



SleepImage[®] System

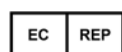
Instructions for Use

Version 2.11

MyCardio® SleepImage Website

These instructions are only 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 English language only, representing the markets where the SleepImage System is currently marketed. These instructions for use are updated periodically, identified by a sequential revision number.

	Manufacturer	MyCardio LLC, dba SleepImage 3003 E 3 rd Ave., Suite 201 Denver, CO 80206, USA support@sleepimage.com www.sleepimage.com
	Instructions for Use Version Number	Please read Instructions for Use carefully and periodically as it is updated from time to time. The current version (D-6.00285 – Rev. 14) was issued on March 22, 2021 – Previous editions are not applicable, as all users always use a current version of the cloud-based SleepImage System. Printed copy will be provided within 7 calendar days if requested at no additional cost. Please contact support@sleepimage.com
	Prescription Use Only	FDA-cleared k182618 : Federal law restricts sales of this device as “by or on the order of a licensed healthcare practitioner”. The FDA Unique Device Identifier (UDI) is *+B315sleepimage.com0.*
	CE Mark	The CE mark is a declaration that the SleepImage System is in compliance with the EU Medical Device Directive.



European Representative

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Singapore Sponsor

BMEC Sleep Care Ltd
82 Ubi Avenue 4
#07-03 Edward Boustead Centre
Singapore 408832

Australian Sponsor

Emergo Australia Level 20
Tower II, Darling Park
201 Sussex Street Sydney
NSW 2000 Australia

Africa Representative

SleepFit Pty Ltd
323 Lynnwood Road
Menlo Park, Pretoria, Gauteng 0102
South Africa

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Disclaimer

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Trademarks

MyCardio™ and SleepImage® are registered trademarks of MyCardio LLC. All other trademarks and registered trademarks used as part of the SleepImage Website are the property of their respective owners.

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.

Revision History

Version Numbers:	Release Date:
Version 2.2 (Initial Release Version)	November 2019
Version 2.3	November 2019
Version 2.4	February 2020
Version 2.5	April 2020
Version 2.6	June 2020
Version 2.7	August 2020
Version 2.8	September 2020
Version 2.9	December 2020
Version 2.10	February 2021
Version 2.11	March 2021

Table of Contents

Introduction	5
Indications for Use	5
Cautions, Warnings	5
Product Support	5
Quality Management System.....	5
SleepImage System Website Navigation Menu	6
The SleepImage System	6
Data Input.....	6
Data Sources	6
Icons used in The SleepImage System	7
SleepImage User Roles	7
Admin Role	7
Clinician Role	8
Account Registration	8
SleepImage Store	10
Credits	10
Credit History Report	10
Orders & Shipping Information.....	11
SleepImage User Tasks	12
Adding & Editing Clinicians	12
Add a Clinician	12
Edit a Clinician	12
Adding, Editing & Removing Patients	13
Add a Patient	13
Edit a Patient	13
Remove a Patient.....	13
Assign Clinicians to Patients.....	14
Share a Patient.....	15
Upload a Study.....	16
Flag a Recorder	16
Review Patient Studies	17
Accepting / Rejecting Uploaded Studies	17
CSV Account Download	18
Patient Overview	18
Study Details.....	19
Study Report	20
Clinician Notes	21
Interactive Graphs	22
3D Spectrogram	23
Signal Quality.....	23
Traces.....	24
Zoom function.....	25
Remove Sleep Studies	26
FAQs	27

Introduction

This document refers to users of the system as “Admin” and “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.

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.

Product Support

SleepImage 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 www.clinical.sleepimage.com. 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 located 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.

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 14971:2012
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 Directive	MDD 93/42/EEC: 2007
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	Recorders: Recorder List	Profile: Edit / Save Account Name Admin Name	Settings: Change Username & Password	Help: Instructions for Use Document Links	Sign Out	Store
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Clinician Users have the following Tabs available to navigate the SleepImage System:

Patients: Patient List	Recorders: Recorder List	Profile: Edit / Save Account Name Admin Name	Settings: Change Username & Password	Help: Instructions for Use Document Links	Sign Out
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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.com>, which can be accessed using commonly used browsers such as Chrome, Edge, Firefox and Safari. The SleepImage System has two user roles: [Administrator](#) and [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	SpO₂
Sampling Rate	100 Hz	75 Hz	1 Hz
Digital Resolution	8 bit	n/a	n/a
Measurement Range	n/a	n/a	0 – 100%
Accuracy Range (70-100%)	n/a	n/a	+/- 3 digits









Data Sources

Data recording devices that have been identified to create digital documents compatible for use with the SleepImage System, meeting the data input acquisition characteristics defined in the table above are the following:

SleepImage M1 (ECG)	Nonin 3150 BLE (PPG)	Checkme O2 (PPG)	SI Ring PO2 (PPG)	SI Ring PO4 (PPG)
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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 and Clinicians.
-  **Remove** Patients and Studies.
-  **Edit** Patients and Clinicians.
-  **View** Individual Patient's Studies.
-  **Assign** Clinicians to Patients.
-  **Flag** Recorders to Patients.
-  **Upload** Patient Studies.
-  **Share** Patient



Read this Website IFU Document in full to learn how to use the SleepImage website.

Read [Sleep Data Recorder IFU](#) to learn how to use the ECG Recorder.

Read [SleepImage Mobile App IFU](#) (Android and iOS) to learn how to use the PPG Recorders (PLETH and SpO₂).

Read [Introduction to SleepImage](#) in full to learn how to use the information SleepImage presents.

SleepImage User Roles

There are two user roles, Admin Role and 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.









Sign Up

- A unique, valid email address is required to Sign Up for an Account. It is recommended that this email address is used as the Admin Username, as it becomes the main contact for the Account, including all Store transactions.

Store

- Only the Admin Role can access the Store, using the email address used to Sign Up for the Account. Sales Orders and Invoices are sent to that email address.








Each Account can have only one Admin role who can perform the following tasks:

-  **Add Clinicians & Patients**
-  **Edit Clinicians & Patients**
-  **Remove Patients**
-  **Assign Clinicians to Patients**
-  **Review Patient Studies**
-  **Flag Recorders** (this feature is optional and designed for convenience)
-  **Upload Studies** (only applicable for ECG Sleep Data Recorder)
-  **Share Patients** with other SleepImage System Users

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
-  Edit Patients
-  Remove Patients
-  Review, Evaluate & write Clinical Notes for Patients
-  Flag Recorders (this feature is optional and designed for convenience)
-  Upload Studies (only applicable for ECG Sleep Data Recorder)
-  Share Patients with other SleepImage System Users


Account Registration

SleepImage Accounts are for licensed healthcare practitioners. 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.

1. Go to www.SleepImage.com and scroll down until you see the “Sign Up” button.
2. Click “[Sign Up](#)”.
3. Enter a **unique & valid email address** for the Admin (this becomes the main contact for the Account).



The image shows a screenshot of the SleepImage System Sign Up registration page. At the top is the SleepImage logo, which consists of the word "sleep" in a sans-serif font and "image" in a script font, with a stylized orange arc above the "i". Below the logo is the heading "SleepImage System Sign Up". Underneath is a form with an orange button labeled "EMAIL" and a series of four dots, with the first dot being orange. Below this is a paragraph of text: "Welcome to SleepImage Account Registration. You are a couple of steps away from signing up for a new SleepImage System account. Please enter your email address in the field below to send yourself an email for verification." At the bottom of the form is a label "Email" next to a text input field, and an orange "Sign Up" button.

4. Click  to send a verification email to your e-mail address.
5. In your Inbox, look for email named: **SleepImage Registration**.
6. Within the email, click on the link as noted below (*ensure that the email is not in your Junk folder*).

Verifying Your Email Address

You have selected AdministratorEmail@domain.com as your contact email address for your account with SleepImage. Please verify that this email address belongs to you by clicking **HERE** to continue your registration process.

- Next, click on the checkbox to open the User Agreements for your review.



SleepImage System Sign Up

REGISTER SELECTION

- ☐ I have read and agree to SleepImage Terms of Use Agreement & Privacy Policy. I consent to the processing of my personal information, including sensitive personal information in the manner set forth in the SleepImage Privacy Policy.

- Read the User Agreements and if you agree, click on the “Agree” button.

I have read and agree to SleepImage Terms of Use Agreement , Privacy Policy & Privacy Practices Concerning Personal Health Information .
I consent to the processing of my personal information, including sensitive personal information in the manner set forth in the SleepImage Privacy Policy.

Agree **Reject**

- Fill in all required information (highlighted fields) and click on “Register”.

Note: It is recommended to use the email that was used to Sign Up for the Account, as the Admin Username. This will make it convenient for the Admin to Sign In to the SleepImage Store, which requires an email address as the Username.



SleepImage System Sign Up

REGISTER ADMIN

<input type="text" value="Clinic Name"/> <input type="text" value="hugi.hilmisson@gmail.com"/>	<input type="text" value="Select time zone or search country/time zone"/>
<input type="text" value="Admin First Name"/> <input type="text" value="Admin Last Name"/> <input type="text" value="Admin Middle Initial (optional)"/>	<input type="text" value="Admin Username"/> <input type="password" value="Admin Password"/> <input type="password" value="Confirm Password"/>
<input type="button" value="Register"/>	

SleepImage Store

At the SleepImage online [Store](#), the Admin may purchase Credits, Sleep-Data Recorders & Accessories.

If you are a Non-U.S. customer, please contact sales@sleepimage.com to ask if SleepImage is available in your country.

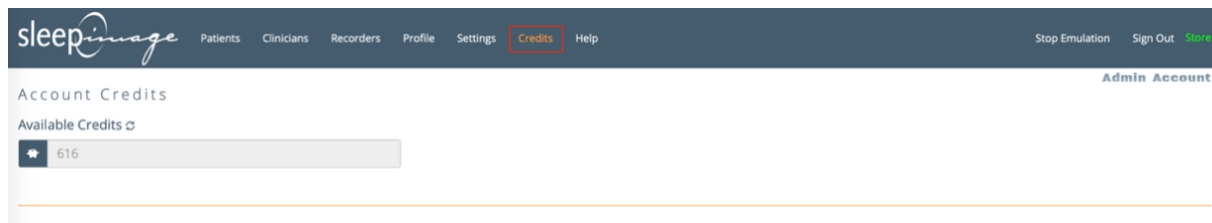


Admin credentials need to be used to Sign In to the SleepImage Store (you may have to allow pop-ups).

1. Click on the [Store](#) button at the top right of the screen.
2. Sign In using the **email address and password created for the Admin role** in your account.
3. Select the products you wish to Purchase by clicking **Add to Cart**.
4. Complete your purchase by checking out.
5. Report Credits will be automatically added to your account after checkout to generate reports for uploaded studies.

Credits

View Available Credits and Credit History in the Credits Tab.



Credit History Report

The Credit History report is exportable for your convenience.

Credit History

Date **11/19/2018 09:02:34 AM**
Time Zone **America/Denver**
Account **NorthernLight**

[Export History](#)


Username	Applied Date	Patient	Patient Id	Type	No. of Studies	Credits	Ending Total
Admin5	11/18/2018 06:58:22 PM	Cansino, Rita		Upload	6	(6)	37
Admin5	11/18/2018 06:56:33 PM	Redding, Ellis		Upload	4	(4)	43
Admin5	11/18/2018 03:53:58 PM	Wilkes, Annie		Upload	1	(1)	47
Admin5	11/18/2018 03:50:20 PM	Sheldon, Paul		Upload	1	(1)	48
Admin5	11/18/2018 02:45:38 PM	Bowman, Dave		Access		(1)	49
Admin5	11/17/2018 11:38:03 PM			Add Credits			50
Admin5	11/16/2018 03:04:07 PM	Goldsmith, Fran		Access		(1)	0
Admin5	11/14/2018 11:40:52 PM			Add Credits			1


Orders & Shipping Information


Select the Store link in the top right-hand corner of the menu bar to view past orders, invoices and shipment tracking information.


Click on **Orders** to see your Order history.


My Account


[Orders](#)


[Addresses](#)



[Payment Methods](#)



[Store Sign-Out](#)



[Clinical Sign-In](#)


Hello (not ? [Log out](#))From your account dashboard you can view your [recent orders](#), manage your [shipping and billing addresses](#), and [edit your password and account details](#).


Click on the **Order Number** to see information relating to each order.


[Orders](#)


[Addresses](#)


[Payment Methods](#)


[Store Sign-Out](#)


[Clinical Sign-In](#)

Next

To save an invoice for your records. Click on the Order number (see above) and Click on the Print Invoice link.

Order details

Product	Total
Report Credits x 2	\$29.98
Subtotal:	\$29.98
Tax:	\$0.00
Payment method:	Visa ending in 5218
Total:	\$29.98

[Print Invoice](#)

The invoice for that Order will open and you can print/save to PDF.

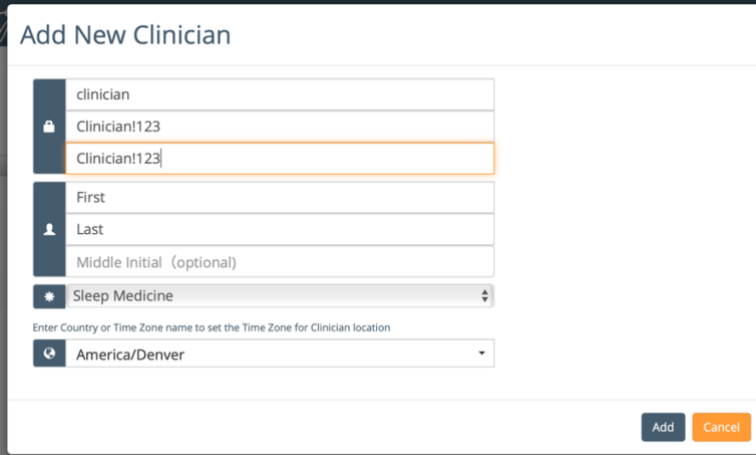
SleepImage User Tasks

Adding & Editing Clinicians

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

Add a Clinician

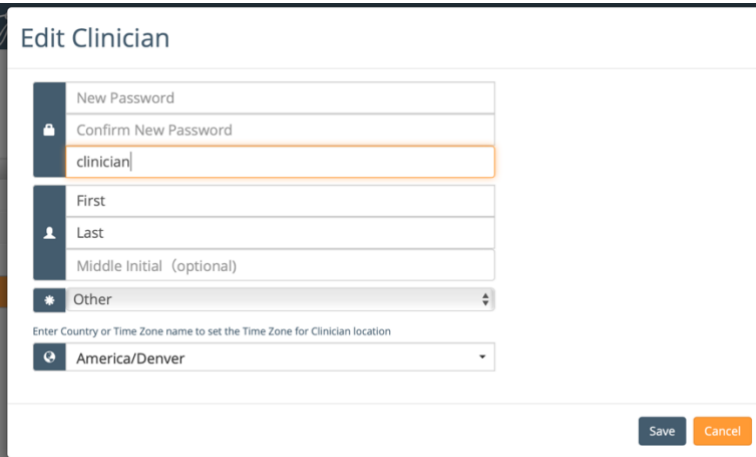
To add a Clinician, click the Plus icon. An Add New Clinician window will appear. Enter Clinician information and Add.



The 'Add New Clinician' form is a modal window with a title bar. It contains several input fields: a text field for 'clinician', a password field for 'Clinician!123', and a text field for 'Clinician!123'. Below these are fields for 'First', 'Last', and 'Middle Initial (optional)'. A dropdown menu is set to 'Sleep Medicine'. Below the dropdown is a text input for 'Enter Country or Time Zone name to set the Time Zone for Clinician location' and a dropdown menu set to 'America/Denver'. At the bottom right are 'Add' and 'Cancel' buttons.

Edit a Clinician

To Edit a Clinician's information, select the Clinician's name, then click the pencil icon. Enter Clinician Information and Save.

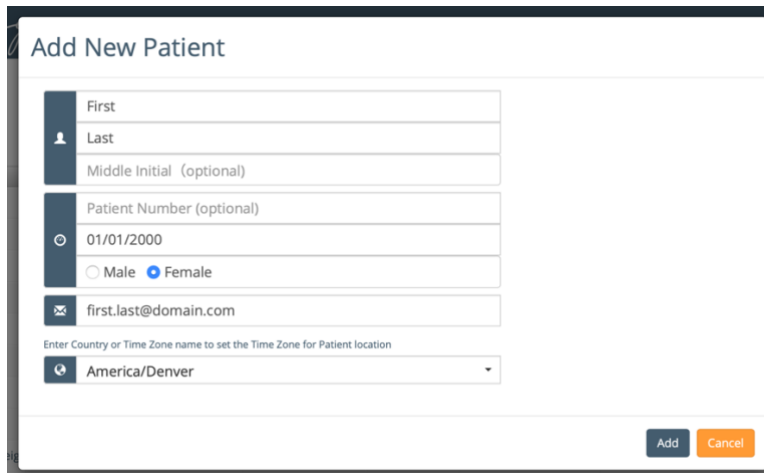


The 'Edit Clinician' form is a modal window with a title bar. It contains several input fields: a text field for 'New Password', a password field for 'Confirm New Password', and a text field for 'clinician'. Below these are fields for 'First', 'Last', and 'Middle Initial (optional)'. A dropdown menu is set to 'Other'. Below the dropdown is a text input for 'Enter Country or Time Zone name to set the Time Zone for Clinician location' and a dropdown menu set to 'America/Denver'. At the bottom right are 'Save' and 'Cancel' buttons.

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.

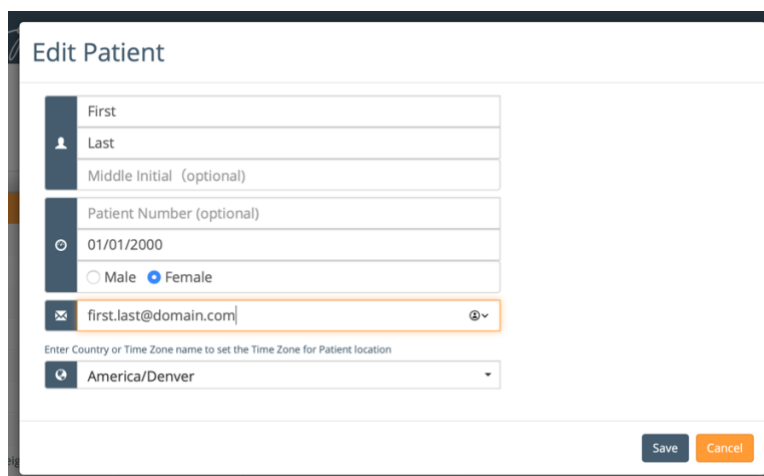


The 'Add New Patient' form contains the following fields and options:

- First (text input)
- Last (text input)
- Middle Initial (optional) (text input)
- Patient Number (optional) (text input)
- Date (01/01/2000) (date picker)
- Gender: ☐ Male ☒ Female
- Email (first.last@domain.com) (text input)
- Time Zone: Enter Country or Time Zone name to set the Time Zone for Patient location (dropdown menu showing America/Denver)
- Buttons: Add (blue), Cancel (orange)

Edit a Patient

To Edit a Patient's information, select the Patient's name, then click the pencil icon. Enter Patient's Information and Save.

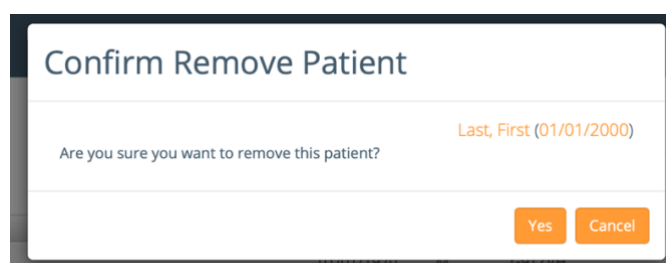


The 'Edit Patient' form contains the following fields and options:

- First (text input)
- Last (text input)
- Middle Initial (optional) (text input)
- Patient Number (optional) (text input)
- Date (01/01/2000) (date picker)
- Gender: ☐ Male ☒ Female
- Email (first.last@domain.com) (text input)
- Time Zone: Enter Country or Time Zone name to set the Time Zone for Patient location (dropdown menu showing America/Denver)
- Buttons: Save (blue), Cancel (orange)

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 will be permanently removed.** Credits used to upload or view their study data will be forfeited.




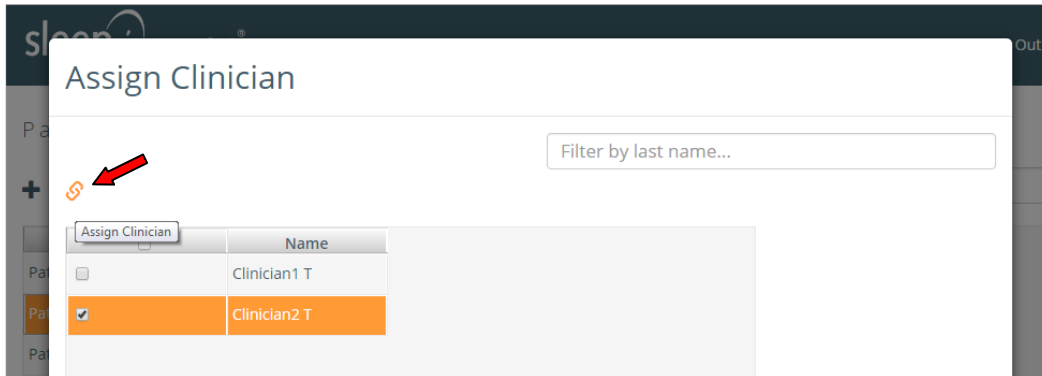
The 'Confirm Remove Patient' dialog contains the following elements:

- Title: Confirm Remove Patient
- Text: Are you sure you want to remove this patient?
- Text: Last, First (01/01/2000)
- Buttons: Yes (orange), Cancel (orange)

Assign Clinicians to Patients


Only the Admin Role can Assign Clinicians to Patients.

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.



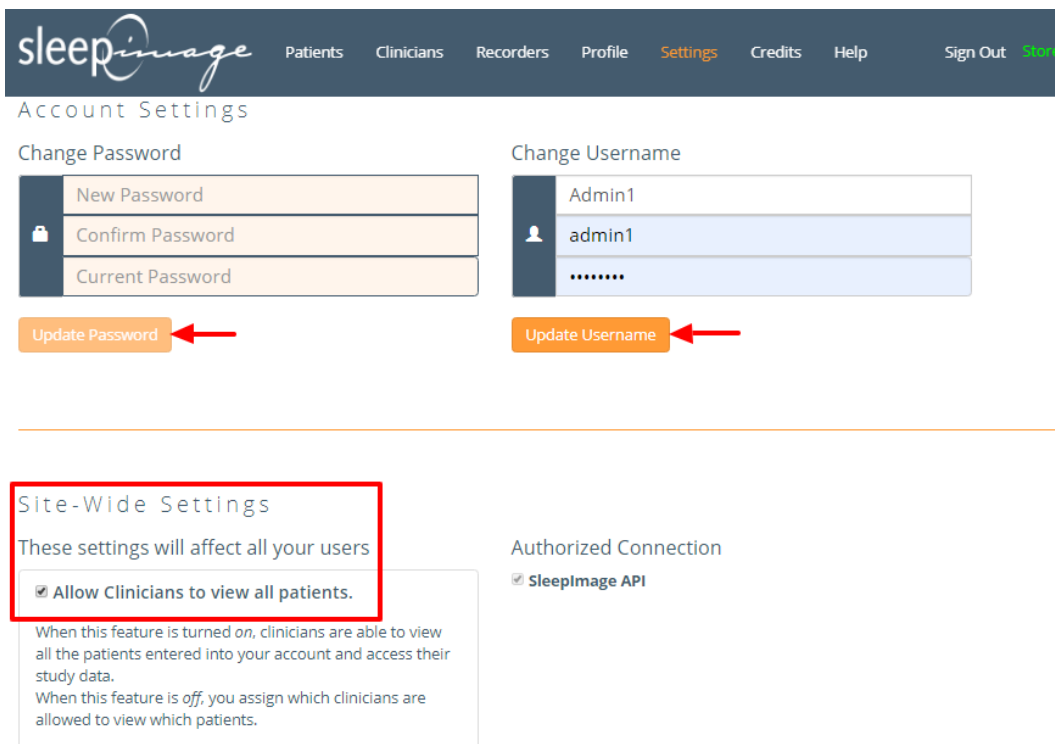
The image shows a modal window titled "Assign Clinician". At the top right is a search bar labeled "Filter by last name...". Below it is a table with two columns: "Assign Clinician" and "Name". The table contains two rows: "Clinician1 T" with an unchecked checkbox, and "Clinician2 T" with a checked checkbox. A red arrow points to the "Assign Clinician" button in the top left corner of the modal.

Assign Clinician	Name
<input type="checkbox"/>	Clinician1 T
<input checked="" type="checkbox"/>	Clinician2 T

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. The Settings Tab is also used to change Username and Password for the Admin Role.



The image shows the "sleepimage" Account Settings page. The top navigation bar includes links for Patients, Clinicians, Recorders, Profile, Settings (highlighted), Credits, Help, Sign Out, and Store. The page is divided into two main sections: "Change Password" and "Change Username".

Change Password: Includes fields for "New Password", "Confirm Password", and "Current Password". A red arrow points to the "Update Password" button.

Change Username: Includes fields for "Admin1", "admin1", and a masked password field. A red arrow points to the "Update Username" button.

Site-Wide Settings: A section highlighted with a red box. It contains the text "These settings will affect all your users" and a checked checkbox labeled "Allow Clinicians to view all patients." Below this is explanatory text: "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: Includes a checked checkbox labeled "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 licenced healthcare professional
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.

Patient List



Name	Last Study	Recorder	Patient Number	DOB	Gender	Patient Id	Shared
Patient, Shared	03/18/2021			01/01/1970	M	ZP979Q	

In the Patient Share screen, enter the email address of the recipient, click the  button, then click yes to confirm.

Share Patient

Are you sure you want to share patient ZP979Q with Patient Recipient (recipient@recipient.com)?


Yes Cancel



recipient@recipient.com


Filter by Clinic name...

If the email address is not found, you'll see an error message saying "the account does not exist....". 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.

Name	Last Study	Recorder	Patient Number	DOB	Gender	Patient Id	Shared
Patient, Shared	03/18/2021			01/01/1970	M	ZP979Q	 Patient Recipient...

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 a patient's profile,
- Delete a patient,
- Delete a patient's study,
- Share a patient (string sharing),
- Accept/Reject pending sleep studies.

Upload a Study

The uploading process is dependent on the Data Recorder used to collect the data for analysis.

Data from PPG Sleep Data Recorders 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. Also review the App infographic instruction page on our website: <https://sleepimage.com/sleepimage-mobile-app/>

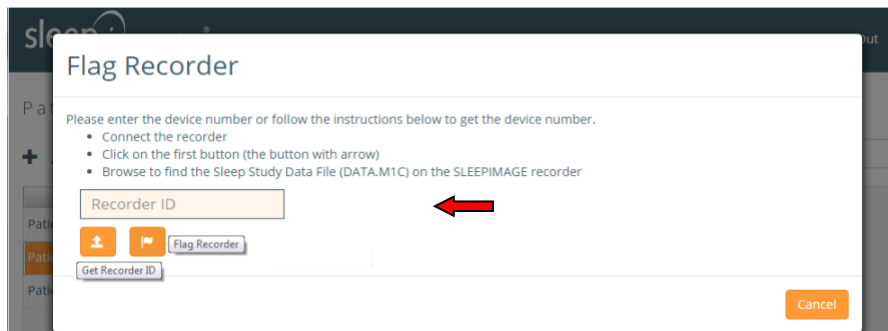
If multiple studies are done on the same patient, studies appear in SleepImage one at a time. [Accept or Reject](#) each study in the Pending list until all studies have been accepted or rejected for report generation.

Data from the ECG Sleep Data Recorder is uploaded manually with USB-cable connecting the recorder to a computer with a supported web browser and internet connection. Please refer to the [Sleep Data Recorder Instructions](#), available in the Help section of your SleepImage account for further information.

Flag a Recorder

Flag a Recorder is an optional tool to help track which Recorder has been assigned to a specific Patient.

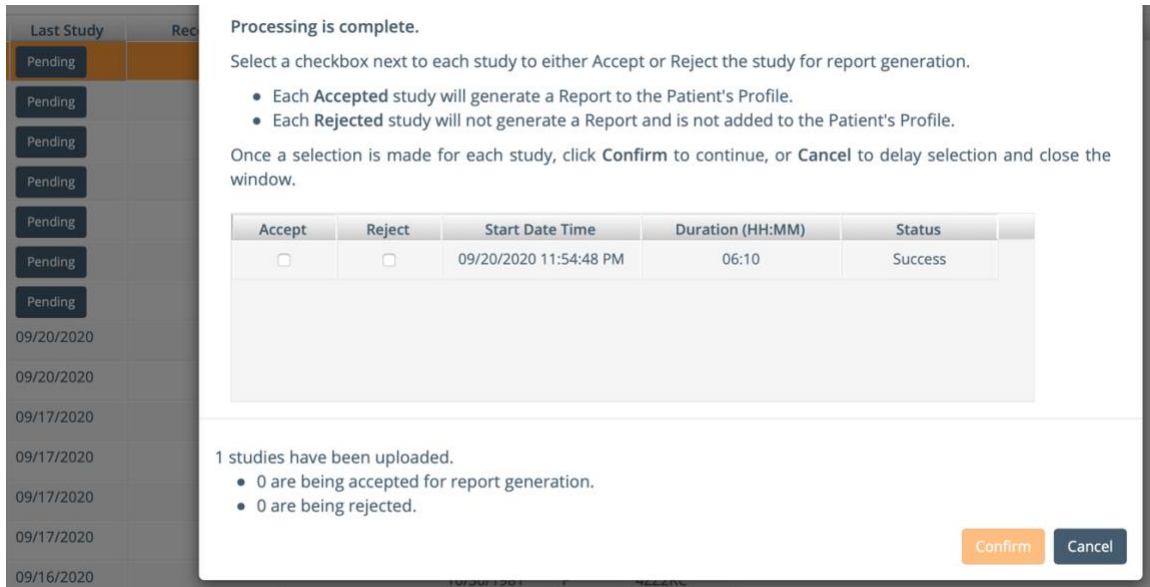
To Flag a Recorder simply click on an active Patient's name/row and click the Flag icon. A screen will appear asking for the Serial Number. Enter the Serial Number in the field. When completed, click on the Flag icon to save.



Flagging the Recorder to another Patient clears the flag from the previous Patient.

Accepting / Rejecting Uploaded Studies

Before a Report is generated the User (Admin or Clinician) has to Accept or Reject studies that are listed as “Pending” for the Patient. Click on “Pending” in the Patient list to open a popup window to “Accept” or “Reject” studies. Accepting studies will use Report Credits and populate the study in the Patient Profile:



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
<input type="checkbox"/>	<input type="checkbox"/>	09/20/2020 11:54:48 PM	06:10	Success

1 studies have been uploaded.

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

Confirm **Cancel**

This ensures that you can verify the Uploaded data contains successful studies before using Report Credits. The Upload Summary displays the start time and date for each study as well as the sleep study's duration in HH:MM and the status of the processing:

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.

Fail – The study can't be processed. The most likely cause is a very short study without enough data for analysis.

Accepted sleep studies utilize Credits for the analysis to generate the SleepImage Report. Credits are used for two purposes:

1) **To View** Patient sleep studies

- One (1) Credit is required for each **ECG Sleep Data Recorder** study accepted for Report generation.
- Two (2) Credits are required for each **PPG Sleep Data Recorder** study accepted for Report generation.
- Reports can be downloaded as a PDF (and study values can be exported as a CSV) to save locally.
- Accepted studies generate a report that is available to review or download for 60 days.

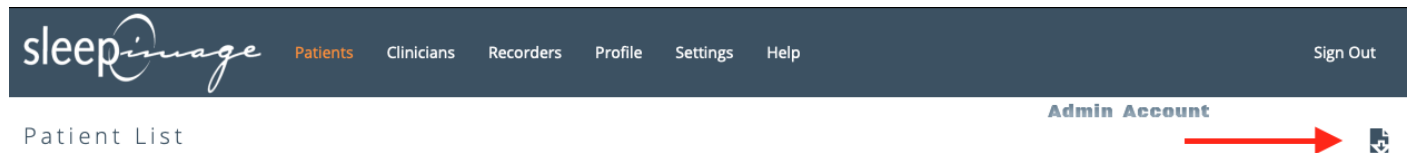
2) **Accessing** expired data for each Patient

- One (1) Credit is required for each study that is older than 60 days to reactivate access to review or download.

Credits are deducted from the credit balance based on the type of the sleep study as explained above and the number of studies accepted for report generation.

CSV Account Download

You can download a single CSV containing all reports in your account, where each row is an individual report. To do that, simply go to your Patient tab and click on the CSV-Download icon in the top right hand corner of the screen.

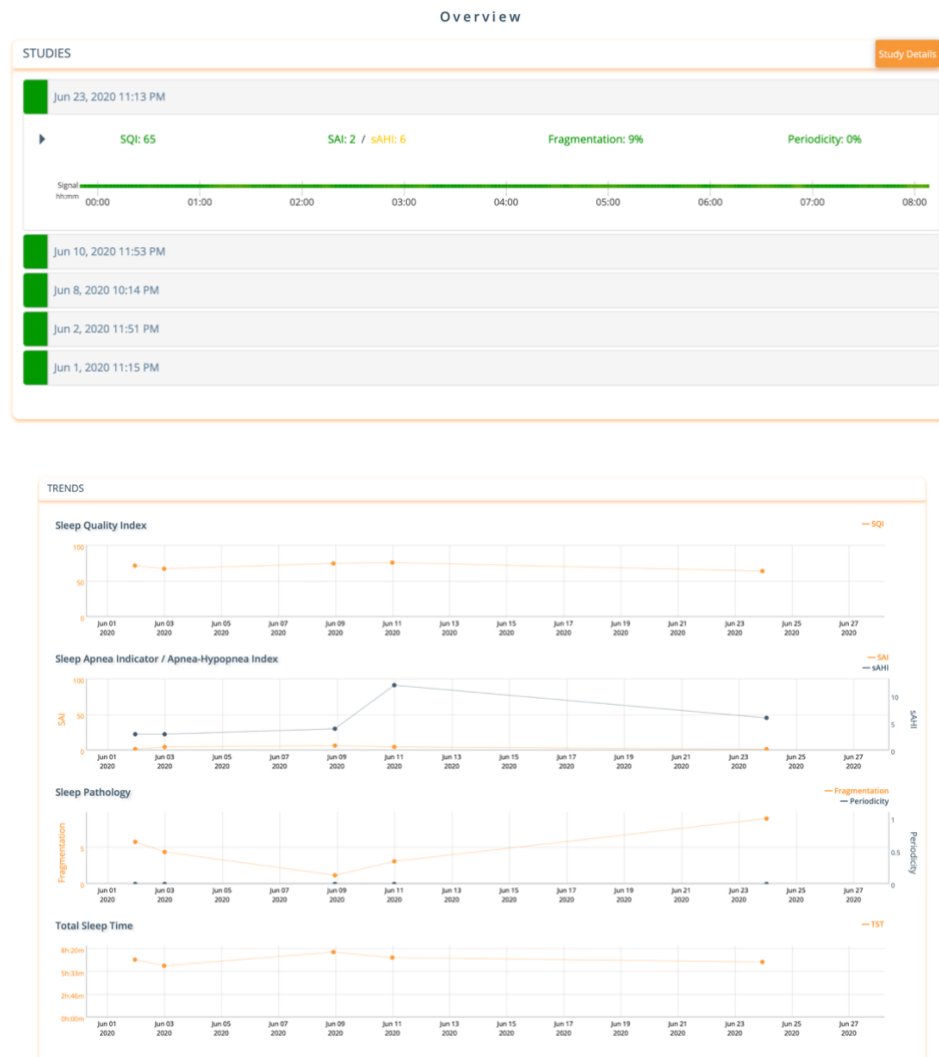


Patient Overview

Select the Patient in the Patient list and either double-click on the Name or click the bar graph icon to open the overview of that patient's list of studies. This overview lists all uploaded and accepted studies for this patient with the latest study at the top of the list. The color-coding to the left of each study indicates the Sleep Quality Index (SQI) as 'Red'; 'Yellow' or 'Green' with reference to expected SQI value that are dependent on age (children / adults).

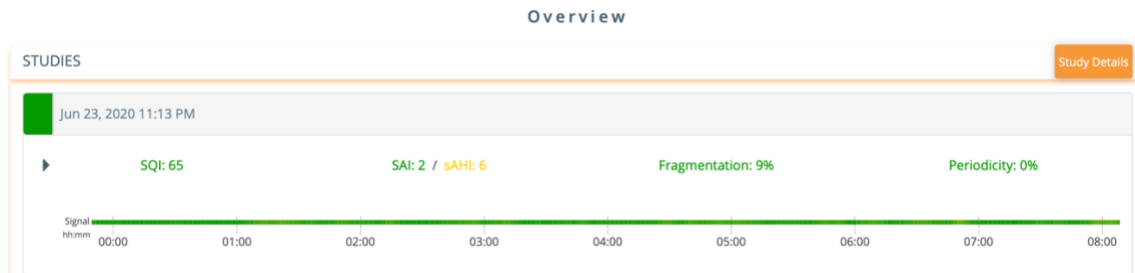
This overview also shows other primary output values color-coded as well as sleep duration and signal quality for a quick review. For further information, please refer to [Introduction to SleepImage](#) that contains comprehensive information regarding how to review the numerical and graphical information to better understand your Patients' sleep.

Trend graphs are also shown on this same page to provide a quick overview of how the primary biomarkers from all studies uploaded for this Patient trend over time, that can assist management of sleep disorder therapy.



Study Details

To review a specific study, select it from the list of studies in the overview and click on Study Details button in the top right-hand corner. The Report can be exported, either as a printable PDF or CSV format to save the output values locally. If patient data access has expired (uploaded more than 60 days earlier), apply a Report Credit to re-access that study. Access to a Patient's previous study data is also made available for 60 days when uploading a new study for that Patient.



To select a different study for review, use the dropdown to choose from the list of the Patient's uploaded studies.

The screenshot shows the 'Study Details' page. At the top, there's a navigation bar with 'sleepimage' logo and links for Patients, Clinicians, Recorders, Profile, Settings, and Help. There are 'Sign Out' and 'Store' buttons. Below the navigation bar, the patient data is shown: 'Patient Data: Doe, John (04/04/1967)'. The 'STUDY DETAILS' section has a 'Return To Overview' button. A 'Selected Study:' dropdown menu is shown with 'Jul 24, 2015 8:00 PM' selected. A red arrow points to the dropdown arrow. To the right, a 'Selected Page:' dropdown menu is shown with 'Reports' selected. Below these, there are 'PDF' and 'CSV' buttons highlighted with a red box. The main content area shows a 'Sleep Quality Report' for 'Jul 24, 2015' from '08:00 pm to 02:26 am'. To the right, patient information is listed: 'Name: John Doe', 'Patient Id: A11004', and 'Date Of Birth: Apr 4, 1967'.

Further information on reviewing the signal quality can be found on the SleepImage website under [Learn More](#).

Study Report

The report is autogenerated displaying information commonly used for sleep evaluation to aid diagnosis or management of sleep disorders. The quality of the data collected during the sleep study is presented on the signal quality line as green (good signal), yellow and red (compromised signal). For further information on Sleep Quality, Sleep Opportunity, Sleep Apnea and Sleep Pathology, click the triangles located to the left of the headlines above the two rows of the colored boxes to expand the view. Snore and Body Position are optional parameters, reported when available, neither is used in calculation of Sleep Quality, Sleep Duration, Sleep Apnea or Sleep Pathology.



Clinician Notes

Add Note

Clinician Notes is a tool that is only available for Clinicians. Published Clinician Notes will become part of the Report. To write Clinician Notes, select the 'Add Note' button below the Report Test Summary.

Clinician Notes is an important tool for the Clinician to document decisions and share with other Clinicians in multi-disciplinary care. When this section is completed click Publish. Multiple notes can be added to each study.

Add Clinician Notes :

☐ Metric ☒ US Customary

Height : ft in Weight : lbs BMI :

Medicare : ☐ Yes ☐ No [Clear](#)

Epworth Sleepiness Scale :

Sleep Complaints :
Select all that apply

<input type="checkbox"/> Excessive Daytime Sleepiness	<input type="checkbox"/> Irregular (Paused Breathing During Sleep)
<input type="checkbox"/> Snoring	<input type="checkbox"/> Bruxism / Teeth Grinding
<input type="checkbox"/> Morning Headaches	<input type="checkbox"/> Waking Up Gasping Or Choking
<input type="checkbox"/> Difficulty Falling Or Maintaining Sleep	

Medical History

Character Count: 0 / 1040

Medications Used :	Treatment Device Used :
1. <input type="text"/>	1. <input type="text"/>
2. <input type="text"/>	2. <input type="text"/>
3. <input type="text"/>	3. <input type="text"/>
Add More	Add More

Diagnosis :
Select all that apply

<input type="checkbox"/> G47.33 Obstructive Sleep Apnea	<input type="checkbox"/> G47.31 Primary Central Sleep Apnea
<input type="checkbox"/> G47.32 High Altitude Periodic Breathing	<input type="checkbox"/> G47.9 Sleep Disorder, Unspecified
<input type="checkbox"/> G47.10 Hypersomnia, Unspecified	<input type="checkbox"/> F51.01 Primary Insomnia
<input type="checkbox"/> R06.3 Periodic Breathing	<input type="checkbox"/> R06.83 Snoring
<input type="checkbox"/> Other Fatigue	<input type="checkbox"/> Other

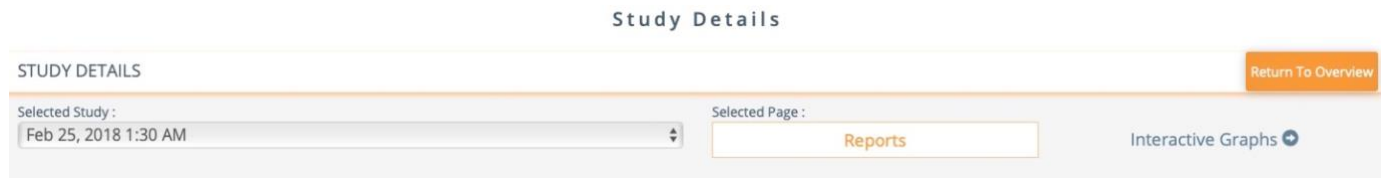
Impressions and Recommendations

Character Count: 0 / 1040

Publish

Interactive Graphs

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



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 to recalculate the auto-generated study output, after moving the Green and Red markers (as shown with the arrow in the following picture). This action narrows the window of analyzed data under review and re-calculates SleepImage values based on the period selected.

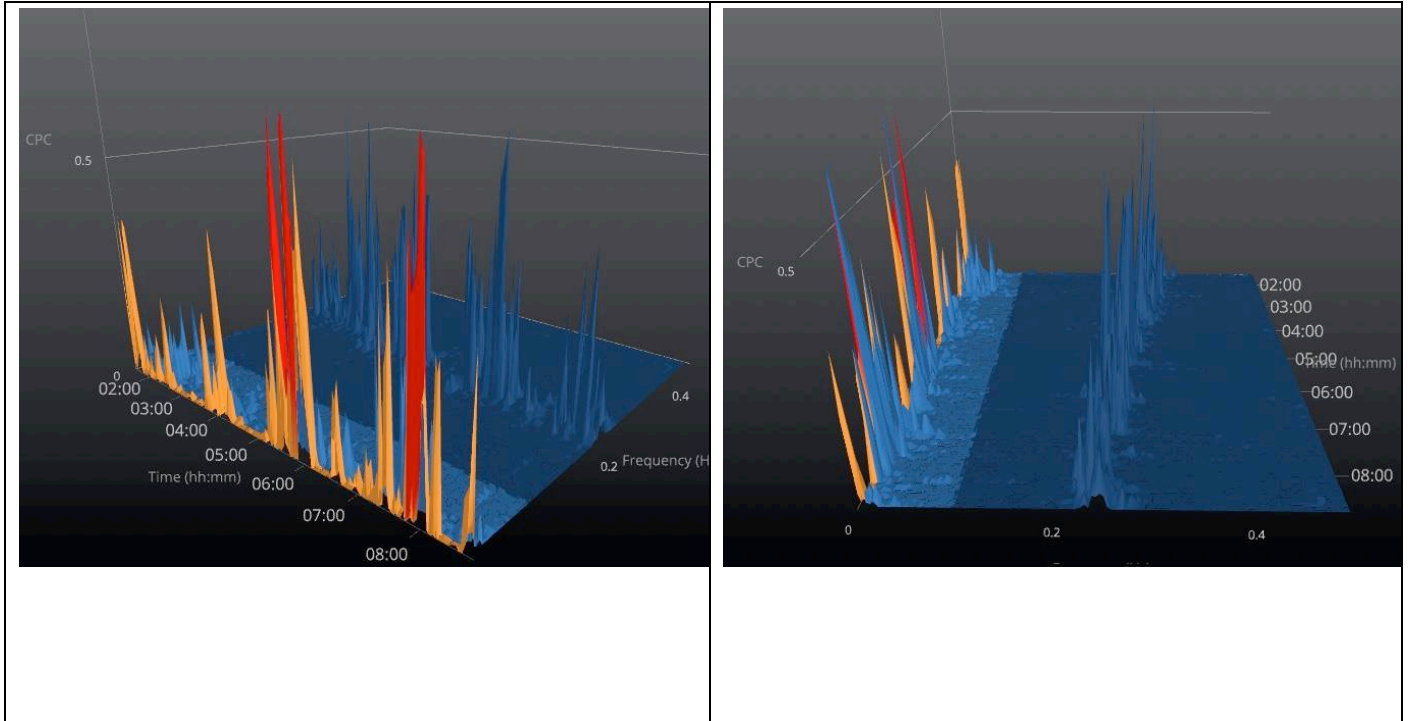


For better view of the peaks on the spectrogram, click on the HFC-, LFC- and vLFC- icons to hide/display each frequency band.

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.



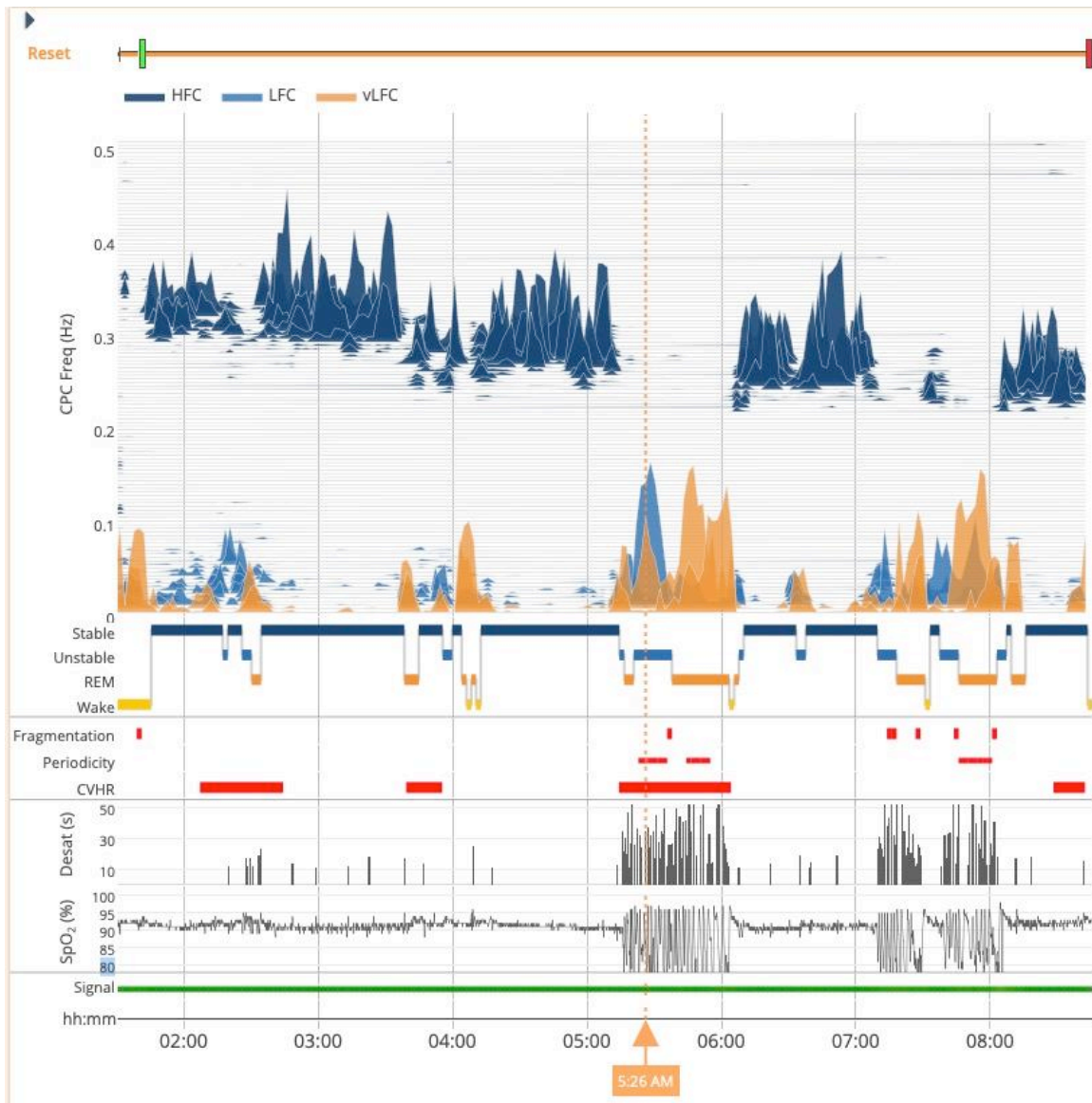
Signal Quality

The SleepImage interface uses color to represent the signal quality. The signal quality is updated continuously throughout the study. Intermittent signal loss is displayed on the "Signal" bar as yellow and frequent or complete signal loss as red. During periods of complete signal loss, the software does not recognize the input signal and the spectrogram will be blank for that time period and no data will be available or analyzed for that time period. Further information on reviewing the signal quality can be found on the SleepImage website under [Learn More](#).

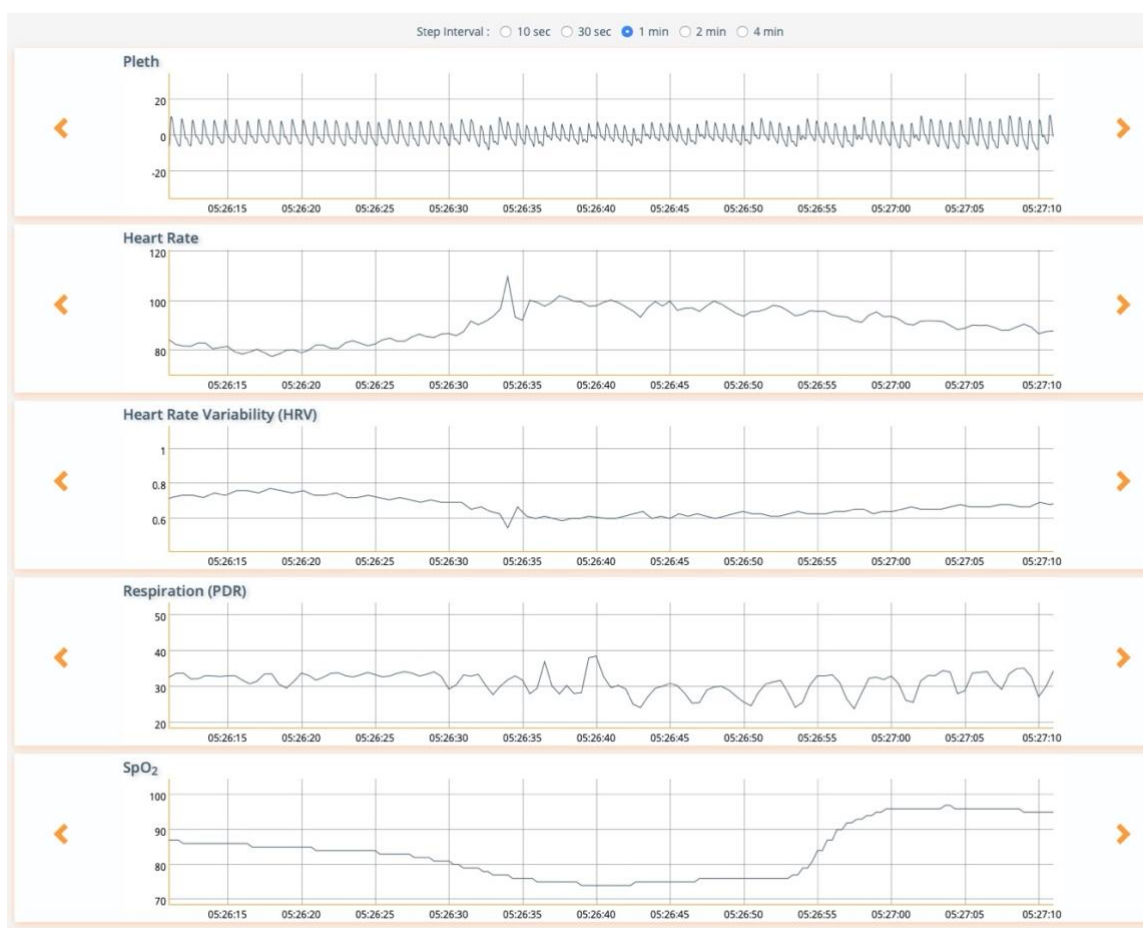
Clinical decisions should not be made using time periods where signal quality is red.

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.

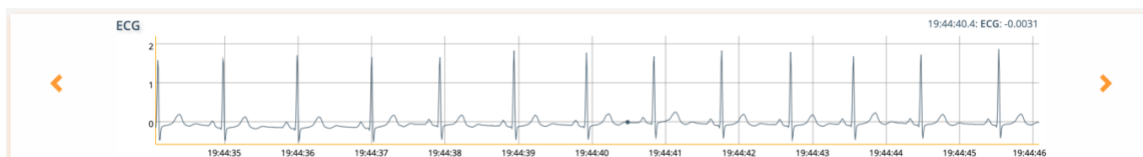


Traces can be set for different time intervals shown in the window. Interval windows can be selected as 10 sec, 30 sec, 1 min, 2 min, or 4 min. Use the arrow buttons to move backward or forward to look for patterns and associations for concurrent events.



Zoom function

For a closer look at any of the Traces, it is possible to Zoom in, either horizontally or vertically, by holding a mouse-click and dragging to the desired zoom function. Double clicking on the Trace will bring it back to its original size.



Remove Sleep Studies

Delete

Clinician Users can remove Patient Studies from the Interactive Graphs 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'.

Deleted studies will be permanently removed and cannot be recovered.

Study Details

STUDY DETAILS

Return To Overview

Selected Study :
Aug 3, 2020 10:23 PM

Selected Page :
Reports

Interactive Graphs

Open 3D

Recalculate

Delete

Delete Study

Aug 3, 2020 10:23 PM

Are you sure you want to remove this study?

Deleting this study will remove it from your account and the action is irreversible.

Yes

No

FAQs

How can I use the Data Recorders to record multiple studies for a Patient?

ECG Sleep Data Recorder will be able to perform approx. 5 sequential studies before depleting battery power. Only record multiple sequential studies for ONE PATIENT before Uploading the data, Resetting the Recorder and prepare it for use with another Patient to ensure that the data is uploaded to the proper Patient.

The PPG Sleep Data Recorders should be charged after each study. These Recorders do not need to be reset as they don't store any data. If the same mobile device is used for more than one Patient **each patient must sign into the app using their unique Patient ID and Date of Birth before using the Recorder**, so reports are uploaded to the correct patient.

Please also review:

- The [Sleep Data Recorder Instructions for Use](#) for more information about the ECG Sleep Data Recorder.
- The [SleepImage Mobile App Instructions for Use](#) for more info about using PPG Recorders to record and upload studies.

Why isn't my Patient in the Patient's List?

Either the Patient profile hasn't been created, or the Admin hasn't Assigned you to the Patient.

Why can't I see the Patient's Studies?

You may be seeking access to the Patient's historical data that was uploaded more than 60 days prior. You can gain access to that data by Applying a Credit which will allow access for 60 days.

Why can't I Upload a study?

ECG Sleep Data Recorder: If the Patient has a pending Upload, no new Uploads can be made. Clear the pending status by following the Accept/Reject Process.

PPG Sleep Data Recorders. If the Patient has a pending Upload, no new Uploads will be sent by the App. Clear the pending status by following the Accept/Reject Process until no new 'Pending' studies appear.

Can I test more than one patient using the same Recorder back-to-back?

ECG Sleep Data Recorder: No. Studies from the ECG Recorder should be uploaded and then reset before the Recorder is given to the next patient.

PPG Recorders: Yes. Data is automatically uploaded from the SleepImage App, but **before** a new patient starts a study, they **MUST** sign into the app using their unique Patient ID and Date of Birth to ensure that reports are uploaded to the correct patient. There is no need to reset PPG Recorders between patients as there is no data stored on the recorders.

How do I interpret my Patient's Sleep Studies?

Please review our most comprehensive tool for learning about the science behind SleepImage, the [Introduction to SleepImage](#) document and look at the [Learn More](#) tab on our website. The information will provide you with the foundation on the science behind the Sleepimage Method (Cardiopulmonary Coupling; CPC), how to evaluate the data presented in the SleepImage Report as well as a number of case-studies.

How are Report Credits utilized?

- 1) Uploading new sleep studies for your patient. Each study requires 1 or 2 Credits, depending on the Recorder used. Patient access remains open for 60 days once credit is applied.
- 2) Accessing historical sleep studies outside the Upload process. If you do not have any studies to upload, but want to access the patient's historical data, 1 Credit can be applied to open patient access for 60 days.