



# SleepImage<sup>®</sup> System Instructions for Use

Version 2.20



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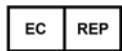
The SleepImage System is a  
Medical Device



**MyCardio® SleepImage Website**

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

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 <b>REF</b>	<b>Instructions for Use Version Number</b>	Please read Instructions for Use carefully and periodically as it is updated from time to time. The <a href="#">current version</a> (Rev. 35) was issued on August 25, 2023 – 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 <a href="mailto:support@sleepimage.com">support@sleepimage.com</a> .
	<b>Medical Device</b>	This product is a Medical Device.
	<b>Prescription Use Only</b>	FDA-cleared <a href="#">K182618</a> : 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 *+B315SLEEPIMAGESYSTEM0/\$\$72.205*
 <b>2862</b>	<b>CE Mark</b>	The CE mark is a declaration that the SleepImage System is in compliance with the EU Medical Device Regulations (EU 2017/745).



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## **Disclaimer**

This document may contain technical inaccuracies or typographical errors. Changes are periodically made to the information herein; these changes will be incorporated in future revisions of this document. MyCardio does not accept any liability for the use or misuse, direct or indirect, of this product. Users must accept all responsibility for any results obtained by or concluded from data obtained by the SleepImage software. All clinical conclusions and decisions that are made based on the use of this product are the responsibility of the User. MyCardio does not accept any liability or responsibility for damages arising out of the use of or inability to use the SleepImage software. Entering personally identifiable patient information is optional and done at the sole discretion of the User, with the exception of date of birth that is used to calculate certain expected values.

## **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.

## **Patent Marking**

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

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

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

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

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

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

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

Japanese Patent Number(s): 5005539; 5005687. Other patent(s) pending.

Other Patents Pending:

WO2019246234A1; WO2020061014A1; WO2021055943A1

## **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

<b>Version Numbers:</b>	<b>Release Date:</b>
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
Version 2.12	June 2021
Version 2.13	July 2021
Version 2.14	August 2021
Version 2.15	January 2022
Version 2.16	March 2022
Version 2.17	May 2022
Version 2.18	June 2022
Version 2.19	August 2022
Version 2.20	December 2022

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## 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.

## NOTICE: Serious Incident / Serious Adverse Event

If a serious incident or serious adverse event occurs involving the SleepImage Software System, immediately contact MyCardio or the appropriate authorized representative listed above.

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

## Intended Patient Group

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

## Product Support

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 <https://clinical.sleepimage.com/login>. All Users will always use the most recent version as the software resides exclusively in the cloud with no requirements for any software to be downloaded onto the user’s local computer. Instructions for Use reflecting the current version are 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.

## Customer Support Policy

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

- Identify their SleepImage Account by name or email (do not share passwords),

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

## Quality Management System

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

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

## SleepImage System Website Navigation Menu

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

Patients: Patient List	Clinicians: Clinician List	Profile: Edit / Save Account Name Admin Name	Settings: Change Password	Help: Instructions for Use Document Links <a href="#">FAQ</a>	Sign Out	Store
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Clinician Users have the following Tabs available to navigate the SleepImage System:

Patients: Patient List	Profile: Edit / Save Account Name Admin Name	Settings: Change Username & Password	Help: Instructions for Use Document Links <a href="#">FAQ</a>	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 (SpO<sub>2</sub>)- signals from electrocardiogram (ECG) and/or photoplethysmogram (PPG) sensors to aid diagnosis of SDB. The software analysis is defined by data acquisition characteristics as shown in the table below:

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









### Data Sources

Data 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 PO2 (PPG)	SleepImage PO4 (PPG)	SleepImage PO6 (PPG)	Checkme O2 (PPG)	Nonin 3150 BLE (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 .
-  **Share** Patient with another SleepImage account
-  **Clinician’s Note** has been published by someone else.
-  **Clinician’s Note** has been published by you.



**Read this Website IFU Document in full** to learn how to use the SleepImage website.  
 Read [SleepImage Mobile App IFU](#) (Android and iOS) to learn how to use the Recorders.  
 Read [Introduction to SleepImage](#) in full to learn how to use the information SleepImage presents.

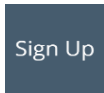


## SleepImage User Roles

There are two 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.









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



To access the Store, use the Admin Username (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** Patients and Clinicians.
-  **Remove** Patients.
-  **Edit** Patients and Clinicians.
-  **View** Individual Patient's Studies.
-  **Assign** Clinicians to Patients .
-  **Share** Patient with another SleepImage account.

### Clinician Role


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

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

-  **Add** Patients.
-  **Remove** Patients and Studies.
-  **Edit** Patients.
-  **View** Individual Patient's Studies.
-  **Share** Patient with another SleepImage account.

## Account Sign Up

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

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

## 2-Factor Authentication (2FA)

SleepImage recommends all users enable 2FA for their SleepImage System access. To enable 2FA, sign in to SleepImage System [HERE](#) and go to the Settings screen. Enter an email address into the field and click the **Enable**

### 2-Factor Authentication (2FA)

[Enable 2FA](#)

**2FA** button.

After you click **Enable 2FA**, the system will send an automated email with a 2FA Verification code and another input field will appear as shown below. Enter the 2FA code into the field and click **Verify 2FA**.

If 2FA is enabled, you will receive a 2FA verification code via email every time you sign in to the SleepImage System.

### 2-Factor Authentication (2FA)

[Cancel 2FA](#)

An email containing a 2FA verification code has been sent to the email address below. Enter the 2FA verification code in the field to the right and click Verify 2FA. If you did not receive the email or entered an incorrect email address, click Cancel 2FA.

### Two Factor Verification

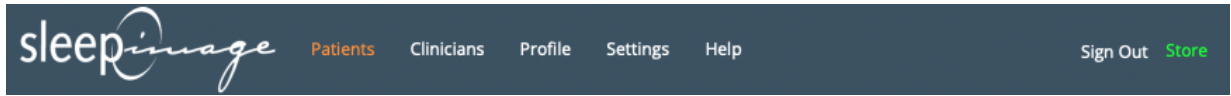
[Verify 2FA](#)

Didn't receive a 2FA code? [Click here to resend](#)

## SleepImage Store

Access the SleepImage online **Store**, using the Admin Username (email) to purchase the Products & Services.

Please contact [sales@sleepimage.com](mailto:sales@sleepimage.com) to ask if SleepImage is available in your country, outside the USA & Canada.



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 or services you wish to Purchase by clicking **Add to Cart**.
4. Complete your purchase by checking out.
5. If purchasing a subscription, the status will be automatically updated in your account after checkout.

### SleepImage Store and My Account

Select the [Store link](#) in the top right-hand corner of the menu bar in the Clinical Portal to place orders, view past orders, invoices, manage your subscription and view shipment tracking information.

Sign in to the [My Account section in the SleepImage Store](#) to view the following information:

Click on **Orders** to see your Order history and print invoices.

Click on **Addresses** to manage your shipping information.

Click on **Payment Methods** to manage your payment information.

Click on **Subscriptions** to manage your subscription.

### My Account



Hello **SleepImage Development** (not **SleepImage Development**? [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](#).

## Subscription Management

Subscriptions are defined by the following parameters:

- Expiration/Renewal Date:
  - The date when the current subscription period ends and automatically renews, unless the subscription has been cancelled.
- Reports Remaining:
  - Number of reports included in each subscription period for a given subscription tier.

To review, cancel or change the payment method for your subscription follow the steps below:

1. Sign into the SleepImage Store on the [My Account](#) page,
2. Click “Subscriptions”,
3. Click “View” next to your subscription,

If you need to change to a different subscription tier, you must first cancel your current subscription. Then, go to the [Store](#) page and sign up for another tier and/or term (monthly/annual).

### My Account

Orders Addresses Payment Methods Subscriptions Store Sign-Out Clinical Sign-In

Status	Active
Start date	54 seconds ago
Last order date	54 seconds ago
Next payment date	June 8, 2022
Payment	Via Credit Cards
Actions	<span>Cancel</span> <span>Change payment</span> <span>Renew now</span>

#### Subscription totals

Product	Total
Subscription - Monthly, Starter x 1 Term: Monthly Tier: Starter <span>Upgrade or Downgrade</span>	
Subtotal:	
Tax:	
Total:	

#### Related orders

Order	Date	Status	Total	
<a href="#">#200304036</a>	May 8, 2022	Completed		<span>View</span> <span>Invoice</span>

#### Billing address

# SleepImage User Tasks

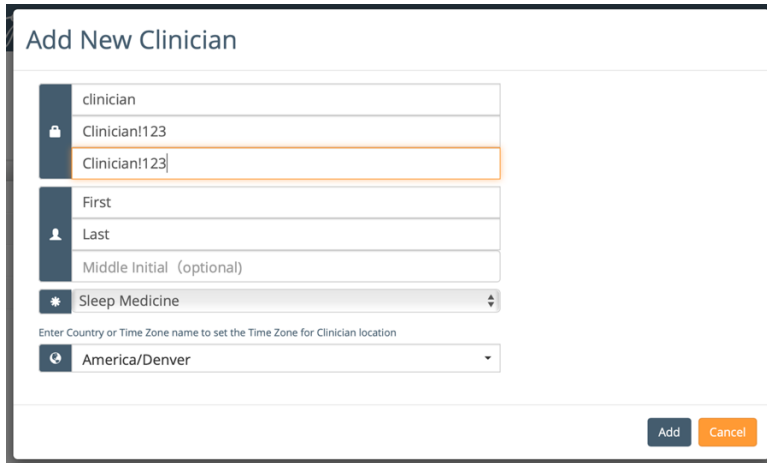
## Adding & Editing Clinicians

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.



**Add New Clinician**

clinician

🔒 Clinician!123

Clinician!123

First

👤 Last

Middle Initial (optional)

\* Sleep Medicine

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

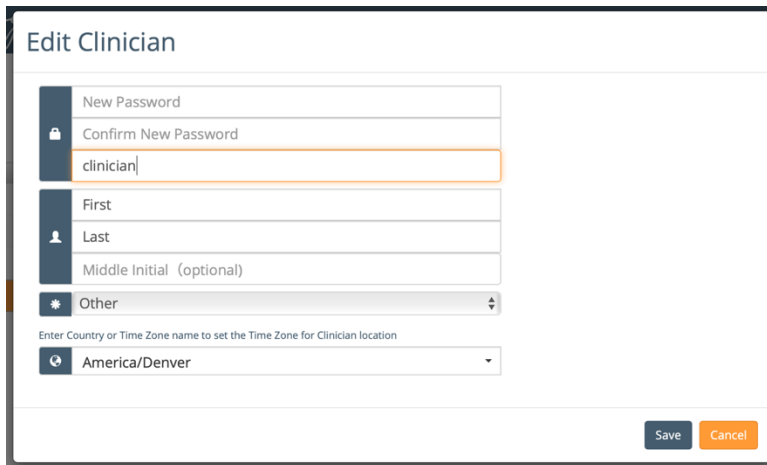
🌐 America/Denver

Add Cancel

Edit a 

Clinician

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



**Edit Clinician**

New Password

🔒 Confirm New Password

clinician

First

👤 Last

Middle Initial (optional)

\* Other

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

🌐 America/Denver

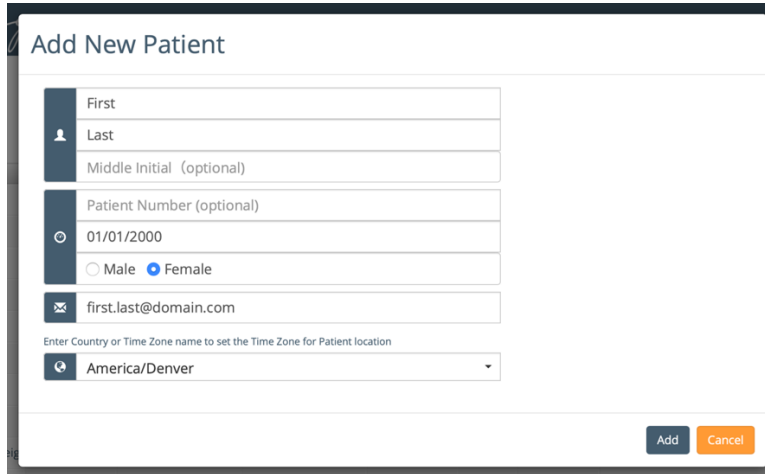
Save Cancel

## Adding, Editing & Removing Patients

Add a 

Patient

To add a Patient, click the Plus icon. An Add New Patient window will appear. Enter Patient information and click Add. If email address is entered, their Patient ID & SleepImage Mobile App download instructions are emailed to the Patient.



**Add New Patient**

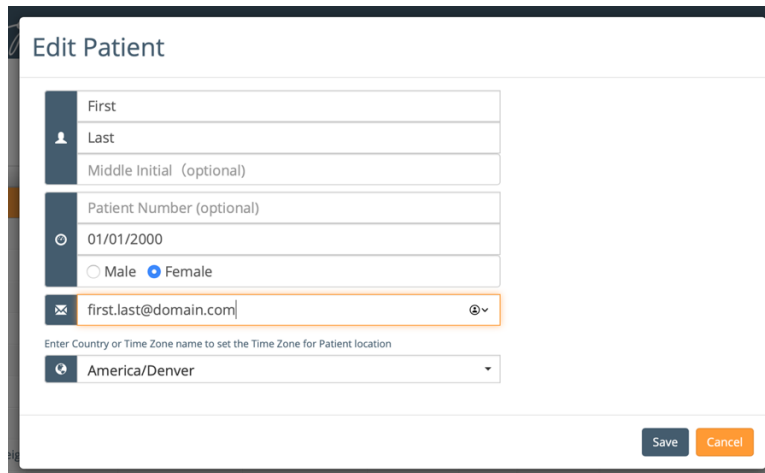
First  
Last  
Middle Initial (optional)  
Patient Number (optional)  
01/01/2000  
 Male  Female  
first.last@domain.com  
Enter Country or Time Zone name to set the Time Zone for Patient location  
America/Denver

Add Cancel

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.



**Edit Patient**

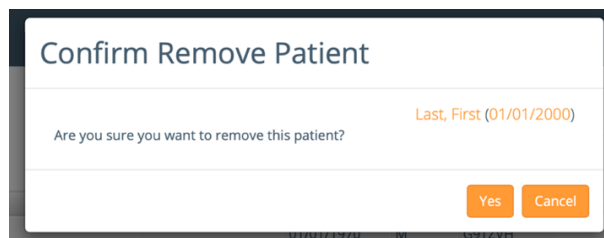
First  
Last  
Middle Initial (optional)  
Patient Number (optional)  
01/01/2000  
 Male  Female  
first.last@domain.com  
Enter Country or Time Zone name to set the Time Zone for Patient location  
America/Denver

Save Cancel

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.



**Confirm Remove Patient**


Are you sure you want to remove this patient? Last, First (01/01/2000)

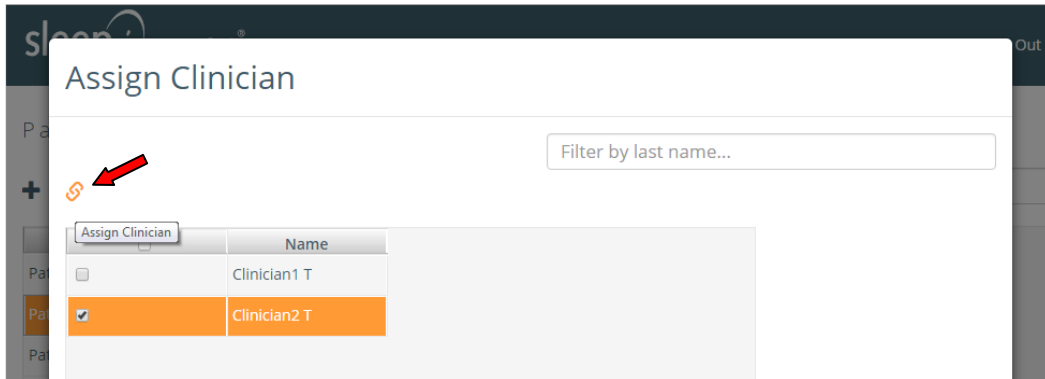
Yes Cancel


## Assign Clinicians to Patients

Only the Admin Role can Assign Clinicians to Patients. Patients created by clinicians will be automatically assigned to that clinician.

Patients created by a Clinician are automatically assigned to that Clinician.

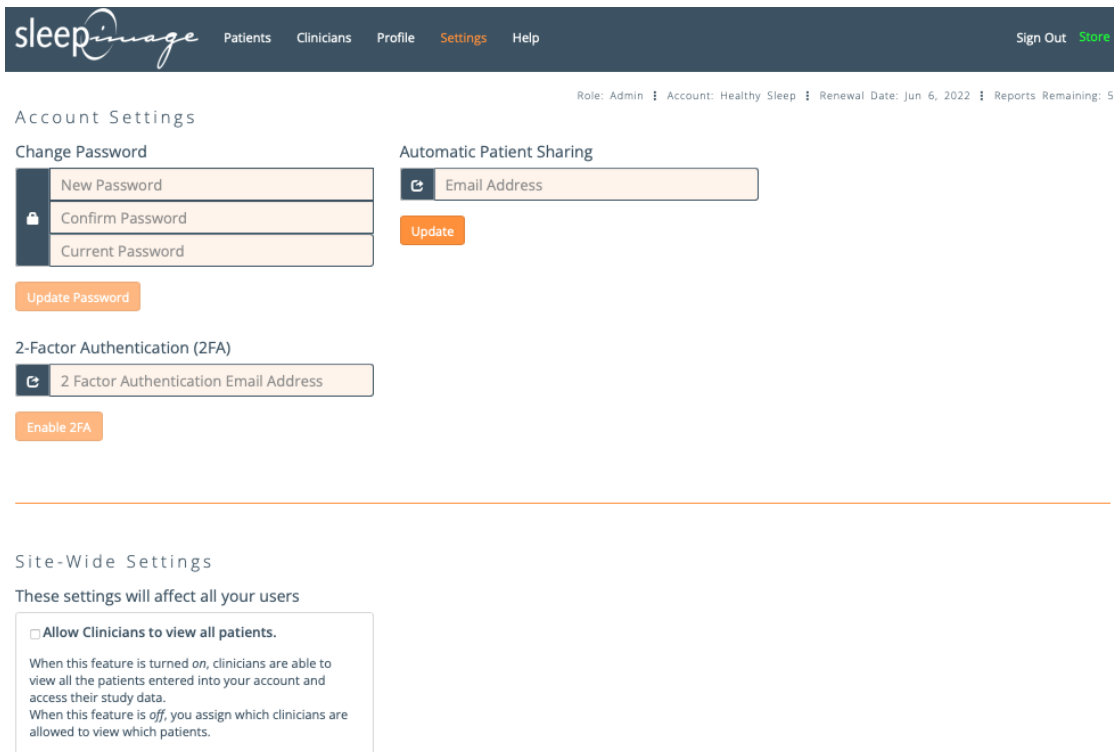
To Assign a Clinician to a Patient, select a Patient from the Patient List and click the Link icon. Check the box next to the Clinician(s) Name(s) to assign the selected Clinician(s) to this Patient. Click the Link icon  to Save.



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

## Allow All Clinicians to View All Patients.

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




## Share a Patient

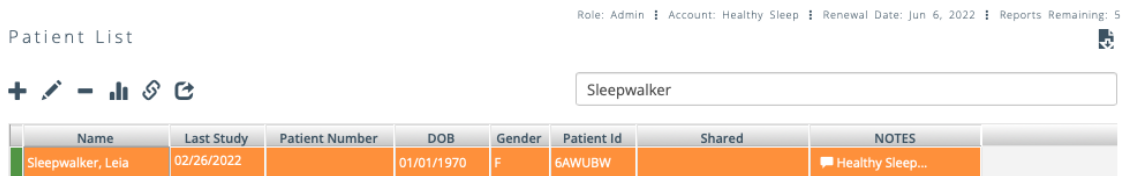
Patients can be shared with other SleepImage System users for clinical collaboration such as having a patient's reports reviewed by a sleep specialist. The original creator of the patient profile is referred to as the "Owner". The collaborator is the "Recipient". Only Owners can initiate sharing a patient. 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 with a SleepImage Account
3. Verify the email address on the recipient's SleepImage Account
4. Confirm that they are willing to review the patient's test results





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

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





Role: Admin | Account: Healthy Sleep | Renewal Date: Jun 6, 2022 | Reports Remaining: 5

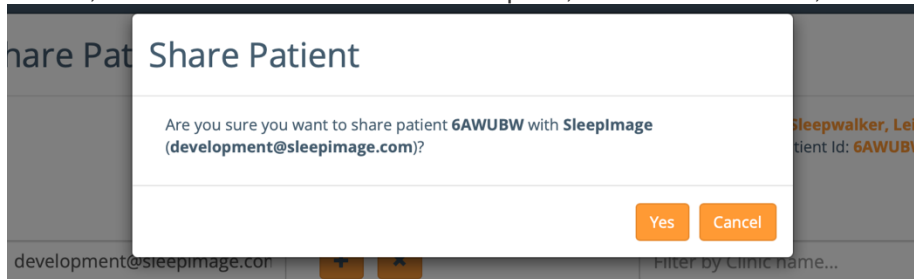
Patient List 

+  -   

Sleepwalker

Name	Last Study	Patient Number	DOB	Gender	Patient Id	Shared	NOTES
Sleepwalker, Leia	02/26/2022		01/01/1970	F	6AWUBW		Healthy Sleep...



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



Share Patient

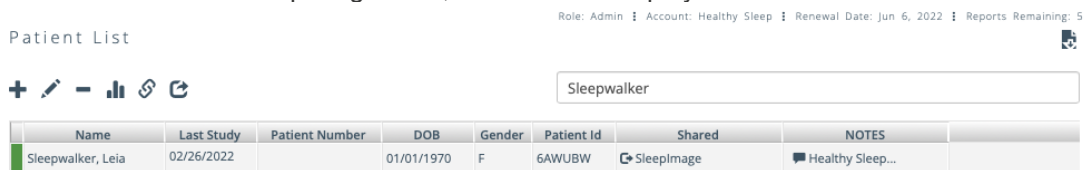
Are you sure you want to share patient **6AWUBW** with SleepImage (development@sleepimage.com)?

Yes Cancel


development@sleepimage.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.




Role: Admin | Account: Healthy Sleep | Renewal Date: Jun 6, 2022 | Reports Remaining: 5



Patient List 


+  -   

Sleepwalker

Name	Last Study	Patient Number	DOB	Gender	Patient Id	Shared	NOTES
Sleepwalker, Leia	02/26/2022		01/01/1970	F	6AWUBW	 SleepImage	Healthy Sleep...

When a patient is shared, the SleepImage System sends an email confirmation to the sender (Patient Owner) and the intended 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.

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

## Automatic Patient Sharing

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

To enable the auto share feature, sign in to your account as the administrator and go to the Settings screen. Enter the email address for the intended recipient and click "Update".

### Automatic Patient Sharing

Update

*While enabled, patient share for any patient can be revoked as usual.*

To disable the auto sharing, (1) delete the email address in the email field and (2) click the "Update" button, but note that this will not revoke sharing for currently shared patients. For information on how to revoke a patient share, please see the "Share a Patient" section.

NOTE: Users should establish a relationship with the intended recipient before sharing patients!

## Upload a Study

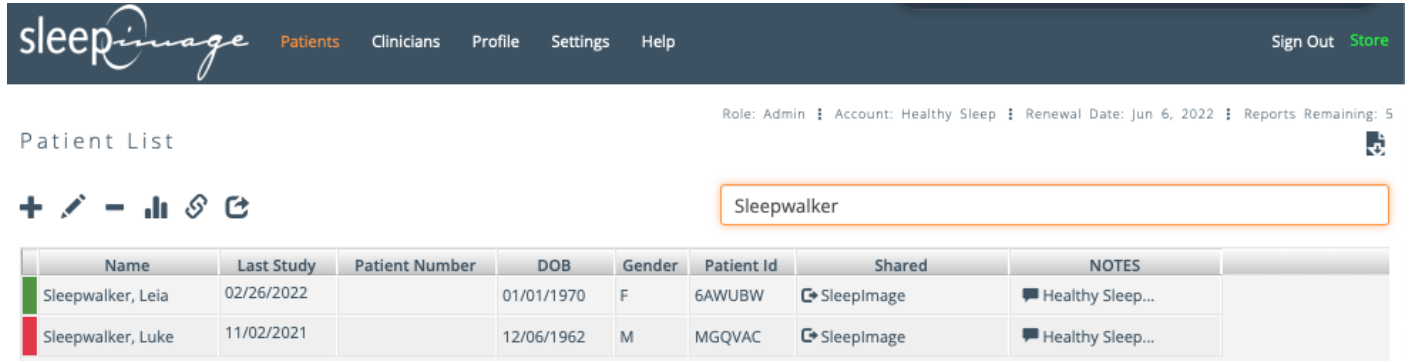
**Patient Data** is uploaded using the SleepImage Mobile App. Please refer to the [SleepImage Mobile App Instructions](#), available in the Help section of your SleepImage account for further information. Also review the App infographic instruction page on our website: <https://sleepimage.com/sleepimage-mobile-app/>

If multiple studies are done on the same patient, studies appear in SleepImage one at a time for SleepImage Users who have selected the "Report Credits" data plan. [Accept or Reject](#) each study in the Pending list until all studies have been accepted or rejected for report generation. SleepImage Users who have selected the "Monthly Subscription" data plans do not have to Accept or Reject each study as all studies will be automatically processed at the time of upload and be visible for viewing and interpretation.

### Study (Report) Generation

When a patient uploads a recording, the recording is processed and a report is automatically generated if the account has an active subscription. Only studies that are 4 hours or longer are counted towards the maximum number of reports for each respective subscription plan.

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

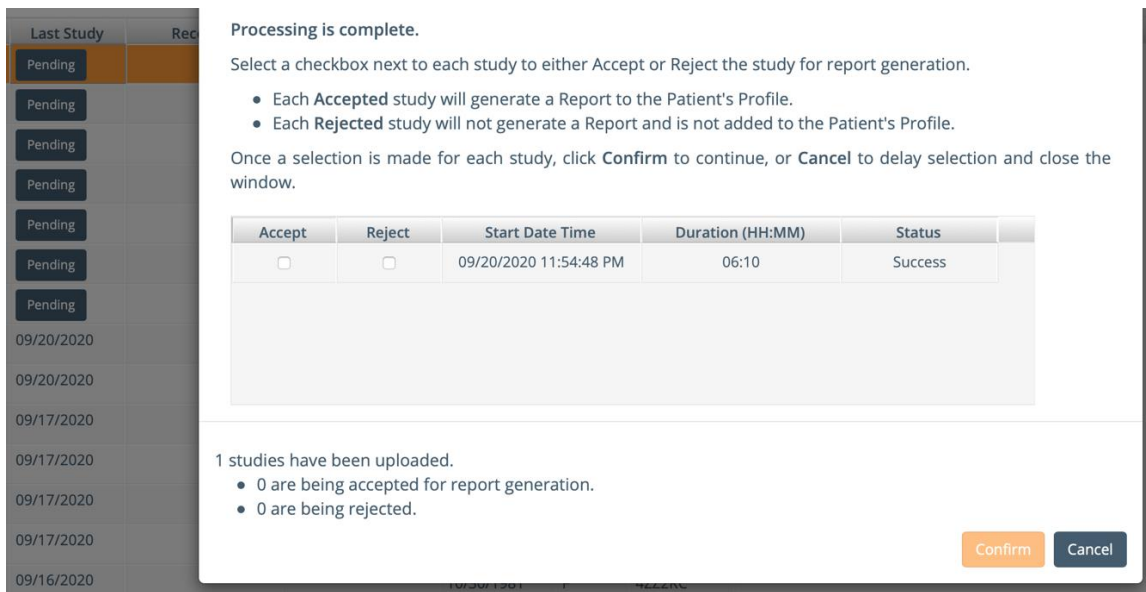


The screenshot shows the SleepImage clinical portal. At the top, there is a navigation bar with the SleepImage logo and links for Patients, Clinicians, Profile, Settings, and Help. On the right, there are links for Sign Out and Store. Below the navigation bar, the user's role is Admin, account is Healthy Sleep, renewal date is Jun 6, 2022, and reports remaining are 5. The main section is titled "Patient List" and contains a search bar with "Sleepwalker" entered. Below the search bar is a table with the following data:

Name	Last Study	Patient Number	DOB	Gender	Patient Id	Shared	NOTES
Sleepwalker, Leia	02/26/2022		01/01/1970	F	6AWUBW	☑ SleepImage	🗨 Healthy Sleep...
Sleepwalker, Luke	11/02/2021		12/06/1962	M	MGQVAC	☑ SleepImage	🗨 Healthy Sleep...

If a subscription is expired, or if all the reports included in the subscription period have been used, a Pending button will be displayed next to the patient’s name if a study is available for report generation. In this case, users will have to renew their subscription before generating the reports. See the Subscription Management section for more information on how to manage your subscription.

After renewing the subscription, click the Pending button and Accept or Reject each study to generate the pending report:



The screenshot shows a dialog box titled "Processing is complete." with the following text:

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.

At the bottom right of the dialog box are "Confirm" and "Cancel" buttons.

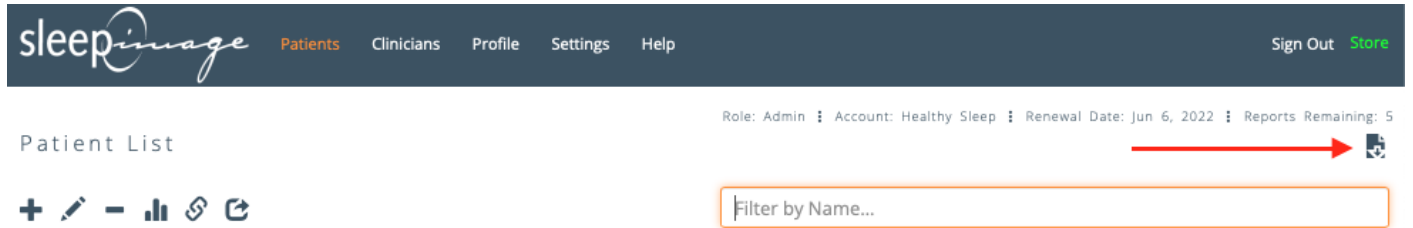
Once a pending study has been accepted/rejected, subsequent reports for that particular patient will resume automatic report generation while the subscription status is active.

**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.

## 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).

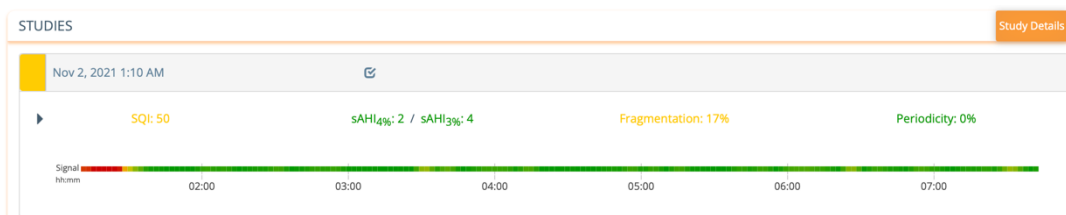
This overview also shows other primary output values color-coded as well as sleep duration and signal quality for a quick review. For further information, please refer to [Introduction to Sleepimage](#) that contains comprehensive information regarding how to review the numerical and graphical information 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 in a PDF, CSV, or DOCX format to save the output values locally.



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

sleepimage Patients Clinicians Profile Settings Help Sign Out [More](#)

Patient Data: **Test, 1** (01/01/1970) Role: Admin | Healthy Sleep | Renewal Date: Aug 2, 2023

### Study Details

STUDY DETAILS Return To Overview

Selected Study: Jun 22, 2022 12:12 AM Selected Page: Reports Raw Data

PDF CSV DOCX (3%) DOCX (4%)

**Sleep Quality Report**  
Jun 22, 2022 | 12:12 AM - 6:34 AM  
Healthy Sleep

Patient Name: 1 Test  
Patient Id: [REDACTED]  
Patient Number: [D] 1234567  
Date Of Birth: 01/01/1970 (52 years)

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

## Study Report

The report is auto generated 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

Clinician Notes is a tool that is only available when the user is signed in as a Clinician. Published Clinician Notes will become part of the Report. To write Clinician Notes, select the

**Add Note**

button below the Test Summary.

Clinician Notes are 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. If a Clinician has already published a note for a particular study, the button will show as 'Edit Note'. Clicking the button will present the latest version of the note which can then be edited and updated.

Every time you publish a note, the system will ask if you would like to send an email notification. To send an email notification, enter email addresses into the field, separated by a comma, and then click "Send". If you click "Close", the system publishes the note but no email notification is sent.

The system will display icons to indicate if a Clinician Note has been published. The icon indicates to the signed in user that they have published a clinician note for that patient (Patient List) or that particular sleep study (Study Overview). A icon indicates that someone else has published a clinician note, with the Clinic Name displayed behind it. If more than See examples below.

### Patient List

Note that when more than one clinic, in addition to the signed in user, has published a note, the system will display "... " behind the first clinic name ("Healthy Sleep...").

Name	Last Study	Patient Numb...	DOB	Gender	Expiration	Patient Id	Shared	NOTES
Sleepwalker, Luke	11/02/2021		12/06/1962	M	01/23/2022	MGQVAC	SleepImage	Healthy Sleep...
Sleepwalker, Leia	05/25/2017		01/01/1970	F	01/11/2022	6AWUBW	SleepImage	SleepImage

### Patient Overview

	Oct 8, 2021 12:13 AM	
	Oct 8, 2021 12:13 AM	SleepImage

## Raw Data

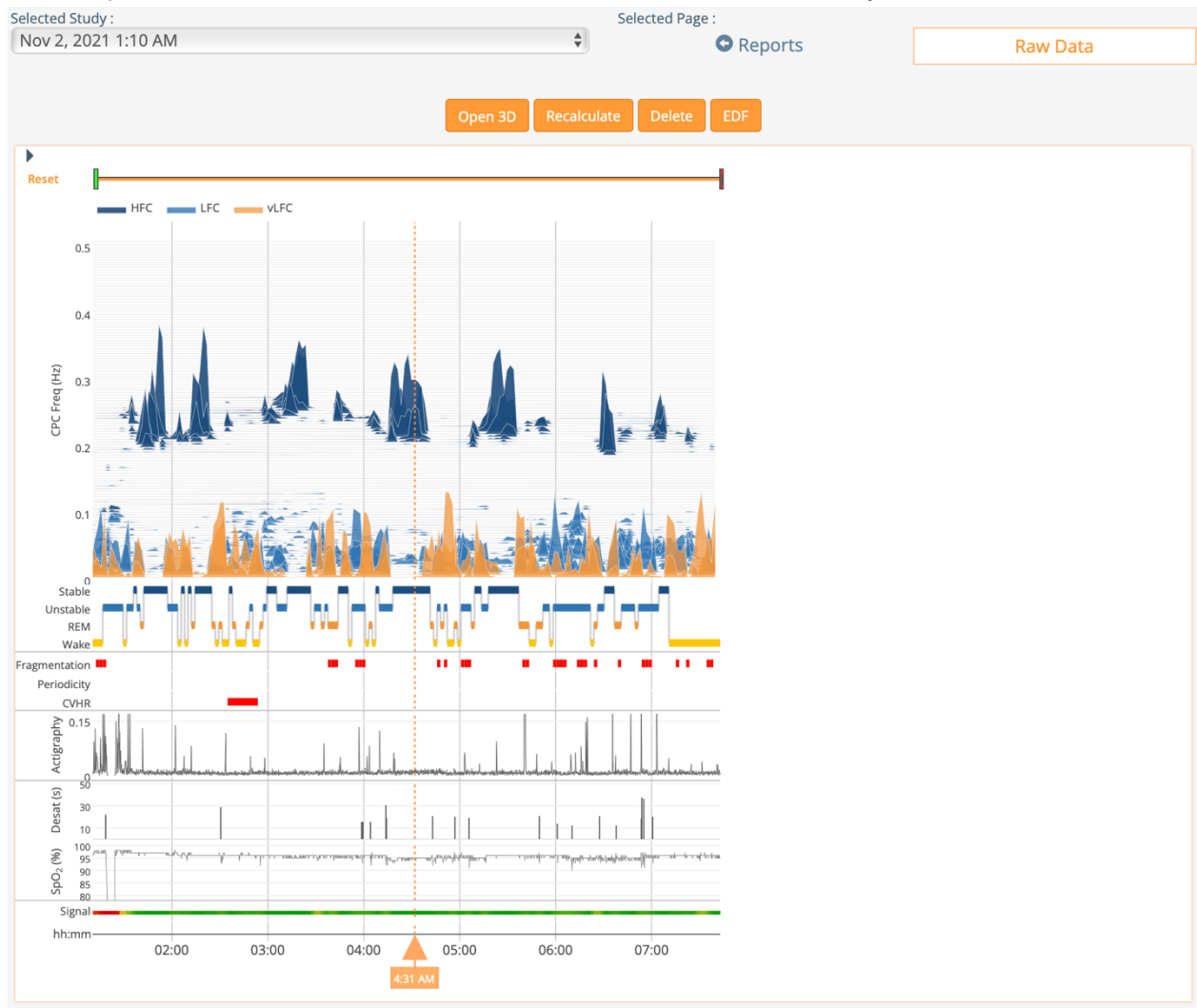
Raw Data is intended to aid clinical decisions. From the Study Details page, select 'Raw Data' button:

STUDY DETAILS Return To Overview

Selected Study :  Selected Page : [Reports](#) [Raw Data](#)

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) SpO<sub>2</sub>, desaturations, body position, snore, actigraphy. The Spectrogram is presented in the Sleep Report. The Spectrogram image is wider or narrower depending on the length of the recording period. The time (in HH:MM) is shown on the signal quality line, below the Spectrogram.

**Recalculate** Clinicians can adjust study duration and add/edit/delete SDB and SpO<sub>2</sub> events to recalculate the auto-generated study output. Moving the Green and Red markers (as shown with the arrow in the following picture) narrows the window of analyzed data under review and re-calculates SleepImage values based on the period selected. See below for detailed instructions on how to modify SDB events.



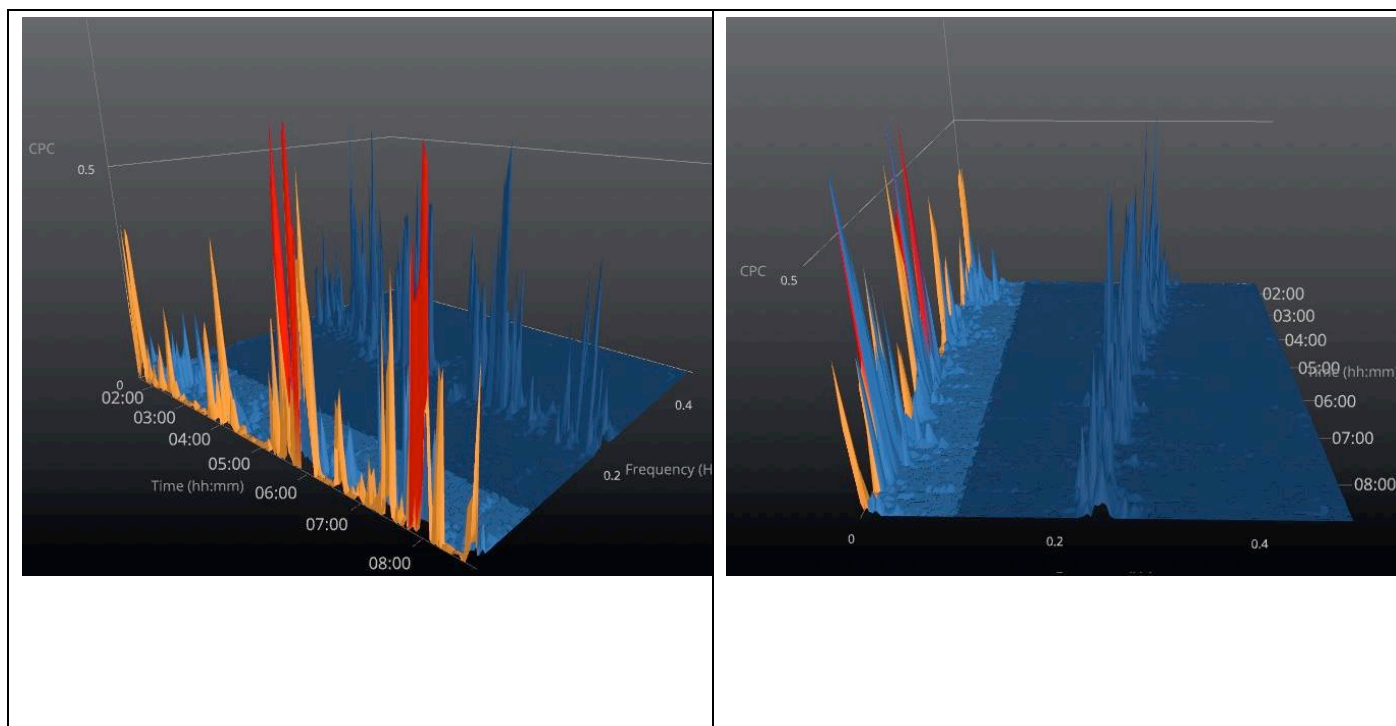


For better view of the peaks on the spectrogram, click on the HFC-, LFC- and vLFC- icons to hide/display each frequency band.

### 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.***

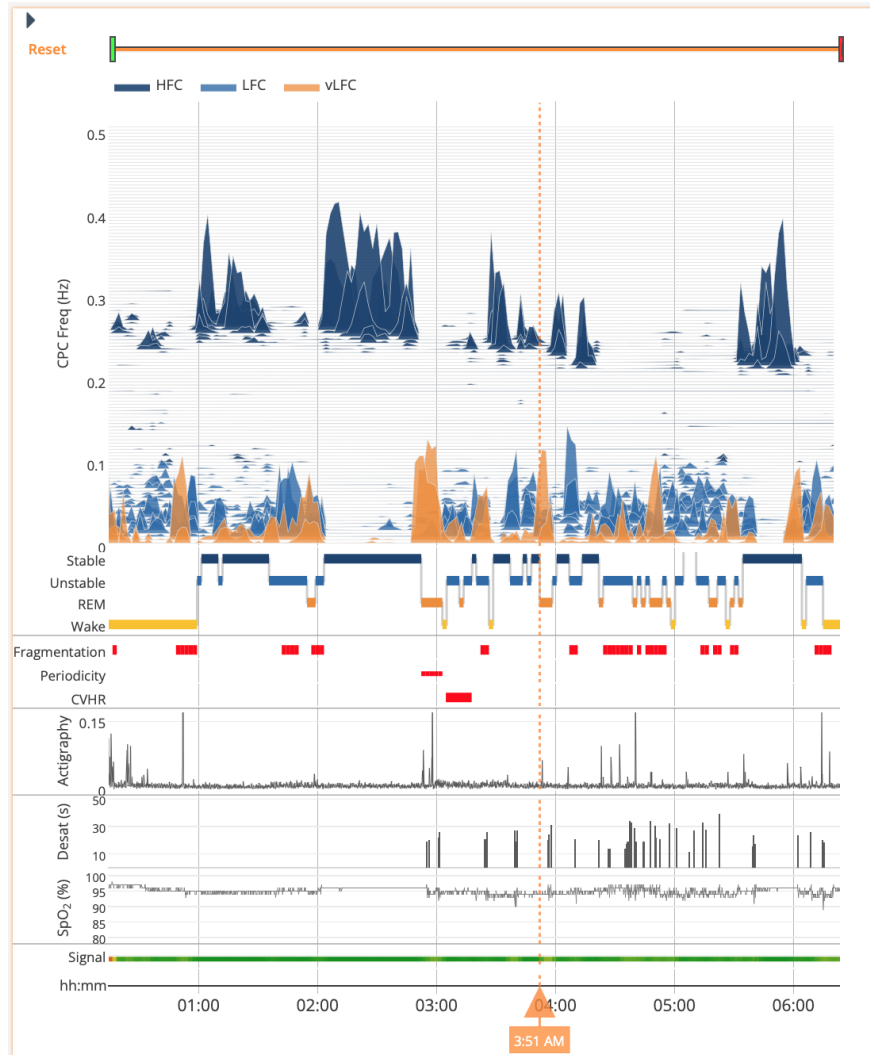


## Traces

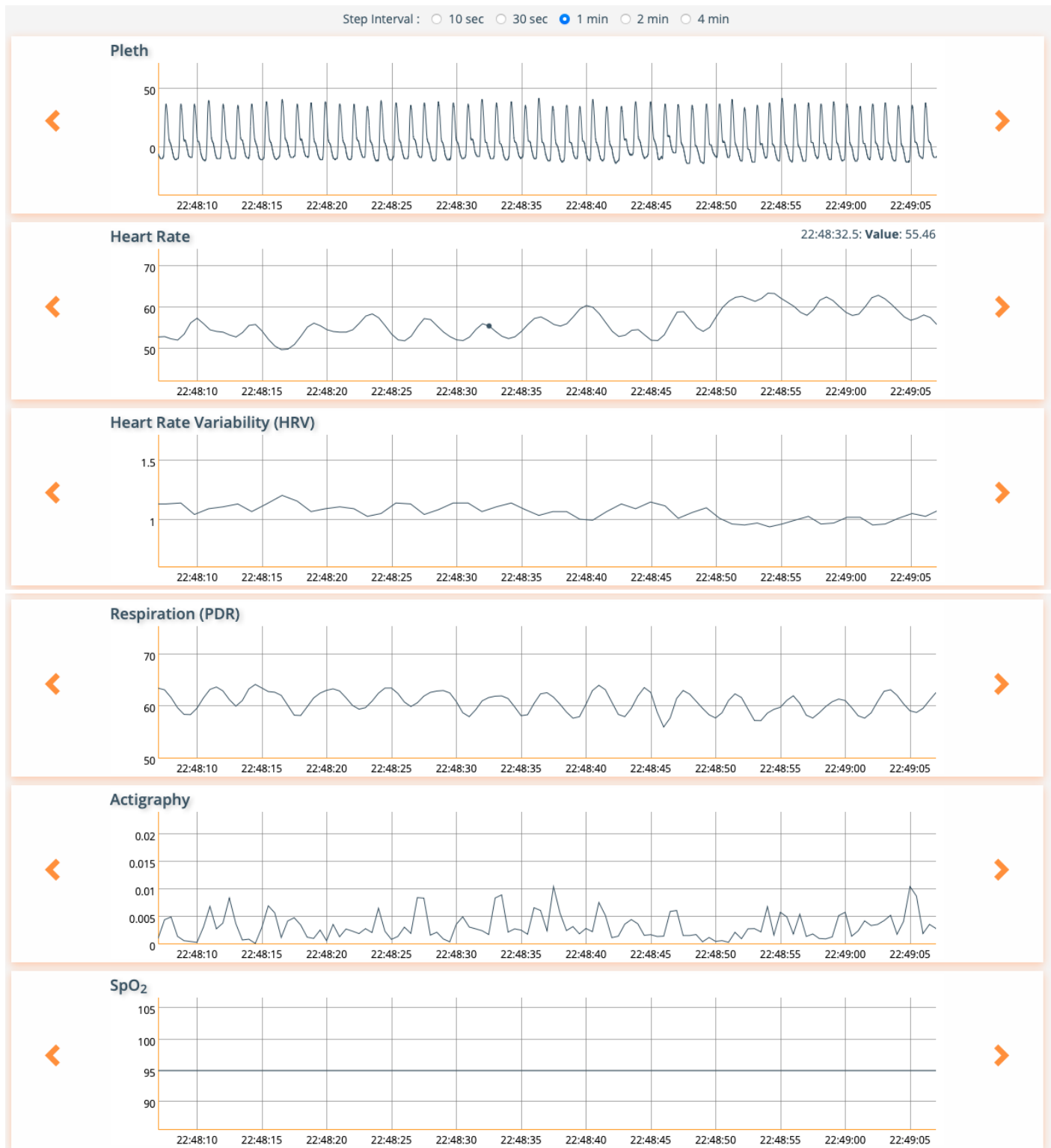
Traces are visual representation of the Raw Data collected (ECG/PLETH, Heart Rate Variability, Snore, Actigraphy, Heart Rate, Respiration and SpO<sub>2</sub>). Traces are useful in conjunction with the Spectrogram to evaluate the Patient's sleep. If there is a time during the sleep study you want to 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.

### EDF Download

Users can download an EDF file of the recorded traces, which includes the plethysmogram (PLETH), Actigraphy, and SpO<sub>2</sub>, by clicking the **EDF** button.



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.



## Manual Scoring (Editing Scored Events)

Clinicians can add, edit, remove and modify the auto-scored SDB and SpO<sub>2</sub> events. To modify the scored report, the clinician will make changes to the included events and then click the “Recalculate” button, which will re-score and save the changes.

### NOTES:

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

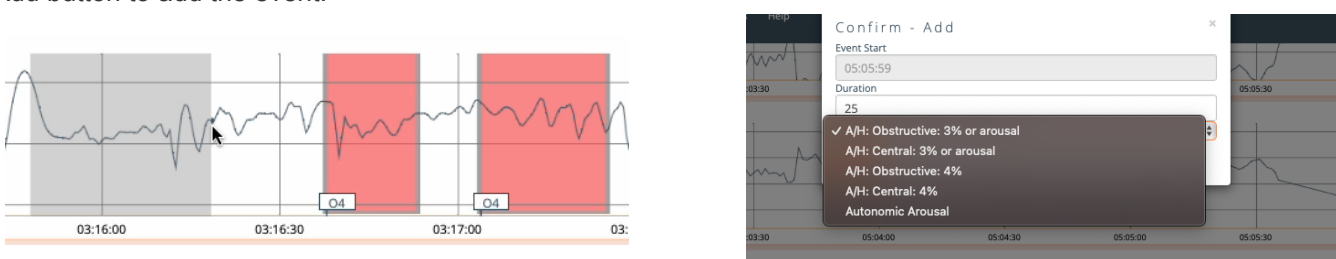
Events are labelled as shown in the table below.

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

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

### Adding Events

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



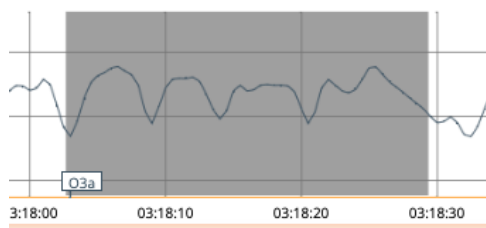
### Editing or Deleting Events

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

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

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

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



Confirm - Change ✕

Event Start  
03:18:03

Duration  
26

A/H: Obstructive: 3% or arousal

Save Delete

## Remove Sleep Studies

Delete

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

**Deleted studies will be permanently removed and cannot be recovered.**

Selected Study :  
Nov 2, 2021 1:10 AM

Selected Page :  
Reports Raw Data

Open 3D Recalculate Delete EDF

### 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