
REMI™
REMOTE EEG MONITORING SYSTEM
FOR HEALTHCARE FACILITY USE

Contents

Symbols Glossary

Symbol	Symbol Title	Explanatory Text	Standard Reference	Standard Title
	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	Graphical Symbols for Use on Equipment
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Symbol	Symbol Title	Explanatory Text	Standard Reference	Standard Title
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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	Radio Frequency Devices
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	Radio Frequency Devices
	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	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
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	Degrees of protection provided by enclosures (IP Code)
	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	Standard Practice for Marking Medical Devices and other Items for safety in the Magnetic Resonance Environment

Symbol	Symbol Title	Explanatory Text	Standard Reference	Standard Title
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	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)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	sensor identification number	Indicates the identification number of the sensor.	N/A	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 devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Medical device	Indicates the item is a medical device.	ISO/DIS 15223- 1:2021 Reference no. 5.7.7	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Symbol	Symbol Title	Explanatory Text	Standard Reference	Standard Title
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1: 2021 Reference no. 5.7.10	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
Rx ONLY	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.	N/A	N/A

Note: The symbols provided above 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.

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	Single-channel disposable EEG sensor
REMI Sticker / sticker	Conductive-adhesive sticker used with REMI Sensors
REMI / REMI System	Remote EEG Monitoring System
REMI Mobile	The mobile medical application that runs on qualified mobile computing platforms.
REMI Montage	The standard order and grouping of 10 channels of EEG data produced by REMI System
REMI Tablet / tablet	A tablet mobile computing platform running REMI Mobile Software to initialize a session
REMI Server	The main server of REMI Cloud that receives sensor data and generates REMI EEG files
REMI Server URL endpoint	The messaging service address where all messages from REMI Mobile are provided to REMI Server
REMI Cloud	Cloud-based servers and storage where REMI EEG is processed and stored
Persyst® Mobile	Cloud-based EEG reviewing software produced by Persyst
Bluetooth® / BLE	Secure, single-device Bluetooth Low Energy protocol, used for wireless communication between REMI Sensors and REMI Mobile software

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.

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 Tablet 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.
- REMI Tablet contains lithium batteries. Under normal charging conditions, the device may become warm. If the device becomes too hot to touch and/or shows signs of swelling, remove the charging cable. Power down the device immediately and contact Epitel for service.

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.
- To reduce the risks associated with an incorrect result, store and operate REMI Tablet, REMI Sensors, and REMI Stickers only as instructed in this manual.
- Advanced Settings on REMI Tablet should only be accessed with the assistance of trained Epitel staff. Changes in device settings can result in delays in the initialization of a new session. To access, contact Epitel for the Device Configuration 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
- REMI Sensors are single-patient use. Do not attempt to reuse REMI Sensors. Once a recording has ended, all active sensors will no longer be able to connect to the computing platform or record EEG. Dispose of all used REMI Sensors at the end of the session.
- REMI Stickers are one-time use. Do not attempt to reuse REMI Stickers after removing REMI Sensors from the patient's scalp.
- REMI Sticker placement sites should be checked daily for any adverse reactions and replaced as needed.
- To reduce the risk of poor signal quality due to poor contact,
  - Ensure that the blue liner side of the sticker is applied to the sensor. The clear liner side of the sticker is intended for patient contact.
  - Ensure that the sticker hydrogels are aligned over the gold electrodes. Failure to do so will result in poor data quality.
  - Do not place the sensor over the patient’s hair. REMI Sensor is meant to be used below the hairline.

- To ensure a good wireless connection between REMI Sensors and the mobile devices:
  - REMI Tablet should be kept within 4m (13 ft) of the patient during session initialization.
- EEG data will not be transmitted by the computing platform or available for clinician review during the time that:
  - The computing platform is without power.
  - 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 Tablet 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 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.
- If REMI Tablet is mounted, ensure that it is securely mounted and that its size and weight do not exceed any limitations of the surface to which it is applied.
- REMI Mobile system updates require that REMI Tablet be powered on and connected. For the fastest and most reliable updates, it is recommended to connect REMI Tablet computing system to Wi-Fi for system updates.
- Artifact Reduction, AR, should always remain toggled **OFF** when viewing REMI EEG data as this feature is not compatible with REMI EEG data.

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 for Healthcare Facility system follows the same workflow for every new session. A session starts on REMI Tablet by collecting basic patient information. REMI Sensors are activated and placed on the patient using REMI Tablet interface for guidance. Then, REMI Tablet begins the active session recording. After completed use, REMI Tablet is reset for the next session.

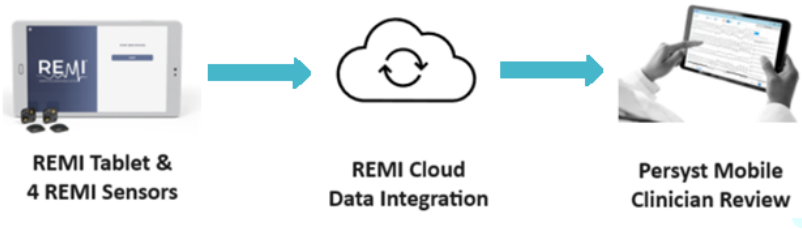
Summary of Devices

REMI for Healthcare Facility system consists of several components: REMI Tablet, four REMI Sensors, and REMI Stickers for sensor adhesion. REMI Tablet software must be configured to the appropriate REMI Server URL endpoint.

REMI Sensors amplify and digitize the EEG from a patient's scalp and transmits that data to REMI Mobile. REMI Mobile platform then uploads the data and patient information to REMI Cloud where the data can be viewed by a clinician. After digitizing, the EEGs are wirelessly transmitted to a qualified mobile operating platform running REMI Mobile software.

Device Communications

Each session begins with initialization and placement of the sensors by the healthcare provider using REMI Tablet. During an active recording, REMI Tablet relays the EEG from four REMI Sensors to REMI Cloud environment where the patient information and sensor EEG data is combined into a Clinician-reviewable EEG record. REMI EEG record is accessible through Persyst Mobile where the four REMI Sensor (eight electrodes) EEG data can be displayed in a montage of up to ten channels.



REMI Tablet Description

REMI Tablet is used for initial placement and initialization of a new REMI session. The user interface for REMI Tablet operating platform is a touchscreen display powered by an A/C adapter and onboard rechargeable battery. With proper cleaning and maintenance, REMI Tablet should be reused for multiple sessions.

Each REMI Tablet has a unique serial number located on the back cover and within the application under the Settings Menu. REMI Mobile software version can also be found in the application's Settings Menu. Legal & Copyright information for REMI Tablet 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. Each REMI Sensor has a unique sensor ID 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.

REMI Cloud Description

REMI Cloud environment is a collection of servers and storage devices where patient information and REMI Sensor data is received from REMI Mobile and an EEG record is created, and Persyst software is run allowing Clinician review of REMI EEG files. A unique REMI Cloud environment, including a unique REMI Server URL endpoint, is configured for each healthcare provider to ensure secure data storage.

Preparation Step - Initialization and Device Setup

Epitel will provide all REMI Mobile devices with the correct server URL and other required information prior to installation of the device. If the computing hardware experiences issues with connection to the REMI Server, see the **Troubleshooting** section in this manual.

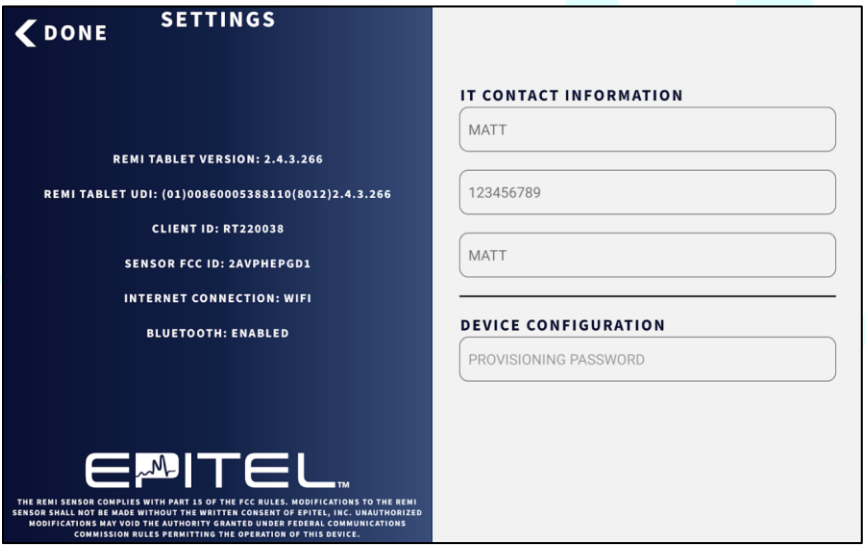
Preparing REMI Tablet

To prepare REMI Tablet for operation, plug REMI Tablet into a wall outlet using the provided cable and adapter. Press and hold the power button until the tablet turns on. The tablet will take a few seconds to boot. Once REMI Tablet boots, it will automatically display the Start Session Screen. In the upper left-hand corner of the Start Session Screen is a “gear” icon that takes the user to the Settings Screen.

IMPORTANT: If the clock screen is shown, swipe up, which will display the Start Session Screen.

Settings on REMI Tablet

The Settings screen provides users with general device and manufacturing information. Additionally, the IT Contact Information can be reviewed and updated from this screen.



REMI Tablet Settings Screen

Device Configuration on REMI Tablet

Device Configuration should only be accessed in case of a service event under the guidance of an Epitel service representative. Improper changes to Device Configuration can make the device inoperable and may delay initialization of new sessions. The Device Configuration is accessible by entering in a secure passcode to the Device Configuration textbox.

Installation and Setup Precautions

CAUTION: Device Configuration on REMI Tablet should only be accessed with the assistance of trained Epitel staff. Changes in device settings can result in delays in the initialization of a new session. To access, contact Epitel for the Provisioning Passcode.

CAUTION: EEG data will not be transmitted by the computing platform or available for clinician review during the time that:

- The computing platform is without power.
- A disconnection occurs between REMI Mobile and REMI Cloud.
- A disconnection occurs between REMI Sensors and REMI Mobile.

CAUTION: REMI Mobile system updates require that the computing platform be powered on and connected. For the fastest and most reliable updates, it is recommended to connect REMI to Wi-Fi for system updates.

IMPORTANT: For optimal performance, REMI Tablet is recommended to be plugged in at all times. REMI Tablet will operate on battery power, however, once the tablet battery drops below 50% capacity a notice will pop up on REMI Mobile application.

Step 1 - New Session Preparation & Initiation

To prepare for a new session, ensure that all of the listed materials are available. A new session begins first with capturing patient data on REMI Tablet. When ready, press the START button on REMI Tablet to begin a new session.

IMPORTANT: To enable reliable connection for initiation of a new session, REMI Tablet must connected to Wi-Fi to avoid interruptions or connectivity errors.

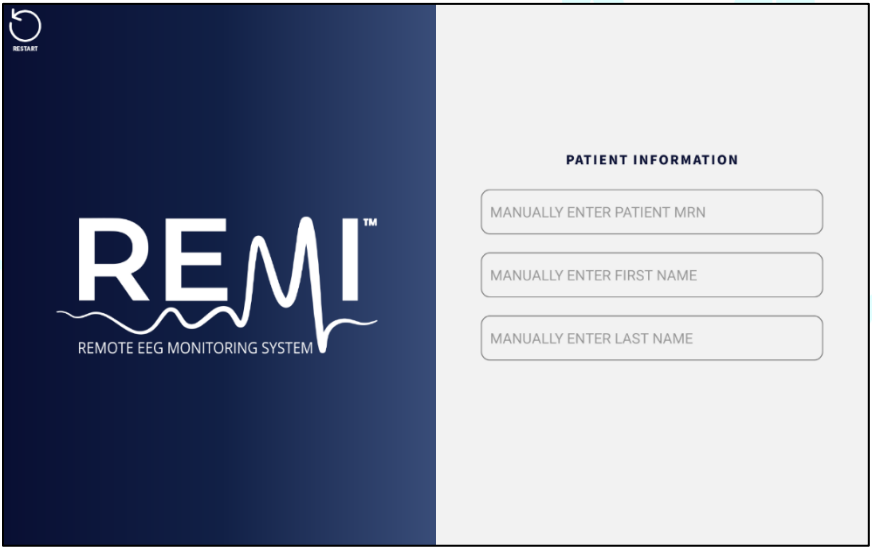
Required Materials for New REMI Session:

- Four (4) REMI Sensors, REMI Stickers, and alcohol prep pads
- One (1) REMI Tablet, fully charged

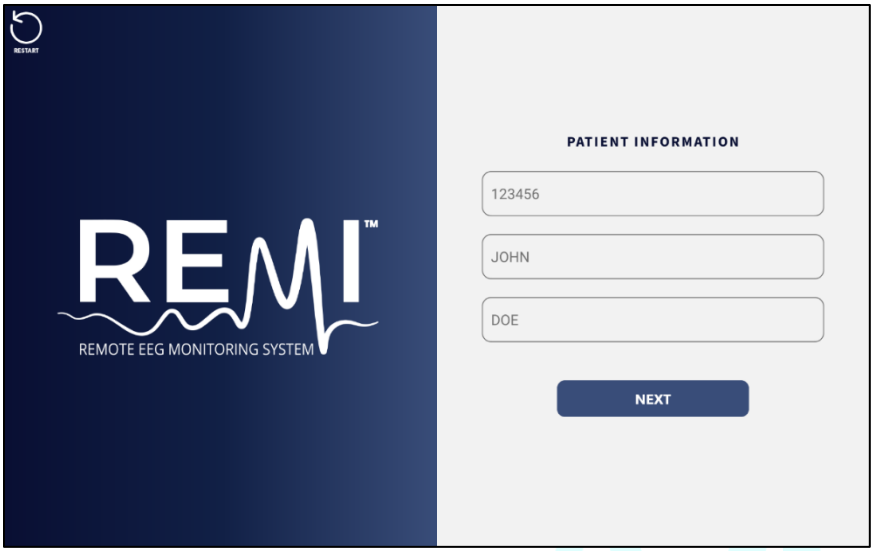
Enter Patient Information

The healthcare provider should be prepared to complete all the following fields to proceed with a new session: patient's medical record number (MRN), first name, and last name.

To enter patient information, touch any field to bring up the touchscreen's alphabetic keyboard. All fields must be completed before transitioning to the next step.



REMI Tablet Patient Information Screen (no fields selected)



REMI Tablet Patient Information Screen (all fields completed)

IMPORTANT: The NEXT button will not appear unless all four fields are complete.

IMPORTANT: You may restart a session at any time by clicking the counterclockwise RESTART arrow in the upper left-hand corner of the screen and confirming. See Restart Session and the End Session sections of this manual for further information.

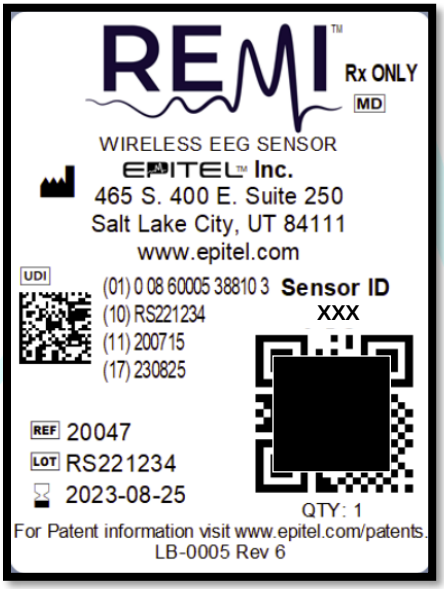
Step 2 - REMI Sensor Identification and Activation

REMI Sensors are individually packaged and programmed and can be used for only one session. Healthcare providers must therefore identify which sensors will be included within the session. REMI Tablet provides step-by-step instructions for this.

Additionally, REMI Sensors are stored in a sleep state. Once a healthcare provider has identified the sensor IDs for the session, they will activate the sensors through a button press to begin wireless communication between REMI Sensors and REMI Tablet.

REMI Sensor Identification

Each REMI Sensor has a unique ID that can be found on the individual packaging and on the underside of the sensor itself. REMI Tablet offers two options to capture the sensor IDs: scan the QR Code located on the bottom right the packages or manually enter the sensor ID using the application keyboard. REMI Tablet will automatically move to Sensor Initialization once all four sensor IDs have been entered.

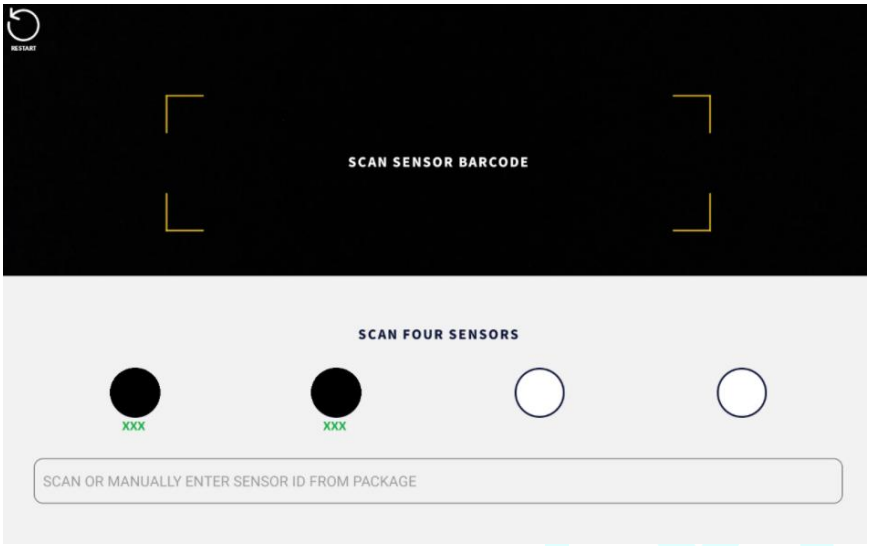


REMI Sensor ID on Individual Packaging (example)

IMPORTANT: Previous versions of REMI Sensor packaging will contain a barcode rather than a QR Code. The tablet scanner will identify either version of the label.

Scan REMI Sensor QR Codes using REMI Tablet

To scan the sensor ID, center the QR Code on the screen. Once the tablet successfully reads the QR Code, the circle will fill and the three digit alpha-numeric sensor ID will appear below. The QR Code of each sensor can only be scanned once to prevent duplication.



REMI Tablet Sensor Identification Screen

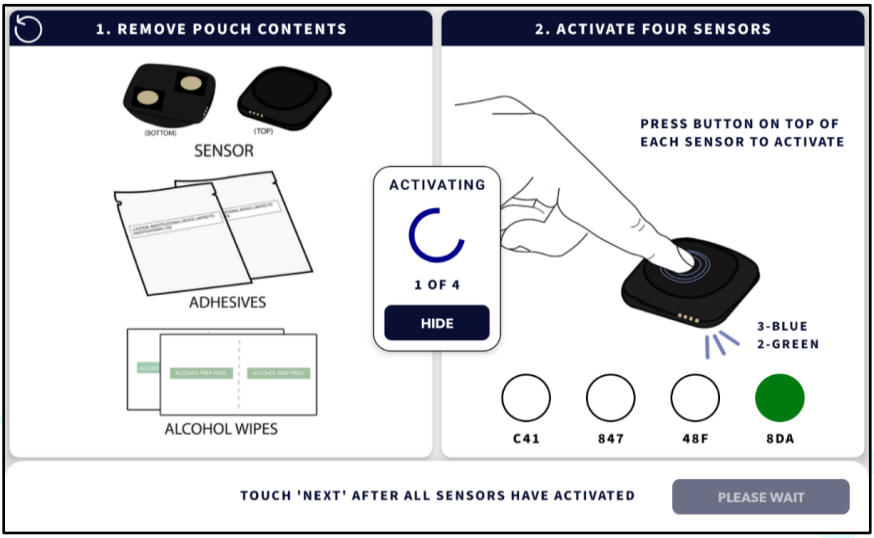
IMPORTANT: Only scan the QR Code at the bottom of packaging. The QR Code in the top left is not scannable by REMI Tablet.

To manually enter the sensor ID, tap the text field and the application keyboard will appear. After entering the sensor ID, select the enter/return arrow to save the ID and move to the next sensor. To return to the QR Code scanning, tap anywhere outside of the keyboard and text field.

REMI Sensor Activation
To activate REMI Sensors, press the center button on the top of the sensor. Once the button has been pressed, the sensor LED (near the four gold pins) will flash blue three times followed by green twice to indicate that the sensor is activated and broadcasting wirelessly.

IMPORTANT: The sensors activated in this step MUST match the sensors that were identified in the previous step. Activating sensors with a different ID will not connect them with the session.

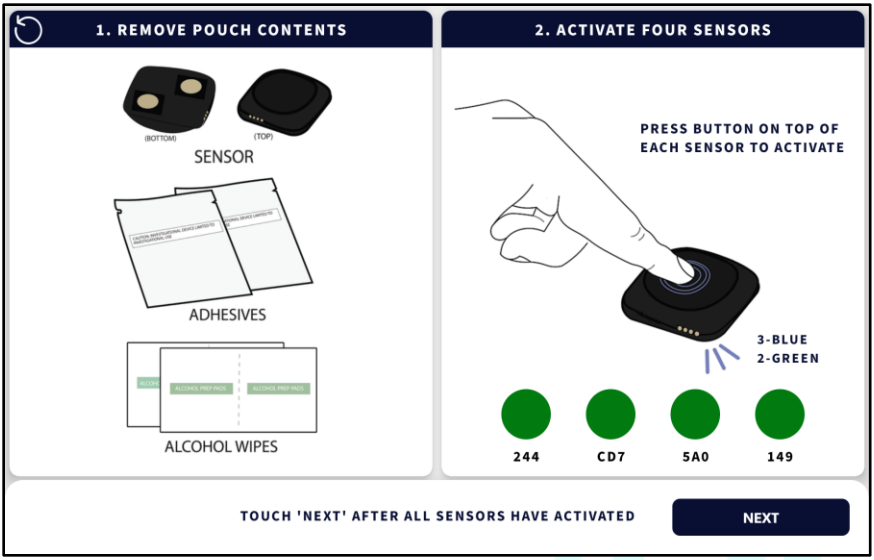
The circle above the respective sensor ID will fill green and the LED will flash green 10 times once REMI Sensor has properly connected with REMI Tablet. Repeat with each sensor.



Sensor Connection Screen (activation in process)

IMPORTANT: If the sensor is activated and working correctly, but the circle does not fill green in REMI Tablet, bring the sensor closer to the tablet.

IMPORTANT: If there is an issue with a sensor, it should be replaced before a recording session begins.



Sensor Connection Screen (activation complete)

When all four sensors activate and connect to REMI Tablet, the text will change from PLEASE WAIT to NEXT. Click the NEXT button to proceed.

IMPORTANT: It may take a number of seconds for each sensor to connect to REMI Tablet. Clicking sensors too quickly can sometimes cause the connection attempt between REMI Tablet and REMI Sensor to fail. This can be avoided by waiting a few seconds between the first button press to activate the sensors. If a sensor is taking too long, try depressing the button again. If any sensor does not connect within 60 seconds, see the **Troubleshooting** section of this manual.

Step 3 - Sticker Application

REMI Sensors require a one-piece conductive-adhesive to properly adhere to the patient's scalp. The adhesive stickers provided within REMI Sensor packages REMI are the only approved adhesion for REMI Sensors.

Sticker Application to REMI Sensors

Although the stickers are double sided, the adhesives are different and order of application matters. To apply the stickers to the sensors, remove blue liner film from the sticker. Line up the clear hydrogels over the gold electrodes on the underside of REMI Sensors. Press smoothly around the edges to ensure proper adhesion.

CAUTION: To reduce the risk of poor signal quality due to poor contact,

- Ensure that the blue liner side of the sticker is applied to the sensor. The clear liner side of the sticker is intended for patient contact.
- Ensure that the sticker hydrogels are aligned over the gold electrodes. Failure to do so will result in poor data quality.

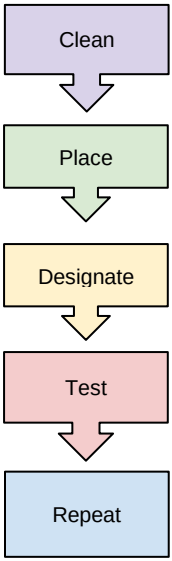
Sticker Placement Screen

Once the stickers are firmly placed on the individual REMI Sensors, remove the clear film from the sticker in preparation for placement on the patient's scalp. Repeat for all REMI Sensors. When ready, click NEXT on REMI Tablet screen.

WARNING: 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.

Step 4 - Sensor Location Designation & Placement

REMI Sensors are not pre-programmed for a specific placement location on the patient's scalp. Therefore, the sensors must be identified and then *assigned* a location using REMI Tablet software. Each placement will follow the same process:



First, use the provided alcohol prep pads to clean the specific location. Ensure the area is dry before placing a REMI Sensor.

Place a REMI Sensor on the patient's scalp at the specific location according to the orientation and location details provided in **REMI Sensor Placement and Orientation Reference Guide**.

Next, designate the placed REMI Sensor to that specific location by pressing its sensor button. The screen will show a green circle when successfully completed.

Finally, test adhesion of the designated REMI Sensor to the scalp by tapping the TEST button on REMI Tablet sensor Placement Screen. When the sensor adhesion test is successfully completed, the sensor will flash its LED green 10 times; REMI Tablet will automatically reset the TEST button to PLEASE WAIT and change the left image to the next Placement location.

Repeat this process for each REMI Sensor until all four sensors have been placed. The workflow follows the same order for designation and placement: Left Ear, Left Forehead, Right Forehead, Right Ear.

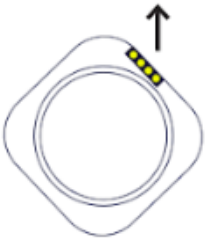
IMPORTANT: If the sensor adhesion test is not acceptable, a notice will appear. Please see the **Poor Electrode Contact Notice** section.

IMPORTANT: Once a sensor has been designated for a specific location, it will maintain that designation throughout the entire duration of the session.

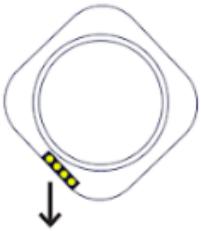
IMPORTANT: A REMI Sensor may be repositioned within the same location area on a patient if initial placement is not optimal, but the sticker adhesion should be confirmed following repositioning. If the sticker is no longer sticky enough, **Step 4 - Sensor Location Designation & Placement** will need to be restarted.

REMI Sensor Placement and Orientation Best Practices
For consistent signal output, orientation and placement of REMI Sensors is critical. For behind the ear placements, position REMI Sensors above the mastoid and as high and close to the hairline as possible. For forehead placements, position REMI Sensors as high on the forehead and as close to the hairline as possible.

Patient Left Side



Patient Right Side



CAUTION: To reduce the risk of poor signal quality due to poor contact, do not place the sensor over the patient's hair. REMI Sensor is meant to be used below the hairline.

IMPORTANT: If REMI Sensor is placed in the incorrect location, the designation can be edited later. Make note of REMI Sensor ID and see the Change Placement section of this manual.

IMPORTANT: Do not push the button on more than one REMI Sensor at this step. Activating more than one sensor will bring up the Multiple sensors Activated error screen. If this occurs, REMI Tablet will ask you to repeat the activation process. See additional instructions in the Multiple sensors Activated Notice section.

IMPORTANT: If the button on REMI Sensor was pressed but the circle is not showing green in REMI Tablet, they may be too far apart to properly communicate or the button was not pressed firmly enough. Bring REMI Tablet closer to the patient and/or firmly press the sensor button again.

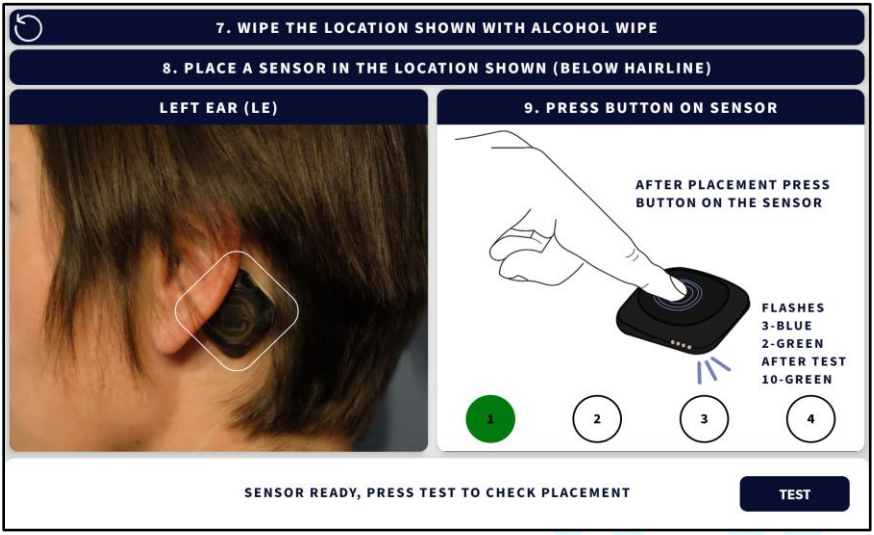
IMPORTANT: If there is an issue with a sensor, it may be replaced before a recording session begins. Touch any one of the circles that is not filled solid green to replace the sensor.

Place and Designate

Sensor Placement Screen: Left Ear (before sensor press)

Sensor Placement Screen: Left Ear (after sensor press

Test Adhesion



Sensor Placement Screen: Left Ear (ready for test)

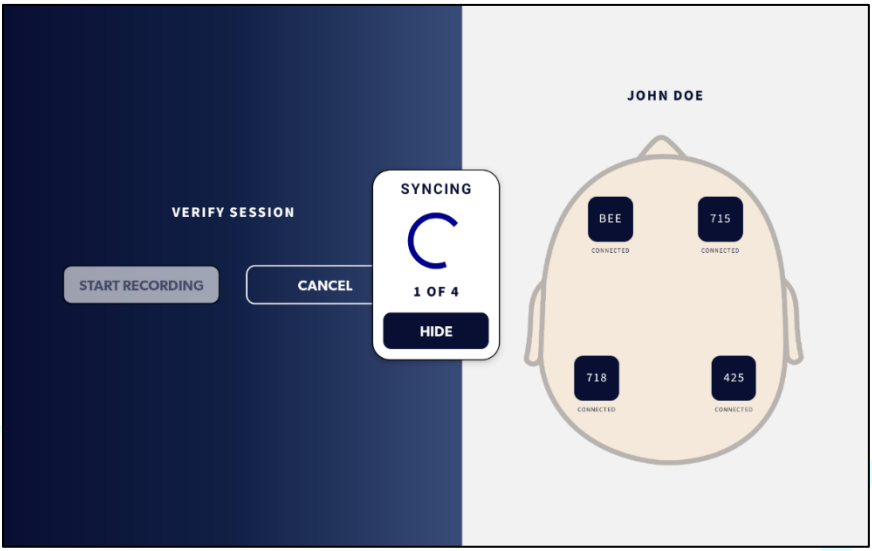
Sensor Placement Screen: Left Ear (after selecting TEST)

Sensor Synchronization

In order to ensure a quality recording from REMI Sensors during the active session, REMI Tablet must synchronize the internal clocks of the sensors. No action is required by the user at this point. After successful placement and testing of the Right Ear, REMI Tablet will transition through sensor synchronization activities. A message box will appear to indicate that sensors are synchronizing.

IMPORTANT: The syncing message box serves as a status indicator for the synchronization process. Selecting “Hide” will remove this indication and synchronization status will no longer be viewable.

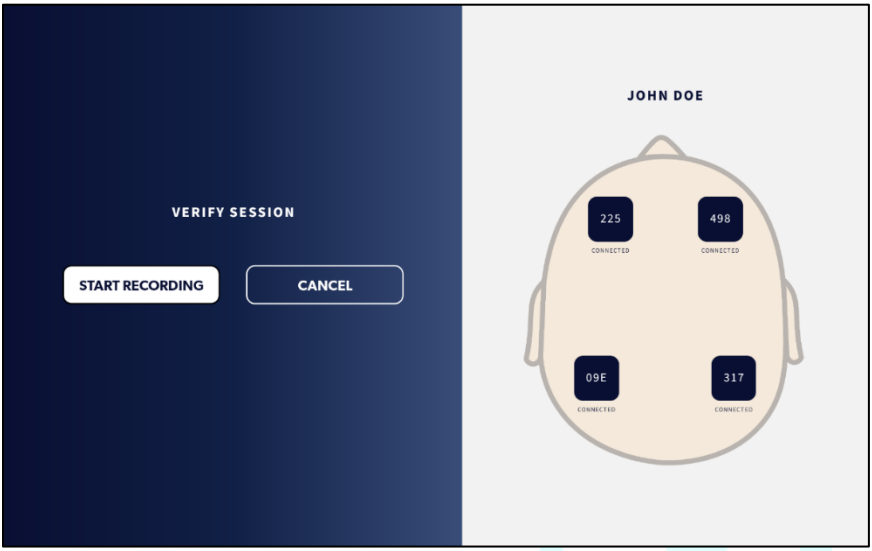
IMPORTANT: Sensor synchronization should only take a few minutes to complete. If the process takes longer, it is recommended to move the tablet closer to the sensors.



Sensor Synchronization In Progress

Step 5 - Verify Session

Before starting a new recording, there are several verification options within REMI Tablet to ensure that the session is ready. Review the information presented on the sensor Verification Screen to ensure the session information is correct. This includes reviewing the patient name and confirming sensor ID and locations are appropriately designated.



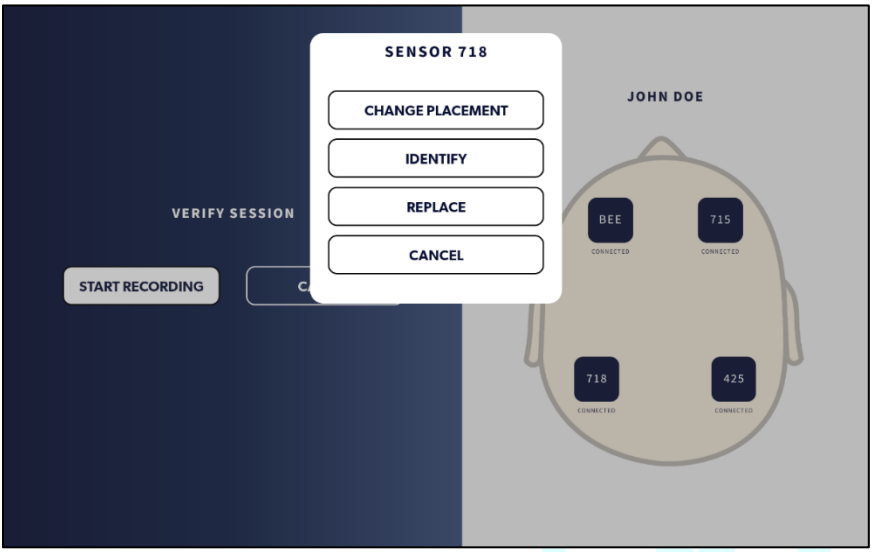
REMI Session Verify Screen (synchronization successful)

IMPORTANT: Sensor Verification Available Actions are not necessary steps to begin handoff.

IMPORTANT: If the patient name is incorrect, the only way to change this data is to completely restart the session, which will wipe any existing information and start from the process beginning.

IMPORTANT: Selecting the CANCEL button on the screen will clear all progress to that point and wipe any patient data. The application will reset and return the user to the Start Session Screen. Dispose of any used REMI Sensors and stickers.

Each REMI Sensor is depicted by its three-digit alpha-numeric sensor ID number. Tap the dark blue square representing the respective REMI Sensor to access the sensor Verification Available Actions. Users can Identify, Replace sensor, and Change Placement for any REMI Sensors. Selecting CANCEL or touching outside of the message boundaries returns the application to the Verify Session Screen.

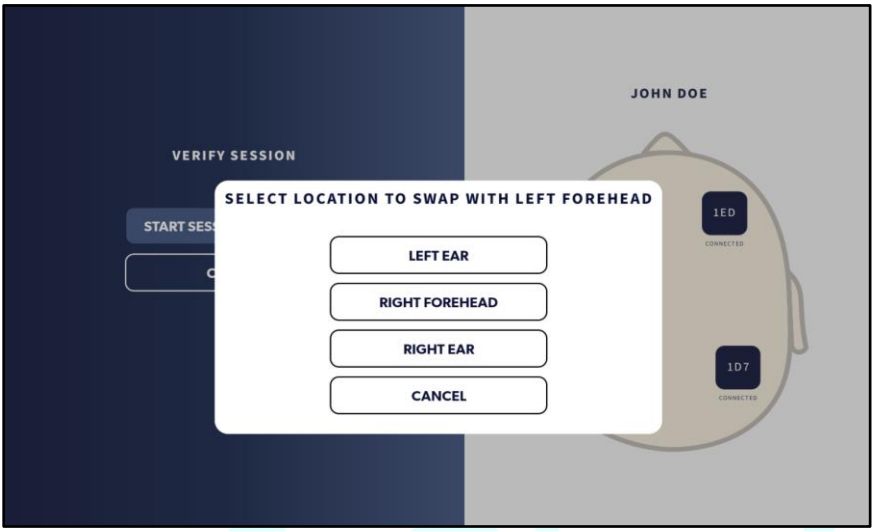


Session Verification Screen with Sensor Verification Available Actions List

Identify (sensor)

The Identify action is useful in confirming physical location of a specifical REMI Sensor on the patient without having to remove REMI Sensor from the patient's scalp. Select the appropriate ID on the Verify Session Screen. After selecting IDENTIFY, REMI Tablet will communicate with REMI Sensor to flash the sensor LED green ten (10) times.

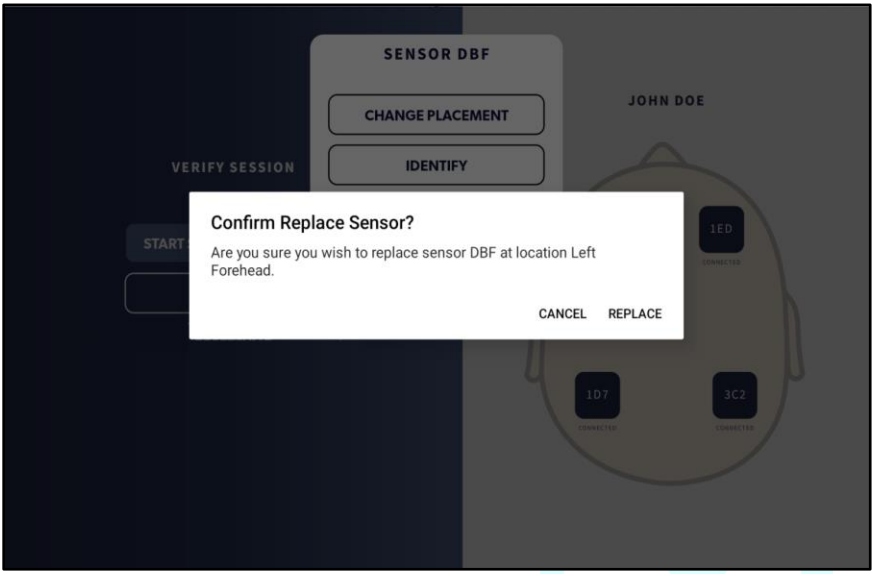
Change Placement (of sensor)
The Change Placement action is useful to redesignate a REMI Sensor location if two locations were placed incorrectly during the **Sensor Location Designation & Placement** step. Identify the incorrectly designated REMI Sensors; refer to the Identify section to identify sensors without physically removing them. After selecting CHANGE PLACEMENT from the sensor Verification Available Actions List, select the second impacted sensor. Completing this action will reorder the location of REMI Sensors on the Verify Session Screen diagram. Note, this only needs to be done once to swap two locations.



Swap Sensor Placement Confirmation Screen

IMPORTANT: This is the only opportunity to change the placement location of a REMI Sensor. Once the handoff has begun, the designation of REMI Sensor locations cannot be updated.

Replace (sensor)
The Replace action is useful if one or more REMI Sensors is experiencing issues. Select the appropriate ID from the available REMI Sensors. After selecting REPLACE from the sensor Verification Available Actions List, the application returns to REMI Sensor Identification & Activation step.

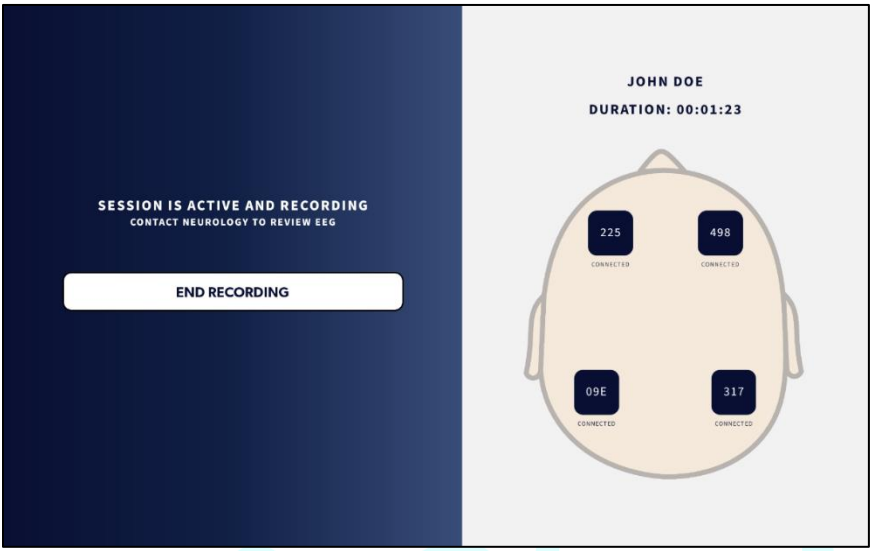


Replace Sensor Confirmation Screen

Step 6 – Managing an Active Session

Active Recording

Selecting START RECORDING from the Verify Session Screen begins the active recording. During the recording, if there are any problems with the Sensors or with connectivity with the REMI-Cloud platform, an alert with troubleshooting instructions will appear with troubleshooting instructions.



Active Recording Screen

During an active recording session, the Sensors depicted in the REMI app will remain solid dark blue. EEG recordings are being sent to the REMI-Cloud platform and are available for an epileptologist to review. Clicking any individual Sensor allows the user to identify the location of the REMI Sensor by sending a command to the sensor in question to blink GREEN.

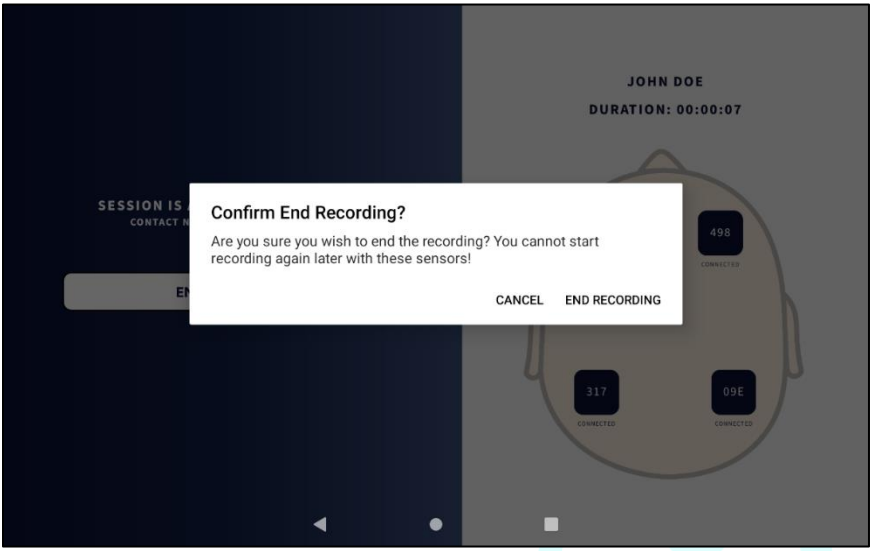
IMPORTANT: The recording will automatically end after 48 hours if not manually ended.

IMPORTANT: For information on monitoring and reviewing the EEG data, refer to **Step 7 - Reviewing Sessions in Persyst Mobile** within this manual.

End Recording

To end a recording, select END RECORDING. A confirmation screen will appear to cancel and go back to the previous screen. Select CONFIRM to end recording.

IMPORTANT: END RECORDING cannot be undone. After ending a recording, the Sensors connected to the REMI Tablet will no longer be able to record or connect to the REMI Tablet.



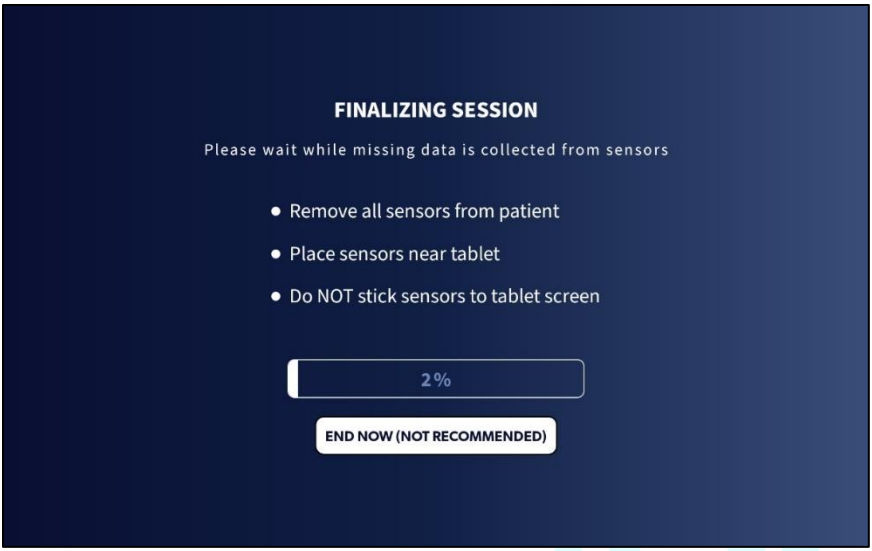
Confirm End Recording Screen

Once a recording has been ended, it will go through a final step to catch-up and update the raw data file. This final processing step can take up to five minutes to complete depending on connectivity during and at the end of the active session.

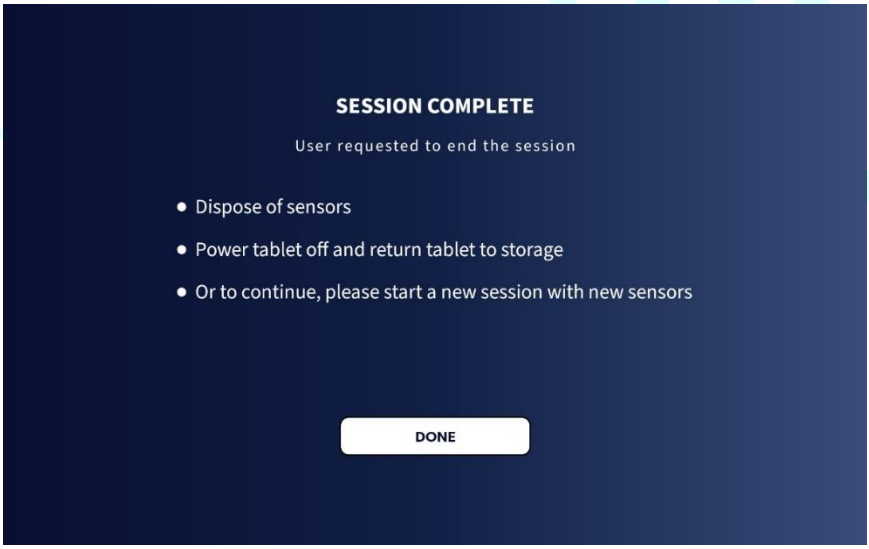
IMPORTANT: The Persyst Mobile EEG file will NOT update with the missing data. To request the updated data, contact your Epitel representative.

CAUTION: REMI Sensors and Stickers are single-patient, one-time use. Do not attempt to reuse REMI Sensors or Stickers. Once a recording has ended all active Sensors will no longer be able to connect to the REMI Tablet or record EEG.

After completing the finalization activities, REMI Tablet will transition to the Session Complete screen. Dispose of the used sensors, power off REMI Tablet and return to storage. Selecting DONE will reset the tablet for a new session.



Finalizing Session Screen



Session Complete Screen

Step 7 - Reviewing Sessions in Persyst Mobile

After selecting START RECORDING, REMI Tablet will begin to capture and transmit EEG data from REMI Sensors to REMI Cloud. REMI Tablet uses near real-time data to upload new data to REMI Cloud. Once stored in REMI Cloud, the EEG data is processed and presented in Persyst Mobile.

No action is required by the patient to ensure data is transmitting, but consistent connectivity is critical to enable near real-time monitoring of the active session. If connectivity is poor during the active recording, the session data will appear incomplete in the Persyst Mobile file until the end of the session.

Accessing Persyst Mobile

REMI Remote EEG Monitoring System has been qualified for use with FDA-cleared Persyst Server and Persyst Mobile software to provide remote review of REMI EEG. Persyst Mobile works on any desktop internet browser or on mobile devices.

A unique Persyst Mobile site is established as a part of the provided REMI Cloud environment. The web address and individual user credentials are available via healthcare network administrator. To access the Persyst Mobile site, log into the Persyst Mobile web address using the username and password provided.

Persyst Mobile Login Screen

Navigating Sessions within Persyst Mobile

The Persyst Mobile of REMI sessions is organized Patient Name and MRN. A green square box will occasionally appear to the left of the patient name to indicate that data is being actively uploaded.

Selecting the Patient Name highlights that patient and lists the beginning and the current end of the patient recording as comments on the right side of the screen. Selecting any of the comments will bring up the patient's EEG record, displayed in the REMI-LR 10-channel montage.

Persyst Mobile Patient Views Screen

IMPORTANT: Any EEG data missed during the ongoing active session file creation is displayed as zero-value data in the Persyst Mobile recordings.

IMPORTANT: Persyst Mobile allows users to annotate patient records to denote electrographic areas of interest during an active session. In addition to user generated comments, REMI Remote EEG Monitoring System enables comments for (1) Beginning of Record and (2) Current End of Record.

Overview of Available Montages

Two different EEG montages are initially available for reviewing a patient's REMI EEG record (REMI-LR, REMI-FB).

CAUTION: Artifact Reduction, AR, should always remain toggled **OFF** when viewing REMI EEG data as this feature is not compatible with REMI EEG data.

REMI-LR Montage

The default montage, REMI-LR, displays the patient's left-sided channels in the first group, then the patient's right-sided channels in the second group. The third group contains the two transverse channels and the fourth group contains the two oblique channels. REMI-LR channel grouping and order most closely reflects the commonly used double-banana montage.

Patient EEG Record Displayed in the REMI-LR Montage

REMI-FB Montage

An alternate montage, REMI-FB, displays the patient's front (or anterior) channels in the first group, then the patient's back (or more posterior channels) in the second group. This montage places frontal channels together and temporoparietal channels together. The third group contains the two longitudinal channels and the fourth group contains the two oblique channels. REMI-FB montage can be selected from the dropdown menu on the top left while viewing a patient record.

Patient EEG Record Displayed in the REMI-FB Montage

IMPORTANT: Persyst Mobile offers several additional user settings and EEG settings that can be adjusted within the EEG record, including: page duration (seconds of data per page), sensitivity (or gain), low frequency filter, high frequency filter, playing speed (pages per second), toggling minor and major gridlines on or off, toggling restrict pen deflection on or off, and toggling high resolution eeg on or off.

Detailed instructions on the use of Persyst Mobile, including how to edit user settings and create your own montages, can be found in the Persyst Mobile User Guide.
https://www.persyst.com/PersystMobile/UserGuide.pdf

Troubleshooting

REMI Remote EEG Monitoring System provides error messages and system notices to support in-app troubleshooting.

Frequently Asked Questions

REMI Sensors

An active recording session will continue even if a REMI Sensor is no longer functioning properly. However, a new session cannot begin without four (4) functioning REMI Sensors. In the case of faulty or unresponsive sensors, the items can be returned to Epitel for replacement. See **Appendix H - Warranty** section of this manual.

What do the different LED colors mean on REMI Sensor?
REMI Sensor has several key patterns for the LED behaviors, after a button press:

- Alternating blue and red flashes - the sensor is active and broadcasting, but not yet connected to REMI Tablet
- Continuous green flashes, up to ten (10) times - the sensor is active and has successfully connected to REMI Tablet
- Continuous red flashes, up to ten (10) times - the sensor is faulty and unfit for use
- Single green flash - the sensor is active and recording

What if I don't see any flashes on a REMI Sensor after pressing the button?
Ensure you are looking towards the corner where the LED is located on REMI Sensor when pressing the button (next to the four gold pins). Note, it can be difficult to observe the LED in bright lighting conditions. If the sensor still does not flash when the button is pressed, the sensor is faulty and unfit for use.

Why is a REMI Sensor continuously disconnecting from REMI Tablet?
Ensure REMI Tablet is close enough to the patient to properly connect. It is recommended to replace REMI Sensor if the disconnection continues and a recording has not yet been started.

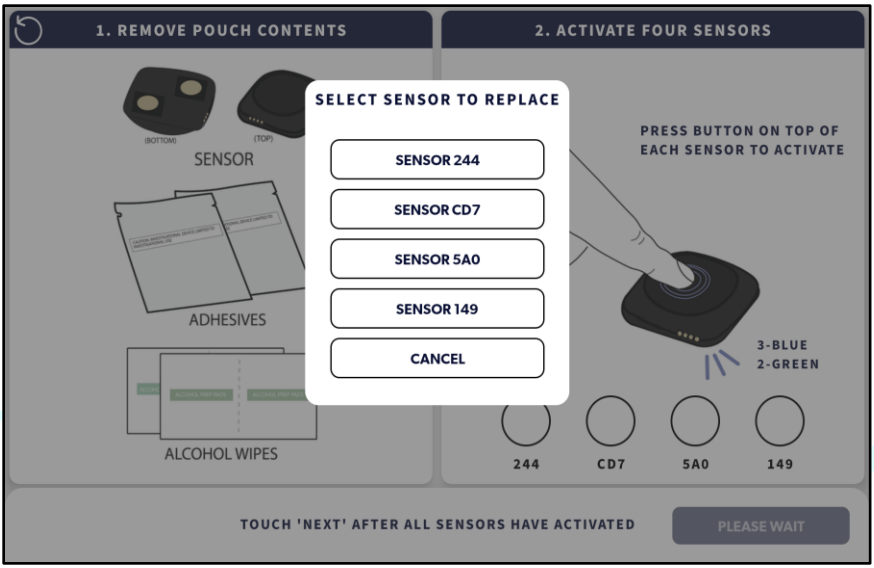
Why won't a REMI Sensor connect to REMI Tablet?
If a REMI Sensor wireless radio is faulty, it will be unable to properly communicate with REMI Tablet. In this case, the LEDs of that REMI Sensor will likely be blinking red. Replace with a new, unused REMI Sensor.

What do I do when a REMI Sensor detaches after a sensor adhesion test has passed?
If a REMI Sensor detaches after a sensor adhesion test, follow the same manual steps to replace the sticker and reapply. Press the button on the sensor three times after applying to patient scalp.

REMI Tablet

A new session cannot begin without an up-to-date and functioning REMI Tablet. In the case of faulty or unresponsive REMI Tablets, first try a hard reboot of the device by pressing the power button on the side of the device and selecting “Restart”. It will take a few seconds to reboot; however, REMI Mobile app will return to the previous screen. If the issue persists, call Epitel support for additional guidance. Faulty items can be returned to Epitel for replacement. See **Appendix H - Warranty** section of this manual.

What do I do if a sensor doesn’t activate during placement?
If REMI Sensor LED blinks red or the LED of REMI Sensor fails to engage, it is not fit for use and should be replaced. To replace a sensor, tap and hold the circle assigned to the sensor ID. A confirmation modal will appear to remove the selected sensor ID. Dispose of the defective sensor and repeat REMI Sensor identification and activation steps to replace.

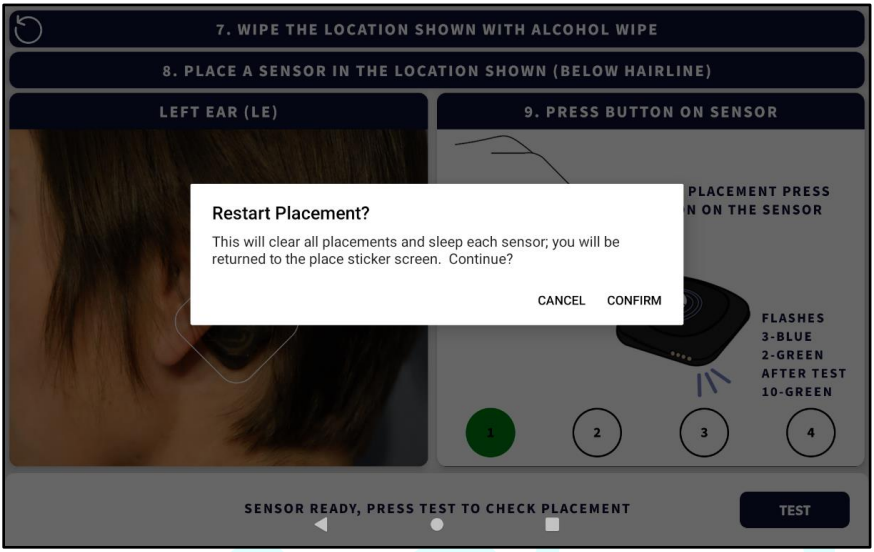


Sensor Scan Screen (replace sensor)

What do I do if REMI Tablet does not start?
Ensure REMI Tablet is plugged in to A/C power before trying to power it on. If not stored properly, the battery will drain and need to recharge before powering up. Refer to **Product Storage** for additional information.

What do I do if REMI Tablet isn’t scanning REMI Sensors?
If REMI Tablet is not able to scan REMI Sensors QR codes, it is possible to manually enter either using the tablet’s touchpad keyboard. To manually enter the IDs, tap the text field and the application keyboard will appear. Be sure to select the enter/return arrow to save the ID. To return to the QR code scanning, tap anywhere outside of the keyboard and text field.

Can I restart the REMI Sensor placement flow?
The Sensor Placement workflow can be restarted and/or reset at any time by clicking the counter-clockwise arrow in the upper left-hand corner of the screen. Selecting CANCEL or touching outside of the message boundaries returns the application to the previous workflow progress. Selecting CONFIRM, resets any existing placement workflow. Remove any previously placed sensors from the patient's scalp and dispose of used stickers. Refer to **Step 3 - Sticker Application** for assistance in replacing the stickers on REMI Sensors.

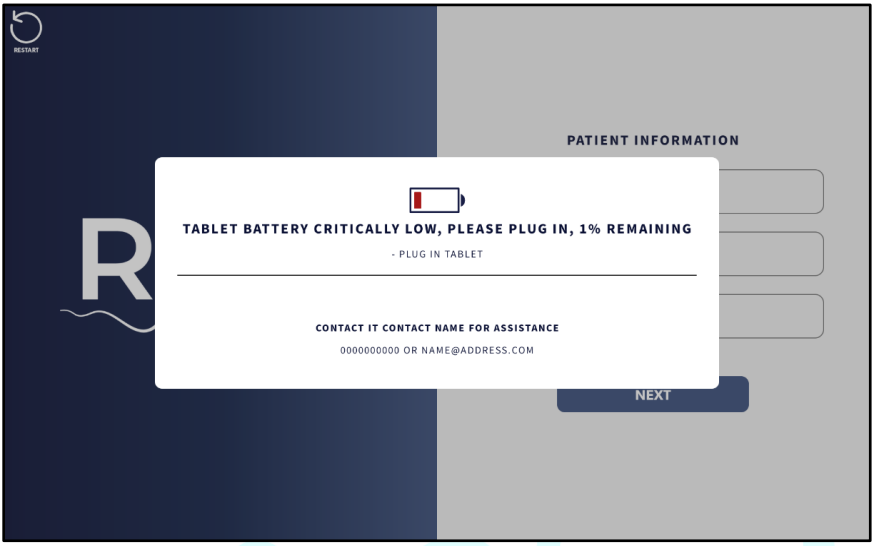


Restart Sensor Placement Confirmation Screen

REMI Tablet General System Notifications

General System Notifications can occur at any point throughout the new session process. They provide information that is helpful or valuable for the user, but will not impede the overall progress if left unresolved. Most notifications will resolve themselves without user intervention.

Low Battery

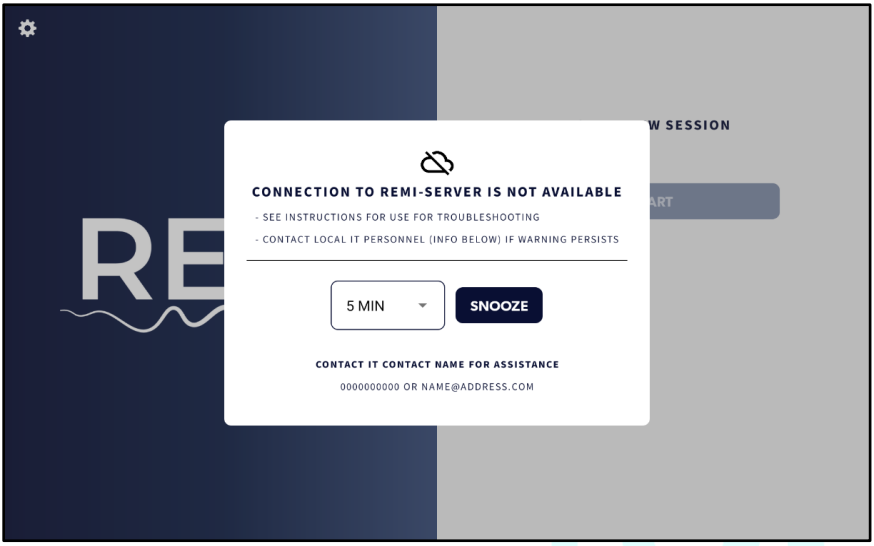


Battery Critically Low Notice

Summary:
When REMI Tablet battery reaches 50% capacity or less and is not plugged into A/C power, this notice will appear.

Troubleshooting:
If REMI Tablet battery power is above 25% you will be able to “snooze” the notice and move forward with current activities. However, if the tablet Battery Low notice appears prior to start of recording OR the battery power is below 25% power, a new session cannot begin until REMI Tablet has been plugged into an A/C power. Connecting REMI Tablet to power will automatically dismiss the tablet Battery Low notice.

Connection to REMI Server is Not Available

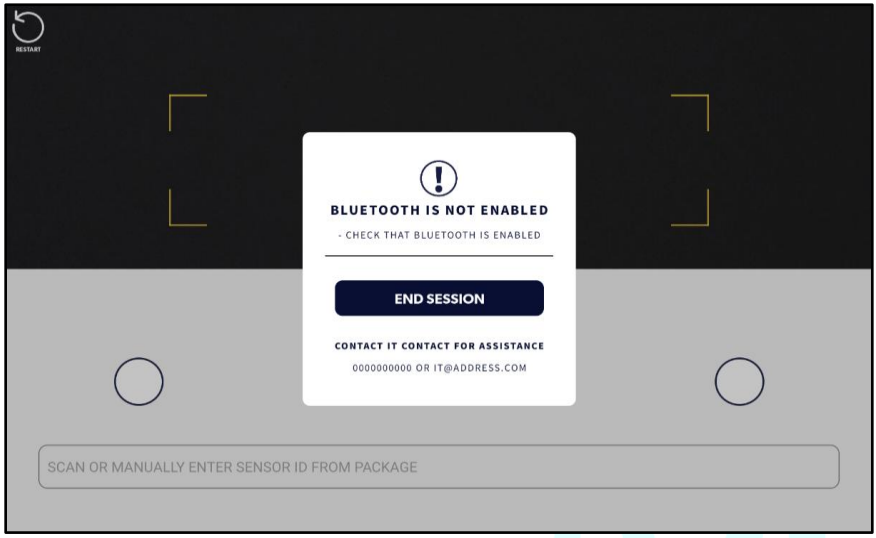


REMI Server Not Available Notice

Summary:
This notice typically appears before starting a new session. REMI Tablet must be connected to REMI Server URL endpoint in order to begin a new session. This connection is established via a Wi-Fi connection or cellular network. In some cases, this notice may be triggered by an issue with REMI Cloud.

Troubleshooting:
Confirm that REMI Tablet has strong connection via a Wi-Fi connection or cellular network. If the issue persists, contact Epitel Customer Support for assistance. The notice will disappear automatically when resolved.

Bluetooth is Not Enabled

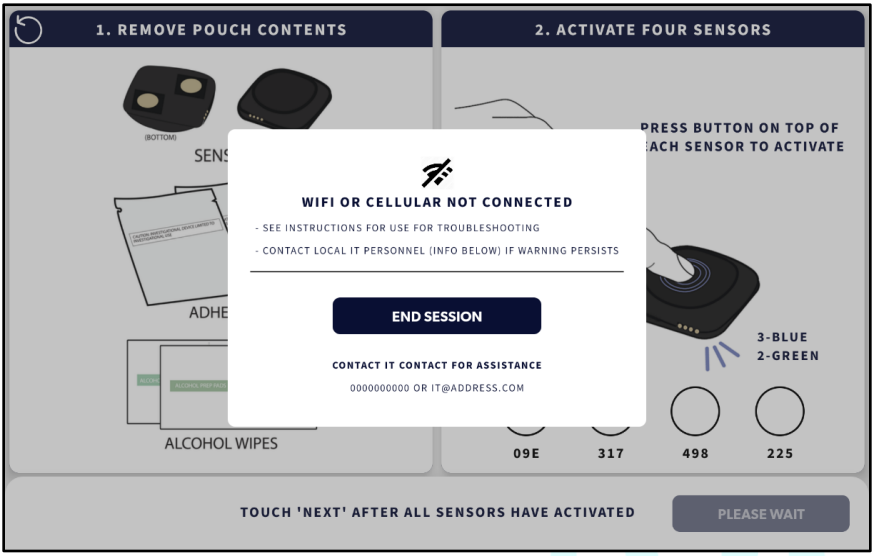


Bluetooth Not Enabled Notice

Summary:
There may be times that REMI Tablet has issues communicating with the sensor because the wireless connection is not enabled.

Troubleshooting:
If this occurs, reboot REMI Tablet by pressing and holding the power button on the side of the device. REMI Mobile application will pick back up where it left off, after the reboot. If unresolved, it may be necessary to toggle REMI Tablet's Bluetooth off/on via REMI Tablet Advanced Settings Menu.

Wi-Fi or Cellular Not Connected



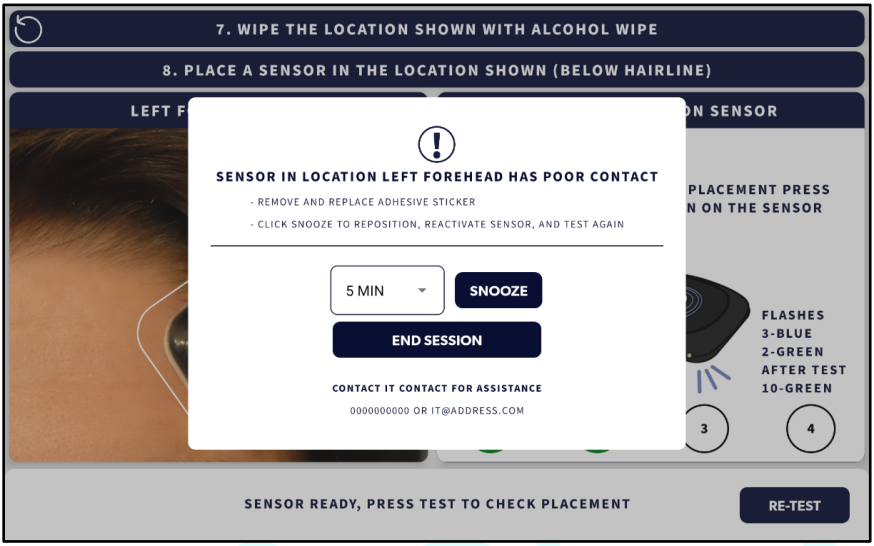
WiFi or Cellular Not Connected Notice

Summary:
This notice appears if the connection issue arises while in the process of setting up a new session. Without an established Wi-Fi connection or cellular network, REMI Tablet will lose its connection to REMI Server URL endpoint.

Troubleshooting:
Confirm that REMI Tablet has strong connection via a Wi-Fi connection or cellular network. To update the Wi-Fi information, select End Session and adjust the Wi-Fi connection through the Settings Menu. The notice will disappear automatically when resolved.

REMI Tablet Step Specific Error Messages
Step Specific Error Messages occur at specific instances in the process and will impede the overall progress if left unresolved. Most errors can be resolved with user intervention.

Sensor in Location Has Poor Contact during Step 4 - Sensor Location Designation & Placement

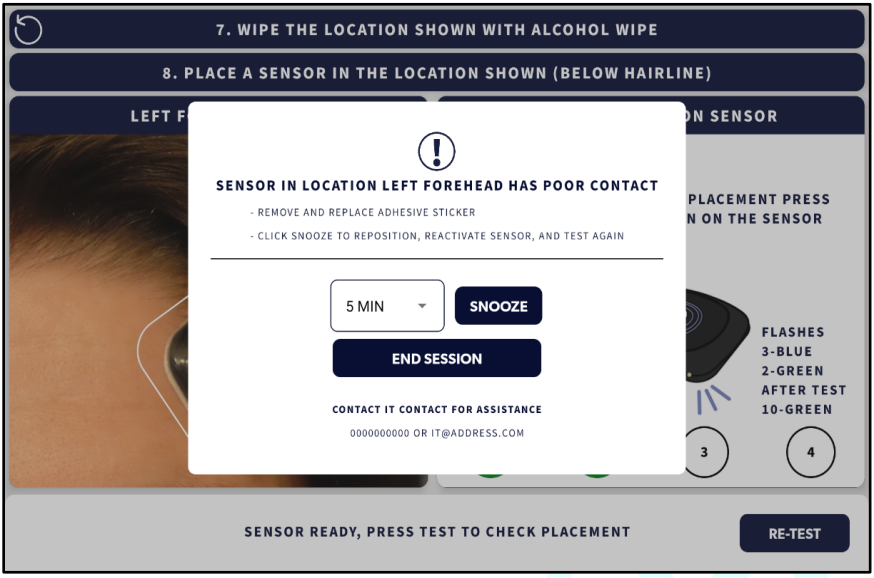


Poor Contact Notice

Summary:
When placing REMI Sensor on the patient's scalp, this error can occur if REMI Sensor does not have appropriate contact with the skin. This notice will occur after selecting TEST if the sensor adhesion test for that sensor is unacceptable and provides users with the option to SNOOZE or END SESSION.

Troubleshooting:
Select SNOOZE to close the notice. Examine the placement of REMI Sensor in question and ensure that REMI Sensor has good contact between the sticker and skin. REMI Sensor can be removed and repositioned, but if the sticker has been contaminated, be sure to replace it with a new sticker. After securing REMI Sensor, press the button and return to REMI Tablet. Select RE-TEST to reattempt the sensor adhesion test.

Sensor in Location Has Poor Contact, Re-Test Failed, during Step 4 - Sensor Location Designation & Placement

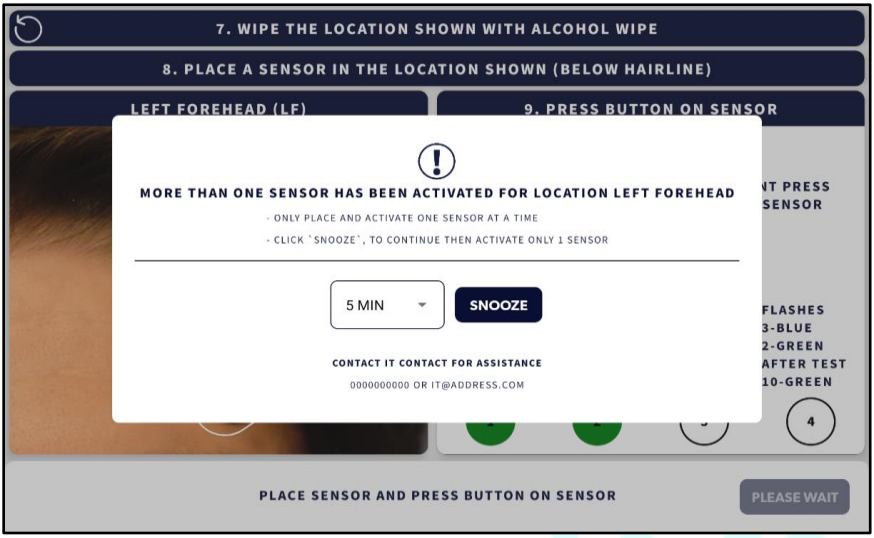


Poor Contact Notice

Summary:
During **Step 3 - Sensor Location Designation & Placement**, a REMI Sensor can re-test sensor adhesion once. If REMI Sensor still has poor sensor adhesion after the second test, replacing the sensor is the only option.

Troubleshooting:
Selecting REPLACE returns the user to **Step 2 - REMI Sensor Identification & Activation**. Be sure to dispose of any used, faulty REMI Sensors.

Multiple Sensors Activated during Step 4 - Sensor Location Designation & Placement

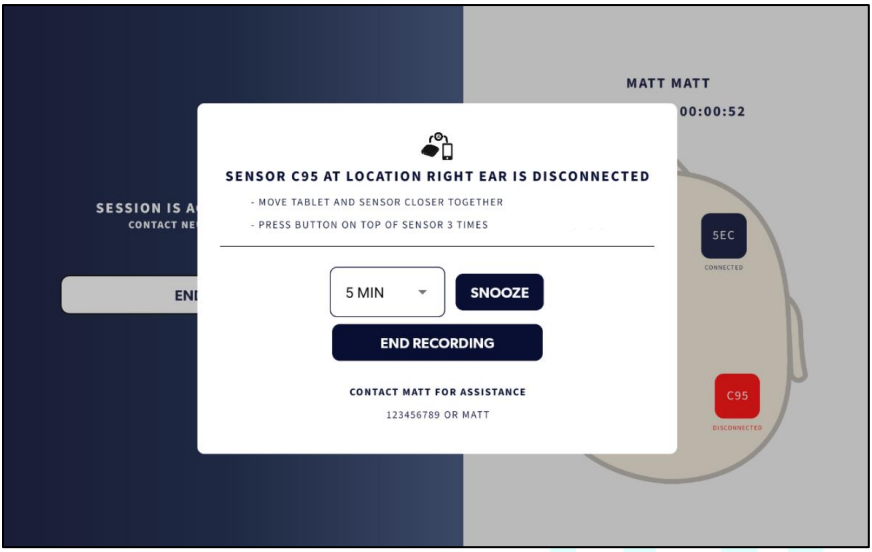


Multiple Sensors Activated Notice

Summary:
The Multiple Sensors Activated Notice will appear when more than one REMI Sensor has been activated during the sensor Location Designation & Placement Steps. This error occurs when REMI Tablet has competing sensors for the current designation. Only one REMI Sensor can be placed at each location and REMI Tablet sends the designation of that location during each individual sensor placement process.

Troubleshooting:
To resolve this issue, REMI Tablet will automatically “inactivate” the competing sensors and prompt a repeat in the designation and placement. Select SNOOZE and repeat the steps for the most recent placement. Note, if a REMI Sensor is already on the patient’s scalp in the location shown, press the center button again on that sensor to activate.

Sensor Disconnect during Step 5 - Verify Session



Sensor Disconnected Notice

Summary:
A REMI Sensor may disconnect from REMI Tablet before and during an active recording. This issue can occur because REMI Tablet is too far from REMI Sensor for reliable connectivity and/or a sensor(s) has reset unexpectedly. In both cases, users can take action to resolve the notice.

Troubleshooting:
First, attempt to bring REMI Tablet closer to the patient. If the disconnection persists, press the button on top of the disconnected sensor three times.

The notice will resolve automatically once it has reestablished the connection. The options to REPLACE REMI Sensor that has disconnected or END THE SESSION are also available if needed. To replace REMI Sensor, click REPLACE (sensor ID) and then CONFIRM and return to **Step 2 - REMI Sensor Identification & Activation**. Be sure to dispose of any used, faulty REMI Sensors.

REMI System Maintenance and Care

Product Cleaning

REMI Tablet should only be cleaned with damp cloths using water, alcohol (70%) or bleach (1.5-2.0%) and should not be immersed in any liquids or gasses. Cleaning of REMI Tablet should be done between each patient's use.

REMI Sensors should only be cleaned with damp cloths using water and should not be immersed in any liquids or glasses. If desired, REMI Sensors may be cleaned when performing a sticker exchange.

CAUTION: REMI Sensors are single-patient use. Do not attempt to reuse REMI Sensors. Once a recording has ended, all active sensors will no longer be able to connect to the computing platform or record EEG. Dispose of all used REMI Sensors at the end of the session.

CAUTION: REMI Stickers are one-time use. Do not attempt to reuse REMI Stickers after removing REMI Sensors from the patient's scalp.

Product Storage

REMI Tablet should be stored in a powered off state. It is recommended to keep the chargers stored with the devices to avoid mixing up cables. The devices are not compatible with most external charging cables.

Server Maintenance

To ensure continued operation of REMI System, Epitel performs routine server maintenance on all servers within REMI Cloud according to a server maintenance plan. Under this plan, routine maintenance will be performed up to once monthly. During routine service maintenance, a loss of server connectivity for a brief time (but no longer than 60 minutes) is expected. This may result in brief loss of patient data during the outage (while the servers reboot) and/or inability to review EEG data collected during the outage.

Once routine server maintenance is completed, connectivity between REMI Mobile and REMI Cloud will be seamlessly restored.

In the event that critical server maintenance is required, Epitel will communicate with healthcare providers to notify them of potential outages and to ensure that there are no negative impacts to patient care. Critical server maintenance may require additional planning to ensure that EEG monitoring sessions are not impacted.

For any questions related to server maintenance, contact Epitel customer service.

REMI Tablet Service and Repair

REMI Tablet do not require any scheduled maintenance, system checks, or calibration. For servicing information or to return a REMI Tablet for repair, contact an Epitel customer service representative.

REMI Mobile Updates
Whenever software updates to REMI Mobile application become available (whether due to cybersecurity enhancements, feature enhancements, resolution of anomalies, etc.), Epitel will coordinate with healthcare staff and IT administrators about the impact of the updates so that staff may determine whether to accept the update, and will assist in implementing all chosen updates. Following notification and coordination, REMI Mobile application updates will be deployed by Epitel.

Product Returns
All components of REMI System that require repair, replacement, or end-of-life recycling should be returned to the address below, only after receiving an MRA number from Epitel Customer Support (support@epitel.com). sensors should be shipped to Epitel in secure, anti-static, padded packaging. Epitel recommends that users keep all original packaging in case of repair or maintenance needs.

Epitel Returns
465 S. 400 E. Suite 250
Salt Lake City, UT 84111
support@epitel.com
www.epitel.com

For questions or comments call (801) 497-6297.

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 Mobile software will notify the user if there are any disconnection issues during the use of REMI System (see **REMI Tablet Step Specific Error Messages**).

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 Appendix F.

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.

REMI Mobile Qualified Operating Systems

REMI Mobile has been developed and qualified for use on Android operating systems. See REMI Mobile Updates above for a description of how Epitel manages updates.

Computing Platform	Computing Platform Operating Systems
REMI Tablet	Android 11 or Higher

Appendix E – Electromagnetic Emissions Declarations

Declaration – Electromagnetic Emissions		
REMI is intended for use in the electromagnetic environment specified below. The customer or the user of REMI should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	REMI disposable sensors must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	REMI disposable sensors are 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
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Appendix F – Electromagnetic Immunity Declarations

Declaration – Electromagnetic Immunity

REMI Sensors are intended for use in the electromagnetic environment specified below. The customer or the user of REMI 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of REMI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

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 strength 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 REMI is used exceeds the applicable RF compliance level above, REMI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating REMI.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix G – 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).
Storage Environment	REMI Sensors have been tested for storage environments of -9°F to 154°F (-23°C to 68°C), 10 to 95% relative humidity (non-condensing). REMI Stickers have been tested for storage environments of 50°F to 104°F (10°C to 40°C), 10 to 95% relative humidity (non-condensing)
Transport Environment	REMI Sensors have been tested for transport environments of -9°F to 154°F (-23°C to 68°C), 10 to 95% relative humidity (non-condensing). REMI Stickers have been tested for transport environments of 50°F to 131°F (10°C to 55°C), 10 to 95% relative humidity (non-condensing)
Storage Duration	REMI Sensors, including REMI Stickers, have a limited shelf-life defined on the package labels.
Typical Operation Time / Expected Service Life	REMI Sensors are capable of collecting and transmitting data for a minimum of 48 hours.

Appendix H – Warranty

Epitel warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be defective, the purchaser may return equipment to Epitel for repair, replacement, refund, or credit at Epitel's option. All returns must be authorized in advance in accordance with Epitel's Returned Goods Policy found in its then current Price List. The warranty on the repaired or replaced unit continues from the purchase date of the original unit. The liability of Epitel under this limited warranty does not extend to any abuse, misuse, modification, improper storage, alteration, further manufacture, packaging or processing of this product or repair by anyone other than a Epitel representative. The following will also void this limited warranty:

- Opening or servicing any component of the computing platform by anyone other than Epitel authorized service personnel.
- Removing system labels by anyone other than service personnel authorized by Epitel.
- Connecting the computing platform to any AC adapter other than the system adapter provided.
- Connecting the computing platform to any unauthorized accessory.
- Installing unauthorized software.
- Modification of system software without authorization by Epitel.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, (INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). THE LIABILITY AND REMEDY STATED IN THIS LIMITED PRODUCT WARRANTY WILL BE THE SOLE LIABILITY OF EPITEL AND REMEDY AVAILABLE TO PURCHASER FOR THIS PRODUCT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND EPITEL WILL NOT BE LIABLE TO PURCHASERS FOR ANY INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS HANDLING OR USE. SOME STATES/COUNTRIES DO NOT ALLOW AN EXCLUSION OF IMPLIED WARRANTS, INCIDENTAL OR CONSEQUENTIAL DAMAGES. YOU MAY BE ENTITLED TO ADDITIONAL REMEDIES UNDER THE LAWS OF YOUR STATE/COUNTRY.

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

Manufacturer:
Epitel, Inc.
465 S. 400 E. Suite 250
Salt Lake City, UT 84111

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:

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

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

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