

SleepView®

User Manual



CleveMed

■ ■ ■ ■ Cleveland Medical Devices Inc.

SLEEPVIEW USER MANUAL



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Chapter 1: Introduction

The SleepView Monitor complies with Part 15 of the FCC rules. 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.

Contraindications

Normal operation may be affected when used in the vicinity of equipment marked with the following symbol: 

This device complies with CFR 47 – Part 15, 15.109(b), 15.249 and 15.247.

See Appendix A : Electromagnetic Immunity and Emissions for more details.

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 with or sold by CleveMed for use with the SleepView system may result in increased emissions or decreased immunity of the SleepView System.

Minimum System Requirements

- Personal computer with 2.4 GHz or higher processor;
- Microsoft® Windows XP Service Pack 3 or higher, or
- Microsoft® Windows Vista, or
- Microsoft® Windows 7;
- 1 GB of installed memory;
- Minimum 2GB free hard disk space
- CD-ROM Drive;
- Mouse or other pointing device;
- One USB port;
- Internet Explorer 8.0 or higher, or
- Firefox 19.0 or higher
- Adobe Acrobat Reader X or higher

PLEASE NOTE: For optimal software performance close other programs while using SleepView.

Intended Use

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

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

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.

Date of Purchase: _____

SleepView Monitor Serial Number: _____

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WARRANTY: CleveMed 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 time of delivery to Purchaser. The obligation of CleveMed under this warranty is limited to the repair, re-work or replacement, at CleveMed's option of any non-conforming product, part or component thereof, which within one (1) year from date of delivery is examined by CleveMed and discloses to CleveMed's satisfaction to have been non-conforming or defective. CleveMed 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 CleveMed. 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 CleveMed. Items not manufactured by CleveMed carry the original manufacturer's warranty. CleveMed makes no warranties, expressed or implied, including without limitation, warranties of merchantability, fitness for particular purpose or performance characteristics, except to the extent set forth herein. Technical support is included free of charge within the warranty period. Technical support for SleepView is offered from 8:00 am to 8:00 pm eastern standard time. CleveMed offers 24/7 technical support for some of its medical products to accommodate urgent customer calls. Non-urgent customer calls made after hours will be subject to additional charges based on CleveMed's hourly rate of \$175 / hour (1hour min).

Chapter 2: About SleepView

General Device Description

SleepView is a type III sleep system capable of recording, displaying, scoring and analyzing 7 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 SleepView Manager with either the web portal www.clevemedsleepview.com or Crystal PSG desktop software. The SleepView Monitor is worn by the patient and is responsible for acquiring the physiological signals (7 channels) 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 7 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)
- Thermistor
- Snore
- Pulse Oximetry
- Respiratory Effort (chest)
- Body Position (supine, prone, left, right, and upright)
- Heart Rate

Chapter 3: Maintenance of SleepView Monitor and Accessories

In order to prevent the spread of bacteria and other germs from one patient to another, supplies and accessories including the respiratory belt, pulse oximeter, and thermistor must be disinfected between uses and/or between patients. The cannula is intended for a single use only, please discard it after completion of study.

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:

1. Gather belts, pulse oximeter, re-usable nasal sensor/thermistor
2. Remove adhesive left over from any tape if tape was used
3. Wipe down thoroughly using disinfecting cloths or spray
4. Wipe dry with clean cloth,
5. Store item for next usage.
6. The exterior of the SleepView must also be wiped clean with a disinfecting cloth or spray or a standard household surface cleanser.

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 with www.clevemedsleepview.com.

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5. If this is the first time you are installing the system, you will be prompted with a dialog entitled "Registration". In order to continue, enter valid clevemedssleepview.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.clevemedssleepview.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.clevemedssleepview.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:

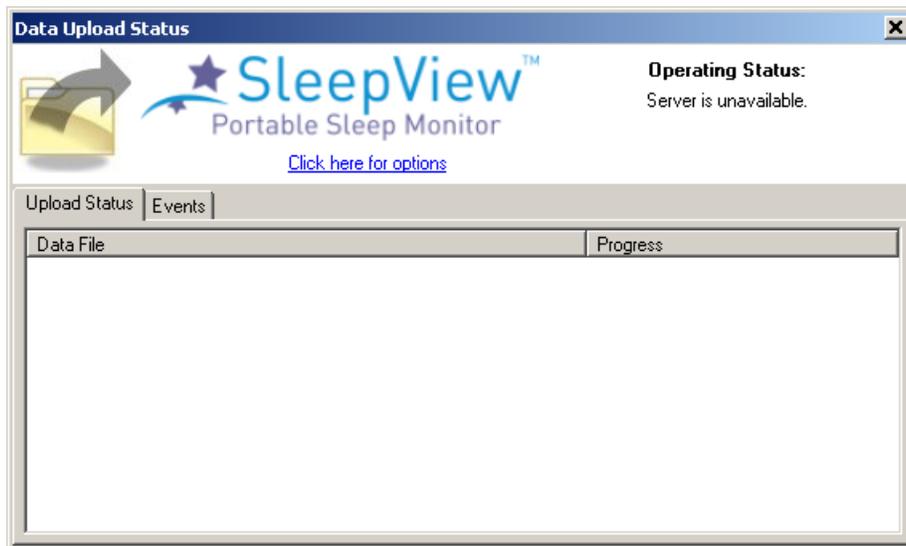
- Indication of idleness “No files to upload”
- Indication of disconnection from the server “Server unavailable”
- Indication of what files are being uploaded active or queued

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 in the “Events” tab.

Chapter 6: Using SleepView with clevemedsleepview.com

SleepView is designed for use with the [clevemedsleepview.com](http://www.clevemedssleepview.com) 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.

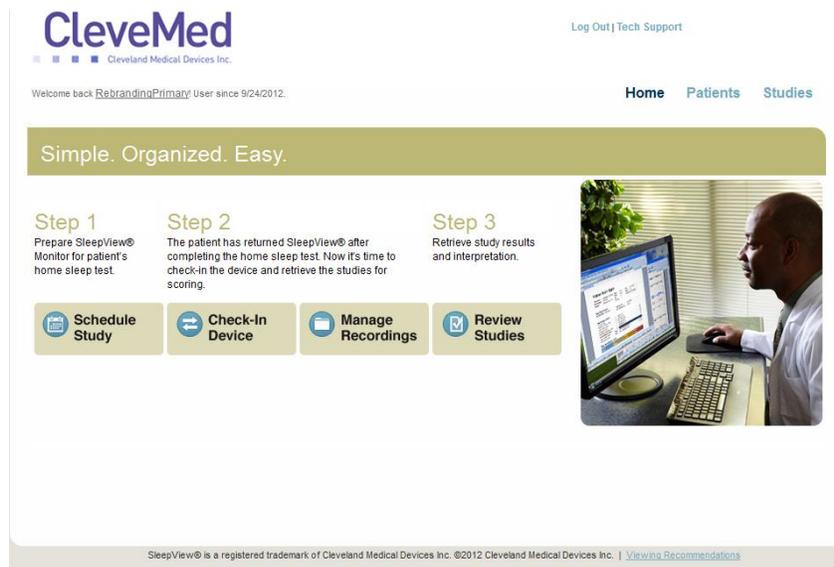
PLEASE NOTE: We recommend viewing the site through Internet Explorer 7, Internet Explorer 8, Internet Explorer 9, Firefox 5.0, or Firefox 6.0

Creating a New Study

1. To begin using the web portal, enter the following address into your web browser:
<http://www.clevemedssleepview.com>.
2. The login page will appear prompting entry of a “User Name” and “Password” in the upper right corner. To enter the site, enter your user name and password and click “Log In”.

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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:

Section	Purpose
<i>Step 1</i> Schedule Study	Create a new study record for an existing or new patient.
<i>Step 2</i> Check-In Device, Manage Recordings	Check in recorded data files from a SleepView and assign those data files to scheduled studies
<i>Step 3</i> Review Studies	Retrieve study reports or check the status of a study.

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- To create a new study, click the “Schedule Study” 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.

Create New Study

Enter Patient Information

Patient ID DOB

Last Name Gender

First Name

MI

Patient ID	First Name	Last Name	MI	DOB	Age	Gender
43937	Gregory	Black		7/18/1963	49	M
7488	Jason	Fuller		5/9/1974	39	M
11345	Jeremiah	Brown	T	12/12/1982	30	M
45730	Felicity	Shawn		9/16/1948	64	F
7053	Jordan	Forrestor		5/22/1942	71	M
6856	Acacia	Judah		7/15/1938	74	F
255021159	Joshua	Moorefield		11/5/1955	57	M
260866137	Edmund	Moore		11/30/1956	56	M
253066030	Ben	Ravens	K	1/9/1957	56	M
259292748	Peter	Wolfsbane	J	12/18/1961	51	M

1 2 3 4 5 ...

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- Select an existing patient by clicking on a name in list provided.

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

Once you have selected, or added the patient to study, the next step will become available.

- The next step “Enter/Edit Study Information” asks that you enter the desired date for the study to take place, as well as the name of the ordering physician. Enter the date of the study in the “Date” field and select the name of the ordering physician from the drop-down menu labeled “Physician.” Click on the “Save Study Info” button to proceed to the next step.

Create New Study

Enter Patient Information

joeusertest, newest (59994)
DOB: 3/3/1975 (36 years old)
Male

Enter/Edit Study Information

StudyID#: 8400116390 [Edit]
Date: 9/13/2011 12:00:00 AM
Physician: Dr. Doctor Test

Enter/Edit ID Into Device

Select Device
NOTE: Enter ID into SleepView Manager Software

Save Device
Commit Study
Cancel Study

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 dropdown 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.

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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 indicated a serious 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 check box 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 ON: If a recording time is programmed, the OFF button on 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 until the programmed OFF time. The programmed auto recording time can be cancelled 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.

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

6. Click <Next> and the “Downloading Parameters” page will appear and begin to send all of the options you selected to the device.
7. Once programming is complete, all of 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”

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

IMPORTANT NOTE: The next steps must be performed in order to commit the settings to the device. You must comply within 2 minutes to ensure proper configuration.

9. Click <NEXT> and the “Insert Battery and Check Device” page will appear. Disconnect the SleepView from the USB cable and within **2 MINUTES** insert a new AAA battery.

10. Press and hold the ON button for at least 3 seconds and verify that 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.

12. Upon clicking <Finish> the SleepView Manager window will close.

13. Click <Commit Study> in the webpage and you are returned to the home screen.

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.

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4. The power LED will illuminate. Typically, it will immediately illuminate green, but it may also flash amber first and then green.

PLEASE NOTE: If at any point the power LED flashes red, this indicates a serious system failure and technical support should be contacted immediately.

5. Click <Next> and the “Download Files” screen will appear and begin to show 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 for at least 3 seconds and disconnect 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.

CleveMed
Cleveland Medical Devices Inc.
 Welcome Frank Llys! [[Log Off](#)]

[Home](#) [Patients](#) [Studies](#)

Manage Recorded Data Sleep Recordings Miscellaneous

Study Name	Study ID	Device ID	Schedule Date						
Lukin, Sebastian 78751	8400118810	None	December 06, 2011						
<table border="1"> <thead> <tr> <th>Date</th> <th>Time</th> <th>Duration</th> </tr> </thead> <tbody> <tr> <td>June 19, 2012</td> <td>09:20 AM</td> <td>7 Hours 30 Minutes 24 Seconds</td> </tr> </tbody> </table>				Date	Time	Duration	June 19, 2012	09:20 AM	7 Hours 30 Minutes 24 Seconds
Date	Time	Duration							
June 19, 2012	09:20 AM	7 Hours 30 Minutes 24 Seconds							
(0) More									
Submit Study									
Kezar, Carita 78752	8400118811	None	September 24, 2012						
<table border="1"> <thead> <tr> <th>Date</th> <th>Time</th> <th>Duration</th> </tr> </thead> <tbody> <tr> <td>September 24, 2012</td> <td>09:39 AM</td> <td>7 Hours 30 Minutes 24 Seconds</td> </tr> </tbody> </table>				Date	Time	Duration	September 24, 2012	09:39 AM	7 Hours 30 Minutes 24 Seconds
Date	Time	Duration							
September 24, 2012	09:39 AM	7 Hours 30 Minutes 24 Seconds							
(3) More									
Submit Study									

[Click to update...](#)

2. Successful recordings will be listed under each scheduled study. If there is one study click “Submit Study.” If there is more than one study listed select one study based on the recording time and duration and then 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.

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

Kezar, Carita 78752		8400118811 Study ID	None Device ID	September 24, 2012 Schedule Date	⌵
●	September 24, 2012	09:39 AM	7 Hours 30 Minutes 24 Seconds		
⊗	September 24, 2012	09:39 AM	0 Hours 0 Minutes 5 Seconds		
⊗	September 24, 2012	09:39 AM	0 Hours 0 Minutes 5 Seconds		
⊗	September 24, 2012	09:39 AM	0 Hours 0 Minutes 5 Seconds		
⌵ Collapse					
					Submit Study ↗

These studies may be the result of training the patient or testing the system before dispensing it or the patient may have not recorded good data over night. 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 option menu. Please follow the onscreen prompts or contact technical support for assistance.

About the Miscellaneous Tab

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

In the event that 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.

PLEASE 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:

Status	Uploaded Date	Tech Notified	Interpreter Notified	Study ID	Ordering Provider	Patient Details
SCHEDULED	--	--	--	8400124187	Family Physicians Center A. Baskerville	Black, Gregory Patient ID: 245987 DOB: 22 Feb 1955
SCHEDULED	--	--	--	8400124188	St. Luke Primary Care Z. Calvin	Fuller, Jason Patient ID: AD022848 DOB: 22 Feb 1948
ASSIGNING	9 May 2013	9 May 2013	9 May 2013	8400124114	Healthcare Clinic S. Doid	Brown, Jeremiah Patient ID: 623544 DOB: 10 Oct 1915
ASSIGNING	13 May 2013	--	--	8400124107	Family Physicians Center D. Edwin	Shawn, Felicity Patient ID: 104150 DOB: 31 Dec 1970
INTERPRETING	10 May 2013	13 May 2013	13 May 2013	8400124101	Carver Sleep Professionals P. Fibber	Forrester, Jordan Patient ID: 25762 DOB: 29 Nov 1944
ASSIGNING	13 May 2013	--	--	8400124099	Family Dental Group H. Gilbert	Juda, Acacia Patient ID: 80035 DOB: 29 Oct 1956
INTERPRETING	13 May 2013	13 May 2013	13 May 2013	8400124095	Carver Sleep Professionals J. Herbert	Blackfield, Carl Patient ID: 13129-00014 DOB: 2 Dec 1985
ASSIGNING	13 May 2013	--	--	8400124094	Family Physicians Center K. Jefferson	Moorefield, Joshua Patient ID: 37090 DOB: 8 Nov 1970
SCHEDULED	--	--	--	8400124092	St. Luke Primary Care A. Kilmanjaro	Moore, Edmund Patient ID: 000000001 DOB: 12 Dec 1953
ASSIGNING	13 May 2013	--	--	8400124096	Family Physicians Center B. Everest	Ravens, Ben Patient ID: 4644 DOB: 12 Aug 1948
SCORING	9 May 2013	13 May 2013	9 May 2013	8400124084	Family Dental Group O. Chorus	Wolfsbane, Peter Patient ID: 01111 DOB: 10 Oct 1987
ASSIGNING	13 May 2013	--	--	8400124083	Dayton Dentists F. Good	Pittsburgh, Susan Patient ID: 2878 DOB: 21 Sep 1980
INTERPRETING	9 May 2013	13 May 2013	13 May 2013	8400124081	Healthcare Clinic K. Lincoln	Violet, Lucy Patient ID: 12649 DOB: 23 Nov 1974
INTERPRETING	9 May 2013	9 May 2013	13 May 2013	8400124079	Neighborhood Family Physicians E. Robbin	Langsdon, James Patient ID: 14267 DOB: 16 Jun 1958
ASSIGNING	13 May 2013	--	--	8400124075	Neighborhood Family Physicians E. Robbin	Xavier, Pedro Patient ID: 46817 DOB: 12 Jul 1980
DELIVERED	9 May 2013	9 May 2013	13 May 2013	8400124066	Dayton Dentists F. Good	McIntyre, Allison Patient ID: 4905 DOB: 20 Dec 1985

The above list can be filtered by selecting the radio button for each status. The list can also be sorted by clicking on any of the column headings. The search box can be used to look for a study. 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.

Patient Details

Delete
Edit

King, Jim (25567386)
 DOB: 5/5/1954 (58 years old)
 Male

Patient Studies
9/24/2012

■ **Status:** Delivered

Date: 9/24/2012 Delete Study

Study ID: 8400118806 Report Ready
(View Doc)

Device ID:

Physician: Dr. Alfonz McGregor

Office: Rebranding Staged Data

Questionnaire Data Edit

Study ID: 8400118806

Study Date: 9/24/2012

Height (inches): 65.0

Weight (lbs): 165

Neck Size (inches): 12.0

BMI: 27.5

Time patient fell asleep: 10:10 PM

Hours patient slept last night: 7

Hours patient slept on a typical night: 8

ESS (/24): 9

Patient's Main Sleep Complaint:
Snoring

Current Medications:
None

Medical History:
None

Click the “Report Ready” 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.

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: Using SleepView Manager (Offline)

Offline usage of the SleepView Manager can be used when an internet connection to clevemedsleepview.com is not available.

Preparing SleepView for a Study (Offline Usage)

Before a device can be sent home with a patient, it must be prepared by entering in information about the study and how it will be collected. The following instruction provides a walkthrough of the configuration process and explains each of the configuration options.

The SleepView manager must be manually opened by locating SleepView from the Windows program list. Select SleepView manager.

IMPORTANT NOTE: preparing a device for a new study will cause all previously recorded studies to be deleted from the device.

1. Click <Prepare device> and 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 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 serious system failure and technical support should be contacted immediately.

4. Click <Next> and the “Prepare device” screen will appear with the recording options
5. Enter a Study ID in the field provided. If you do not have a Study ID, click the checkbox labeled “I don’t have a Study ID” and a default “(UNKNOWN)” ID will be used for your study.

PLEASE NOTE: it is recommended that a study id is assigned to each study to allow for better data management.

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6. If you would like the SleepView unit to automatically turn on and remain on for a specified duration, click the check box labeled “Begin recording at a specified time and duration” and select the desired start time and duration (specified in hours and minutes).

PLEASE NOTE: see note on “automatic on” below.

If the study you are scheduling is being 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.

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 of the options you selected down to the device.
8. Once programming is complete, all of 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 unit 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.

IMPORTANT NOTE: the next steps must be performed in order to commit the settings to the device. You must comply within 2 minutes to ensure proper configuration.

10. Click <NEXT> and the “Insert Battery and Check Device” page will appear. Disconnect the SleepView from the USB cable and within **2 minutes** insert a new AAA battery.
11. Press and hold the ON button for at least 3 seconds and verify that 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.

13. A green power LED indicates that the unit is ready for the study. Turn off the unit prior to sending home with a patient.

14. Click <Finish> and the SleepView Manager window will return to the main screen.

AUTOMATIC ON: if a recording time is programmed, the off button on the SleepView will be disabled during the set recording duration. The patient may turn the system on early, for example if they chose to go to bed early, by pressing to on button. The system will continue to record until the programmed off time. The programmed auto recording time can be cancelled by holding the off button, pressing the on button, and then releasing the off button after the LEDs rapidly flash amber.

Downloading Study Data from SleepView Monitor (Offline Usage)

When a patient returns a SleepView, the study data must be downloaded to a computer before it can be sent for review and interpretation. The following instructions will provide a walkthrough of the process of downloading data from a SleepView.

1. Click <Download data> and 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 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 serious system failure and technical support should be contacted immediately.

4. Click <Next> and the “Download Files” screen will appear and begin to show 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.
5. Wait until the transaction is complete and the <Finish> button becomes available
6. Click <Finish> and you will be returned to the main screen.
7. Press the OFF button for at least 3 seconds until the LED turn off and disconnect from the PC.

Chapter 10: 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 if a different size 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 CleveMed, please contact your sales representative for information.

SleepView can be used in conjunction with CPAP at 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 boot up 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 start up.	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.

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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.

	Red	Amber	Green
Power	Not Recording	Low Battery	New Battery
Cannula	Not Connected or Poor Signal	N/A	Good Signal
Thermistor	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). Before returning a unit to their doctor, a patient may turn the unit on by pressing and holding the “ON” button for at least 5 seconds. After that time the status LEDs will display in one of the following ways:

1. LEDs flash green indicating a good quality study was recorded.
2. LEDs flash red indicating a bad quality study was recorded.

After using smart-check press the OFF button to turn off the device.

Chapter 11: Tips for Dispensing SleepView

Steps for Dispensing SleepView to patients:

- Verify that the SleepView has been cleaned (See Chapter 3)
- Use SleepView Manager software to program the study ID and recording time
- Place a new battery in the SleepView
- 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.

- Verify that the correct size belt is connected to the SleepView
- Train the patient on hooking up the sensors and give them hookup instructions
- Instruct the patient to use Smart-Check to verify diagnostic data was recorded.
- Instruct the patient to turn OFF the SleepView by pressing the OFF button for 3 seconds.

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Appendix A: Electromagnetic Immunity and Emissions

Guidance and manufacturer's declaration – electromagnetic immunity			
The SleepView System is intended for use in the electromagnetic environment specified below. The customer or the user of the SleepView System should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40% <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5% <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SleepView System requires continued operation during power mains interruptions, it is recommended that the SleepView System be powered from an uninterruptible power supply or a battery.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SleepView system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.3 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SleepView system is used exceeds the applicable RF compliance level above, the SleepView system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SleepView system. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Recommended separation distances between portable and mobile RF communications equipment and the SleepView system			
The SleepView system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SleepView system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SleepView system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Guidance and manufacturer's declaration – electromagnetic emissions		
The SleepView System is intended for use in the electromagnetic environment specified below. The customer or the user of the SleepView System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SleepView uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SleepView System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	