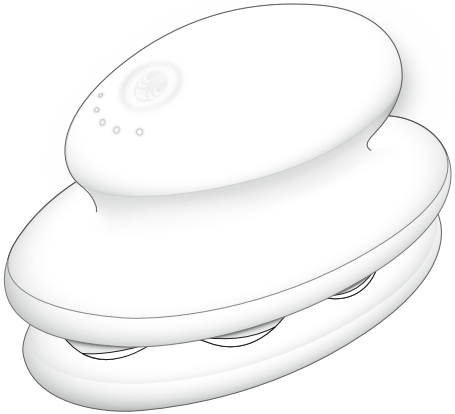
NU SKIN®

RenuSpa iO™



USER'S MANUAL

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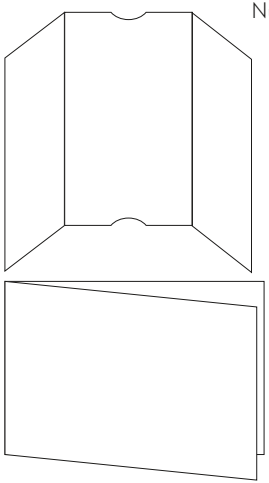
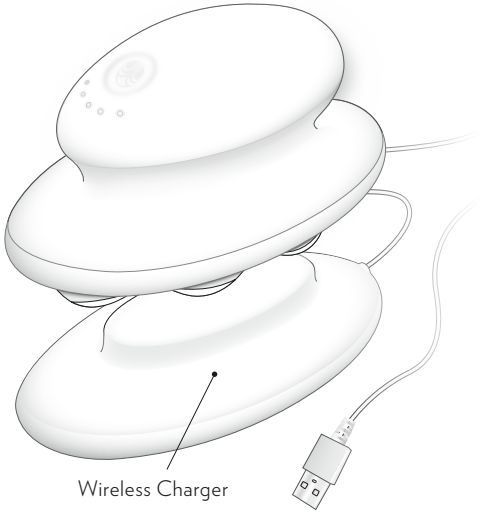
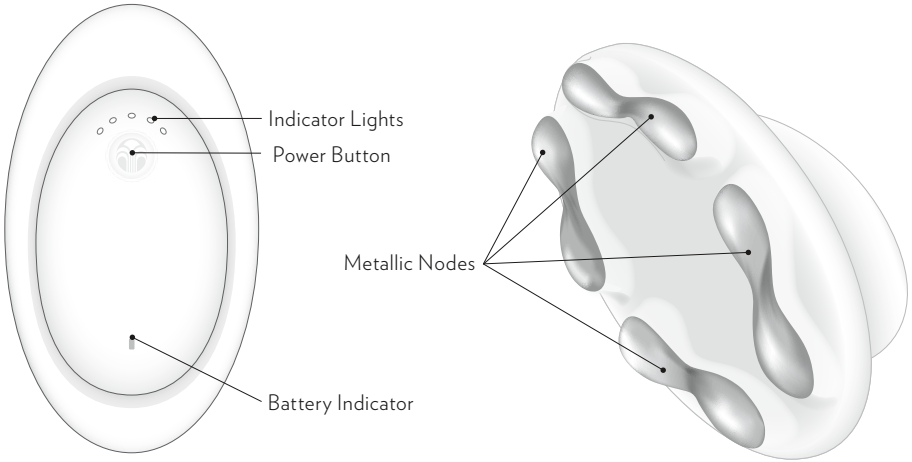


Nu Skin Conductive Gel

Nu Skin® RenuSpa iO™ device



DEVICE COMPONENTS



INTENDED USE

The Nu Skin® RenuSpa iO™ device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.

DESCRIPTION

Nu Skin RenuSpa iO emits an electrical current conducted to the skin through Nu Skin Conductive Gel. The patient is the intended operator of the Nu Skin RenuSpa iO device. All of Nu Skin RenuSpa iO functions are safe for patient use. Nu Skin RenuSpa iO device does not prevent, diagnose, or treat any medical condition. It is suitable for home use and manufactured by Nu Skin Enterprises.

For external use only.

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS

Please read the following before using your Nu Skin® RenuSpa iO.™

CONTRAINDICATIONS FOR USE

The Nu Ski RenuSpa iO with Nu Skin® Conductive Gel is contraindicated for use on the:

- Head and face
- Throat, Neck, or Décolleté
  - Do not use the device over your neck or throat. It could cause muscle spasms. Those spasms may result in difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Chest, thorax, or upper back
  - Do not use the device across your chest or thorax. Electrical current around the chest may cause heart rhythm disturbances increasing the risk of cardiac fibrillation. This could be lethal.
- Groin
- Areas that can't sense touch

It is also not intended for:

- Children
- Persons with reduced:
  - Physical
  - Sensory
  - Mental capabilities

Do not use it if you:

Have a/n:

- Metal implant
- Pacemaker
- Implanted defibrillator
- Other implanted electronic devices
- Suspected or diagnosed epilepsy
- Seizure disorder
- Open sore or wound
- Problematic or sensitive skin

Or are:

- Allergic to gels or metal
- Sensitive to contact with metals

- Pregnant or trying to get pregnant
- Prone to pityriasis rosea
- Epileptic

WARNINGS

WARNING Nu Skin® RenuSpa iO™ stimulates your body's skin with microcurrents. Be careful when applying microcurrents to your skin. The device provides electrical stimulation when it is on and in contact with your skin.

- Check with your doctor before use if you:
  - Have sensitive skin
  - Wear body piercings
  - Are chronically ill
- Speak with your doctor before using the device. It may cause lethal heart rhythm disturbances in susceptible individuals.
- Do not use it to apply electrical stimulation over painful areas. If you have painful areas, talk to your doctor before using RenuSpa iO.
- Do not use it on areas of skin that lack normal sensation. It may result in irritation.
- Only use the device on normal, clean, healthy skin.
- Do not use the device to apply electrical stimulation on:
  - Open wounds
  - Rashes
  - Swollen, red, infected, or inflamed areas
  - Skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins)
- Do not use the device over or near cancerous lesions or diseased tissues.
- Do not use the device near electronic monitoring equipment, including:
  - Cardiac monitors
  - ICDs
  - Pacemakers
  - ECG alarms
- Do not use the device to apply electrical stimulation to the skin without Nu Skin® Conductive Gel as it may irritate your skin.
- Apply an ample amount of Nu Skin Conductive Gel to the skin. As needed, apply more Conductive Gel to all contact points.
- Nu Skin Conductive Gel should not be reused.
- Do not operate while bathing or showering.
- To reduce the risk of shock, irritation, fire, or injury, do not fully immerse your Nu Skin RenuSpa iO.
- Do not place or store the device or charger where it may fall or be pulled into a bathtub, shower, sink, or toilet.
- To prevent the possibility of injury, never expose the device to heat. Do not store near a heat source, such as a radiator, fire, or heat vent. Do not leave in a hot vehicle.
- Do not leave the device in the extreme cold or heat (e.g., below freezing, in a hot vehicle).

- Use in a home setting out of direct sunlight.
- Do not use the device while sleeping.
- Do not use it with other devices at the same time.
- Do not use the device to apply electrical stimulation while:
  - Driving
  - Using machinery
  - Engaging in any activity that can put you at risk of injury
- Do not modify the device.
- Do not use more often than recommended.
- Nu Skin® RenuSpa iO™ is for individual use only.
- While using this device, do not touch any other:
  - person
  - electrically live parts
  - protective earth conductors
- Using Nu Skin RenuSpa iO close (e.g., 1 m) to a shortwave or microwave therapy medical equipment may produce instability in the Nu Skin RenuSpa iO electrical output.
- Avoid the use of the device near or stacked with other equipment or devices. This could result in the device not working properly. If such use is necessary, observe all equipment to ensure it operates normally.
- Do not use accessories, transducers, and cables other than those specified or provided by Nu Skin®. This could increase electromagnetic emissions or decrease the electromagnetic immunity of the device and result in improper operation.
- Do not use portable RF equipment closer than 12 inches (30 cm) to any part of Nu Skin RenuSpa iO, including cables specified by Nu Skin. This could degrade the performance of the device. RF equipment, like cell phones, can affect medical equipment.
- To the reduce the risk of strangulation or injury, keep the device out of the reach of children. Ensure that they do not play with the device or charger. Check the location of all cables. Make sure the wires are not dangling, loose, or in reach of children.

PRECAUTIONS

- Speak with your doctor before using the device. Follow any precautions from your doctors. Individuals should discuss these conditions with their doctor and use caution if they have:
  - Suspected or diagnosed heart disease
  - Tendencies to bleed internally
  - Undergone a recent surgical procedure
- The long-term effects of electrical stimulation are not known.
- Do not press hard on the device during use. Apply enough gentle pressure for constant contactbetween the metallic nodes and your skin.
- Do not use the device if it has been damaged. Damaged devices are at risk of shock, irritation,
- fire, or injury.
- The safety of electrical stimulation during pregnancy or when on a period is not known. Use caution in these cases.

- Nu Skin® RenuSpa iO™ is an electrical device. It may be subject to interference from other devices. Avoid using near strong sources of electric and magnetic fields (EMFs). This includes hair dryers and electric shavers while in use. It could result in improper operation. Always make sure that the device is working properly before use.

ADVERSE REACTIONS

You may have stinging, redness, or irritation on your skin from the treatment. You may have skin irritation or sensitive skin due to the device or conductive medium (Nu Skin® Conductive Gel). Stop using it immediately if you have irritation or prolonged redness. Seek medical advice if necessary. Stop using the device if you have pain during or following the treatment. Stop using the device and consult your doctor if you have any adverse reactions. Report any adverse reactions to Nu Skin Support Services. If you have any questions about the safe use of this device, please call Nu Skin Support Services: 1-800-487-1000.

TEMPERATURE

Only charge the device in conditions between 41°F to 113°F (5°C to 30°C). Only store the device in conditions between -13°F to 140°F (-25°C to 60°C). Ideally store and charge at room temperature. Charging and storing the device outside of these ranges will adversely affect the device. It could increase the risk of injury or a damaged device.

BEFORE YOU GET STARTED

Prior to use, please read all the safety and warning information. This will help you determine if you or those using the Nu Skin RenuSpa iO able to use the device safely.

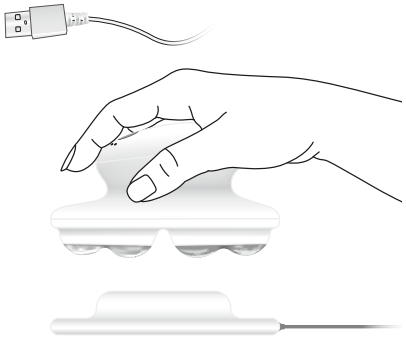
Nu Skin RenuSpa iO is designed to be used by adults without the need for:

- Unique skills
- Training
- Prior knowledge

If you need help with setup, or usage please call Nu Skin Support Services at 1-800-487-1000.

CHARGING YOUR NU SKIN® RENUSPA iO™

- Fully charge your Nu Skin RenuSpa iO before your first use.
- Connect the USB plug of the Nu Skin RenuSpa iO Wireless Charger to a USB adapter. Then plug it into a wall outlet. Place Nu Skin RenuSpa iO on the Nu Skin RenuSpa iO Wireless Charger to begin charging.
- While the device charges, the battery light will breathe green. Once the device is charged, the battery light will be solid green.
- When the battery level is low the battery light will turn amber. If the battery of the device is critically low, the battery light will flash amber.
- Nu Skin RenuSpa iO may feel warm after charging. Remove it from the charger and allow it to cool down before starting a session.



Our rechargeable battery significantl contributes to waste reduction. Learn more about our sustainability initiatives by visiting nuskin.com/sustainability.

NOTE: If the battery is too low, the device will turn off when the user tries to power it on. The battery does not have enough charge to perform a session. If there are no indicator lights, the device needs to be charged. Indicator lights will activate once the device is charged.

WARNING

- Only use the Nu Skin® RenuSpa iO™ Wireless Charger for charging.
- Check cabling and connection before each use.
- Only use the Nu Skin RenuSpa iO Wireless Charger and a certified (IEC 60950-1, IEC 62368-1)

USB-enabled adapter

- Do not charge in a room with a temperature above 86°F (30°C).
- Do not charge this device near water.
- Prior to charging, ensure both the Nu Skin RenuSpa iO and the Nu Skin RenuSpa iO Wireless Charger are completely dry. Always place your Nu Skin RenuSpa iO and Nu Skin RenuSpa iO Wireless Charger on a heat-resistant, stable, flat surface when charging.
- Do not keep the charger plugged in when not in use or after the device has reached full charge.

CONNECTING NU SKIN® RENUSPA iO™ TO THE NU SKIN VERA® APP

To unlock the full Nu Skin RenuSpa iO experience, scan the QR code to download the Nu Skin Vera® app from the App Store or Google Play. Follow the app instructions to connect to your device.

Download on the App Store

GET IT ON Google Play

PAIRING YOUR NU SKIN® RENUSPA iO™

1. Download the Nu Skin Vera® app.
2. Ensure your phone's Bluetooth®* is enabled.
3. Sign in to Nu Skin Vera.
   - Already have a Nu Skin account? Use it to sign in.
   - New to Nu Skin? Sign up—it's easy!
4. Tap "Devices" in the navigation bar.
5. Tap "Pair New Device."
6. If the device is off, press the Power button to turn the device on.
7. Tap "Connect."
8. The device will pair and you're ready to go.

* The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by NSE Products, Inc. is under license. Other trademarks and trade names are those of their respective owners.

USING YOUR NU SKIN® RENUSPA iO™

MEET YOUR NU SKIN RENUSPA iO DEVICE

Nu Skin RenuSpa iO delivers more of the benefits *every* body needs to feel their best. It's the personalized wellness and beauty device that gives you confidence that is as real as your results.

First, check for any damage before using. Use your Nu Skin RenuSpa iO as instructed.

NOTE: The metallic nodes are applied to the body.

YOUR NU SKIN RENUSPA iO DEVICE SESSION

Use Nu Skin RenuSpa iO with Nu Skin® Conductive Gel on clean skin. for the best results. Use the device 3 to 5 times a week per area. Do not use the device daily. Each session will last 5 minutes.

STEP 1. APPLY NU SKIN CONDUCTIVE GEL

Smooth a generous layer of gel on the area you want to treat.

If you plan on more than one session, only apply gel to the area to be immediately treated (see page 11). Apply more gel as needed.

STEP 2. STARTING A SESSION

Press the Power button to turn the device on. All five indicator lights will glow. The device will emit a tone. To begin, place Nu Skin RenuSpa iO where you have applied Nu Skin Conductive Gel. Your session will start.

STEP 3. DURING THE SESSION

Each minute will count down by the sound of a tone and a light turning off.

PRO TIP: A lack of gel may cause a loss of conductivity. Apply more gel to your skin. Ensure the device is in contact with both your skin and the gel for optimal use.

The device will make an alert tone if you are moving it too quickly. Hold the Power button until the lights turn off to turn it off.

UPPER ARM USE

Lightly glide the device over the skin up toward your armpit and back down in slow circular movements, following the contours of the arm.

*Avoid any sensitive areas like the neck or décolleté.

ABDOMINAL USE

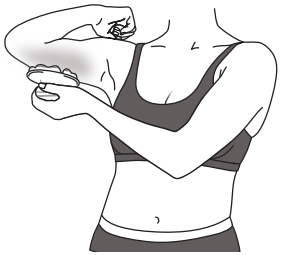
Lightly glide the device over the skin in close circular motions around the navel and following the contours of the outer abdomen.

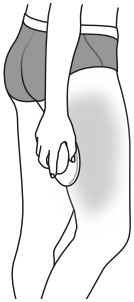
*Avoid going too high or too low into any sensitive areas.

THIGHS AND BUTTOCKS USE

Lightly glide the device over the skin on the thighs up and in toward the body's center. Pause at the buttocks to make circular motions. Glide back down again using slow, smaller circular motions, following the contours of the thigh and buttocks.

*Avoid any sensitive areas.





CLEANING AND CARING FOR YOUR NU SKIN® RENUSPA IO™

After each use, use a slightly damp, lint-free wipe/s to clean any gel, skin, or other materials from the device and charger. Continue to wipe until it is visibly clean. Store in a cool, dry place. Do not place the device under water or any liquid at any time. Using dry, non-linting wipe/s, thoroughly dry the external surfaces of the handheld device and charger.

Do not use harsh chemicals or abrasives on your device or charger.

TROUBLESHOOTING

If you have any unexpected operation or events, please call Nu Skin Support Services at: 1-800-487-1000.

MOVEMENT ALERTS DURING USE

The device will emit a sound if you are moving it too quickly. The session will continue when you resume the correct movement speed. Lightly glide the device over the desired skin using slow, circular motions.

LOSS OF CONDUCTIVITY DURING USE

If the metallic nodes lose contact with your skin, the current will be interrupted, causing Nu Skin RenuSpa iO to pause, emit a tone, and the indicator lights to breathe.

PRO TIP: A lack of serum or gel may cause a loss of conductivity. Apply more product to your skin and ensure the device is in contact with both your skin and the product for optimal use.

MOVEMENT ALERTS DURING USE

The device will emit a sound if you are moving too quickly. The session will automatically resume when you resume the correct movement speed. Slowly glide the device over the targeted areas.

RESET BLUETOOTH® CONNECTION

If you have problems pairing with Nu Skin Vera® or if you need to unpair your device from your phone, conduct a Bluetooth reset.

1. Disconnect from Nu Skin Vera within the app by navigating to Device Settings > Forget this Device.

2. Disconnect your phone.
   - **iPhone:** Navigate to your phone's Settings > Bluetooth > My Devices > NuSkinBDiO > Forget This Device.
   - **Android:** Navigate to your phone's Settings > Connections > Bluetooth > Settings icon > Forget/Unpair.
3. Place Nu Skin RenuSpa iO on the charger.
4. Press and hold the Power button for 5 seconds.

   Wait for:

   - Indicator lights 1–5 to flash once.

*The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by NSE Products Inc. is under license. Other trademarks and trade names are those of their respective owners.

FACTORY RESET

To factory reset your Nu Skin® RenuSpa iO.™

1. Disconnect from Nu Skin Vera® within the app by navigating to Device Settings > Forget this Device.
2. Disconnect from your phone.
   - **iPhone:** Navigate to your phone's Settings > Bluetooth® > My Devices > NuSkinBDiO > Forget This Device.
   - **Android:** Navigate to your phone's Settings > Connections > Bluetooth® > Settings icon > Forget/Unpair
3. Place Nu Skin RenuSpa iO on the charger.
4. Press and hold the power button for 10 seconds.

Wait for:
- Indicator lights 1–5 to flash once.

Keep pressing and holding until:
- All indicator lights flash 3 times (at 10 seconds).

MAINTENANCE AND DISPOSAL

For routine maintenance of your Nu Skin® RenuSpa iO,™ please refer to the section titled "Cleaning and Caring for Your Nu Skin RenuSpa iO Device."

Inspect your rough, damaged, or defective surfaces. In case of any damage or defect, do not use the device. Contact Nu Skin Support Services.

WARNING: Please do not modify the device. Do not attempt any repairs yourself. The device does not have user-serviceable parts. To ensure a long battery life, charge Nu Skin RenuSpa iO whenever the low battery light is on.

To support optimal performance, avoid leaving Nu Skin RenuSpa iO unused for lengthy periods between charges. Please note that the device is not provided in a sterile condition. The device should not be used in oxygen-rich settings rich.
For help maintaining your device, please call Nu Skin Support Services at: 1-800-487-1000.

DEVICE DISPOSAL

Dispose of your device properly according to local laws and regulations. The device contains a lithium-ion battery, which requires disposal separate from household waste. When the device reaches its end of life, contact your local waste management department to learn about proper disposal and recycling options.

Dispose of batteries properly for your area.

REPLACEMENT AND WARRANTY

Limited Two-Year Warranty: Nu Skin guarantees your device to be free from defects in materials and workmanship for two years from the original date of consumer purchase. This warranty does not cover damage to the product due to misuse or accident. This includes dropping the device. If the product becomes defective within the two-year warranty period, please call your local Nu Skin Support Services.
Please do not ship damaged devices by air.

PATENTS

Nu Skin® RenuSpa iO™ has US patents pending.

TECHNICAL DESCRIPTION AND SPECIFICATIONS

NU SKIN® RENUSPA IO™ SPECIFICATIONS

- Model: BS2RM
- Device Dimensions: 130 X 35.6 X 74.7 X 74.0mm (5.1″ × 2.9″ × 2.9″)
- Device Weight: 190 grams (approx. 6.7 oz.)
- Liquid Ingress Protection:
  - **IP25**—Protected against solid foreign objects > 12.5 mm Ø. Water protected from low-powered water jets
  - **IP27**—Protected against solid foreign objects > 12.5 mm Ø. Water protected from temporary immersion, up to one meter (3 ft 3 in) depth.
- Service Life: 2 years.
- Shelf Life: 6 months.
- Classification : Type BF 

ELECTRICAL

- Maximum Output: 22V, 640µA, 8.3Hz
- Output Waveforms: Monophasic, delivered in a burst of pulses
- Pulse duration, repetition frequency, series frequency: 60ms, 8.3Hz, 0.414Hz
- Power Supply: Internally Powered, Rechargeable Lithium-Ion Battery

		Test values measured with an error not exceeding ±10%
Treatment (duration)	Treatment Load Resistance (ohm—Ω)	Current (micro-Amperes—µA, Avg.)
5 minutes	10K	510
	2K	600
	500	620
Rated Supply Voltage: 3.6 VDC		

NU SKIN® RENUSPA iO™ WIRELESS CHARGER SPECIFICATIONS

- Model: BS2RCA
- Dimensions (unpackaged): 1159.0 × 22.6 × 74.0MM (45.6″ × 0.9″ × 2.9″)
- Weight: 74 grams (approx. 2.6 oz.)
- Liquid Ingress Protection: **IP24**—Protected against solid foreign objects > 12.5 mm Ø. Water protected from splashing water.
- Service Life: 2 years.
- Shelf Life: 6 months.

ELECTRICAL

- Input: 5V ⎓ 500mA
- Output: 115.9kHz, 8.7dB (uA/m) @10m, ranging from 110kHz to 130kHz

The Nu Skin® RenuSpa iO™ wireless operation is safe and complies with RF Exposure requirements

POWER SUPPLY

Power the charger with a certified USB-A enabled adapter with the following electrical ratings:

- Output: 5V ⎓ 500mA (min).
- Class II rated (IEC 60950-1, IEC 62368-1).

NOTE: While charging, Nu Skin RenuSpa iO is isolated from the main electrical supply by the power supply adapter and charger. Do not use an adapter with ratings different than those specified. Do not attempt charging with other chargers.

ENVIRONMENTAL CONDITIONS

- Operating: 41°F to 113°F (5°C to 40°C), 15 to 95% rH,* 700hPa to 1060hPA.
- Charging: 41°F to 86°F (5°C to 30°C), 15 to 95%rH,* 700hPa to 1060hPA.
- Transport and Storage: -13°F to 140°F (-25°C to 60°C), 0 to 95% rH.*

*Assuming (non-condensing)

SAFETY FEATURES

The Nu Skin RenuSpa iO was tested with the Nu Skin RenuSpa iO Wireless Charger. The Nu Skin RenuSpa iO system conforms to the listed standards.

Conforms to EN IEC/UL: 60601-1, 60601-1-2, 60601-1-11, 60601-2-10, 62133-2, 62366-1

FCC

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2AZ3A-BS2RM

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Federal Communications Commission (FCC) Statement 15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

9. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
10. For portable operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.

FCC Wireless charger

Federal Communications Commission (FCC) Statement 15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated, keeping the radiator at least 15 cm or more away from the person's body.

ELECTROMAGNETIC COMPATIBILITY (EMC)

Avoid using near strong sources of EMF like hair dryers and electric shavers in-use. RF equipment, like cell phones, can affect medical equipment.

EMISSIONS AND IMMUNITY TEST LEVELS

TEST STANDARD	TEST LEVEL
Conducted Disturbances (conducted EMISSIONS) CISPR 11	Class B Group 1 Minimum and Maximum Rated Voltage
Electromagnetic radiation disturbance (radiated EMISSIONS) CISPR 11	Class B Group 1 120V, 60Hz
IEC61000-3-2	Class A (Harmonics)
IEC61000-3-3	10 Min
IEC61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air
IEC61000-4-3	10V/m 80MHz – 2,7GHz 80% AM at 1kHz
IEC61000-4-4	± 2kV 100kHz repetition frequency
IEC61000-4-5	± 0,5kV, ± 1kV
IEC61000-4-6	3V 0,15MHz – 80MHz 6V in ISM and amateur radio bands between 0,15MHz and 80MHz 80% AM at 1kHz
IEC61000-4-8	Any voltage: 5V
IEC61000-4-11	Minimum and Maximum Rated Voltage: 0–5V
Clause 8.10	Test Frequency: 2 450 Band: 2 400 – 2 570 Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 Pulse modulation: 217Hz Max Power: 2W Distance: 0,3m Immunity Test Level: 28V/m
Clause 8.11	8 A/m at 30 kHz 65 A/m at 134.2 kHz 7.5 A/m at 13.56 MHz

REPORTING ADVERSE EVENTS

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions,product quality problems, therapeutic inequivalence/failure, and product use errors with humanmedical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has had a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your healthcare provider may choose not to complete the form. Your healthcare provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgment from the FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn.

The form is available at www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

Call the FDA: 1-800-FDA-1088 to report by telephone.

Reporting Form FDA 3500 is commonly used by health professionals.

The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf.

Symbol	Symbol
	Warning
	Relative Humidity Limits
	Temperature Limits
	Follow instructions for use
	Type BF Applied Parts—Stimulator is a Type BF Applied Part
	Dispose of Batteries Properly for Your Area
IPXY	X—Protection from **solid** objects Y—Protection from **liquids/water**

Symbol	Definition
	Direct Current
	Interference may occur in the vicinity of equipment marked with this symbol for non-ionizing radiation
	Manufacturing Information
	Class III Protection Against Electric Shock
SN	Serial Number
LOT	Batch Code
UDI	Unique Device Identifier
	Charge only with specified charger

CLASSIFIED
UL
Exxxxx

MEDICAL—GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601 - 1:2005/(R)2012 and A1:2012/(R)2012 and A2:2021)