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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" password or common words and passwords which are the same for each device and vulnerable to public disclosure.
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Introduction
This document refers to users of the website 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.

The website is an interactive and flexible application designed to analyze and display uploaded ECG data collected during sleep. The website stores sleep study data with Patient demographics provided by the Admin or Clinician. Sleep study data is presented in the form of tables and graphics and has tools to track trending information collected from multiple studies for each Patient.

Before using the SleepImage website, please read this manual carefully.

Icons used in SleepImage
- **Add** - allows you to Add to your Lists (Patients and Clinicians).
- **Remove** - allows you to Remove Patients and Studies (*Only Clinicians can remove studies*)
- **Edit** - allows you to edit Patients and Clinicians.
- **View** - takes you to the Patient Data page.
- **Assign** - takes you to the Assign Clinician Window.
- **Flag** - allows you to Flag a recorder to a user.
- **Upload** - takes you to the Upload Studies window.
- **Apply** - used to Apply Product Keys to add Credits.

Intended Use
The SleepImage System is medical software that establishes sleep quality, intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders based on Electrocardiogram (ECG) recordings, typically collected during sleep. The results of these analyses are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and sleep pathology. These presentations and reports are intended to inform or drive clinical management. The SleepImage System is intended for use on a general-purpose computing platform. It is not a monitor and does not issue alarms.

Indications for Use
The SleepImage System is medical software that establishes sleep quality. The SleepImage system analyzes, displays and summarizes ECG data, typically collected during sleep that is intended for use by or on the order of a Health Care Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management.

Cautions, Warnings
The Sleep Data Recorder and SleepImage Application Software do not monitor or diagnose the patient and do not issue any alarms. It is assumed that users are trained in the usage of the Internet and personal computers before reading this manual.

Supported Browsers
SleepImage is designed for modern, supported browsers such as: Chrome, Edge, Firefox and Safari. *Microsoft stopped supporting Internet Explorer (IE) in 2016. To use our site effectively, please use one of the browsers above.*

Certifications
- The CE mark is a declaration that the SleepImage Website and Sleep Data Recorder are in compliance with the EU Medical Device Directive.
- The SleepImage Website complies with ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices.
- The SleepImage Website is cleared by the FDA (K163696).
- The FDA Unique Device Identifier (UDI) is "-B315sleepimage.comO."
The SleepImage Corporate Website

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

SleepImage has been created to help the healthy and the sick. Our technology and system are valuable within the sleep industry because of the ease of use, low cost, accuracy and the ability to screen large populations no matter whether your protocol screens symptomatic or asymptomatic individuals. The SleepImage system is used across a wide range of healthcare and wellness practices...cancer clinics, sleep labs, hospitals, dental practices, pediatrics, sports medicine, etc.

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

Data Acquisition Characteristics

The SleepImage System is a standalone, sleep health evaluation application that provides automated analysis of cardiovascular and respiratory waveforms. The SleepImage System is Software as a Medical Device (SaMD).

The SleepImage Software analyzes evenly sampled normal sinus rhythm ECG waveforms. SleepImage can successfully analyze data that meets the following recommended minimum data acquisition characteristics.

<table>
<thead>
<tr>
<th>Data Acquisition Characteristics</th>
<th>ECG</th>
<th>SpO2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sampling Rate</strong></td>
<td>100 Hz</td>
<td>1 Hz</td>
</tr>
<tr>
<td><strong>Digital Resolution</strong></td>
<td>8 bit</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Measurement Range</strong></td>
<td>n/a</td>
<td>0 – 100%</td>
</tr>
<tr>
<td><strong>Accuracy Range (70-100%)</strong></td>
<td>n/a</td>
<td>+/- 3 digits</td>
</tr>
</tbody>
</table>

Data Sources

- SleepImage M1 [Sleep Data Recorder]
- EDF files containing ECG data collected during sleep that are consistent with the acquisition characteristics mentioned above.

The above list of hardware devices is provided for informational purposes 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 Sources list will be updated as additional Recorders and Data File types are identified and allowed by MyCardio. If your data source is not listed or does not meet the above acquisition characteristics, please contact SleepImage Support.

If the data source has not been allowed for use in the system and you attempt to upload, the following error message will display "The data you are attempting to upload is not recognized by SleepImage. Please contact support@sleepimage.com to see if your data source can be identified and allowed."
SleepImage User Roles

**Admin Role**

The Admin role is designed for a dedicated Practice Manager, Head Administrator, or equivalent in an organization. This role performs all website functions: adds, edits, and removes Patients, and has access to Patient data. The Admin also adds and edits Clinician Accounts including Assigning Patients to their Clinicians. This role can also be used by smaller practices with one Clinician. The Clinician in this case will use the Admin role to create the account and then set up their own Clinician role. The email address on this account receives Sales Orders and Invoices from the SleepImage Store.

The workflow as you use the account can be summarized as follows:

**Sign Up** at [https://clinical.sleepimage.com](https://clinical.sleepimage.com)
- A unique, valid email address is required to sign up for a SleepImage account
- This email is the main contact for the account and receives system and order emails

**Visit the Store** to Purchase Recorders, Electrodes and Credits
- **Sleep Data Recorder Kits** include: ECG Cable, Computer Cable & electrodes for 3 tests.
- **Electrodes** are bundled in a variety of quantities.
- **Credits**:
  - authenticate your Report Credits purchase and enable the credits for use in your account
  - allow you to upload new (and access to previous) studies & reports
  - don’t expire unless used

**Read these Instructions for Use in full** to learn how to use the SleepImage website

**Read the Sleep Data Recorder Instructions for Use** to learn how to use the Recorder

**Add Clinicians** – Add profiles for Clinicians who will review sleep Studies

**Add Patients** – Add a profile for each Patient who will be performing Sleep Studies

**Assign Clinicians** – Clinicians can only see Patients they add and Patients the Admin assigns.

**Apply Product Keys** to add Credits for Report access.

**Upload Studies** – Have patient perform sleep Studies then upload to their Patient profile.

**Reset Recorder** - Reset the Recorder so that it is ready for the next Patient
**Clinician Role**

Clinician user profiles are added by the Admin Role.

The Admin will provide the Clinician with their username and password information. Once signed in, the Clinician role can upload, delete, view, monitor, and analyze their assigned Patients’ uploaded sleep studies. They can also add, edit and remove Patients as well as **Apply Product Keys** to add Credits. Credits are purchased using the **Admin** profile, but Product Keys can be applied to add Credits by either role.

**The process to get started can be summarized as follows:**

1. **Sign In** to the Corporate account, using the credentials provided by the Admin.
2. **Read these Instructions for Use in full** to learn how to use the SleepImage website:
   - Read the **Sleep Data Recorder Instructions for Use** to learn how to use the Recorder.
   - Read the **Clinical IFU** in full to learn how to use the information SleepImage presents.
3. **Add Patients** – if not already completed by Admin.
5. **Document Notes** regarding Patient Studies as needed.

---

**Patient Testing Workflow (example)**

When you’re ready to test a patient:

- **Purchase** and **Add Credits** to your SleepImage profile.
- **Add Patient** to your Patient list.
- Insert Fresh Batteries into the Recorder. (See the **Sleep Data Recorder Instructions for Use**)
- Send the patient home with: a Recorder, the blue ECG cable, instructions, and Electrodes:
  - Recorder holds ~5 studies.
  - Study quantity for each patient is the clinician’s choice, but more than one night is recommended.
  - Electrodes are single-use only. Include enough electrodes to complete the number of studies to be collected.
- Patient returns the Recorder.
- **Upload studies** to that Patient’s profile.
- **Confirm** the studies uploaded successfully by reviewing Patient Studies page.
- **Reset the recorder** to clear the memory.
- You now have 60 days to **review**, and **save** that patient’s studies to PDF.
Admin Account Registration
SleepImage Accounts are for licensed healthcare practitioners. There may only be one Admin profile per organization. You’ll need a unique, valid email address, an Internet connection and a supported browser to complete registration.

1. Go to www.SleepImage.com and click on “Sign In”
2. You’re now at the Sign In/Sign Up page. Click “Sign Up” in the top right corner

3. Enter a unique email address for the Admin (this becomes the main contact for the Account)
4. Click to send a verification email to your entered address
5. Next, go to your email and find the 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 Administrator@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.

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

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.
8. Read the User Agreements and, if you agree, click on the Agree button to acknowledge that you have read and agree with the User Agreements.

   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]

9. Fill in all required information (highlighted fields) and click on "Register".
   *Note: The Admin Username can be, but is not required to be, an email address.*

   ![Register Admin Form](image)

10. Sign In to your new Admin account
11. Upon Sign In, you will see your new account.
12. **Visit the store** to purchase Recorders, Electrodes and Credits.

   ![Store Menu](image)

13. **Apply the Product Key** to add purchased Credits to your profile.
14. **Add Patients**
15. **Add** and **Assign** Clinicians

   *Congratulations on setting up your SleepImage account!*
**SleepImage Store**

At the SleepImage online Store, the Admin will purchase Credits, Recorders and Electrodes. The store is only accessible through the Admin’s SleepImage account. Currently, the Store only accepts orders for U.S. payments and shipments. If you are a Non-U.S. customer, please set up your account, then contact Sales to help complete your order by sending an email including: your name, company name, username, and phone number to weborders@sleepimage.com.

When you click on Store, a new browser window will open and you will be automatically signed into the SleepImage Store. (you may have to allow pop-ups) Your SleepImage Username and password login provide automatic access to the Store. Purchase Recorders, Electrodes and Credits:

1. Click on the Store button at the top right of the screen.
2. Go to the Membership & Report Credits Tab and pick your desired quantity of credits.
3. Enter the quantity you wish to Purchase and click Add to Cart
4. Go to Accessories and add Sleep Data Recorders to the Cart as in quantities as needed to cover your Patient testing schedule. Each Sleep Data Recorder Kit comes with: 1 Sleep Data Recorder, enough Electrodes for three tests, 1 ECG Cable, 1 Computer Cable and 1 Instruction Card.
5. Then add Electrodes & extra ECG Cables to the Cart in quantities as desired.
6. Complete your purchase by checking out.
7. Check your email. The Sales Order contains Product Keys for Report Credits purchased. Product Keys are used to upload and access SleepImage Reports.

**NOTE:** You can review Sales Orders and find Product Keys for purchased credits within the Store, by clicking on your name at the top right of the store. This takes you to your Store Dashboard. Click on View Order to see information relating to each order and to see the Product Keys purchased therein.
Report Credits
When Patient sleep studies are Uploaded to SleepImage for CPC analysis Credits are utilized for Report generation. Each study (screened for successful data by SleepImage’s upload process then accepted by the Admin or Clinician) requires 1 Credit. Credits are available for purchase in the Store. Once purchased, the Credits are added to the account by applying a Product Key (Product Keys are sent to you via email and can also be found in the Store’s Order History) in the Credits Tab of your Account. Credits are used for two purposes.

1) **Uploading** Patient sleep studies
   - One (1) Credit is required for each study accepted for Report generation.
   - Part of the **Upload process** is to select the studies you wish to generate Reports for and which studies to discard (such as: if the study has insufficient data). This way you will always know if your patient has successful studies before outlaying any credits.
   - Reports can be downloaded as a PDF (and study values can be exported as a CSV) then saved to the Patient’s digital medical history file on your network in a secure fashion.
   - When new sleep studies are accepted for Report generation, user access to that Patient’s data remains active for 60 days.

2) **Accessing** historical data for each Patient
   - If the Patient’s data has become inactive, one (1) Credit can be used to reactivate access to historical data for a period of 60 days.
   - Each previously generated Report remains accessible in each Patient’s profile (unless deleted by a Clinician), so even if the Patient’s profile has expired, the data is retained by SleepImage in the event you need to re-access their records.

![Apply Credit To Patient](image)

Please note that per our Terms of Use (and Patient Privacy requirements) the patient to upload ratio is 1:1. Sleep studies from multiple patients cannot be uploaded to a single patient profile.
Credits Tab
The Credits Tab is where you will add the Credits to your Account, View the Number of Available Credits and can review the Credit History Report.

Product Keys are used to Authenticate your Report Credits purchase and enable the credits for use in your account. Once purchased, Product Keys can be found in the emailed sales order and in the Store’s order history. Once Product Keys have been applied to your account, Credits can be used amongst all Admins and Clinicians.

Apply a Product Key to add Report Credits
1. Go to the Credits Tab in your account.
2. Enter Product Key in the Apply Product Key field and click the Apply button.
3. The Confirm Add Credits window opens.
4. Click Yes to confirm.
5. Credits are now added to the account.

Credit History Report
Below the Report Credits fields on the same Tab is the Credit History report. A list of all credit activity is seen here. The Credit History report is exportable for your convenience.
Clinicians Tab
The Clinicians Tab is where the Admin manages Clinicians by creating and editing each Clinician’s Username and Password. Use the icons in the upper left of the Clinician Tab to Add/Edit a Clinician. If your Clinician list is long, use the Filter field to find a Clinician by entering all or part of the Clinician’s name. The results will filter the page depending on the characters typed in the field.

Clinicians will not see this Tab. Only Admins can Add and Edit Clinicians.

Add a Clinician
To add a Clinician to SleepImage, click the Add icon in the top left of the Patients Tab. An Add New Clinician window will appear. Enter Clinician information and click Add. Next, Add Patients and Assign Clinicians to their Patients.

Edit a Clinician
To Edit a Clinician’s information, Click on the Clinician’s row to highlight, then click on the pencil icon. When you’ve completed your edits, click Save.
Assign a Clinician

Clinicians can Add, Edit and Remove Patients when they are logged into their account. When Patients are added by another User the Admin must assign the Clinician to the Patient so the Clinician can view the Patient profile. Patient data is not accessible when expired, but you can Upload a new study or Apply a Credit to access the patient’s historical studies.

Assign a Clinician: click on the Patient’s row and click the Link icon. Check the box next to the Clinician(s) assigned to this Patient. When you’ve completed edits, click the Link icon to Save.

Un-assign a Clinician: uncheck the box next to the Clinician name. Click the Link icon to save.

Allow Clinicians to View All

To automatically allow all patients on the account to see all active patients, use the check box in the Settings Tab to enable this feature. To remove this Site-Wide setting, simply uncheck the box. Read more about Clinicians.
Patients Tab
The Patients Tab is where you manage your patient list. Use the icons to: Add, Remove or Edit a patient, View Patient Data, Assign Clinicians, Flag a Recorder, and Upload Studies. If your patient list is long, use the Filter field to find a Patient by entering all or part of the patient’s name. The List will filter results based on the characters typed in the field. You can click on the top of any column to sort.

Add a Patient
To add a Patient to SleepImage, click the add icon in the top left of the Patients Tab. An Add New Patient window will appear. Enter Patient information and click Add to save the profile. Clinicians are automatically assigned to the Patients they enter. If the Admin enters the Patient, the Admin will need to assign a Clinician to the Patient to grant Clinician access to the Patient’s sleep studies.

Edit a Patient
To Edit a Patient’s information, Click on the Patient’s row to highlight then click on the Pencil icon. When you’ve completed your edits, click Save.

Remove a Patient
Removing a patient is a permanent action. The Patient and all studies will be permanently removed and any remaining Credit on that patient will be forfeited. To remove a Patient, Click on the Patient’s row to highlight then click on the Remove icon.
Save Reports to PDF

A Patient's **profile must be active** to access and review their Studies and reports. Should you wish to retain reports for offline review, save reports as PDFs.

To save a Patient Report to PDF:
- Go to the Patient List and double click on the Patient's name
- Choose the Study you wish to save from the list
- Go to the Report Tab for that Study.
- Click on the PDF Button
- Save the PDF to the Patient's Digital file on your computer network in a secure fashion.
Upload a Study

Once Patients have completed their sleep study and returned the Sleep Data Recorder, select the Patient from the Patient List, then upload the study as shown below. Please note that per our Terms of Use (and Patient Privacy requirements) the patient to upload ratio is 1:1. Sleep studies from multiple patients cannot be uploaded to a single patient profile.

The workflow allows you to either Accept or Reject studies before a Report is generated. This ensures that you can verify the Upload 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, insufficient data or Fail.

**Success** – This indicates that the study is likely to have sufficient data for CPC analysis. If the total recording duration is over 4 hours, the system categorizes it as successful, but the study may not have enough data for CPC analysis depending on how long the patient wore the recorder before falling asleep and after waking up. In that circumstance, the study may contain partial CPC analysis and a Spectrogram but will not be categorized via Decision Assist.

**Insufficient Data** – The recording duration is less than 4 hours and may be of limited clinical value. It may contain partial CPC analysis and a Spectrogram but will not be categorized via Decision Assist.

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

To Upload Sleep Studies

1. Sign in to SleepImage and Connect the Recorder to a USB port on the computer. If the AutoPlay setting is on, plugging the device into your computer may open an AutoPlay window. Close this window to proceed.

2. Click on the Patient's name or anywhere on that row to highlight, and then click on the Upload icon.

3. Upload Studies window opens. Read instructions and verify Patient name at the top right of the window.

4. Press the Upload Button Navigate to the SLEEPIMAGE drive, then double click on the DATA.M1C file.
5. Upload will begin. *Upload speed depends on your internet carrier’s speed and the quantity of studies uploading.*

The data processing is in progress now.

| Uploading Data 100% | Processing Data 50% |

6. When the upload is finished, the window indicates the upload and processing were successful. This message stays on-screen for about 10 seconds.

| Uploading Data 100% | Processing Data 100% |

7. After processing is completed, the list of studies will be presented for your Acceptance or Rejection.
   - **Accepted** studies will be converted into Reports and viewable in the Patient’s Report List.
   - **Rejected** studies are discarded and will not be saved.
   - **Credits** required for Report Generation are listed in the summary at the bottom of the window.

8. Once a selection is made for each study, click **Confirm**.
   - If you **Cancel**, processing stays in a Pending status. The next time you review your patient list there will be a **Pending** button in the “Last Study” column. You will be unable to upload any further studies to that patient until the actions in Steps 7 & 8 are cleared.

9. **Credits** are deducted from available credit balance based on the quantity accepted for report generation.

10. **View the Patient’s Study Details** to verify the new reports have populated the profile. Access to the newly uploaded reports as well as the patient’s historical report data, if any, is available for the next 60 days.

11. **Reset the Sleep Data Recorder**. Don’t forget to read the *Sleep Data Recorder IFU* for more info about the Recorder.
Reset Recorder
The Recorder should always be reset after uploading. The action of resetting clears previous studies to ensure the Recorder is ready for the next patient. Sleep studies from multiple patients cannot be commingled in a single patient profile. Always Upload Studies before resetting.

To reset using a Computer:
- Plug Recorder into computer USB port
- Wait for Communication Light to turn green
- Press & hold Center Button until Communication Light flashes yellow
- Release the button.
- Communication Light changes to green...immediately disconnect Recorder from Computer.

To Reset using a USB charger:
- Using black USB cable, connect the Recorder to a charger.
  (Wall or Car chargers both work)
- The Communication Light will flash yellow then stop.
- Press and hold Center Button until Communication Light flashes yellow.
- Release the button.
- No lights should be blinking.
- Disconnect Recorder from the charger and cable.

If no lights are visible after reset, your Recorder is ready for the next study.

If you observe a flashing Yellow Communication Light:
Sleep studies cannot be recorded if Communication Light is blinking. It is necessary to clear the light before a new study can be performed. Customers may encounter an issue during Reset for a few common reasons:

- **Battery Arm has been damaged**  The copper battery arm may be bent or broken
- **Batteries are not installed properly**  Both batteries must be underneath the copper battery arm
  Both batteries should have proper polarity (+ side up)
- **Recorder was unplugged too early**  Communication light must be green before disconnecting
- **Recorder was unplugged too late**  Some Operating Systems may attempt to write data to connected peripherals. If the disconnection is not performed quickly after the light turns green, the OS may try to index the Recorder as it would a USB thumb drive. The Recorder rejects files the OS writes to it during indexing causing the Communication Light to flash yellow.

Please inspect the battery compartment to ensure that batteries are installed correctly and that the copper battery arm has not sustained any damage. Then, repeat either reset process until the Recorder resets properly and no further lights are observed. Please also review the Sleep Data Recorder Instructions for Use for more information about the Recorder.
Reviewing Patient Studies

To view a Patient’s Studies, click on the Patient’s row and click on the View Patient Data icon. You may need to Apply credit to see an Overview of the Patient’s previously uploaded Studies and trending Sleep Metrics. Applied Credits allow Study access for 60 days after application. Click on the Study Details Button to access individual studies. Admins can access all Patients on the account. Clinicians can view data for any Patient they’re assigned to. Learn more about Uploading new studies.

The Red, Yellow & Green colors on the patient data screens are part of SleepImage’s Decision Assist feature. Please see the Decision Assist section of this manual to learn more.
Study Details

The Study Details screen shows the Sleep Quality Report, contains the Clinician Notes field and lets you generate a printable PDF by clicking the PDF button. You can also export the Study Values to CSV by clicking the CSV button. (Note that CSV files can be opened using Microsoft Excel.) If Patient access has expired, apply Report Credit to access the Patient’s historical data.

The most recently generated Report appears on the screen when you access study details. To select a different study date, use the dropdown to choose from the list of the Patient’s uploaded studies.

To review a Patient’s Study in depth, click on Interactive Graphs.

Clinician Notes

If you want to make an observation about a particular study as a record that will stay with that Report, use the Notes field found at the bottom of the Report. Type your notes and click Publish. The Notes will remain part of the record for that Study and will be visible to any Clinician assigned to that Patient. Only Clinician users can make notes to Patient Studies.
Interactive Graphs
When reviewing Study Details, visit the Interactive Graphs screen to review the Spectrogram, the 3D Spectrogram, as well as the Traces of information recorded for the duration of the sleep study: ECG, Heart Rate Variability, Snore, Actigraphy, Heart Rate and Respiration.

For more information on how to utilize the data provided by SleepImage, go to the help Tab of your Account and download and read the PDF document called "Clinician’s Guide to SleepImage" which can be found in the Help Tab of your SleepImage account. The Clinician’s Guide contains a comprehensive review of the Clinical aspects of the SleepImage system with guidelines for how to review the Graphs for associations and patterns to better understand your Patients' sleep.
**Spectrogram**

The Spectrogram is an overall visual representation of how the Patient slept. It is a graphical representation of sleep variables like: body position, actigraphy, snore, CVHR and signal quality. The Spectrogram image is wider or narrower depending on how long the Sleep Data Recorder was worn by the Patient. The time (in HH:MM) is shown along the bottom of the Spectrogram.

**Clinician users** can manipulate the graph to recalculate the study by moving the two slider bars, located on either side of the image and clicking on the **Recalculate** button. This action narrows the window of data you are reviewing and re-calculates SleepImage values for the Patient Report discounting the data now excluded. Recalculating might be used, for example, if the patient had sleep onset latency in that study which the Clinician determined to be of little clinical significance. The timeline can be adjusted to the time of sleep onset and recalculated. This lets you review the Patient’s Sleep Variables absent the latency. Clinician Users can also toggle HFC, LFC and vLFC peaks of the spectrogram on and off to isolate coupling types by clicking the labeled HFC, LFC and vLFC markers to hide/display the peaks.
**3D Spectrogram**

The 3D Spectrogram allows you to look at the SleepImage Spectrogram in 3D for a more detailed viewpoint of the frequency ranges. To see this graph, click on the Open 3D button. This view helps interpret sleep quality and differentiate different Sleep-Disordered Breathing (SDB) phenotypes.

The 3D Spectrogram is fully interactive and can be pivoted to better analyze the Patient’s sleep.
Traces

Traces are used in conjunction with the Spectrogram to evaluate the Patient’s sleep quality. If there is a time on the spectrogram you want to investigate more closely, click on the time along the bottom of the spectrogram. This sets the window of reference for the Traces.

Next, set your interval (how much time you want showing in the trace field) to either 10 sec, 30 sec, 1 min, 2 min, or 4 min. Then use the arrow buttons (circled in red below) to move backward or forward from that point in time. This lets you look for patterns and associations for concurrent events (i.e. body position and snoring, or increased actigraphy during a period of unstable sleep).

For more information on this, consult the PDF document called "Clinician’s Guide to SleepImage" which can be found in the Help tab of your SleepImage Account.
**Zoom function**

Zooming in or out on one trace will zoom all traces to the same size.

1. To zoom in horizontally (on the time line), left mouse click, hold & drag horizontally to the desired size.

![ECG graph](image1.jpg)

2. To zoom in on the vertical axis left mouse click, hold & drag vertically to the desired zoom size.

![ECG graph](image2.jpg)

3. Double clicking on a trace will bring the trace back to its original size.
**Remove Studies**

**Clinician Users** are able to remove Studies for Patients they are assigned to. To remove a Patient’s Studies, click on the Patient’s row and click on the View Patient Data icon to open the Patient Data screen. This screen houses all Studies uploaded to that Patient’s profile. **Deleted studies will be permanently removed and cannot be recovered.**

To Remove a Patient Study:
Click on the study you wish to remove and click on the Delete button.

![Delete Study Screen](image)

If you wish to proceed with the removal of a study, click on **Yes**. To cancel the action, click **No**.

![Delete Study Confirmation](image)

Again, deleting a study is an **immediate, permanent** action, so use this feature with caution.

**Flag a Recorder**

Flagging a Recorder is a utility that Users might find helpful when loaning Recorders out to Patients. It is an optional and simple tool that lets you see the list of Recorders in your account and “flag” it to a specific Patient. Most organizations have their own internal protocols for tracking equipment. This function is **not** intended to replace those practices but can be used as a visual aid to help ensure you are uploading a study to the correct Patient.

To Flag a Recorder, simply click on an active Patient’s name/row and then click the Flag icon. A screen will appear that will provide options for entering the serial number. When completed, click on the Flag Recorder icon. Flagging the Recorder to another patient clears the flag.

![Flag Recorder Screen](image)
SleepImage Decision Assist

The SleepImage Decision Assist for objective Sleep Disorder Evaluation diagram is a visual workflow tool to aid clinical evaluation of sleep disorders to inform or drive clinical management. It is recommended to take into consideration the results of multiple tests for clinical decision-making. The Decision Assist utilizes the following four key sleep metrics:

**Sleep Quality Index (SQI)** is an overall measure of sleep health on a scale of 0-100 which includes a measure of sleep stability, sleep fragmentation, sleep duration and sleep pathology. An SQI ≤ 55 indicates poor sleep quality.

**Sleep Apnea Indicator (SAI)** is a measure of Cyclic Variation of Heart Rate (CVHR) during unstable breathing, detecting oscillations in cardiac intervals that are often associated with prolonged cycles of sleep apnea. An SAI ≥ 15 indicates moderate to severe SDB.

**Elevated Low Frequency Coupling broad-band (e-LFCbb)** is a frequency band analysis which correlates with sleep fragmentation and Obstructive Sleep Apnea (OSA). An e-LFCbb ≥ 15% indicates Obstructive SDB.

**Elevated Low Frequency Coupling narrow-band (e-LFCnb)** is a frequency band analysis which correlates with periodic breathing or Central Sleep Apnea (CSA). An e-LFCnb >2% indicates Central SDB.

Please review the *Clinical Instructions for Use* for more detailed information regarding these sleep metrics.

The Decision Assist will automatically tag each sleep study into one of four categories.

- **Clear Evidence of Sleep Disorder**
  Review patient history for moderate to severe SDB symptoms.

- **Evidence of Sleep Disorder**
  Review patient history for Insomnia, mild SDB, Restless Legs or Periodic Limb Movement related symptoms.

- **No Evidence of Sleep Disorder**
  Study does not indicate the presence of a sleep disorder.

- **No Studies/Insufficient Data**
  No study has been uploaded or the study does not contain sufficient data for Decision Assist analysis.
**Decision Assist Workflow**

**Objective Sleep Disorder Evaluation**

- **Signal Quality Mostly Green?**
  - **No**
  - **Sleep Duration ≥ 4 hrs?**
    - **No**
      - **SQI ≤ 55**
        - **SAI ≥ 15**
          - **No**
            - **eLFCbb <15% and eLFCoal ≤2%**
          - **Yes**
            - **eLFCbb ≥15% and eLFCoal ≤2%**
    - **Yes**
      - **SAI ≥ 15**
        - **eLFCbb ≥15% and / or eLFCoal >2%**
      - **Yes**
        - **eLFCbb ≥15% and / or eLFCoal >2%**

**Evidence of Sleep Disorder**
- **Review patient history for symptoms of:**
  - Insomnia
  - Restless Legs or Periodic Limb Movement

**Clear Evidence of Sleep Disorder**
- **Review patient history for symptoms of:**
  - Moderate to Severe Sleep Disordered Breathing

**Disclaimer:** This Flowchart is intended to assist clinicians to evaluate sleep disorders to inform or drive clinical management; it is not a diagnosis of a sleep disorder. SleepImage is not responsible for any use of this information.
Recorders Tab

The Recorders Tab displays all Sleep Data Recorders on the account and their Assigned status. This list is auto-populated when you purchase Recorders. Each Recorder has a unique Serial Number identifier. If you have more than one account, be sure to purchase the Recorder from the account you’d like to use it on…Recorders are usable on one account only.

If you are utilizing the Flag Recorders tool on the Patient’s page, you can see if a Sleep Data Recorder is assigned to a Patient, and the date of assignment.

Serial Numbers

The Serial Numbers shipped to you will appear on the Shipping Notice sent to the email registered with SleepImage upon processing by the shipping department.
Profile Tab

The Profile Tab allows SleepImage Users to change certain Profile information. Simply type the new information in and click **Save**.

**Admins** can change the Clinic Name, email address, name and location of the organization.

**Clinicians** can update their name, specialty and location.
**Settings Tab**

The Settings Tab allows you to change your Username and Password. Type the new information, confirm as needed, and press the Update button. There is also a setting in this Tab that can be used to automatically allow all clinician users to see all patients.

To undo this Site-Wide setting, simply uncheck the box. Read more about Clinicians and Assigning Patients.

**Help Tab**

Users can find Instructions for Use documents in this Tab along with the Clinician’s Guide to SleepImage, the Decision Assist Document and other helpful tools and links.

**Documentation**
- SleepImage System Website Instructions For Use Credits Plan
- Sleep Data Recorder Instructions for Use
- Decision Assist For Objective Sleep Screening
- Clinician’s Guide to SleepImage
- Performing a SleepImage Study - User Card

**Tools**
- Sleep Data Recorder Manager
  - Sync the recorder time on a Windows PC
  - Time Sync Instructions

**Tutorials**
- Video Tutorials on YouTube

Contact Support at support@sleepimage.com

This Tab will be updated from time to time to update IFUs, tools, tutorials, and other system messages.
FAQs

Can I record more than one study at a time?
Absolutely! We do, in fact, recommend multi-night studies for each Patient. The Recorder can be used for multiple study nights (for the same patient) without uploading in between. The Recorder will be able to perform approximately 5 sequential studies before depleting battery power.

The main thing to be aware of when running multiple nights are to be sure to Upload and Reset the recorder between patients to ensure that the data is uploaded to the proper patient. Also, the upload and processing times will understandably be longer due to more data being uploaded and processed at the same time. Credits are required to generate a Report for each study Accepted for processing.

Please also review the Sleep Data Recorder Instructions for Use for more information about the Recorder.

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 as their Clinician.

Why can’t I see the Patient’s Studies?
If you are seeking access to the Patient’s historical data absent the Uploading process, you can gain access to the Patient’s previously uploaded data by Applying a Credit which will allow access to that Patient’s data for 60 days.

Why can’t I Upload a study?
If the Patient has a pending Upload, no new Uploads can be made. Clear the pending status by following the Accept/Reject Process in step 7 of Uploading studies to clear the previous Upload then Upload new studies starting at Step 1.

Can I test more than one patient on the same Recorder without Uploading?
No. per our Terms of Use (and Privacy Policy requirements) the patient to membership ratio is one-to-one. Sleep studies from multiple patients cannot be commingled in a single patient profile. The Recorder should always be uploaded and then reset to clear all data to ensure the Recorder is ready for the next patient.

How do I interpret my Patient’s Sleep Studies?
A good start would be the Decision Assist document in the Help Tab of your account. In addition, one of our most comprehensive tools for learning about the science behind SleepImage is our Clinical Instructions for Use document. It will provide you with a foundation in CPC, a primer on evaluating SleepImage Reports as well as a number of case-studies. CPC technology is described in detail in medical textbook literature, including:

“Principles and Practice of Sleep Medicine. sixth edition. chapter 166 [Kryger; Roth; Dement]”
and

How Report Credits utilized?
Report Credits are used for two processes.

1) Uploading new sleep studies for your patient. Each accepted study requires 1 Credit. 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, a Credit can be applied to open patient access for 60 days.

What do the Recorder lights mean?
Please review the Sleep Data Recorder Instructions for Use for more information about the Recorder.