1. Product Overview

The REVIAN 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 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 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 has no known contraindications.
2. 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. Lift the top cover from 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-Micro-USB Cable
  - Travel Bag

5. Remove the accessory kit and carefully read the Quick Start Guide.
6. Remove the accessories contained inside the accessory kit:
   - USB-to-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 micro-USB cable.

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3. 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.

![Cap Illustration](image)

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

To Adjust Headliners:

1. A sensor detects when the Cap is on the head. 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.

![Headliner Adjustment](image)

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.

![Fit Test](image)

**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.
4. Connecting the Cap to the Mobile App

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 iTunes® or Google Play® store.
2. Click the Register button as a new user and follow the email verification and registration process to obtain your login credentials or login with your established account credentials.
3. Upon initial login, a day zero picture will be requested. See “Taking Progress Photos” for more information.
4. Set the Bluetooth to “ON” in the mobile device. Disconnect from any previously connected devices, like a smart watch, prior to performing a treatment, if applicable.
5. Place the Cap on the head to activate. A sensor detects when the Cap is properly placed on the head.
6. On the treatment page, click on the yellow Bluetooth icon. This will initiate scanning to find the REVIAN Cap.
   - If the REVIAN app does not locate a Cap, try charging the cap for a few seconds to reset it then place it on your head and try again.

7. Press the blue “Connect” button to the right of the mobile device under “Manage Caps” and the Cap will pair with the mobile app. Once successfully paired, an auditory tone will be heard, and the treatment page will return.

8. New firmware will be released as new versions are available. If the device shows a “New Firmware” 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.

15. 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.

9. A pop-up message will appear once the firmware has successfully updated. The update may be deferred once but will occur automatically the next time there is Bluetooth connection. The device will show a “Firmware Update” pop-up before it automatically updates.

NOTE: If the device shows an “error” pop-up when updating firmware, the firmware will resolve the problem and attempt to download again immediately after.
6. Taking Progress Photos

Seeing is believing! It is important to document progress while using the Cap with before and after photos. Upon initial login, the REVIAN mobile app will require a day zero picture. Every 90 days the mobile app will prompt a new progress photo be taken to evaluate the effectiveness of treatments. The gallery page allows comparison of the affected areas as treatments progress.

For Best Results:

- Take the picture with the mobile phone in the vertical orientation so the photo is in portrait mode like the inset example above.
- Maintain consistency in position, lighting and camera 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.
- The mobile app camera permits photo retakes until a photo is accepted. Once accepted, the photo cannot be replaced or retaken.
- The mobile app camera permits positioning of the image to fit in the predefined square. Pinch to resize and center the image.

7. Performing a Treatment

To begin a treatment, place the Cap on the head and connect via Bluetooth. A tone will be heard once the Cap has been properly connected. Press the white play button within the round dial on the treatment page.

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

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 until the full 10 minutes of the prior treatment 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 but charging the Cap between treatments is a good way to ensure it is fully charged when needed.
8. 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 AC adaptor in either orientation into an indoor outlet and then insert micro-USB cable connector into micro-USB port located on top of the Cap. The charging port in the Cap will illuminate when successfully charging. Once fully charged, the light will turn off. To disconnect, unplug the AC adaptor from the indoor outlet and the micro-USB cable connector from the Cap.

**Charging Light Indications:**
- When the Cap is charging the charging port will illuminate.
- When charge is complete the charging port light will turn off.

**NOTE**: While charging, the Cap will disconnect from the mobile app and will NOT allow a treatment to be delivered. The Cap should be positioned while charging in an orientation that allows for an easy removal of the charging cable.

**DO NOT CLEAN THE CAP WHILE CHARGING.**

9. App Tour

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

- 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 **STATUS** page includes reminders, daily convenience scheduling, and weekly progress indicators. To set reminders, press the ‘SET REMINDERS’ button and preselect specific week days and times to receive treatment notifications.

When the battery is too low to perform a treatment, and needs to be charged, a battery icon and indicator message will appear. This can occur prior to or during a treatment.
10. App Tour

- The **PROGRESS** page includes a monthly treatment history calendar with current day (marked blue), successful (marked green), and missed treatment days (not marked).

11. App Tour

- The **TREATMENT** page identifies remaining treatments for the week, with successful treatments (marked green), missed treatments (marked grey) and remaining treatments (marked blue). The Cap connection status is shown at the bottom of the screen with Bluetooth and battery level indicators. This page allows a treatment to start and pause within the allotted 10 minutes.

- The **GALLERY** page records baseline and follow-up pictures to track visual progress of *REVIAN* treatments. The center page slider button displays both the day zero image and most recent picture. This allows comparison of the affected areas as treatments progress.

- The **SETTINGS** page is for account administration, including password updates, push notifications, and Cap connection management.
12. 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 on head.

- Visually inspect interior of 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 leave the Cap charging between treatment sessions.
- For easy travel and added support, store the Cap on support base when in the travel bag.
- Replacement headliners are recommended every 90 days to maintain proper fit and cleanliness. They are available as needed at REVIAN.com/shop.

13. Troubleshooting

This section summarizes the most common problems users could potentially encounter with the REVIAN 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.

<table>
<thead>
<tr>
<th><strong>App Messages</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“Check Bluetooth”</td>
<td>This message appears when Bluetooth needs to be turned on, connected, or is scanning.</td>
</tr>
<tr>
<td>“Scanning for Devices”</td>
<td>This message appears when Bluetooth is scanning to find the Cap.</td>
</tr>
<tr>
<td>“Please put Your Cap Back On”</td>
<td>This message appears when the Cap has been removed or is not detected by the biosensor.</td>
</tr>
<tr>
<td>“Connect to the Internet for more treatments”</td>
<td>This message appears when the mobile app has not been connected via Wi-Fi or Cellular in more than 7 calendar days to allow data transfer.</td>
</tr>
<tr>
<td>“New Firmware Available”</td>
<td>This message appears when new firmware is available and ready to install.</td>
</tr>
<tr>
<td>“Firmware Needs to be Updated”</td>
<td>This message appears if the update was deferred the first time and the mobile app will now automatically update the firmware.</td>
</tr>
<tr>
<td>“Firmware Update Successful”</td>
<td>This message appears if the update was successful.</td>
</tr>
</tbody>
</table>

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

14. Error Messages

<table>
<thead>
<tr>
<th><strong>Error Messages</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>“The Cap needs to cool down”</td>
<td>This message appears, with a temperature warning icon, when the temperature exceeds the maximum allowable operating temperature.</td>
</tr>
<tr>
<td>“Battery Low. Treatment not possible.”</td>
<td>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.</td>
</tr>
<tr>
<td>“Firmware Update Failed”</td>
<td>This message appears when there is a problem updating the firmware. The firmware will automatically resolve the problem and attempt to update again.</td>
</tr>
</tbody>
</table>

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

15. Cap Audible Tones

1. Bluetooth Connected / Treatment Complete
2. Treatment Started
3. Treatment Stop/Pause
4. Treatment Resume
5. Treatment Temperature Abort
16. Troubleshooting

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 at least once every seven days to continue treatments.

**NOTE:** If there is a connectivity issue or the mobile app is non-functional, force close and then relaunch the REVIAN app.
<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>POSSIBLE CAUSE</th>
<th>SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The mobile app is being nonresponsive to commands</td>
<td>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.</td>
<td>Swipe up and close out of the mobile app and relaunch it. Update your mobile device. Delete and reinstall the app.</td>
</tr>
<tr>
<td>The Cap has successfully paired and has been properly placed on the head, but a treatment will not start</td>
<td>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.)</td>
<td>Reposition the Cap. The Cap may not be fitting appropriately. Try moving up to the next back headliner size.</td>
</tr>
<tr>
<td>The Cap is not pairing with the mobile device</td>
<td>Bluetooth is not enabled on your mobile device.</td>
<td>Enable Bluetooth on mobile device.</td>
</tr>
<tr>
<td>The mobile device has connected to another Bluetooth device, and not the Cap</td>
<td>Check mobile device settings and ensure device isn’t already paired with another device.</td>
<td>Force the mobile app to scan for the Cap by tapping “Manage Caps” in “Settings” page. Plug the Cap into the AC Charger for a few seconds to reset it then try again.</td>
</tr>
<tr>
<td>The mobile app is showing a high temperature pop-up message</td>
<td>The internal temperature of the Cap may have reached a higher than normal operating setting.</td>
<td>The Cap may need to cool before continuing treatment, remove the Cap for a brief period and allow to cool.</td>
</tr>
<tr>
<td>The mobile app is showing a low battery pop-up message</td>
<td>The battery may not be in a fully charged state.</td>
<td>Place the Cap on the support base and charge for at least 30 minutes.</td>
</tr>
<tr>
<td>The mobile app is unable to start a treatment</td>
<td>The iOS or Android mobile device’s internal software was updated prior to the REVIAN app updating.</td>
<td>Update the REVIAN app.</td>
</tr>
<tr>
<td>The mobile app will not open</td>
<td>The mobile device is an outdated version and is not compatible with the mobile app.</td>
<td>Your iOS device must have a version of 10.X+ Your Android device must have a version of 6.X+.</td>
</tr>
<tr>
<td>The mobile app will not download firmware or software updates</td>
<td>The cloud server is unavailable. The device software is incompatible with the REVIAN app.</td>
<td>Check mobile device for Wi-Fi connection and/or verify Internet connection. Ensure your mobile device is updated to the latest version.</td>
</tr>
<tr>
<td>The Cap is allowing multiple treatments within a 24-hour period</td>
<td>Software and/or firmware error.</td>
<td>Force close and re-launch the REVIAN app. Contact REVIAN.com/support.</td>
</tr>
</tbody>
</table>
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

2. OPERATIONAL MODES

• CHARGING MODE: When the Cap is on the support base and plugged in it is in CHARGING mode. A LED indicator located inside the Cap near the micro-USB charging port will illuminate blue. The battery should be charged from a depleted state to a full charge within 90 minutes. 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 Cap on support base and then insert micro-USB cable end into the top port. When the Cap is fully charged, the charging port light will turn off. Leave Cap on support base and then remove micro-USB 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.

• 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, allowing the user 10 minutes to restart the treatment. Treatment time remaining is stored in the Cap until completion of the paused treatment.

*Please read all instructions in manual before using REVIAN 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
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 treatments are stopped for several weeks or more, 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 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 bath tub 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 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 warranty and may cause harm to user.

**CAUTIONS**

- If the REVIAN 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 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 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.

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 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.

THE COMPANY MAKES NO OTHER WARRANTIES FOR 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 device that has the REVIAN mobile app installed on it and can connect and control the Cap.

**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.

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### FREQUENTLY ASKED QUESTIONS

**What is the REVIAN 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 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 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 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 Cap Safe?** Yes, it is safe to use. The LEDs utilized by the REVIAN 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 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 Cap while taking photosensitizing medications, shampoos, lotions or other therapies?** No, you should not use REVIAN while taking these therapies. Consult your physician regarding use of these products with REVIAN.

**Can I use the REVIAN 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. Sharing treatments could reduce or eliminate efficacy of the treatment.
How can I track my treatments? A unique feature of the REVIAN 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 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 90 minutes. 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 the Cap is charging it will appear illuminated blue and once the charge is complete the light will turn off.

Do I need to use Bluetooth to connect to the Cap? The REVIAN 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? You only need to have Bluetooth connection for your mobile device to start a treatment with the Cap, but you must authenticate your account at least once per week via cellular or Wi-Fi to continue using the mobile app for treatments.

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 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 at REVIAN.com/shop. For best coverage of the scalp when using the Cap, part your hair to maximize exposure to MLT to reach thinning areas.

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. 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.

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.

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 REVIAN.com to reset.

What is the useful service life of the Cap? The Cap and accessories* are warrantied 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 suited for everyone? REVIAN 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:

8. CUSTOMER SUPPORT

If the REVIAN System is not functioning as outlined in these instructions for use, please refer to REVIAN.com/support for additional troubleshooting details.

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## Guidance and manufacturer’s declaration - electromagnetic emissions

The REVIAN 101 is intended for use in the electromagnetic environment specified below. The Customer or the user of the REVIAN 101 should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>REVIAN 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>REVIAN 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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
### 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).

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electromagnetic discharge (ESD)</td>
<td>±8 kV contact</td>
<td>PASS</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±15 kV air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/burst</td>
<td>±2 kV for power supply lines</td>
<td>PASS</td>
<td>Mains power quality should be that of a typical commercial, hospital or home healthcare environment.</td>
</tr>
<tr>
<td>IEC 61000-4-4</td>
<td>±1 kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1 kV line(s) to line(s)</td>
<td>PASS</td>
<td>Mains power quality should be that of a typical, hospital or home healthcare environment.</td>
</tr>
<tr>
<td>IEC 61000-4-5</td>
<td>±2 kV line(s) to earth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines</td>
<td>&lt;5 % $U_T$ (&gt;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 &lt;5 % $U_T$ (&gt;95 % dip in $U_T$) for 5 sec</td>
<td>PASS</td>
<td>Mains power quality should be that of a typical commercial or hospital or home healthcare environment. If the user of REVIAN requires continued operation during power mains interruptions, it is recommended that REVIAN be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>IEC 61000-4-11</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60 Hz) magnetic field</td>
<td>30 A/m</td>
<td>PASS</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital or home healthcare environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 Emissions

The REVIAN 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.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>3 Vrms</td>
<td></td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the REVIAN 101, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td>150 kHz to 80 MHz</td>
<td>3 V</td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 V/m</td>
<td></td>
<td>$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$</td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td>80 MHz to 2700 MHz</td>
<td>10 V/m</td>
<td>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range.</td>
</tr>
</tbody>
</table>

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.

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* 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 101 is used exceeds the applicable RF compliance level above, the REVIAN 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 101.

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>$d = \left[ \frac{3.5}{v_i} \right] \sqrt{P}$</td>
<td>$d = \left[ \frac{3.5}{E_i} \right] \sqrt{P}$</td>
</tr>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.379</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.79</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 SYSTEM

The REVIAN 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 Cap (Figure E1). Communications of treatment is transmitted once Cap is activated. No known hazards exist from the REVIAN 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. PhotonMD will continually monitor any associated risks with using the REVIAN System, including any new risks, associated with changes to IT network.
APPENDIX F – FCC COMPLIANCE

The REVIAN 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 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 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 for additional assistance.