Sleep Data Recorder
Instructions for Use
Model PL6 & PL7
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Certifications & Device Classifications

| CE 0413 | The CE mark declares that the Sleep Data Recorder is in compliance with the EU Medical Device Directive. |
| ETL US | The ETL mark is a product safety declaration that the Sleep Data Recorder has been independently tested and certified to applicable U.S. and Canadian product safety standards. |


The Sleep Data Recorder complies to the following product safety standards:
- IEC 60601-1:2001 2nd ed.: MEDICAL ELECTRICAL EQUIPMENT-PART 1: GENERAL REQUIREMENTS FOR SAFETY.

The Sleep Data Recorder is cleared by the FDA (K092003).

- Classified as type BF according to the degree of protection against electric shock. Mode of operation: Continuous.
- Attention. Consult accompanying documentation.
- In accordance with the European regulation on Waste of Electrical and Electronic Equipment (WEEE) the Sleep recorder may not be disposed of as unsorted municipal waste and should be returned to MyCardio when it is ready for disposal.

SN | Serial Number.

Date of manufacture may contain serial number.
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Introduction
This document may refer to users of the Sleep Data Recorder generally as “User” or “Users,” licensed Healthcare Practitioners as “Clinician” or “Clinicians” and individuals under their care as “Patient” or “Patients”. The SleepImage System is Software as a Medical Device (SaMD), designed to automatically analyze and display Electrocardiogram (ECG) and optionally it analyzes and displays oxygen saturation data (SpO2). This information is intended to assist Healthcare Professionals in evaluating Sleep Disorders. Before using SleepImage, please read this manual carefully paying particular attention to the Warnings and Cautions.

Intended Use
The Sleep Data Recorder is intended for use by a physician or a trained technician for the collection of physiological (Actigraphy) and Electrocardiogram (ECG) recordings during sleep that will be used for screening different sleep associated disorders. The intended environment is any dry space used for sleeping.

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

Data Acquisition Characteristics
The SleepImage Software analyzes evenly sampled normal sinus rhythm ECG waveforms. SleepImage can successfully analyze data that meets the recommended minimum data acquisition characteristics specified in the Website Instructions for Use.

Data Sources
• SleepImage M1 Sleep Data Recorder
• EDF files containing ECG data collected during sleep

This list will be updated as additional Recorders and File types are identified and allowed by MyCardio.

Warnings and Cautions
• The Sleep Data Recorder is not to be used as a heart monitor and is not defibrillator proof.
• Long term contact with ECG electrode may cause skin irritation; wash area after each use.
• The Sleep Data Recorder generates and can radiate radio frequency energy and electromagnetic interference may result. The Recorder has been tested and found to comply with the limits set forth in IEC 60601-1-2 for Medical Devices, which provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.
• Electrostatic discharges (ESD) may cause artifacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity as well as friction against carpets, clothing, and sheets made from artificial fibers.
• The performance of the Sleep Data Recorder can be affected by intense electromagnetic fields. Do not operate the Sleep Data Recorder in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment.
• Use only with electrodes provided by or validated by MyCardio. The use of other electrodes with this device may impair signal quality, body position accuracy and overall performance.
• The Sleep Data Recorder does not increase the safety risk for pacemaker patients as long as the pacemakers comply with the EN50061 standard of electrical safety of medical devices. Nevertheless, it is not advisable to do an impedance test on pacemaker patients since it might cause the pacemaker to switch to the interference mode. The user should contact the pacemaker manufacturer or consult the accompanying documents regarding the certifications and requirements of use for the pacemakers.
• Classified as ordinary equipment regarding ingress of liquids: not drip-proof, splash-proof nor watertight.
• Not suitable for use in presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
• Do not use damaged or used electrodes or cables.
• No serviceable parts except battery replacement. Please take care not to bend or break the battery arm.
Sleep Data Recorder
The Sleep Data Recorder is designed as a tool to work with the SleepImage software which analyzes data collected by the Recorder. To learn more about SleepImage and the different product offerings, visit: [www.SleepImage.com/get-started](http://www.SleepImage.com/get-started)

With the purchase of a new Sleep Data Recorder Kit you will find the following items in the box:

- Sleep Data Recorder
- Computer Cable (Black)
- Electrode Cable (Blue)
- CR2016 coin cell Batteries (inside Recorder)
- Patient User Manual (laminated card)
- Electrodes - one pouch

Cleaning
The Sleep Data Recorder is not waterproof and cannot withstand immersion in water nor excessive abrasion. To clean the Recorder, use a slightly damp cloth to remove dirt then use an isopropyl alcohol wipe to disinfect. **Do not** use harsh solvents such as acetone or any harsh antiseptics such as Viraguard or Citrus II as they may damage Recorder surface and harm Recorder labelling. **Avoid contact of liquids** with Recorder’s inner parts and connectors. **Do not bend or break the battery contact arm.**

Specifications
- **Battery type:** 2 x CR2016, 3.0 volt, 90 mAh Batteries. (Note: We purchase [Part P138-ND from DigiKey](http://www.DigiKey.com))
- Battery pair recording time: ~50 hours or 6 x 8 hour studies.
- Recorder Data Storage capacity: ~50 hours or 6 x 8 hour studies.
- Dimensions: 3.1” x 1.9” x 0.5”
- Weight: 0.8 oz.
- Operating and storage temperature range: 40° F - 10° F; 0 - 95% RH, non-condensing
Recorder Indicator Lights

This reference lets you know what the lights mean when they appear on the Sleep Data Recorder. Meanings can differ based on the type of function you are performing with the Recorder at the time you see the light so there may be several different possibilities referenced below.

Heart Light

- Flashing Green - Signal detected, recording in progress.
  ➢ Light will become quite dim so as not to disturb the wearer’s sleep (visible in very low light only)
- Flashing Yellow - Searching for signal.
  ➢ Pressing the center button for a few seconds initiates “Search mode.” The yellow heart light will flash when searching for an ECG signal then will change to flashing green (see Heart Light - Flashing Green above)

Battery Light

- Flashing Yellow - Replace Batteries
  ➢ If the Recorder has insufficient power to run an overnight test the battery light will flash yellow and the recording will not start. Replace the batteries before performing another Sleep Study.

Note: It is possible for the batteries to be so low that they are unable to flash the battery light. After changing batteries or pressing the center button ensure that the yellow heart light is observed.

Communication Light

- Solid Green - The Recorder is connected to computer.
- Flashing Green - Computer is communicating to the Recorder.
- Flashing Yellow
  ➢ Connecting with Computer
    The communication light will flash yellow while connecting with the computer and resetting the recorder.
  ➢ Memory is full, upload studies to SleepImage.
    If the Recorder has insufficient memory to run a Sleep Study the yellow communication light will flash and the recording will not start. Upload Studies to SleepImage before performing another Sleep Study.
  ➢ Battery Arm is “sandwiched” between batteries. See Installing and Replacing Batteries Step 2
  ➢ Battery Arm has been damaged. See the photo at the bottom of page 7 of this IFU to assess.
  ➢ Reset disconnection was not immediate/process was interrupted
    o If the reset was interrupted due to unplugging early, the reset will need to be attempted again.
    o To save power, some PCs shut down power to USB ports which will cause you to lose connection to the Recorder thus interrupting the Reset process. The reset will need to be attempted again.
  ➢ Safe Mode - Some computer operating systems (OS) attempt to write data to connected peripherals, trying to index the Recorder as it would a USB thumb drive. The Recorder rejects the attempt causing the Recorder to enter Safe Mode and the light will flash yellow. The Recorder cannot operate while in Safe Mode. Please use the USB Charger method to reset the Recorder.

No Lights

After being Reset, the Recorder enters a low power idle mode. No lights will be visible on the Recorder. However, if no lights flash on the Recorder after pressing the Center Button, there are three likely reasons:

- The batteries are completely depleted and don’t have sufficient power to flash the battery light.
- Battery Arm is “sandwiched” between batteries. See Installing and Replacing Batteries Step 2
- Battery Arm has been damaged. Consult this photo to assess your Recorder.
Installing and Replacing Batteries

Sleep Data Recorders use two CR2016 3v 90mAh coin cell batteries that should be replaced before deployment to each patient and after every 4 studies. These batteries can be sourced locally at pharmacies and retail stores, or through online retailers at reduced prices. We order part P138-ND from DigiKey.

1) Open Recorder rear door using Phillips head screwdriver. Gently remove old batteries. **Do not bend or break battery contact arm.** A damaged battery contact arm cannot be repaired.

2) Place two CR2016 coin cell batteries **underneath** the battery arm in battery compartment with (+) surfaces up. Polarity is important to ensure power to the Recorder. Both batteries should be underneath the battery arm. **Do not bend or break battery contact arm. A damaged battery contact arm cannot be repaired.**

3) Close battery door, gently tighten screw. Do not over-tighten.

4) Heart light flashes yellow after batteries are changed. Recorder is looking for an ECG signal in preparation for a Sleep Study. If Recorder does not find a signal, it turns itself off in ~20 min.

Check **battery compartment for optimum condition each time you replace batteries.**

- The battery arm should be intact and not bent out of position.
- The mounting tape on the back of the battery door should be in place and in good condition.
- The batteries should be correctly positioned underneath battery arm, + side up.
- The battery door should be securely closed, but not overly tightened.

Mounting Tape:
Maintains compression on the Battery Arm to ensure good contact. Over time, it may become compressed, with possible impact to connectivity. Replace as needed.

Battery Arm
Responsible for carrying the power supplied by the batteries to run the Recorder. Please take care not to bend or break the Battery Arm. Without it, the Recorder will not function. This part cannot be replaced/repaird.
Patient Testing

As this Instructions for Use document is intended for a professional user, the Clinician should provide instructions on how to record a sleep study with the Recorder when sending the device home with a Patient. The Patient instructions are duplicated on the front of each Electrode Pouch as well as on the Patient User Manual (laminated card) included with the Recorder Kit (example pictured below) and available to print from a PDF in the Help Tab of your SleepImage account.

Providing Instructions

There are three resources that we have created so that you can provide instruction for your patients. Please use any, or all, of these tools to help your patient with performing a sleep study:

- **Patient User Manual**: Laminated card Included in the Recorder Kit
- **Printable Patient User Manual**: In Help Tab ([Performing a SleepImage Study - User Card](#))
- **YouTube Video**: [Sleep Date Recorder – Preparation for Wearing](#)

![Performing a SleepImage Study](#)

Clinician User Pre-Test Check List

- **Upload** any studies that are on the Recorder
- **Install** new batteries
- **Reset** the Recorder
- No lights should be blinking
- Periodically **sync the Recorder’s Time Clock**
- Check Electrode expiry date

Note on Battery Replacement

We do not recommend allowing Patients to replace the Recorder batteries as they are not as familiar as you are with the Recorder and may inadvertently bend or break the battery arm. Damaged battery contact arms cannot be repaired.

Multiple Night Recordings

We encourage using the Recorder for multiple studies for the same patient. If using fresh, quality CR2016 3v 90 mAh batteries, the Recorder should be able to perform approximately 4 sequential studies before depleting battery power. The number of sequential studies can vary, but four is average.

The main thing to be aware of when running multiple nights are to be sure to **upload** and **reset** the recorder **between patients** to ensure that there is no commingling of Patient data. Also, upload and processing will understandably take a bit longer due to more data being managed simultaneously.
Uploading Studies

Once Patients have completed their sleep study and returned the Sleep Data Recorder, select the Patient from the Patient List, then upload the study as shown below. Please note that per our Terms of Use (and Patient Privacy requirements) the patient to upload ratio is 1:1. Sleep studies from multiple patients cannot be uploaded to a single patient profile. Please note: SleepImage is designed for modern browsers such as: Chrome, Edge, Firefox and Safari. (IE has not been a supported by Microsoft since 2016 and is not recommended for use with SleepImage)

The workflow allows you to either Accept or Reject studies before a Report is generated. This ensures that you can verify the Upload contains successful studies before using Report Credits. The Upload Summary displays the start time and date for each study as well as the sleep study’s duration in HH:MM and the status of the processing: Success, insufficient data or Fail.

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

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

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

**To Upload Sleep Studies**

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

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

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

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

The data processing is in progress now.

- Uploading Data 100%
- Processing Data 50%

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

- Uploading Data 100%
- Processing Data 100%

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

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

9) View the Patient’s Study Details to verify the new reports have populated the profile.

10) **Reset the Sleep Data Recorder** so the Recorder is ready for the next Patient.
Reset Recorder

The Recorder should always be reset after uploading sleep studies. The action of resetting clears any previous studies to ensure the Recorder is ready for the next patient. Sleep studies from multiple patients cannot be commingled in a single patient profile.

Ensure studies have been Uploaded before resetting. Resetting clears all studies from Recorder.

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

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

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

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

➢ Battery Arm has been damaged  The copper battery arm may be bent or broken
➢ Batteries are not installed properly  Both batteries must be underneath the copper battery arm  Both batteries should have proper polarity (+ side up)
➢ Recorder was unplugged too early  Communication light must be green before disconnecting
➢ Recorder was unplugged too late  Some computer operating systems attempt to write data to connected peripherals, trying to index the Recorder as it would a USB thumb drive. The Recorder rejects the attempt causing the Recorder to enter Safe Mode and the light to flash yellow. The Recorder cannot operate while in Safe Mode. Please use the USB Charger method above.

Please inspect the battery compartment to ensure that batteries are installed correctly and that the copper battery arm has not sustained any damage. Then, repeat either reset process until the Recorder resets properly and no further lights are observed.
Recorder Time Sync Tool

Inside the Sleep Data Recorder is a Real Time Clock. The RTC has an internal battery which maintains a charge by drawing energy from the coin cell batteries. Occasionally, the internal clock may lose or gain time which can accumulate sufficiently to cause sleep/wake times to be incorrect. We recommend running this tool periodically to ensure that your sleep studies display the correct time. Download Recorder Manager from the Help Tab to your Windows PC and run the sync tool.

1) Click on the **Sleep Data Recorder Manager** link on the Help Tab

Tools

Sleep Data Recorder Manager
Sync the recorder time on a Windows PC

2) Save the File to the location of your choosing.

3) Double click on the downloaded file to open it and click on **Run**

4) Follow the Instructions to complete the installation and press **Finish**
5) The installation will create an Icon on the Windows PC’s desktop.

6) Double clicking on the Icon will open the Device Manager window.

7) Plug in the Recorder with the black Computer Cable and click on “Find Recording Device”
   a) The Clock does not need Reset, you’ll see the following. Close the Device Manager.

   b) If the Clock needs resetting, you will see the following. Proceed to Step 8

8) Click on OK and then press the Set Device Time button.

9) Reset Process will run until the time is set.

10) Once the time is set, close the Device Manager.
Troubleshooting

No Study/Insufficient Data
A study may show no data for any of the following possible reasons:

1) **Not enough battery power to perform a study.**
   - The recorder firmware will recognize if the battery will not be able to complete an 8+ hour study and will not initialize recording.

2) **Poor Connection**
   - If the electrodes do not have proper adherence to the skin (which could be due to: lotion, body hair, or incorrect electrode placement) it may not have enough data to produce a report. It is also possible that the blue Electrode cable has been broken.

3) **Recorder was Reset before upload attempt.**
   - Resetting the recorder clears the recorder memory allowing for further uploads. If the recorder was reset before uploading, the study was deleted during the Reset process.

4) **Recorder was not Reset properly**
   - If the communication Light was on when given to the patient, the Recorder will not Record. Sleep studies cannot be recorded if Communication Light is blinking. It is necessary to clear the light before a new study can be performed – See Reset page

Communication Light Flashing
The communication light may continuously flash for any of the following possible reasons:

1) **Memory is full,** upload studies to SleepImage.
   - If the Recorder has insufficient memory to run a Sleep Study the yellow communication light will flash and the recording will not start. Upload Studies to SleepImage before performing another Sleep Study.

2) **Battery Arm is “sandwiched” between the batteries.** See Installing and Replacing Batteries Step 2

3) **Battery Arm has been damaged** - See the photo at the bottom of page 7 of this IFU to assess.

4) **Recorder was not Reset properly** – See Reset page

Can’t Upload/Can’t See Study
You may encounter an error message/non visible study due to:

1) **No study is on the device** - See the No Study section above.

2) **You are using an unsupported Browser** - See section on Supported Browsers

Battery Life

1) **Battery Arm has been damaged** - See the photo at the bottom of page 7 of this IFU to assess.

2) **The battery door could be too loose** causing intermittent contact with batteries draining them quickly.

3) **The batteries are not of the correct voltage/mAh value** - The batteries should be 3v and 90 mAh. Some CR2016s have 80 mAh, but we use the 90 mAh 2016s. We order part P138-ND from DigiKey.

4) **The batteries could be “duds” and they depleted while awaiting purchase and use.

5) **Battery Arm is "sandwiched" between the batteries.** See Installing and Replacing Batteries Step 2

Please Review the Self Help Documentation in the Help Tab of your account. Should this not resolve your issue please email support@sleepline.com with the following info in the email: User Name, SleepImage Company Name, Serial Number of Recorder, Browser used, and a description of the issue encountered. Please include screenshots/pictures, if applicable.