



Product Overview

The REVIAN RED System is to be used in male and female patients with androgenetic alopecia in ages 18 and above. It is a non-invasive, hands-free, over-the counter medical device operated via mobile app to promote hair growth. REVIAN RED is intended for a daily 10-minute treatment. A treatment can be paused after it is initiated, the remaining treatment time must be used prior to the initiation of another treatment.

Indications for Use: REVIAN RED is indicated to treat androgenetic alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss; and to treat androgenetic alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2, or frontal patterns of hair loss, both with Fitzpatrick Skin Types I - IV.

Contraindications for Use: REVIAN RED has no known contraindications.

REVIAN[®] RED SYSTEM

Model: REVIAN 101
Part Number: 10000-10001

Instructions for Use

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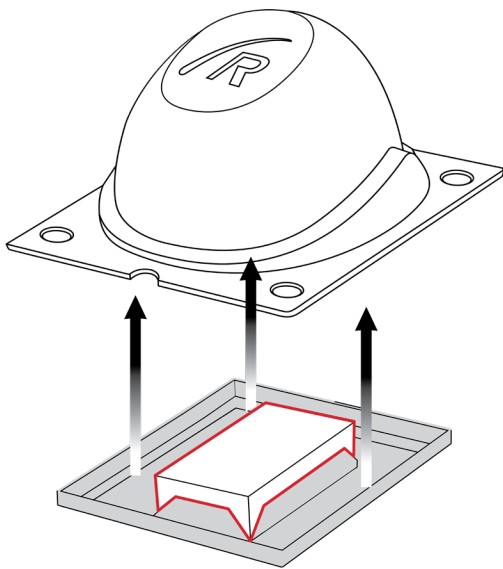


Product Contents



CAUTION: DO NOT cut through the protective storage box to avoid any damage to the device.

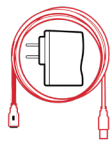
1. Carefully cut the tape covering the shipping box to not damage the storage box inside.
2. Remove the storage box from the shipping box.
 - Cut the tape dots located on the sides of the storage box.
3. Open the one seal on the storage box to reveal the Cap and support base.
4. Lift the support base to reveal the accessory kit.



Accessory Kit:



3 Back Adjustment Headliners



AC Adaptor with USB-to-Magnetic Cable

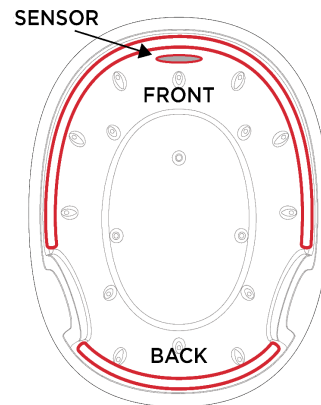


Travel Bag

5. Remove the accessory kit and carefully read the Quick Start Guide on the box lid or in the app manual.
6. Remove the accessories contained inside the accessory kit:
 - USB-to-Magnetic Micro-USB cable
 - Travel Bag
 - AC Adaptor
 - Adjustment Headliners
7. Charge the Cap for at least one hour prior to use with the AC adaptor and magnetic micro-USB cable.

Adjusting the Cap

The Cap comes with front standard and back 10mm headliners installed as illustrated below. The Cap should not be loose enough that it falls off the head with ease, nor should it fit too tightly. A proper fitting Cap is an important step for a reliable treatment.



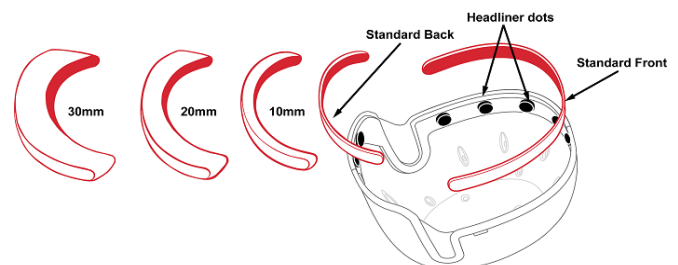
NOTE: Light emitting area (emission aperture) shown above. Applied Part.

To Adjust Headliners:

1. A sensor detects when the Cap is on the head and close to your forehead. If the Cap needs adjustment, remove the 10mm back headliner from the headliner dots. If loose, replace with the optional 20 or 30mm back headliner. If tight, replace with the optional standard back headliner.



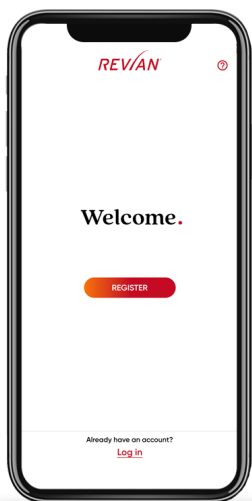
2. Fit test: press the Cap against your forehead. If a pinky finger can still fit between the Cap and the back of your head, then the Cap is too loose.



NOTE: To ensure proper sensor connection, the thick headliners should only be used in the back of the Cap. The front headliner is only to be replaced for sanitary purposes. For consistent fit and wear, it is suggested to replace headliners every three months. Replacement headliners can be ordered at REVIAN.com.

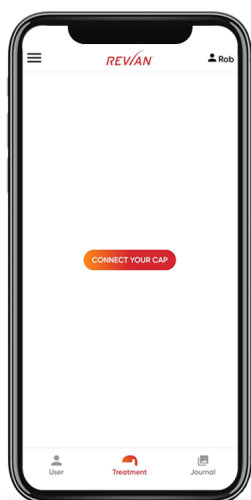
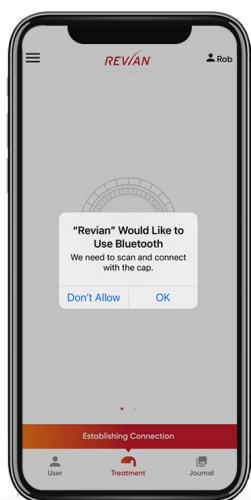
Connecting to the Cap

The Cap must be connected via Bluetooth® to its controller, the REVIAN mobile app, for a treatment to begin.



1. Download the REVIAN mobile app on a mobile device from the App Store® or Google Play® store.
2. For a first-time use, click the **REGISTER** button and follow the registration process and email verification to obtain your login credentials or login through the **Log In** link with your established credentials.
3. Upon initial login, you will be taken to a Connect Your Cap screen. See below for the next steps.
4. Set the Bluetooth setting to "ON" in the mobile device. Disconnect from any previously connected devices, like a smart watch,

prior to performing a treatment, if applicable. Your device may ask for permission to use your Bluetooth. Respond with Accept or OK so that the Cap can communicate with the app.

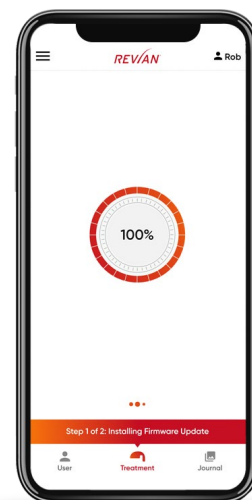
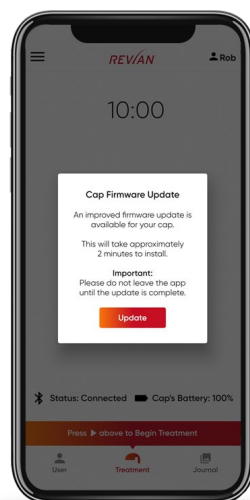


5. A sensor detects when the Cap is properly placed on your head. Place the Cap on your head to activate the sensor or put your finger over the sensor located in the forehead area of the cap. Press the **CONNECT YOUR CAP** button once the cap is activated.

If the REVIAN app does not locate a Cap, try restarting the app or charging the cap for a few seconds to reset it then place it on your head and try again.

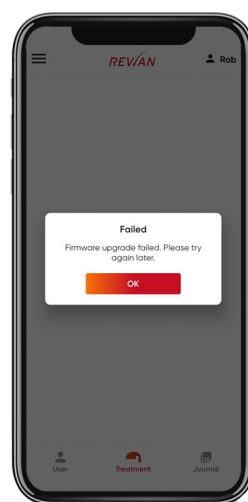
Cap Firmware

New firmware will be released as new versions are available. If the device shows a "Cap Firmware Update" pop-up, allow the mobile app to initiate a Cap update. Do not leave the mobile app while firmware is updating, this should only take about two minutes.



Once the firmware has successfully updated, the Cap will turn off and reset. Reconnect the Cap as described previously.

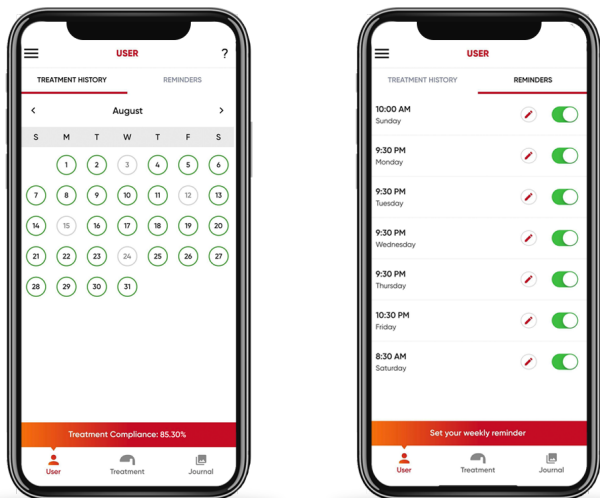
NOTE: When connecting to the Cap, BT pairing can only occur within the mobile app, NOT within the general settings menu on a mobile device.



NOTE: If the device shows an "Failed" pop-up when updating firmware, the firmware will resolve the problem and attempt to download again immediately after or on your next login.


User Control

The REVIAN mobile app makes hair regrowth simple by enabling personal control. This tour highlights the key functions within the mobile app.




- The **User** button in the bottom tray is where you can keep up with your treatment history, compliance and set reminders. Completed treatments are circled on the calendar and the compliance is automatically listed in the red bar at the bottom. In the reminders tab you can set or toggle a weekly reminder to pop up on your device.

Performing a Treatment

To begin a treatment, place the Cap on the head and press the "Treatment" icon at the bottom of the screen. Press the "Connect Your Cap" button and connect via Bluetooth (see page 2). A tone will be heard once the Cap has been properly connected. Press the center play button  within the round dial on the treatment page to start.

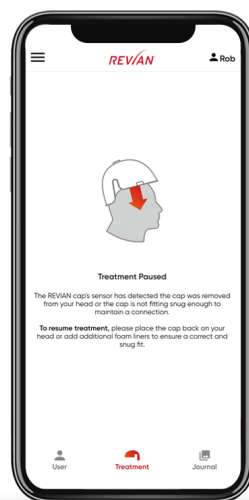


The treatment can be paused by pressing the pause icon  or removing the Cap. For immediate shutdown, remove the Cap from the head.

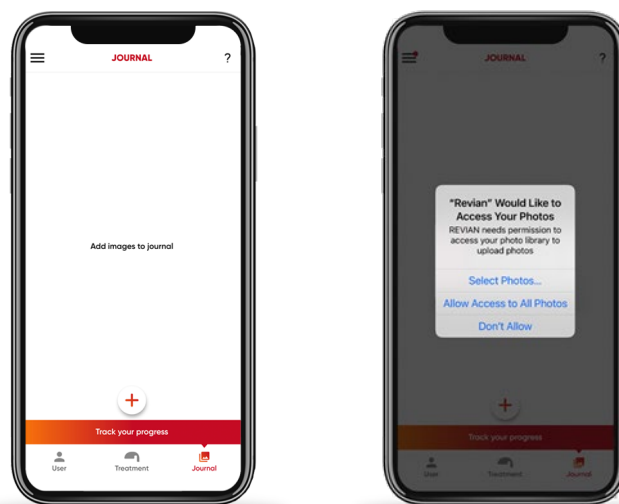
To resume the treatment paused by removing the Cap, just place the Cap again on your head and it will automatically pick up where it left off. Only a single 10-minute treatment can be initiated daily. Time remaining will be displayed on the mobile app screen. Another treatment cannot be initiated on a

later day until the full 10 minutes of the prior treatment (once started) has been completed.

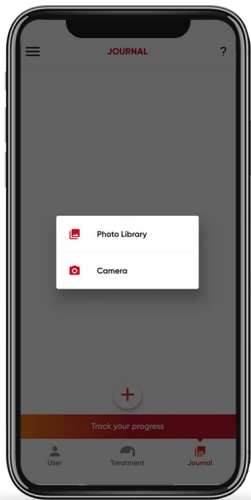
NOTE: Once treatment is complete, the Cap will emit an auditory tone. Place Cap back on support base for optimal protection. The Cap will perform at least two treatments before needing to be recharged and for optimal battery life should be charged after the second treatment and not daily.



Taking Progress Photos



Seeing is believing! It is important to document progress while using the Cap with before and after photos. To take advantage of this benefit, choose the "Journal" icon at the bottom of the screen. The first time you use this feature it will ask for permission to access your photos. You can limit access to just select photos or all. We take your privacy seriously and will never share your photos unless we get permission from you. See our privacy policy for more details. You can add images or utilize your phone's camera to take new ones. Once the photo is added you can also touch on the photo thumbnail to enlarge it or delete it.



For Best Results:

- Maintain consistency in position, lighting, and angle for all photos.
- Avoid fluorescent lighting and using flash.
- Style hair in same condition for each photo.
- Hold the camera at an arm's length away from the top of head or get another person to help.

NOTE: While charging, the Cap will disconnect from the mobile app and will NOT allow a treatment to be delivered.

The magnetic charging cable connects to a magnetic insert in the port. Best practice for unplugging the cable from the port is tilting to one side to break the magnetic hold. Sudden pulling from directly above could remove the insert in the port. If accidentally removed, re-insert straight in and follow best practice above.

DO NOT CLEAN THE CAP WHILE CHARGING.

When the battery is too low to perform a treatment, and needs to be charged, a battery icon and indicator message will appear. While connected, this can occur prior to or during a treatment. If during a treatment go ahead and remove the cap and connect to the charging system. Once charged, the treatment will resume when the Cap is worn.

Charging the Cap



WARNING: DO NOT connect this equipment with any other equipment not provided in the accessory kit.

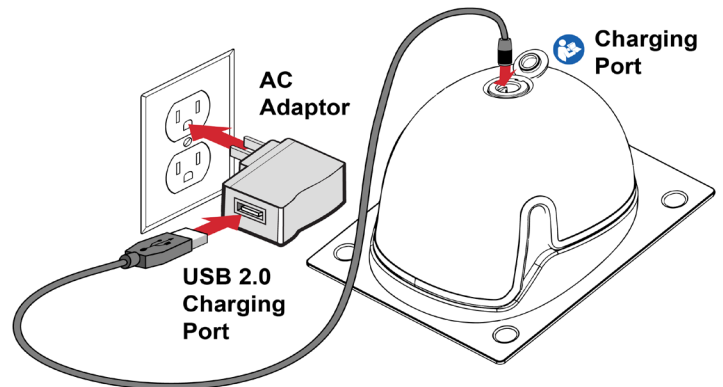
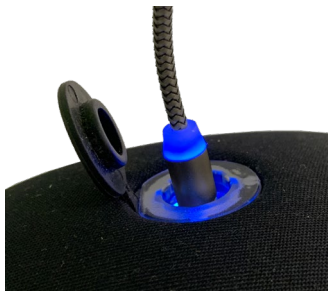
WARNING: The micro-USB cable may be a strangulation hazard.

Attach the micro-USB cable to the AC adaptor. The Cap should be left on the support base. Plug the AC adaptor in either orientation into an indoor outlet and then insert the magnetic cable connector into the port located on top of the Cap. The charging port in the Cap will illuminate when successfully charging. Once fully charged, the light will softly alternate on/off every 4 seconds. The magnetic cable also has a small blue light that will stay illuminated as long as it has power. To disconnect, unplug the AC adaptor from the indoor outlet and the magnetic cable connector from the Cap.




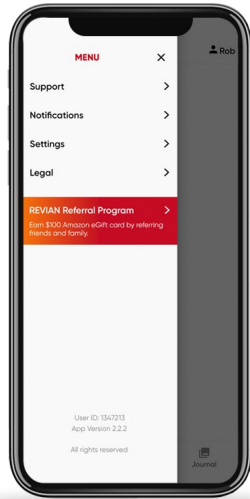
Charging Light Indications:

- When the Cap is charging the charging port will illuminate blue.
- When the battery is fully charged the charging port light will softly flash every 4 seconds.
- When the cap is charging, the app is not connected and will not provide a battery level. To determine the battery level, disconnect the charging cable from the cap and connect the cap to the app (see page 3) . The battery level will be displayed on the treatment page.



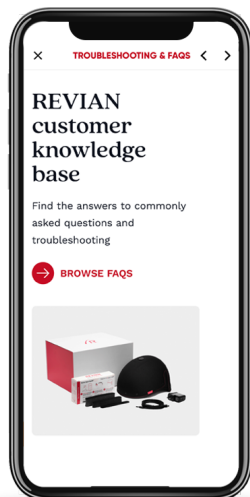
Menu Tour

- The **MENU**  can always be accessed in the upper-left corner of the screen. This presents a set of options to find content and information for interacting within the application in various ways.
- The **SUPPORT** page includes Troubleshooting and FAQs linked to our Knowledge Base. There is also a link to the latest Instructions for Use document.
- **NOTIFICATIONS** are messages from the REVIAN Team to keep you updated on the latest news and offers that are available. A red number icon may be present to let you know how many unread messages are present.
- **SETTINGS** allow you to edit your user profile, *Add a 2nd User* or *Log out* of the application.
- Under **LEGAL** you will find information about our Terms of Service, Warranty, Privacy Policy, Patents, or disclosures about Open-Source features.
- **REVIAN Referral Program** is an offer to allow you to share with friends and family and get rewards!
- **User ID and App Versions** details are also shared at the bottom of this menu slider. Use these when looking for the latest revision of the app or during support tickets to help troubleshoot any issues you may be having with the app.



SUPPORT >

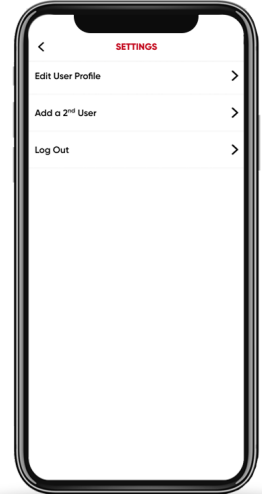
- In the **Troubleshooting** section you can find answers to commonly asked questions and troubleshoot issues. If you are unable to find the answer to your question, there is a link button to create a support ticket with the REVIAN team.



- **INSTRUCTIONS FOR USE** are the latest downloadable instructions for the use of the REVIAN Cap and control application. This convenient, included set of mobile instructions are available anytime or place you need them.

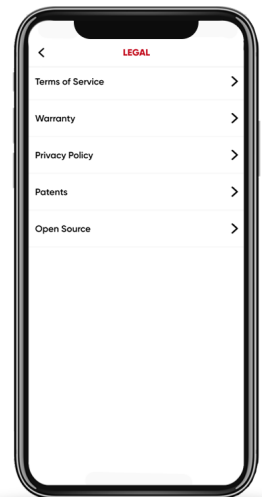
SETTINGS >

- **Edit User Profile** – Edit your personal settings including your name, email, and password.
- **Add a 2nd User** – REVIAN allows a second user to connect to a Cap with a one-time licensing fee. Follow the link in the app to find out more.
- **Log Out** – log completely out of the application.



LEGAL >

- **Terms of Service** – Provisions and terms for use of REVIAN services.
- **Warranty** – Limited warranty listed (see page 11 of this document for full text).
- **Privacy Policy** – discloses the privacy practices for the REVIAN website, user dashboards, applications, and admin portals.
- **Patents**– This page is to satisfy the marking requirements of 35 U.S.C § 287. All patents for this product are listed here.
- **Open Source** – Definition requirements for open-source software.



Cleaning and Travel

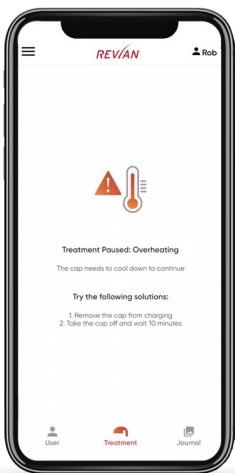


WARNING: DO NOT wash or submerge Cap at any time. DO NOT use cleaning agents or solvents to clean Cap as this may discolor or degrade the fabric or damage internal electronics.

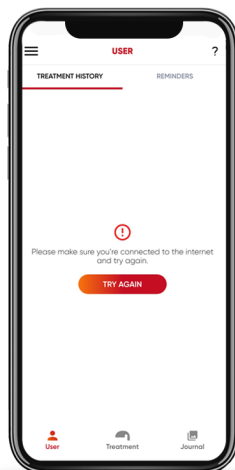
WARNING: Travel bag may be a suffocation hazard if placed over nose and mouth. DO NOT place bag over the head.

- Visually inspect interior of the Cap for film, debris, or possible damage. A damaged cap should not be used. Email support@revian.com for help.
- Clean the Cap monthly by wiping with a soft cloth lightly moistened with water. Allow to air dry before storage. DO NOT CLEAN THE CAP WHILE CHARGING.
- Store the Cap on the support base in either the storage box or travel bag when not in use.
- As a reminder, it is recommended to charge the Cap every 2-3 treatments to reduce charging cycles on the battery.
- For easy travel and added support, store the Cap on support base when in the travel bag.
- Replacement headliners are recommended to maintain proper fit and cleanliness. Contact support@revian.com if you would like to purchase additional headliners for your Cap.

Troubleshooting Messages



The Cap will halt a treatment if the internal temperature exceeds the maximum allowable operating temperature. Allow the Cap to cool down before continuing a treatment.



The mobile app must be in use and the mobile device connected to the internet to continue treatments.

Troubleshooting

This section summarizes the most common problems users could potentially encounter with the REVIAN RED System. If you are unable to solve the problem with the information provided below, please visit revian.com/support// for more information.

Messages and sound signals during use:

The mobile app will display messages on occasion. These will appear as direct messages or icons in the mobile app.

App Messages	
"Check Bluetooth"	This message appears when Bluetooth needs to be turned on, connected, or is scanning.
"Scanning for Devices"	This message appears when Bluetooth is scanning to find the Cap.
"Please put Your Cap Back On"	This message appears when the Cap has been removed or is not detected by the biosensor during a treatment.
"Connect to the Internet for treatment"	This message appears when the users phone or device is not connected to the internet.
"New Firmware Available"	This message appears when new firmware is available and ready to install.
"Firmware Needs to be Updated"	This message appears if the update was deferred the first time and the mobile app will now automatically update the firmware.
"Firmware Update Successful"	This message appears if the update was successfully transmitted to the Cap.

There are specific messages that will appear as an alert if the mobile app is not performing properly.

Error Messages	
"The Cap needs to cool down"	This message appears, with a temperature warning icon, when the temperature exceeds the maximum allowable operating temperature.
"Battery Low. Treatment not possible."	This message appears, with a battery icon, when the battery is too low to perform a treatment and needs to be charged. This can occur prior to or during a treatment.
"Firmware Update Failed"	This message appears when there is a problem updating the firmware. The firmware will automatically resolve the problem and attempt to update again.

There are five different audible tones that will be heard when certain actions take place.

Cap Audible Tones	
1.	Bluetooth Connected / Treatment Complete
2.	Treatment Started
3.	Treatment Stop/Pause
4.	Treatment Resume
5.	Treatment Temperature Abort

Troubleshooting continued

PROBLEM	POSSIBLE CAUSE	SOLUTION
The mobile app is being nonresponsive to commands	<p>The mobile app was left open or in an unknown state from the previous time it was used</p> <p>iOS or Android device needs to be updated</p>	<p>Swipe up and force close out of the mobile app and relaunch it</p> <p>Update your mobile device with latest software.</p> <p>Delete and reinstall the app</p>
The Cap has successfully paired and has been properly placed on the head, but a treatment will not start	The Cap sensor doesn't detect the Cap as being positioned correctly on the head (A "Place Cap on Head" pop-up message is shown)	<p>Reposition the Cap or place your finger over the forehead sensor. If your finger activates the cap, it is likely a fit issue. Your forehead is needed to be against this sensor to operate.</p> <p>The Cap may not be fitting appropriately. Try increasing the thickness of the <u>back</u> headliner size only.</p>
	The mobile device is not connected to the internet	Connect the mobile device to the internet while the mobile app is in use
The Cap is not pairing with the mobile device	Bluetooth is not enabled on your mobile device	Enable Bluetooth on mobile device
	The mobile device has connected to another Bluetooth device, and not the Cap	Check mobile device settings and ensure device isn't already paired with another device
	The mobile app is not scanning for the Cap	<p>Force the mobile app to scan for the Cap by tapping "Connect your Cap" on the treatment page .</p> <p>Plug the Cap into the AC Charger for a few seconds to reset it then try again.</p>
The mobile app is showing a high temperature pop-up message	The internal temperature of the Cap may have reached a higher-than-normal operating setting	The Cap may need to cool before continuing treatment, remove the Cap for a brief period and allow to cool
The mobile app is showing a low battery pop-up message	The battery may not be in a fully charged state	Place the Cap on the support base and charge for at least 30 minutes or until the solid light starts to softly blink every 4 seconds (full charge).
The mobile app is unable to start a treatment	The iOS or Android mobile device's internal software was updated prior to the REVIAN app updating	<p>Make sure the cap is on your head, charged and not plugged in.</p> <p>Restart the REVIAN app or check for updates to the REVIAN app in the app store.</p>
The mobile app will not open	The mobile device is an outdated version and is not compatible with the mobile app	<p>Try to delete and reinstall the app from the app store on your device.</p> <p>Your iOS device must have a software version of 10.X+ to work properly</p> <p>Your Android device must have a software version of 6.X+ to work properly.</p>

PROBLEM	POSSIBLE CAUSE	SOLUTION
The mobile app will not download firmware or software updates	The cloud server is unavailable The device software is incompatible with the REVIAN app	Check mobile device for Wi-Fi connection and/or verify Internet connection Ensure your mobile device is updated to the latest version
The Cap is allowing multiple treatments within a 24-hour period	Software and/or firmware error	Force close and re-launch the REVIAN app Contact revian.com/support/

NOTE: *If there is a connectivity issue or the mobile app is non-functional, force close and then restart the REVIAN app. If that does not fix the problem, delete the app and reinstall from the app store on your mobile device. Contact customer support if this does not resolve the issue at support@revian.com or on the website at revian.com/support/.*

Learn More

Please read all instructions in manual before using REVIAN RED Cap.



This warning symbol appears next to information about possible safety and product risks. Please be sure to follow all warning and safety information.

Table of Contents:

1. Storage and Operation
2. Operational Modes
3. Recommended Usage
4. Warnings and Cautions
5. Warranty
6. Glossary
7. FAQs
8. Customer Support



1. STORAGE AND OPERATION

- **Storage Temperature:**
5–35°C (41–95°F)
- **Relative Storage Humidity:**
Up to 90%, non-condensing
- **Operating (Use / Charging) Temperature:**
15–35°C (59–95°F)
- **Relative Operating Humidity:**
Up to 90%, non-condensing
- **Atmospheric Pressure:**
700 hPa to 1060 hPa
- **Cap Dimensions and Weight:**
Height: 15.87 cm (6.25 in) x Width: 20 cm (7.87 in) x Length: 22.86 cm (9 in), Weight: 155 g (0.34 lbs)
- **Head Circumference Size Range:**
54 cm (21.26 in) – 64 cm (25.20 in)
- **AC Charger:**
Input 100–240V, 50Hz/60 Hz
- **Battery:**
Lithium Polymer – Lithium polymer batteries are classified by the US federal government as non-hazardous waste. Refer to local requirements for disposal or recycling instructions.
- **Optical Characteristics:**
1.67 mW/cm², 620–660 nm +/- 10 nm, per IEC 60601-2-57 (1st edition): 2011.
- **Temperature Limiting Requirement:**
A temperature sensor is embedded into the device to prevent the inside surface of Cap from exceeding 46°C (108°F). The device will go into a reduced power mode until the internal temperature is lowered to the appropriate range.
- **Bluetooth Low Energy Module:**
ISM Band 2.402 to 2.480 GHz operation.
- It is recommended to keep the support base and product box for storage to protect against product damage.
- **REVIAN app compatibility:**
Most Android based devices 6.X+ operating system and manufactured within last three years
iOS device 10.X+ operating system

2. OPERATIONAL MODES

- **CHARGING MODE:** When the Cap is plugged in it is in CHARGING mode. An LED indicator located inside the Cap near the micro-USB charging port will illuminate blue. The charging cable connector will illuminate blue always when connected to AC power. The battery should be charged from a depleted state to a full charge within 4 hours. The battery will have enough charge to run multiple treatments.

NOTE: While charging, the Cap will NOT allow a treatment to be delivered. For best results when charging, place the Cap on the support base and then insert the cable end into the top port. When the Cap is fully charged, the charging port light will blink every 4 seconds. Leave the Cap on the support base and then remove the charging cable. Class II medical equipment.

- **SLEEP/STANDBY MODE:** When the Cap is removed from AC Power but not activated, it will be in its lowest power consumption state and is in a SLEEP/STANDBY mode. The battery indicator, treatment LEDs, and Bluetooth module will not be active. To bring the Cap out of SLEEP/STANDBY mode it should be placed on the head or hold the copper-colored forehead sensor.
- **ACTIVE MODE:** When the Cap is placed on the head it is in ACTIVE mode. This mode will turn on the Bluetooth module, allowing for pairing with the mobile app. The Cap will stay in this ACTIVE mode for 60 seconds after placement while attempting to pair with the mobile app. Failure to pair or if removed from the head will cause the Cap to go into SLEEP/STANDBY mode to save battery.
- **TREATMENT MODE:** When the Cap is activated, successfully paired with the mobile app, and placed in position for treatment, it is in TREATMENT mode. Treatment begins once the play icon  is pressed on the treatment screen of the mobile app. An audible tone will be heard, and the treatment countdown clock begins. Upon completion of the 10-minute treatment an audible tone will be heard, then the Cap will switch back to SLEEP/STANDBY mode. Only a single treatment can be initiated within a given calendar day.
- **PAUSE MODE:** When the Cap is removed or when the pause icon  is pressed on the mobile app during a treatment session, the Cap is in PAUSE mode. LEDs will turn off until the cap is placed back on the head. Treatment time remaining is stored in the Cap until completion of the paused treatment.

Learn More

3. RECOMMENDED USAGE

- Use the Cap daily, for 10 minutes at any convenient time.
- Use indoors or in a cool, dry area. This product is not intended for exposed use outdoors.
- Use only on dry or towel dried hair.
- If REVIAN RED treatments are stopped for several weeks or more, natural hair loss may resume.
- Commit to disciplined daily use and be patient, as it may take a full hair cycle of 16–26 weeks to achieve initial results.
- Patient is the intended operator of this device.
- REVIAN RED is not a defibrillation proof device.

4. WARNINGS AND CAUTIONS

WARNINGS

- DO NOT use the USB-to-micro-USB cable or AC adaptor if either are damaged.
- DO NOT use the Cap or AC adaptor if either has been exposed to water. Visit revian.com/support/ for additional information.
- DO NOT place the Cap or support base in or near water. If exposed to water unplug the device immediately from the power outlet.
- DO NOT reach into water to retrieve the device while plugged into an outlet.
- DO NOT use the Cap while in the bathtub or the shower.
- DO NOT use the Cap if you are taking photosensitizing medications, shampoos, lotions, or other therapies that sensitize the skin to light. Consult your physician regarding use in these conditions.
- DO NOT use with wet hair.
- DO NOT insert foreign objects into micro-USB receptacle on top of the Cap (Water resistant to IP22 standards).
- DO NOT use any cables, adaptors, or products that are not provided or approved for the device as this may result in non-compliance.
- DO NOT use any cables, adaptors, or products that are not provided or approved for the device, as they may negatively interfere with the EMC performance.
- Interference may occur with other electrical equipment near the REVIAN RED Cap due to the use of mobile Radio Frequency (RF) communications.
- The Cap has NO user-serviceable parts and any attempt to remove internal components will void the warranty and may cause harm to the user.

CAUTIONS

- If the REVIAN RED Cap meets water, humidity, or excessive perspiration, allow to dry before use, charging or storage.
- Use of cleaning agents or solvents are not recommended and may damage the REVIAN RED Cap.
- The battery is rechargeable but not intended as a user-replaceable part.
- Use the Cap only as intended and described in the application instructions. Any attempt to bypass the approved mobile app or hardware will void the warranty.
- If pregnant or nursing, consult your primary care physician regarding use of the Cap in these conditions.
- Keep the Cap out of reach of children and pets.
- The Cap is to be operated at a temperature of at least 15°C (59°F).
- Use of the Cap is intended for a single registered user.
- Keep the micro-USB port cover located on top of the Cap closed when not charging.
- BATTERY: Risk of Fire and Burns. Do Not Open, Crush, Heat Above 100°C or Incinerate. Follow Manufacturer's Instructions.
- Do not look directly into LED lights.

5. LIMITED WARRANTY

The Company warrants that this Device will be free from manufacturing defects in material and workmanship for a period of twelve (12) months from the date of delivery. The Company does not warrant that the operation of the Device will be error-free or uninterrupted. The user is responsible for the proper maintenance and handling of the Device. No warranty is extended to any Device that has been altered, physically damaged, or modified in any way. The limited warranty does not cover problems caused by user acts (or failures to act), the acts of others or event(s) beyond the reasonable control of the Company.

If Device fails to meet the warranty set forth above, then the Company will, at its option, either (i) repair the defective Device, (ii) provide a free replacement Device or (iii) replacement parts. Any replacement Device or part will be comparable in function but may not be identical to the original. The replacement or repaired Device is warranted for the remainder of the original warranty period.

If the Device or any component thereof is defective or otherwise does not function properly within the Limited Warranty period (as defined above), contact the Company at www.revian.com/support/ to submit a Warranty claim. All returns must be authorized by the Company prior to receipt. Once a return is authorized, the Company will issue a Return Merchandise Authorization (RMA) number and provide instructions on how to return the Device.

6. GLOSSARY

Cap: The external, Bluetooth device that the user will wear on their head, connected to the REVIAN mobile app controller, to facilitate hair growth.




















Mobile Device: The personal device that has the REVIAN mobile app installed on it and can connect and control the Cap (NOT included unless specified).










Successful Treatment: Completing a 10-minute treatment session for day initiated.

Unsuccessful Treatment: Not initiating a new treatment on a specific one calendar day before 12:00 a.m. of the following day.

User: The authorized person who can log into the mobile app and perform a treatment.

MLT™: Modulated Light Therapy enhances natural healing mechanisms by targeting specific biochemical processes with precise intensity, dose and wavelengths of light.

	REVIAN MOBILE APP – this symbol represents the mobile app controller
	BLUETOOTH – this symbol appears when Bluetooth is connected or scanning or waiting for connection.
	CHARGE BATTERY – this symbol may appear prior to treatment or during treatment
	MENU – this symbol reveals the mobile app menu when clicked
	TEMPERATURE WARNING – this symbol appears when the Cap needs to cool down
	CAPS BATTERY LEVEL – this symbol appears during an active connection of the cap with the app there is a % battery level listed at the bottom of the treatment screen.
	POSITION CAP ON HEAD – this symbol appears when the Cap has been removed or is not placed properly on the head
	USB 2.0 – this symbol represents USB 2.0 to micro-USB cable the Cap uses to recharge
	CATALOG NUMBER – this symbol represents any number used to identify an item in a catalog
	LOT CODE – this symbol is accompanied by a batch code
	MANUFACTURER – this symbol is accompanied by the name and address of the product manufacturer
	SEE INSTRUCTIONS FOR USE – this symbol refers to the Instructions for Use for further definition
	MANUFACTURED DATE – this symbol is accompanied by a date
	TEMPERATURE LIMITATION – this symbol indicates the upper or lower limit of temperature
	PACKAGE DAMAGE – this symbol appears as a warning to not use the device if the package is damaged
	KEEP DRY – this symbol appears if a device is required to be kept dry
	LED – this symbol represents the use of LEDs
	NON-IONIZING – this symbol represents non-ionizing electromagnetic radiation
	INTERNET CONNECTION – this symbol appears when the mobile app has not connected to the internet in seven days to allow data transfer

	IP 22 – this symbol represents water spray protection of the Cap
	QUANTITY – this symbol represents the number of devices
	HUMIDITY LIMITATION – this symbol indicates the upper or lower limit of humidity
	ATMOSPHERIC PRESSURE LIMITATION – this symbol indicates the environmental limitation for the device
	TYPE BF APPLIED PART – this symbol indicates this is a “Body Floating” applied part in concern with electrical contact
	CAUTION – this symbol appears next to information about possible safety and product risks
	NUMBER – this symbol represents a current version number
	INSTRUCTIONS MANUAL – this symbol references the manual for charging instructions
	USE BY – this symbol is accompanied by the useful product life service date

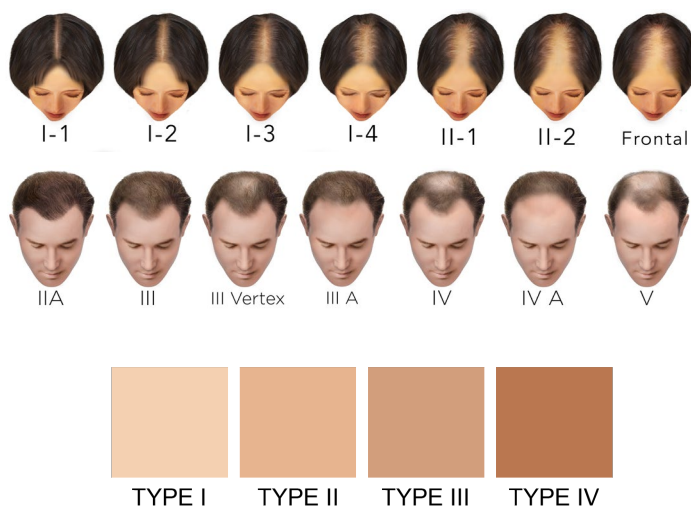
7. FREQUENTLY ASKED QUESTIONS

- **What is the REVIAN RED Cap?** A wearable medical device that is worn on the head to reverse hair loss. The approximate size of the Cap is: Height: 15.87 cm (6.25 in) x Width: 20 cm (7.87 in) x Length: 22.86 cm (9 in), Weight: 155 g (0.34lbs)
- **How is the REVIAN RED Cap shipped?** After order completion, the Cap will be shipped via the method you selected when you placed your order. If free shipping was selected the REVIAN RED cap will be shipped to the address, you provided via FedEx Ground/Home Delivery or United States Postal Service (USPS) Priority Mail.
- **How is the REVIAN RED Cap controlled?** The Cap is controlled by the user and links to an application on a portable device (iPhone, iPad, Android device) via Bluetooth communications.
- **How does it work?** The Cap uses Modulated Light Therapy (MLT)™ that stimulates hair follicles to promote growth and restoration. To learn more about MLT, visit and refer to the technology section at revian.com.
- **Is the REVIAN RED Cap Safe?** Yes, it is safe to use. The LEDs utilized by the REVIAN RED Cap are specifically programmed to deliver a specific dose of light that is strong enough to be effective while still safe. While some light sources (like lasers) can cause damage to the eyes, the LEDs used in the REVIAN RED Cap do not harm the eyes or retina.
- **Are there any potential side effects?** No side-effects have been observed.
- **Can I use the REVIAN RED Cap while taking photosensitizing medications, shampoos, lotions, or other therapies?** No, you should not use REVIAN RED while taking these therapies. Consult your physician regarding use of these products with REVIAN RED.
- **Can I use the REVIAN RED Cap while pregnant and/or nursing?** Consult your physician regarding use in these conditions.
- **Can I share my Cap?** The Cap treatment is to only be used by a single user on one account for 10 minutes a day. If you would like to share the cap with your spouse or partner click the “Add a 2nd User” link under the Settings tab in the Menu.
- **What is the progress wheel and why has it appeared?** The progress wheel will appear when there is an indication of a loss or slow server connection while trying to upload data.

FAQ - Continued

- **How can I track my treatments?** A unique feature of the REVIAN RED Cap is the ability to automatically track your treatments and progress. The Cap must be connected via Bluetooth for a treatment to start. A treatment does not need Bluetooth connection to continue after the treatment has started. At the end of a treatment the Cap will download the treatment data to the mobile device. However, if Bluetooth connection was severed or lost during a treatment the data will be sent the next time the Cap connects to the mobile app.
- **How will I know to charge my Cap?** An interrupt message will appear on the mobile app, "REVIAN RED Cap battery needs charge" if conditions are not met during each initial pairing with the mobile app. The battery should be charged from a depleted state to a full charge within 4 hours. The battery will have enough charge to run at least two treatments. There are also visual indicators that show the state of the Cap's charge when connected to the app. When the Cap is charging the port will appear illuminated blue and once the charge is complete the light will lightly flash every 4 seconds.
- **Do I need to use Bluetooth to connect to the Cap?** The REVIAN RED Cap must be connected via Bluetooth for a treatment to start. However, once a treatment has started, the Bluetooth connection can be severed, and the Cap will continue until the 10-minute treatment is completed.
- **Do I need to connect to Wi-Fi or Cellular to start a treatment?** Yes, an authorization for a treatment can only be started while connected.
- **When will I see results?** The Cap is recommended to be used once a day for 10 minutes. Every individual is different, but visible hair growth should be observed during the initial six months of treatment (introductory treatment phase). REVIAN RED can be used indefinitely. However, once treatments are stopped then hair loss may resume.
- **How do I clean my Cap?** You can clean the Cap by simply wiping it down with a lightly moistened cloth. Visit the MANUAL section of the mobile app for more information.
- **How do I purchase additional items?** Visit the REVIAN website for additional items or email us at support@revian.com.
- **How should I style my hair when performing a treatment?** For best coverage of the scalp when using the Cap, part your hair to maximize exposure to MLT to reach thinning areas.
- **Why should I attach headliners?** The recommended headliners not only ensure proper fit of the Cap, but they also provide additional comfort and help maintain cleanliness.
- **Is this a "use it or lose it" treatment plan?** Yes. We recommend that you initiate and complete a treatment every day. If you do not initiate a treatment on any given day, then it will be lost for that day.
- **Do I need to disconnect from other BT connected devices?** Yes. IF you experience connection issues, disconnect from any previously connected devices like a smart watch prior to performing a treatment. Once a treatment has been initiated you may resume the use of other BT devices.
- **Can I switch to other apps during my treatment?** Yes, once a treatment has been initiated you can use your device as you normally would.
- **Where can I find my login information?** Emails sent to you by REVIAN will contain the login email address you provided. If you forgot your password, go to the "forgot password" area on the mobile app or members.revian.com to reset.

- **What is the useful service life of the Cap?** The Cap and accessories* are warranted for 12 months. They have been life tested to be safe and useful for at least two years under daily use. If the Cap is well maintained and undamaged, it may last up to 3-4 years based on estimated battery life. *Headliners are suggested to be replaced every three months for consistent fit and sanitary reasons
- **How do I dispose of my Cap properly after it's useful service life?** This Cap contains a lithium polymer battery that is classified by the U.S. government as non-hazardous waste. Refer to your local requirements for disposal and recycling.
- **Is REVIAN RED suited for everyone?** REVIAN RED is FDA-cleared for males who have Norwood-Hamilton classifications of IIa to V patterns of hair loss and in females who have Ludwig-Savin scale classifications of I-1 to I-4, II-1, II-2, or frontal patterns of hair loss, both with Fitzpatrick Skin Types I-IV. Compare yourself to the chart below:



**If you cannot find the answer to your question, refer to the REVIAN website at revian.com/support/ to search our Knowledge Base for additional answers and the latest information about our product.

8. CUSTOMER SUPPORT

If the REVIAN RED System is not functioning as outlined in these instructions for use, please refer to [Revian.com/support/](https://revian.com/support/) for additional troubleshooting details.

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Email: support@revian.com

APPENDIX A – ELECTROMAGNETIC EMISSIONS

Table 1. Guidance and manufacturer's declaration – electromagnetic emissions – for all ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 c).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The REVIAN RED 101 is intended for use in the electromagnetic environment specified below. The Customer or the user of the REVIAN RED 101 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	REVIAN RED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	REVIAN RED is suitable for use in all establishments other than domestic 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

Table 2. Guidance and manufacturer's declaration -electromagnetic immunity - for all ME EQUIPMENT and ME SYSTEMS (see 5.2.2.1 f).

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The REVIAN RED 101 is intended for use in the electromagnetic environment specified below. The customer or the end user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	PASS	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	PASS	Mains power quality should be that of a typical commercial, hospital or home healthcare environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	PASS	Mains power quality should be that of a typical, hospital or home healthcare environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T) for 5 sec	PASS	Mains power quality should be that of a typical commercial or hospital or home healthcare environment. If the user of REVIAN RED requires continued operation during power mains interruptions, it is recommended that REVIAN RED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	PASS	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital or home healthcare environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

APPENDIX C – Electromagnetic Immunity

Table 3. Guidance and manufacturer's declaration – electromagnetic immunity For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING (see 5.2.2.2).

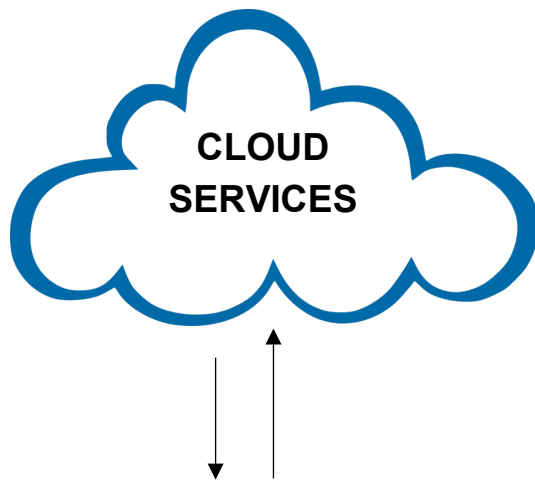
Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The REVIAN RED 101 is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF	3 Vrms	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the REVIAN RED 101, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [3.5 / V] \sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		$d = [3.5 / E] \sqrt{P}$ 80 MHz to 800 MHz $d = [7 / E] \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF	3 V/m	10 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b
IEC 61000-4-3	80 MHz to 2700 MHz		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 the REVIAN RED 101 is used exceeds the applicable RF compliance level above, the REVIAN RED 101 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the REVIAN RED 101. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

APPENDIX D – PORTABLE AND MOBILE RF COMMUNICATIONS

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the ME Equipment or ME System – for ME Equipment and ME Systems that are not Life-Supporting.

Recommended separation distance between portable and mobile RF communications equipment and the REVIAN RED 101			
The REVIAN RED 101 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REVIAN RED 101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REVIAN RED 101 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{v_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.379	0.379	0.727
1	1.2	1.2	2.3
10	3.79	3.79	7.27
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.			

APPENDIX E – CHARACTERISTICS OF THE IT-NETWORK FOR THE REVIAN RED SYSTEM

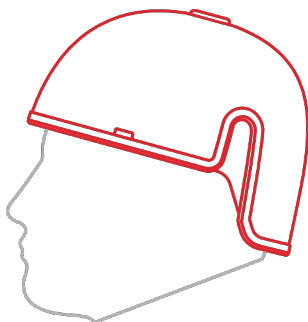


Wi-Fi/Cellular



REVIAN Cap

Bluetooth (BT) Connection



The REVIAN RED System connects to a cloud service on the internet via user defined Wi-Fi or Cellular connections. There are no specific technical specifications or security requirements for this connection.

Information flows between the REVIAN mobile application running on an iOS or Android operating system and REVIAN cloud services as well as between the REVIAN app and the REVIAN RED Cap (**Figure E1**). Communications of treatment is transmitted once Cap is activated. No known hazards exist from the REVIAN RED device connecting to an IT network. Connection to IT networks including other equipment could result in previously unidentified risks to patients, operators, or third parties. REVIAN will continually monitor any associated risks with using the REVIAN RED System, including any new risks, associated with changes to IT network.

APPENDIX F – FCC COMPLIANCE

The REVIAN RED Cap contains transmitter Module RN4020 FCC ID: T9JRN4020

This module is used to connect via Bluetooth the Cap to a mobile device running the REVIAN mobile app

The REVIAN RED Cap 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. The REVIAN RED device generates, uses and can radiate radio frequency energy, and if not 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 the Cap does cause harmful interference to radio or television reception, which can be determined by turning the Cap off and on by removing it from head, disconnecting from the mobile device running the REVIAN mobile app, and charging the Cap; the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the Cap and/or mobile device running the REVIAN mobile app.
- Increase the separation between the Cap and mobile device running the REVIAN mobile app.
- Visit [REVIAN.com](https://www.revian.com) for additional assistance.