User Manual for REMI Ambulatory Use

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

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.	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 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 Tablet	A tablet mobile computing platform running REMI Mobile Software
REMI Smartwatch	A mobile computing platform running REMI Mobile session 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 EEGs are sent to a qualified mobile operating platform running the REMI Mobile software. REMI Mobile relays the EEG from four Sensors to the REMI Cloud running Persyst software. The EEG data is accessible through Persyst Mobile where the four REMI Sensor (eight electrodes) EEG data is displayed as a montage of up to ten channels.

The user interface for the REMI Tablet operating platform is a 10" LCD touchscreen display. REMI Tablet power is provided through an A/C adapter and onboard rechargeable battery.

The user interface for the REMI Smartwatch operating platform is a 2" LCD touchscreen display. REMI Smartwatch power is through an A/C adapter and onboard rechargeable battery.

The user interface for REMI Sensors is a single button within each Sensor. Sensor power is through a single-use primary coin cell battery. 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. 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 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. The REMI System is indicated for use with adult and pediatric patients (6+ years).

Contraindications

- The REMI System should not be used on any children under the age of 6 years.
- 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 / REMI Smartwatch 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 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 REMI Sensors before performing a magnetic resonance imaging (MRI) scan. Do not bring any REMI System components into a MR environment.

Precautions

- Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
- Avoid using 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 / Smartwatch, Sensors and Stickers 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.
- **To reduce the risk of damaging Sensors**, follow the sensor sticker replacement process as instructed in this manual.

- REMI Sensors and Stickers are single-patient, one-time use. Do not attempt to reuse REMI Sensors or Stickers.
- REMI Stickers should be replaced daily and REMI Sensors can only be used for a single patient EEG recording session. Once a recording has ended all active Sensors will no longer be able to connect to the computing platform or record EEG.
- Ensure that the Sticker hydrogels are aligned over the gold electrodes. Failure to do so will result in poor data quality.
- 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.
- Do not place the Sensor over hair. The REMI Sensor is meant to be used below the hairline. Placing the Sensor over hair may result in improper attachment to the scalp that may affect performance.
- In the case that a Sensor has fallen off of the scalp after a recording session has started, the user should initiate a Single Sticker Change as described in the **Single Sticker Replacements** section of this manual.
- REMI Sensor wireless range is a maximum of 10m and it is recommended*ƒ* that the REMI computing platform be kept within 4m of the patient to ensure a good wireless connection between the Sensors and the computing platform.
- REMI Sensors will record and store data from immediate placement until the end of the prescribed duration, but must be within 10m of the REMI Smartwatch to wirelessly transmit the data. It is recommended that the patient stay within 4m of the REMI Smartwatch for at least 8 hours a day. A suggested use is to set up the charging station near patient sleeping arrangements.
- 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.
- EEG data will not be transmitted by the computing platform or available for clinician review during the time that disconnection occurs.
- The REMI Smartwatch must be powered on and connected to cellular and/or internet in order to send data via REMI Cloud to the Clinician viewing platform. It is recommended to set up the charging station in an area of reliable connectivity. When able to successfully reconnect to REMI Sensors, the REMI Smartwatch will initiate a data catch-up process at regular intervals, starting with the oldest missed recording data first.
- 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 / Smartwatch computing system 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.
- The REMI Sensor electrodes should not come into contact with any conductive parts other than the REMI Sticker.
- The use of a defibrillator while wearing REMI Sensors may affect EEG recordings and Sensor functionality.
- If the 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 the computing platform be powered on and connected. For the fastest and most reliable updates, it is recommended to connect the REMI Tablet / Smartwatch computing system to Wi-Fi for system updates.

- DO NOT DISPOSE OF THE SENSORS. Ensure the Smartwatch stays connected and powered on during the end-of-session screen.

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 occurs.

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.

Patients and/or caregivers are intended to use the ambulatory components of the REMI System as described by this manual.

This manual provides complete information on how to operate REMI in both cases.

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 and Smartwatch have a unique serial number located on their back cover. The REMI Mobile software version number can be found in the application About menu. The Smartwatch serial number and software version number can be found in the About menu.

REMI Tablet and REMI Smartwatch Operation

REMI Mobile software will initially be provisioned and configured on REMI Tablet / REMI Smartwatch by healthcare facility personnel alongside Epitel staff. After initial provisioning, the computing platforms and REMI Mobile software are ready-to-use.

To operate the REMI Tablet, 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.

To prepare the REMI Smartwatch for operation, plug the REMI Smartwatch in the DC jack and into a wall outlet. Once the REMI Smartwatch is fully charged, it is ready for use. Press the physical green power button until the smartwatch turns on. The smartwatch will take a few seconds to boot.

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.

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

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 the REMI Tablet / Smartwatch computing system to Wi-Fi for system updates.

IMPORTANT: For optimal performance, the REMI Tablet computing platform 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.

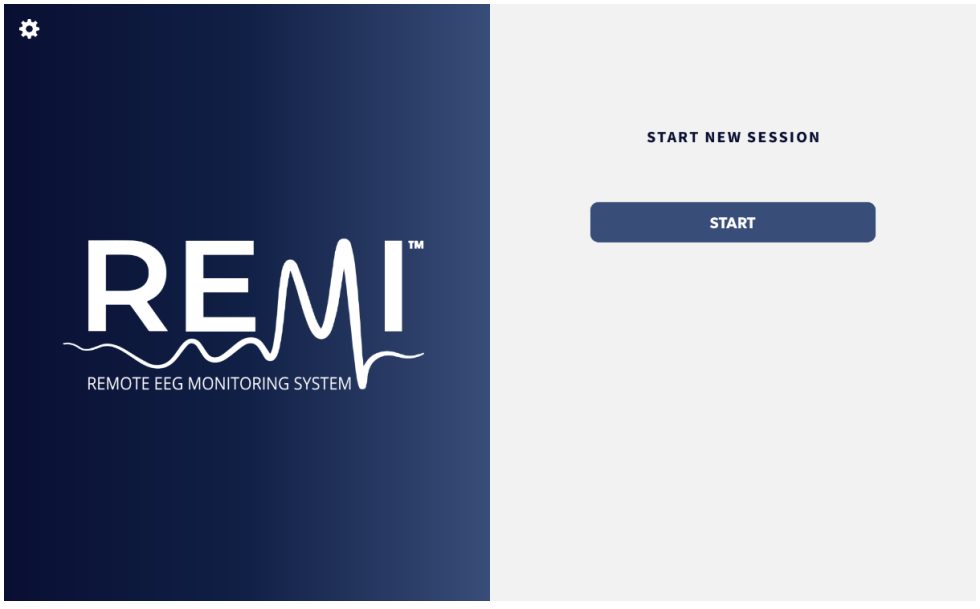
IMPORTANT: For optimal performance, the REMI Smartwatch is recommended to be plugged in when possible. The REMI Smartwatch will also operate on battery power. Once the Smartwatch battery drops below 25% capacity an alert may pop up on the REMI Mobile application.

IMPORTANT: To enable regular clinician review, it is recommended to keep the REMI Smartwatch powered on and connected via Wi-Fi or cellular for at least 8 hours each day throughout a recording session.

Session Initialization

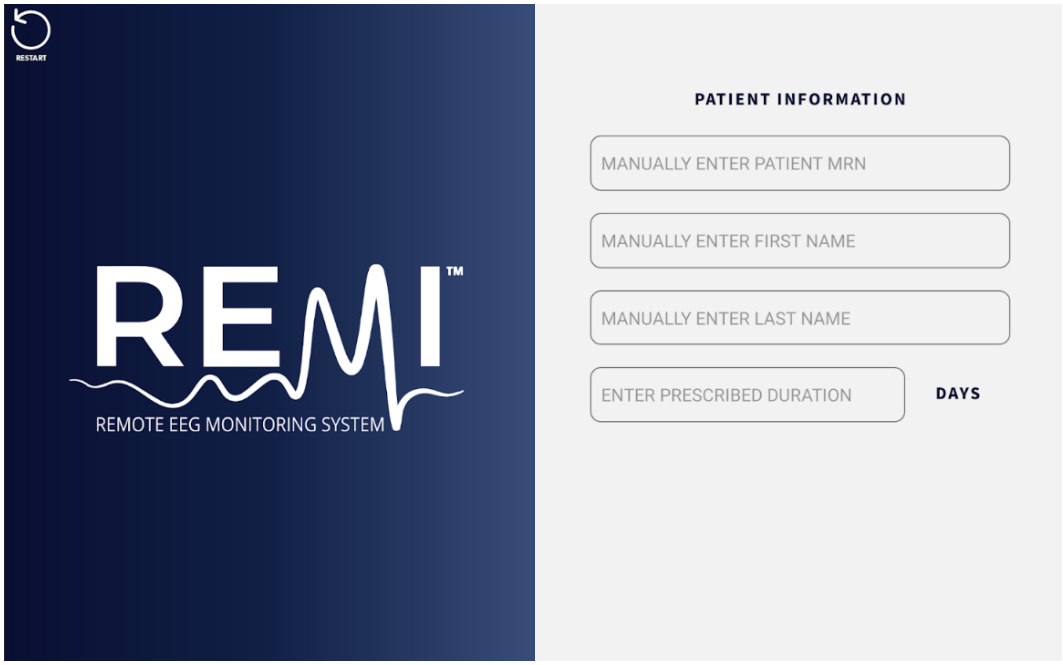
Session initialization occurs on the REMI Tablet. Once the REMI Tablet boots, it will automatically display the Start Session Screen, as shown below. If the clock screen is shown, swipe up, which will display the Start Session Screen. Press the START button to begin a new session. In the upper left-hand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

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

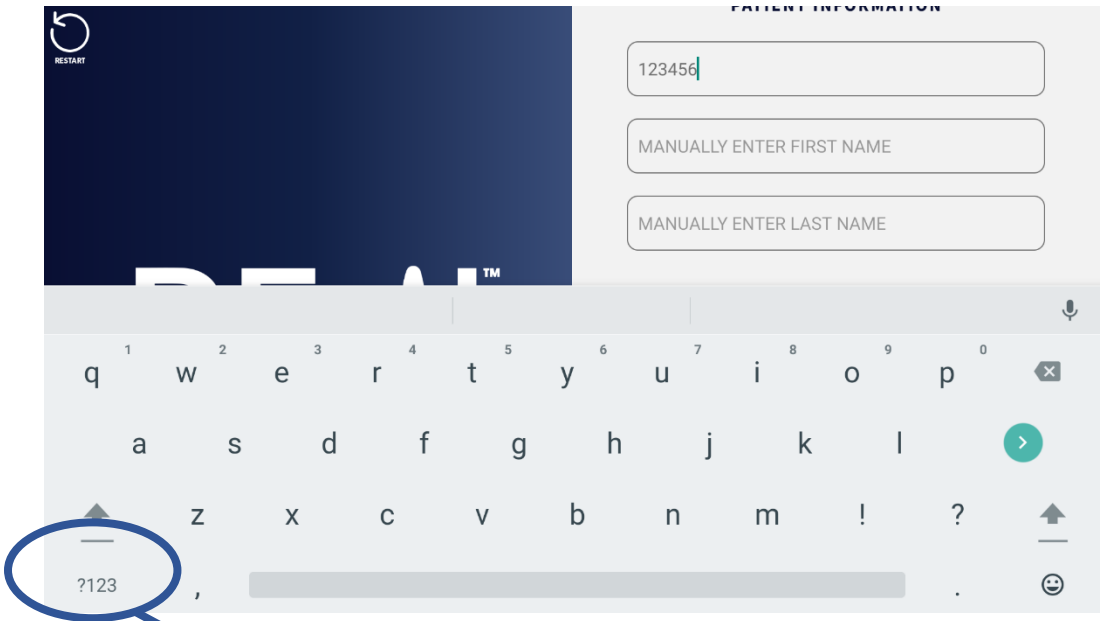


Enter Patient Information and Prescribed Session Duration

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.



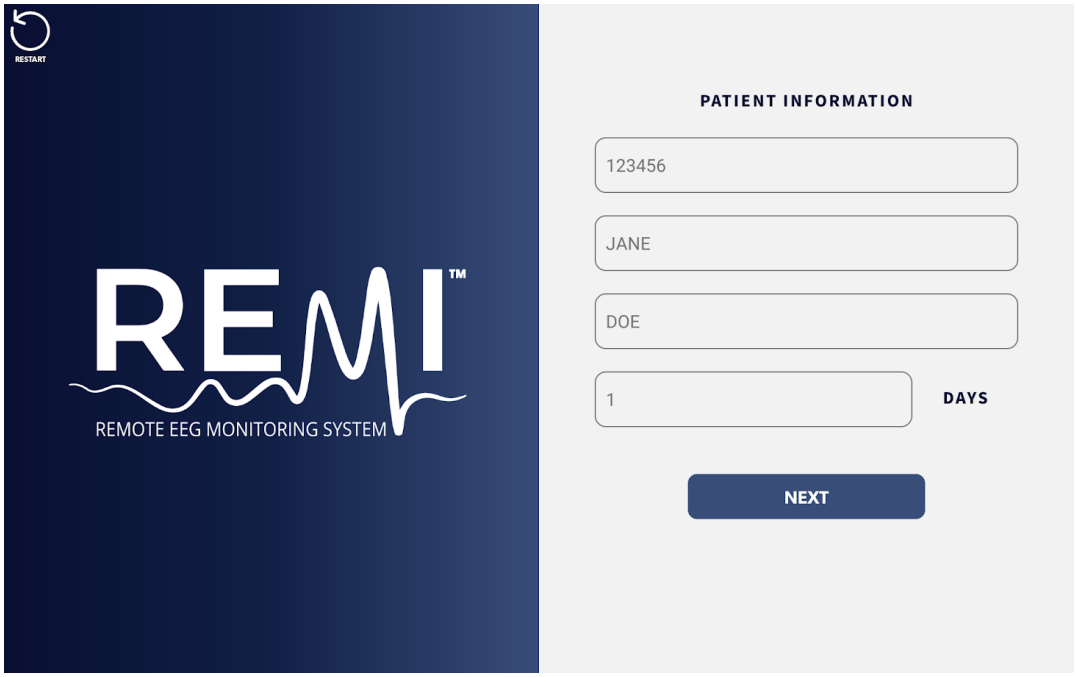
To switch to a numeric keyboard, click the "?123" button in the bottom left as shown in the circle below.



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.

Enter the patient's medical record number (MRN), first name, last name, and prescribed monitoring duration (in days) in the fields. Once patient information has been entered, click the NEXT button to proceed. You will also need to enter the duration of the study on the tablet. The enter/return button on the tablet is displayed as a green > on the tablet keyboard.

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



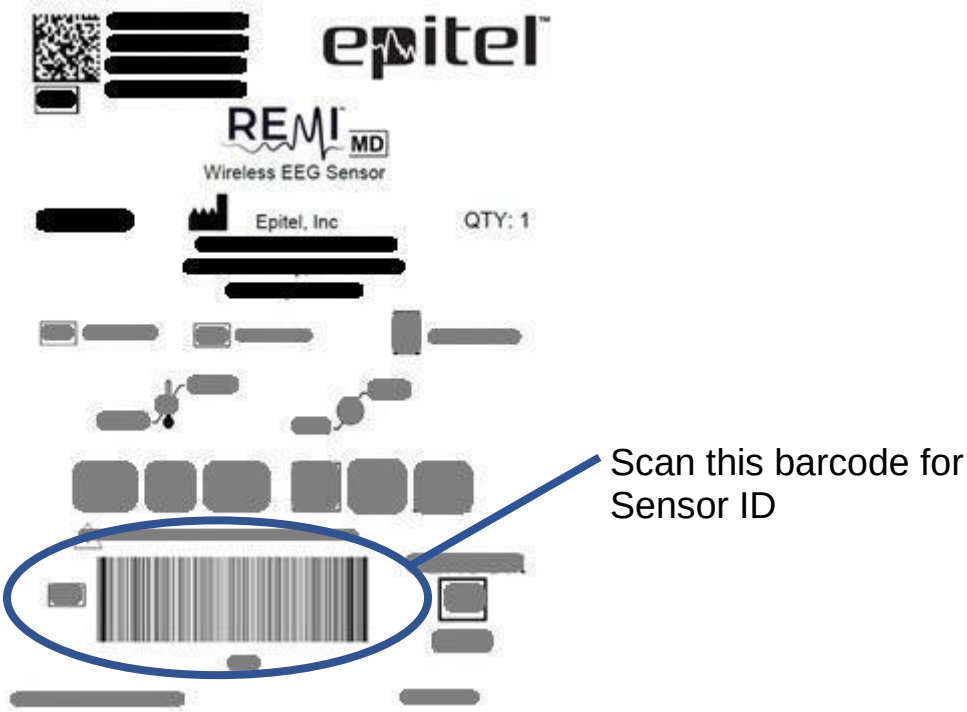
IMPORTANT: You may restart a session at any time by clicking the counterclockwise

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.

REMI Sensor Preparation for Initial Placement

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.

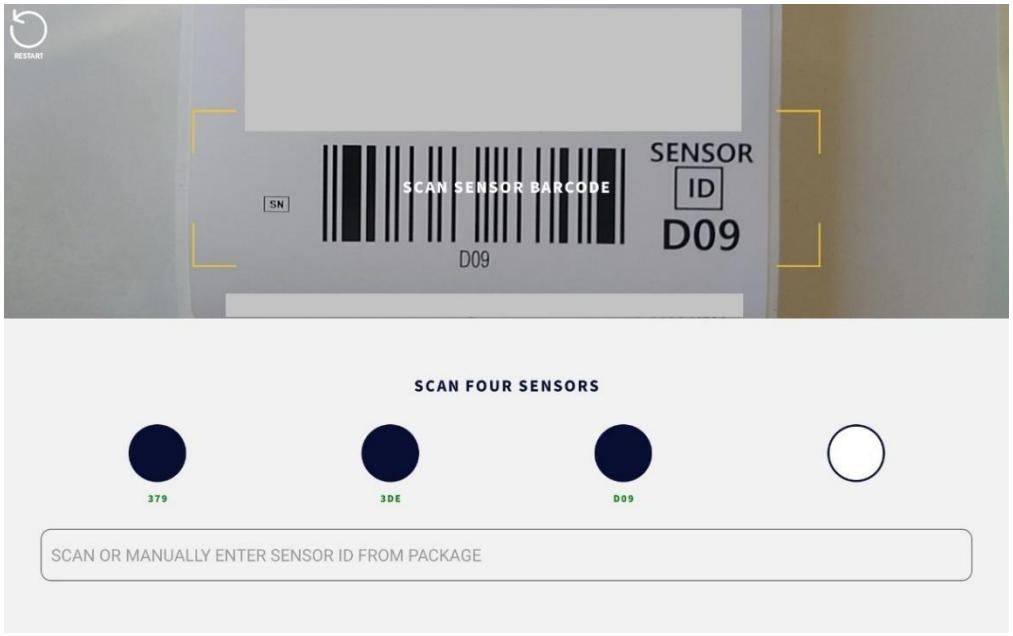


Scan REMI Sensor Barcodes
Use the REMI Tablet rear camera to scan the barcode on each of the four Sensor packages as shown.

IMPORTANT: Only scan the barcode at the bottom of packaging. The QR code 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.

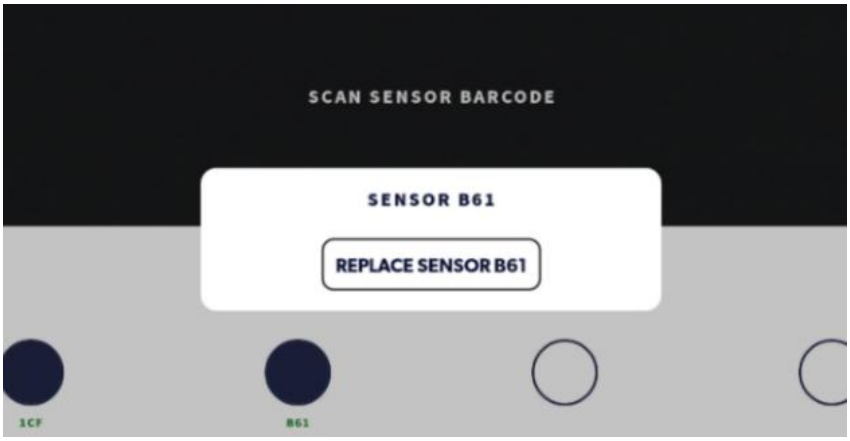
If a barcode is not scanning or did not scan correctly due to issues such as damaged packaging or camera, manually enter the Sensor ID, located on the Sensor packaging, using the keyboard as described earlier. After entering the Sensor ID using the keyboard, select the enter/return arrow to save the ID and move to the next Sensor. 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 incorrect Sensor identifying information was entered, it can be replaced by clicking the blue circle above the 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 following example, a Sensor with the ID “B61” is being replaced.

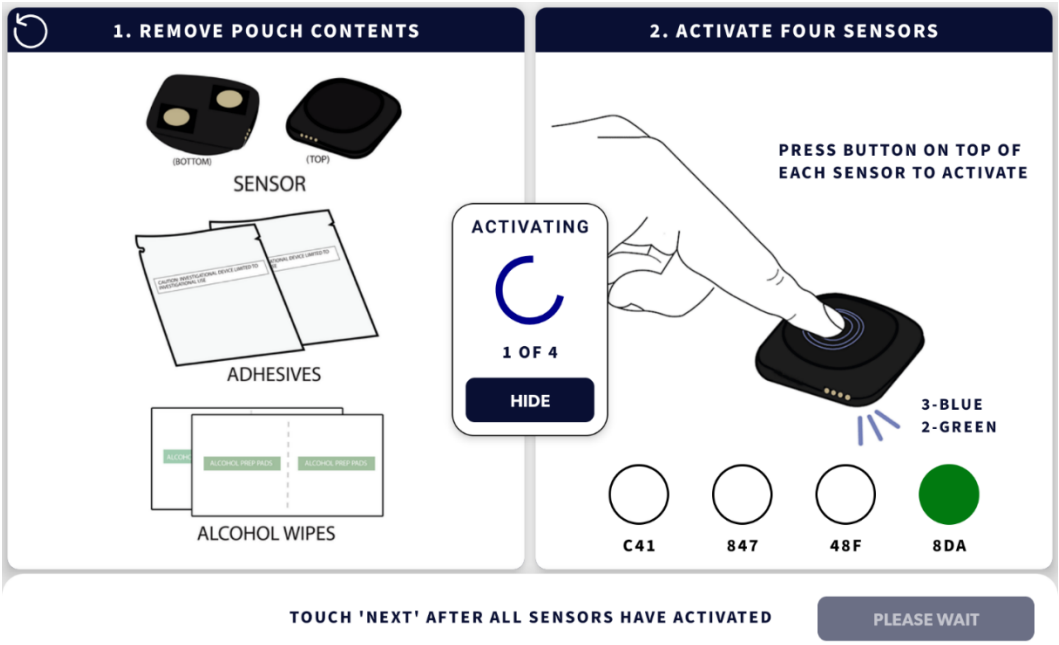


REMI Sensor Initialization

- Remove the contents of each Sensor pouch.
- Remove the Sensor from the pink protective covering.
- Bring the Sensor close to the Tablet and press 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.

- When the Sensor connects to the REMI Tablet, the circle above that Sensor ID will fill green and its LED will flash green 10 times.
- Repeat these steps until all four Sensors have been activated. In the following example, 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 from PLEASE WAIT to NEXT.**



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

IMPORTANT: A sensor can be replaced at any time during this step. To replace a sensor, tap and hold the circle assigned to the sensor in question, and wait for the modal to appear to replace the 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: If a Sensor LED blinks red, this means the Sensor is not fit for use. Should this happen, hold your finger on the circle indicating the missing Sensor and you will be prompted to replace the Sensor with a new one.

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: Clicking Sensors too quickly can sometimes cause the connection attempt between REMI Mobile and REMI Sensor to fail. This can be avoided if you wait a few seconds

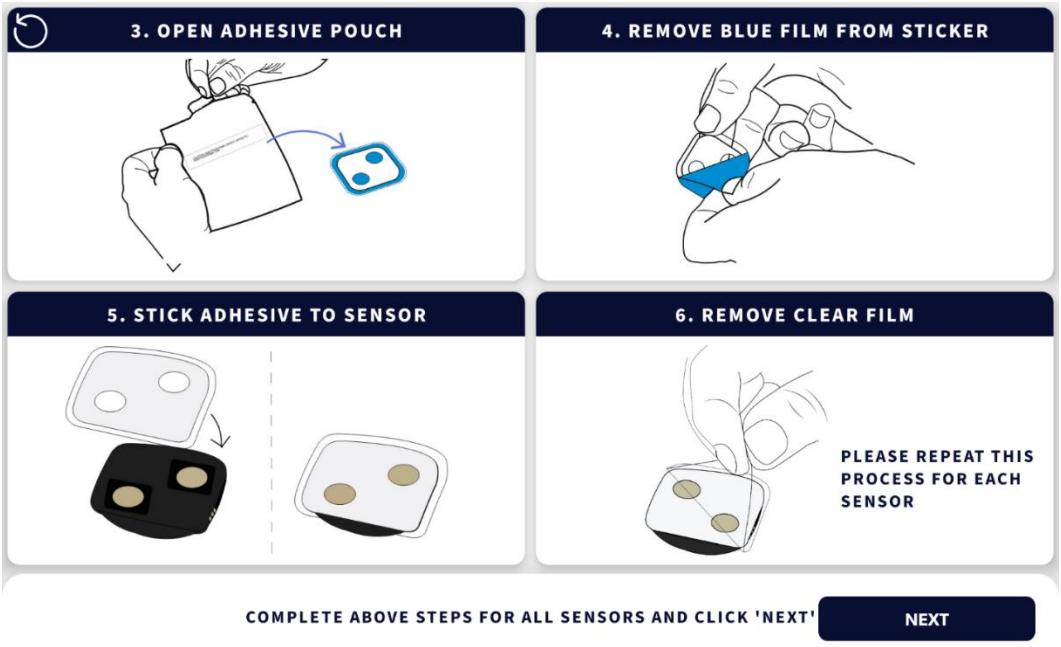
between the first button press to activate the Sensors. If a Sensor is taking too long, try depressing the button again. If any Sensor does not connect within 60 seconds, see the **Troubleshooting** section of this manual.

Sensor Placement

Applying a Sticker to REMI Sensor

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

- 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: 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.

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 from 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.

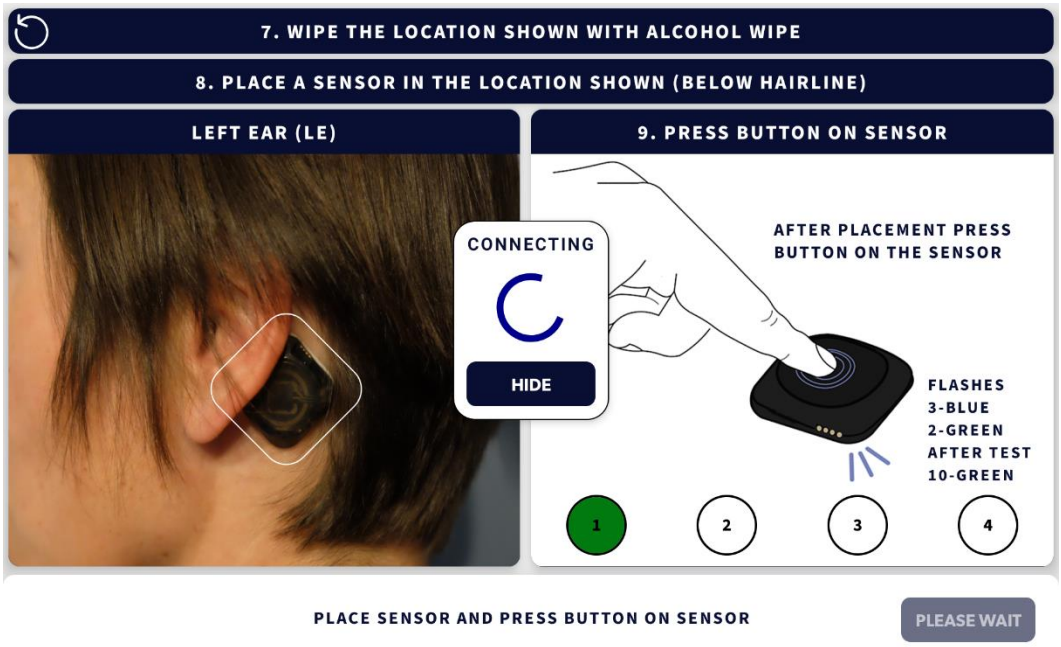
IMPORTANT: Do not activate more than one Sensor at this step. Activating more than one Sensor will bring up the **Multiple Sensors Activated Alert** error screen. If this occurs, the REMI Tablet will ask you to repeat the activation process. See instructions in the **Multiple Sensors Activated Alert** 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. A Sensor may be repositioned on a patient if initial placement is not optimal, but Sticker adhesion should be confirmed following repositioning. If the Sticker is no longer sticky enough, you will need to

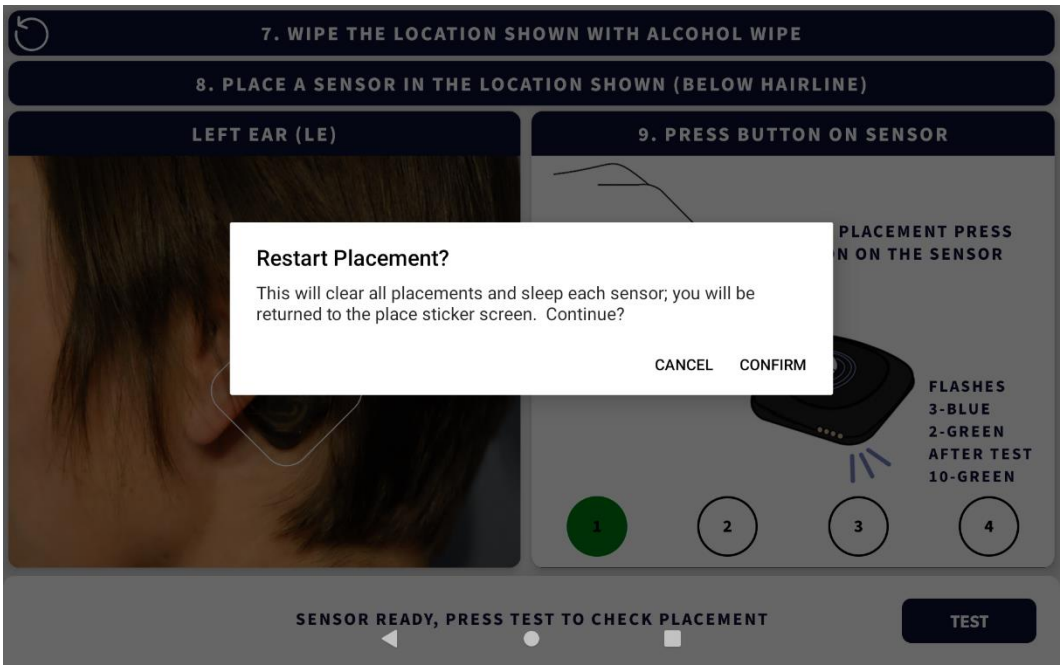
restart **Sensor Placement**.

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.



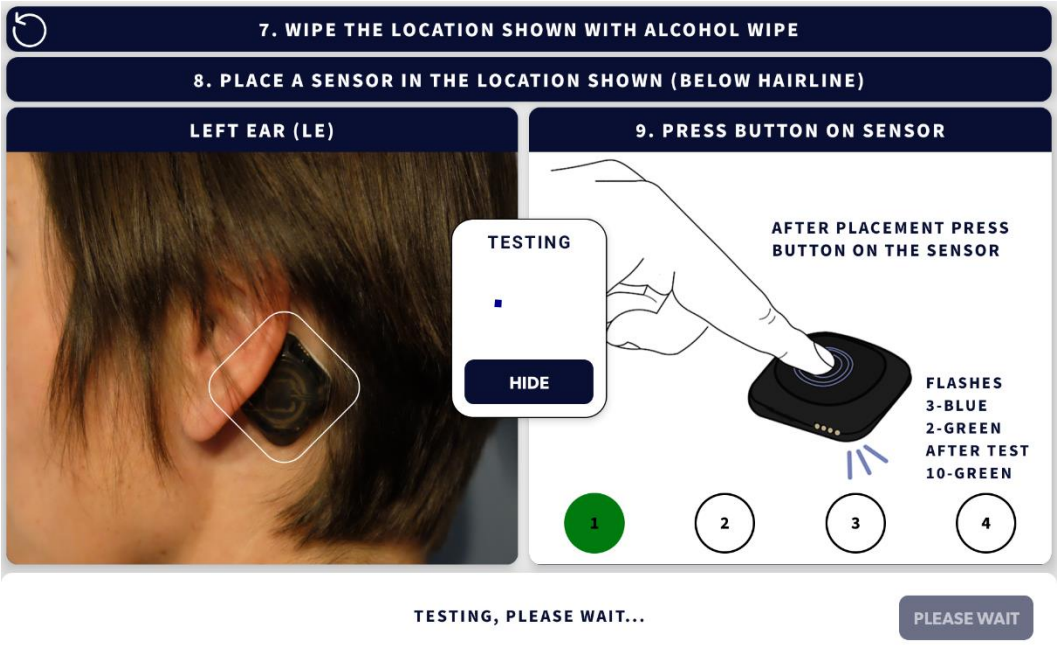
Restart Placement

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 a REMI Sensor has been placed on the scalp and connected, it is now time to test Sensor Electrode Contact Quality (ECQ). 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 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.

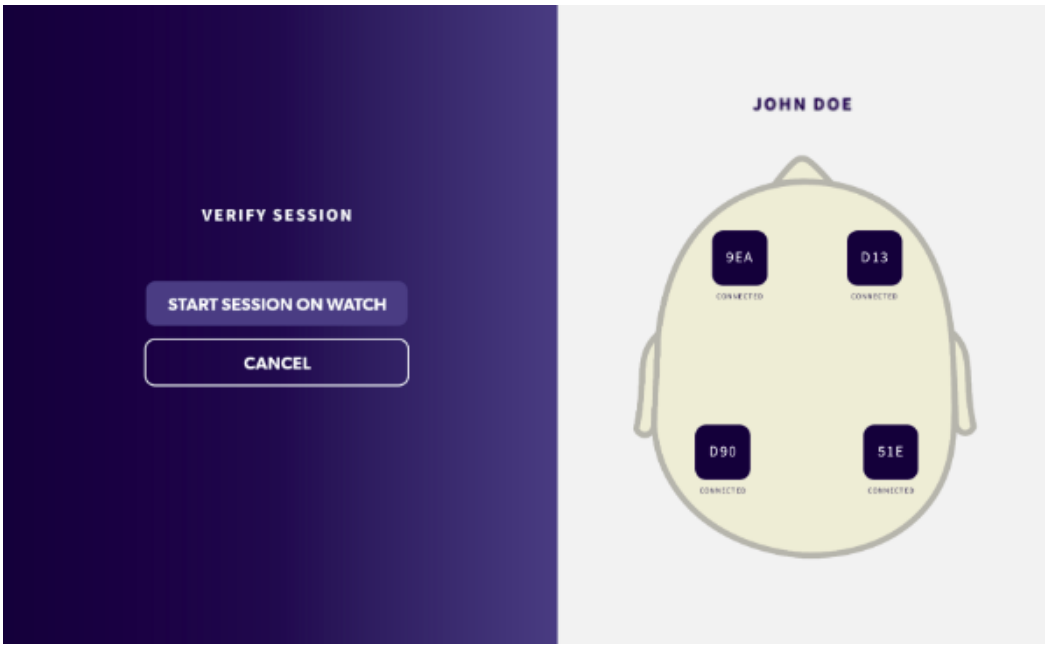
Once all Sensors have synced, the message box will disappear allowing you to proceed to **Session Verification**.

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.



- 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.

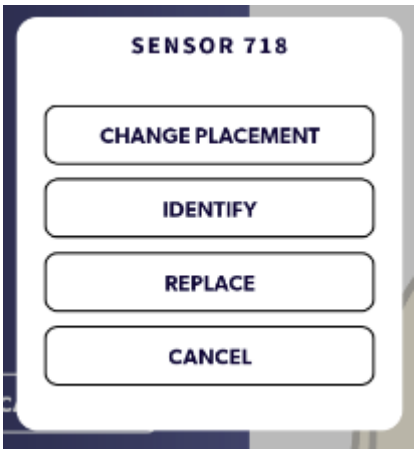
Check to ensure each Sensor is in the correct location on the patient. Each Sensor is depicted by its three-digit alpha-numeric Sensor ID number. If you are unsure of the location, it is possible to “locate” a Sensor by instructing it to flash its LED green. See the **Identify Sensor** section of this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

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.

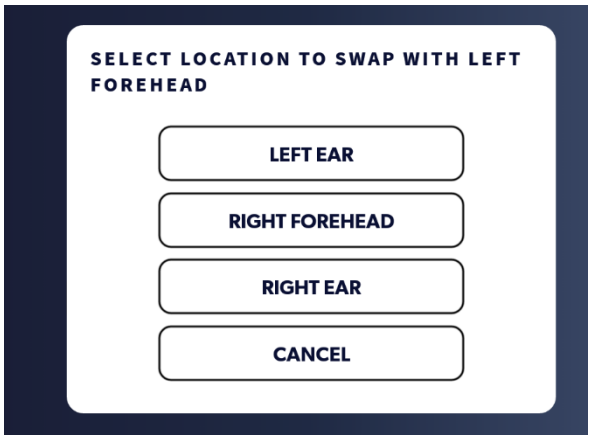
Identify Sensor

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. 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.



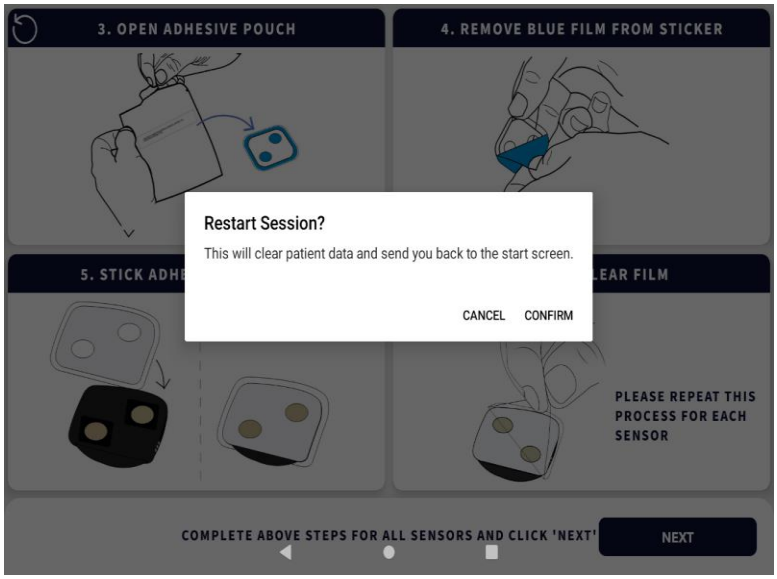
Replace Sensor

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.



REMI Smartwatch Handoff

Prepare REMI Smartwatch for Handoff

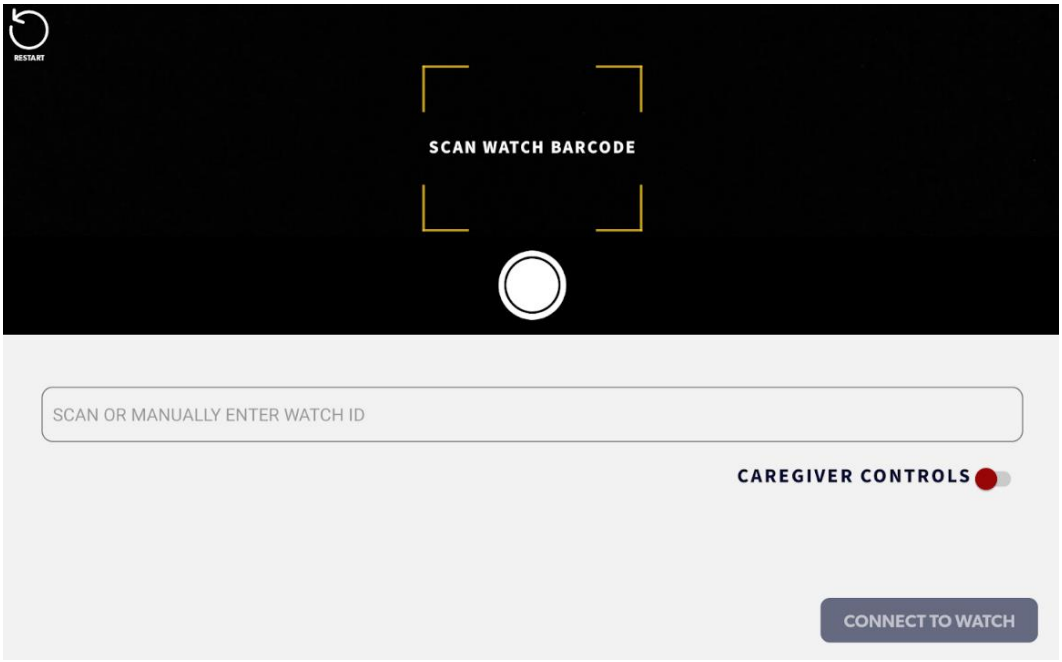
Ensure that the REMI Smartwatch that will be used during the patient's monitoring session is powered on. The watch power can be turned on and off by holding the physical green button on the right side of the watch. The REMI Smartwatch screen will sleep if left inactive for over one minute. To reactivate the screen, press the physical green button on the right side of the watch. If a clock is displayed on the screen, you will need to swipe up from the bottom of the screen to access the onboard REMI Mobile software.

The REMI Smartwatch must be provisioned before it can be used for a recording session. The REMI Smartwart is properly provisioned if the watch face shows a Scan screen containing the Watch ID ((RW#######) and a corresponding QR code. If the Watch ID and QR code are not showing, please refer to the ***Provisioning Smartwatch*** discussion in the **Troubleshooting** section of this manual.

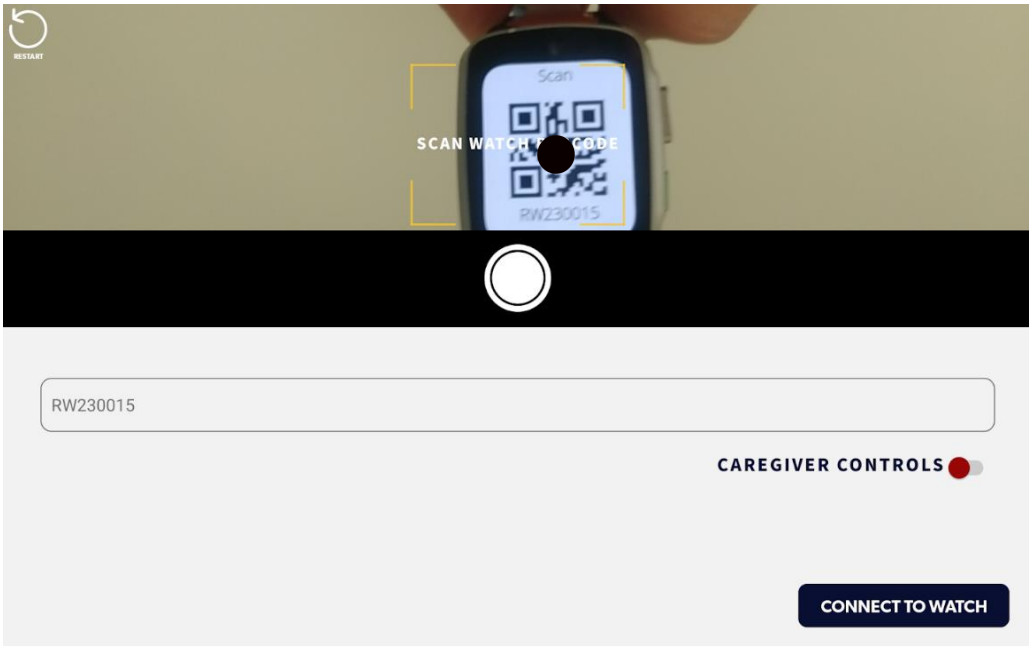
Completing the Handoff

To begin the handoff process to the watch, select the START SESSION ON WATCH button from the Verify Session screen on the REMI Tablet.

After clicking the START SESSION ON WATCH button on the REMI Tablet's Verify Session Screen, the Scan Watch Barcode Screen will appear as shown.



Use the REMI Tablet rear camera to scan the REMI Smartwatch QR Code.

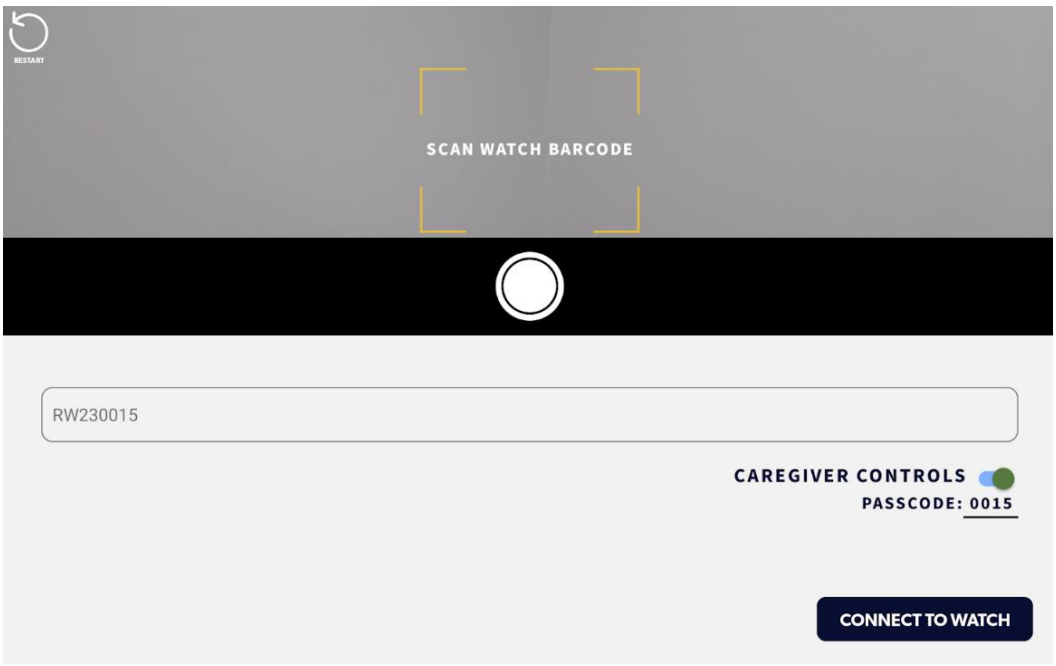


IMPORTANT: Only scan the QR Code of the REMI Smartwatch that will be used for patient monitoring.

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, the QR Code will populate the text field. If the QR Code is not scanning or does not scan correctly, manually enter the Watch ID, located on the REMI

Smartwatch screen directly below the QR Code. Manual entry using the REMI Tablet keyboard is described in the **Acquiring the Barcode** section of this document.

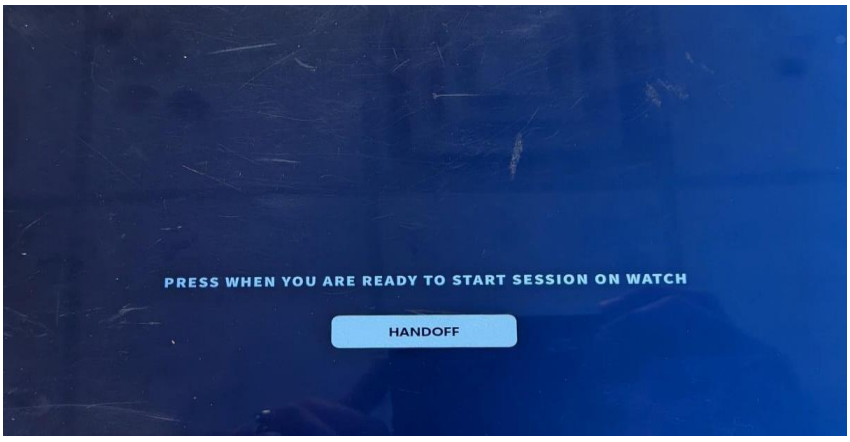
Enabling/Disabling Caregiver Controls
The Caregiver Controls is a feature that enables a caregiver to lock and unlock functionality within the Smartwatch. To enable, toggle the setting to the right. The code to unlock the Caregiver Controls is the last four digits of the Watch ID. The passcode will auto-populate after the watch has been successfully scanned.



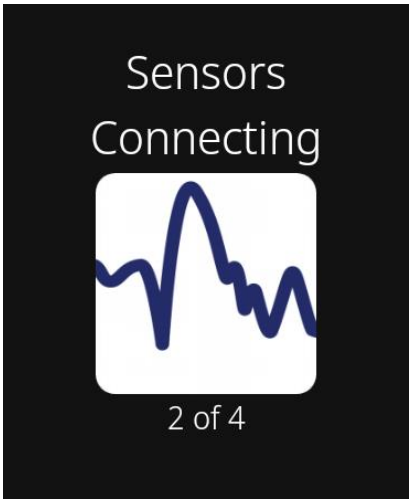
 = Toggle Enabled

 = Toggle Disabled

Click on the CONNECT TO WATCH button on the REMI Tablet to begin the watch provisioning process. After pressing the CONNECT TO WATCH button, the Watch Handoff Screen will appear on the REMI Tablet as shown below. Click on the HANDOFF button to initiate handoff.

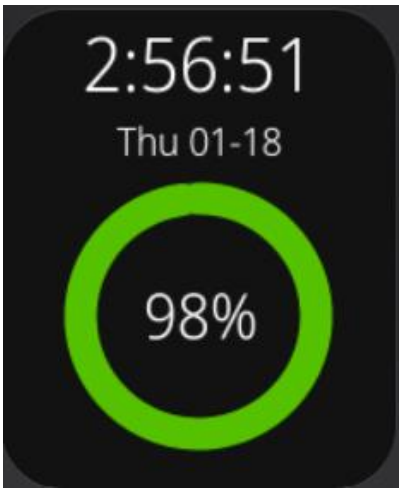


The REMI Smartwatch screen will update with sensor connection status once handoff commences as shown below. The REMI Tablet screen will also show handoff status while handoff is in process as shown below.



IMPORTANT: Try to maintain a distance less than 4m between the REMI Smartwatch, REMI Tablet, and REMI Sensors to ensure successful and timely handoff. It is recommended to minimize the distance as much as possible for the most efficient handoff.

Once handoff is complete, the REMI Smartwatch screen will update to show that a recording has transitioned to the watch as shown below. The screen shows current time, date, and percentage of battery charge. The REMI Tablet screen will also show that the handoff is complete, and that recording has commenced on the REMI Smartwatch as shown below. Press the DONE button on the REMI Tablet screen to restart REMI Mobile software in preparation for a future REMI monitoring session.

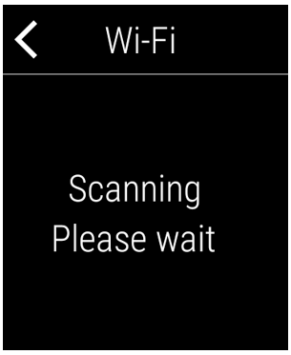



REMI™
REMOTE EEG MONITORING SYSTEM
WATCH IS SUCCESSFULLY PROVISIONED AND IS RECORDING
DONE

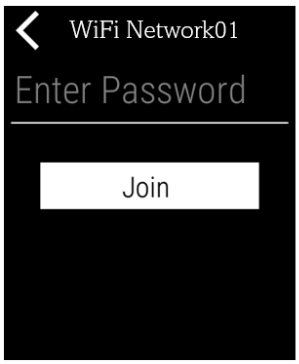
REMI Smartwatch Wi-Fi Setup

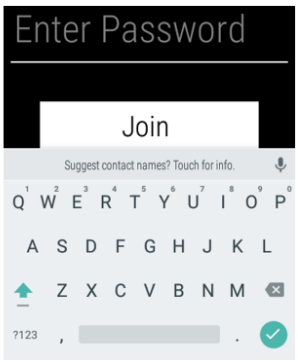
To enable Wi-Fi, swipe RIGHT from the home screen to access the Options menu. Select the WI-FI SETUP icon to access the Wi-Fi setup.

Select the preferred Wi-Fi network. The scanning step may take several minutes as available Wi-Fi Networks might not appear until the network scan is complete. If the incorrect Wi-Fi Network was selected, touch the “<” symbol next to the network name to return to the Wi-Fi network selection screen.



Select ENTER PASSWORD to enable the onscreen keyboard. Enter the network password and click the green > before pressing JOIN. You can select SHOW PASSWORD while entering password to review input if needed.





If the password entered is incorrect, the Smartwatch will give a PASSWORD INCORRECT error message. Once the correct password has been entered, a check mark will appear next to the Wi-Fi name on the Wi-Fi network selection screen.

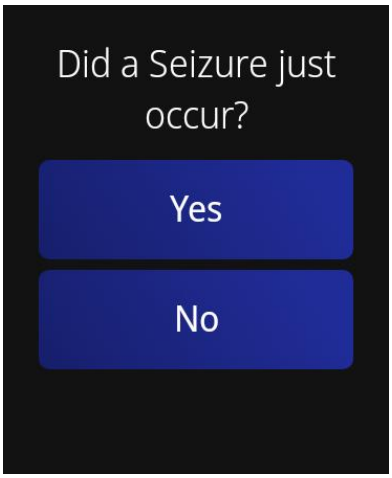
CAUTION: REMI Sensors will record and store data from immediate placement until the end of the prescribed duration, but must be within 10m of the REMI Smartwatch to wirelessly transmit the data. It is recommended that the patient stay within 4m of the REMI Smartwatch for at least 8 hours a day. A suggested use is to set up the charging station near patient sleeping arrangements.

CAUTION: The REMI Smartwatch must be powered on and connected to cellular and/or internet in order to send data via REMI Cloud to the Clinician viewing platform. It is recommended to set up the charging station in an area of reliable connectivity. When able to successfully reconnect to REMI Sensors, the REMI Smartwatch will initiate a data catch-up process at regular intervals, starting with the oldest missed recording data first.

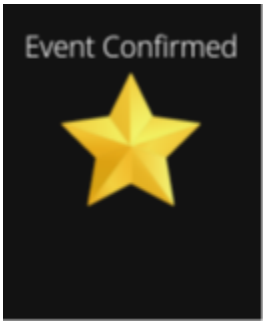
IMPORTANT: The REMI Smartwatch should be connected to Wi-Fi to enable more reliable and consistent connectivity.

Logging a Seizure Event

The REMI Smartwatch is intended to handle a monitoring session throughout the patient's prescribed monitoring duration. The REMI Smartwatch also provides a means to mark a suspected seizure event on the patient's monitoring record. Press the physical silver button on the right side of the REMI Smartwatch to activate the "Did a Seizure Just Occur?" screen as shown below.



Press the NO button on the screen if the screen was unintentionally opened. Press the YES button on the screen if a seizure event may have just occurred. If the YES button is pressed, the Event Confirmed Screen will be displayed momentarily on the REMI Smartwatch.



Double clicking the physical silver button will also log an event without screen interaction.

Sensor Sticker Replacements

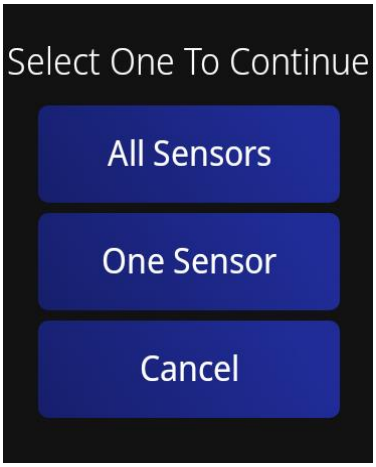
Initiate Sensor Sticker Change

A REMI ambulatory monitoring session is intended to be completed over the course of a prescribed monitoring period. During the monitoring session, REMI Stickers will need to be removed either once daily or at a patient's discretion (e.g., to shower/bathe).

CAUTION: REMI Stickers should be replaced daily and REMI Sensors can only be used for a single patient EEG recording session. Once a recording has ended all active Sensors will no longer be able to connect to the computing platform or record EEG.

To change a Sticker, swipe to the right or to the left on the REMI Smartwatch screen. Swiping will activate the Options Screen as shown. Press the CHANGE STICKERS button to begin a sticker change process.

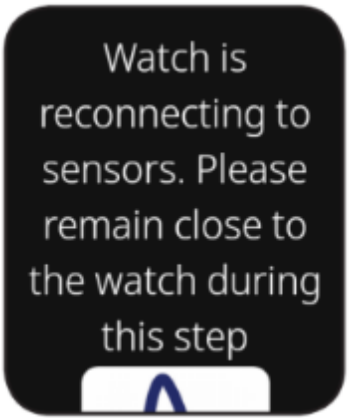
Two options are made available when selecting the CHANGE STICKERS button. Select the ALL SENSORS button to change Stickers on all 4 Sensors or the ONE SENSOR button to change the Sticker on a single Sensor. Once a button has been selected, step by step screens guide you through each Sticker Change process.

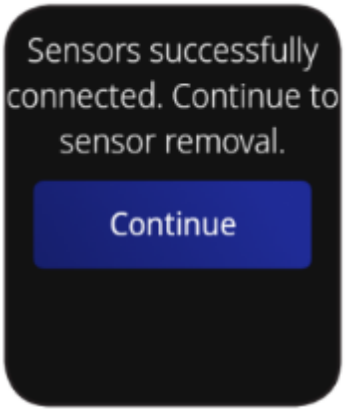


Confirm Sticker Replacement

If you select All Sensors, you will then proceed to a confirmation screen. Select CONTINUE to

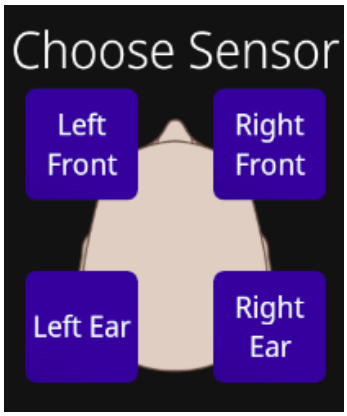
proceed with the All Sensor Sticker Change and the Smartwatch will automatically begin reconnecting to Sensors. Keep your Smartwatch close to your Sensors for the fastest reconnection. Once your Sensors are successfully connected to your Smartwatch, proceed to the next step to remove all Sensors from scalp.

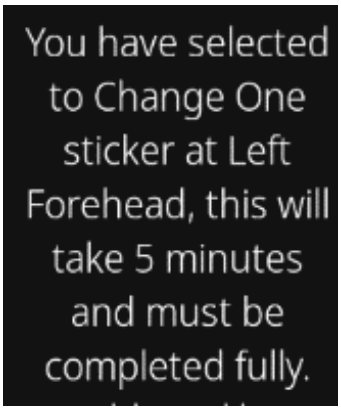




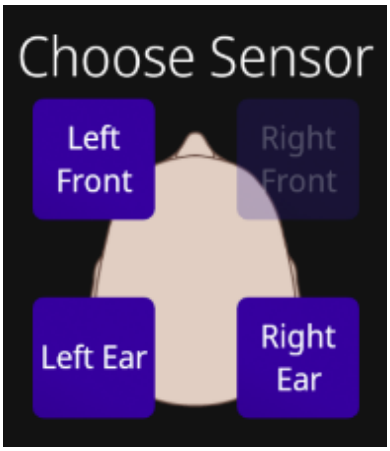
IMPORTANT: Do not remove your Sensors until Sensors have successfully reconnected. Failure to do so may cause damage to your Sensors and can cause issues to the recording.

If you are completing One Sensor Sticker Change, you will first need to select which Sensor's Sticker you are replacing. After selecting, you will be prompted for confirmation to complete the process in full.

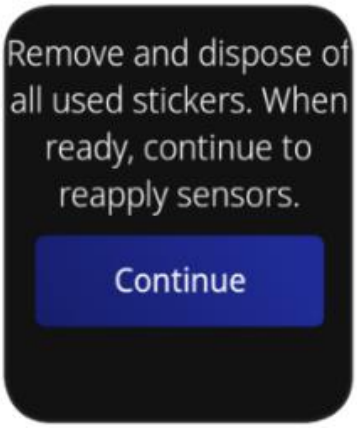




IMPORTANT: If you have lost a Sensor or removed a Sensor from the session at any point, then you will not be able to select that Sensor during this process.

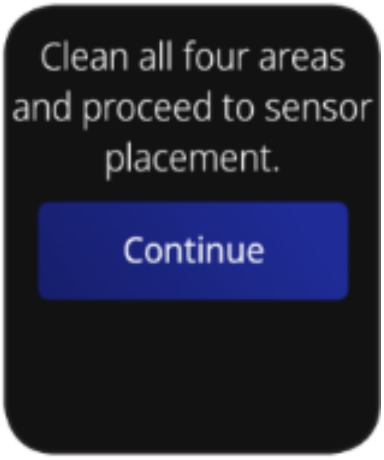


Remove Sensor(s) from Scalp & Dispose of Used Sticker(s)
For an All Sensor Sticker Change, remove all Sensors from your forehead and from behind your ears. For a Single Sticker Change, remove only the selected Sensor. Once removed, select CONTINUE to remove Stickers.



IMPORTANT: If you need to remove Sensors for an extended period of time, initiate an All Sensor Sticker Change and pause after removing Sensors and disposing of used Stickers. The Smartwatch will stay on this screen until you are ready for the next step. It is recommended you keep your Smartwatch on the charger if you plan to be gone for longer than 30 minutes.

Clean Scalp
When you are ready to continue with Sensor placement, prepare the Sensor location(s) on your scalp with the provided alcohol wipe(s) (i.e., the same location(s) where the Sensors previously positioned on your scalp).

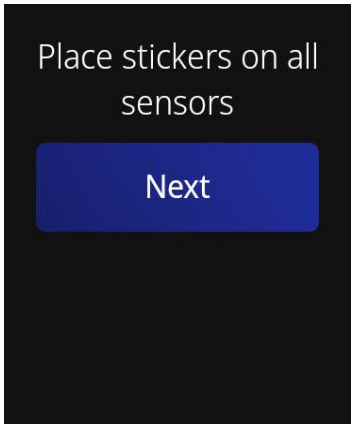


CAUTION: Do not place the Sensor over hair. The REMI Sensor is meant to be used below the hairline. Placing the Sensor over hair may result in improper attachment to the scalp that may affect performance.

For an All Sensor Sticker Change, prepare the locations on your forehead and behind your ears. For a Single Sticker Change, prepare only the selected location. Once all affected scalp locations are prepared, select CONTINUE.

Place New Stickers on Sensors

You will then be instructed to PLACE STICKERS ON (ALL) SENSOR(S). REMI Sensors attach to the scalp with a one-piece conductive-adhesive Sticker.



For an All Sensor Sticker Change, apply new Stickers to all four Sensors. For a Single Sticker Change, apply a new Sticker to only the selected Sensor.

- Open a Sticker package and remove the Sticker.
- 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.

When applying Stickers to Sensors, follow the next guide (ensuring that you removing the blue liner when applying the Sticker to the Sensor).:

CAUTION: 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.

Select NEXT after Sticker(s) have been placed on all selected Sensor(s).

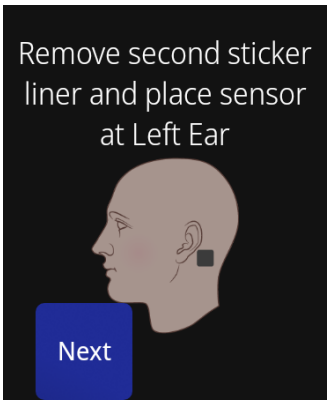
Identify Sensor for Placement

For an All Sensor Sticker Change, press the button on any Sensor to identify the Sensor and determine its scalp placement location. Then select NEXT and wait for the Sensor to respond. This step does not apply to aSingle Sticker Change.

Remove Second Liner and Place Sensor

You will then be prompted to remove the second Sticker liner and place the Sensor in the specified location. Remove the liner per the next guide:

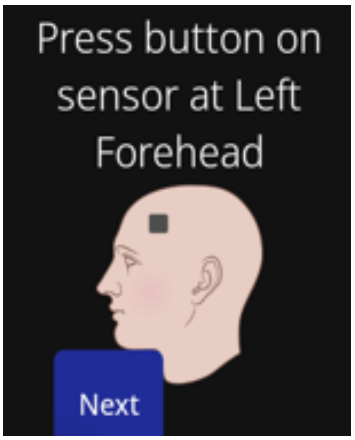
The message will also inform you of the location for the Sensor and display an image of that location. Place the Sensor at the location instructed on the Smartwatch. After you are satisfied with the placement of the Sensor, select NEXT to continue.



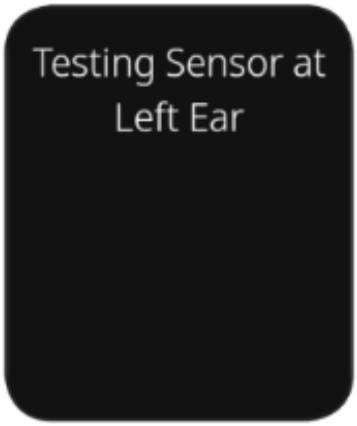
Note: In this example, the Sticker is for LEFT EAR. This same set of instructions will be provided for each Sensor as it is placed on the scalp during an All Sensor Sticker Change.

Activate Sensor after Placement

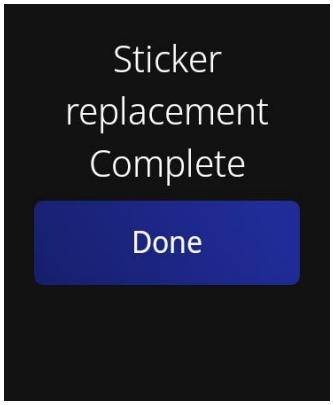
After placement on the scalp, press the button on the Sensor again, then select NEXT.



Allow time for the Smartwatch to reconnect to the Sensor. The Sensor and Smartwatch will then start to connect automatically. The next screens will progress without interaction. Wait while the Smartwatch screen displays the following two screens.

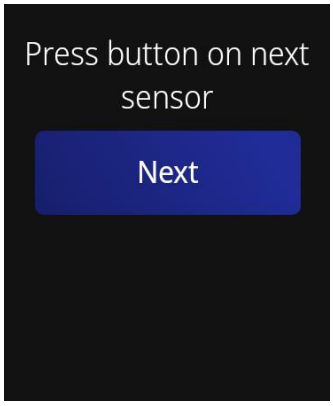


The system will alert you if the Sensor has poor contact, and you will be prompted to check placement, replace the Sticker, and retest that Sensor. If completing a Single Sensor Sticker Change, the process is complete once this Electrode Contact Quality (ECQ) test is successful. Select DONE and you will be returned to the “IN SESSION” screen.

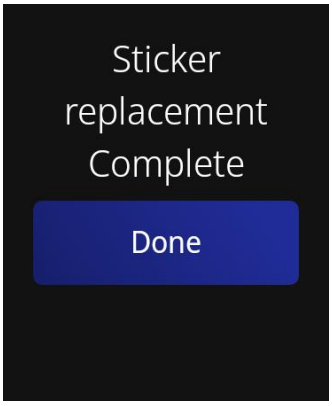


If completing an All Sensor Sticker Change, the process will continue following successful ECQ testing. The Smartwatch will guide you through the second Sensor application and testing by

requesting you to PRESS BUTTON ON NEXT SENSOR. Follow the screens until all Sensors have been replaced.



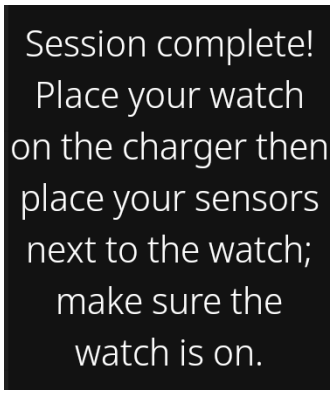
Once the final Sensor has been placed, the Smartwatch will send a final sync message to ensure quality of recording. During this step, it is important that you stay next to your Smartwatch. The sync process is complete when the screen displays the message STICKER REPLACEMENT COMPLETE. Select DONE and you will be returned to the “IN SESSION” screen.



End of Session Process

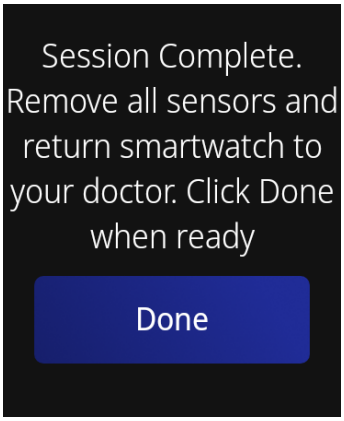
After your prescribed session length, the Smartwatch will initiate its end-of-session activities. The Smartwatch will notify you of the session completion, instructing you to keep the Smartwatch turned on and charging, and to store the Sensors next to the Smartwatch.

The system is in its final processing stage. Avoid interacting with the Smartwatch or Sensors, and be advised that this process may take up to 5 days.



CAUTION: DO NOT DISPOSE OF THE SENSORS. Ensure the Smartwatch stays connected and powered on during the end-of-session screen.

After final processing has completed, you will receive a final SESSION COMPLETE message. Please power down the Smartwatch and return it along with all Sensors to your clinician or their prescribed destination at your earliest convenience.



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 Smartwatch or record EEG.

IMPORTANT: You may be prompted to replace a sensor sticker during the duration of wearing the sensors. Follow the guided instruction to remove sensors and replace stickers. At prescribed intervals, normally every 24 hours, the watch will automatically request that “All Stickers” be changed. While this may be delayed, it is advised that stickers be replaced at these 24 hour intervals.

IMPORTANT: Ending a recording will permanently disable REMI Sensors. After ending a

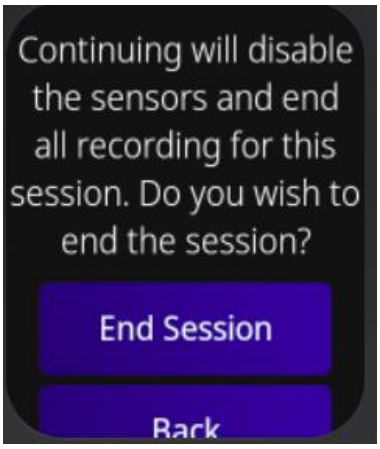
recording, the Sensors connected to the REMI Smartwatch will no longer be able to record or connect to the REMI Smartwatch.

End Session Before Prescribed Duration Complete
If you need to end a session on the watch earlier than the prescribed duration, you can do so using the “End Session” functionality within the application. Access the Options Menu, and select “End Session” from the list of actions.

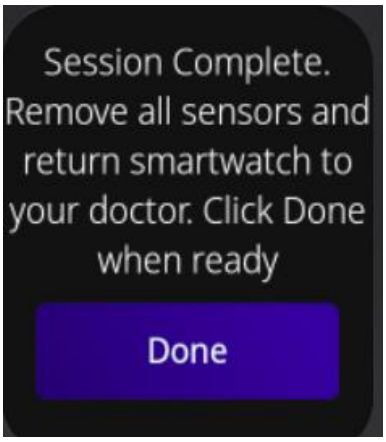
After selecting “End Session”, you will be prompted to provide a passcode. The passcode for this functionality is the same across all REMI Smartwatches: 7364 (REMI).

If you mistype the passcode, the device will inform you and allow you unlimited attempts to correctly enter the passcode. Selecting the <- back arrow will take you back to the Options Menu.

After successfully entering the correct passcode, you will be prompted with a confirmation to end the session ahead of the prescribed duration.



“Back” returns you to the Options Menu. “End Session” will disable the sensors and end the recording for the session.

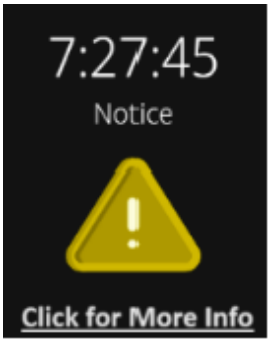


IMPORTANT: If you choose to end the session early, the sensors will no longer record EEG data and the Smartwatch will no longer pull any missing data from the sensors. This functionality is only recommended if a fully recorded session is no longer necessary.

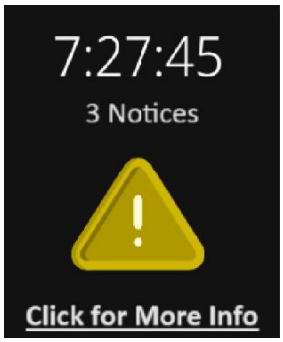
REMI Mobile Warning Alerts

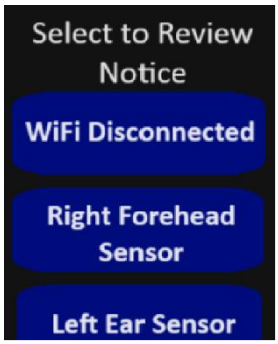
Notice of Open Warning Alerts

If the system experiences any system notifications, you will be alerted through the REMI Mobile user interface as shown below. Selecting the screen takes you to information on the warning alert that triggered the notices.

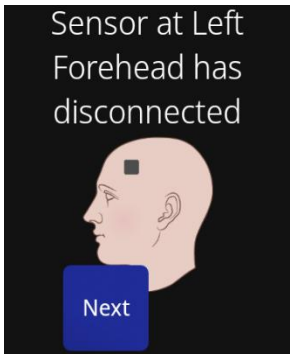


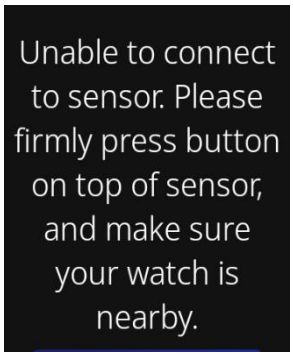
In the case of multiple notices at once, you will be informed of the count of open notices and review all open notices at the moment. Selecting the screen takes you to a summary of all open notices. From there, you can navigate to the details of each individual alert.

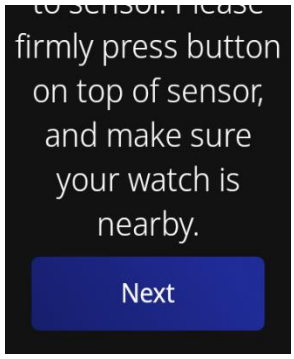




Sensor Disconnect – During Sticker Change





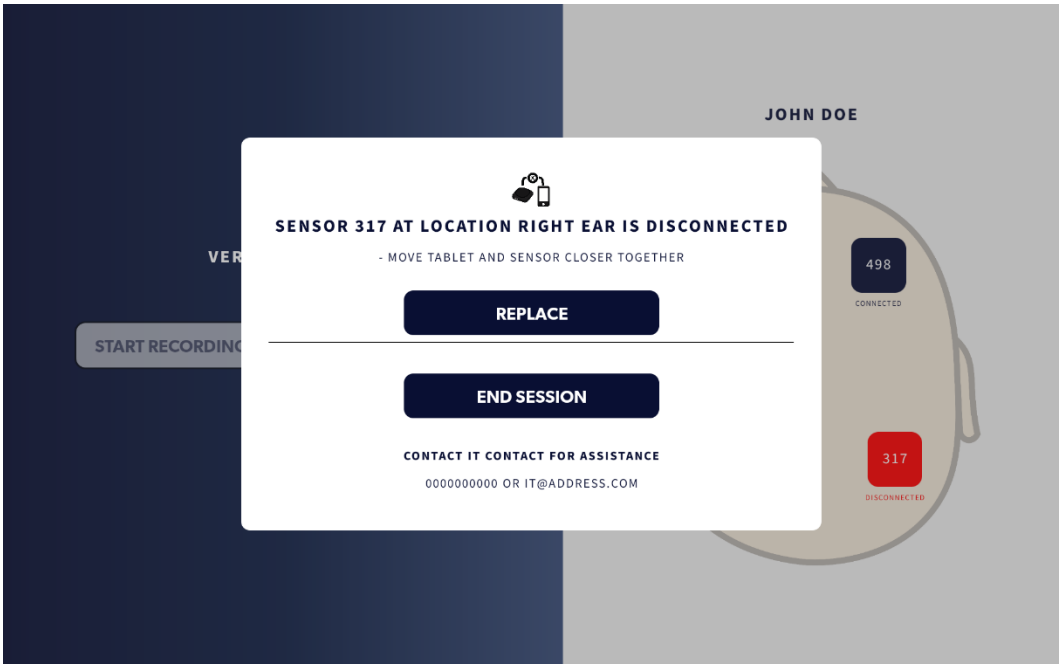


During a Sensor Sticker Change, a Sensor may have difficulty reconnecting with the Smartwatch. This may occur during the Sensor Placement and Time Sync steps. Consider moving the REMI Smartwatch closer to a disconnected Sensor to facilitate reconnection before completing the in-app troubleshooting.

If the Sensor is unable to reestablish connection, the in-app workflow will remove the Sensor

from the recording. The overall recording will continue with the remaining connected Sensors, but you will not be able to use that Sensor again. Set the disconnected Sensor aside until the end of your session and return it with your Smartwatch and all other Sensors.

Sensor Disconnect – Prior to Handoff

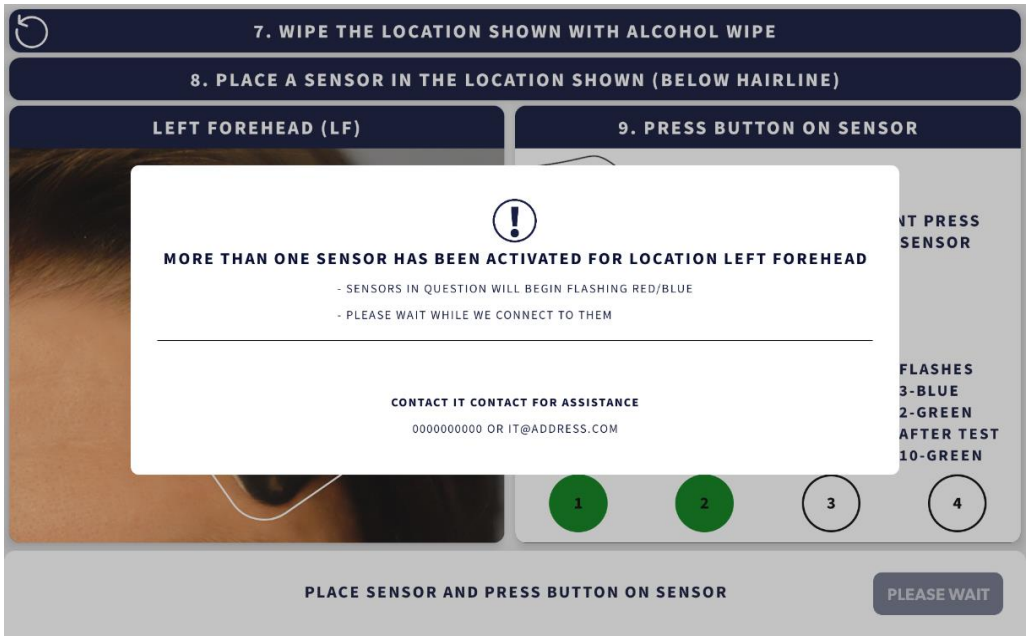


A REMI Sensor may disconnect from the REMI Tablet before an active recording begins. The alert screen will appear with the options to replace the Sensor that has disconnected or end the session, as shown. To replace the Sensor, click REPLACE (sensor ID) and then CONFIRM. This will direct you back to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

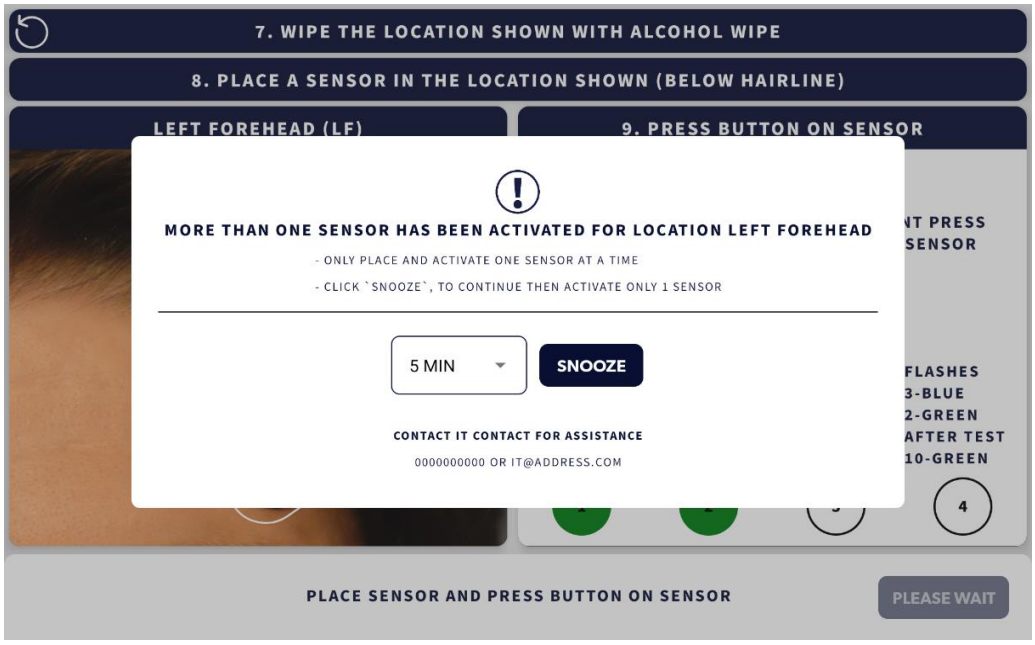
CAUTION: REMI Sensor wireless range is a maximum of 10m, and it is recommended that the computing platform be kept within 4m of the patient to ensure a good BLE connection between the Sensors and the computing platform.

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 on the REMI Tablet

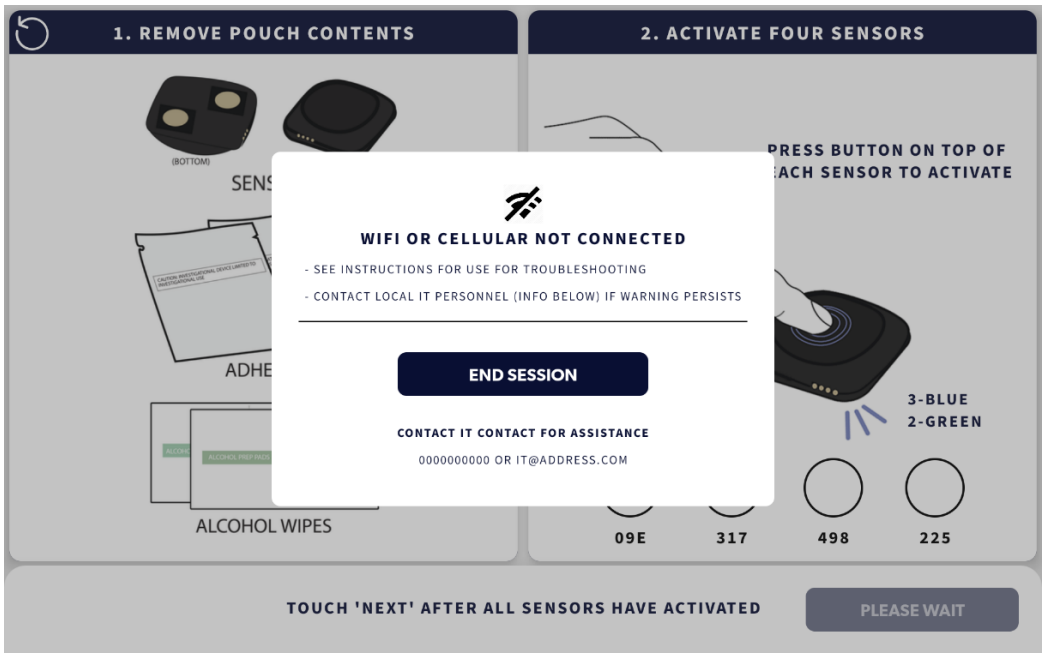


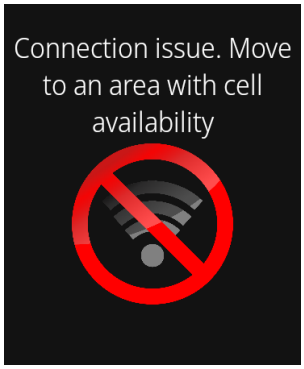
The Multiple Sensors Activated Alert Warning will appear if you activate more than one Sensor while placing Sensors on the scalp during the Sensor Placement procedure. The REMI Tablet will automatically turn off the conflicting activated Sensors and ask you to repeat the current placement. The SNOOZE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





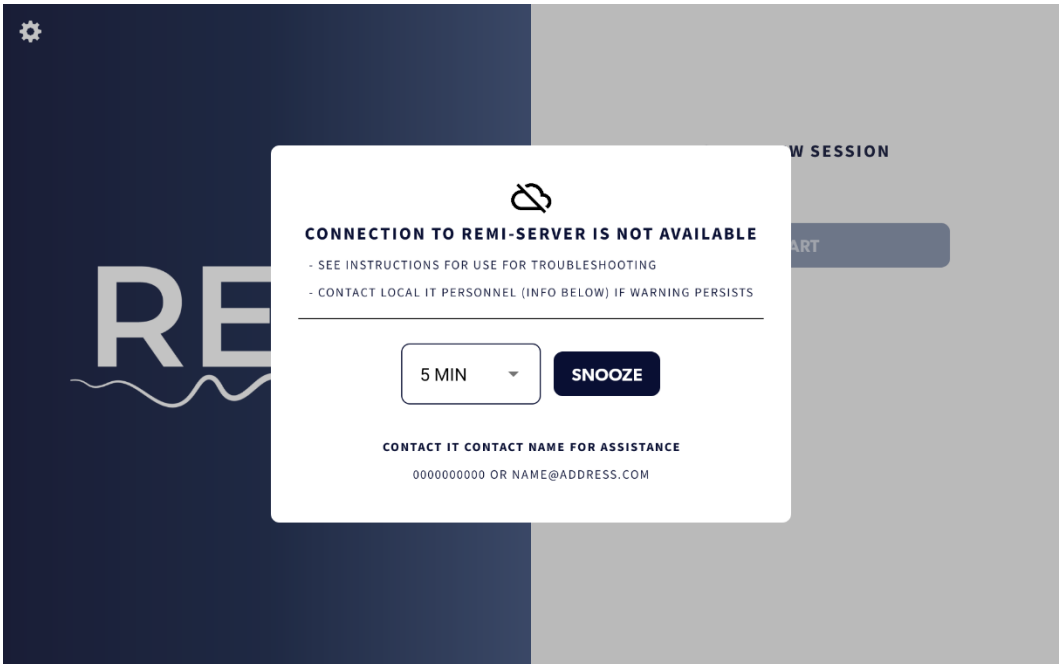
REMI Mobile must be connected via Wi-Fi or cellular to transmit EEG data to the REMI Cloud. Ensuring good connectivity will ensure EEG data is available for clinician review. Should the computing platform lose connectivity, an alert screen will appear, and all REMI Sensors will begin to flash their LEDs alternating red and blue. Note, you may need to move the computing platform to a different location if REMI Mobile continues to lose connectivity. Should the computing platform reconnect to Wi-Fi or cellular, the alert screen will automatically disappear.

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

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

IMPORTANT: The REMI Tablet 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 on the REMI Tablet

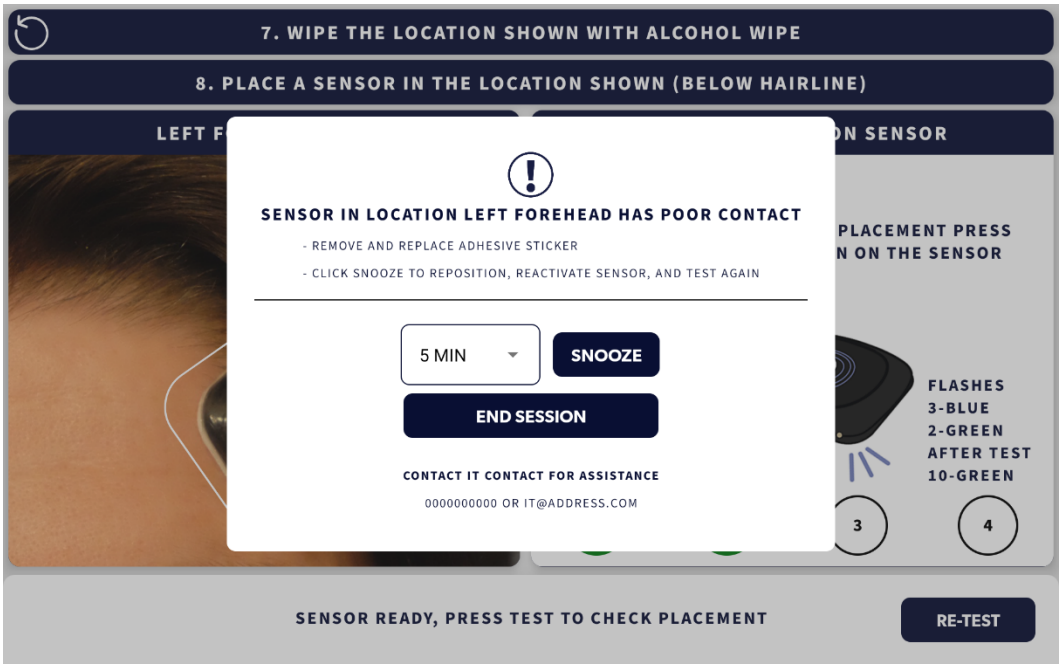


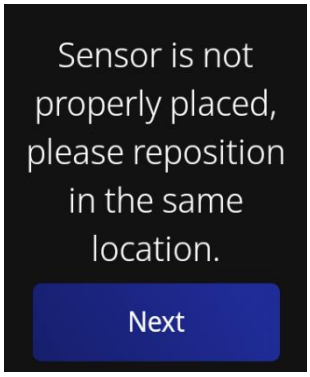
The REMI Cloud Server must be functioning for the REMI System to function properly. Should the REMI Cloud Server have an error, an alert screen will appear, as shown, and all REMI Sensors will begin to flash their LEDs alternating red and blue. Should the error end, the alert screen will automatically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

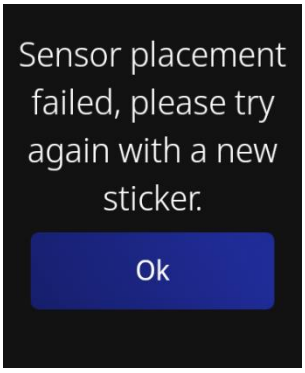
IMPORTANT: You will not be able to proceed through the Initialization process until the REMI Cloud Server Error is discontinued if the error occurs before a recording has started.

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 a Poor ECQ message box appears, 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.

On REMI Tablet, 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: During initial placement on the tablet, 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.

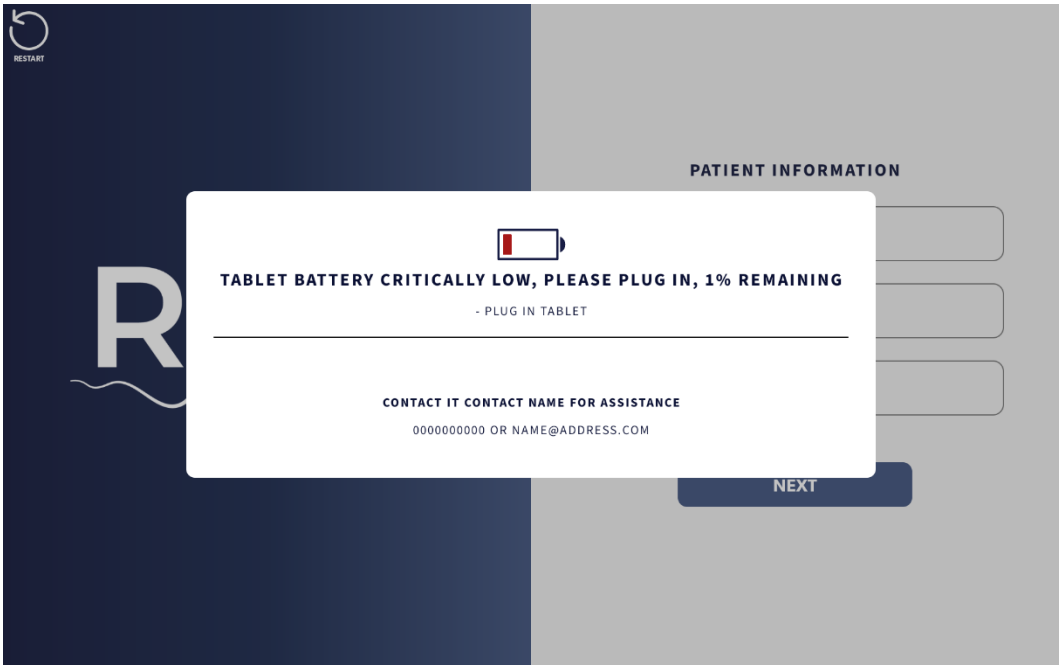
IMPORTANT: During an active session on the Smartwatch, a user will be informed if poor ECQ occurs. The Smartwatch will prompt the user to start a Single Sensor Sticker Change on the impacted Sensor. If poor ECQ is detected during the sensor sticker change, the Sensor and Sticker ECQ can be re-tested. If ECQ is not resolved through these initial tests, the user will be prompted to replace the Sticker one more time. If poor ECQ continues after this troubleshooting, the Sensor will be deemed not fit for use and will be removed from the session.

Low Battery

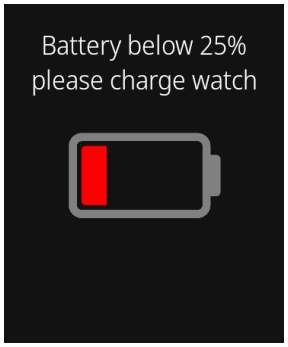
It is recommended that the REMI Tablet be plugged into A/C power at all times. Should the battery reach 50% capacity or less and is not plugged into A/C power, an alert screen will appear. All REMI Sensors will begin to flash their LEDs alternating red and blue. If REMI Tablet battery power is above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

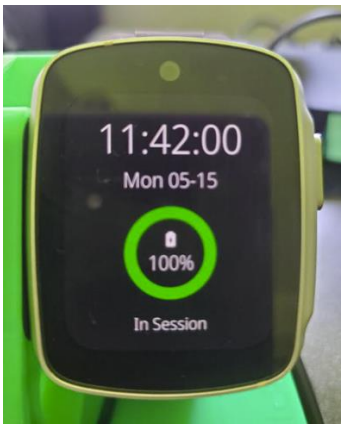
IMPORTANT: The alert screen will have the information of the IT person to contact at your institution including name, phone number, and email address. Contact IT if this alert persists.



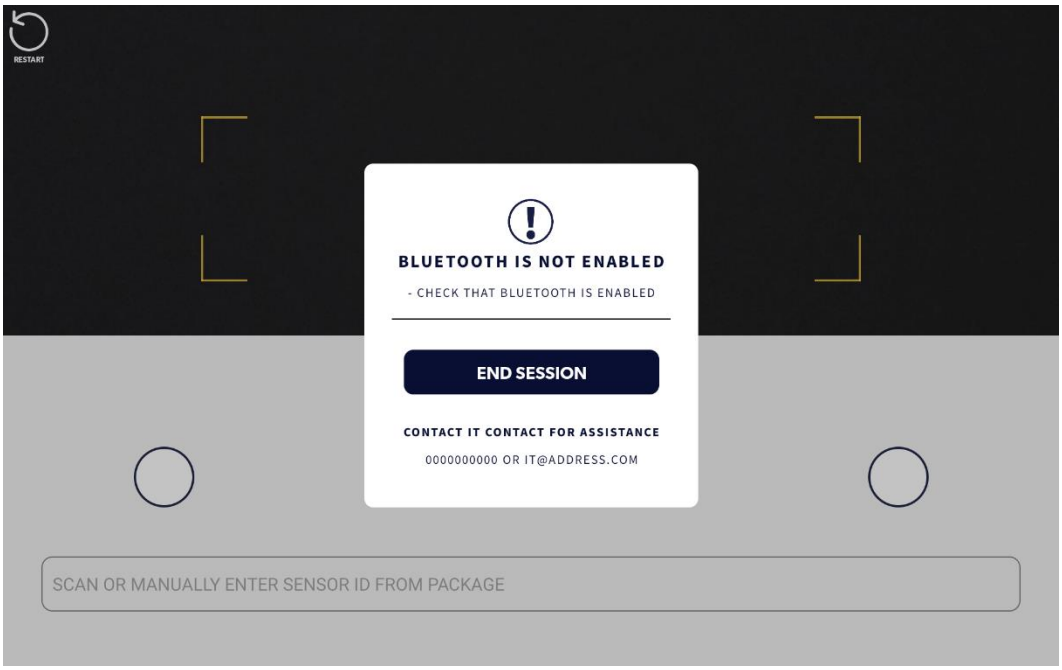
For optimal performance, the REMI Smartwatch is recommended to be plugged in when possible. The REMI Smartwatch will also operate on battery power. Once the Smartwatch battery drops below 25% capacity an alert will pop up on the REMI Mobile application.



IMPORTANT: The REMI Smartwatch operates most efficiently when properly charged. To confirm that the device is properly connected to the charger, the Smartwatch screen will show a charging status.

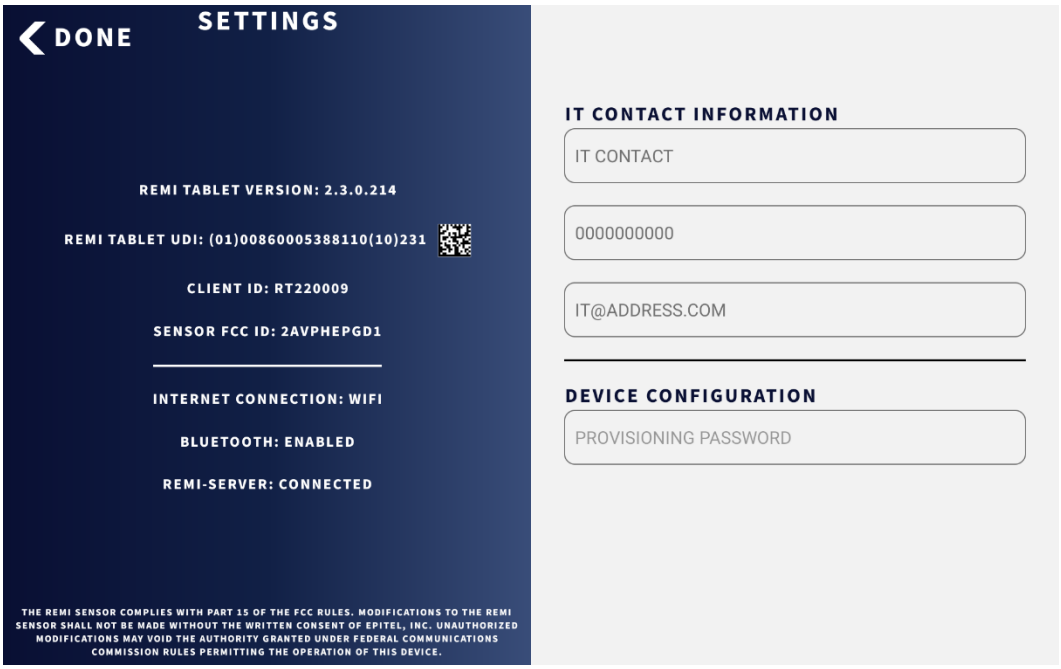

11:42:00
Mon 05-15
100%
In Session

Bluetooth Error on REMI Tablet



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.

REMI Tablet 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.

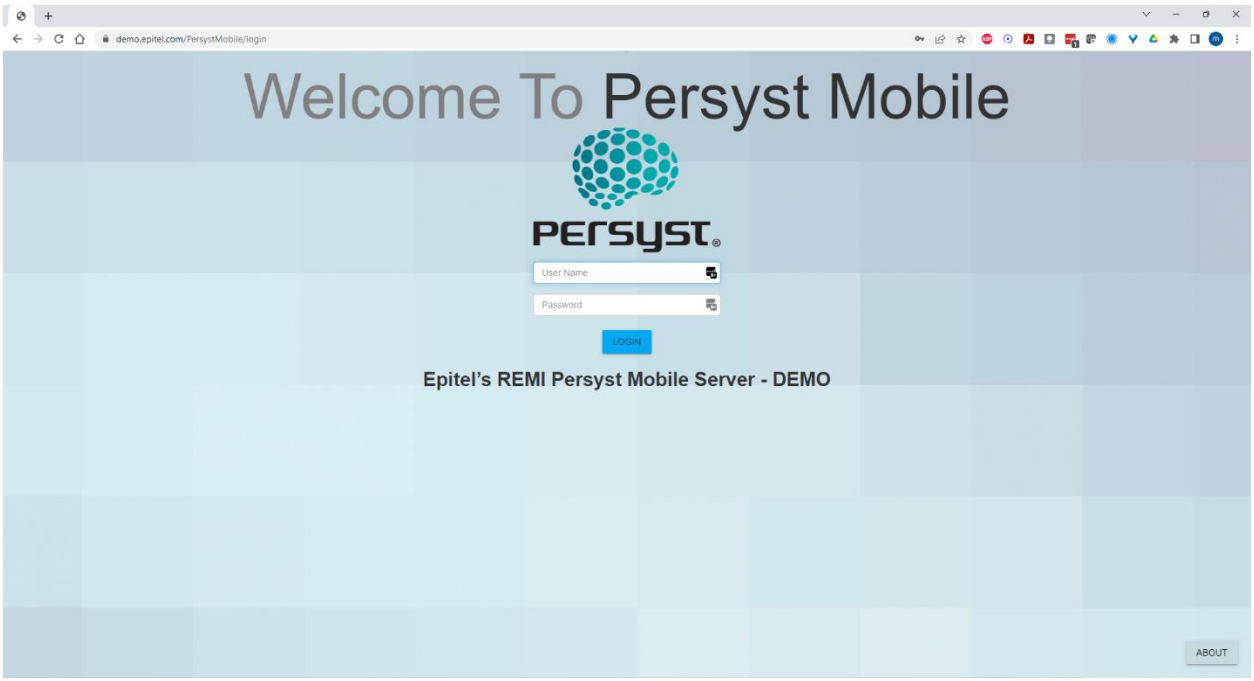
Accessing Session Diagnostic Information for Customer Support

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 within the Options menu. Swipe RIGHT from the home screen to access the Options menu, then scroll to the bottom of the menu to view Additional Info, where the Watch ID, REMI Mobile software version number, and Session ID are provided.

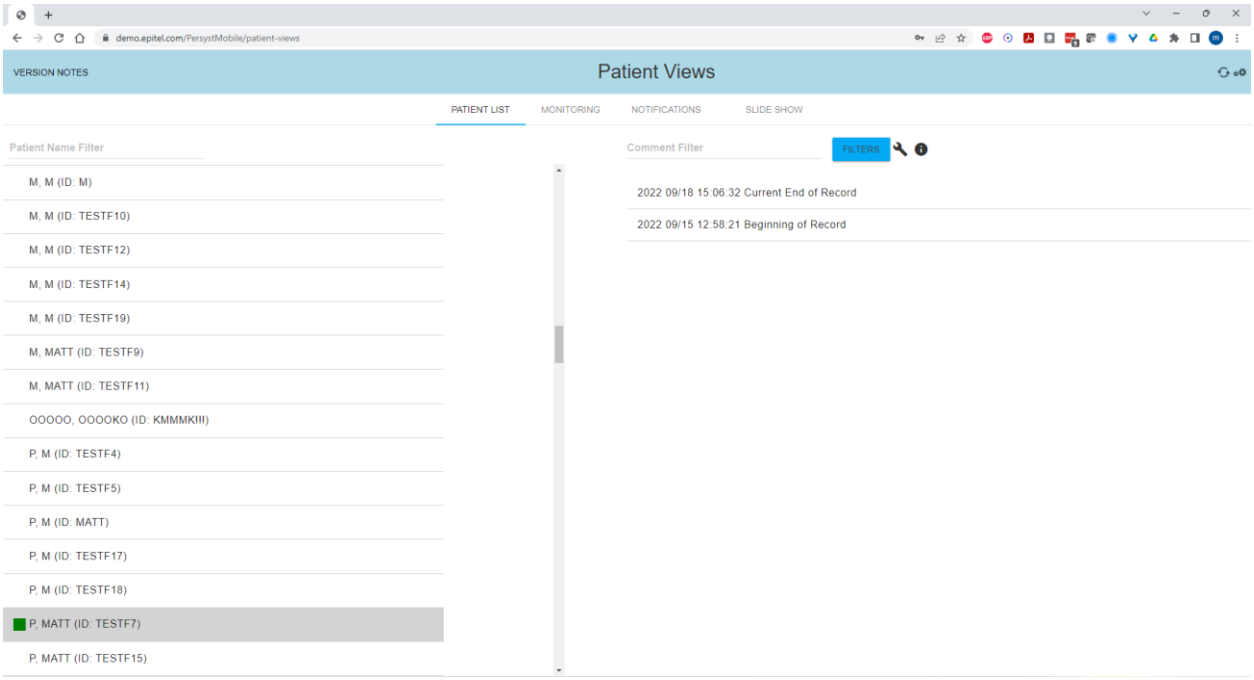
Hiding the Options menu can be done by clicking the BACK button.

Persyst™ Mobile for EEG Review

REMI has been qualified for use with 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. 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 following image. 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. 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 the patient – In the case that a Sensor has fallen off of the scalp after a recording session has started, the user should initiate a Single Sticker Change as described in the **Single Sticker Replacements** section of this manual.

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. 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 to run on battery power. We recommend keeping the REMI Tablet plugged in to A/C power during use and while in storage.

REMI Smartwatch is unresponsive – Attempt to restart the Smartwatch by pressing and holding the physical green button on the right side of the watch. 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 Smartwatch becomes unresponsive during an active recording, it will restart, reconnect with all REMI Sensors, and continue recording. If the Smartwatch continues to be unresponsive, please contact Epitel Customer Support.

The REMI Smartwatch will not boot – Ensure the Smartwatch is plugged in to A/C power before trying to boot the Smartwatch. It may be that the battery has drained and needs time to recharge to run on battery power. If the Smartwatch continues to be unable to boot, please contact Epitel Customer Support.

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

The REMI Sensor barcode will not scan – Barcodes 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 Sensor 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 Smartwatch QR code will not scan – If the QR code is difficult to scan, we recommend manually entering the REMI Smartwatch ID using the REMI Tablet touchpad keyboard. See the **REMI System Used in Ambulatory Settings** section of this manual.

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. A Sensor may be repositioned on a patient if initial placement is not optimal, but Sticker adhesion should be confirmed following repositioning. If the Sticker is no longer sticky enough, you will need to restart **Sensor Placement**.

The REMI Smartwatch displays a yellow triangle with an exclamation mark – A yellow triangle with an exclamation mark indicates an error within the recording device. Swipe from right to left and follow the in-app instructions to resolve the error.

Before Handoff, the Smartwatch does not display a Watch ID and QR Code – If a QR is not showing on the watch screen, the Smartwatch may not be properly provisioned. You may see a camera screen or a prompt to allow for accessibility. If the Smartwatch is requesting camera access, select the “Accept” button and then the watch camera will be activated. You can then provision the Smartwatch by using the camera on the top of the watch face to scan the QR code in the watch packaging as shown below.

EMC Compliance

The 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 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

FCC ID: 2AVPHEPGD1
REMI Tablet FCC ID: 2AJZP-G450A1
REMI Watch FCC ID: 2AJZP-A4100

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 computing platform t be kept within 4m of the patient to ensure a good wireless connection between the Sensors and the computing platform. The REMI Mobile software will alert the user if there are disconnection issues (see **REMI Mobile Warning Alerts** section). If this occurs, bring the computing platform 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 computing platform 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 or home Wi-Fi connection and/or a cellular connection for wireless communication between the REMI Mobile and the REMI Cloud platform.

- REMI Tablet connectivity will be set up and tested initially by the hospital administration IT department alongside Epitel staff.
- REMI Smartwatch communicates natively via cellular connection and can be configured 1) by hospital administration IT department alongside Epitel staff to connect to hospital Wi-Fi and 2) by the patient / caregiver to communicate via a home Wi-Fi network.

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 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 Wi-Fi network and/or a cellular network.

- All REMI Tablet 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.
- REMI Smartwatch communicates natively via cellular connection and can be configured by the patient / caregiver to communicate via a Wi-Fi network.

If a problem occurs with the wireless communication between a qualified computing platform, the REMI Mobile software will alert the user (see **REMI Mobile Warning Alerts** section). REMI Mobile only operates on dedicated qualified computing platforms. Only REMI Mobile is accessible to the platform user, and no attempt should be made to access and install any other software or alter any system-level settings on the computing platform.

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 and REMI Smartwatch Service and Repair

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

REMI Mobile Updates

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. Following notification and coordination, REMI Mobile application updates will be deployed by Epitel.

Sensor Specifications

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), 10 to 95% relative humidity (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 their 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.

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
REMI Smartwatch	Wear OS 3.0 or higher

Product Cleaning

The REMI Tablet and REMI Smartwatch 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 gases. Cleaning of REMI Tablet and REMI Smartwatch should be done between each patient 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 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

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

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 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

<table>
<tr><th colspan="4">Declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">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</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Electrostatic discharge (ESD) IEC 61000-4-2</td><td>± 8 kV contact
± 15 kV air</td><td>± 8 kV contact
± 15 kV air</td><td>Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</td><td>30 A/m</td><td>30 A/m</td><td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial magnetic field or hospital environment</td></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>Not applicable</td><td>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 √ P</td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>d = 1,2 √ P 80 MHz to 800 MHz

d = 2,3 √ 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</td></tr>
</table>

Declaration – electromagnetic immunity			
			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 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 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 the computing platform 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 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 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

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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