REMI™

REMOTE EEG MONITORING SYSTEM
FOR AMBULATORY USE

Patient Manual for Ambulatory Use

Table of Contents

Safety Information

Please read, understand, and follow all safety information contained in these instructions prior to using REMI™ Remote EEG Monitoring System. Retain these instructions for future reference.

Acronyms, Abbreviations, and Definitions

EEG	Electroencephalography
REMI Sensor / sensor	Disposable EEG sensor
REMI Sticker / sticker	Conductive-adhesive sticker used with REMI Sensors
REMI / REMI System	Remote EEG Monitoring System
REMI Mobile App / REMI Mobile	The mobile medical application that runs on qualified mobile computing platforms.
REMI Tablet / tablet	A tablet mobile computing platform running REMI Mobile Software to initialize a session
REMI Phone / phone	A phone mobile computing platform running REMI Mobile Session in the ambulatory environment
REMI Cloud	Cloud-based servers and storage where REMI EEG is processed and stored
Bluetooth® / BLE	Secure, single-device Bluetooth Low Energy protocol, used for wireless communication between REMI Sensors and REMI Mobile software
Operating System / OS	Native software that allows smart devices to run applications and programs

Indications for Use

The REMI Remote EEG Monitoring System is indicated for use in healthcare settings where near real-time and/or remote EEG is warranted and in ambulatory settings where remote EEG is warranted. REMI uses single use, single patient, disposable, wearable sensors intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for a duration up to 30 days.

The REMI System uses the REMI Mobile software application that runs on qualified commercial off-the-shelf mobile computing platforms. REMI Mobile displays user setup information to trained medical professionals and provides notifications to medical professionals and ambulatory users. REMI Mobile receives and transmits data from connected REMI Sensors to the secure REMI Cloud where it is stored and prepared for review on qualified EEG viewing software.

REMI does not make any diagnostic conclusion about the subject's condition and is intended as a physiological signal monitor. REMI System is indicated for use with adult and pediatric patients (6+ years).

Contraindications

- REMI System should not be used on any patients who knowingly have a hypersensitivity to acrylics, silicones, and hydrogels.
- REMI Sensors should not be placed on a patient’s scalp if there are open wounds at the sensor target locations.
- REMI System should not be used on any children under the age of 6 years.

Operator Profile

REMI System can be used by trained medical professionals who wish to record electroencephalograms as described in the Indications for Use section above.

Patients and/or Caregivers are intended to use the ambulatory components of REMI System as described by this manual. For additional information on the broader REMI System, refer to the **Clinician Manual for Ambulatory Use** available through a qualified healthcare provider.

Explanation of Signal Word Consequences

Signal Word	Consequence
WARNING	Indicates a hazardous situation, which, if not avoided, could result in major injury and/or death.
PRECAUTION / CAUTION	Indicates a hazardous situation, which, if not avoided, could result in minor injury and/or property damage.
IMPORTANT	Indicates a special item of note that the user must be aware of for the system to work properly.

Warnings

- To reduce the risk of bodily injury,
  - Do not ingest REMI Sensors or stickers.
  - Only use power adapters for REMI Phone operating platform as provided by Epitel, and only connect the power adapters to properly tested and grounded AC outlets. Do not connect the power adapters to an AC outlet controlled by a wall switch.
- To reduce the risks associated with cleaning, follow all cleaning instructions included in this manual. Establish and follow a cleaning schedule.
- Do not apply REMI Sticker to any surfaces other than the sensor or patient's scalp prior to use in order to maintain proper adhesive performance.
- REMI System is considered magnetic resonance (MR) unsafe. Remove all REMI Sensors before performing a magnetic resonance imaging (MRI) scan. Do not bring any REMI System components into a MR environment.

Precautions

- Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
- Avoid using REMI Sensors near strong radio frequency signals or portable and/or mobile RF devices to reduce the risks associated with very strong electromagnetic fields.
- To avoid artifacts in a computed tomography (CT) image of the skull, remove REMI Sensors prior to execution of the CT procedure.
- Advanced Settings on REMI Phone should only be accessed with the assistance of trained Epitel staff. Changes in device provisioning settings can result in delays in the initialization of a new session. To access, contact Epitel for the Provisioning Passcode.

- To reduce the risk of damaging REMI Sensors,
  - Do not immerse the sensors in a liquid or subject them to any sterilization processes.
  - Do not impact, puncture, or cut them with any objects.
  - Follow the sensor sticker replacement process as instructed in this manual and in the **Clinician Manual for Ambulatory Use**.
- REMI Sensors can only be used by one patient, for one session. At the end of your recording, the sensors will no longer be able to record EEG.
- REMI Stickers can only be worn once. The stickers will lose their stickiness after they have been removed from your scalp. You should dispose of the used stickers every time you remove the sensor like you would a bandaid or other skin adhesive.
- Check your skin around sensor placement sites daily. If you experience any adverse reactions (e.g., redness, itching, or swelling), remove your sensors and contact your clinic.
- When using a fresh REMI Sticker:
  - Make sure that the blue liner side is applied to the sensor. The clear liner side is meant to contact your skin.
  - Be sure to align each of the sticker's circles with the sensor's gold electrodes.
  - Try to avoid getting any of your hair between the sensor and your scalp when you reapply your sensors. Hair will reduce stickiness and may cause issues with your REMI EEG recording.
- Always try to keep your phone within 13 feet (or 4 meters) of your sensors. If your phone is too far away, it will struggle to communicate with your sensors. It is recommended to keep the phone in your pocket, near your bed, or otherwise nearby at all times to avoid any delays in sending data to your clinician.
- Do not let the phone battery die. Charge your phone intermittently while you are awake and keep it charging near your bed while you sleep. Only use the power adapters that are provided by your clinician. Other phone charging cables may not be compatible with REMI Phone.
- EEG data will not be transmitted by the computing platform or available for clinician review during the time that:
  - A disconnection occurs between REMI Mobile and REMI Cloud.
  - A disconnection occurs between REMI Sensors and REMI Mobile.
- The radio frequency field strength generated by REMI Sensors is at a level considered safe to use with other medical devices. However, if another device experiences electromagnetic interference when REMI Sensors are nearby, consider moving the sensors away from that device.
- REMI System, including REMI Sensors and stickers are not packaged sterile.
- REMI Sensors and REMI Phone computing systems contain batteries and should be stored in appropriate environments as described herein.
- No modification is allowed of any equipment described herein. Only authorized Epitel personnel are permitted to repair any component of REMI System.

- REMI Sensor gold electrodes should not come into contact with any conductive parts other than REMI Sticker.
- The use of a defibrillator while wearing REMI Sensors may affect EEG recordings and REMI Sensor functionality.
- REMI Mobile system updates require that REMI Tablet / REMI Phone be powered on and connected. For the fastest and most reliable updates, it is recommended to connect REMI Phone computing system to Wi-Fi for system updates.
- The "**Add Event**" button does NOT notify your doctor or emergency services. For emergencies, contact your local emergency services or dial 911.

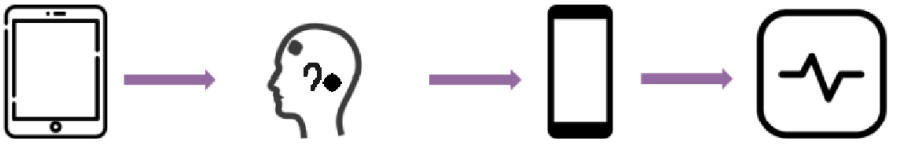
Adverse Reactions

While unlikely, a patient may have an adverse allergic reaction to REMI Sticker (e.g. they have unknown hypersensitivity to acrylics or hydrogels). Immediately discontinue use if any redness, excessive itching, or swelling occurs.

Section 1 - Getting Started with REMI

Overview of REMI System

To get started with REMI Ambulatory, your clinician uses a REMI Tablet to start your EEG session and place your sensors. Once your sensors are securely in place, your clinician will connect your sensors to a REMI Phone. If you have any questions about the session initiation process, please refer to the **Clinician Manual for Ambulatory Use** available through your healthcare provider.



The REMI Tablet is only used for session initiation. Once set-up, you will go home with your REMI Phone and sticker kits for your daily sticker changes.

Information on REMI Sensors

After initial placement, the REMI Sensors will begin recording. The sensors work by amplifying and digitizing the EEG from the patient's scalp. REMI Sensors are held in place using special REMI Stickers that stick to your skin. The stickers are not intended to be reused. You should replace your stickers every time you remove a sensor and dispose of the used sticker, just like you would a bandaid or other skin adhesive.

CAUTION: To reduce the risk of damaging REMI Sensors, do not immerse the sensors in a liquid or subject them to any sterilization processes.

CAUTION: To reduce the risk of damaging REMI Sensors, do not impact, puncture, or cut them with any objects.

CAUTION: REMI Sensors can only be used by one patient, for one session. At the end of your recording, the sensors will no longer be able to record EEG.

Information on REMI Phone

The REMI Phone is critical for a successful REMI Session. It runs the REMI Mobile App, wirelessly receiving information from your sensors and sending it to your clinician using either cellular or Wi-Fi.

CAUTION: Always try to keep your phone within 13 feet (or 4 meters) of your sensors. If your phone is too far away, it will struggle to communicate with your sensors. It is recommended to keep the phone in your pocket, near your bed, or otherwise nearby at all times to avoid any delays in sending data to your clinician.

CAUTION: Do not let the phone battery die. Charge your phone intermittently while you are awake and keep it charging near your bed while you sleep. Only use the power adapters that are provided by your clinician. Other phone charging cables may not be compatible with REMI Phone.

REMI Phone Home Screen - In Session

You can interact with the REMI Mobile App using your REMI Phone touch screen. The app allows you to log different activities throughout your session. For additional information on logging events and activities, please refer to **Section 3 - Sticker Changes & Sensor Placement** and **Section 4 - Logging Suspected Events for Clinician Review**.

Going Home with REMI

REMI Sessions can run for multiple days. Your clinician will set the duration of the recording during the initial setup. You should plan to wear the sensors as much as possible throughout your prescribed duration. This includes wearing your sensors throughout the day and while sleeping.

Along with your REMI Sensors and your assigned REMI Phone, your clinician will send you home with the following materials:

- An adequate number of Daily Sticker Kits, which include four (4) new REMI Stickers and four (4) alcohol wipes, to allow you to change and replace REMI Stickers throughout your REMI EEG recording session
- One (1) REMI Phone charger and charging cable

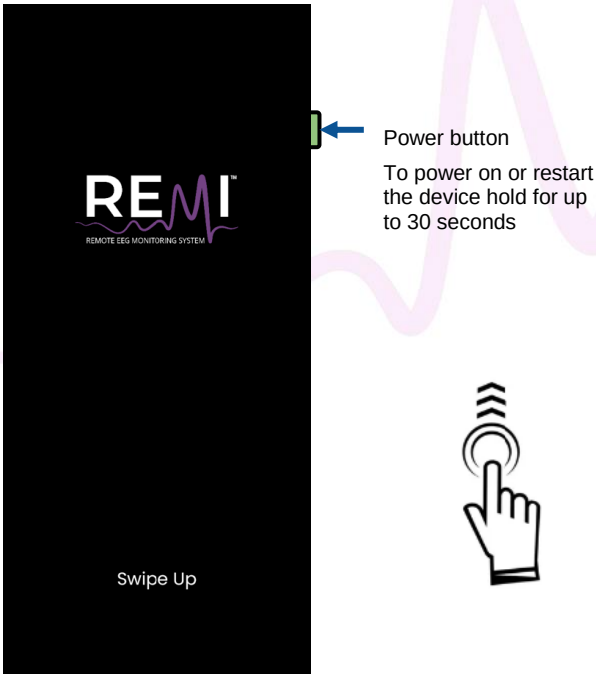
An unopened Daily Sticker Kit (right) with its contents: REMI Stickers (upper left), Alcohol Wipes (lower left)

Section 2 - Navigating REMI Mobile on Your REMI Phone

The REMI Mobile App has two (2) default screens: sleep screen and home screen. During your session, you are able to interact with both by using your phone's touch screen. If you need to restart your phone at any time, press and hold the green button on the right side of the device.

Sleep Screen

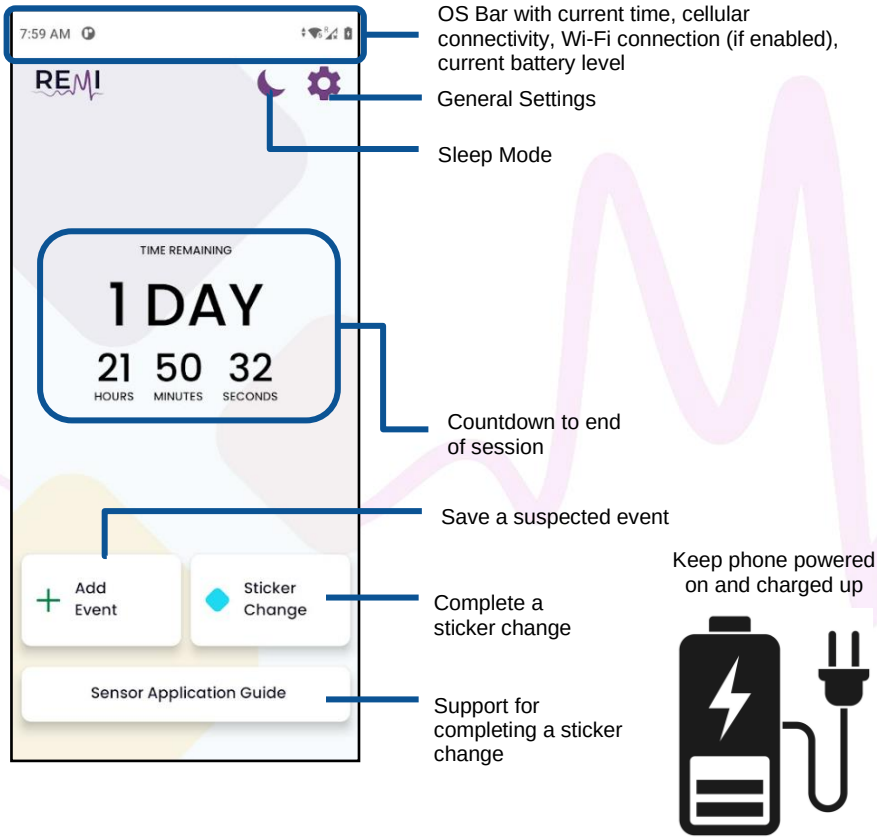
The sleep screen is intended to limit battery drain during your REMI EEG recording session. This screen will automatically appear after several minutes of inactivity OR if you select the "moon" Sleep Mode icon on the home screen. To unlock and access the home screen, swipe up from the bottom of the screen using a finger.



Sleep Screen (with navigation notes)

Navigating the Home Screen

The home screen is the primary screen for interacting with the REMI Mobile App. From this screen, you can find a countdown to the end of your REMI EEG recording session, view current battery power levels, check connectivity to cellular or Wi-Fi, save a suspected event, complete a sticker change, and access general settings.



Home Screen (with navigation notes)

Best Practices for REMI Phone

Follow these three tips to ensure your REMI Phone is functioning optimally.

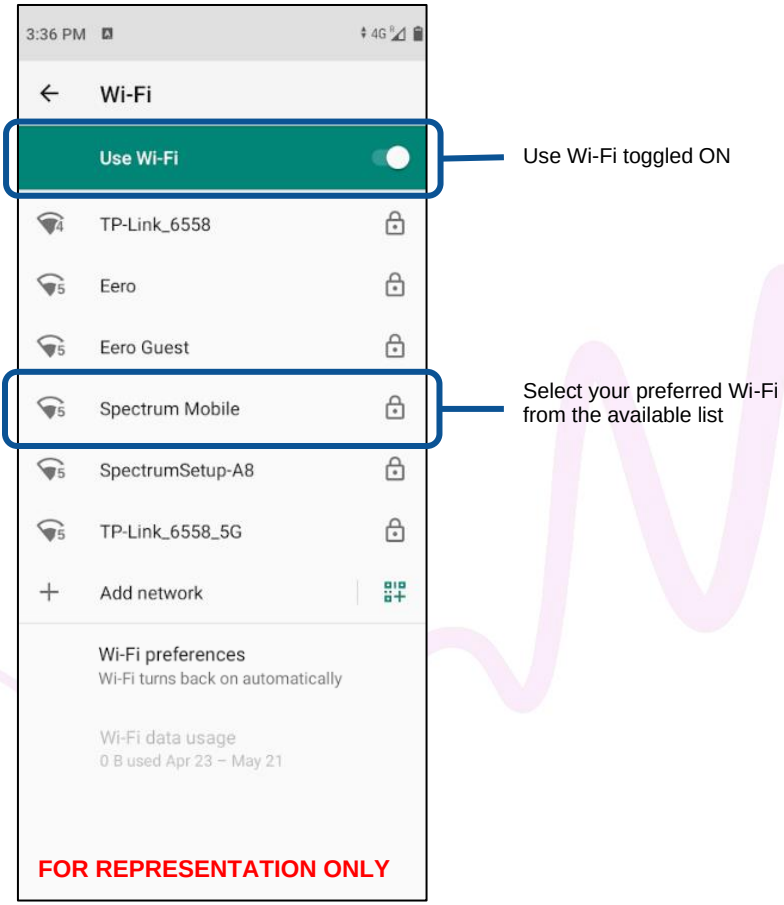
1. Keep your REMI Phone within 3 ft of the sensors at all times; including keeping it near your bedside while you sleep
2. Avoid letting the battery die during or after the active recording
3. Connect to strong Wi-Fi whenever possible

Setting Up a New Wi-Fi

Connecting to Wi-Fi allows for the most consistent and reliable connection on your REMI Phone. Setting up a new Wi-Fi connection on your REMI Phone is similar to setting up other smart devices. First, navigate to the General Settings menu by selecting the gear icon on the Home Screen. From the General Settings, you can also view information for customer support contact, general device and session details, and manufacturing information.

After you open the Wi-Fi Settings menu, you will see a list of available Wi-Fi connections. Select your preferred connection. If the Wi-Fi connection is protected, you will need to enter the appropriate password to connect.

General Settings Menu (with navigation notes)



Wi-Fi Settings Menu (with navigation notes)

IMPORTANT: If a public network (i.e. airports, malls, and libraries) requires anything in addition to a passcode (such as acceptance of terms and conditions), then your REMI Phone will be unable to complete the connection.

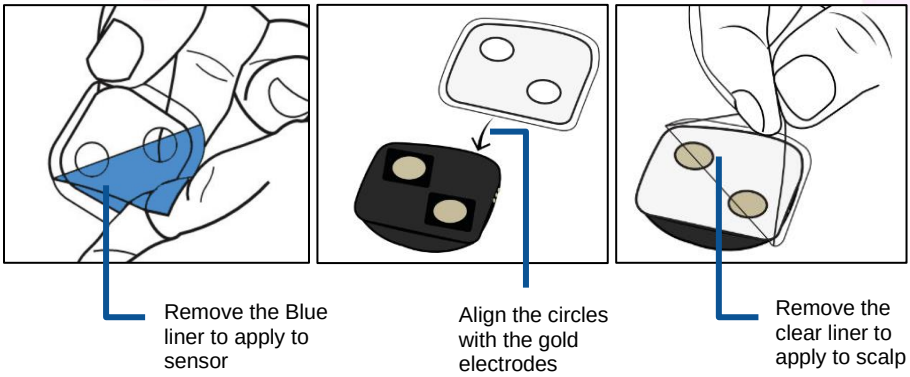
Section 3 - Sticker Changes & Sensor Placement

Steps to Complete a Sticker Change

Whether you are replacing all four stickers or want to reposition a single sensor, you should follow the same process to remove, replace, and reapply your sensors. You will need to grab one of your daily sticker kits. Reminder, daily sticker kits include four (4) new REMI Stickers and four (4) alcohol wipes.

CAUTION: Check your skin around sensor placement sites daily. If you experience any adverse reactions (e.g., redness, itching, or swelling), remove your sensors and contact your clinic.

1. Remove the sensor(s) from your scalp and keep track of where your sensors were previously placed. It is important that the sensors are placed in the same location that your clinician originally applied them.
2. Remove and dispose of all used sticker(s).
3. Open a new sticker pouch when you are ready to apply a new sticker to the sensor. Remove the **BLUE** liner from the sticker, then apply the exposed sticker to the sensor. Be sure to align the circles with the gold electrodes.
4. Use the provided alcohol wipes to clean your scalp. Make sure your skin is fully dried before reapplying the sensor.
5. When ready, remove the clear plastic liner from the sticker.
6. Place the sensor back in its original location. Use the “Sensor Application Guide” to ensure the sensors are properly placed.
7. Finally, after reapplying the sensor to your skin, press the top of the sensor **three (3) times.** You should be able to feel a button click with each press.



CAUTION: REMI Stickers can only be worn once. The stickers will lose their stickiness after they have been removed from your scalp. You should dispose of the used stickers every time you remove the sensor like you would a bandaid or other skin adhesive.

CAUTION: REMI Sensors can only be used by one patient, for one session. At the end of your recording, the sensors will no longer be able to record EEG.

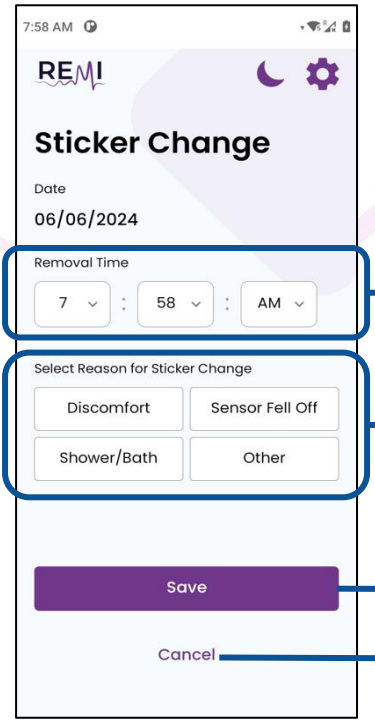
IMPORTANT: Sticker changes can cause “noise” in your EEG data. Therefore, every sticker change should be logged on the REMI Phone so that your healthcare provider, upon reviewing your REMI EEG record, can see times when a sticker change has occurred. Refer to the **Logging a Sticker Change for Clinician Review** within this manual for additional information.

Logging a Sticker Change for Clinician Review

REMI Phone has the ability to log sticker changes. This feature allows you to create notes in the EEG record that inform your healthcare provider when and why you changed your stickers. Select the “Sticker Change” button on the Home Screen to begin.

The feature will default the Removal Time with the current time, but you have the ability to adjust this if needed using the dropdowns. You may also Select Reason for Sticker Change. When you click “Save”, you will receive a confirmation that the activity was saved. If you wish to exit without saving the event, select “Cancel” to return to the Home Screen.

Sticker Change Screen (with navigation notes)



Dropdowns available to adjust the Removal Time as needed

Select a reason for the sticker change; you may only select one

Logs activity to the session record for clinician review

Returns to Home Screen without saving

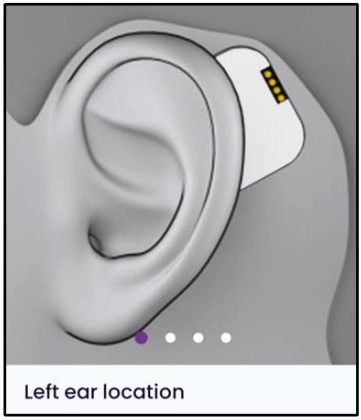
Using the Sensor Application Guide

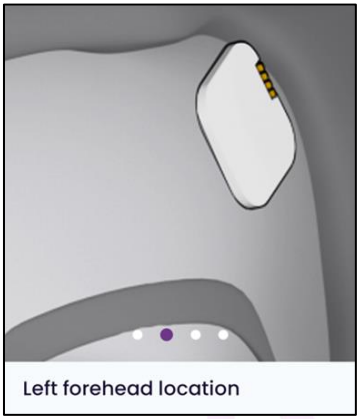
If you would like a visual to help with placing the sensors back on your scalp, you can find detailed information using the REMI Mobile App's "Sensor Application Guide", accessible at any time through the Home Screen. This guide contains details for each location, including guiding visuals to confirm orientation and location.

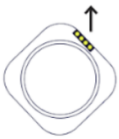
Left Ear Location - Sensor Application Guide (with navigation notes)

IMPORTANT: After reapplying the sensor to your skin, press the top of the sensor **three (3) times**. You should be able to feel a button click with each press.

Sensor Orientation and Placement

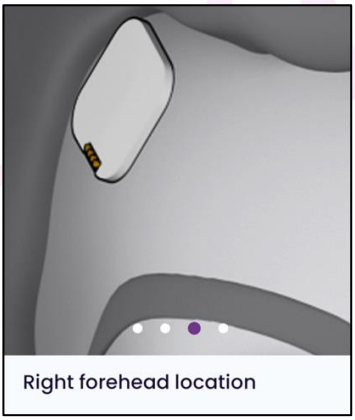


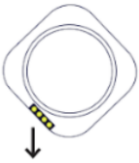




Left Side
Rotate the gold dots to point upwards

Left Side Locations - Excerpts from Sensor Application Guide





Right Side
Rotate the gold dots to point downwards

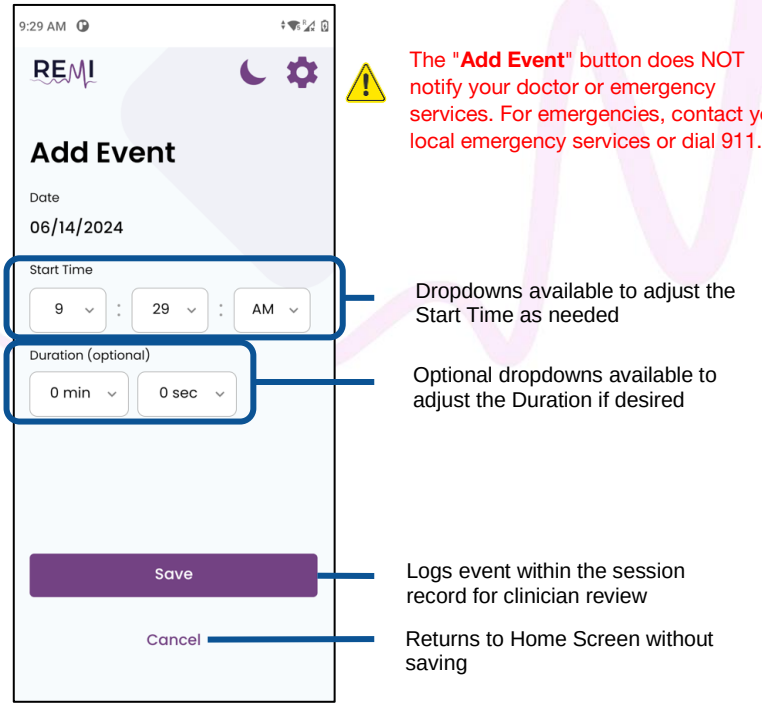
Right Side Locations - Excerpts from Sensor Application Guide

CAUTION: Try to avoid getting any of your hair between the sensor and your scalp when you reapply your sensors. Hair will reduce stickiness and may cause issues with your REMI EEG recording.

Section 4 - Logging Suspected Events for Clinician Review

Similar to a written seizure diary, the REMI Mobile App has the ability to log suspected events throughout the duration of your recording. This feature allows you or your caregiver to create notes in the EEG record that your healthcare provider can review.

Select the “Add Event” button on the Home Screen. The feature will automatically fill the Start Time with the Current Time, but you can adjust using the dropdowns. You can also add additional information on the Duration of the suspected event. When you select “Save”, you will receive a confirmation that the event was saved. The suspected event will be logged as a note in the REMI EEG record that your clinician can view. If you wish to exit without saving the event, select “Cancel” to return to the Home Screen.

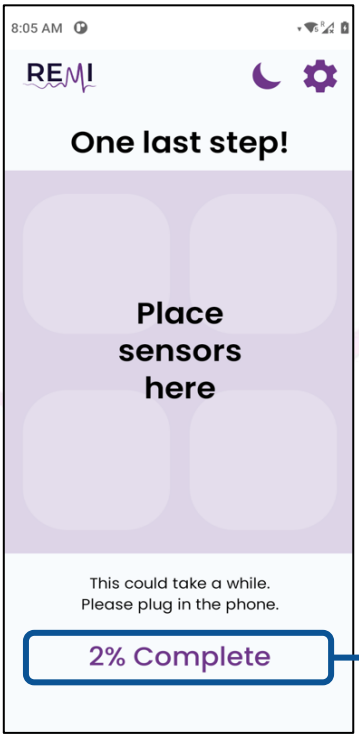


Add Event Screen (with navigation notes)

Section 5 - End of Session Activities

Once you have reached the end of your prescribed REMI EEG recording duration, your REMI Phone will automatically begin its end of session activities. This final step is important in finalizing your data for clinician review.

Remove all of your sensors and be sure to discard the used stickers. Place the sensors on or near your REMI Phone and **press each sensor button three times**. REMI Mobile will retrieve final information from your sensors to create a complete REMI EEG record. This can sometimes take up to a few days. Be sure to leave the sensors there until REMI Mobile displays an “All done!” screen.



Keep phone powered on and charged up

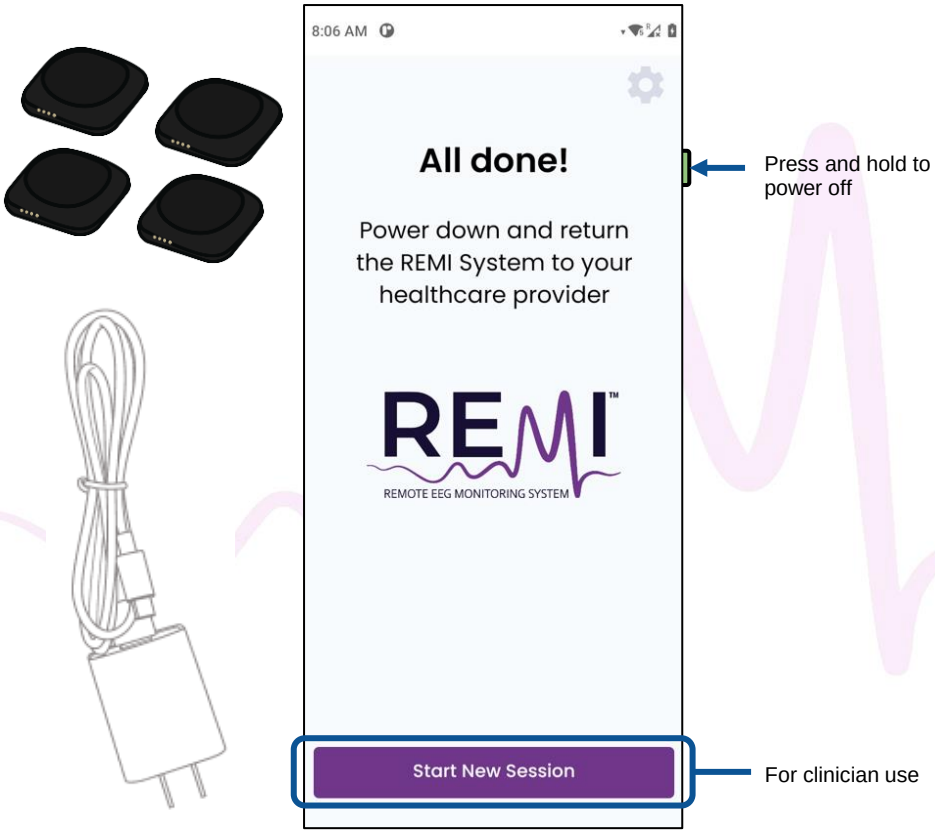
Progress indicator

This can take anywhere from a few minutes to a few days

One last step! Screen (with navigation notes)

Return REMI Device to Your Healthcare Provider

Once the End of Session activities are complete, power off your REMI Phone and return your sensors, phone, and charging cable to your healthcare provider.



All done! Screen (with navigation notes)

Section 6 - Troubleshooting

The REMI Mobile App provides system notices to support session troubleshooting. In case of medical or healthcare questions, always contact your healthcare provider. For technical assistance, call Epitel at:

Phone: (801) 497-6297
Email: support@epitel.com

Frequently Asked Questions

REMI Sensors

For technical specifications or more detailed information on your REMI Sensors, please refer to **Clinician Manual for Ambulatory Use**, available through your qualified healthcare provider.

I lost a sensor, what now?

If you lose or damage one of your REMI Sensors, the remaining sensors will continue to record your EEG. Be sure to let your healthcare provider know that you've lost a sensor; they will provide you with next steps.

What if I need to remove my sensors for an extended period of time?

If you need to remove your sensors for longer than an hour, the Sticker Change screen can be completed and saved at the time of removal. The sensors can be applied after the extended time with no further interaction with the phone. You should inform your healthcare provider if you have removed your sensors for an extended period of time.

What do the different LED colors mean on REMI Sensor?

When you press the top of the sensor, you may notice an LED light. The LED should remain dark unless you intentionally press the sensor.

After pressing the top of the sensor, you may see one of the following:

- Single green flash - the sensor is active and recording; this is the most common LED pattern you will see.
- Continuous red flashes, up to ten (10) times - the sensor will not record EEG; inform your healthcare provider if you notice that your sensor is blinking red after a button press.
- Spontaneous blue and red flashes - the sensor is active and broadcasting; the LED will return to its normal dark state without any additional action from you; inform your healthcare provider if you notice this for over an hour.

How do I clean my REMI Sensors?
REMI Sensors should only be cleaned with a damp cloth using water and should never be immersed in any liquids. REMI Sensors can be cleaned as often as you perform a sticker change.

I can't remember my original sensor location! What should I do?
If you forget your sensor locations, you can use the Sensor Application Guide, accessible through the REMI Mobile App's Home Screen, for guidance. Each screen within the guide provides the sensor ID of the appropriate REMI Sensor for that location. You can confirm the sensor IDs by removing the sticker on the bottom of the sensors and examining the 3-digit alphanumeric label. Refer to the **Using the Sensor Application Guide** in this manual for additional information.

REMI Phone
For technical specifications or more detailed information on your REMI Phone, please refer to **Clinician Manual for Ambulatory Use**, available through your healthcare provider.

How do I clean my REMI Phone?
You can clean your REMI Phone by using a cloth dampened with diluted cleaning agent like bleach or alcohol. Do not immerse the device in any liquids.

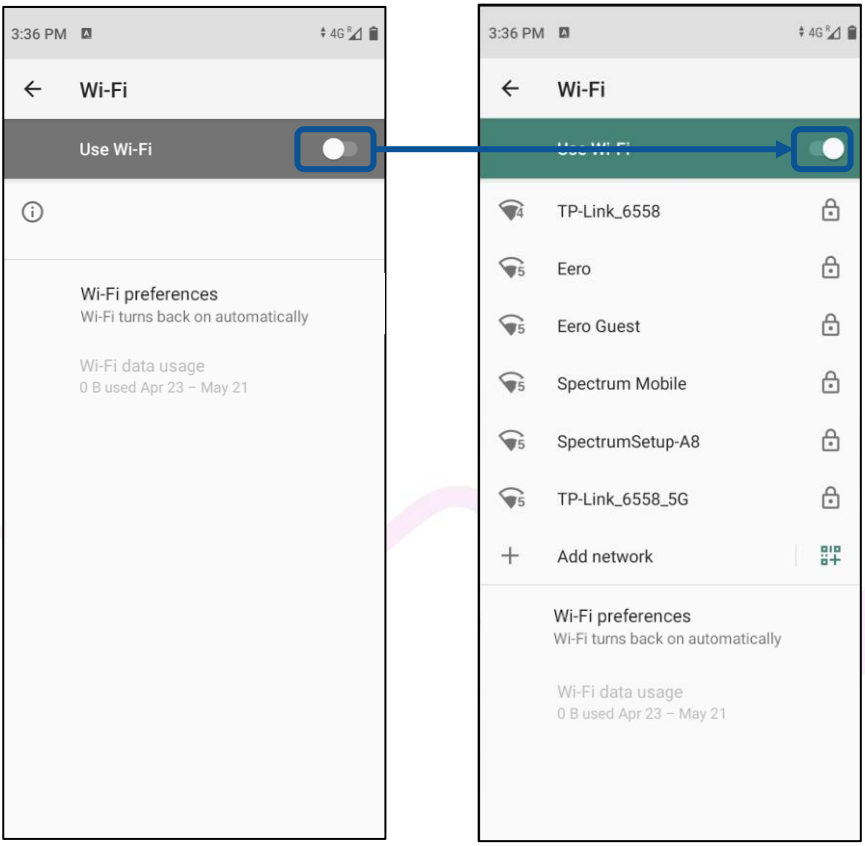
My phone is not responding when I interact with it, is something wrong?
When your phone is unresponsive, it may be necessary to force a hard reboot. You can do this by pressing and holding the green power button on the side of the device and selecting "Restart". It will take a few seconds to reboot. The phone should return to the screen you were previously interacting with.

Why won't REMI Phone charge with my personal phone charger?
You should only charge your phone using the labeled charger and charging cable provided by Epitel. Although you may have your own phone charger, the REMI Phone is not compatible with fast charging cables typically provided with personal smart devices. If you use other chargers or cables, the phone may not charge properly.

What do I do if REMI Phone does not start?
Before trying to power up your phone, always make sure your Phone is plugged into its charger. The battery can drain and the device can shut down as a result. You will need to recharge the phone for up to thirty minutes before powering up. You can start the device by pressing and holding the green power button for 30 seconds.

My phone is damaged, what do I do?
All repairs, updates, and returns are managed through your healthcare provider. If your phone becomes damaged or lost, please contact your provider for next steps.

I tried to add my Wi-Fi, but I don't see a list of available Wi-Fi networks.
If you do not see a list of available connections, double check that the “Use Wi-Fi” toggle is switched ON. After toggling the switch ON, give the device a few minutes to find nearby available connections.



Wi-Fi Settings Menu - Toggle “Use Wi-Fi”

My phone died! Is my session ruined?
If left off the charger for too long, the phone battery may drain and die. That's okay! At your earliest convenience, put the phone on the charger. Once the battery is no longer critically low, you can restart the REMI Mobile App by pressing and holding the green power button for 30 seconds. This will return you to your REMI EEG recording session. Your session will re-establish connection once rebooted and will continue through its remaining prescribed duration. Please note, if the phone battery dies for an extended period of time this may cause a slight delay in completion of the end of session activities.

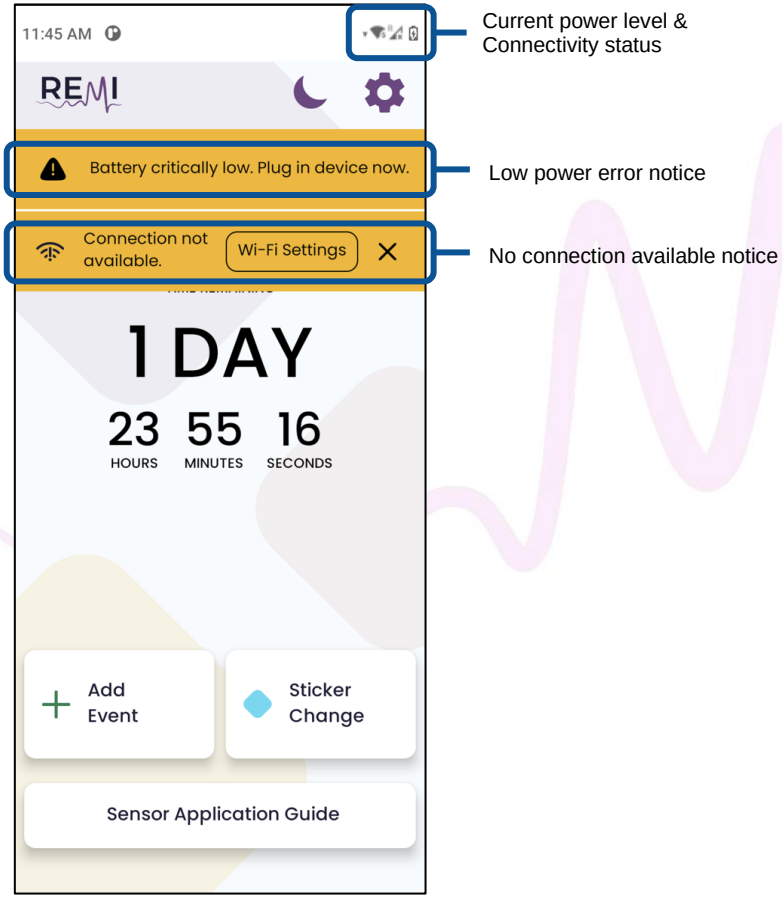
What is the QR Code for?
At the end of your session, if you select "Start New Session" you will be taken to the "Ready for use screen". This screen is for clinician use only. Power down the phone and return it to your healthcare provider at your earliest convenience.

Can I call for assistance using my REMI Phone?
Your REMI Phone does **not** support general phone functionality. In case of emergencies, you should always use other means to call for assistance. Additionally, the "Add Event" functionality is **not** an alerting feature and **will not** contact any medical support.

REMI Phone System Ready Screen

REMI Phone Error Notifications

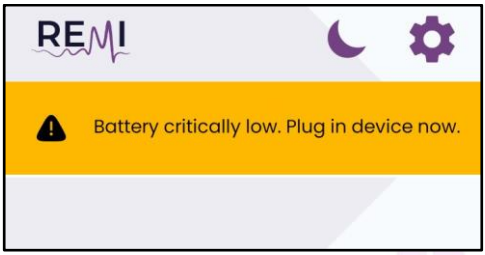
The REMI Mobile App has a few error notifications that can occur and can impede the overall session if left unresolved. You can readily resolve most errors.



REMI Mobile App List of Notifications (with navigation notes)

Low Battery

If your REMI Phone battery level is too low, you will receive the “Battery critically low” notification. The only way to resolve this issue is to plug your device in using the provided Charger and Charging Cable. The notification will go away with sufficient charge.

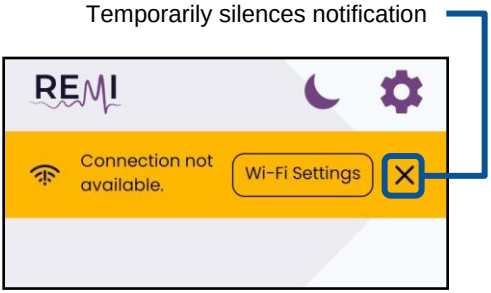


“Battery critically low” Notification

Connection Not Available

If your REMI Phone loses connection, you will receive the “Connection not available” notification. You can lose connection if you do not have a strong enough cellular connection or if you are not connected to a functional Wi-Fi. To resolve this issue, you should connect to a reliable Wi-Fi source if possible. If you happen to be traveling briefly out of cellular or Wi-Fi range, you can temporarily silence the notification by selecting the “X”.

This notification will resolve on its own when you return to reliable Wi-Fi and/or cellular service.



“Connection not available” Notification (with navigation notes)

Compliance and Certification Appendices

Appendix A - EMC Compliance

REMI Sensor complies with the EMC requirements of IEC 60601-1-2 and IEC 60601-1-11 (see Appendices A & B) to ensure that it will operate in healthcare facilities and in the home. To prevent RF interference with or from REMI System, portable and mobile RF communications equipment should be kept away from REMI components at distances specified in Appendix B.

Appendix B - FCC Intentional Radiator Certification

REMI Sensor FCC ID: 2AVPHEPGD1
This equipment contains an intentional radiator approved by the FCC under the FCC ID numbers shown above. This device 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 undesirable operation.

NO MODIFICATION: Modifications to the sensor shall not be made without the written consent of Epitel, Inc. Unauthorized modifications may void the authority granted under Federal Communications Commission rules permitting the operation of this device.

FCC Part 15 Information to the User

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not set up and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular REMI session. If REMI System does cause harmful interference to other radio or television reception, which can be determined by turning REMI System operating platform off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the affected receiving antenna.
- Increase the separation between REMI System and the affected receiver.
- Connect REMI operating platform into an outlet on a circuit different from that to which the affected receiver is connected.
- Consult Epitel support for help.

Appendix C – FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Appendix D - Technical and Security Information

Wireless Communication

REMI System uses Low Energy Radio Frequency (RF) operating at 2.45 GHz (maximum 1mW) for wireless communication between REMI Sensors and REMI Tablet.

- REMI Tablet should be kept within 4m (13 ft) of the patient during session initialization.
- REMI Phone be kept within 4m (13 ft) of the patient while actively recording. It is recommended to set up the charging station near patient sleeping arrangements.

REMI System uses Wi-Fi connection and/or a cellular connection for wireless communication between REMI Mobile and REMI Cloud platform.

- All REMI Tablet wireless communication settings are configured by authorized Epitel personnel and healthcare provider's IT professionals during initial REMI System setup and installation. These settings are password-protected, and they must not be altered by anyone outside of the administrative users.
- REMI Phone communicates natively via cellular connection and can be configured by the patient / caregiver to communicate via a Wi-Fi network.

REMI Mobile software will notify the user if there are any disconnection issues during the use of REMI System. For additional information, **Clinician Manual for Ambulatory Use** available through a qualified healthcare provider**.**

REMI System complies with the IEEE C63.27-2017 American National Standard for Evaluation of Wireless Coexistence standards. To prevent RF interference with or from REMI System, portable and mobile RF communications equipment should be kept away from REMI components at distances specified in the **Clinician Manual for Ambulatory Use.**

Cybersecurity

REMI Sensor communicates with REMI Mobile software through secure single-device BLE protocols. There is no patient identifying information communicated between REMI Mobile and REMI Sensors. Once a sensor is connected to a REMI operating platform running REMI Mobile software, the sensor firmware and connection protocol cannot be changed or altered by the user. There are no specific user instructions for the sensor that pertain to Cybersecurity controls.

REMI Mobile software communicates with REMI Cloud using an encrypted HTTPS protocol via a Wi-Fi network and/or a cellular network.

REMI Cloud runs on the Amazon Web Services™ (AWS) cloud platform and follows AWS best practices for HIPAA security and compliance, including end-point protections and limited/secured user access. Access to patient data via Persyst Mobile running on REMI Cloud platform is password protected. Reviewing physicians should not share their passwords with anyone. Should a reviewing physician's password become compromised, please notify Epitel immediately for support.

Appendix E – REMI Sensor Specifications and LED Indications

General Specifications

Physical Size:	27 mm L x 27 mm W x 5.8 mm H
Weight:	5.0 g
Power Source:	Internal CR2025 3 V Lithium Coin Cell (not rechargeable)
Communication Interface:	Low Energy Wireless Radio Frequency (RF) – 2.45 GHz (maximum 1mW)
User Interface:	Single key membrane keypad for activation and status indication

Recording Specifications

Number of Signal Channels:	1
Sample Rate:	256 Hz
Recording Range:	± 500 µV, 12-bit
Amplifier Passband:	0.8 Hz – 92 Hz

Electrode Specifications

Number of Electrodes:	2 (Signal and Reference)
Electrode Size:	6.0 mm diameter circular
Electrode Spacing:	17.7 mm center-center
Electrode Type:	Hard gold electrode

LED Status Indication – Button Press

No LED or 2 x Red	sensor error (if persistent, sensor cannot be used)
3 x Blue then 2 x Green	sensor activated and waiting for connection
1 x Green	sensor working correctly
5 x Red	sensor retired (no wireless connection allowed)

Compliance Standards	IEC-60601-1, IEC-60601-2-26, IEC-60601-1-2, IEC-60601-1-11, IEC 62133-2, IEEE C63.27, ISO 10993, ISTA-6-FEDEX-A, IEC 62366, IEC 62304
Degree of Protection	Type BF Applied Part (REMI Sensor)
Ingress Protection	IP47 – Protected against solid foreign objects of 1.0 millimeters and greater. Protected against the effects of temporary immersion in water.
Operation Environment	REMI Sensors have been tested for operation environments of 37°F to 100°F (3°C to 38°C), relative humidity above 10% (non-condensing), 525 to 795 mmHg (700 to 1060 hPa).
Typical Operation Time / Expected Service Life	REMI Sensors are capable of collecting and transmitting data for a minimum of 48 hours.

Appendix F - Additional REMI Device Information

REMI Phone Description

REMI Phone is used for ongoing recording and processing of a REMI session. The user interface for REMI Phone operating platform is a touchscreen display powered by an A/C adapter and onboard rechargeable battery. With proper cleaning and maintenance, REMI Phone should be reused for multiple sessions. Each REMI Phone has a unique serial number located on their back cover and within the application under the Settings Menu. REMI Phone software version can also be found in the application's Settings Menu. Additionally, Legal & Copyright information for REMI Phone software is accessible through the Advanced Settings screen.

REMI Sensor Description

The user interface for REMI Sensors is a single button within each sensor. The power is through a single-use primary coin cell battery for each sensor. Using its wireless link, the sensors can exchange EEG data and commands with REMI Mobile application running on REMI Tablet or REMI Phone. Each REMI Sensor has a unique serial number located on the sensor packaging.

REMI Sensors attach to the patient's scalp via a conductive-adhesive sticker. This sticker is made of a medical adhesive with conductive hydrogel disks and has been tested for biological safety. Each sticker has a unique lot number located on the sticker packaging. REMI Sensors and stickers should be disposed of after each use.

Additional REMI Device Descriptions

Please refer to **Clinician Manual for Ambulatory Use** available through a qualified healthcare provider for additional information on the following items:

- Device descriptions of REMI Tablet, REMI Cloud, or REMI System Device Communications
- Warranty policy
- Electromagnetic Emissions Declarations
- Electromagnetic Immunity Declarations

Appendix G - Symbols Glossary

Note: The symbols provided below are applicable to medical use of REMI System, including REMI Mobile software application. REMI Mobile application operates on a qualified mobile computing platform (e.g., tablet, phone) which may support other uses and bear additional unlisted symbols.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Type BF applied part	The equipment provides protection against electrical shock and electrical current leakage. Applied parts are considered to be REMI Sensors with adhered stickers.	IEC 60417 Reference no. 5333
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for “batch code” are “lot number”, “lot code” and “batch number”.	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1: 2021 Reference no. 5.3.8. (ISO 7000-2620)
	Federal Communications Commission	Indicates the device has been tested to comply with FCC standards and has been approved	CFR Title 47 Chapter I Subchapter A Part 15
FCC ID	Federal Communications Commission Identification	A unique identifier assigned to a device registered with the United States Federal Communications Commission	CFR Title 47 Chapter I Subchapter A Part 15
	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.	ISO/DIS 15223-1:2021 Reference no. 5.7.7
IP47	Ingress protection	Protected against solid foreign objects of 1.0 millimeters and greater. Protected against the effects of temporary immersion in water.	IEC 60529
	MR unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503 Reference no. Table 2, Symbol 7.3.3; 7.4.9.1; Fig. 9
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)

Symbol	Symbol Title	Explanatory Text	Standard Reference
	sensor identification number	Indicates the identification number of the sensor.	N/A
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1: 2021 Reference no. 5.2.7. (ISO 7000-2609)
	Medical device	Indicates the item is a medical device.	ISO/DIS 15223-1:2021 Reference no. 5.7.7
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)
	Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1: 2021 Reference no. 5.7.10
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)
Rx ONLY	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.	N/A

Legal and Regulatory Information

This document was, as far as possible, accurate at the time of release, though subsequent changes may have been made. Epitel reserves the right to alter specifications and details as required. Late-breaking information may be supplied separately for completeness.

Product
REMI – Remote EEG Monitoring System

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Users should contact Epitel for assistance with setting up, using or maintaining equipment if needed, or to report unexpected operations or events. For support contact Epitel at any of the following:

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For Patent information, visit www.epitel.com/patents.

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