



User Manual

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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 - mobile medical application that runs on qualified mobile computing platforms
- REMI Phone / phone - A mobile platform running REMI Mobile Software
- REMI Cloud - Cloud-based servers and storage where REMI EEG is processed and stored
- Bluetooth® - Secure, single-device Bluetooth Low Energy protocol

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 (1+ 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.

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.

Warnings

- 1) The REMI System has not been validated for use on any children under the age of 1 year old. Adverse events in particular have not been evaluated, including potential adverse skin reactions, inaccurate readings, etc.
- 2) To reduce the risk of bodily injury,
 - a) Do not ingest REMI Sensors or stickers.
 - b) Only use the power adapter and cable provided with the REMI Phone.
- 3) To reduce the risks associated with cleaning, follow all cleaning instructions included in this manual found in REMI System Overview.
- 4) 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.

- 5) 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.
- 6) Skin Prep Pads are Flammable – keep away from fire, flame.
- 7) Keep Skin Prep Pads away from individuals with a tendency to swallow objects. If swallowed, contact a Poison Control Center immediately.

Precautions

- 1) Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
- 2) To avoid artifacts in a computed tomography (CT) image of the skull, remove REMI Sensors prior to execution of the CT procedure.
- 3) Advanced Settings Menu is not intended for patient access and is only accessible by your provider or through assistance of trained Epitel staff.
- 4) To reduce the risk of damaging REMI Sensors,
 - a) Do not immerse the sensors in a liquid.
 - b) Do not impact, puncture, or cut them with any objects.
 - c) Follow the sensor sticker replacement process as instructed in this manual and in the **REMI Sticker Change Guide**.

- 5) 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 Band-Aid or other skin adhesive.
- 6) 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 clinician.
- 7) When using a fresh REMI Sticker:
 - a) Make sure that the side of the sticker with the blue liner is applied to the sensor. The side with the clear liner is meant to contact your skin.
 - b) Be sure to align each of the sticker's circles with the sensor's gold electrodes. Improper alignment will impact quality of your EEG recording.
 - c) 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.
- 8) 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.
- 9) Do not let the phone battery die. Charge your phone while you sleep and whenever possible while

- you are awake.
- 10) If your phone is disconnected from Wi-Fi and cellular, then EEG data will not be transmitted for clinician review.
 - 11) REMI Sensors are designed for use with other medical devices. However, if you suspect the REMI equipment is interfering with another device, contact your clinician immediately.
 - 12) Skin contacting REMI System components are not sterile.
 - 13) If the surface of your REMI Phone is uncomfortably hot: discontinue use, remove it from charge, and power it off. Please contact Epitel or your clinician.
 - 14) Do not attempt to modify the REMI system and accessories in any way. Modification may interfere with proper device function.
 - 15) REMI Sensor gold electrodes should not come into contact with any conductive parts other than REMI Sticker.
 - 16) 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.

REMI System Overview

REMI Sensors record EEG data from your scalp and transmit it to the REMI Mobile Application. Sensors are held in place using special REMI Stickers that stick to your skin, refer to **REMI Sticker Change Guide**. The REMI Phone runs the REMI Mobile Application, which wirelessly sends information to your clinician using either cellular or Wi-Fi. For additional information, please refer to the **Patient Quick Start Guide**.

REMI Phone and sensors should only be cleaned with damp cloths using water. Do not immerse in liquids.

Relevant Cautions: 4a, 4b, 8, 9

Section 1 – Using Your REMI Phone

Keep your phone powered on and charged throughout your session. To power up your phone, press and hold the power button on the right side of the device for up to thirty seconds.

Relevant Cautions: 9

The REMI Mobile App has two (2) default screens: sleep screen and home screen. The sleep screen will automatically appear after several minutes of inactivity

OR if you select the “crescent 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.

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.

Setting Up a New Wi-Fi

Connecting to Wi-Fi allows for the most consistent and reliable connection on your REMI Phone. For additional information on connecting to Wi-Fi, please refer to the **Patient Quick Start Guide**.

Logging Suspected Events for Clinician Review

Select the “**Add Event**” button on the Home Screen to log a suspected seizure event. When you select “**Save**”, you will receive a confirmation that the event was saved. You cannot edit notes once an event has been saved. Select “**Cancel**” to return to the Home Screen without saving.

Section 2 - Sticker Change & Sensor Orientation

When to Complete a Sticker Change

Stickers can be changed as often as necessary to ensure the highest quality recording. You should replace your stickers every time you remove a sensor and dispose of the used sticker, just like you would a band aid or other skin adhesive. Change all four stickers daily or if any of the following situations occur:

- One or more sensors fall from your scalp
- A sensor feels loose against your skin
- You experience discomfort and need to adjust the sensor's placement
- You want to remove the sensors temporarily for any reason

Relevant Cautions: 6

Steps to Complete a Sticker Change

To complete a sticker change, you must remove the used stickers, apply new stickers, and reapply the sensors to your scalp. Please refer to **REMI Sticker Change Guide** in your daily sticker kit for specific information on applying the stickers. You can find detailed information using the REMI Mobile App's "**Sensor Application Guide**", accessible at any time through the Home Screen or refer to the **Patient Quick**

Start Guide.

Relevant Cautions: 5, 7a, 7b, 7c

Logging a Sticker Change Using Your REMI Phone

You should select the “**Sticker Change**” button on the Home Screen to log your sticker changes. When you click “**Save**”, you will receive a confirmation that the activity was saved. Select “**Cancel**” to return to the Home Screen without saving.

Section 3 - End Session

At the end of your prescribed REMI EEG recording duration, your REMI Phone will automatically begin its end of session activities. This final step can sometimes take up to a few days to complete.

Make sure that the REMI phone is powered on and connected to Wi-Fi or cellular during this step. **Keep the phone on charge** so the battery does not die.

Remove all your sensors and discard the used stickers. Place the sensors on or immediately near or directly on your REMI Phone and **press each sensor button three times**. Leave the sensors there until REMI Mobile displays an “All done!” screen. Once the End of Session activities are complete, return everything to your healthcare provider.

Section 4 – Error Notifications

REMI Phone Error Notifications

“Battery critically low” notification means that the phone needs to be charged. Connect your device to power, and the notification will go away with sufficient charge.

“Connection not available” notification means you have lost connection to Wi-Fi and/or cellular. You should connect to a reliable Wi-Fi source if possible. You can temporarily silence the notification by selecting the “X”.

Section 5 - Compliance and Certification Appendices

Appendix A: REMI System Compliance Standards

REMI Sensor complies with the EMC requirements of IEC 60601-1-2 and IEC 60601-1-11 to ensure that it will operate in the home.

Additional Compliance Standards	IEC-60601-1, IEC-60601-2-26, 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).

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 Eptel 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) and Wi-Fi or cellular for wireless communication







Cybersecurity








REMI system has been assessed for cybersecurity, including secure proprietary Bluetooth communication, end-to-end encryption overed Wi-Fi or cellular communication, and secure HIPAA compliant storage.

Appendix E - 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	Explanation
	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.
	Catalog number - Indicates the manufacturer's catalog number so that the medical device can be identified.

Symbol	Explanation
	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".
	Use-by date - Indicates the date after which the medical device is not to be used.
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.
	Federal Communications Commission - Indicates the device has been tested to comply with FCC standards and has been approved
FCC ID	Federal Communications Commission Identification - A unique identifier assigned to a device registered with the United States Federal Communications Commission
	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".
IP47	Ingress protection - Protected against solid foreign objects of 1.0 millimeters and greater. Protected against the effects of temporary immersion in water.
	MR unsafe - An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

Symbol	Explanation
	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.
	Serial Number - Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Non-sterile - Indicates a medical device that has not been subjected to a sterilization process.
	Medical device - Indicates the item is a medical device.
	Manufacturer - Indicates the medical device manufacturer.
	Unique device identifier - Indicates a carrier that contains unique device identifier information.
	Date of manufacture - Indicates the date when the medical device was manufactured.
Rx ONLY	Prescription use only - Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

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