

REVIAN[®] *RED* *SYSTEM*

Model: REVIAN 101 | Part Number: 10000-10001

Read all instructions before using the REVIAN Red System.

Instructions for Use



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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.

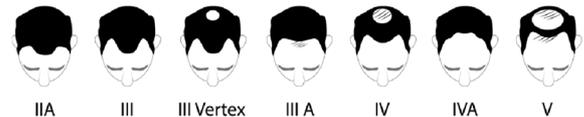
Recommended Usage

- 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.

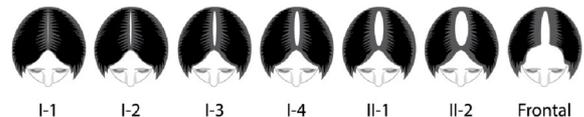
Skin Types



Norwood-Hamilton Scale for Men

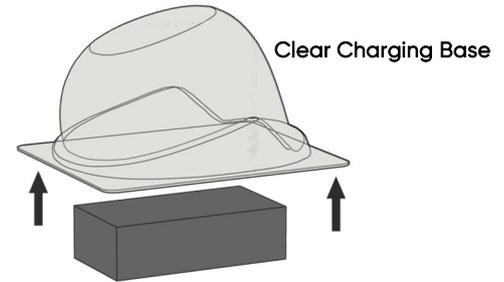


Ludwig-Savin Scale for Women



DEVICE & ACCESSORIES

1. Carefully remove the shrink wrap from the storage box.
2. Remove the sleeve holding the top and the bottom of the box together. Open the box.
3. The contents of your package will contain the following:
 - REVIAN Red Cap
 - Clear Charging Base
 - Accessory Kit
4. Lift up the Clear Charging Base and remove the Accessory Kit. The contents of the Accessory Kit will contain:
 - Headliner Adjustment Kit
 - AC Adaptor Accessory Kit with USB-C
 - Travel Bag



Accessory Kit



3 Back
Headliners



AC Adaptor &
USB-A to USB-
C Cable



Travel
Bag

WARNINGS & CAUTIONS

WARNINGS

- DO NOT use the Charging 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 Clear Charging 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 have a medical condition that makes your skin sensitive to sun or light or if you are using photo-sensitizing medications, shampoos, lotions, or other therapies that sensitize the skin to light. Consult your physician regarding use in these conditions.
- DO NOT insert foreign objects into 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 negatively interfere with the EMC performance and result in non-compliance.

WARNINGS & CAUTIONS

WARNINGS

- Interference may occur with other electrical equipment near the REVIAN Red Cap due to the use of mobile Radio Frequency (RF) communications.
- DO NOT attempt to remove internal components of the device. 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.
- DO NOT connect this equipment with any other equipment not provided in the Accessory Kit.
- DO NOT use cleaning agents or solvents to clean the Cap as this may discolor or degrade the fabric or damage internal electronics.
- The long term effects of prolonged use of the REVIAN Red Cap are unknown. Consult your Health Care Provider.
- DO NOT use with wet hair.
- The Charging Cable may be a strangulation hazard.
- DO NOT wash or submerge Cap at any time.
- Travel Bag may be a suffocation hazard if placed over nose and mouth. DO NOT place bag over the head.

WARNINGS & CAUTIONS

CAUTIONS

- Keep the Cap out of reach of children and pets.
- Use of the Cap is intended for no more than two (2) registered users.
- Keep the Charging 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. See Appendix III.
- Do not look directly into LED lights.
- If the REVIAN Red Cap meets water, humidity, or excessive perspiration, allow to dry before use, charging or storage.
- The battery is rechargeable but not intended as a user-replaceable part.
- Use the Cap 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.

CHARGING THE CAP

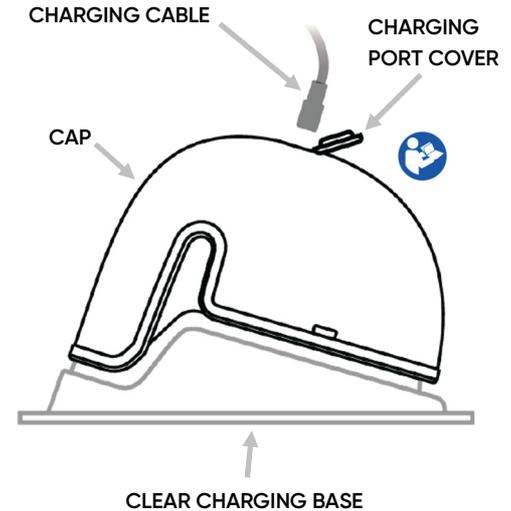
WARNING: DO NOT connect this equipment with any other equipment not provided in the Accessory Kit.

Contact Customer Support or email support@revian.com for replacement charging components.

WARNING: The Charging Cable may be a strangulation hazard.

IMPORTANT: DO NOT operate (use or charge) the Cap near a heat source.

IMPORTANT: DO NOT clean the cap while charging.



Fully charge the Cap in a cool, dry area prior to the first use with the AC Adaptor and Charging Cable provided in the Accessory Kit. Place the Cap on the Clear Charging Base. Attach the Charging Cable to the AC Adaptor. Plug the AC Adaptor in either orientation into an indoor outlet and then insert the Charging Cable into the Charging Port located on top of the Cap. The Cap should be positioned in an orientation while charging that allows for an easy removal of the Charging Cable.

The Charging Port in the Cap will turn **solid blue** when charging is in process. Once fully charged, the light will **pulse blue** intermittently every 4 seconds. To disconnect, unplug the AC Adaptor from the indoor outlet and unplug the Charging Cable from the Cap. Close the Charging Port Cover.

CHARGING THE CAP

When the battery is too low to perform a treatment, and needs to be charged, a battery icon and indicator message will appear on the REVIAN Mobile App. While connected, this can occur prior to or during a treatment. If during a treatment, go ahead and remove the Cap and charge the Cap. Once charged, the treatment will resume when the Cap is placed back on the head.

- **The Cap will disconnect from the REVIAN Mobile App and will NOT allow a treatment to be delivered.**
- To determine the battery level, disconnect the Charging Cable from the Cap and connect the Cap to the REVIAN Mobile App. The battery level will be displayed on the treatment screen.

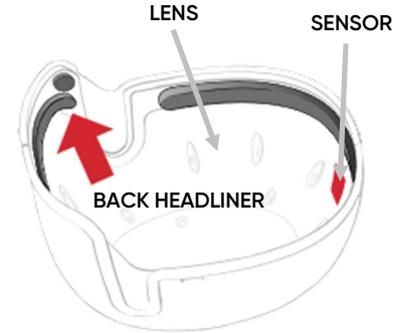
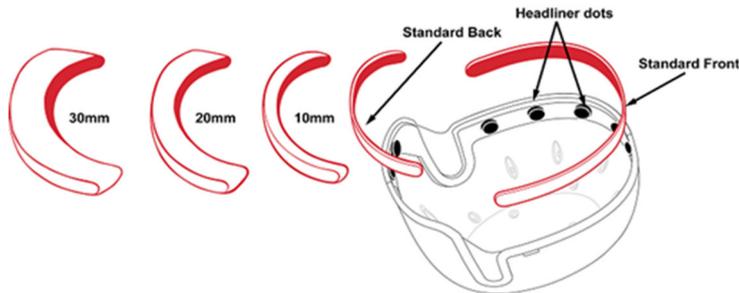


ADJUSTING THE CAP FIT

The Cap comes with front standard and back 10mm Headliners installed. 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 important to activate the sensor.

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 back 10mm Headliner from the Headliner Hook dots. If loose, replace with the optional back 20mm or 30mm 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: The clear plastic Lens is the Applied Part and allows the light to pass through to the scalp (emission aperture). See Appendix IV.

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](https://www.REVIAN.com)

CAP AUDIBLE TONES

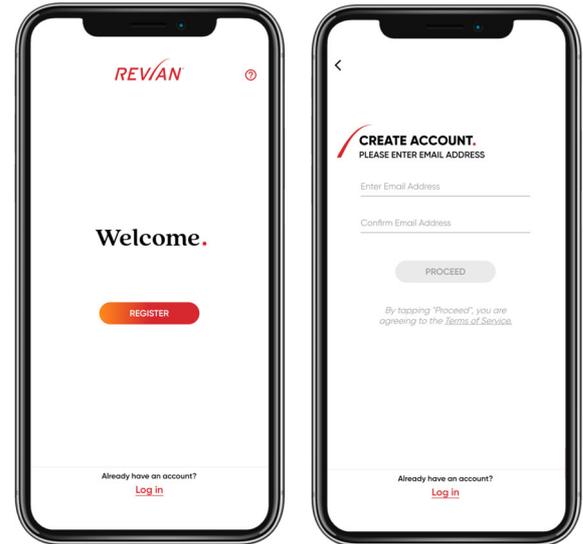
The REVIAN Red Cap is programmed to deliver audible tones that represent a specific status. The table below shows the meaning of each specific tone.

	Tone	Tone Meaning	Occurs When . . .
	X 8	Bluetooth Connection	The Cap and the Mobile App have successfully connected.
	x 3	Treatment START	The Cap is on your head and the Play (▶) button is tapped in the Mobile App.
	x 1	Treatment PAUSE	The Cap is removed from your head during a treatment and the Cap's sensor is deactivated OR the Pause (⏸) button is tapped in the Mobile App.
	x 2	Treatment RESUME	The Cap is placed back on your head after pausing a treatment and the treatment resumes OR the Play button is tapped in the Mobile App.
	x 3	Treatment COMPLETE	Your full 10-minute treatment has completed. You can remove the Cap from your head.
	X 3	Treatment ABORT	The Cap has automatically paused the treatment due to an over temperature condition.

REGISTERING YOUR ACCOUNT

1. To get started, search “**Revian**” in the Apple App Store® or Google Play® Store and download to your mobile device.
2. For first time users, tap the **REGISTER** button on the Welcome Screen.
3. Register with a valid email address. A verification email will be sent and you must click through the verification link from your mobile device to continue.
4. Once registered, pay close attention to the five educational onboarding screens. You can reference these screens in Appendix VI.
5. To continue, you must acknowledge that the REVIAN Red System is to be used only once per day per user.

NOTE: The REVIAN Mobile App must be in use and the mobile device connected to the internet to start a treatment.

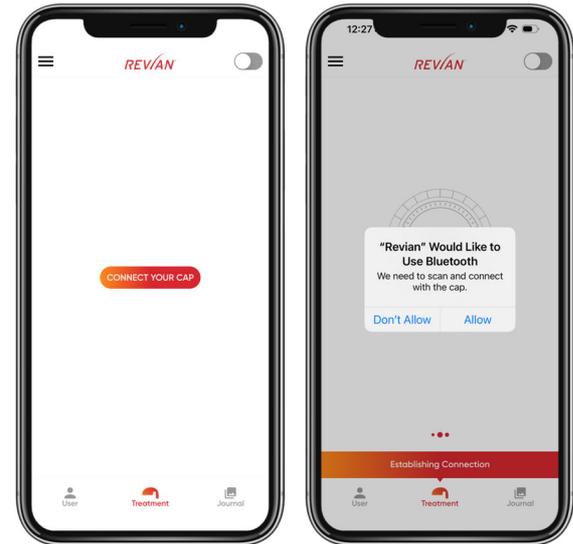


**** For existing users, to log in, tap LOG IN at the bottom of the Welcome Screen.****

CONNECTING TO THE CAP

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

1. Once logged in, you will be taken to the Treatment Screen displaying the **CONNECT YOUR CAP** button.
2. For first time users, when prompted you must allow Bluetooth permission. This is a one-time permission. Disconnect from any previously connected devices, like a smart watch, prior to performing a treatment, if applicable.
3. A sensor located in the front inside of your Cap detects when the Cap is properly placed on your head.
4. Place the Cap on your head to activate the sensor. Tap the **CONNECT YOUR CAP** button. The status bar in the Mobile App will state "Establishing Connection" and an audible tone will emit from the Cap once successfully connected.



If the REVIAN App does not locate a Cap, try the following:

- On your mobile device, confirm Bluetooth is turned on.
- Make sure your Cap has been charged.
- The Cap has to be on your head and fit snugly for the sensor to activate a treatment. To adjust the fit of your Cap, use the back Headliners provided in your REVIAN Red System.

NOTE: When connecting to the Cap, Bluetooth pairing can only occur within the REVIAN Mobile App, NOT within the general settings menu on a mobile device.

PERFORMING A TREATMENT

IMPORTANT: DO NOT operate (use or charge) the Cap near a heat source.

1. To begin a treatment, place the Cap on your head and tap the **CONNECT YOUR CAP** button in the Mobile App.
2. Once connected, a 10-minute timer will display. Tap the **PLAY** button in the round dial to start your treatment. The Cap will emit an audible tone when the treatment begins.
3. The treatment can be paused by tapping the **PAUSE** button in the round dial or by removing the Cap from head.
4. To resume a paused treatment, simply place the Cap on your head again and the treatment will automatically pick up where it left off.



Treatment Paused

The Cap's sensor has detected the Cap was removed from your head or the Cap is not fitting snug enough to maintain a connection.

To resume treatment, please place the Cap back on your head or add additional Headliners to ensure a correct and snug fit.



PERFORMING A TREATMENT

Continued

5. An audible tone will emit from the Cap once the treatment has completed.
6. Leave the Cap on your head until you have verified the treatment successfully recorded by viewing the Completed Treatment checkmark in the Mobile App.
7. Only a single 10-minute treatment can be initiated daily. Another treatment cannot be initiated on a later day until the full 10 minutes of the prior treatment (once started) has been completed.

Temperature Limiting Feature:

A temperature sensor is embedded into the device to prevent the inside surface of Cap from exceeding 46 °C (108 °F). The REVIAN Mobile App will display a message and the device will go into a reduced power mode until the internal temperature is lowered to the appropriate range.

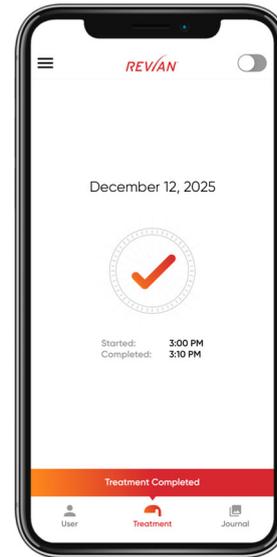


Treatment Paused: Overheating

The Cap needs to cool down to continue.

Try the following solutions:

1. Remove the Cap from charging
2. Take the Cap off and wait 10 minutes



NOTE: Once treatment is complete, place the Cap back on the Clear Charging Base for optimal protection. The Cap will perform at least two treatments before needing to be recharged.

USER CALENDAR & REMINDERS

The REVIAN Mobile App allows you to track your treatment history and set reminder notifications for future treatments. To access, tap **USER** in the bottom footer of the Mobile App.

Treatment Calendar

- Completed treatments are circled in green on your calendar and missed treatments are circled in grey.
- Your treatment compliance is shown at the bottom of the screen.
- Treatment compliance is calculated by taking your total number of treatments divided by the total number days since your first treatment through yesterday.

Reminders

- To receive push notification reminders, you must accept notification permission when prompted for the first time.
- Push notification reminders are sent once per day based on the day and time you set.



Treatment

It is time for your daily treatment

now

TAKING PROGRESS PHOTOS

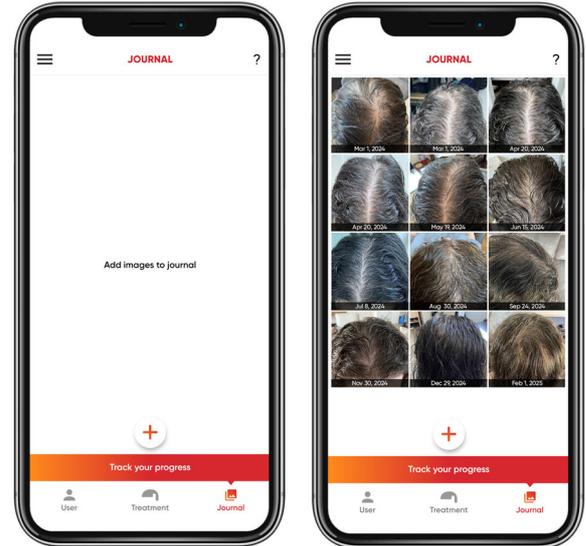
Seeing is believing! It is important to document progress while using the Cap with Before & After photos. To access this feature, tap **JOURNAL** in the bottom footer of the Mobile App.

The first time you access your Journal to add images, you will be prompted for permission to access your photos and/or camera. We take your privacy seriously and we will never share your photos unless we receive written permission from you. See the Revian Privacy Policy for more details.

You can add photos from your phone's library or utilize your phone's camera to take new ones. Once the photo is added, you can tap on the photo thumbnail to view in slideshow mode. Tap **SETTINGS** ⚙️ icon to edit date, download, or delete photo.

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.



LIGHT & DARK MODE

The REVIAN Mobile App allows users to choose a visually comfortable interface depending on whether they are in a bright or low-light environment.

The Mobile App is defaulted to Light Mode, however, you may switch between Light & Dark Mode by navigating to the **TREATMENT** screen and using the On/Off toggle located at the top right of the screen.



ADDING A 2ND USER

A 2nd user in the household is permitted to use the Cap under their own registered account.

IMPORTANT: The primary account holder must complete their first treatment before the invitation for a second user will be able to be sent.

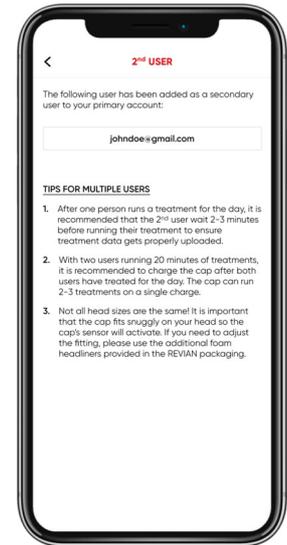
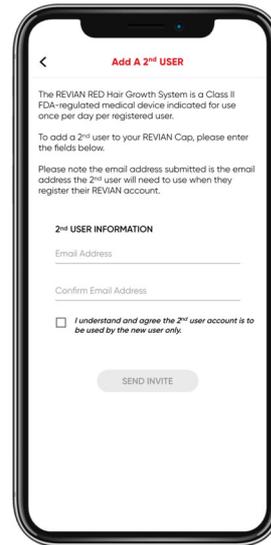
IMPORTANT: You must be on Mobile App Version 2.2.2 or newer.

To Add a 2nd User

1. In the Mobile App, tap **MENU** icon in the top left corner.
2. Tap **SETTINGS** and then tap **ADD A 2ND USER**.
3. Enter the email address of the 2nd user.

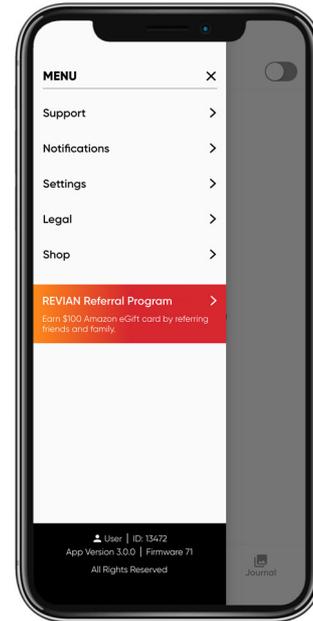
IMPORTANT: The email address submitted should be that of the 2nd user.

4. Check the box to acknowledge that you agree the 2nd user account is to be used by the new user only.
5. Tap **SEND INVITE**.
6. The 2nd user will receive an email with subject line "Revian: You've been added as a 2nd user." Check spam folder if email is not received within a few minutes. Follow steps in the email to complete registration process for the 2nd user.



MOBILE APP MENU

- The **MENU** ☰ can always be accessed in the upper-left corner the screen. This presents a set of options to find content and information for interacting within the application in various ways.
- The **SUPPORT** screen provides access to Troubleshooting and FAQs, the latest Instructions for Use document, as well as a link to purchase Accessory Parts.
- **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.
- **SHOP** provides you quick access to purchase products from our online store.
- User ID and App Version details are displayed 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.



The Revian Referral Program is an offer to allow you to share with friends and family and get rewards!

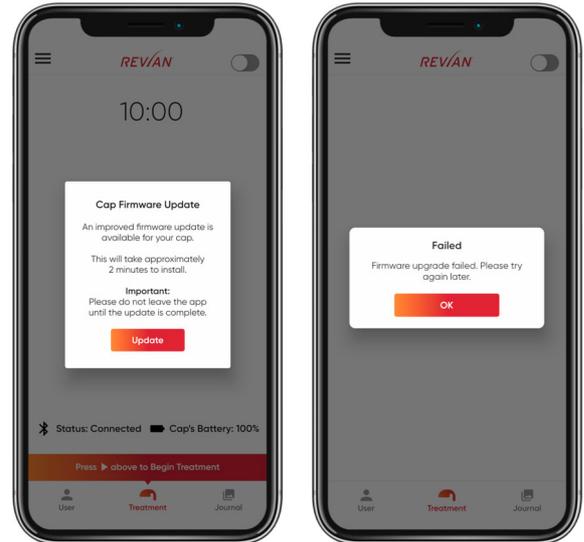
CAP FIRMWARE

New firmware will be released as new versions are available. If the device shows a “Cap Firmware Update” pop-up, allow the REVIAN Mobile App to initiate a Cap update.

Do not leave the REVIAN Mobile App while firmware is updating, this should only take about two minutes. The progress of the update will be shown in the REVIAN Mobile App.

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

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



CLEANING & TRAVEL

-  **WARNING:** DO NOT wash or submerge Cap at any time.
-  **WARNING:** 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 Clear Charging 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 the Clear Charging Base when in the Travel Bag.
- Replacement Headliners are recommended to maintain proper fit and cleanliness. Headliners can be purchased on the Revian website: <https://revian.com/product/revian-headliner-universal-kit/>

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.

MOBILE APP MESSAGES: The REVIAN Mobile App will display messages on occasion. These will appear as direct messages or icons in the REVIAN Mobile App.	
"REVIAN Cap Not Found"	This message appears when Bluetooth needs to be turned on or is unable to locate the Cap.
"Establishing Connection"	This message appears when Bluetooth is scanning to find the Cap.
"Treatment Paused"	This message appears when the Cap has been removed or is not detected by the sensor during a treatment.
"Failed" (Log In)	This message appears when the user's 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 Update Successful"	This message appears if the update was successfully transmitted to the Cap.

ERROR MESSAGES: There are specific messages that will appear as an alert if the Cap is not performing properly.	
"Treatment Paused: Overheating"	This message appears, with a temperature warning icon, when the temperature exceeds the maximum allowable operating temperature.
"Low Battery"	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.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	POTENTIAL SOLUTION
The mobile app is being nonresponsive to commands	The Mobile App was left open or in an unknown state from the previous time it was used. iOS or Android device needs to be updated.	<ul style="list-style-type: none"> • Swipe and force close out of the mobile app and relaunch it. • Update your mobile device with latest software. • Delete and reinstall the Mobile App.
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 the Cap on Head" pop-up message is shown).	<ul style="list-style-type: none"> • 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. • The Cap may not be fitting appropriately. Try increasing the thickness of the back Headliner size only.
	The mobile device is not connected to the internet.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Enable Bluetooth on mobile device.
	The mobile device has connected to another Bluetooth device, and not the Cap.	<ul style="list-style-type: none"> • Check mobile device settings and ensure device isn't already paired with another device.
	The Mobile App is not scanning for the Cap.	<ul style="list-style-type: none"> • Force the Mobile App to scan for the Cap by tapping "Connect your Cap" on the treatment page. • Plug the Cap into the AC Charger for a few seconds to reset it then try again.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	POTENTIAL SOLUTION
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.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • 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 Mobile App updating.	<ul style="list-style-type: none"> • Make sure the Cap is on your head, charged and not plugged in. • Restart the Mobile App or check for updates to the Mobile App in the App store.
The Mobile App will not open.	The mobile device is an outdated version and it is not compatible with the REVIAN Mobile App.	<ul style="list-style-type: none"> • Try to delete and reinstall the Mobile App from the app store on your device. • Your iOS device must have a software version of 13.X+ to work properly. • Your Android device must have a software version of 9.X+ to work properly.
The Mobile App will not download firmware or software updates.	The cloud server is unavailable The device software is incompatible with the REVIAN Mobile app.	<ul style="list-style-type: none"> • 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.	<ul style="list-style-type: none"> • Force close and re-launch the REVIAN Mobile App • Contact revian.com/support/

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	POTENTIAL SOLUTION
The Cap allows a treatment longer than 10 minutes..	Software or firmware error.	<ul style="list-style-type: none">Place the Cap on the Support Base and allow the Cap to complete the treatment on the Clear Charging Base.
Some of the Treatment LEDs are not turning on.	Damage to hardware.	<ul style="list-style-type: none">Contact Customer Support at support@revian.com or on the website at revian.com/support.

NOTE: If there is a connectivity issue or the REVIAN Mobile App is non-functional, force close and then restart the REVIAN Mobile App. If that does not fix the problem, delete and reinstall the Mobile App 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.

APPENDIX I: PRODUCT SPECIFICATIONS

Cap Dimensions

Height: 15.87 cm (6.25 in)

Width: 20 cm (7.87 in)

Length: 22.86 cm (9 in)

Cap Weight

155 g (0.34 lbs)

Head Circumference

54 cm (21.26 in) - 64 cm (25.20 in)

Optical Characteristics

1.67 mW/cm²

620-660 nm +/- 10 nm

per IEC 60601-2-57 (1st edition): 2011

Temperature Limiting Feature:

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.

Battery

Lithium Polymer: Lithium polymer batteries are classified by the US federal government as hazardous waste. Refer to local requirements for disposal or recycling instructions.

AC Charger

Input 100-240V, 50Hz/60Hz

Service Life

3-4 years

Bluetooth Low Energy Module

ISM Band 2.402 to 2.480 GHz operation

REVIAN Mobile App Compatibility

Android Devices: Most Android based devices running operating systems 9.X+ and manufactured within the last three years

iOS devices: Operating Systems 13.X+

APPENDIX II: STORAGE & OPERATING CONDITIONS

Storage

- **Storage Temperature**
5-35 °C (41-95 °F)
- **Relative Storage Humidity**

Up to 90% non-condensing

NOTE: It is recommended to keep the Clear Charging base and product box for storage to protect against product damage.

Operating (Use or Charging)

- **Operating Temperature**
15-35 °C (59-95 °F)
- **Relative Operating Humidity**
Up to 90% non-condensing
- **Atmospheric Pressure**
70 kPa to 106 kPa

APPENDIX III: DISPOSAL

REVIAN Red is powered by a Lithium Polymer battery. Lithium polymer batteries are classified by the US federal government as hazardous waste. Refer to local requirements on how to dispose or recycle devices containing lithium polymer batteries.

 **WARNING:** DO NOT attempt to remove internal components of the device. 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.

APPENDIX IV: DEFINITIONS & SYMBOLS

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

User: The authorized person who can log into the REVIAN 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



MENU – this symbol reveals the mobile app menu when clicked



POSITION CAP ON HEAD – this symbol appears when the Cap has been removed or is not placed properly on the head



CAP'S BATTERY LEVEL – this symbol appears during an active connection of the Cap with the Mobile App there is a % battery level listed at the bottom of the treatment screen

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

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

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



CHARGE BATTERY – this symbol may appear prior to treatment or during treatment



TEMPERATURE WARNING – this symbol appears when the Cap needs to cool down



BLUETOOTH – this symbol appears when Bluetooth is connected or scanning or waiting for connection.



INTERNET CONNECTION – this symbol appears when the Mobile App has not connected to the internet in seven days to allow data transfer

APPENDIX IV: DEFINITIONS & SYMBOLS



NON-IONIZING – this symbol represents non-ionizing electromagnetic radiation



CAUTION – this symbol appears next to information about possible safety and product risks



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



SERIAL NUMBER – this symbol is accompanied by the manufacturer's serial number



QUANTITY – this symbol represents the number of devices



MANUFACTURER – this symbol is accompanied by the name and address of the product manufacturer



MANUFACTURED DATE – this symbol is accompanied by a date



TYPE BF APPLIED PART – this symbol indicates this is a “Body Floating” applied part in concern with electrical contact



USB Trident Logo – this symbol represents the USB Connection the Cap uses to recharge



INSTRUCTIONS MANUAL – this symbol references the manual for charging instructions



SEE INSTRUCTIONS FOR USE – this symbol refers the User to the Instructions for Use for further information



IP22 – this symbol represents water spray protection of the Cap



PACKAGE DAMAGE – this symbol appears as a warning to not use the device if the package is damaged



TEMPERATURE LIMITATION – this symbol indicates the upper or lower limit of temperature



HUMIDITY LIMITATION – this symbol indicates the upper or lower limit of humidity



KEEP DRY – this symbol appears if a device is required to be kept dry



ATMOSPHERIC PRESSURE LIMITATION – this symbol indicates the environmental limitation for the device

APPENDIX V: OPERATIONAL MODES

CHARGING MODE: When the Cap is plugged in it is in CHARGING mode. An LED indicator located inside the Cap near the Charging Port will illuminate blue. 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 Clear Charging 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 Clear Charging Base and then remove the charging cable. Class II medical equipment.

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.

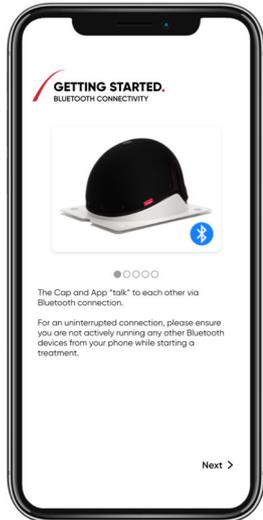
TREATMENT MODE: When the Cap is activated, successfully paired with the Mobile App, and placed in position for treatment, it is in TREATMENT mode. Treatment begins once the play icon is pressed on the treatment screen of the Mobile App. An audible tone will be heard, and the treatment countdown clock 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.

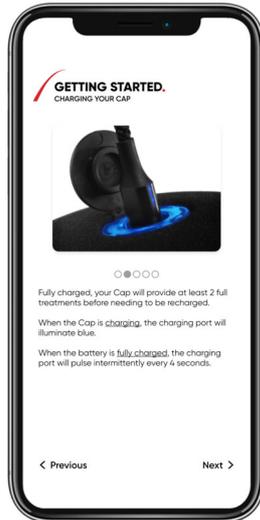
SLEEP/STANDBY MODE: When the Cap is removed from AC Power but not activated, it will be in its lowest power consumption state and is in a SLEEP/STANDBY mode. The battery indicator, treatment, LEDs, and Bluetooth module will not be active. To bring the Cap out of SLEEP/STANDBY mode it should be placed on the head or hold the copper-colored forehead sensor.

APPENDIX VI: MOBILE APP ONBOARDING SCREENS

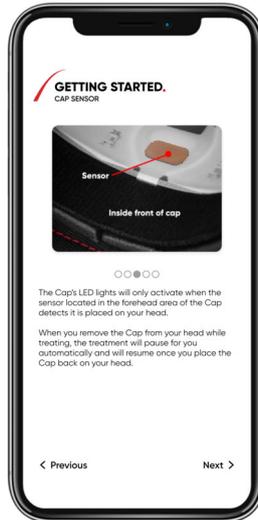
The first time the REVIAN Mobile App is downloaded, the user will be navigated through five (5) educational onboarding screens. Those screens are referenced below.



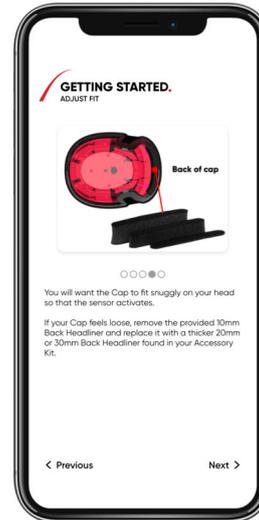
Onboard Screen 1



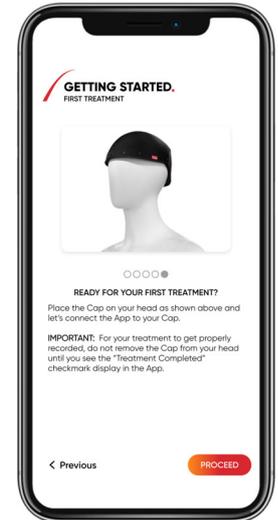
Onboard Screen 2



Onboard Screen 3



Onboard Screen 4



Onboard Screen 5

APPENDIX VII: FREQUENTLY ASKED QUESTIONS

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.

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.

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? If you would like to share the Cap with another person in your household, navigate to the Menu in the REVIAN Mobile App, tap Settings, and tap “Add a 2nd User.”

Do I need to connect to Wi-Fi or Cellular to start a treatment? Yes, and authorization for a treatment can only be started while connected.

APPENDIX VII: FREQUENTLY ASKED QUESTIONS

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, “Low Battery” 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 indications that show the state of the Cap’s charge when connected to the Mobile 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.

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 unplugging the Cap and wiping it down with a cloth lightly moistened with water.

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.

APPENDIX VII: FREQUENTLY ASKED QUESTIONS

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 Bluetooth 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 BlueTooth devices.

Where can I find my login information? Send an email to support@revian.com along with your Order Number, and Customer Support will provide you with your login information.

Can I switch to other apps during my treatment? Yes, once a treatment has been initiated you can use your mobile device as you normally would.

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.

How do I purchase additional items? Visit the Revian website for additional items.

What is the useful service life of the Cap? 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.

****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.**

APPENDIX VIII: ELECTROMAGNETIC EMISSIONS

Table 1. Guidance and manufacturer’s declaration—electromagnetic emissions—for all ME EQUIPMENT and ME SYSTEMS.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
<p>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.</p>		
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 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 IX: ELECTROMAGNETIC IMMUNITY

Table 2. Guidance and manufacturer's declaration—electromagnetic immunity—for all ME EQUIPMENT and ME SYSTEMS.

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	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 commercial, 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, 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, hospital or home healthcare environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

APPENDIX IX: ELECTROMAGNETIC IMMUNITY

Table 3. Guidance and manufacturer’s declaration—electromagnetic immunity for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING.

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	Electromagnetic Environment—Guidance
Conducted RF IEC 61000-4-6	3 V _{RMS} 150kHz to 80MHz	3V	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 application to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz	10 V/m	Recommended separation distance: $d = [3.5 / V] \sqrt{P}$; $[3.5 / E] \sqrt{P}$ 80 MHz to 800 MHz; $[7 / E] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range. 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 X: 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 SYTEMS 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 $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	80 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.

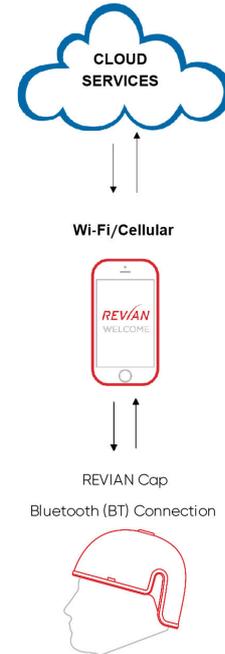
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

APPENDIX XI: CHARACTERISTICS OF THE IT-NETWORK FOR THE REVIAN RED SYSTEM

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 App running on an iOS or Android operating system and Revian cloud services as well as between the REVIAN Mobile App and the REVIAN Red Cap. Communications of treatment is transmitted once the 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 XII: FCC COMPLIANCE

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

This module is used to connect the Cap to a mobile device running the REVIAN Mobile App via Bluetooth.

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:

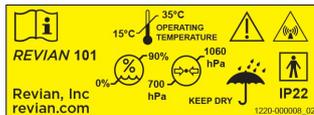
- Reorient or relocate the Cap and/or mobile device running the REVIAN Mobile App.
- Increase the separation between the Cap and mobile device running the REVIAN Mobile App.
- Visit [revian.com](https://www.revian.com) for additional assistance.

APPENDIX XIII: PRODUCT LABELS

REVIAN Red
Device ID Label



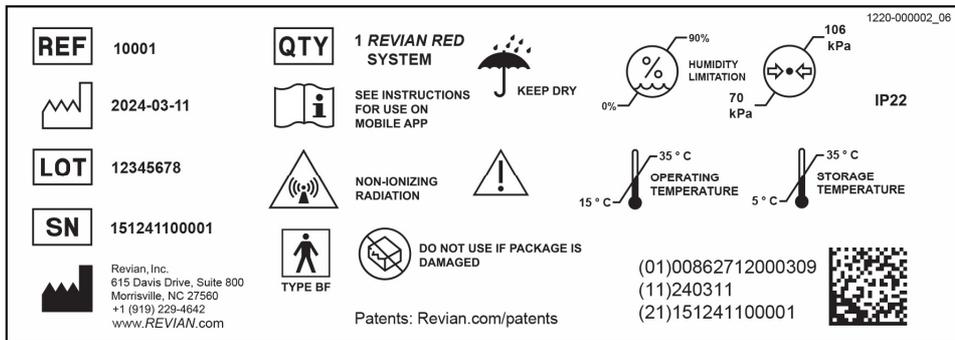
REVIAN Red
Device Symbol Label



See Instruction
Manual Label



REVIAN Red
Package Label



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