
REMI™
REMOTE EEG MONITORING SYSTEM

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 the 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
	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

Symbol	Symbol Title	Explanatory Text	Standard Reference	Standard Title
	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
IPX3	Protected against spraying water	Protected against spraying water up to a 60 degree angle.	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
	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
	Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO15223-1: 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

Table of Contents

Safety Information

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

Acronyms and Abbreviations

EEG	Electroencephalography
REMI Sensor / Sensor	Single-channel disposable EEG sensor
Sticker	Conductive-adhesive sticker accessory used with REMI Sensors
REMI / REMI System	Remote EEG Monitoring System
REMI-Mobile	The mobile device Android™ application running on the REMI Tablet
REMI Tablet	The tablet hardware running REMI-Mobile software
REMI-Cloud	Cloud-integrated server processes necessary for the REMI System
Persyst-Mobile	Cloud-based EEG processing and reviewing software by Persyst

Device Description

REMI Sensors amplify and digitize the electroencephalogram (EEG) from a patient's scalp. After digitizing, the EEG are sent to the REMI Tablet running the REMI-Mobile software application. REMI-Mobile combines the EEG from four Sensors with patient information and relays the data to REMI-Cloud server running Persyst Server software. The EEG data is accessible through the Persyst Mobile interface.

IMPORTANT: Note that Persyst Mobile active trends such as Spectrograms or Amplitude Integrated EEG are not available with REMI as REMI is strictly for remote raw EEG data review.

The user interface for the REMI Tablet is a 10" LCD touchscreen display. The user interface for REMI Sensors is a single button keypad within each Sensor. REMI Tablet power is through an A/C adapter as well as limited onboard rechargeable battery. Sensor power is through a single-use primary coin cell. Using its wireless link, the Sensors can exchange EEG data and commands with the REMI-Mobile application running on the REMI Tablet.

REMI Sensors attach to the patient's scalp via a conductive-adhesive sticker accessory. This Sticker is made of a medical acrylic and foam adhesive with conductive hydrogel disks and has been tested for biological safety.

Indications for Use

The REMI System is intended to be used in healthcare settings where near real-time and/or remote EEG is warranted. REMI uses REMI disposable Sensors – a single use, single patient, disposable, wearable Sensor intended to amplify, capture, and wirelessly transmit a single channel of electrical activity of the brain for up to 48 hours. The REMI-Mobile software and REMI Tablet are intended to receive and transmit data from four REMI Sensors to secure cloud storage for subsequent viewing and reviewing of EEG on third-party software.

REMI does not make any diagnosis or recommendations and is intended only as a physiological signal monitor. REMI Sensors are intended for use by trained medical professionals in a professional healthcare facility environment.

REMI Sensors are intended for use with adult and pediatric patients (6+ years). (Rx only).

Contraindications

- The REMI System should not be used on any children under the age of 6 under any circumstances.
- The 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.
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.
- **To reduce the risk of bodily injury**, only use power adapters for the REMI Tablet 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 contaminate the Sticker. Sticker contamination can cause skin irritation and improper attachment of Sensors to the scalp that may affect performance.
- The REMI System is considered magnetic resonance (MR) unsafe. Remove all four REMI Sensors before performing a magnetic resonance imaging (MRI) scan. Do not bring any REMI System components into an MR environment.

Precautions

- Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
- Avoid using the 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 the REMI Tablet and Sensors and Sticker accessories only as instructed in this manual.
- **To reduce the risk of damaging Sensors**, do not immerse the Sensors in a liquid or subject them to any sterilization processes.
- **To reduce the risk of damaging Sensors**, do not impact, puncture, or cut them with any objects.
- 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.
- 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 hair. The REMI Sensor is meant to be used below hairline. Placing the Sensor over hair may result in improper attachment to the scalp that may

affect performance.

- Do not continue to use a Sensor if it has fallen off of the scalp after a recording session has started.
- REMI Sensor wireless range is a maximum of 10m and it is recommended that the REMI Tablet be kept within 4m of the patient to ensure a good wireless connection between the Sensors and the REMI Tablet and to ensure EEG data is available for clinician review.
- EEG data will not be transmitted by REMI Tablet or available for clinician review during the time that the REMI Tablet is without power.
- 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 REMI Sensors away from that device.**
- The REMI System, including REMI Sensors and Stickers are not packaged sterile.
- The Sensors and REMI Tablet 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 the REMI System.
- Assure 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.

Adverse Reactions

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

Operator Profile

The REMI System can be used by trained medical professionals who wish to record electroencephalograms as described in the **Indications for Use** section above. This manual provides complete information on how to operate REMI.

Product Identifiers

Each REMI Sensor has a unique serial number located on the Sensor packaging. Each Sticker has a unique lot number located on the Sticker packaging. Each REMI Tablet has a unique serial number located on the back of the tablet. The REMI-Mobile software version number is located in the application settings.

REMI Tablet Operation

REMI Tablet and REMI-Mobile software will initially be provisioned and configured by hospital administration IT department alongside Epitel™ staff. After initial provisioning, REMI Tablet and REMI-Mobile software are ready-to-use. To operate, plug the Tablet power supply in the DC-in jack and into a wall outlet. Press the power button until the Tablet turns on. The Tablet will take a few seconds to boot.

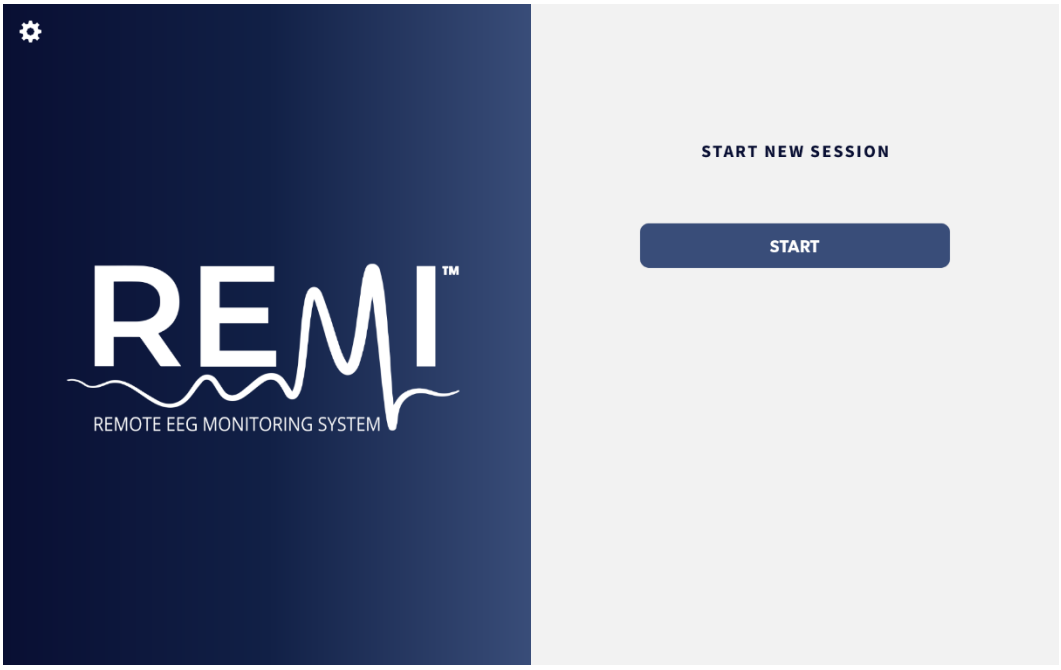
CAUTION: EEG data will not be transmitted by REMI Tablet or available for clinician review during the time that the REMI Tablet is without power.

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

Session Initialization

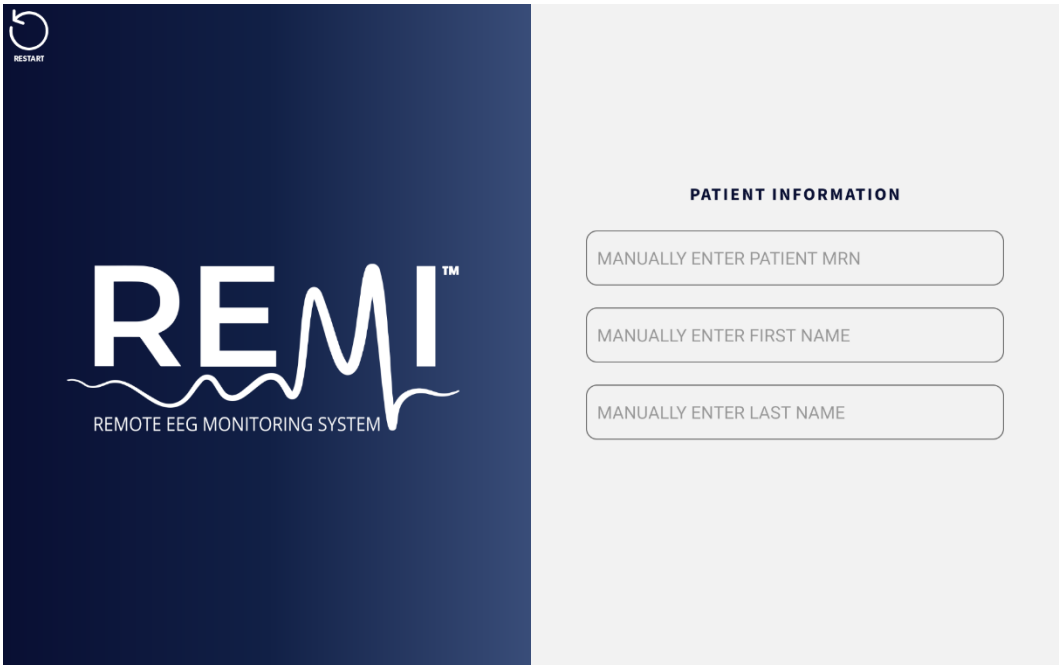
Once the REMI Tablet boots, it will automatically display the Start Session Screen, as shown below. If the clock screen is shown, swipe up, which will display the Start Session Screen. Press the START button to begin a new session. In the upper left-hand corner of the Start Session Screen is a "gear" icon. Pressing the gear icon takes you to the Application Settings Screen.

IMPORTANT: Only the IT representative at your facility should change any of the application settings. Contact your IT representative listed on the screen for help.

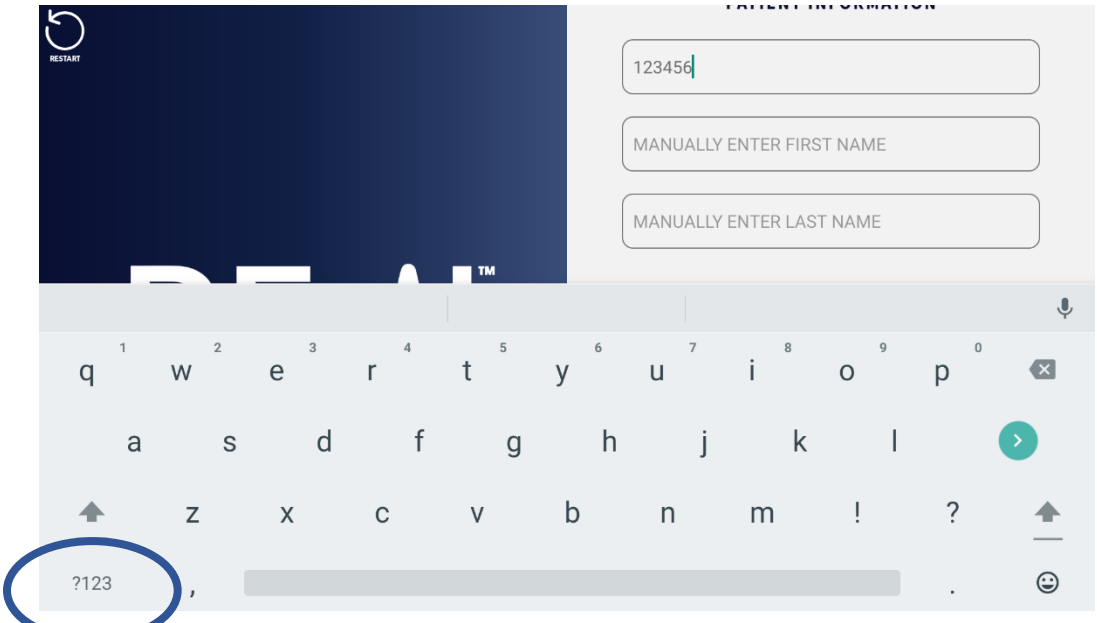


Enter Patient Information

To enter patient information, touch the screen in the field MANUALLY ENTER PATIENT MRN. This field is the patient's medical record number. This action will bring up the Tablet touchscreen's alphabetic keyboard.

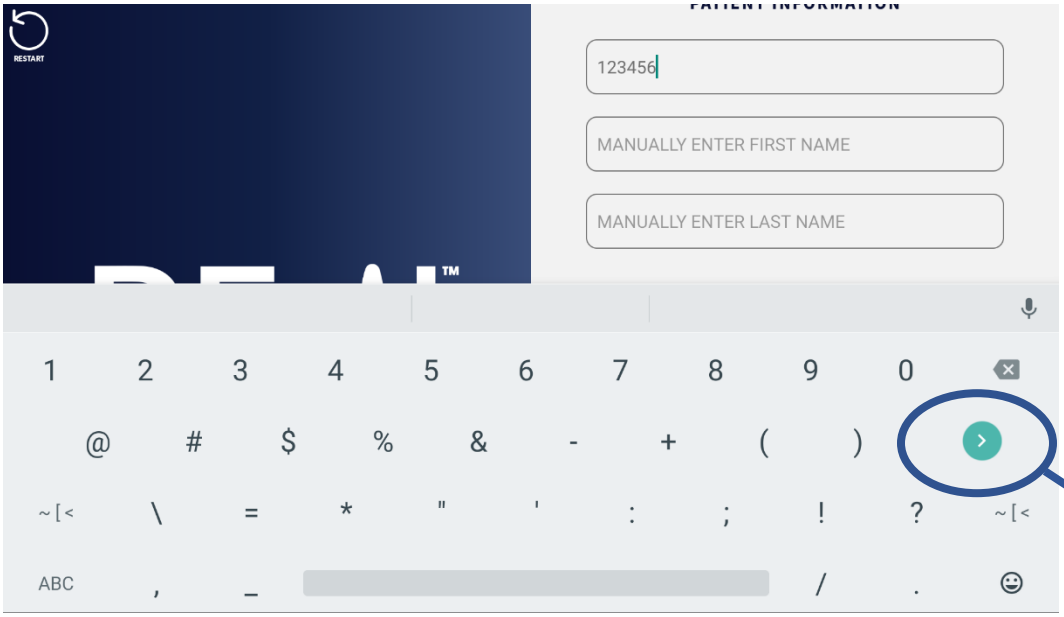


To switch to a numeric keyboard, click the "?123" button in the bottom left as shown in the circle below.



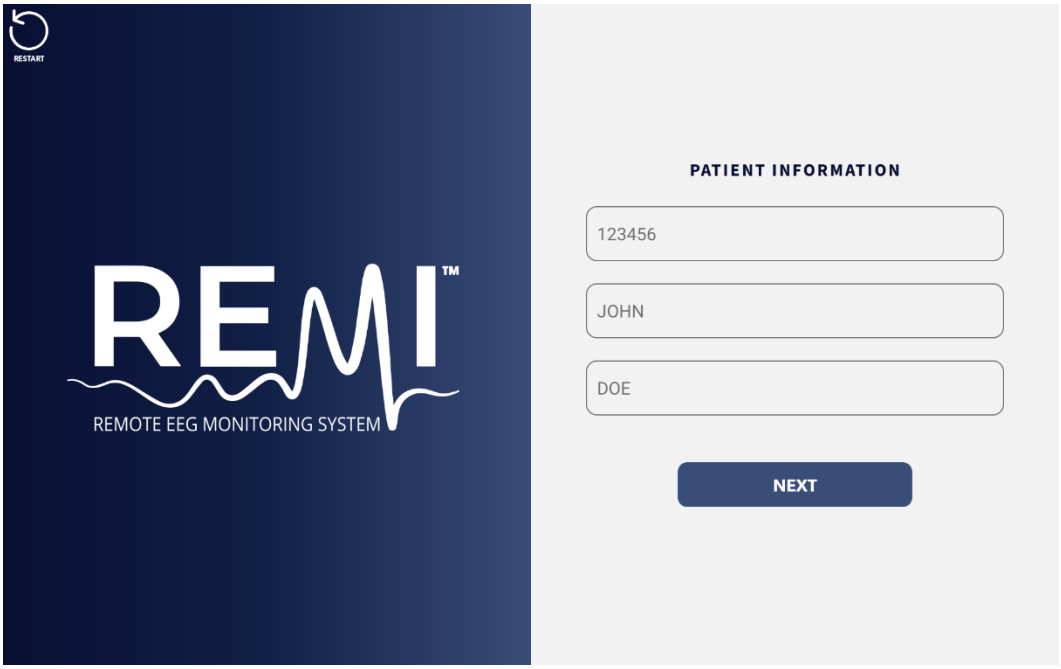
To switch back to the tablet's alphabetic keyboard, click the "ABC" button (which will be located in the same position on the numeric keyboard). Likewise, to switch back to the numeric keyboard, click the "?123" button once again.

To hit Enter/Return, click the “>” button as shown in the circle below.



Enter the patient’s medical record number (MRN), First Name, and Last Name in the fields. Once patient MRN, First, and Last name fields have been entered, click the NEXT button to proceed.

IMPORTANT: The NEXT button will not appear unless all three 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.

REMI Sensor Initialization

Retrieve Four REMI Sensors

REMI Sensors are packaged individually in a pouch and grouped in a single box with four Sensors. You will need four Sensors for each recording session. Each Sensor has a unique serial number barcode and Sensor ID on the package labeling, as shown in the bottom image below.

Scan this barcode for Sensor ID

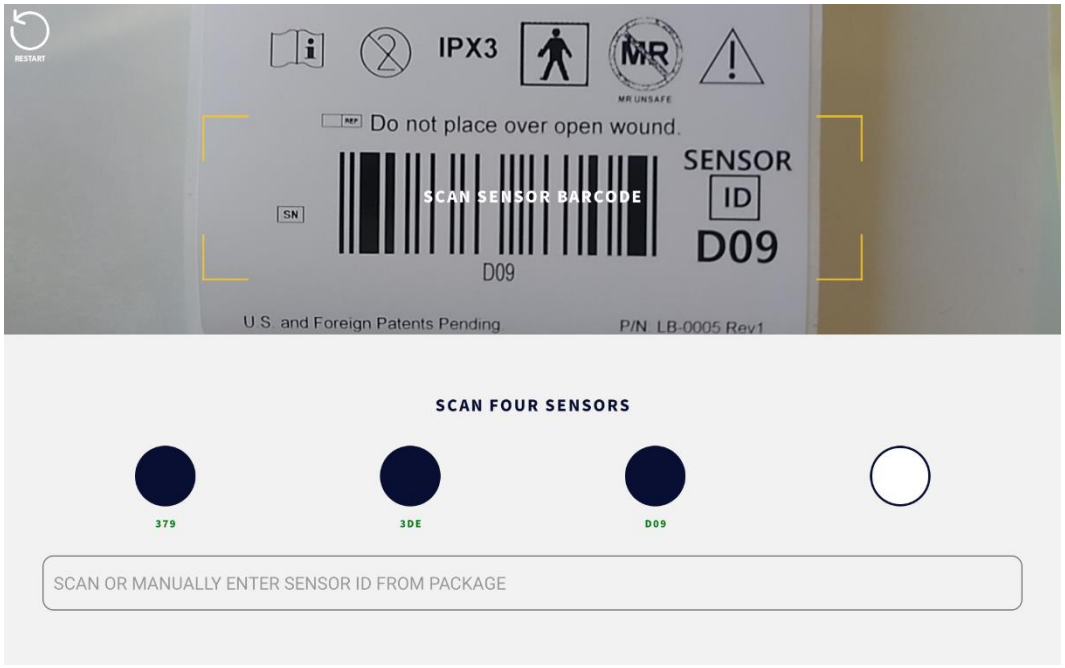
Scan REMI Sensor Barcodes

Use the REMI Tablet rear camera to scan the barcode on each of the four Sensor packages as shown below.

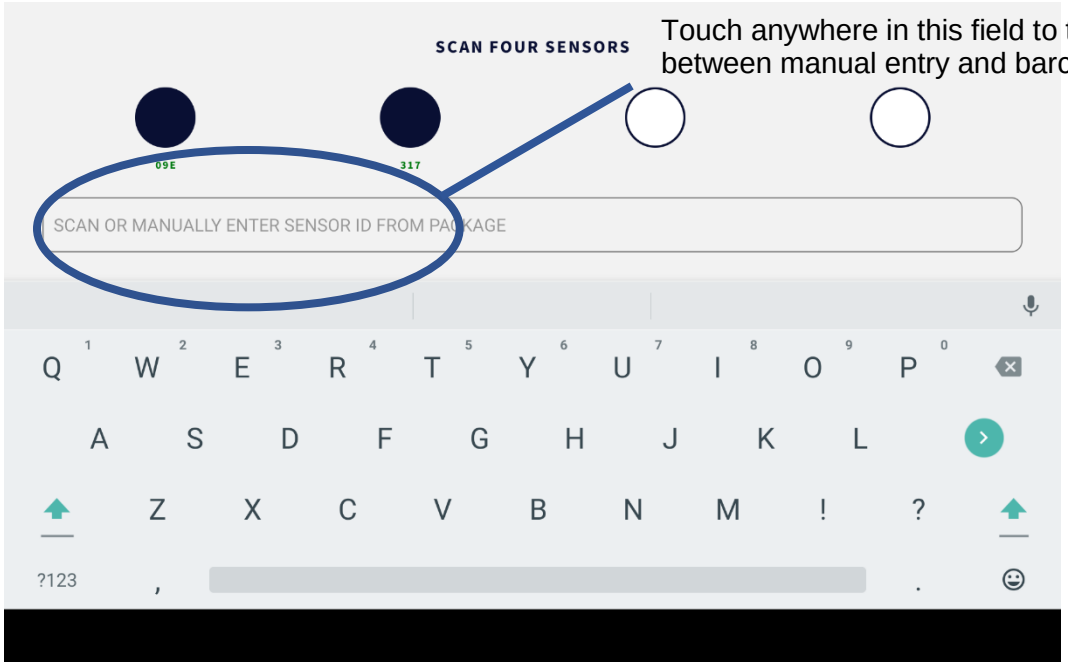
IMPORTANT: Only scan the barcode at bottom of packaging. The 2D barcode in the top left is not scannable by the REMI Tablet.

Acquiring The Barcode

Center the barcode on the screen. Move the Tablet closer or further away from the barcode to fill the screen with the barcode image. The Tablet will automatically read each barcode. Once the Tablet detects the barcode a blue circle will fill and the first three alpha-numeric digits of the serial number, which is the same as the Sensor ID, will appear in green text below the circle. The barcode of each Sensor can only be scanned once to prevent duplication. If a barcode is not scanning or did not scan correctly due to issues such as damaged packaging or camera, manually enter the Sensor ID, located on the Sensor packaging, using the keyboard as described earlier. REMI-Mobile will automatically move to Sensor Initialization once all four Sensor IDs have been entered.

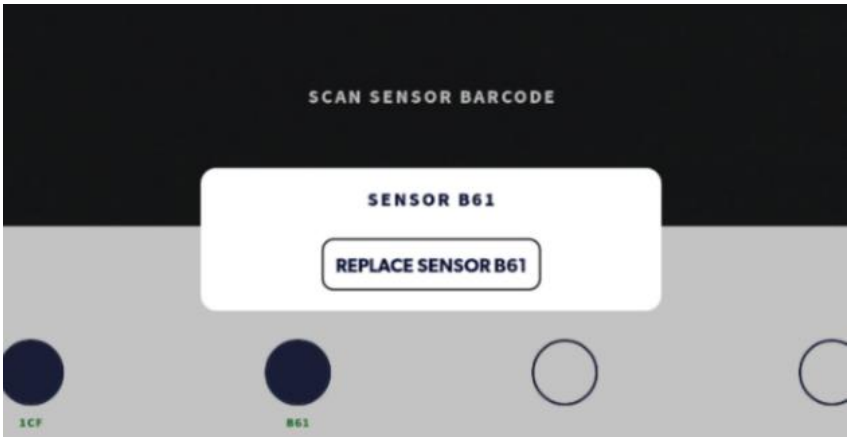


IMPORTANT: If you have manually entered a Sensor ID and wish to return to the barcode scanning, click anywhere in the text field that says SCAN OR MANUALLY ENTER SENSOR ID FROM PACKAGE.



REMI Sensor Replacement

If the wrong Sensor identifying information was entered, it can be replaced by clicking the blue circle above the incorrect Sensor ID, which will bring up a Replace Sensor message box, as shown below. Selecting “REPLACE SENSOR XXX” will remove the incorrect information, allowing you to re-enter or rescan the correct Sensor identifying information. In the example below, a Sensor with the ID “B61” is being replaced.



REMI Sensor Initialization

- Remove the contents of each Sensor pouch.
- Remove the Sensor from the pink protective covering.
- Depress the center button on REMI Sensor to activate, as demonstrated on the screen.
  - 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 functioning properly and activating.
- Each Sensor will then wirelessly connect to the REMI Tablet. **Note that it may take a number of seconds for each Sensor to connect to the REMI Tablet. Bring the Sensor close to the Tablet during this procedure.**
- When the Sensor connects to the REMI Tablet, the circle above that Sensor ID will fill solid green. Additionally, the Sensor will flash its LED green 10 times.
- Repeat these steps until all four Sensors have been activated. In the example below, one Sensor (“8DA”) has connected to the Tablet. Sensors with the IDs “C41”, “847”, and “48F” have not yet connected to the REMI Tablet.
- When all four Sensors activate and connect to the REMI Tablet, the text will change from PLEASE WAIT to NEXT. Click the NEXT button to proceed. **Note, it can take some time between the last Sensor circle turning green and PLEASE WAIT changing to NEXT.**

IMPORTANT: If there is an issue with a Sensor, it may be replaced before a recording session begins. See instructions for replacing a REMI Sensor.

IMPORTANT: A Sensor can be checked at any time to verify it has been activated and is working correctly. Press the button on the Sensor, similar to the step described above. The Sensor LED will flash green once to indicate a functioning Sensor.

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

IMPORTANT: Do not use a Sensor that does not flash green when the button is pressed. See instructions for replacing a Sensor that does not flash green.

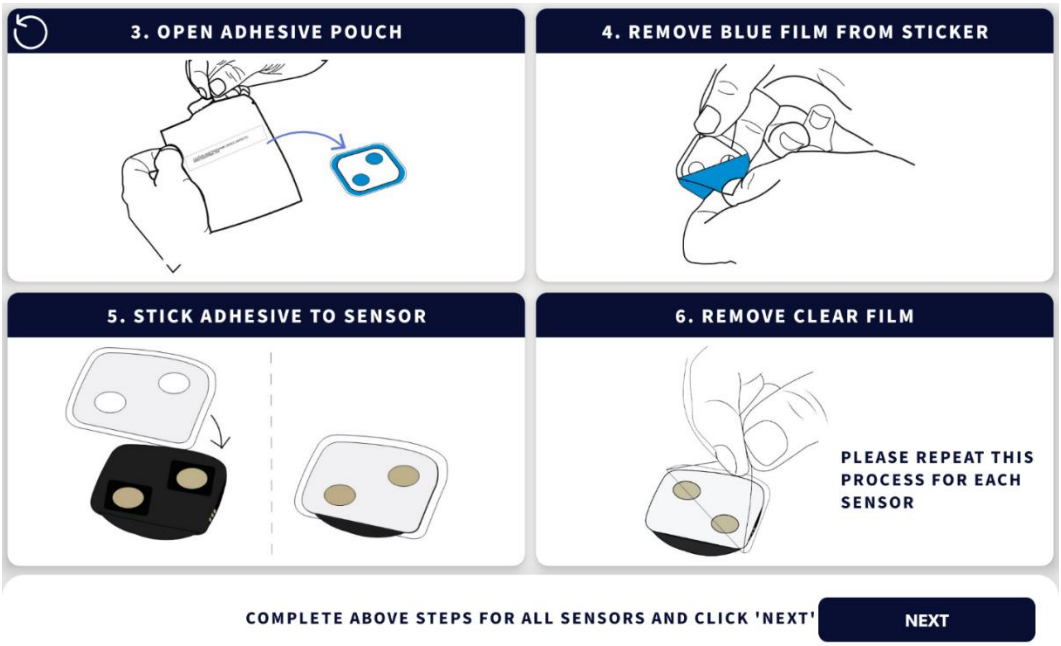
IMPORTANT: If it takes longer than 60 seconds for the REMI Tablet to connect to any one Sensor, see the **Troubleshooting** section at end of manual.

Sensor Placement

Applying a Sticker to REMI Sensor

REMI Sensors attach to the scalp with a one-piece conductive-adhesive sticker accessory.

- Open a Sticker package and remove one of the two available Stickers.
- Remove **blue** liner film from the Sticker.
- Line up the clear hydrogels over the gold electrodes, visible through the clear film, on the bottom of the Sensor and firmly stick the Sticker's exposed adhesive to the Sensor. Press smoothly around the edges to ensure a good stick.
- Remove the clear film from the Sticker without removing the Sticker from the REMI Sensor.
- When this is complete for all four Sensors, click NEXT on the Tablet screen.



WARNING: Do not contaminate the Sticker. Sticker contamination can cause skin irritation and improper attachment of Sensors to the scalp that may affect performance.

CAUTION: Ensure that the Sticker hydrogels are aligned over the gold electrodes. Failure to do so will result in poor data quality.

CAUTION: Assure 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.

IMPORTANT: The Stickers are one-time use and will no longer be sticky enough to properly attach to the Sensor if it has been removed once before. **If you misplace the Sticker during alignment, peel the sticker off of the Sensor and replace with a new Sticker.**

Applying REMI Sensor to the Scalp

Prepare the location on the scalp shown on the screen with the alcohol wipe provided in each REMI Sensor pouch. Apply the Sensor in the location shown on the screen. If you accidentally place the Sensor in an incorrect location or a different location than what's shown on the screen, follow the instructions on the following page to **Restart Placements** (you may not need to remove the misplaced Sensor and/or Sticker in the process).

Locating the REMI Sensor in REMI-Mobile

Once the REMI Sensor has been placed on the scalp, press the center button to locate the Sensor in REMI-Mobile. The LED on the Sensor should flash Blue 3 times followed by Green 2 times, signifying it is functioning properly. When the Sensor automatically reconnects to the REMI Tablet, the circle "1" will fill solid green in REMI-Mobile indicating that the Left Ear location has now been located and connected. If this occurs properly, the button in the bottom right will change from PLEASE WAIT to TEST. The Sensor can now be tested as described in **Testing REMI Sensor After Placement and Activation. Note, it may take some time between the circle turning green and PLEASE WAIT changing to TEST.**

CAUTION: Do not place the Sensor over hair. The REMI Sensor is meant to be used below hairline. Placing the Sensor over hair may result in improper attachment to the scalp that may affect performance.

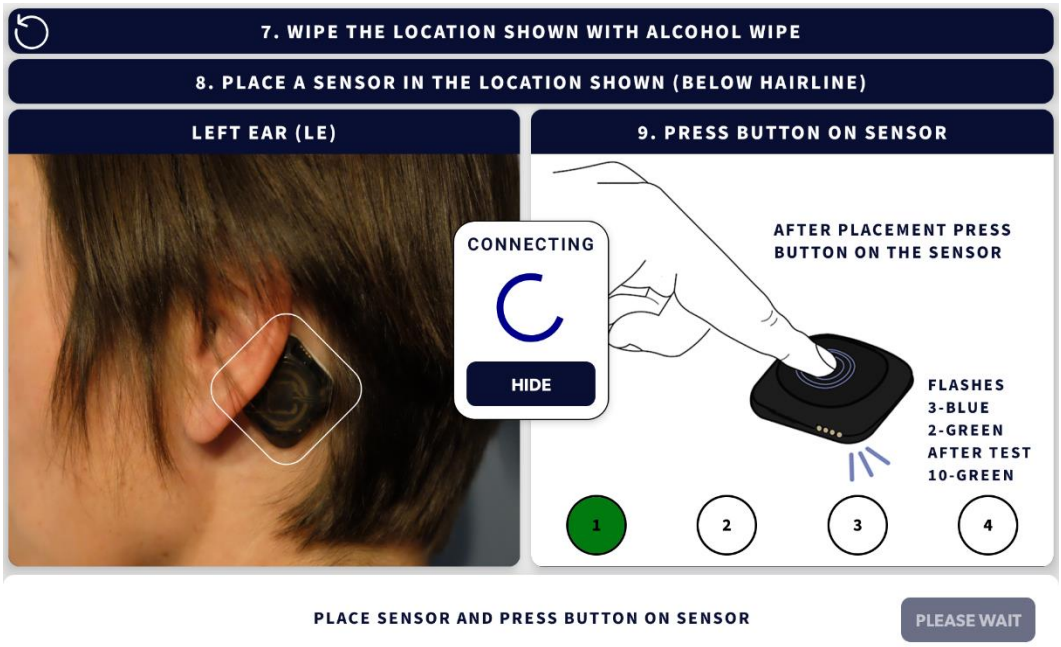
IMPORTANT: If you believe the Sensor is activated but the circle is not showing green in REMI-Mobile, the Sensor can be verified. Press the button on the Sensor, similar to the step described above. The Sensor LED will flash green once to indicate a functioning Sensor. If the Sensor is activated and working, but the circle does not fill green in REMI-Mobile, bring the Sensor closer to the REMI Tablet.

IMPORTANT: Do not activate more than one Sensor at this step. Activating more than one Sensor will bring the up the **Multiple Sensors Activated Alert** error screen. If this occurs, the REMI Tablet will ask you to repeat the activation process. See instructions in the **Multiple Sensors Activated Alert** section.

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. See instructions for replacing a Sensor.

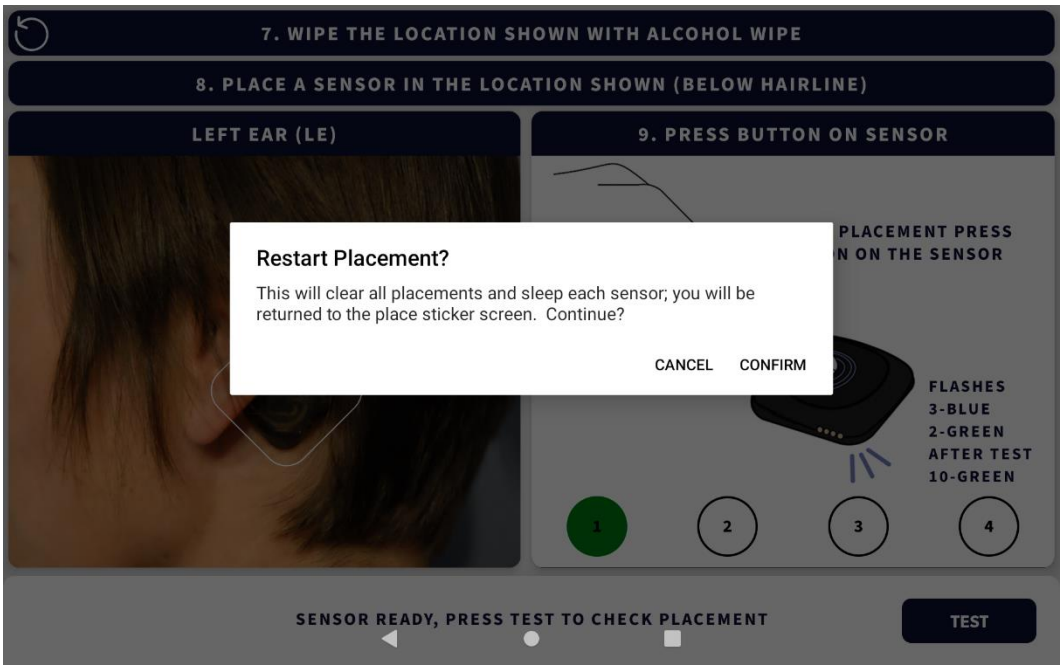
IMPORTANT: The Stickers are one-time use and will no longer be sticky enough to properly attach the Sensor to the scalp if it has been removed once before. **If you misplace the Sensor, peel off the Sticker and use a new Sticker to reposition the Sensor on the scalp**.

IMPORTANT: You may restart and/or reset the Sensor placement at any time by clicking the Restart Placement button that looks like a counter-clockwise arrow in the upper left-hand corner of the screen. See the **Restart Placement** section of this manual. If you placed the Sensor in the incorrect location it will be possible to change locations later. See the **Change Sensor Placement** section of this manual.



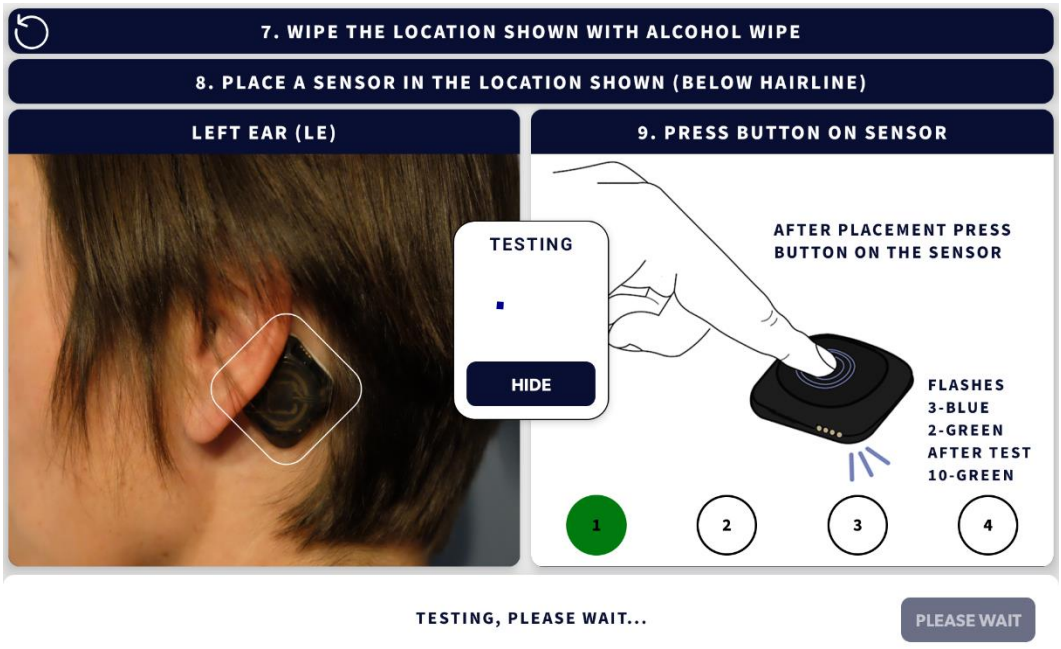
Restart Placement

If you have made a mistake at any time during the placement procedure, simply start over by clicking the Restart Placement button that looks like a counter-clockwise arrow in the upper left-hand corner of the screen. This will bring up a confirmation message box that asks if you would like to restart the placement procedure. Touching outside of the message box boundaries or clicking CANCEL will take you back to the screen you were working from previously. Clicking CONFIRM will take you back to the start of the placement and activation process beginning with the placement behind the left ear.



Testing Sensor After Placement and Activation

Once REMI Sensor has been placed on the scalp and connected, it is now time to test Sensor electrode contact quality. Touch the TEST button on the bottom right of the REMI-Mobile Sensor Placement Screen.



The REMI Tablet will instruct the REMI Sensor to test the electrode contact quality (ECQ) between the Sensor and the scalp. **If the ECQ is good, the Sensor will flash its LED green 10 times; REMI-Mobile will automatically reset the TEST button to PLEASE WAIT and change the left image to the next Placement location**. If the ECQ is bad, an alert will appear. Please see the **Poor Electrode Contact Alert** section. Repeat the Placement and Testing

procedure for the Left Forehead, Right Forehead, and Right Ear locations as instructed by REMI-Mobile.

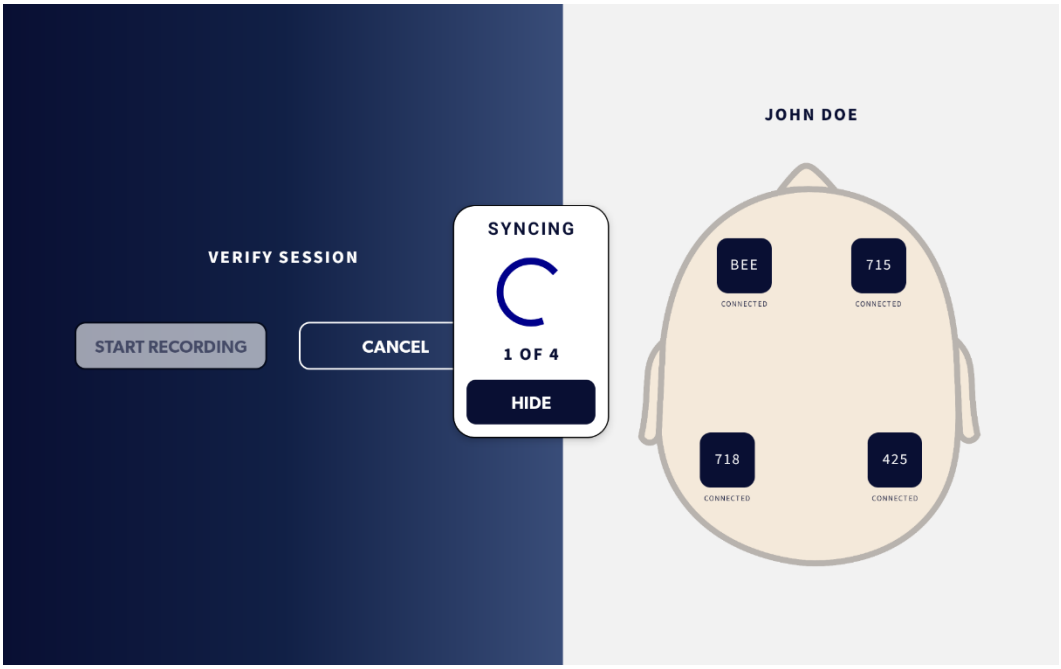
Sensor Sync

REMI-Mobile will automatically synchronize all connected Sensors once all placement and testing procedures have been completed. This process may take several minutes. A message box will appear to indicate that Sensors are syncing.

- If you wish to cancel a session before syncing is complete, touch the HIDE button to remove the Syncing message box and then click the CANCEL button. Once you have clicked the CANCEL button, click the CONFIRM button to end the session and start over from the beginning.

Once all Sensors have synced, the message box will disappear allowing you to proceed to **Session Verification**.

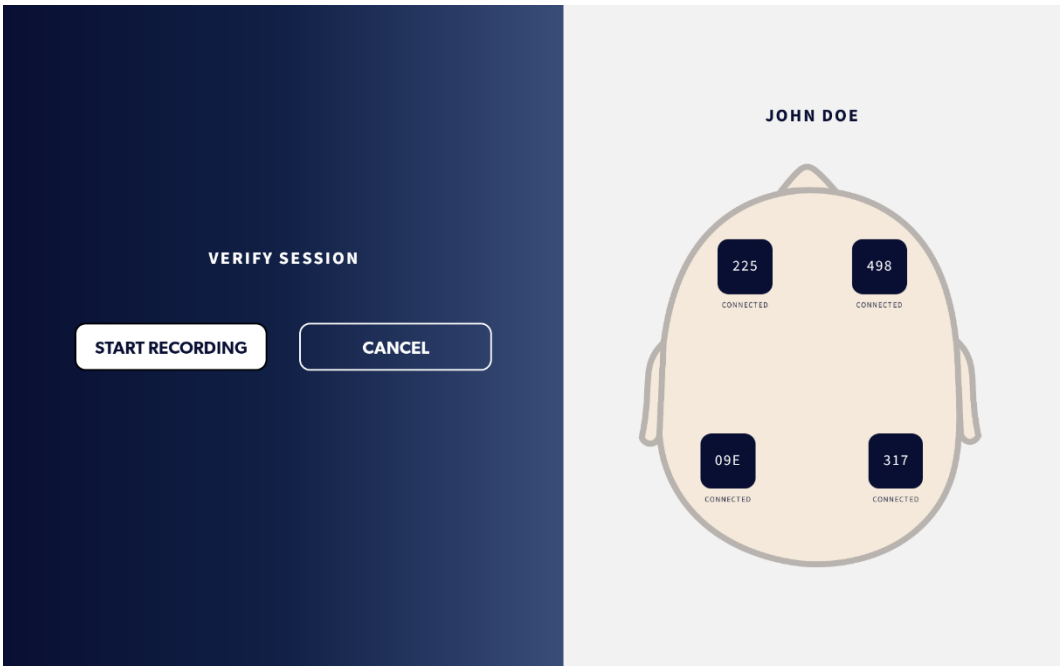
IMPORTANT: The Syncing message box serves as a status indicator for the sync process. It is not recommended to “hide” the Syncing message box while Sensors are syncing or you will not be able to view sync status.



IMPORTANT: If there is an issue with sync, you may be instructed to replace a Sensor before continuing to Session Verification. See the **Replace Sensor** section of this manual.

Session Verification

Verify that all patient and Sensor information is displayed correctly on the Verify Session Screen shown below.



- Check to ensure patient name is correct. If patient name is incorrect you must click CANCEL and then CONFIRM to end the session and start over from the beginning. See the **End Session** section of this manual for details. Note, you can leave the Sensors attached to the patient and just re-initialize and reactivate them from there.

Check to ensure each Sensor is in the correct location on the patient. Each Sensor is depicted by its three-digit alpha-numeric Sensor ID number. If you are unsure of the location, it is possible to “locate” a Sensor by instructing it to flash its LED green. See the **Identify Sensor** section of this manual. Note, identifying placement, changing placement, or replacing Sensors are not a necessary step to begin recording. If all information has been entered correctly, click START RECORDING to begin a recording session.

IMPORTANT: If two Sensors are in the wrong location it is possible to “swap” them in REMI-Mobile without having to remove the Sensors from the patient. See the **Change Sensor Placement Location** section of this manual.

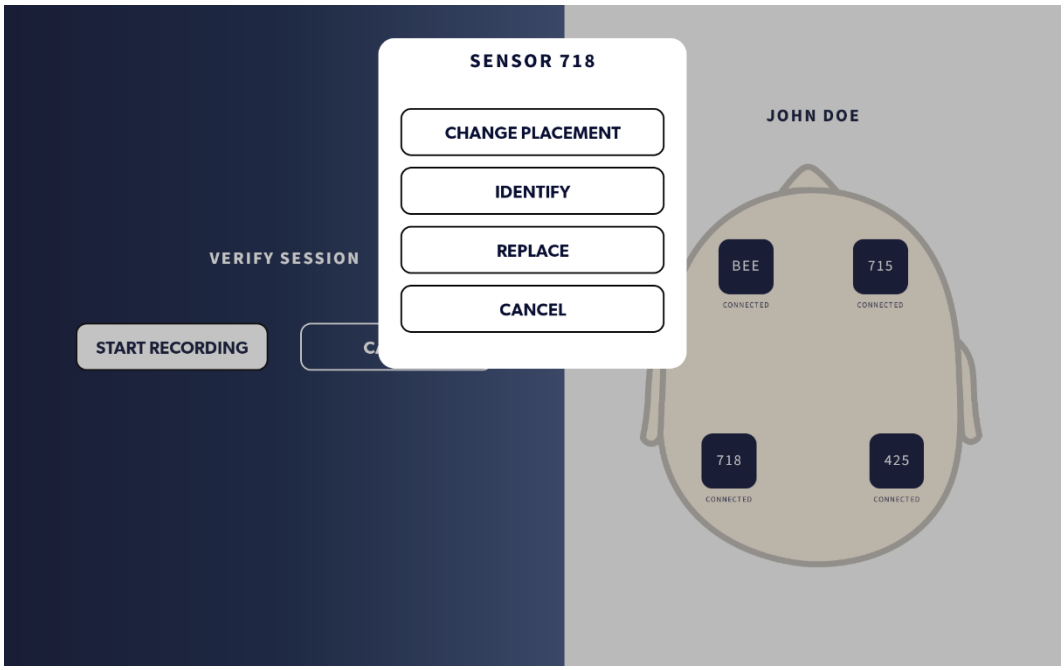
IMPORTANT: If a Sensor is not working properly, it is possible to replace the Sensor at this point. See the **Replace Sensor** section of this manual.

IMPORTANT: Once a recording session has been started, EEG and patient information will be made available for review. It will only be possible to stop a recording and end a session after this point. It will no longer be possible to change patient information, change the Sensor placement, or replace the Sensor after a recording session has been started.

IMPORTANT: After 48 hours the recording will automatically end. See **End Recording** section in this manual for details.

Identify Sensor

REMI-Mobile may be used to identify the location of a REMI Sensor by flashing the Sensor LED green. Click on the Sensor that you wish to identify in the head diagram on the screen. A "Sensor" window will appear as shown below. Click IDENTIFY. REMI-Mobile will communicate with the Sensor to flash the LED green 10 times. The Sensor window will disappear and the Sensor in the head diagram will turn solid green while the Sensor LED is flashing green. After the LED flashes 10 times it will automatically stop and the Sensor in the head diagram on the display will go back to solid blue.



Change Sensor Placement Location

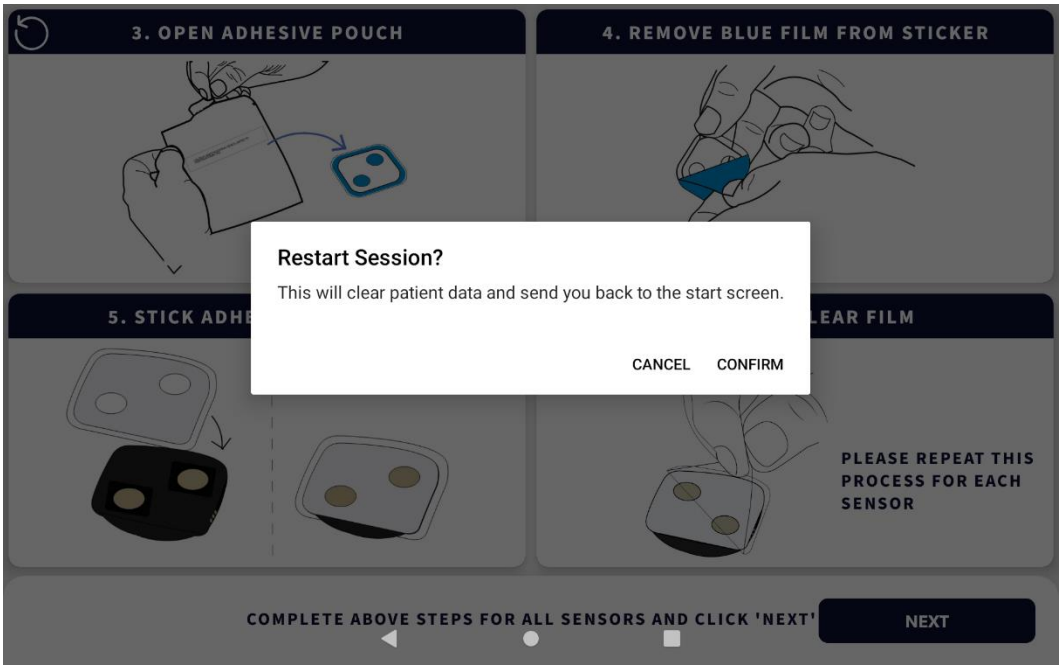
It is possible to change the placement location of a REMI Sensor ***only*** before a recording has started. Click on the Sensor that you wish to change in the head diagram on the screen. A "Sensor" window will appear as shown above in Identify Sensor. Click CHANGE PLACEMENT. The "Sensor swap" screen will appear, as shown below. You will then be able to choose which other Sensor you would like to swap locations. Confirm Sensor swap by clicking CONFIRM or click CANCEL or touch anywhere on the screen to return to the Verify Session screen without changing Sensor placements. Swapping locations will reorder the location of the Sensors on head diagram. **Note, this only needs to be done once to swap two locations.** You may also click CANCEL on the Sensor swap screen or touch anywhere on the screen to return to the Verify Session screen without changing Sensor placements. You can always verify that the Sensors are now in the proper location. See **Identify Sensor** section of this manual for details.

Replace Sensor

It is possible to replace a Sensor that may be having issues such as connectivity, ***only*** before a recording has started. Click on the Sensor that you wish to change in the head diagram on the screen. A “Sensor” window will appear as shown above in Identify Sensor. From the Sensor Screen, click REPLACE, which will allow you to replace a Sensor as described earlier.

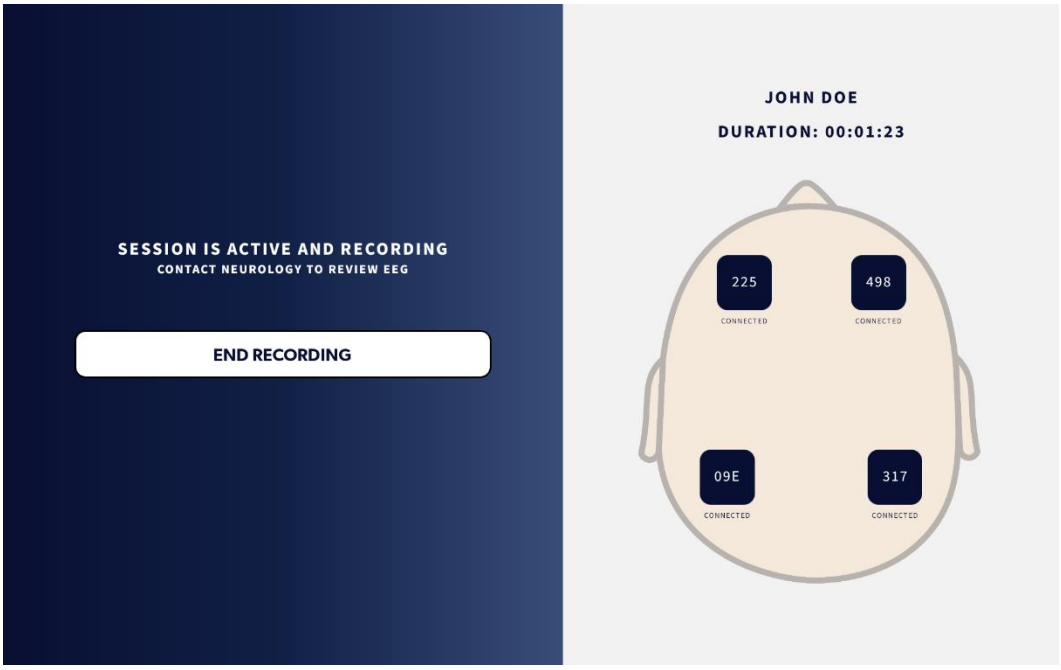
Restart Session

It is possible to restart the session and begin from the beginning at any time before a recording has started. You may restart and/or reset the Session by clicking the Restart Session button that looks like a counter-clockwise arrow in the upper left-hand corner of the screen. This will bring up the Restart Session window that will ask you to confirm or cancel the selection. Once confirmed, all data will be cleared and you will return to the Start Session Screen.



Active Recording

Once you click START RECORDING from the Verify Session Screen, the Active Recording Screen will appear as shown below. If there are any problems with the Sensors or with connectivity with the REMI-Cloud platform, an alert with troubleshooting instructions will appear during the active recording.

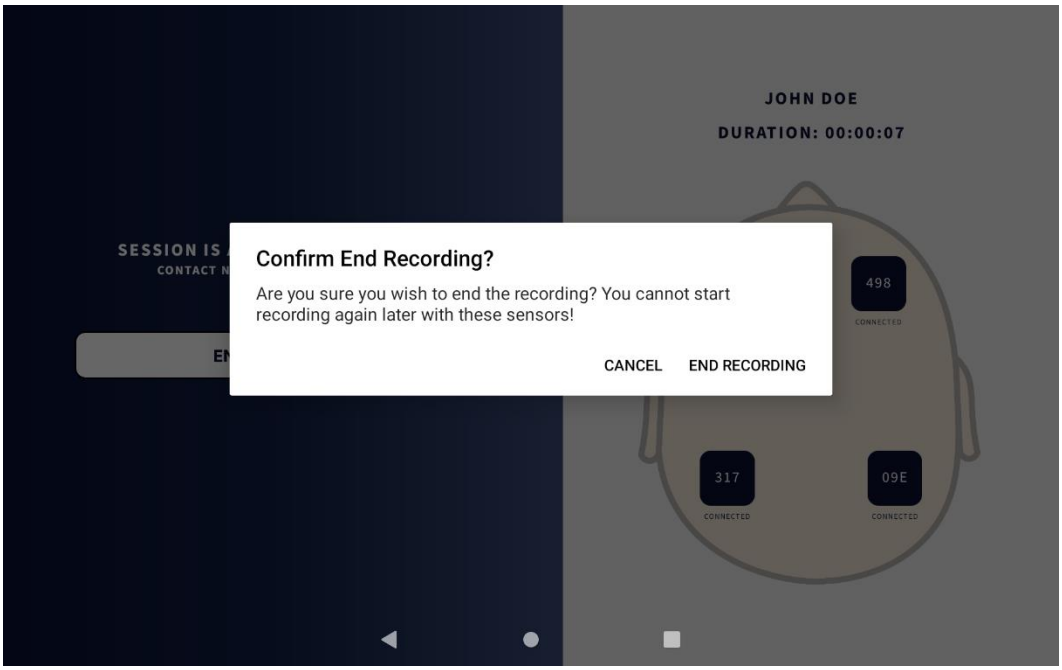


During an active recording session, the Sensors depicted in the REMI app will remain solid dark blue. EEG recordings are being sent to the REMI-Cloud platform and are available for an epileptologist to review. Clicking any individual Sensor will allow you to identify the location of the REMI Sensor. See the **Identify Sensor** section of this manual. From the **Active Recording** screen, it is possible to end a recording by clicking and confirming END RECORDING. See **End Recording** section of this manual on how to end a recording.

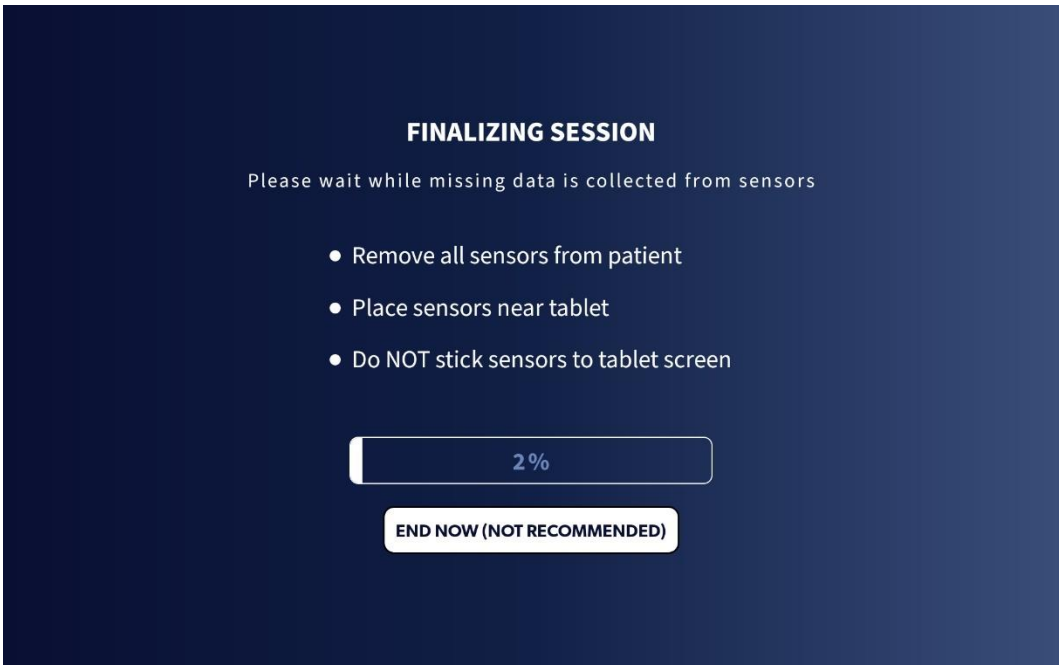
IMPORTANT: After 48 hours the recording will automatically end. See **End Recording** section of this manual for details.

End Recording

It is possible to end a recording from the **Active Recording** screen as well as from some of the alert screens. To end a recording click END RECORDING. A screen will appear asking you to confirm end recording or to cancel and go back to the previous screen, as shown below. You may also touch anywhere on the screen to return to the previous screen. To confirm you want to end a recording click CONFIRM.



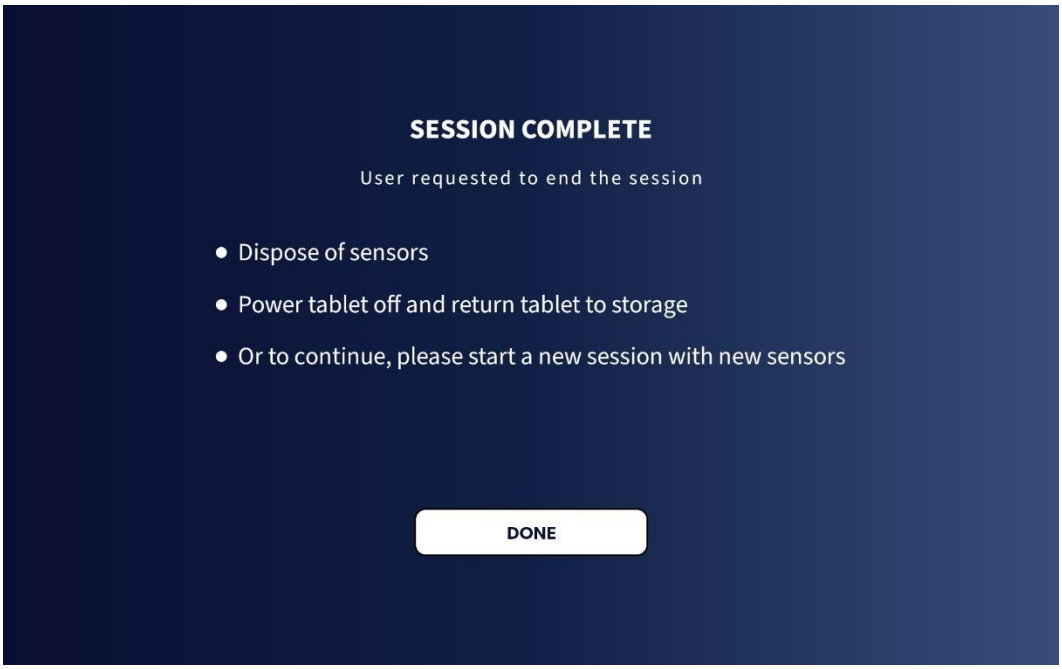
Ending a recording will take you to one of two screens. If the REMI app does not have all of the EEG data from each REMI Sensor it will need up to five minutes to finalize the session, as shown below. The Finalizing Session screen instructs you to remove all Sensors from the patient and place the Sensors near the Tablet. A progress bar will indicate REMI app progress towards finalizing the session. Once the progress bar reaches 100% the REMI app will automatically progress to the Session Complete Screen.



You may also end the session immediately, although this is not recommended. To end the session immediately, click END NOW. Ending the session immediately will automatically progress to the Session Complete Screen shown below.

If the REMI app has all the EEG data from each REMI Sensor you will be automatically taken to the Session Complete Screen shown below.

The session complete screen instructs you to dispose of Sensors and return the REMI Tablet to storage, plugged in to the AC wall outlet. Click DONE to confirm the REMI-Mobile restart, then OK to return to the Start Session screen.



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.

CAUTION: Do not continue to use a Sensor if it has fallen off of the scalp after a recording session has started.

IMPORTANT: Ending a recording will permanently disable REMI Sensors. After ending a recording, the Sensors connected to the REMI Tablet will no longer be able to record or connect to the REMI Tablet.

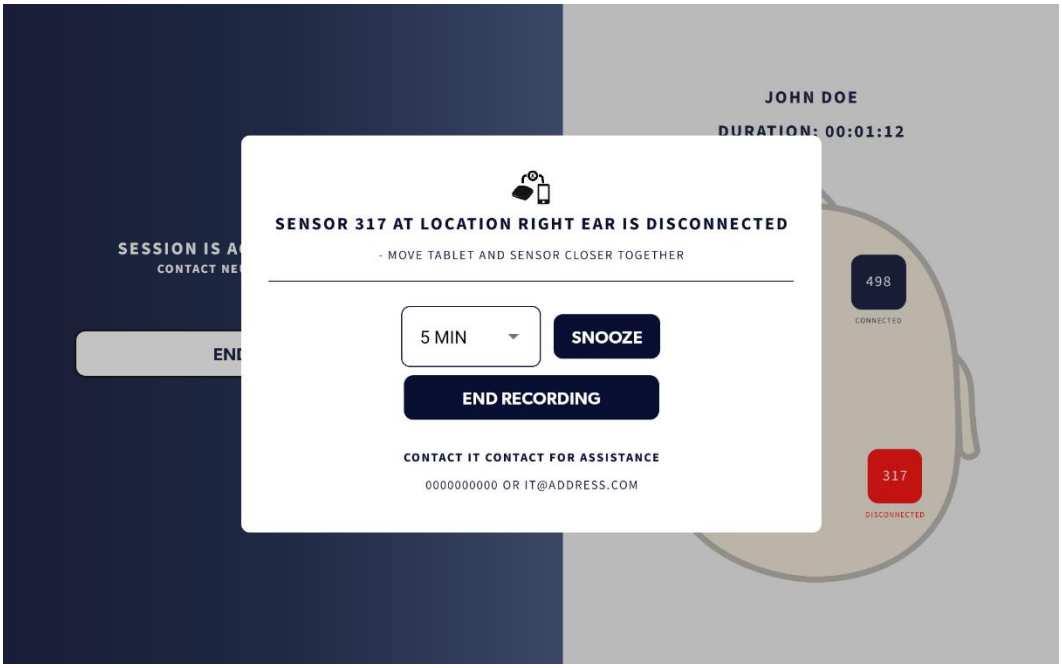
End Session

It is possible to end a session prior to starting a recording if there are issues such as WiFi and/or cellular failure, Sensor Disconnection, etc. Ending a session will erase all patient information from the REMI Tablet and reset the REMI Sensors.

Sensor & Sticker Disposal

REMI Sensors and Stickers should be disposed of at the end of a recording session or if a session is ended prematurely. Although there are no restrictions on disposing the Sensors and Stickers in normal garbage, follow your medical center guidance on disposal of hospital waste.

REMI-Mobile Warning Alerts
Sensor Disconnect – During Active Recording



REMI Sensors may lose their wireless connection with the REMI Tablet. It is recommended to keep the REMI Tablet as close to the patient as possible where the screen of the REMI Tablet is within view. If a disconnection occurs during a recording session the LED on the Sensor that is disconnected will begin to flash alternating red and blue. An alert screen will pop up on the REMI app to indicate which Sensor is no longer connected as shown below.

CAUTION: REMI Sensor wireless range is a maximum of 10m and it is recommended that the REMI Tablet be kept within 4m of the patient to ensure a good BLE connection between the Sensors and the REMI Tablet and to ensure EEG data is available for clinician review.

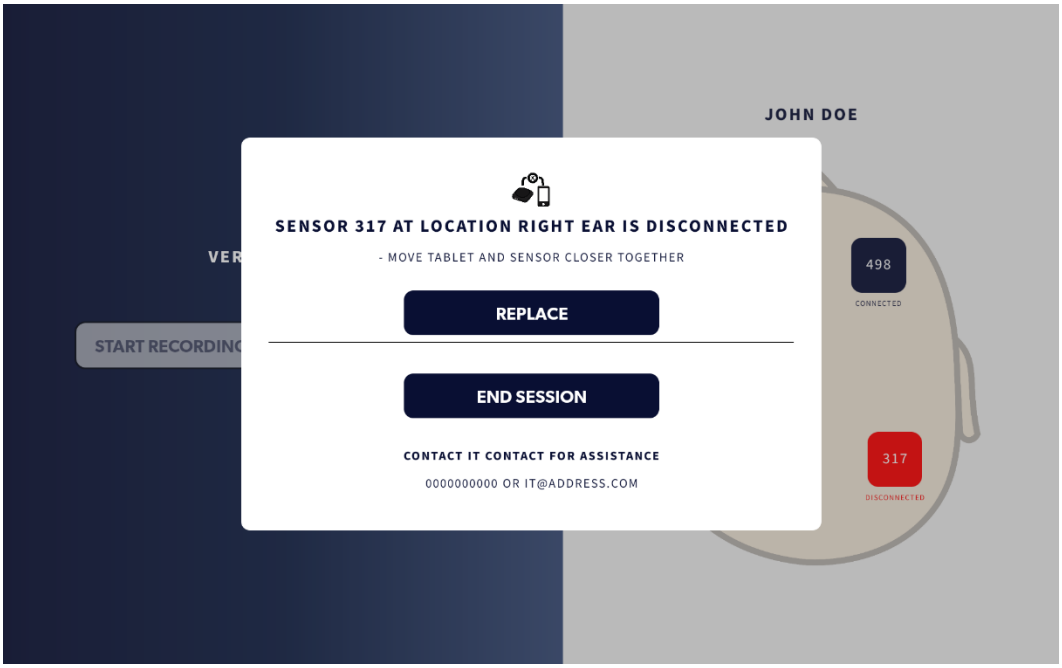
If the Sensor re-establishes a connection with the REMI Tablet, this alert screen will automatically disappear. Otherwise it is possible to “snooze” the alert screen. To snooze the alert screen, set the snooze duration (up to 30 minutes) and click SNOOZE.

If the alert screen was snoozed and the Sensor is still disconnected from the REMI Tablet the Active Recording screen will show the Sensor in red. If the Sensor re-established a connection with the REMI Tablet during this time the Sensor will go back to blue indicating that it is recording properly.

If after the snooze duration selected expires and the REMI Sensor has not re-established a connection with the REMI Tablet, the alert screen will reappear. You will again be able to snooze the alert screen by repeating this process.

The alert screen will allow you to end the recording. To end a recording click END RECORDING. See the **End Recording** section of this manual.

Sensor Disconnect – Prior to Active Recording

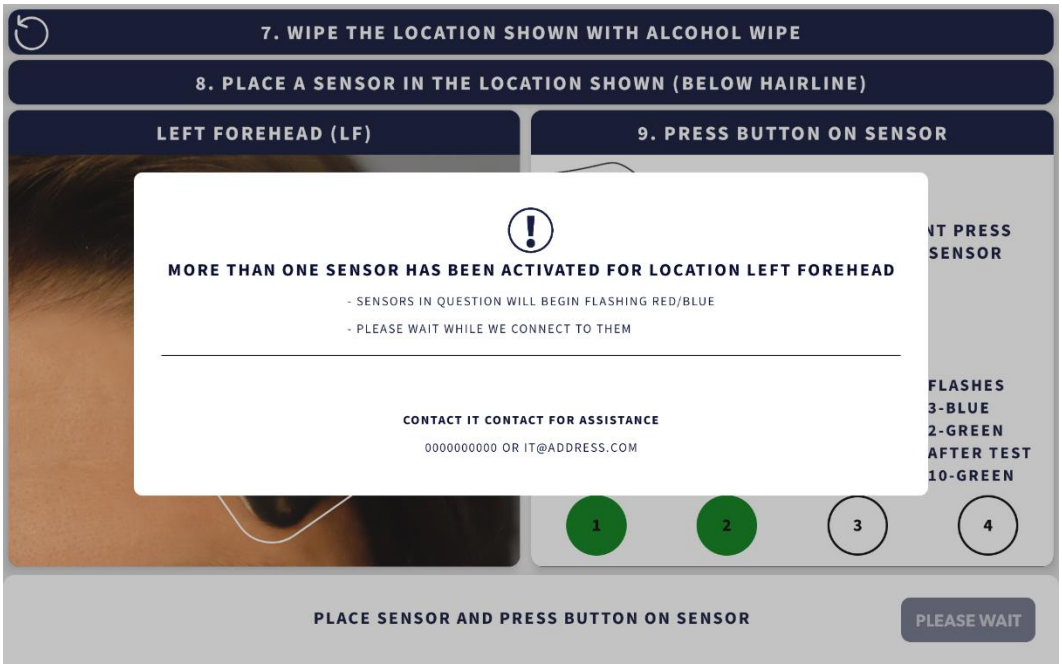


A REMI Sensor may disconnect from the REMI Tablet before an active recording begins. The alert screen will appear with the options to replace the Sensor that has disconnected or end the session, as shown below. To replace the Sensor, click REPLACE SENSOR (sensor ID) and then CONFIRM. This will direct you back to entering a new Sensor ID as described in the **REMI Sensor Activation** section earlier.

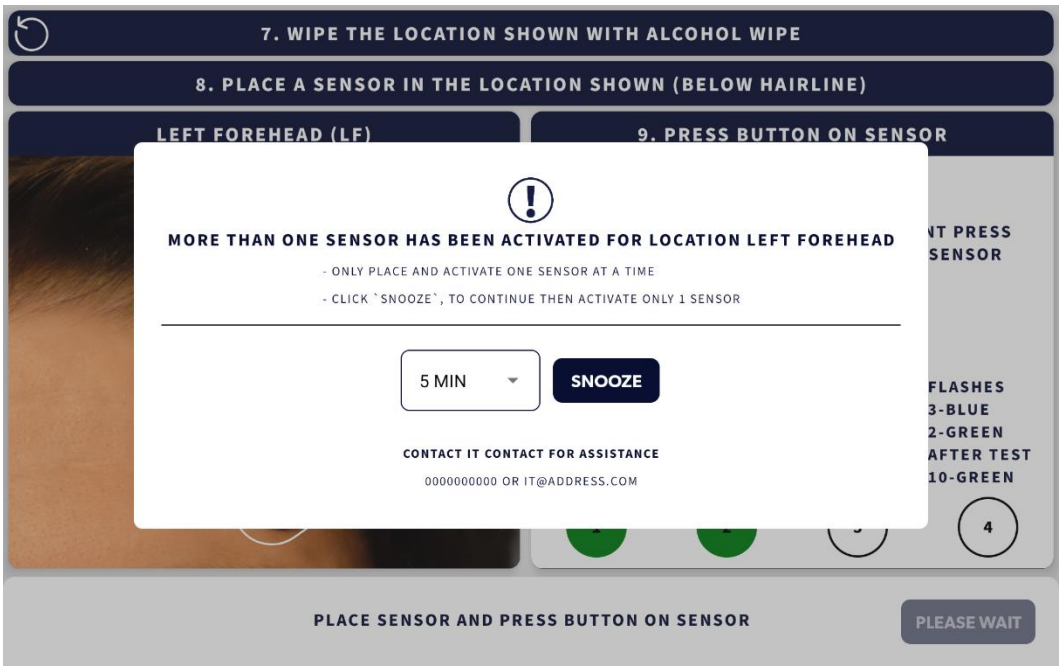
CAUTION: REMI Sensor wireless range is a maximum of 10m and it is recommended that the REMI Tablet be kept within 4m of the patient to ensure a good BLE connection between the Sensors and the REMI Tablet and to ensure EEG data is available for clinician review.

IMPORTANT: You will not be able to proceed through the Initialization process until the Sensor has re-established a connection with the REMI Tablet if the alert screen is active before a recording has begun.

Multiple Sensors Activated

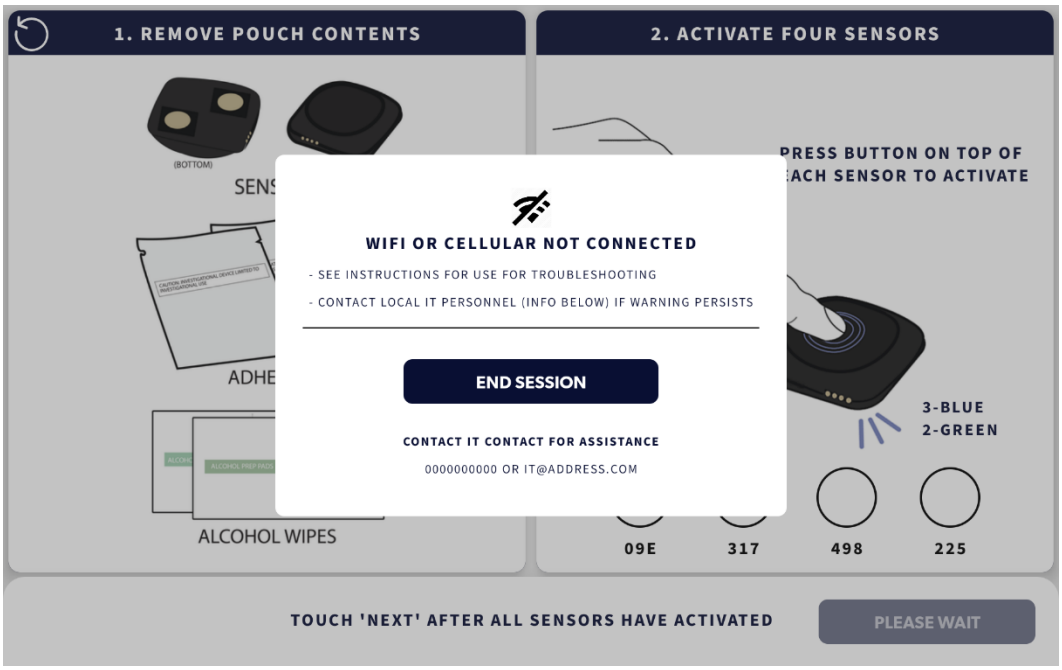


The Multiple Sensors Activated Alert Warning will appear if you activate more than one Sensor while placing Sensors on the scalp during the Sensor Placement procedure. The REMI Tablet will automatically turn off the conflicting activated Sensors and ask you to repeat the current placement. The SNOOZE button will appear when the REMI Tablet has reset the Sensors.



Click SNOOZE and follow the steps on the REMI-Mobile app. Note, if you placed a Sensor on the scalp in the location shown already then you do not need to remove it. Simply press the center button again to activate. Follow the steps in the app as normal.

REMI Tablet Connectivity Failure



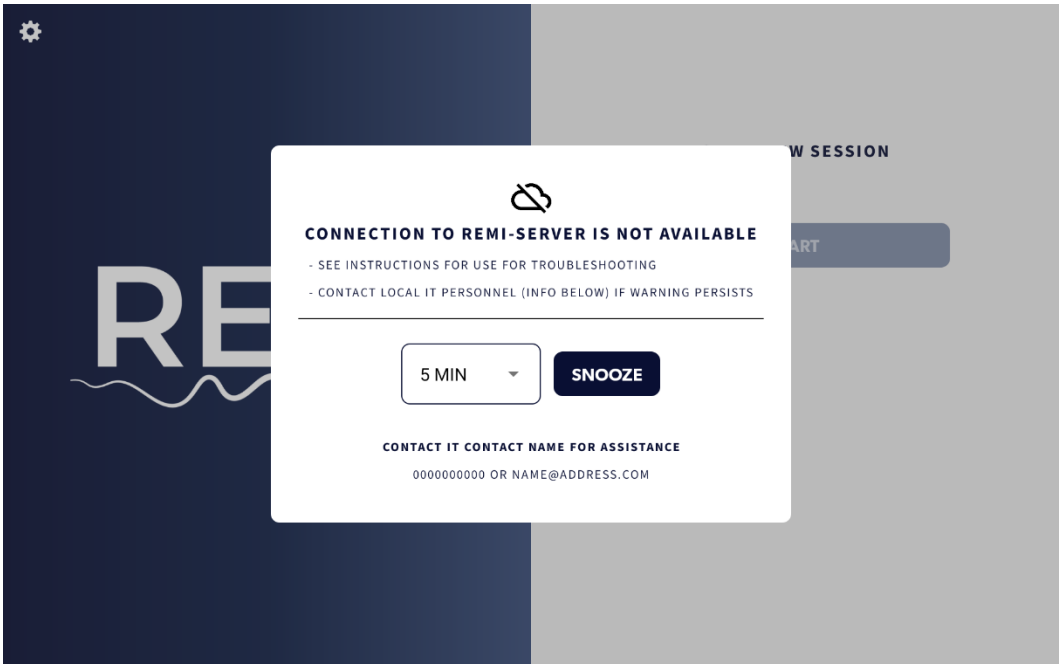
The REMI Tablet must be connected to WiFi or cellular to function properly. Ensuring good connectivity with the help of medical center IT staff will ensure EEG data is available for clinician review. Should the REMI Tablet lose connectivity, an alert screen will appear and all REMI Sensors will begin to flash their LEDs alternating red and blue. Note, you may need to move the Tablet throughout the room in case the REMI Tablet loses connectivity. Should the REMI Tablet reconnect to WiFi or cellular, the alert screen will automatically disappear.

CAUTION: EEG data will not be transmitted by REMI Tablet or available for clinician review during the time that disconnection occurs.

IMPORTANT: You will not be able to proceed through the Initialization process until the connectivity is re-established if the REMI Tablet loses connectivity before a recording has started.

IMPORTANT: The alert screen will have the information of the IT person to contact at your institution including name, phone number, and email address. Contact Epitel Customer Support or IT if this alert persists.

REMI-Cloud Server Error

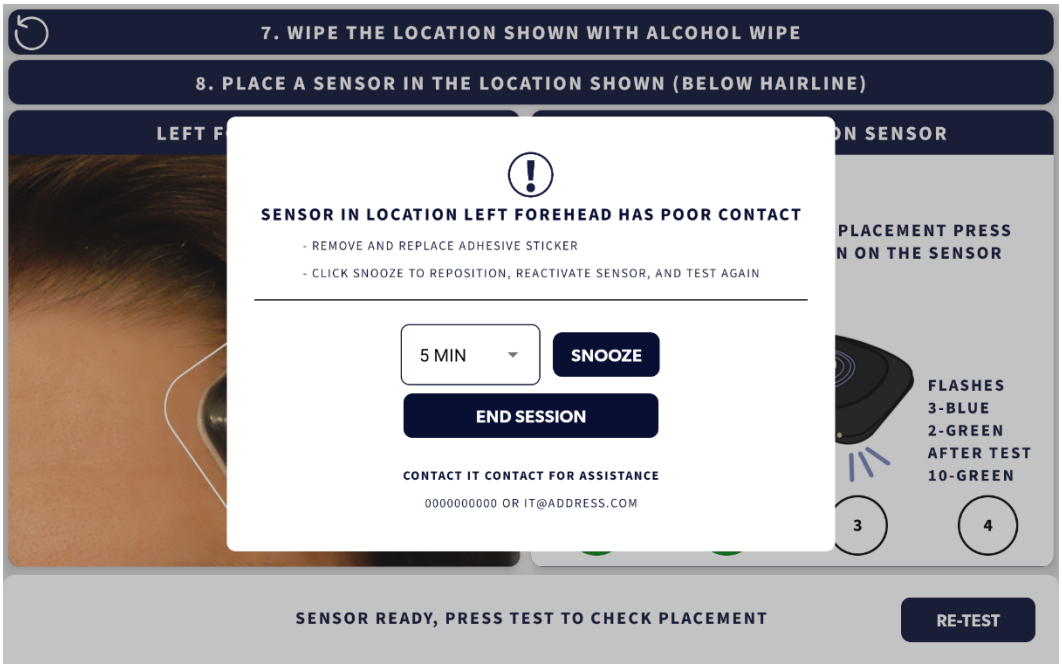


The REMI-Cloud Server must be functioning for the REMI System to function properly. Should the REMI-Cloud Server have an error, an alert screen will appear, as shown below, and all REMI Sensors will begin to flash their LEDs alternating red and blue. Should the error end, the alert screen will automatically disappear.

IMPORTANT: You will not be able to proceed through the Initialization process until the REMI-Cloud Server Error is discontinued if the error occurs before a recording has started.

IMPORTANT: The alert screen will have the information of the IT person to contact at your institution including name, phone number, and email address. Contact Epitel Customer Support or IT if this alert persists.

Poor Electrode Contact



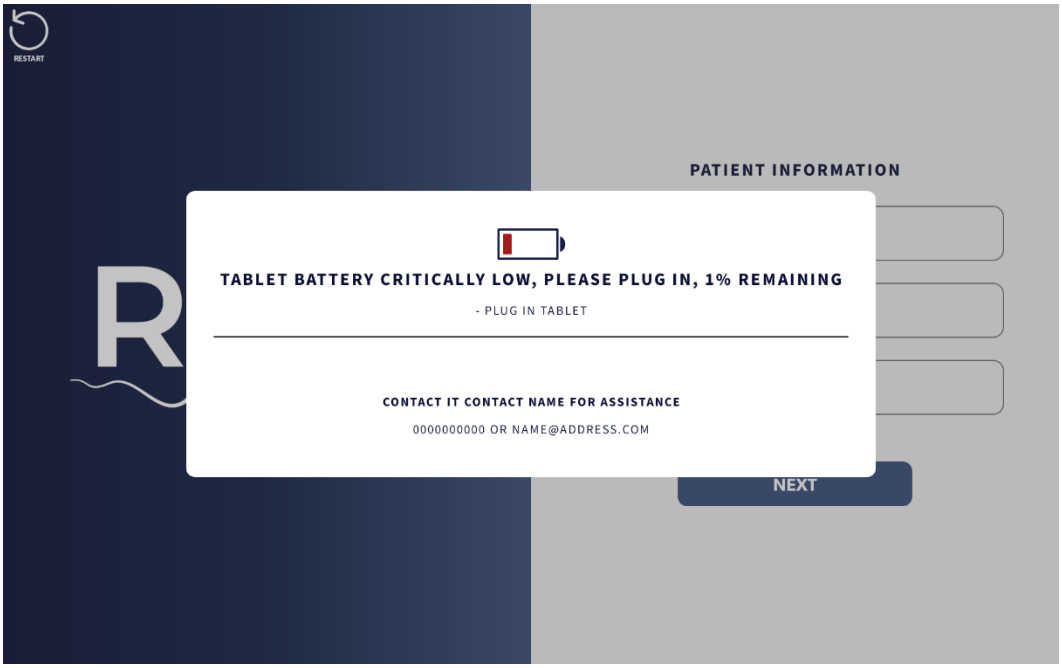
REMI-Mobile will check the electrode contact quality (ECQ) when the user clicks TEST after the placement of each Sensor. An alert will be displayed with troubleshooting advice if a Sensor has poor ECQ, with the option to SNOOZE or END SESSION, as shown above. SNOOZE can be chosen to close the alert, re-activate the Sensor, and then retest the Sensor.

If the Poor Electrode Contact Quality message box appears during REMI Sensor placement, it is recommended that you replace the Sticker and reapply the Sensor in the same location on the scalp, ensuring to place the Sensor as close to below the hairline as possible so that the clear hydrogels make good contact between the scalp and the gold electrodes on the Sensor.

If there are still issues with the Sensor ECQ after re-testing, the Sensor can be replaced by clicking REPLACE (which will be where SNOOZE is shown above). END SESSION can always be chosen to end the session and return to the Start Screen.

IMPORTANT: A Sensor can only be re-tested once. If the Sensor still has poor ECQ after the second test, replacing the Sensor is the only option.

Tablet Battery Low

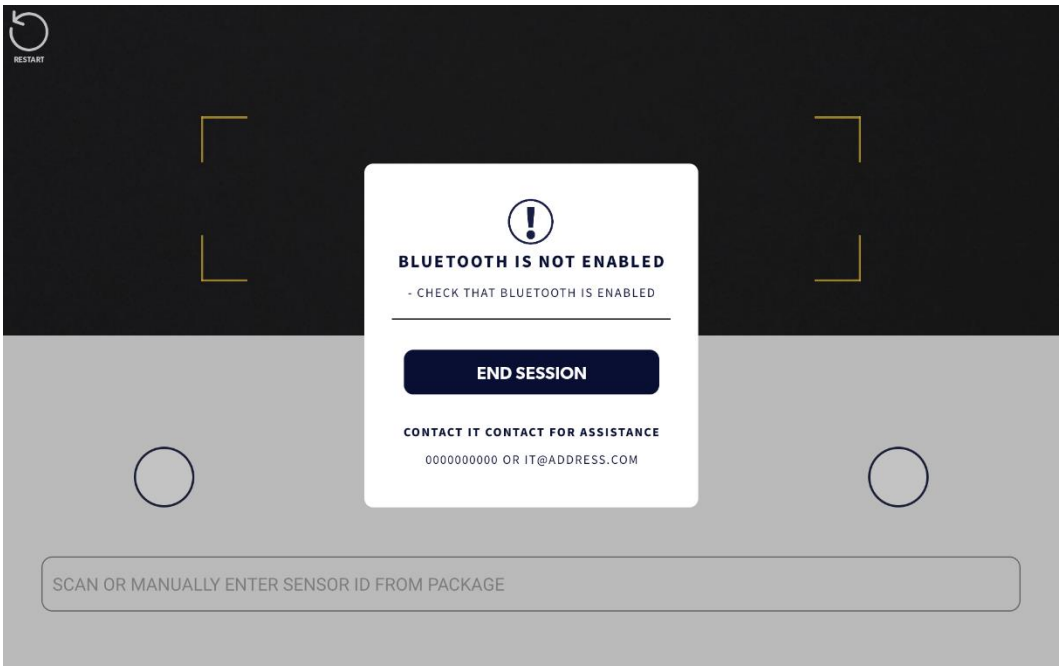


It is recommended that the REMI Tablet be plugged into A/C power at all times. Should the battery reach 50% capacity or less and is not plugged into A/C power, an alert screen will appear. All REMI Sensors will begin to flash their LEDs alternating red and blue. If REMI Tablet battery power is above 25% you will be able to “snooze” the alert screen.

IMPORTANT: If the Tablet Battery Low alert appears prior to start of recording, you will not be able to proceed through the Initialization process. Plug the REMI Tablet into A/C power to automatically turn off the Tablet Battery Low alert.

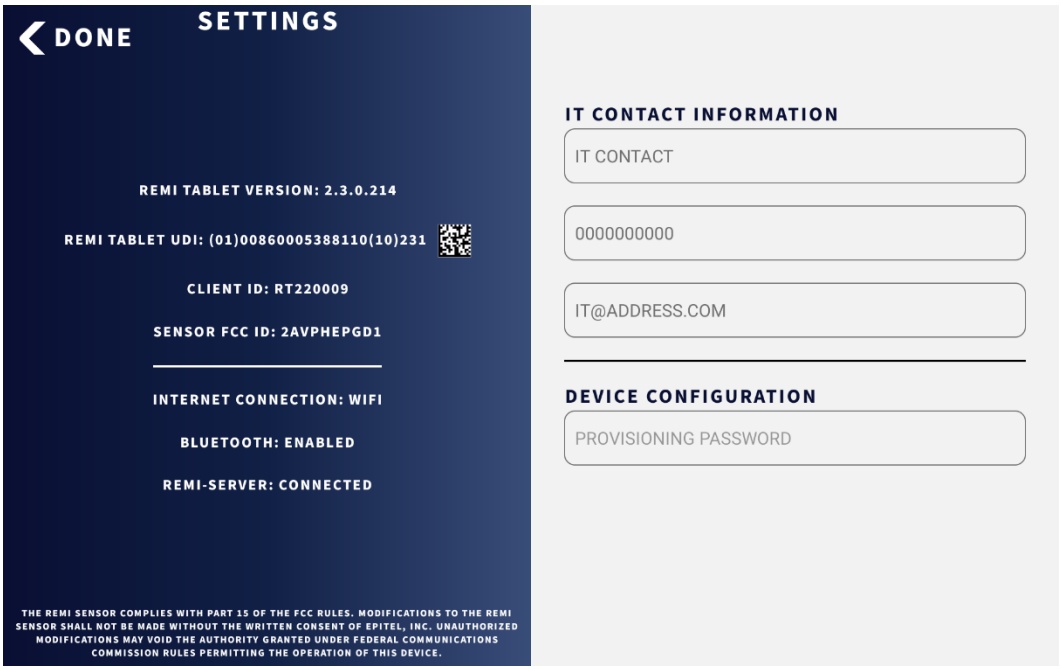
IMPORTANT: The alert screen will have the information of the IT person to contact at your institution including name, phone number, and email address. Contact IT if this alert persists.

Tablet Bluetooth Error



While rare, there may be times that the REMI Tablet has issues communicating with the sensor and the Bluetooth Error alert screen will appear as shown above. If this occurs, follow the instructions in the alert to reboot the REMI Tablet. The REMI-Mobile application will pick back up where it left off, after the reboot. If unresolved, it may be necessary to have IT personnel enter the Settings screen to turn on Bluetooth connectivity.

Settings

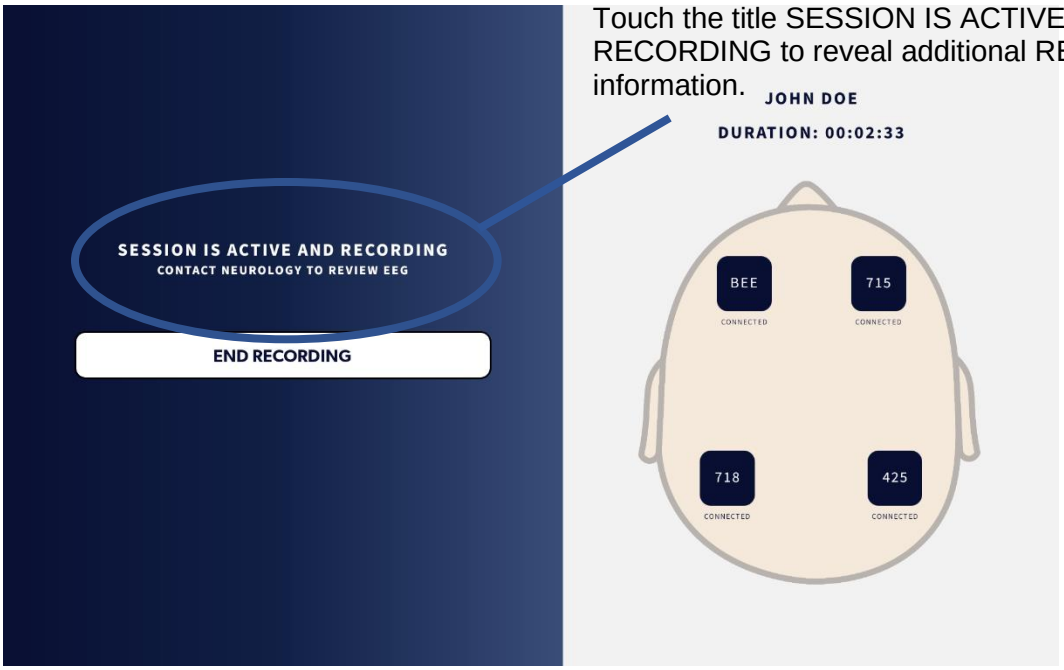


The settings screen provides the REMI-Mobile software version number along with regulatory information and connectivity information for the REMI Tablet and Sensors. The institution's IT Contact information can be modified on this screen.

IMPORTANT: Device Configuration information should not be changed without the support of Epitel and your hospital's IT department, as this may affect REMI Tablet connectivity.

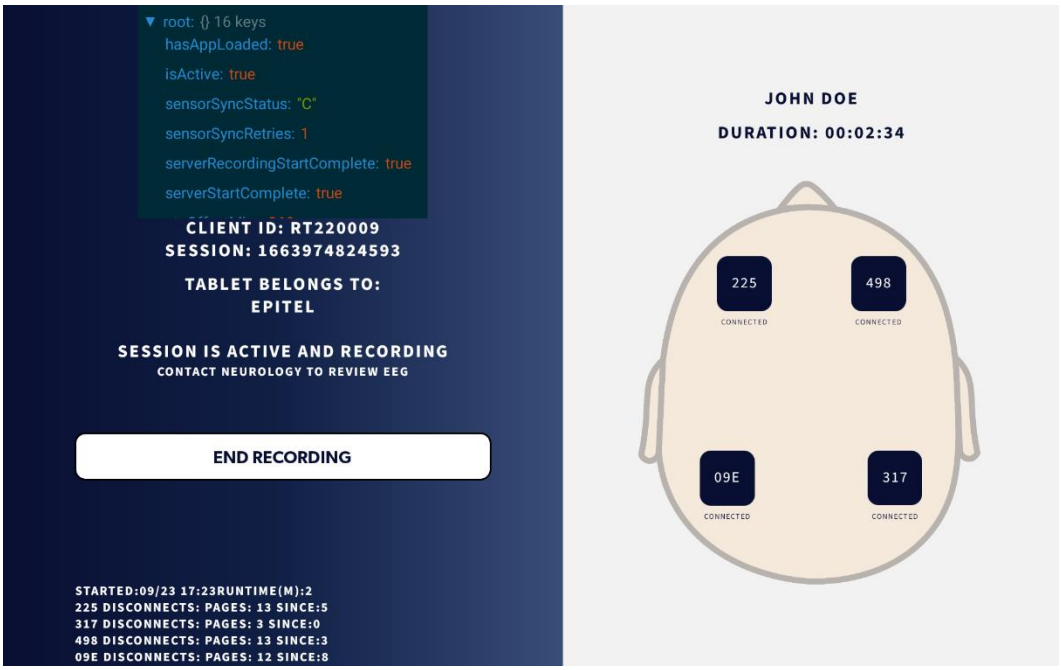
Accessing Session Diagnostic Information for Customer Support

Once active recording has begun, you may want to discuss an ongoing session with Epitel Customer Support. If Epitel Customer Support asks you to provide additional REMI session information, you may obtain this information by clicking on the title SESSION IS ACTIVE AND RECORDING in the Active Recording Screen.



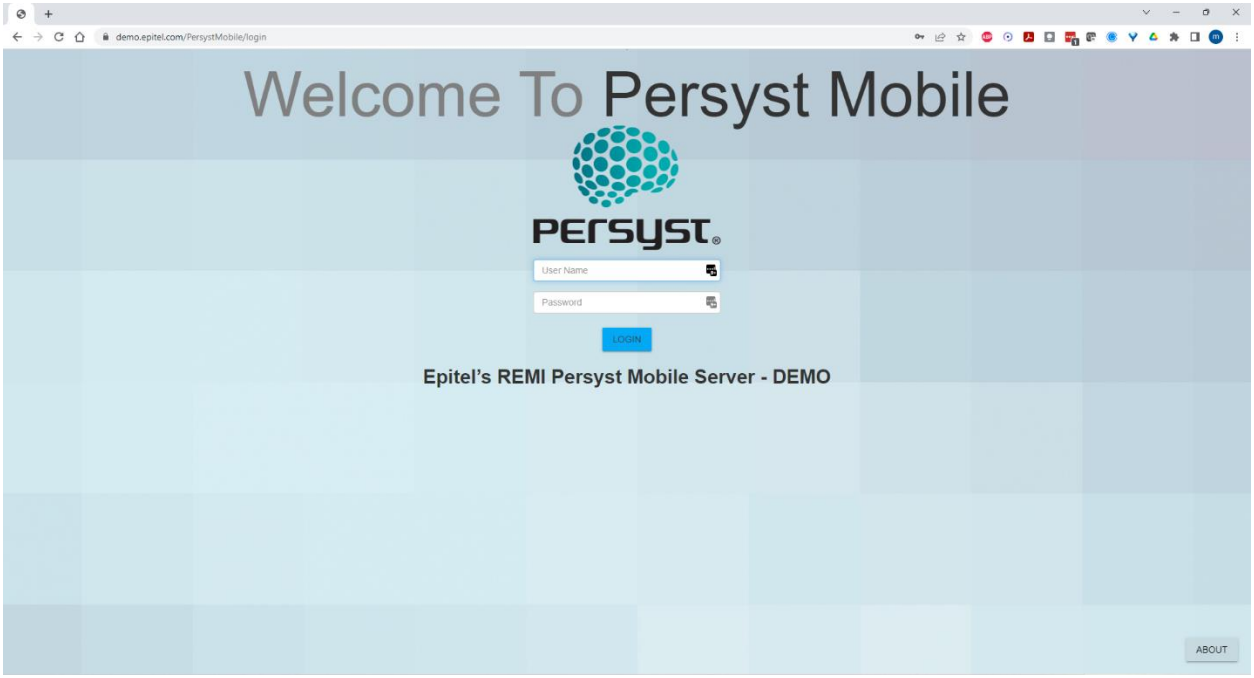
Touch the title SESSION IS ACTIVE AND RECORDING to reveal additional REMI session information.

Hiding the additional information can be done by clicking again on the title SESSION IS ACTIVE AND RECORDING.

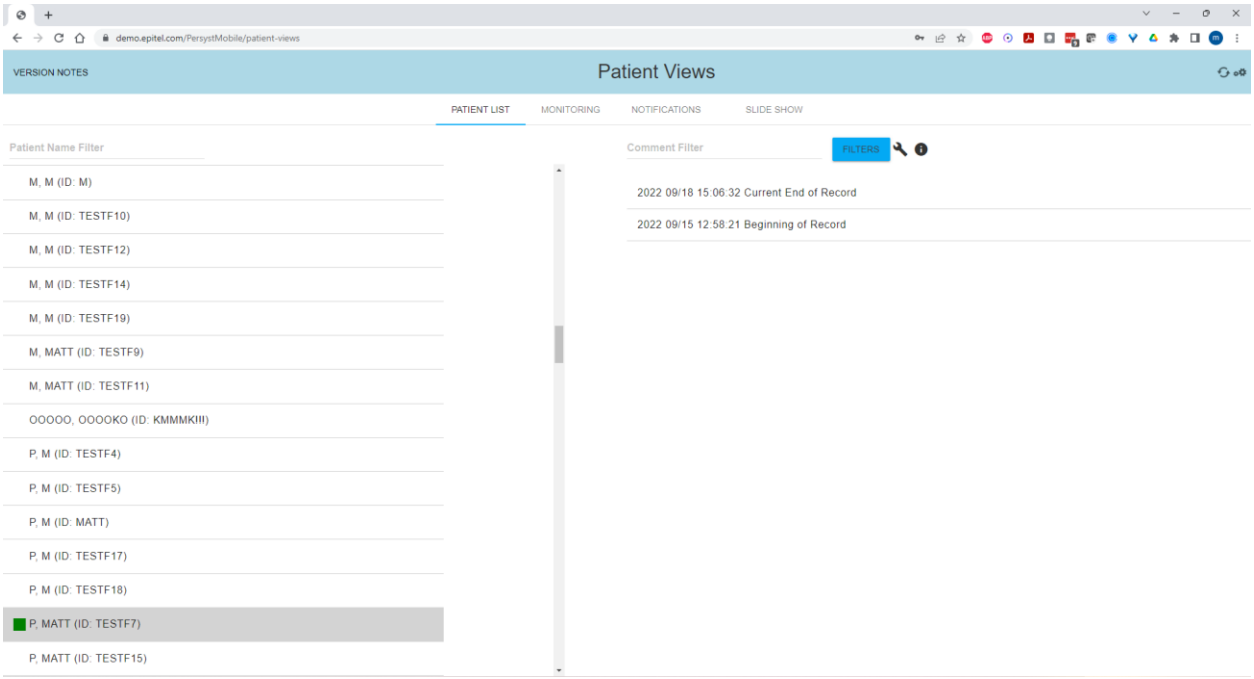


Persyst™ Mobile for EEG Review

REMI uses FDA-cleared Persyst Server and Persyst Mobile software to provide remote viewing of EEG. Persyst Mobile works on any desktop internet browser or on mobile devices. Epitel recommends using only desktop browsers for remote review of REMI Sensor EEG from REMI. To access patient EEG, log into the Persyst Mobile web address, which will look like the screen below. The web address and your credentials are available from your health care network administrator.



Once logged in, a list of Patient Names will appear, similar to the image below. Patients with active recordings will have a green square box to the left of their name. The patient name and MRN (ID) are displayed.



Clicking on a patient name on the left side of the screen will highlight that patient and list the current end and beginning of the patient recording as comments on the right side of the screen, as shown above. Clicking either of the comments will bring up the patient's EEG record, displayed in the REMI 10-channel montage, similar to the image on the following page. All settings for the display can be configured by clicking the gears icon in the upper right of the screen.

IMPORTANT: Any data missed due to issues such as REMI Sensor disconnections is displayed as zero-value data in the Persyst display.

Troubleshooting

A REMI Sensor continuously disconnects from the REMI Tablet – Ensure the REMI Tablet is close enough to the patient to properly connect. We recommend replacing the REMI Sensor if the disconnection continues and a recording has not yet been started. See the **Replace Sensor** section of this manual. We recommend either ignoring or removing the Sensor that continues to disconnect after a recording has been started. Note that a recording session will continue even if a REMI Sensor is no longer functioning properly.

A REMI Sensor will not connect to the REMI Tablet – It may be necessary to replace a Sensor prior to starting a recording if it fails to connect to the REMI Tablet. We recommend using a different Sensor. The unused Sensor that is not connecting to the REMI Tablet can be returned to Epitel for replacement. See **Warranty** section of this manual.

A REMI Sensor has fallen off of the patient – REMI Sensors and Stickers are single-use only. Do not attempt to reuse Sensors if they have fallen off of the patient.

REMI Tablet is unresponsive – Attempt to restart the Tablet by pressing and holding the power button and clicking Reboot. It will take a few seconds to reboot; however the REMI app will take you back to the screen where you left off. For example, if the Tablet became unresponsive during an active recording, it will restart, reconnect with all REMI Sensors, and continue recording. If the Tablet continues to be unresponsive, please contact Epitel Customer Support or IT.

The REMI Tablet will not boot – Ensure the Tablet is plugged in to A/C power before trying to boot the Tablet. It may be that the battery has drained and needs time to recharge in order to run on battery power. We recommend keeping the REMI Tablet plugged in to A/C power during use and while in storage.

The WiFi and/or cellular connection is intermittent – It may be necessary to find a physical location in the room where both WiFi and/or cellular and a connection between the REMI Tablet and REMI Sensors is reliable. We recommend that if there are WiFi and/or cellular “dead spots” in the room that the patient be moved to a location where WiFi and/or cellular is more reliable. If WiFi and/or cellular continues to be intermittent, contact IT.

The REMI Sensor barcode will not scan – The REMI Sensor barcode can be difficult to scan in low-light conditions, if the barcode was damaged or scratched, or if the barcode is incomplete. If the barcode is difficult to scan, we recommend manually entering the REMI Sensor ID using the REMI Tablet touchpad keyboard. See the **REMI Sensor Activation** section of this manual. Note, once a barcode has been scanned the REMI Tablet will not allow you to rescan the barcode. Make sure you have not already scanned the REMI Sensor barcode. If the REMI Sensor ID appears below one of the filled blue circles then that Sensor barcode has already been scanned or entered.

The REMI Sensor does not flash when I press 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 and a recording has not yet been started, we recommend replacing the Sensor. See the **Replace Sensor** section of this manual. If the Sensor still does not flash when the button is pressed after a recording has been started, we recommend first trying to use the REMI Tablet to Identify the Sensor. See **Identify Sensor**

section of this manual. If identifying a Sensor fails to flash the LED, we recommend either ignoring or removing the Sensor that continues to disconnect after a recording has been started. Note that a recording session will continue even if a Sensor is no longer functioning properly.

I mixed up the locations of where I placed the REMI Sensors – It is possible to relocate REMI Sensors before a recording has started. See **Change Sensor Placement** section of this manual. Note, do not try to reposition a REMI Sticker. Stickers are one-time use and will no longer be sticky enough to properly attach the Sensor to the scalp if they have been removed once before. Always use a new Sticker when repositioning the Sensor on the scalp.

One or more REMI Sensors are flashing red and blue – Red and blue flashing light on the REMI Sensors indicate that there is an alert. Check the REMI-Mobile application for an alert with reason and status displayed. The alert on REMI-Mobile will have troubleshooting instructions. Additional instructions may be found above and on each of the Alert sections of this manual.

EMC Compliance

The REMI System electronic components (REMI Sensor and REMI Tablet) comply with the EMC requirements of IEC 60601-1 (see Appendices A & B). To prevent RF interference with or from the REMI System, portable and mobile RF communications equipment should be kept away from the REMI components at distances specified in Appendix B.

FCC Intentional Radiator Certification

REMI Sensor FCC ID: 2AVPHEPGD1
REMI Tablet FCC ID: 2AJZP-G450A1

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.

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 installed 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 installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment 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 receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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.

Wireless Communication

The REMI System uses Low Energy Radio Frequency (RF) operating at 2.45 GHz (maximum 1mW) for wireless communication between REMI Sensors and the REMI Tablet. Sensor wireless range is a maximum of 10m and it is recommended that the REMI Tablet be kept within 4m of the patient to ensure a good wireless connection between the Sensors and the REMI Tablet. The REMI-Mobile software will alert the user if there are disconnection issues (see **REMI-Mobile Warning Alerts** section). If this occurs, bring the REMI Tablet closer to the patient to re-establish wireless connection between the Sensors and REMI Tablet. A recording session will not be able to be started until all four Sensors have a good wireless connection to the REMI Tablet through the REMI-Mobile software. If a Sensor is unable to establish this connection during session initialization, the Sensor can be replaced (See the **Replace Sensor** section of this manual).

The REMI System uses the hospital WiFi connection and/or a cellular connection for wireless communication between the REMI Tablet and the REMI-Cloud platform. Connectivity will be set up and tested initially by the hospital administration IT department alongside Epitel staff. The REMI-Mobile software will alert the user if there are any disconnection issues during the use of the REMI System (see **REMI-Mobile Warning Alerts** section). If connectivity cannot be established or continues to have issues, notify hospital IT staff immediately and/or discontinue use of the REMI System. Only the hospital IT staff can alter the connectivity settings on the REMI Tablet.

The 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 the REMI System, portable and mobile RF communications equipment should be kept away from the REMI components at distances specified in Appendix C.

Cybersecurity

REMI Sensor wireless communication with the REMI-Mobile software is secured through single-device proprietary connection protocols. There are no specific user instructions for the Sensor that pertain to Cybersecurity controls. Once a Sensor is packaged and sent to the user, the Sensor firmware and connection protocol cannot be changed or altered by the user. If a problem occurs with the wireless communication between the Sensor and REMI-Mobile, the REMI-Mobile software will alert the user (see **REMI-Mobile Warning Alerts** section). There is no patient identifying information communicated between REMI-Mobile and REMI Sensors.

The REMI-Mobile software communicates with the REMI-Cloud platform using an encrypted protocol via a hospital WiFi network and/or a cellular network. All wireless communication settings are configured by authorized Epitel personnel and hospital administration IT professionals during initial REMI setup and installation. These settings are password-protected and they must not be altered by anyone outside of the hospital administration IT department. If a problem occurs with the wireless communication between REMI-Mobile and the REMI-Cloud platform, the REMI-Mobile software will alert the user (see **REMI-Mobile Warning Alerts** section). The REMI-Mobile software is the only software authorized to be installed and run on the REMI Tablet. Only the REMI-Mobile software is accessible by the user on the REMI Tablet, and no attempt should be made to access and install any other software or alter any system-level settings on the REMI Tablet.

The REMI-Cloud platform 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 the REMI-Cloud platform is password protected. Reviewing physicians should not share their passwords with anyone. Should a reviewing physician’s password become compromised, please alert hospital administration immediately, who can then notify Epitel.

Server Maintenance

The REMI Remote EEG Monitoring System uses the REMI-Cloud Server to store data and operate Persyst™ Mobile. The REMI-Cloud Server 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.

To ensure continued operation of the REMI-Cloud Server, Epitel performs routine server maintenance according to a server maintenance plan. Under this plan, routine maintenance will

be performed up to once monthly. During routine service maintenance, you can expect to see a brief loss of server connectivity for a brief time (but no longer than 60 minutes). This may result in brief loss of patient data during the outage (while the REMI-Cloud Server reboots) and/or inability to review EEG data collected during the outage.

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

In the event that critical server maintenance is required, Epitel will communicate with hospital IT administrators to alert 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 REMI-Cloud Server routine maintenance, contact your Epitel customer service representative.

REMI Tablet Service and Repair

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

REMI-Mobile Upgrades

Whenever software updates to the REMI-Mobile application become available (whether due to cybersecurity enhancements, feature enhancements, resolution of anomalies, etc.), Epitel will coordinate with hospital 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.

Sensor Specifications

Compliance Standards	IEC-60601-1, IEC-60601-2-26, IEC-60601-1-2, IEC 60086-4, IEEE C63.27, ISO 10993, ISTA-6, IEC 62366, IEC 62304
Degree of Protection	Type BF Applied Part (REMI Sensor)
Water Ingress Protection	IPX3 – Protected against spraying water up to a 60 degree angle
Operation Environment	60°F to 80°F (16°C to 27°C), 10 to 95% relative humidity (non-condensing)
Storage and Transport Environment	50°F to 105°F (10°C to 40°C), 10 to 95% relative humidity (non-condensing)
Storage Duration	REMI Sensors, including their Sticker accessory, have a limited shelf-life defined on the package labels.

REMI-Mobile Software Updates

All software updates will be installed by Epitel personnel only. Epitel will notify customers of the availability of new software updates and make arrangements for installation of selected upgrades.

Product Cleaning

The REMI Tablet should only be cleaned with damp cloths using water or alcohol and should not be immersed in any liquids or gases. Cleaning of REMI Tablet should be done between each patient use.

CAUTION: REMI Sensors and Stickers are single-patient, one-time use. Do not attempt to reuse REMI Sensors or Stickers.

Product Returns

All components of the 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

Appendix A – 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 in order 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 B – Electromagnetic Immunity Declarations

Declaration – electromagnetic immunity			
REMI Tablet and 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	<u>REMI Sensor</u> 3 Vrms 150 kHz to 80 MHz <u>REMI Tablet</u> 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: $d = 1,2 \sqrt{P}$
Radiated RF IEC 61000-4-3	<u>REMI Sensor</u> 3 V/m 80 MHz to 2.7 GHz <u>REMI Tablet</u> 10 V/m 80 MHz to 2.7	3 V/m 80 MHz to 2.7 GHz	$d = 1,2 \sqrt{P}$ 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

Declaration – electromagnetic immunity			
	GHz		recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, **a** should be less than the compliance level in each frequency range, **b** Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which 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 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 – 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 CR2016 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:	Hydrogel over hard gold electrode

LED Status Indication – Button Press

No LED or 2 x Red	Sensor error
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)

LED Status Indication – Without Button Press

10 x Green	External command used to identify Sensor
Continuous Red & Blue	User alert used to notify user that an error occurred. Review the instructions on REMI Tablet and/or the Troubleshooting in this manual.

Appendix E – 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, purchaser may return same 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 REMI Tablet by anyone other than Epitel authorized service personnel.
- Removing system labels by anyone other than service personnel authorized by Epitel.
- Connecting the REMI Tablet to any AC adapter other than the system adapter provided.
- Connecting the REMI Tablet 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 warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

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

Website: www.epitel.com
Technical Support: support@epitel.com

LB-0001 Rev 4