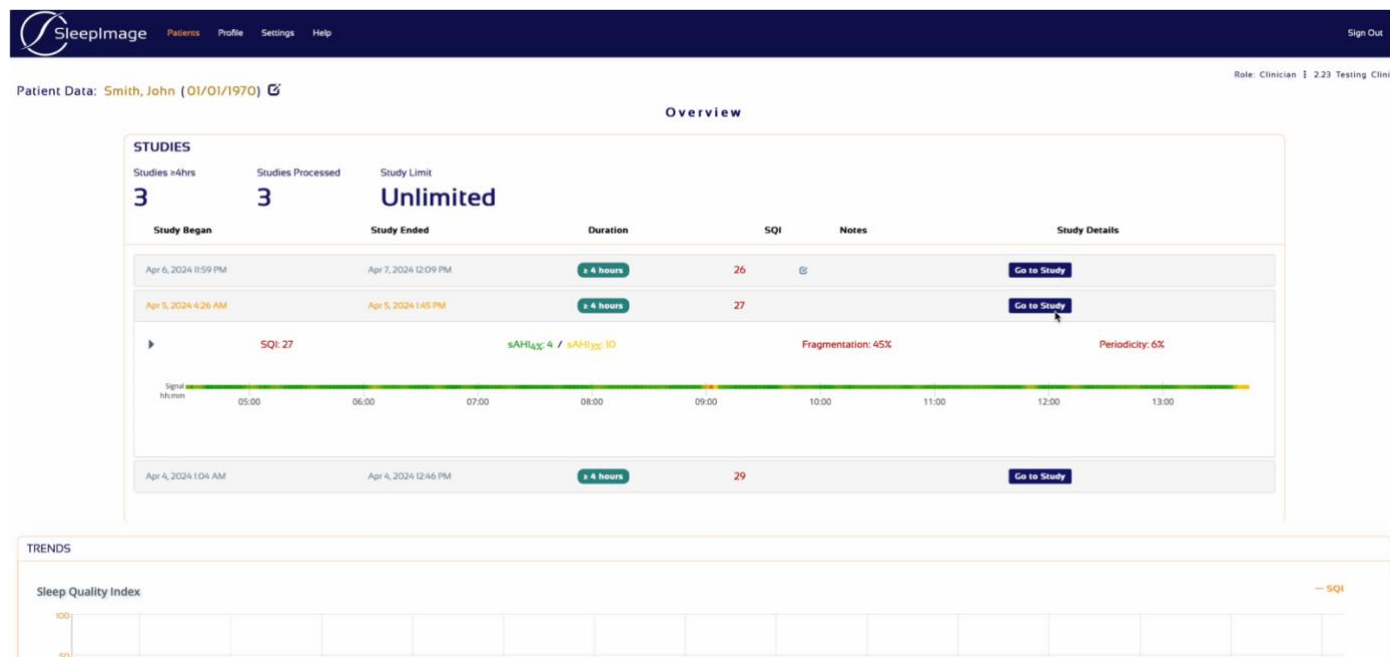
Patient Overview Page

- Accessing the Patient Overview**– To open the Patient Overview, select the patient from the list and either double-click their name or click the bar graph icon.
- Studies**–This list is an overview that displays all uploaded, and accepted, studies for a patient with the most recent Study at the top.
- Study Duration**– The 'Duration' column, in the 'Studies' section, shows the total recorded sleep time. It indicates either '≥4 hours' or '<4 hours.' Studies marked as '≥4 hours'
 - will** count towards a patient's Current Study Count, and
 - will** count against the 'Reports Remaining' value in the account's subscription (if processed through a subscription).

Studies marked as ‘<4 hours’ are processed into reports, but do not count towards the patient’s Current Study Count value or the account’s ‘Reports Remaining’ value.

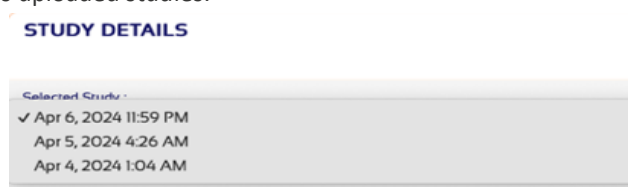
○ **NOTE: Studies under 4 hours are always processed free of charge regardless of billing method.**

- **Sleep Quality Index (SQI)**– Each study’s Sleep Quality Index (SQI) is displayed with color-coded values (Green, Yellow, and Red) that indicate how closely the patient’s SQI compares to expected values based on their age.
- **Reviewing Studies**– Selecting a study expands the view to show additional color-coded metrics, including sleep duration and signal quality for a quick review. For a detailed guide on these metrics, please refer to the [Introduction to SleepImage](#) to better understand your patient’s sleep.
- **Trends**– Trends are displayed as graphs on this page, showing how primary biomarkers from all uploaded studies have changed over time, which can help in managing sleep disorder therapies.
- **Study Details**– To review a specific study in detail, locate it in the overview and click the “Go to Study” button.



Study Details

The Study Details Screen shows information about a specific study. To select a different study for review, use the dropdown to choose from the list of the Patient’s uploaded studies.



Signal Quality

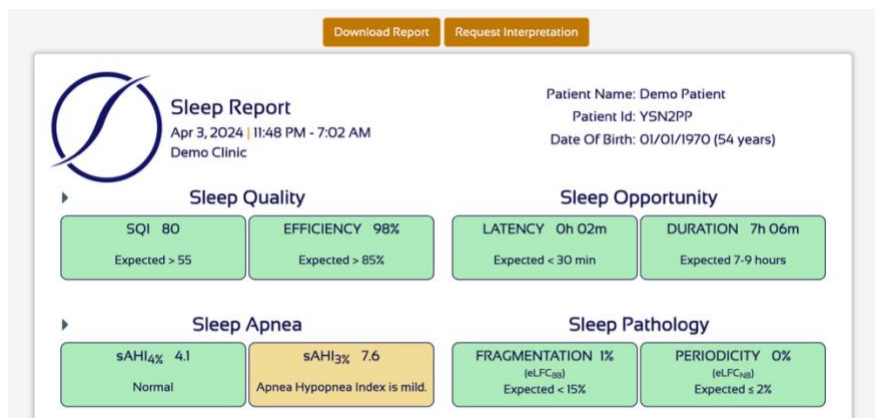
The SleepImage System interface uses color to represent the signal quality. The quality of the collected signal data is presented on the Signal line, which contains color-coded indicators (Green, Yellow, and Red) representing the strength of the signal quality. Frequent or complete signal loss is presented as Red, intermittent signal loss is presented as Yellow, and no signal loss is presented as Green.

Clinical decisions should not be made using time periods where signal quality is red.

During periods of complete signal loss, the software does not recognize the input signal. The spectrogram will be blank for that time period and no data will be available or analyzed. The [Case Studies Page](#) of the SleepImage website contains information that describes potential signal quality issues.

Selected Page: Reports

The Study Report page displays information commonly used for sleep evaluation to aid diagnosis or management of sleep disorders. A copy of this Report can be downloaded in [PDF](#), [CSV](#), or [DOCX](#) formats via the “Download Reports” button at the top. The Report language and filename can also be changed when downloading the Report.



Further information on Sleep Quality, Sleep Opportunity, Sleep Apnea, and Sleep Pathology, can be found by selecting the triangles on the left of the relevant headline.

Clinician Notes

Close Note

Add Clinician Notes :

Patient Medical Data:

☒ Metric ☐ US Customary

Height : m cm Weight : kgs BMI :

Medicare : ☐ Yes ☒ No [Clear](#)

Epworth Sleepiness Scale :

Sleep Complaints :

Select all that apply

☒ Excessive Daytime Sleepiness

☒ Snoring

☒ Morning Headaches

☒ Difficulty Falling Or Maintaining Sleep

☐ Irregular / Paused Breathing During Sleep

☒ Bruxism / Teeth Grinding

☐ Waking Up Gasping Or Choking

This is the first admission for this 56 year old woman, Convey the acute or chronic nature of the problem and who states she was in her usual state of good health until establish a chronology, one week prior to admission. At that time she noticed the abrupt onset (over a few seconds to a minute) of chest pain onset

Character Count: 961 / 5000

Medications Used :

1. [⊕](#)

2. [⊕](#)

[Add More](#)

Treatment Device Used :

1. [⊕](#)

[Add More](#)

Diagnosis :

Select all that apply

☐ G47.33 Obstructive Sleep Apnea

☐ G47.32 High Altitude Periodic Breathing

☐ G47.10 Hypersomnia, Unspecified

☐ R06.3 Periodic Breathing

☐ R53.83 Other Fatigue

☐ G47.31 Primary Central Sleep Apnea

☐ G47.9 Sleep Disorder, Unspecified

☒ G.47.00 Insomnia Disorder

☐ R06.83 Snoring

☐ Other

Select Template

Impression

Character Count: 0 / 5000

Select Template

Recommendations

Character Count: 0 / 5000

[Publish](#)

Clinician Notes are an important tool for the Clinician to document decisions and share with other Clinicians in multidisciplinary care.

The Clinician Notes tool is only available when the user is signed in as a Clinician, and any Published Clinician Notes will become part of the Report.

To write a Clinician Notes, select the  button below the Test Summary. The Clinician Notes will be automatically prepopulated with any stored Patient Medical Data. You can edit or remove this information, and when this Note is completed click the 'Publish' button.

NOTE: If a Clinician has already published a note for a particular study, the button will show as 'Edit Note' and clicking the 'Edit Note' button will present the most up-to-date version of this patient's note, which can then be edited and updated.

Interpretation Templates are available for use within the Clinician Notes tool, where you can select a template that can be used to prepopulate the Impressions and/or the Recommendations fields. You may edit these fields before saving the note. For more information about Interpretation Templates, please refer to the [Manage Interpretation Templates section](#).

Every time you publish a note, the SleepImage System will ask if you would like to send an email notification. To send an email notification, enter email addresses into the field, separated by a comma, and then click “Send”. If you click “Close”, the System publishes the note but no email notification is sent. The language of the notification may also be selected.

If you would like to send email notification(s), please enter the email addresses below, separated by a comma. If this note is for a shared patient for which you are the recipient, the patient owner's (the sender) email address will be automatically populated in the field

English (U.S.)

Send Close

If you have updated Patient Medical Data before publishing a note, the SleepImage System will also ask if you want to update the stored Patient Medical Data on the patient’s profile for subsequent studies. You may select ‘Yes’ to update the profile with the revised medical data, or ‘No’ to only save the revised medical data in the Clinician Note.

Medical Data Changed

You have unsaved Patient Medical Data.

Would you like to save these changes to the server?

Yes No

An Interpretation Template is not updated by edits made in a Clinical Note.

The SleepImage System will display icons on the Patient List and Study Overview screens to indicate if a Clinician Note has been published:

- The  icon indicates to the signed in user that they have published a Clinician Note for that patient (Patient List) or that sleep study (Study Overview).
- The  icon indicates that another user has published a Clinician Note, and the Clinic Name for that user’s account will be displayed behind the icon.

Note: When more than one clinic, in addition to the signed in user, has published a note, the SleepImage System will display “...” behind the first clinic name (e.g., “SleepImage Test Account...”).

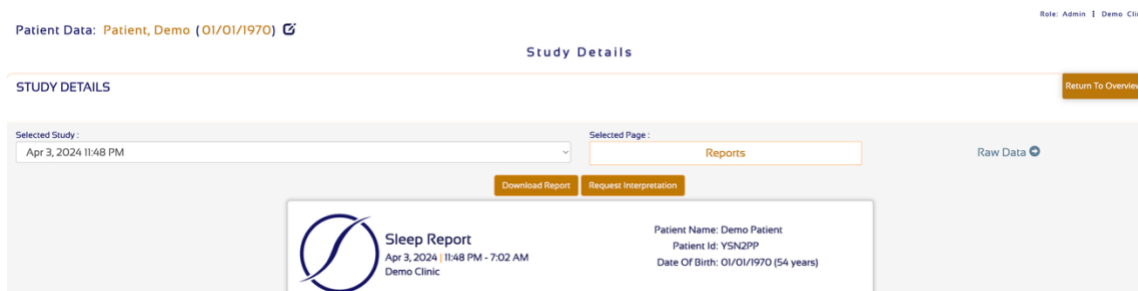
NOTES

  SleepImage

  Healthy Sleep

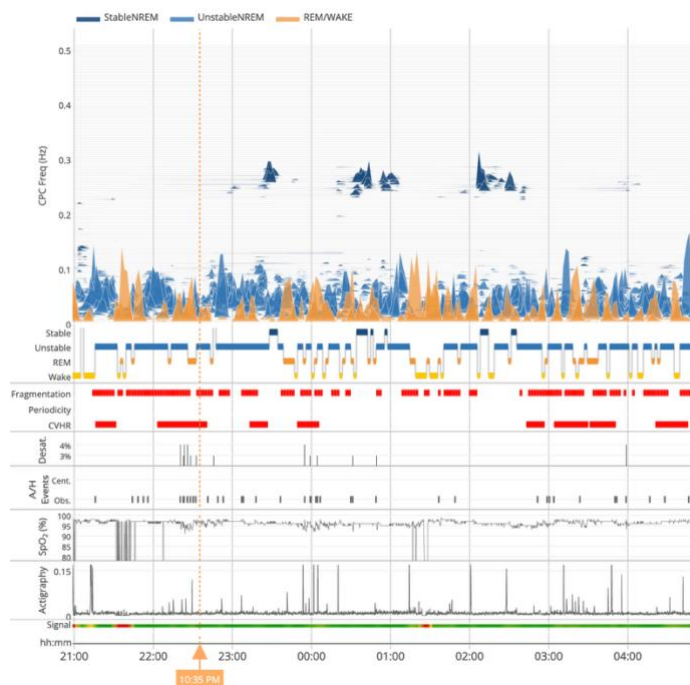
Selected Page: Raw Data

Raw Data is intended to aid clinical decisions. From the Study Details page, select 'Raw Data' button:



The Spectrogram

The Spectrogram is an overall visual representation of the entire sleep period. It also shows a graphical representation of recorded variables such as: signal quality, the sleep pathology biomarkers (Fragmentation and Periodicity), CVHR, transitions between sleep states, and (when recorded) SpO₂, desaturations, body position, snore, actigraphy.



The Spectrogram is presented in the Sleep Report. The Spectrogram image is wider or narrower depending on the length of the recording period. The time (in HH:MM) is shown on the signal quality line, below the Spectrogram.

Recalculate

Clinicians can adjust study duration and add/edit/delete SDB and SpO₂ events to recalculate the auto-generated study output. Moving the Green and Red markers and clicking the 'Recalculate' button narrows the window of analyzed data under review and re-calculates SleepImage values based on the period selected. [See below for detailed instructions on how to modify SDB events.](#)



Study Details

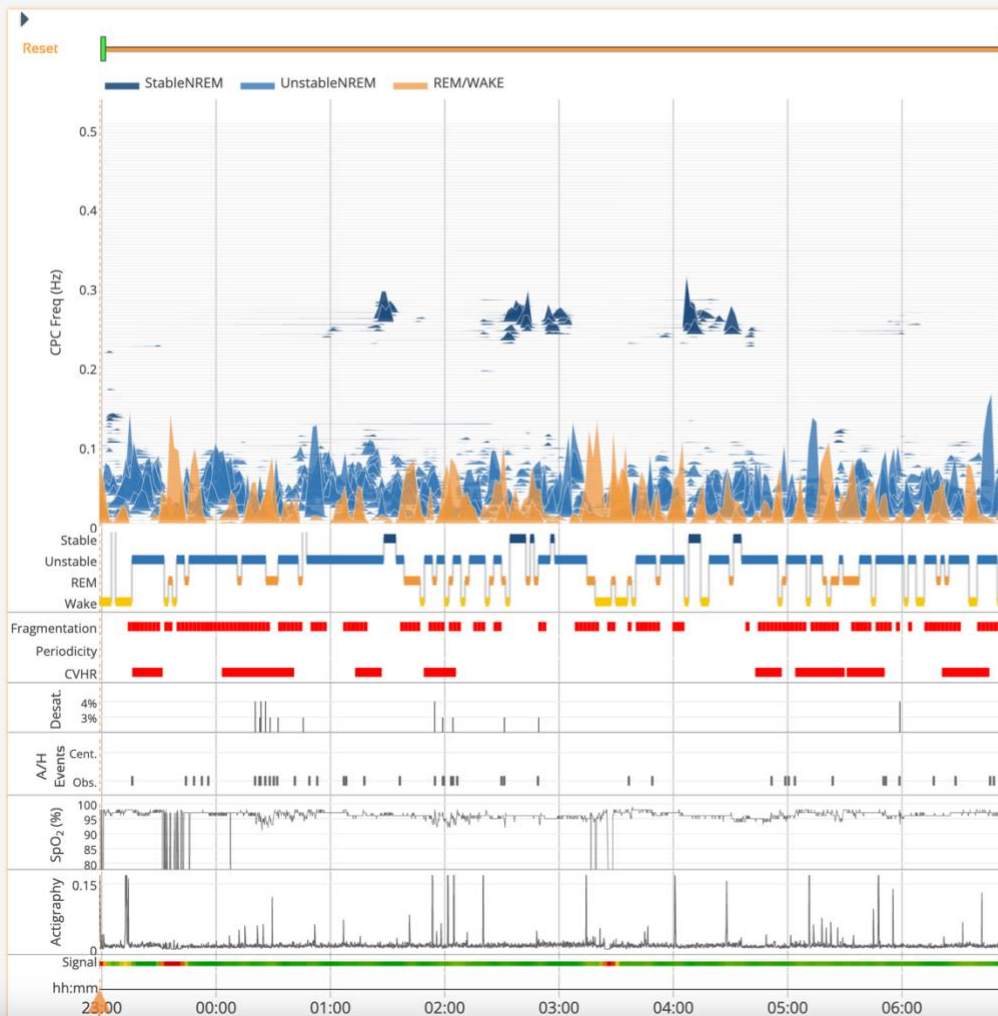
STUDY DETAILS

[Return To Overview](#)

Selected Study :

Apr 5, 2024 10:58 PM

Selected Page :

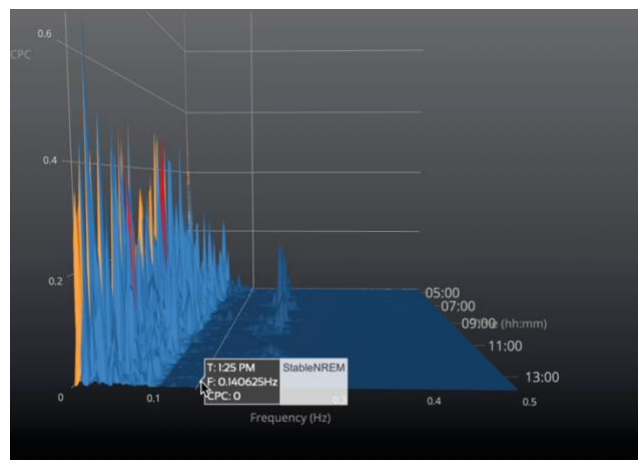
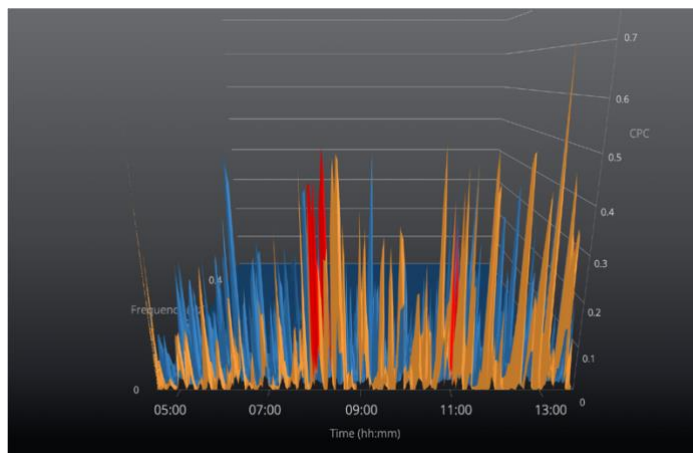
[Reports](#)[Raw Data](#)[Open 3D](#)[Recalculate](#)[Delete](#)[EDF](#)

For better view of the peaks on the spectrogram, click on the HFC-, LFC- and vLFC- icons to hide/display each frequency band.

3D Spectrogram

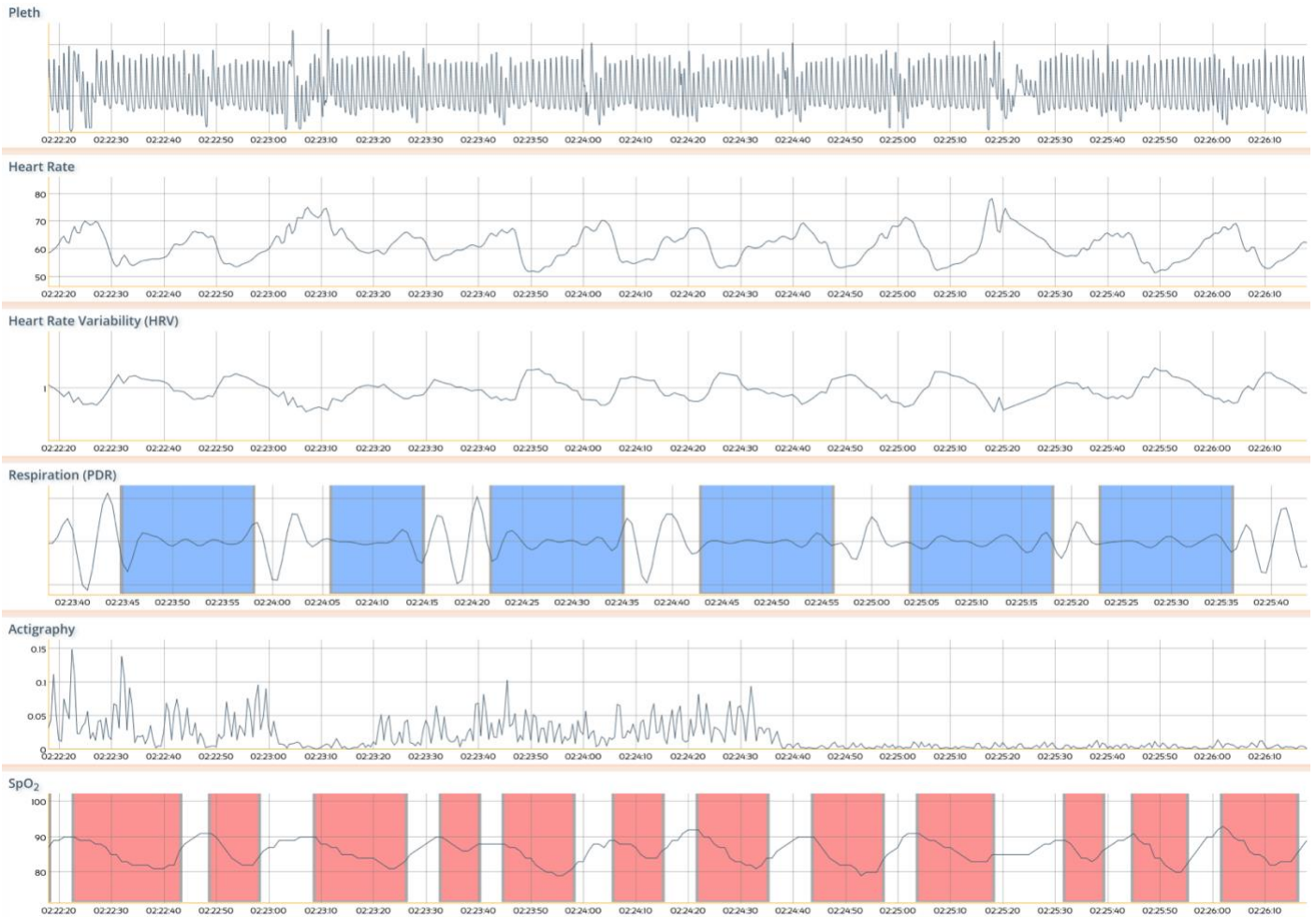
Open 3D

The 3D Spectrogram is fully interactive and can be pivoted to analyze the Patient's sleep. Clicking the 'Open 3D' button will open a pop-up window where the spectrogram can be rotated for a better visual of all the frequency bands. This view helps differentiate SDB phenotypes as obstructive or central.



Traces

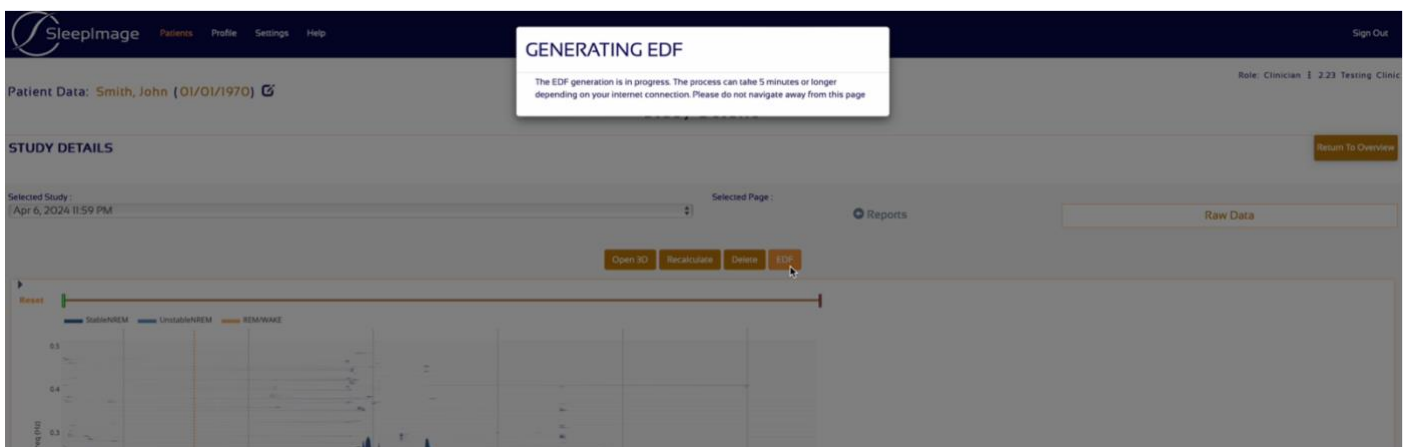
Traces are visual representation of the Raw Data collected (ECG/PLETH, Heart Rate Variability, Snore, Actigraphy, Heart Rate, Respiration and SpO₂). Traces are useful in conjunction with the Spectrogram to evaluate the Patient's sleep. If there is a time during the sleep study you want to review more closely, click on the time along the bottom of the spectrogram and a timestamp as well as a dotted, orange-colored line will be shown to confirm the window of reference shown in the Traces.



Traces can be set for different time intervals, shown in the window. Interval windows can be selected as 10 sec, 30 sec, 1 min, 2 min, or 4 min. Use the arrow buttons to move backward or forward to look for patterns and associations for concurrent events.

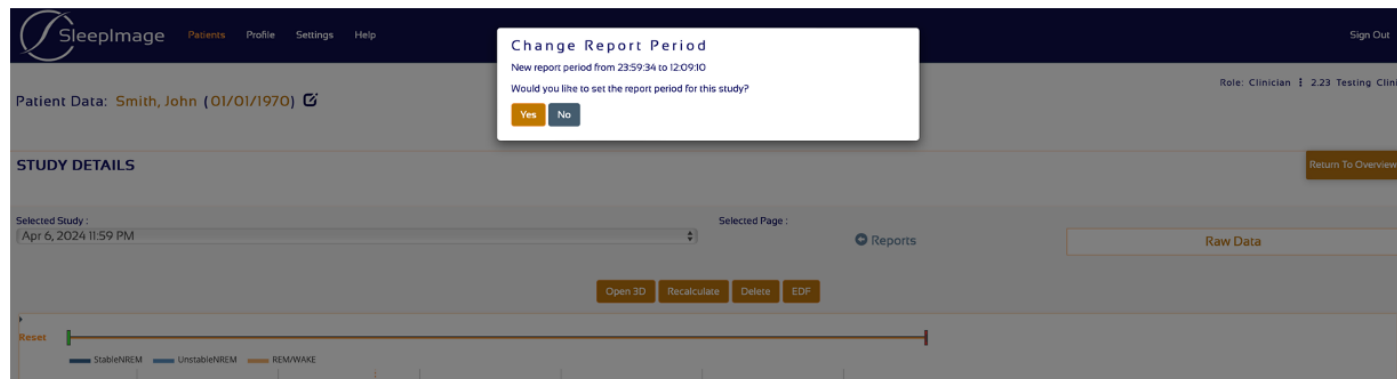
EDF Download

Users can download an EDF file of the recorded traces, which includes the plethysmogram (PLETH), Actigraphy, and SpO₂, by clicking the **EDF** button.



Manual Scoring (Editing Scored Events)

Clinicians can add, edit, remove, and modify the auto-scored SDB and SpO₂ events. To modify the scored report, the clinician will make changes to the included events and then click the “Recalculate” button, which will re-score and save the changes.



NOTES:

- **The SleepImage System only stores two versions of the report: one default (auto-scored) and one modified.** The default version can be generated again by clicking the Reset button. Clicking the Reset button will reset the study to the auto-scored results and will remove all user changes, so please use caution!
- The functionality to add or edit events is meant to give clinicians full control over what events are included. Therefore, the System does not apply any rules dictating whether an added/edited event is included or not and all added/edited events will be included in the calculations.
- Only studies processed after **December 12th, 2022**, are available for manual scoring.

How Events Are Labeled

Event Type Label ¹	Event Type Annotation ²	Color Indicator	Display Trace	Included in Parameter(s)
A/H: Obstructive: 3% or arousal	(*)O3a	Red	Respiration	sOAI3%, sOAI4%, sAHI3%, sAHI4%, sRDI
A/H: Obstructive: 4%	(*)O4	Red	Respiration	sOAI4%, sAHI4%, sRDI
A/H: Central: 3% or arousal	(*)C3a	Blue	Respiration	sCAI3%, sCAI4%, sAHI3%, sAHI4%, sRDI
A/H: Central: 4%	(*)C4	Blue	Respiration	sCAI4%, sAHI4%, sRDI
Autonomic Arousal	(*)aa	Purple	Respiration	sRDI
3% Desaturation	(*)3%	Blue	SpO ₂	ODI3%
4% Desaturation	(*)4%	Red	SpO ₂	ODI4%
Artifact (SpO ₂)	(*)Af	Purple	SpO ₂	N/A

¹ “A/H” indicates the event is either an apnea or hypopnea.

² When a new event is added, or if the clinician edits a system generated event, an asterisk (*) is added to the Annotation tag to indicate that the event is a user added/modified event.

Important! Clinicians need to save changes by clicking the Recalculate button at the top of the screen.

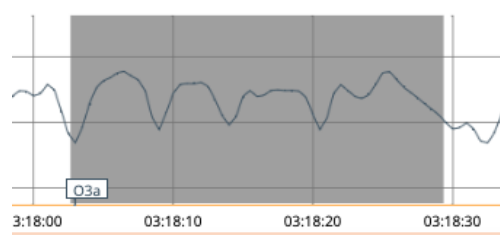
Adding Events

Events are added by clicking and dragging the mouse cursor on the trace as shown below (left). Afterwards, a dialog window (right) will be displayed with the event parameters. The event start time is determined by where the user clicks in the trace display. Once the event dialog is displayed, the clinician can edit the duration and the event type. Click the Add button to add the event.



Editing or Deleting Events

Events can be modified or deleted by clicking the annotation tag in the bottom left of the event box. After clicking the tag, the dialog box (right) will appear where you can either edit the duration and/or Event type and click Save or click the Delete button to delete an Event.



Confirm - Change
✕

Event Start

Duration

A/H: Obstructive: 3% or arousal

NOTE: When a system-generated Event is deleted, that event becomes grayed out but is not removed from view as shown below (left). Events added by you will disappear when deleted. To reverse deletion of system generated events, simply click the annotation tag again and click save.

Remove Sleep Studies

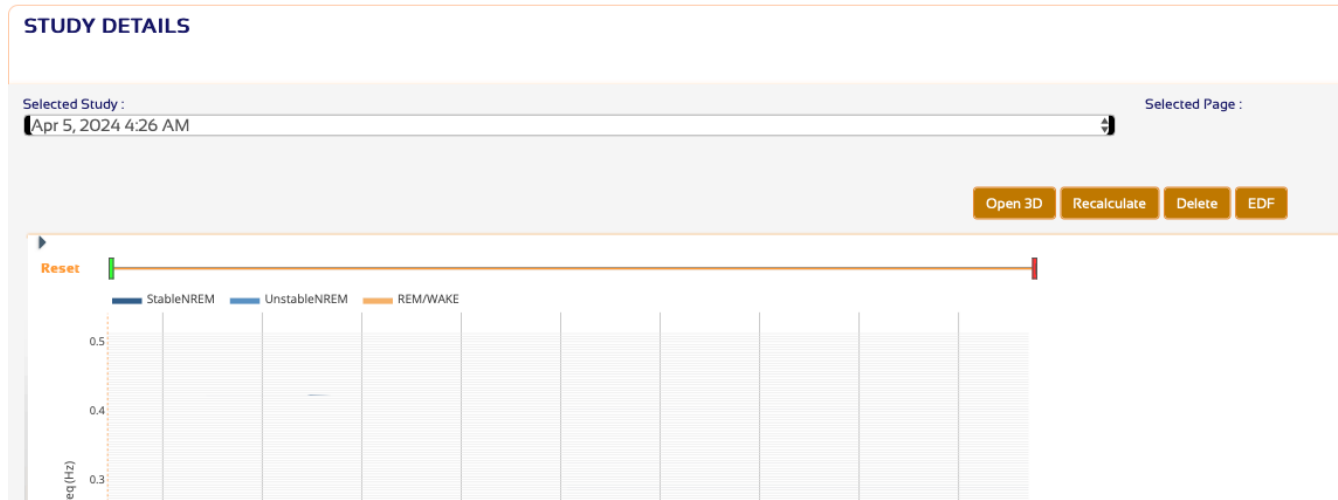
Delete

Clinician Users can remove Patient Studies from the Raw Data page by clicking on the Delete button. This is a two-step process, to proceed to Permanently Remove the study, click ‘Yes’, to cancel, click ‘No’.



Patient Data: **Smith, John** (01/01/1970)

Study Details



Deleted studies will be permanently removed and cannot be recovered.

