SleepView®

User Manual

BEACONBIOSIGNALS

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Chapter 1: Introduction

Intended Use

The SleepView is intended for recording of physiological signals to aid in research and/or diagnostic purposes in professional and home healthcare environments.

This device is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

Contraindications

Normal operation may be affected when used near equipment marked with the following symbol: 

This device complies with CFR 47 – Part 15, 15.109(b), 15.249 and 15.247 and passed testing according to IEC 60601-1-2:2014. The operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT NOTE: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate the equipment.

Warnings

- Improper routing of leads may result in a choking hazard.
- Do not use in conjunction with an external defibrillator.
- Only use the recommended 'AAA' size batteries.
- Follow all local regulations when disposing of used batteries or devices.
- Never dispose of batteries or devices in a fire.
- Never place batteries or devices on or in heating devices such as microwave ovens, stoves, or radiators.
- Never crush or puncture the battery.
- Use of cables or accessories not provided or sold by Beacon Biosignals for use with the SleepView system may result in increased emissions or decreased immunity of the SleepView System.
- Do not submerge under water.

Minimum System Requirements

- Personal computer with 2.4 GHz or higher processor;
- Microsoft Windows 8.1, 10 or newer;
- 1 GB of installed memory;
- Minimum 2 GB free hard disk space;
- CD-ROM Drive;
- Mouse or another pointing device;
- One USB port;
- Chrome (see Web Portal for supported browsers);
- Adobe Acrobat Reader X or higher.

Package Contents And Warranty Information

Thank you for your recent purchase. For your benefit, we recommend that you record the pertinent details below. If necessary, this information will allow us to better serve your needs.

WARRANTY

Beacon Biosignals warrants the products delivered hereunder: 1) to be free from defects in material and workmanship under normal use and service; and 2) to meet applicable specifications and description at the time of delivery to Purchaser. The obligation of Beacon Biosignals under this warranty is limited to the repair, re-work or replacement, at Beacon Biosignals' option of any non-conforming product, part or component thereof, which within one (1) year from date of delivery is examined by Beacon Biosignals and discloses to Beacon Biosignals' satisfaction to have been non-conforming or defective. Beacon Biosignals shall in no event be liable to Purchaser or to Purchaser's customers for any incidental or consequential damages, or other commercial loss, however, occasioned. Warranty does not apply if the device is damaged by accident, abuse, misuse, misapplication, or is modified without the written permission from Beacon Biosignals. Breaking the tamper-proof seal (label) will void warranty. This warranty includes servicing and/or replacing any instrument or part thereof, except batteries and expendable supplies, returned to the factory for that purpose with transportation charges prepaid by Beacon Biosignals. Items not manufactured by Beacon Biosignals carry the original manufacturer's warranty. Beacon Biosignals makes no warranties, expressed or implied, including without limitation, warranties of merchantability, fitness or performance characteristics, except to the extent set forth herein. Technical support is included free of charge within the warranty period. Technical support outside of the warranty period or after hours may be subject to additional charges based on Beacon Biosignals' hourly rate. Contact Beacon Biosignals for more details.

Date of Purchase:

SleepView Monitor Serial Number

Chapter 2: About SleepView

General Device Description

SleepView is a type III sleep system capable of recording, displaying, scoring and analyzing physiological signals for sleep studies. The system is also capable of generating flexible, customizable reports for efficient interpretation and diagnosis. The SleepView system consists of one hardware component, SleepView® Monitor, and a software component. The software is web based and hosted by Beacon. For more information visit **https://beacon.bio/sleepview-portal.** The SleepView Monitor is worn by the patient and is responsible for acquiring the physiological signals from sensors on the body. The SleepView Monitor amplifies, samples, and digitizes the physiological signals and stores the data in internal memory.

SleepView Monitor

The SleepView monitor can record up to 8 signals (summarized below). The SleepView monitor is powered by one AAA battery, typically lasting for more than 10 hours of data acquisition time.

Signals Measured

- Airflow (pressure based, compatible with CPAP)
- Auxiliary (thermistor, IDcheck™ or Respiratory Effort)
- Snore
- Pulse Oximetry
- Respiratory Effort (chest)
- Body Position (supine, prone, left, right, and upright)
- Heart Rate
- Sleep/wake (actigraphy)

Chapter 3: Accessories, Sensors, and Maintenance

Several types of sensors are available for use with SleepView. Beacon Biosignals offers prepackaged and sealed study kits with all of the disposable supplies needed for a study which facilitates transport and handling.

Airflow

A nasal oral cannula is most commonly used with SleepView to detect nasal and oral airflow as well as snore. The cannula is single use. Please see below for disposal instructions. A nasal cannula can also be used combined with a thermistor.

Pulse Oximetry

A soft pulse oximetry finger sensor is packaged in the SleepView starter kit. This soft pulse oximeter is not disposable. Please see below for cleaning instructions. Wrap style and disposable sensors are also available.

Respiratory Effort

The SleepView interfaces directly with a RIP (respiratory inductive plethysmography) belt. Reusable and single use ReadyRIP™ belts are available. Belts should be worn over clothing. Please see below for cleaning instructions for the Reusable belt. ReadyRIP belts cannot be reprocessed between patients and will need to be discarded after each patient.

Auxiliary

The auxiliary port accepts three types of sensors:

Thermistor

A thermistor can be used as a measure of airflow. An oral thermistor is commonly combined with a nasal cannula.

Second Respiratory Effort Belt

A second respiratory effort belt (RIP belt) can be used on the auxiliary port. An interface cable is required for an effort belt to be used with the auxiliary port. If a second belt is used the primary belt should be worn on the chest and the secondary belt on the abdomen.

IDcheck™

The IDcheck sensor is used to verify the identity of the patient recording the sleep test. Beacon Biosignals customer service can provide more information about using an IDcheck sensor.

Cleaning Or Disposal: SleepView And Accessories

To prevent the spread of bacteria and other germs from one patient to another, multi-use supplies and accessories including the respiratory belt, pulse oximeter, and thermistor must be disinfected between uses and/or between patients per instructions below.

Single use sensors including the cannula and disposable ReadyRIP belts must be discarded after completion of the study by throwing them in the trash.

Cleaning Supplies

The following supplies are commonly used. They are recommended; however, similar products of equal strength may be chosen:

- Sani-Cloth®
- CaviWipes®
- Cavicide®

Procedure

- Gather reusable belts, pulse oximeter, reusable nasal thermistor.
- Remove adhesive left over from any tape if tape was used.

Wipe down thoroughly using disinfecting cloths or spray.

- Wipe dry with clean cloth.
- Store item for next usage.

The exterior of the SleepView must also be wiped clean with a disinfecting cloth or spray or a standard household surface cleanser.

Maintenance

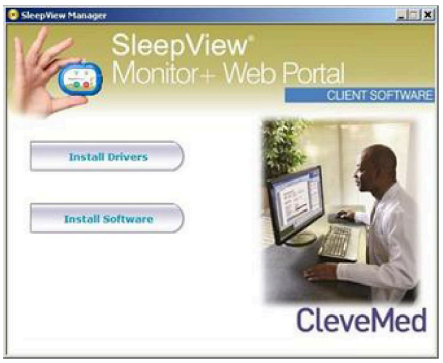
SleepView does not require calibration. The SleepView software can be updated by customers. The SleepView Manager software will alert users that an update is available as long as the computer is connected to the internet. Follow the software prompts to download and install any updates. Please contact customer service with any questions.

Chapter 4: SleepView Manager Software

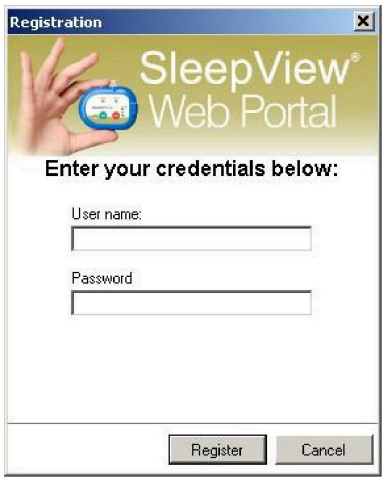
The SleepView Manager software is used to prepare the SleepView Monitor for collecting patient data and to download the data collected as part of a study. The SleepView interfaces with the PC through a micro USB port located inside the battery door. The battery must be removed to connect the USB cable. The SleepView Monitor must be manually turned on by pushing the ON button after connecting to the PC.

Installing The SleepView Manager Program

1. Insert the SleepView Manager Installation CD-ROM into your computer's CD-ROM drive. It should automatically open the SleepView Manager splash screen as shown below. If this does not occur, please navigate to the CD-ROM folder and double-click "SOFTWARE_MENU.EXE"



2. Click "Install Drivers" and follow the on-screen prompts to complete driver installation.
3. Click "Install Software" and follow on-screen prompts to install the SleepView Manager Software.
4. Once the software has been installed you may be prompted to register the system at **www.clevemedsleepview.com.**
5. If this is the first time you are installing the system you will be prompted to enter valid clevemedsleepview.com credentials (username and password) using the fields provided and click <Register>. If you do not have a username or password then click <Cancel> and contact technical support for assistance.



PLEASE NOTE: If you are unable to register the system with www.clevemedsleepview.com at the time of installation, you can re-initiate registration by selecting "Upload Client" from the SleepView Manager Program menu. Additionally this dialog will appear after every reboot until you have registered the system with **www.clevemedsleepview.com.**

Chapter 5: Data Upload Management

An important component of the SleepView Manager called the "PSG Upload Client" runs continuously in the background to ensure any data taken from a SleepView device will be transferred to the website. Once registered, this component automatically starts and as a rule, will always be running even after a reboot without user intervention. The component runs quietly as an icon in the system tray only notifying the user using balloon tips when major system state changes occur such as:

- Initial connection to server is established.
- Connection to server is lost.
- An upload begins after being idle.

Additional information about the upload process can be viewed from the Uploader window, which can be accessed by double-clicking on the Uploader icon. The top portion of the main screen provides the general operating status of the system, which can include:

- Indication of idleness "No files to upload"
- Indication of disconnection from the server "Server unavailable"
- Indication of what files are being uploaded active or queued

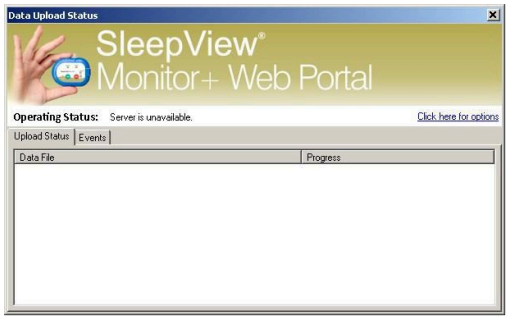
The bottom portion of the window offers two information tabs:

- Upload Status — showing the progress of files being uploaded.
- Events — showing time stamped events of all major events including when files were uploaded, completed and what errors occurred.

PLEASE NOTE: The information in the "Events" tab is duplicated in the log files that reside in the Program folder of this application.

Upload Status

The software is configured to monitor a specific directory for files. When files become available it immediately queues them for upload to the server. The software employs multiple threads to do its work, which can be configured using the options screen. As shown in the picture at the left, the "Upload Status" tab will show the upload progress of one or more files with additional information provided in the "Operating Status" field in the top portion of the window. This field will display the number of files being actively uploaded "Uploading" and the number of files pending upload "queued".



Events

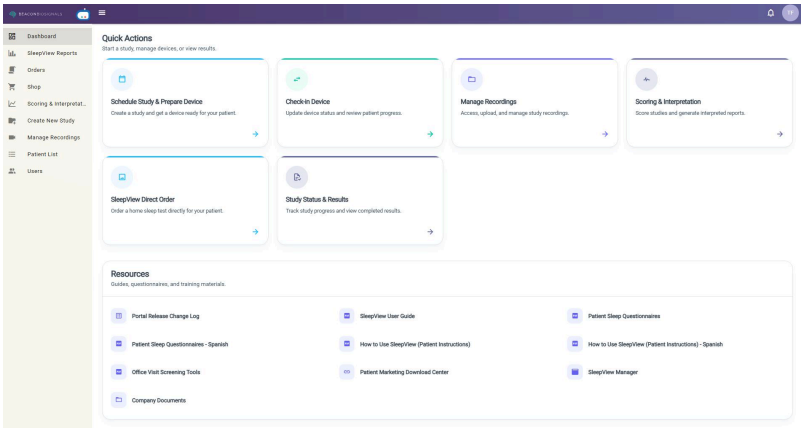
All operations including upload begin, end and completion along with any errors during processing are logged to a date-stamped log file in the application directory. These events can be viewed live on the “Events” tab.

Chapter 6: Using SleepView with SleepView® Web Portal v2

SleepView is designed for use with the SleepView® Web Portal v2 website which provides a guided workflow for patient and study management. The SleepView Manager software is integrated with the website at specific points in the process.

Creating A New Study

1. To begin using the web portal, enter the following address into your web browser: **SleepView® Web Portal v2.**
2. Click the "login" button in the upper right corner. To enter the site, enter your username and password and click "Log In".
3. The main page of the site will appear and is separated into three sections indicated by the text at the top right of the page:



Section	Purpose
Home	Provides access to workflow tasks
Patients	Provides patient management functions
Studies	Provides study management functions

The "Home" page provides three main tasks that are part of the portal workflow indicated as buttons within the section:

STEP 1

Schedule Study

Create a new study record for an existing or new patient.

STEP 2

Check-In Device, Manage Recordings

Check-in recorded data files from a SleepView and assign those data files to scheduled studies

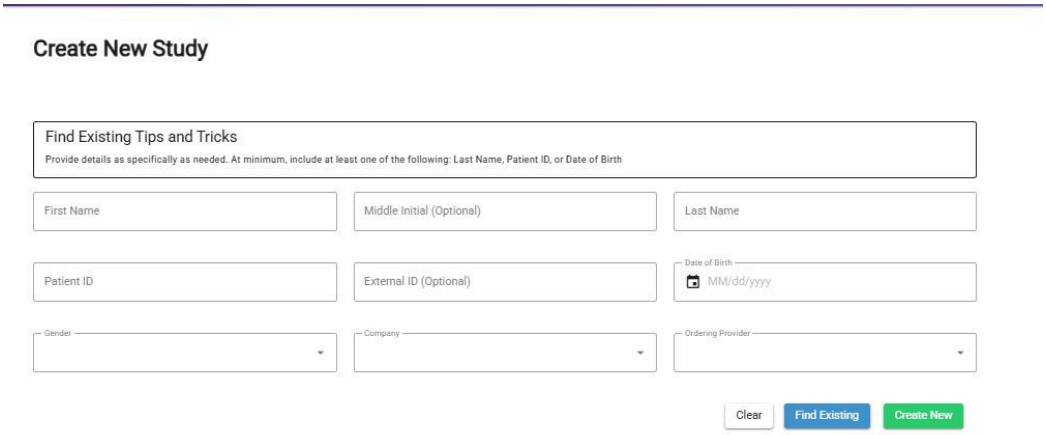
STEP 3

Review Studies

Retrieve study reports or check the status of a study.

4. To create a new study, click the "Scheduled study & prepare device" button from the "Home" page and the following page will appear

PLEASE NOTE: The Patient List will be empty if this is the first time you are scheduling a study with the company.



5. Select an existing patient by clicking on a name in the list provided. Once you have selected or added the patient to study, the next step will become available.

PLEASE NOTE: If this is a new patient, enter the new patient information in the fields provided and click “Create New”.

7. The final step of study creation is "Enter/Edit ID into Device". Each SleepView device that is registered with the portal is provided in the drop-down menu labeled "Select Device". Select the device that is used for the study. If the desired SleepView Monitor has never been registered with the system, select "New Device" from the drop-down box.
8. Click "Prepare Device" and the website will start the SleepView Manager software.

PLEASE NOTE: If this is the first time you are using the system with your web browser, you may receive a security warning since the website is executing a program on your machine. The warning will vary depending on the browser you are using, and will offer you the option to allow the website to access the secured resource. If you experience any problems with this, please contact technical support.

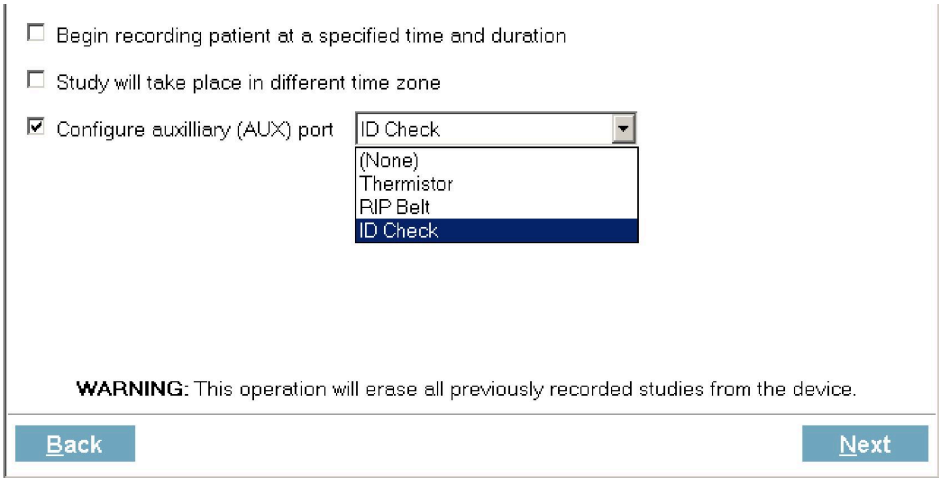
IMPORTANT NOTE: Preparing a SleepView Monitor for a new study will cause all previously recorded studies to be deleted from it.

The "Connect Device" page will appear with instructions on how to connect the system to the PC.

1. Connect your SleepView to the computer using the USB cable provided. There is a connection inside the battery compartment for one end of the USB cable.
2. Once the SleepView is connected to the computer, press and hold the ON button until the power LED illuminates.

PLEASE NOTE: A green or flashing amber LED is not a concern; however, if at any point the power LED flashes red, this indicates a system failure and technical support should be contacted immediately.

3. Click <Next> and the “Prepare device” screen will appear with the recording options.



4. If you would like the SleepView unit to automatically turn on and remain on for a specified duration, click the checkbox labeled "Begin recording at a specified time and duration" and select the desired start time and duration (specified in hours and minutes). It is recommended that the recording duration only last as long as the patient is likely to sleep so that the Smart Check can be used in the morning.

AUTOMATIC RECORDING NOTE: If a recording time is programmed, the OFF button on the SleepView Monitor will be disabled during the set recording duration. The patient may turn SleepView ON early (for example, if they chose to go to bed earlier than scheduled) by pressing the ON button. SleepView will continue to record for the programmed duration time. The programmed auto recording time can be canceled by pressing down the OFF button, then pressing the ON button, and then releasing the OFF button after the LEDs rapidly flash amber.

5. If the study you are scheduling will be done at a location in a time zone different from the one your computer is set to, check the checkbox labeled "Study will take place in a different time zone" and select the time zone using the drop-down list provided. This will adjust the internal clock within the SleepView to the time zone where the study will be performed.
6. Configure the auxiliary port for the appropriate sensor that will be used for the study. If no sensor will be used, select "(None)" to disable the LED for this channel only. It will remain off during use.

IMPORTANT NOTE: The next step will cause all previously recorded studies to be deleted from the device.

7. Click <Next> and the "Downloading Parameters" page will appear and begin to send all the options you selected to the device.
8. Once programming is complete, all the operations will report "DONE" next to its label and the <NEXT> button will become active. Click <Next> and the "Insert Battery and Check Device" page will appear.

PLEASE NOTE: If you did not program the SleepView Monitor to automatically turn ON then "N/A" will appear next to "Setting auto-start time"

9. The SleepView will turn OFF after programming is complete.

10. Press and hold the ON button until the power LED lights green.

> **IMPORTANT NOTE:** If the power LED does not illuminate green and flashes amber, then the settings did not properly transfer into the device.

11. A green power LED indicates that the unit is ready for the study. Turn OFF the unit prior to sending home with a patient. Upon clicking <Finish> the SleepView Manager window will close.
12. Upon clicking <Finish> the SleepView Manager window will close.

Check-In Study Data From SleepView Monitor

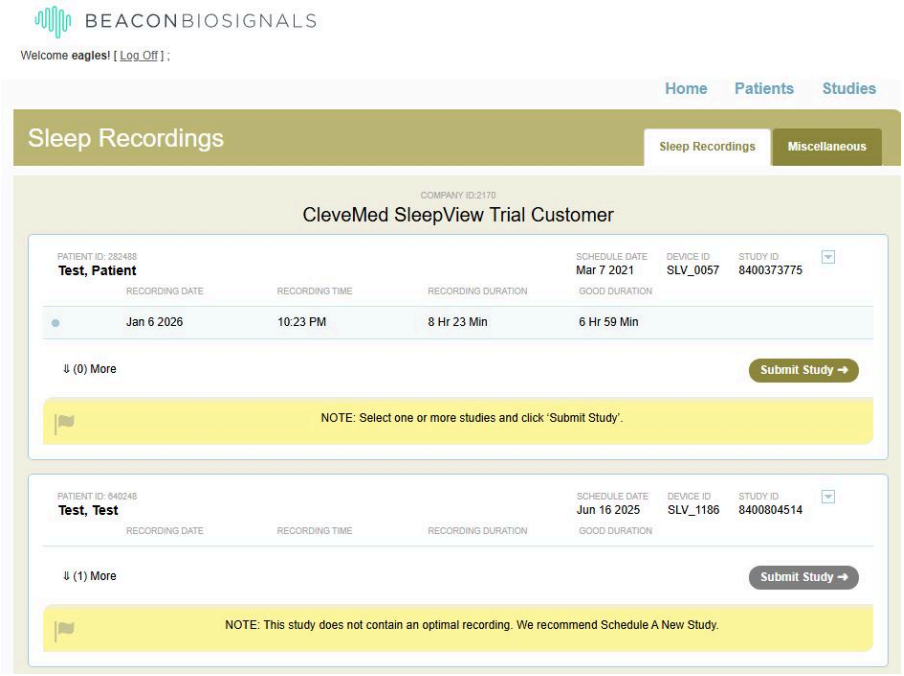
When a patient returns a SleepView, the study data must be uploaded to the portal before it can be submitted for review and interpretation. The following instructions will provide a walkthrough of the process of transferring data from a SleepView Monitor to Portal.

From the home page select Step 2 Check-In Device.

1. The "Connect Device" page will appear with instructions on how to connect the system to the PC.
2. Connect your SleepView to the computer using the USB cable provided. There is a connection inside the battery compartment for one end of the USB cable.
3. Once the SleepView is connected to the computer, press and hold the ON button for at least 3 seconds.
4. The power LED will illuminate. Typically, it will immediately illuminate green, but it may also flash amber first and then green.
5. Click <Next> and the "Download Files" screen will appear and begin to show the progress of files being transferred from the device to the computer. Two progress bars will be shown. The top progress bar shows the progress of the current file being downloaded. The second one shows the overall progress of the entire transaction.
6. Wait until the transaction is complete and the <Finish> button becomes available. Press the OFF button on the SleepView until the power LED turns off and disconnect it from the PC.
7. Click <Finish> and you will be returned to the home screen.
8. At this point, SleepView data will be transferred to the portal and processed to become available within the “Manage Recordings” section.

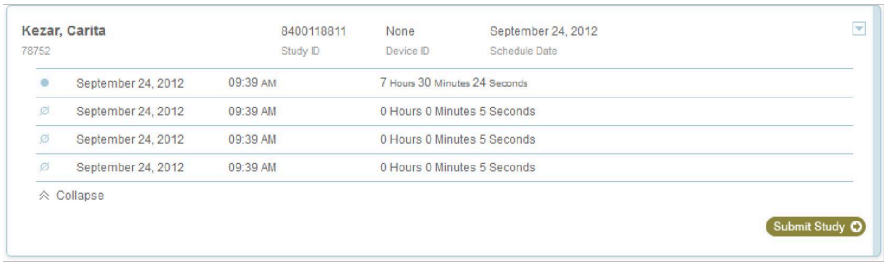
Chapter 7: Manage Recordings

1. On the home page, select “Step 2 Manage Recordings” to assign the data files to scheduled patient studies. You will be presented with a list of scheduled studies with recordings uploaded to them.



2. Successful recordings will be listed under each scheduled study. If there is one study click "Submit Study." If there are more than one study listed, select one study and click "Submit Study."
3. A questionnaire will appear and will need to be filled out before the selected recording can be submitted to review.
4. Repeat the above steps for any remaining studies.

Clicking the double arrow at the bottom left of the study list will expand to show suboptimal recordings.



These studies may be the result of training the patient or testing the system before dispensing it, or the patient may not have recorded good data overnight. Please contact technical support if you have any questions about these studies.

The blue arrow at the top right of the study list is an options menu. Please follow the on-screen prompts or contact technical support for assistance.

About The Miscellaneous Tab

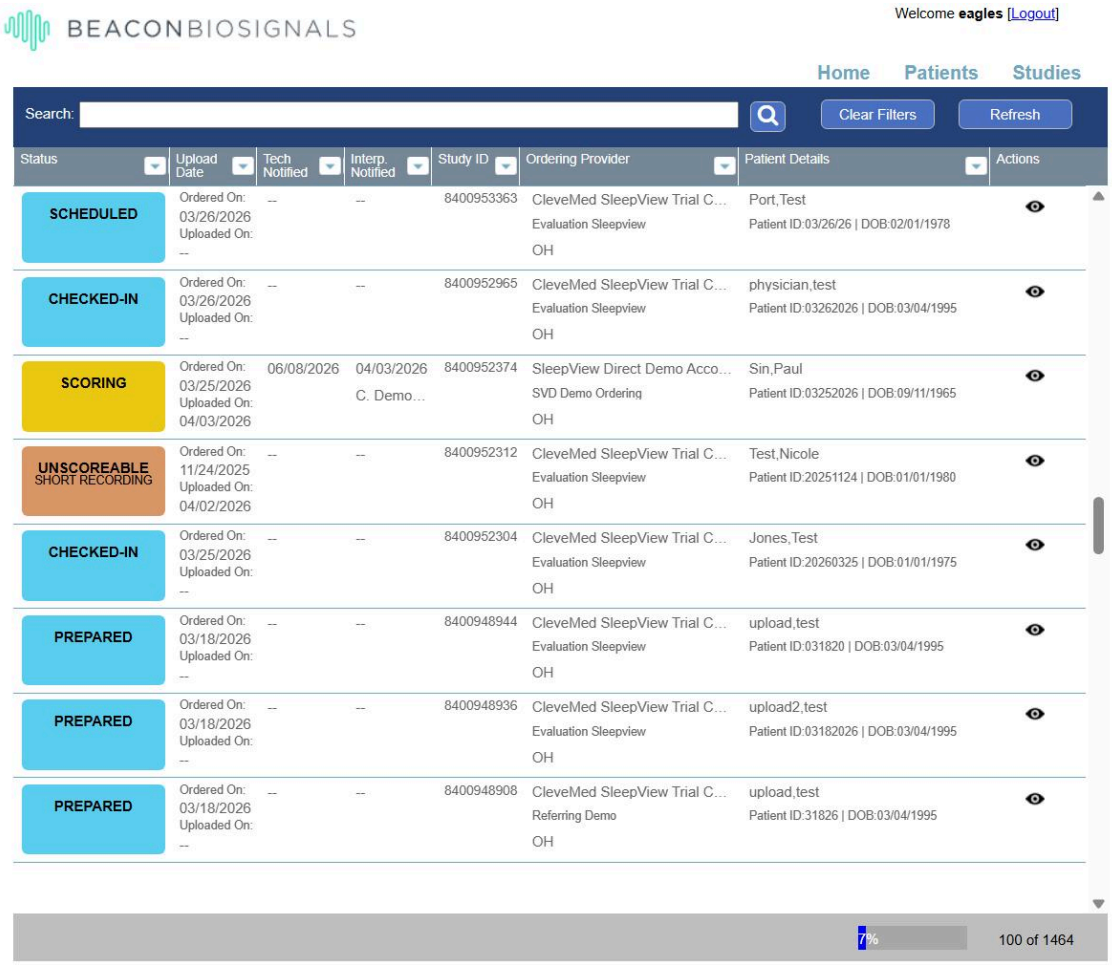
If a study is uploaded that does not match a scheduled study or as part of a scheduled study and was not submitted for review, it will be listed on the “Miscellaneous” tab.

If a study was not properly acquired and submitted without a proper “Study ID”, you may need to look for it in this list and try to match the time, date, and unit ID, to the actual study date and time and SleepView Monitor that went home with the patient.

IMPORTANT NOTE: The “Miscellaneous” Tab is not designed to be a part of regular system usage. It is offered only to manage situations that may occur if the user fails to follow the recommended steps to using SleepView. Please contact technical support if you are having difficulty with the system usage.

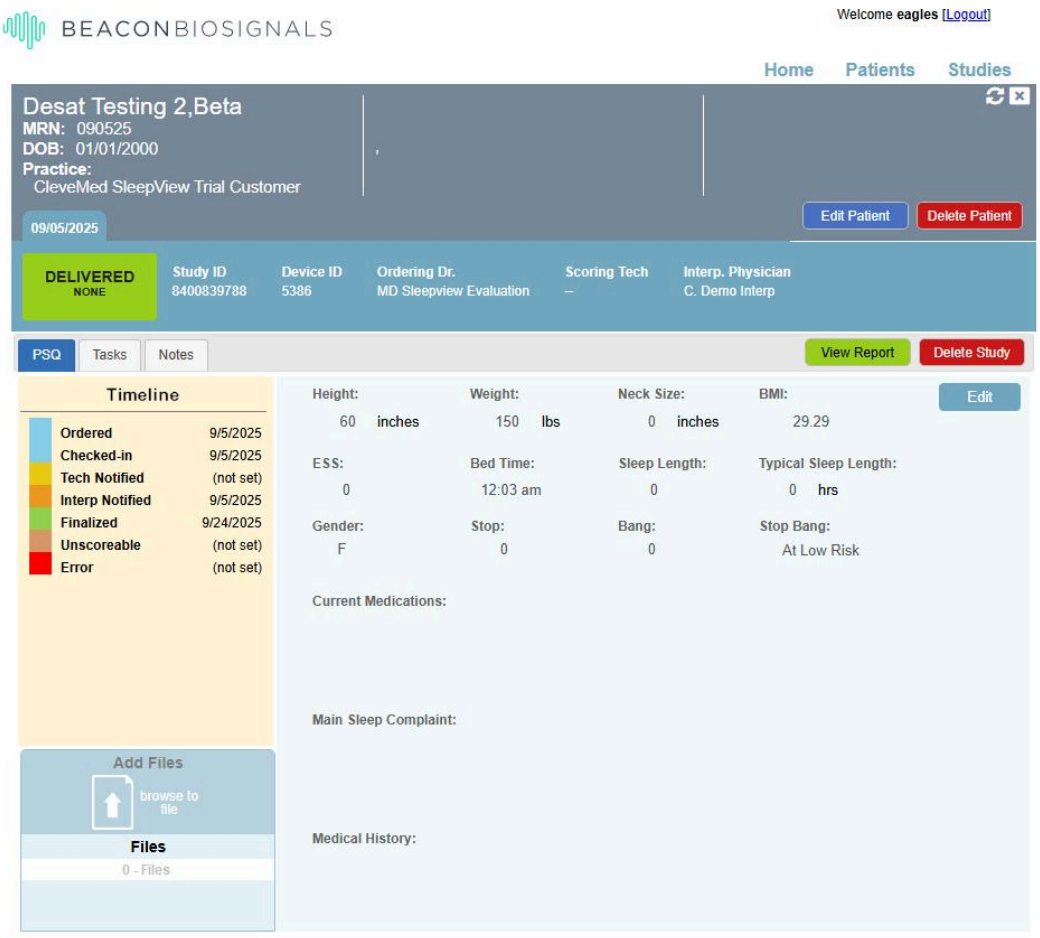
Chapter 8: Reviewing Studies

To review a study, click “Review Studies” from the “Home” page and a list of available studies for your practice will be presented:



The list can be searched, filtered, and sorted by selecting the menu button at the top of each column. Click on the study you would like to view and a study detail page will appear.

The study detail page has two sections: "Patient Details" displays the patient information at the top of the page. "Patient Studies" provides one or more tabs representing each study the system has for that patient. The tab for the study you selected will be highlighted. Within the selected tab are presented summary information about the type of study and equipment used, as well as access to the questionnaire and reports.



Click the "view report" button to view, save or print the study report in PDF. Each report is electronically signed by the interpreter. An e-mail will be sent to the primary contact for your practice when a report is completed by the interpreter.

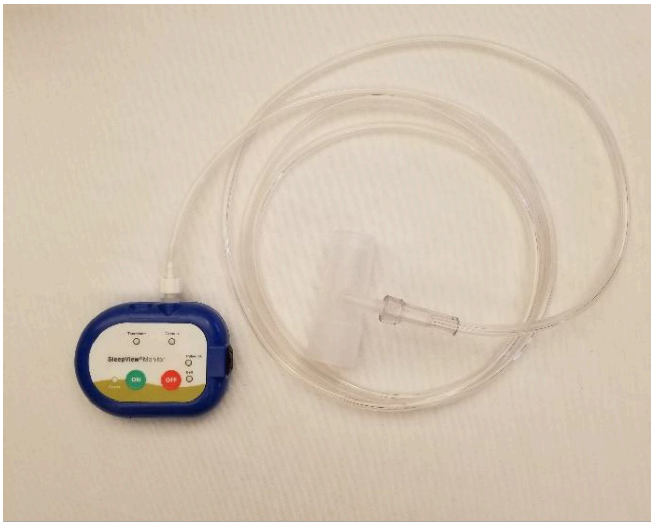
PLEASE NOTE: In order to verify electronically signed documents, you must use Adobe Acrobat Reader X or higher to view the signed PDF report.

Chapter 9: Collecting Data

A new AAA battery should be used for each overnight study. A new battery will typically last for more than 10 hours of continuous recording. The SleepView mounts directly on the respiratory effort belt. It is recommended that the SleepView only be detached from the belt when a new belt is needed. The SleepView and the belt may be cleaned with the same cleaner while they are connected to each other as described in Chapter 3.

The belt with the SleepView should be placed on the patient first. Next, the cannula, thermistor, and pulse oximetry sensor may be placed. After the sensors are positioned on the patient the SleepView Monitor can be turned ON. Patient instructional materials are available from Beacon Biosignals — please contact your sales representative for information.

SleepView can be used in conjunction with CPAP at a set pressure of 20 cm water or less. A standard pressure line adaptor is placed in line with the CPAP hose. Tubing is then run from the pressure line adaptor to the cannula input on the SleepView in place of a cannula. The recorded airflow signal will appear the same as a signal without treatment. The SleepView does not record the set CPAP pressure.



LED Signal Status Indicators

After the sensors are placed the SleepView should be turned on. The SleepView Monitor will go through a brief boot up process. The LED indicators will flash during the bootup process as described in the table.

LED Action	Indication	Action Required
All LEDs flash green OFF 5 times	This indicates that the device has its Auto Start Time enabled.	None, unless it wasn't supposed to be set.
All LEDs quickly flash amber OFF 10 times	This indicates that the device has just had its Auto Start Time disabled by holding the off button on startup.	None, unless it wasn't meant to be overridden.
All LEDs are momentarily green	This is the normal boot indication	None — this state should be very short before the unit starts. If all LEDs remain, turn the device OFF and back ON.

After the boot process, the LED indicators will display the status of each sensor. The LED should be green for all sensors that are supposed to be collecting data for the study.

LED	Red	Amber	Green
Power	Not Recording	Low Battery	New Battery
Cannula	Not Connected or Poor Signal	N/A	Good Signal
Auxiliary (LED remains off if sensor set to none)	Not Connected	Poor Signal	Good Signal
Pulse Oximeter	Not Connected	Poor Signal	Good Signal
Belt	Not Connected	Poor Signal	Good Signal

The sensor indicators will remain lit for 90 seconds. Then all but the power LED will turn OFF. At any time the power button may be depressed to turn ON the indicators for an additional 60 seconds. During normal recording, the power indicator will pulse green.

At the end of the study, the patient must press and hold the OFF button to turn the device OFF manually. Alternatively, the device can be programmed to turn OFF automatically using the SleepView Manager software.

Smart Check Feature

The SleepView offers a feature for the patient to see if the system collected enough data that is of good quality (at least 2 hours). Each time the unit is turned OFF, the status LEDs will show a light moving in a circular pattern to indicate the following:

1. LEDs show green circle pattern to indicate a good quality study was recorded.
2. LEDs show red circle pattern to indicate a good quality study has NOT been recorded.

PLEASE NOTE: For patients that are color blind, please note that the green LEDs indicating a good quality study rotate in a clockwise direction while the red LEDs will rotate in counter-clockwise direction.

If the patient did not notice or remember the Smart Check result (e.g. the device was set to automatically turn OFF), the patient can simply turn the SleepView back ON and then turn it OFF again to see the Smart Check result.

Chapter 10: Tips for Dispensing SleepView

Steps for Dispensing SleepView to patients:

1. **Verify the SleepView Has Been Cleaned**
   Verify that the SleepView has been cleaned. See Chapter 3.

2. **Program the Study Using SleepView Manager**
   Use SleepView Manager software to program the study ID and recording time.

3. **Place a New Battery**
   Place a new battery in the SleepView.

4. **Turn the SleepView ON**
   Turn the SleepView ON.

PLEASE NOTE: Verify that the LED indicators flash green five times and that the power LED turns green. This confirms the recording time has been programmed and the battery is fully charged.

5. **Verify Correct Belt Size**
   Verify that the correct size belt is connected to the SleepView.

6. **Train the Patient on Sensor Hookup**
   Train the patient on hooking up the sensors and give them hookup instructions.

7. **Instruct the Patient to Turn OFF and Use Smart Check**
   Instruct the patient to turn OFF the SleepView by pressing the OFF button until the LED changes. Instruct the patient to use Smart Check to verify diagnostic data was recorded.

Appendix A: Technical Specifications

System Specifications

Specification	Value
Storage Temperature / Humidity	-25 to 70°C / 25 to 95% (non-condensing)
Operating Temperature / Humidity	5-40 °C / 15-93% (non-condensing)
Case Weight (all parts & accessories)	4 lbs
Patient Unit Weight	2 oz / 57 g (approx. with battery)
Number of Channels	8 channels
Resolution	12 bits
Power Source	1 AAA alkaline battery
Battery Life	10 hours continuous use
User Control	ON/OFF membrane switch
Case Material	Polycarbonate (20% glass fiber)
Indicators	Power On, Low Battery, Good Signal for Auxiliary, Nasal Cannula, RIP Belt, and Pulse Oximetry sensors

Channel & Sensor Table

Channel Name	Sensor
Respiratory Effort	RIP Belt
Body Position	Internal 3-axis accelerometer
Auxiliary	Thermistor, IDcheck, or RIP Belt
Airflow	Nasal Cannula
Snore (derived from airflow)	Nasal Cannula
Pulse Oximetry	Pulse Oximetry sensor
Heart Rate	Pulse Oximetry sensor