

REV/AN[®]

Instructions for Use



lyte[™]

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1. PRODUCT OVERVIEW

The REVIAN Lyte System is intended to be used within the home for 10-minutes once a day by male and female individuals with androgenetic alopecia who are 18 years of age and older; it is intended as a non-sterile, SINGLE USER, multiple-use device. The REVIAN Lyte device emits visible light to treat androgenetic alopecia and promote hair growth. Operation requires the user to place the device onto their head for 10 minutes. A treatment can be paused after it is initiated; however, the remaining treatment time must be used prior to the initiation of another treatment.

Indications for Use: REVIAN Lyte is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - 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.

Skin Types



Type I

Type II



Type III

Type IV

Norwood-Hamilton Scale for Men



IIA

III

III Vertex

III A

IV

IVA

V

Ludwig Scale for Women



I-1

I-2

I-3

I-4

II-1

II-2

Frontal

1. PRODUCT OVERVIEW

Contraindications for Use:

REVIAN Lyte has no known contraindications at this time.

Recommended Usage:

- Use the Cap daily, for 10 minutes at any convenient time.
- The Cap is only intended to be used by a single user.
- Use indoors in a cool, dry area. This product is not intended to be used outdoors or around water.
- Use only on dry or towel dried hair.
- If REVIAN Lyte 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.

2. DEVICE & ACCESSORIES

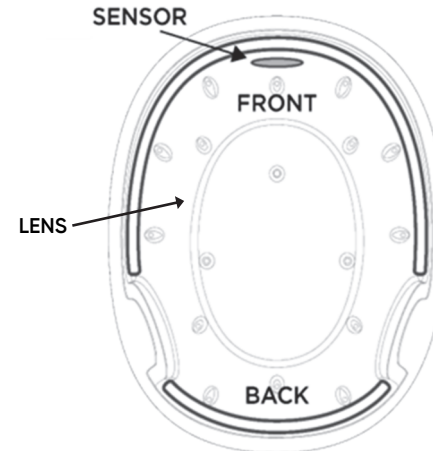
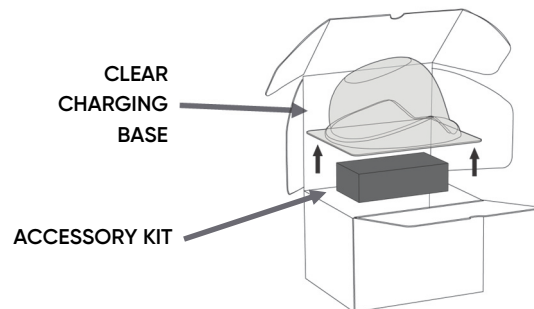
1. The contents of your package will contain the following:

- REVIAN Lyte Cap
- Clear Charging Base
- Accessory Kit
- Instructions for Use

IMPORTANT: Inspect your Cap for damage before the first use

2. 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



NOTE: The clear plastic Lens is the Applied Part and allows the light to pass through the scalp (emission aperture). See Appendix IV.

Accessory Kit



3 Back
Adjustment
Headliners



AC Adaptor &
USB-A to USB-C
Cable

3. WARNINGS & CAUTIONS

WARNINGS

- The USB Charging Cable may be a strangulation hazard.
- DO NOT use the Cap on any other part of the body other than the head.
- DO NOT perform more than one 10-minute treatment in a day.
- 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 clean the cap while charging.
- DO NOT use any cables, adaptors, or products that are not provided or approved for the device, as they may negatively interfere with the device's performance.
- DO NOT attempt to replace the battery or remove internal components. The Cap has NO user-serviceable parts and any attempt to remove internal components or modify the Cap will void the warranty and may cause harm to the user.
- DO NOT expose the Cap to heat or fire, crush the Cap, or attempt to remove the battery. The REVIAN Lyte Cap utilizes a lithium polymer battery and may result in fire and serious injury if tampered with.
- The long term effects of prolonged use of the REVIAN Lyte Cap is unknown. Consult your Health Care Provider.

3. WARNINGS & CAUTIONS

CAUTIONS

- Do not use the Cap, Charging Cable or AC adaptor if any are damaged.
- Do not submerge the Cap in water.
- Take care not to shine the light from the Cap in your eyes or in other's eyes.
- Do not store or charge the Cap near a heat source.
- If the REVIAN Lyte Cap is exposed to water, humidity or excessive perspiration, allow to dry before use, charging or storage.
- Keep the Cap out of reach of children and pets.
- Do not use the Cap near other mobile RF equipment as it may impact the performance of the Cap.
- Do not use cleaning agents or solvents to clean the cap as this may discolor or degrade the fabric or damage the plastic lens.

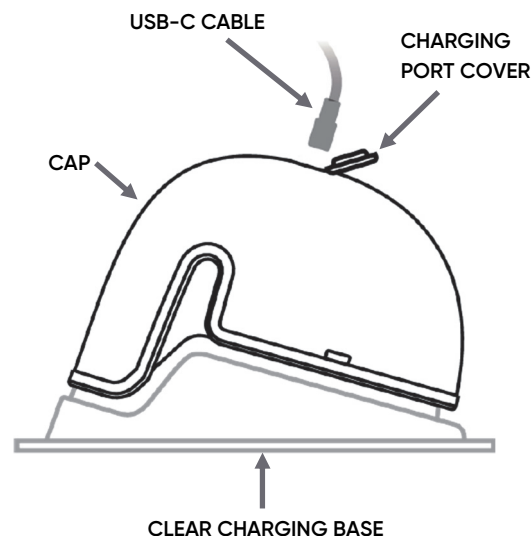
4. CHARGING THE CAP

Fully charge the Cap in a cool, dry area prior to the first use with the AC Adaptor and USB-C cable provided in the Accessory kit. Place the Cap on the Clear Charging Base. Attach the USB cable to the AC adaptor. Plug the AC adaptor in either orientation into an indoor outlet and then insert the USB-C connector 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**. To disconnect, unplug the AC Adaptor from the indoor outlet and the USB-C cable from the Cap. Close the Charging Port Cover.

IMPORTANT:

The Cap will NOT allow a treatment to start while being charged.

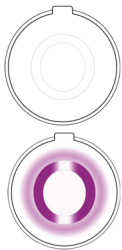


- ⚠ WARNING:** DO NOT expose the Cap to heat or fire, crush the Cap, or attempt to remove the battery. The REVIAN Lyte Cap utilizes a lithium polymer battery and may result in fire and serious injury if tampered with.
- ⚠ WARNING:** DO NOT use any cables, adaptors, or products that are not provided or approved for the device, as they may negatively interfere with the device's performance.
- ⚠ WARNING:** The USB cable connector may be a strangulation hazard.
- ⚠ WARNING:** DO NOT clean the cap while charging.

5. CHARGING PORT INDICATOR LIGHTS

The indicator lights located in the Cap's charging port displays in two states, SOLID and PULSE, in the colors of Orange, Yellow, Green, Blue, and Violet.

Charge Your Cap



Pulse Violet

Charging In-Progress



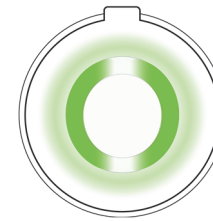
Solid Blue

Fully Charged



Pulse Blue

Ready for Treatment



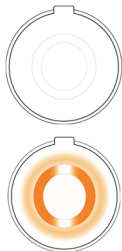
Solid Green

Finish Partial Treatment



Pulse Green

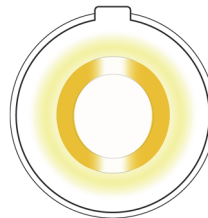
Device Error



Pulse Orange

* Contact Customer Service if the charging port pulses orange

Device Over-Temperature



Solid Yellow

** If the charging port indicator shows solid yellow, the cap will need to cool before continuing the treatment. A temperature sensor is embedded into the device to prevent the inside surface of Cap from exceeding 46°C (108°F). The device will automatically pause a treatment if this temperature is reached. When yellow light in the charging port turns off, the partial treatment can be resumed.

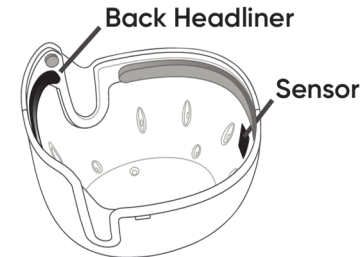
6. TONES

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

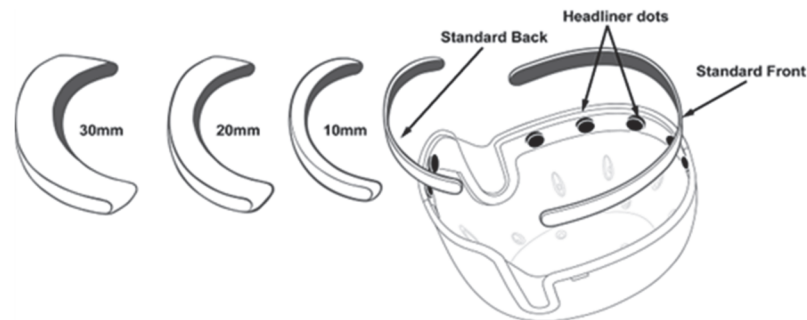
	Tone	Tone Meaning	Occurs When . . .
	x 3 x 2 x 1	Treatment START	The Cap is placed on your head and the Cap's sensor is activated. The treatment will start within 5 seconds.
	x 2 	Treatment PAUSE	The Cap is removed from your head during a treatment and the Cap's sensor is deactivated.
	x 2 	Treatment RESUME	The Cap is placed back on your head after pausing a treatment and the treatment resumes.
	x 3 	Treatment COMPLETE	Your full 10-minute treatment has completed. You can remove the Cap from your head.

7. ADJUSTING THE CAP FIT

The activation sensor that allows your Cap to run a treatment is located on the inside front of the cap. The Cap must have a snug fit against your forehead to operate.



If the Cap feels loose on your head, swap out the back headliner with a thicker back headliner provided in your accessory kit. 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. For consistent fit and comfort, it is suggested to replace headliners every three months. Replacement headliners can be ordered at [REVIAN.com](https://www.REVIAN.com).



IMPORTANT: To ensure proper sensor activation, the thick headliners should only be used in the back of the Cap. Do not place them in the front of the Cap.

8. PERFORMING A TREATMENT

 **WARNING:** DO NOT perform more than one 10-minute treatment in a day.

IMPORTANT: The Cap will NOT allow a treatment to start while being charged

Starting a Treatment

With the Cap fully charged, disconnect the charging cable from your Cap's charging port. Close the Charging Port Cover. Ensure the indicator light in the Cap's charging port is solid green. Place the Cap on your head.

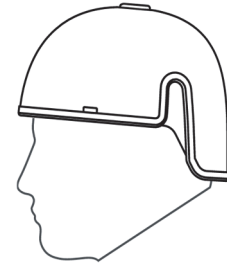
The treatment will begin once you hear a sequence of 3 short tones, followed by 2 short tones, and then 1 extended tone. After your 10-minute treatment fully completes, you will hear a 3-tone sequence, indicating that you can remove the Cap from your head.

Pausing a Treatment

In the event you need to pause your treatment, remove the Cap from your head. After you remove the Cap, you will hear two descending tones. Set the Cap on the Clear Charging Base. The Cap's charging port will flash green for 2 minutes.

If the partial treatment is not resumed in two minutes, the Cap will go to a low power mode. Your treatment will be stored on the Cap. Resume the partial treatment at any time by placing the Cap on your head. You will hear two ascending tones and the previous treatment will resume.

IMPORTANT: You must complete the full 10-minute treatment before starting a new treatment.



9. STORAGE & MAINTENANCE

Storage Between Uses

 **WARNING:** DO NOT expose the Cap to heat or fire.

 **CAUTION:** Keep the Cap out of reach of children and pets.

- Store the Cap on the Clear Charging Base in a cool, dry area when not in use.
- Keep the Charging Port Cover located on top of the Cap closed when not charging.
- It is recommended to leave the Cap charging on the charging base between treatment sessions.

Cleaning the Cap

 **WARNING:** DO NOT clean the Cap while charging.

 **CAUTION:** DO NOT wash or submerge the Cap at any time.

 **CAUTION:** DO NOT use cleaning agents or solvents to clean the Cap as this may discolor or degrade the fabric or damage the plastic lens.

- Cleaning should be performed monthly for best results.
- **IMPORTANT:** Close the Charging Port Cover.
- Visually inspect interior for film debris or possible damage. A damaged Cap should not be used.
- Clean the clear lens of the Cap by wiping with a soft cloth lightly moistened with water. Allow to air dry before using or storing.

10. FREQUENTLY ASKED QUESTIONS

How often should I use the REVIAN Lyte Cap?

Once per day. 10-minutes a day.

How soon can I expect to 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 Lyte can be used indefinitely. However, hair loss may resume if treatments are stopped.

What happens if I'm not able to complete my 10-minute treatment?

You must complete the 10-minute treatment before the Cap allows a new 10-minute treatment to start. The Cap's indicator light will flash green if there is partial treatment remaining on the Cap. You may resume a paused treatment at any time.

How should I style my hair when performing treatment?

For best coverage of the scalp when using the Cap, part your hair to maximize exposure of the LEDs to reach thinning areas.

How do I know if a treatment is running while the Cap is on my head?

It is recommended to either go into a dark room or use a reflective surface, such as a mirror, to see the red light emitting out of the Cap.

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 often should I charge my Cap?

It is recommended to leave the Cap charging between treatment sessions.

How will I know when to charge the Cap?

The indicator light in the Cap's charging port will pulse violet when it is time to charge your Cap.

10. FREQUENTLY ASKED QUESTIONS

The cap feels warm on my head, is it safe to use?

It is normal for the Cap to generate some heat. The Cap was subjected to safety testing to ensure the temperature never reaches unsafe levels. Additionally, the Cap has a built-in temperature sensor so that if the temperature reaches a certain point, the power level will be reduced and the indicator light in the Cap's charging port will turn solid yellow.

The Cap keeps giving an over-temperature error and I'm not able to complete a treatment. What should I do?

Treatments should be completed indoors and within the specified operating temperatures (15–35°C [59–95°F]). If the Cap still gives you this error, submit a support ticket at revian.com.

The Cap stopped my treatment before I expected to. What should I do?

Remove the Cap from your head to see the color of the Charging Port. See Section 5 for the meaning of the color. If pulsing green, consider adjusting the fit of your Cap by exchanging the Headliner. See Section 7.

What should I do if the device does not turn off after a treatment?

Remove the Cap from your head. Place the Cap on the Charging base and allow the Cap to run until the LEDs turn off.

What should I do if the device will not start a treatment?

Plug the Cap in to charge. Verify the blue charging lights come on. Unplug the Charging Cable and verify the green light comes on. If the green light doesn't come on, submit a support ticket at revian.com.

Is REVIAN Lyte safe to use while pregnant or breast feeding?

We recommend you consult directly with your physician regarding treatment during pregnancy or while breast feeding.

Can I travel with REVIAN Lyte?

The Cap is travel-friendly and can be taken onboard a flight. There is no special clearance required by TSA to carry Cap onboard.

11. TROUBLESHOOTING & CUSTOMER SUPPORT

REVIAN maintains an up-to-date Knowledge Base for common questions and troubleshooting. The Knowledge Base can be accessed through the REVIAN website. To access the Knowledge Base on the web, please visit:

<https://revian.com/support/existing-customers/>

Creating a Support Ticket

Customer support tickets can be created through the Revian website. To create a support ticket on the website, please visit: revian.com/support/existing-customers/ticket/ or you can email [**support@revian.com**](mailto:support@revian.com).

If you have questions about a medical condition, always seek the advice of your physician or another qualified health professional.

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

166 g (0.37 lbs)

Head Circumference Size Range:

54 cm (21.26 in) – 64 cm (25.20 in)

Optical Characteristics:

620–660 nm +/- 10 nm

Spectral Irradiance: $2.2 \times 10^{-1} \text{ W/m}^2$

Radiant Power: 0.50–0.53 W

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

AC Charger:

Input 100–240V, 50Hz/60Hz

Service Life

Approximately Four (4) Years

(1500 Daily Treatments)

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.

Time to Full Charge:

240 minutes

Time from Minimum Storage Temperature to Room Temperature:

Approximately 45 minutes

Time from Maximum Storage Temperature to Room Temperature:

Approximately 45 minutes

Temperature Limit:

A temperature sensor is embedded into the device to prevent the inside surface of Cap from exceeding 46°C (108°F). The device will automatically pause a treatment if this temperature is reached. When the yellow light turns off in the charging port, the partial treatment can be resumed.

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 (Use/Charging) 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 Lyte 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 replace the battery or remove internal components. The Cap has NO user-serviceable parts and any attempt to remove internal components or modify the Cap will void the warranty and may cause harm to the user.

APPENDIX IV: WARNING SYMBOLS & DEFINITIONS



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



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



SEE INSTRUCTIONS FOR USE—this symbol refers to the Instructions for Use for definition



MANUFACTURED DATE—this symbol is accompanied by a date



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



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



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



IP22—this symbol represents water spray protection of the Cap



QUANTITY—this symbol represents the number of devices within the package



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



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



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



WARNING or CAUTION—this symbol appears next to information about possible safety and product risks



INSTRUCTION MANUAL—this symbol references the manual for charging instructions

APPENDIX V: PRODUCT & PACKAGE LABELS

REVIAN Lyte
Device ID Label



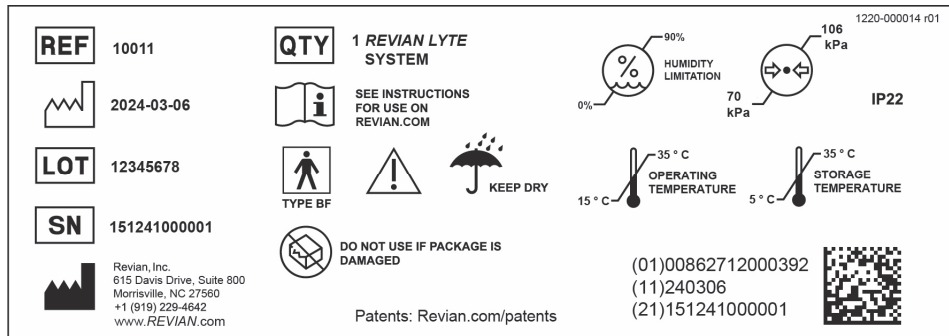
REVIAN Lyte
Device Symbol Label



See Instruction
Manual Label



REVIAN Lyte
Package Label



APPENDIX VI: 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			
The REVIAN Lyte device is intended for use in the electromagnetic environment specified below. The Customer or the user of the REVIAN Lyte should assure that it is used in such an environment.			
Emissions Test	Standard	Compliance	Electromagnetic Environment—Guidance
RF Emissions	CISPR 11	Group 1	REVIAN Lyte 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 Lyte 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 /	IEC 61000-3-2	Not Applicable	

This equipment has been tested and found to comply with the limits for a Group 1 Class B device, pursuant to IEC/EN 60601-1-2, 4th edition. These limits are designed to provide reasonable protection against harmful interference. This device, if not installed and used in accordance with the instructions, may cause harmful interference to other equipment. However, there is no guarantee that interference will not occur in a particular setting. If this device does cause harmful interference to other devices, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Charge or run the device in another location.
- Connect the other equipment into an outlet on a circuit different from that to which the device is charging.
- Contact Customer Support.

APPENDIX VII: 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 Lyte device is intended for use in the electromagnetic environment specified below. The Customer or the user of the REVIAN Lyte device 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 Lyte requires continued operation during power mains interruptions, it is recommended that REVIAN Lyte 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.

VII: ELECTROMAGNETIC IMMUNITY

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity—for all ME Equipment and ME Systems that are not LIFE-SUPPORTING.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The REVIAN Lyte device is intended for use in the electromagnetic environment specified below. The Customer or the user of the REVIAN Lyte device 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 RF equipment, including peripherals such as antenna cables and external antennas, should be used no closer than 30cm (12in) to any part of the device during treatment.
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 should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following

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 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 Lyte device is used exceeds the applicable RF compliance level above, the REVIAN Lyte device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the REVIAN Lyte device.

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



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