Revi

Surgical Technique Guide

Caution: Federal law restricts this device to sale by or on the order of a physician

Blue Wind MEDICAL

Preface

Important This document provides instructions for use and recommended guidelines exclusively for the Revi System supplied and manufactured by BlueWind Medical Ltd.

It is important to read and understand this document before performing the implantation procedure and using the Revi System.

Copyright Notice

Trademarks

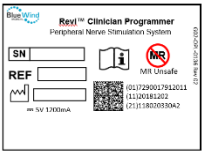
Safety Compliance Labels

The Revi components are each fitted with a safety compliance label, the location of which is illustrated in Figure 1 through Figure 3.

Important Do not use the device if the label is missing.

Revi Clinician Programmer

The Clinician Programmer tablet has a safety compliance label affixed to the rear panel (Figure 1). See Table 1 for an explanation of the relevant symbols.



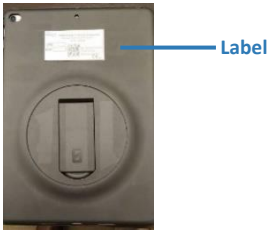


Figure 1 Revi Clinician Programmer - Label Location

Revi Wearable Device

The Revi Wearable Device has a safety compliance label affixed to the rear of the device (Figure 2). See Table 1 for an explanation of the relevant symbols.

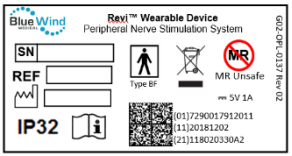


Figure 2 Revi Wearable Device - Label Location

Revi Implant

The Revi Implant has a safety compliance label affixed to the rear of the sterile pouch (Figure 3). See Table 1, for an explanation of the relevant symbols.

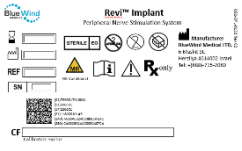


Figure 3 Revi Implant - Label Location

Explanation of Safety Symbols

Table 1 Safety Label - Explanation of Symbols

Symbol	Table Heading	Symbol	Table Heading
	Serial Number		Date of Manufacture (YYYY-MM-DD)
	Catalog Number		Manufacturer
	Consult Instructions for Use		Dispose of properly after use
	Prescription device		Type BF Applied Part
	Use by		Do not use if package is damaged
	Caution		Do not resterilize
	Calibration Factor		Ingress Protection
	Sterilized by Ethylene Oxide		MR Conditional
	Do not reuse		MR Unsafe
	USA Federal Communications Commission compliance		

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Glossary

Terms and Acronyms

Table 2 Terms and Acronyms Used in this Guide

Term/Acronym	Meaning
CP	Clinician Programmer - see Revi Clinician Programmer definition, below.
Diathermy	Diathermy uses high-frequency electromagnetic currents to generate heat in body tissues for therapeutic relief of pain, improving mobility, or increasing blood flow and can use microwave, ultrasound, or short -wave energy.
Electrocautery	Medical procedure which uses electrical current to cut, coagulate, or remove tissues. The electrocautery device generates high-frequency direct electrical currents, typically in the radiofrequency range, which are delivered through a metal tip or electrode. It is different than electrosurgery which uses alternating current. When the electrode comes into contact with the target tissue, the electrical current generates heat, which causes the tissue to be cut, coagulated, or ablated
Electrosurgery	The surgical use of high-frequency electrical current — applied locally with a metal instrument or needle — used for cutting or destroying tissue..
Revi Clinician Programmer (CP)	An application running on an iPad (tablet device) with dedicated charger and is the system's interface used by the healthcare providers for treatment control, status evaluation, parameter programming and data acquisition.
Revi Implant	An implantable wireless neurostimulation component that is implanted in the vicinity of the tibial neurovascular bundle.
Revi System	Peripheral nerve stimulation device intended for home-care use. The system comprises the Revi Implant, the Revi Wearable Device (with its own battery charger) and the Revi Clinician Programmer (with its own battery

Term/Acronym	Meaning
	charger).
Revi Wearable Device	The external component of the Revi System, provides power to the Revi Implant and enables control over the stimulation. The Wearable is used during the implantation without the leg band and inside a sterile sleeve to perform an intaoperative test stimulation
RF	Radio Frequency
Tachyphylaxis	Deterioration in response to therapy over time. In neuromodulation, this refers to neural tolerance.
Treatment Session	Therapy delivered by the Revi System for a duration (typically between 30-60 minutes), at the discretion of the treating clinician/surgeon.
Urinary Urgency	Complaint of sudden, compelling desire to pass urine which is difficult to defer.[1]
UUI	Urgency Urinary Incontinence: Complaint of involuntary loss of urine associated with urgency.[1]

[1] Kocjancic et al., ICS Guidelines, Neurourology and Urodynamice, 2022; 41: 140-145

Introduction

General Information

This manual provides information for the implantation of the Revi Implant. This document serves as instructions for use and provides general surgical guidelines.

Note: *For an overview of the Revi Peripheral Nerve Stimulation Therapy, clinical considerations, Warnings and Precautions and detailed instructions on operation of the Revi System, including the Clinician Programmer, refer to the Revi Clinician Programmer User Manual.*

Indications for Use

The Revi System is indicated for the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency.

Contraindications

Patients contraindicated for the Revi therapy are those who:

- Are unable, or do not have the necessary assistance, to operate the Revi System.
- Are men who have Benign Prostatic Hyperplasia (BPH) or other lower urinary tract obstructions.
- Are implanted with any metallic implant in the immediate area (8 in/20 cm distance) intended for implantation.
- Have nerve damage that could impact treatment.
- Are at high surgical risk or patients with multiple illnesses or active general infections that expose them to excessive bleeding or delayed or non-healing wounds.
- Have known allergies to one of the implant materials (see implant specifications on page 65).
- Are pregnant
- Have open wounds or sores on the lower leg or foot
- Had prior surgery in the implant area
- Had previous, unhealed trauma in the implant area
- Have pitting edema (≥2+) in the lower leg
- Have Venous disease/insufficiency in the lower leg

- Have Arterial disease/insufficiency in the lower leg
- Have Vasculitis or dermatologic conditions in the lower leg
- Have infections near the implantation site in the lower leg

Use in Specific Populations

The safety and effectiveness of this therapy has not been established for:

- Patients under the age of 18
- Patients with progressive, systemic neurological diseases (e.g., Parkinson's disease, multiple sclerosis (MS), etc.).

Safety Information

The Warnings and Precautions provided in this manual are directed to the treating clinician/surgeon.

Prior to using the Revi System, the treating clinician/surgeon should read and understand all instructions of the Revi System. Surgeons should be experienced with similar surgical procedures and should be trained by a BlueWind Medical representative prior to performing the procedure.

Important safety information for the Revi Clinician Programmer tablet hardware is available in the iPad User Guide available at www.apple.com.

Note: *Detailed safety information for the patient is provided in the Revi Implant Patient Leaflet, included in the Implant package.*

Important Make sure the patient receives and understands the instructions before discharge from the clinic.

Warnings

⚠ WARNING **Warnings for use of the Revi System are outlined below, together with recommendations of the manufacturer.**

Clinician Training

Before surgical implantation of the Revi Implant, treating clinicians/surgeons should be trained on the implantation procedure and use of the Revi System.

Driving/Operating Machinery - Limitations During Treatment

Patients whose normal daily activities include driving or operating machinery should be aware of the fact that it is not recommended to do so at any time during a Revi Treatment Session.

Flammable Fuel, Chemicals, or Environmental Hazards

The Revi Wearable Device and Clinician Programmer are not suitable for use in the presence of flammable fuel, fumes or chemicals, including flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

When the system is turned on, or in use, it could potentially ignite the chemicals or fumes, causing severe burns, injury or death to patient and staff.

Medical Therapies/Procedures

The following therapies and procedures may cause injury to the patient, and/or permanent damage to the Implant, particularly if used in close proximity to the device:

- Diathermic therapy
- Electrosurgery
- Electrocautery
- Radiation therapy
- High-output ultrasound/High-intensity focused ultrasound/Lithotripsy
- Transcutaneous Electrical Nerve Stimulation (TENS)
- Bone growth stimulation
- RF (Radio Frequency) ablation
- Laser procedures
- Therapeutic magnets
- Hyperbaric chamber

Note: *The compatibility of the Wearable Device was not verified with any medical therapy / procedure and thus should be removed prior to any therapy / procedure.*

Diathermy

Patients implanted with the Revi Implant should not be exposed to shortwave, microwave or ultrasound diathermy, at any location on the body or in their vicinity. Energy from these devices can be

transferred through the Implant, causing severe injury or damage to the Implant.

Electromagnetic Interference

Although the Revi System is suitable for use in all establishments, including clinics, hospitals and domestic environments, the following warnings apply:

- Do not use the Wearable Unit within 12 inches (30 cm) of:
  - Consumer electronic devices, such as TV sets, laptops, tablets and smartphones.
  - Metallic objects and strong magnets
- The Revi Wearable Device must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.

For guidance regarding the Clinician Programmer's hardware electromagnetic compatibility refer to the iPad User Guide at www.apple.com

Magnetic Resonance Imaging (MRI)

For use of MRI when the Revi is implanted refer to “MRI Conditional Labeling” below.

- Do not conduct an MRI examination on a patient implanted with the Revi until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can potentially result in heating of the Implant, resulting in damage to surrounding tissue, damage to the Implant and unexpected changes in stimulation.
- A responsible individual with expert knowledge about MRI, such as an MR trained radiologist or MRI physicist, must assure all procedures in this guideline are followed and that the MRI scan parameters comply with the recommended settings during the MRI examination. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this section.
- Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations/uncomfortable stimulation, or unusual sensations.
- The Revi System should not be activated during the MRI procedure.

- All external components and accessories of the Revi System are MR Unsafe and are contraindicated for the MRI environment and not allowed into the MRI suite. Therefore, the External Control Unit and Clinician Programmer must be removed before the patient is allowed into the MRI environment.
- The Revi Implant has not been tested in simultaneous combination with other devices in the MRI environment.

MRI Conditional Labeling

The Revi Implant is MR conditional as defined in ASTM F2503-13.

A patient implanted with the Revi Implant may be safely scanned anywhere in the body, under the following conditions:

1) MR system with static field of 1.5 T or 3.0 T. MRI may also be performed at field strengths less than 1.5 T.
2) Maximum spatial gradient in the static field of 30 T/m.
3) Maximum scanner gradient slew rate of 200 T/m/s.
4) For 1.5 T MR scanners:
    a. Landmark above the waist. Normal or first level controlled operating mode with maximum whole-body SAR of 4 W/kg. No restrictions on scan time due to implanted device. Actual scan time according to MRI scanner guidelines.
    b. Landmark below the waist. Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan duration of 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks). Actual scan time according to MRI scanner guidelines.
5) For 3T MR scanners:
    a. Landmark above the waist. Normal or first level controlled operating mode with maximum whole-body SAR of 4 W/kg. No restrictions on scan time due to implanted device. Actual scan time according to MRI scanner guidelines.
    b. Landmark between the waist and the knee (not including the knee). Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan duration of 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks). Actual scan time according to MRI scanner guidelines.
    c. Landmark at the knee and below. Normal operating mode with maximum whole-body SAR of 2 W/kg. Allowed scan

duration of 30 minutes of continuous RF (a sequence or back-to-back series/scan without breaks). Wait 30 minutes before the next imaging session. Actual scan time according to MRI scanner guidelines.

The health state of the patient or the presence of other implants may require reduction of the MRI limits.

Information from non-clinical tests of MRI interactions on Revi Implant

RF heating was measured at 1.5 T and 3 T in phantom tests performed according to ASTM F 2182-11a. Under the conditions of the IFU, the maximum temperature rise during MRI of tissues near the Revi Implant is acceptable and is not expected to cause thermal damage to the surrounding tissue.

Magnetic force was measured according to ASTM F2052-15. Fixation of the device to the tissue will prevent device movement in the MRI static field.

Image artifact was measured according to ASTM 2119-13 in a 3T clinical MR system. Maximum artifact beyond the implant was 1.2 in (3 cm) for the spin echo sequence and 1.6 in (4 cm) for the gradient echo sequence. It may be possible to reduce artifact by use of suitable scan sequences.

Following ISO/IEC 10974 (2018) multiple exposures of Revi Implant to MRI electromagnetic fields were made at 1.5 T and 3 T. These exposures did not damage the device. RF and gradient fields during MRI are not expected to elicit unintended stimulation.

Implantable Devices

The effect of the Revi System on the operation of other implanted devices, such as, other neurostimulators, and implantable drug pumps, is not known. In particular, if the Revi System is implanted close to one of these devices, they may have sensing problems and/or may not function correctly. Potential interference issues should be investigated before surgery by clinicians involved with both devices. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

Neurostimulator Interaction with Implanted Cardiac Devices

If a patient is in need of defibrillation or cardioversion, the first consideration is their survival.

External defibrillation or cardioversion can damage the Implant. After external defibrillation, confirm that the Revi System is working as intended. The stimulation pulses produced by the Revi System may interact with cardiac devices that sense cardiac activity, leading to inappropriate behavior of the cardiac device and the Revi Implant.

Precautions

Treating Clinicians/Surgeons should follow current clinical guidelines as applicable and should use their discretion to determine whether the patient should fail or not tolerate more conservative treatments before using the Revi System.

⚠ CAUTION **Precautions for use of the Revi System are outlined below, together with recommendations of the manufacturer**.

Metal Objects and Implants

External and implantable metal objects can impact the communication between the Revi Wearable Device and Implant when placed in proximity to the system. This may prevent or reduce the system's abilities for stimulation.

Metal items should be kept at a distance of at least 8 in (20 cm) away from the Revi Wearable Device while delivering stimulation.

Strenuous Activities and Excessive Force

Patients should avoid strenuous activities (and excessive force) that put the Revi Implant under extreme stress. If the Implant casing is ruptured or pierced due to outside forces, the Implant will no longer be functional, and injury may result.

The following examples of strenuous activities can damage the Revi Implant resulting in loss of symptom relief and possible additional surgery: Gymnastics, Mountain biking, Skiing, Sky diving.

Less extreme activities should not impact the Revi Implant: Running, Jogging, Road biking, Swimming.

SCUBA Diving or Hyperbaric Chamber

SCUBA diving or going inside a hyperbaric change may damage the implant.

Electromagnetic interference

Electromagnetic interference from some electronic equipment or mobile devices may disrupt the communication between the Revi

Wearable Unit and Clinician Programmer or between the Revi Wearable Unit and the Implant in certain situations, causing the stimulation to either stop or be uncomfortable.

As a precaution, follow these guidelines:

- If you suspect that an EMI equipment or environment is affecting the function of your Revi System, avoid performing the therapy session around that item by doing the following:
  - Move away from the electrical item
  - Turn off the electrical item (if possible)
- If you are unable to eliminate the interference or believe the interference has altered the effectiveness of your therapy, you should contact your clinician.

Sources of strong EMI can result in the following:

- Patient injury, resulting from heating of the Revi System that causes damage to surrounding tissue.
- System damage, which may require surgical replacement due to change in symptom control.
- Operational changes to the Revi Wearable Unit, causing it to turn on or off or to reset the settings, resulting in loss of stimulation or return of symptoms, causing a need for reprogramming.
- Unexpected changes in stimulation, leading to a sudden increase or change in stimulation, which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged, nor would it cause direct injury. In rare cases, the change in stimulation may cause you to fall and be injured.

Strong Electromagnetic Fields

Strong electromagnetic fields can impact the communication between the Revi Wearable Unit and the Implant in certain situations, causing the Stimulation to either stop or be uncomfortable.

As a precaution, avoid performing Therapy Sessions around:

- Power lines or power generators.
- Electric steel furnaces.
- Large stereospeakers.
- Short-wave or microwave therapy equipment.

Note: *For more details, refer to Electromagnetic Specifications on page 68.*

Theft Detectors and Security Screeners

Everyday electrical devices are not likely to affect Revi. There are strong sources of EMI that have a higher risk. These include theft detectors or security screeners such as those used at department stores, and/or airports.

It is possible that such devices may affect the communication between the Revi Wearable Unit and the Implant, causing the stimulation to either stop or be uncomfortable. Security screeners may also detect the metal in the Implant. Airport authorities advise patients to carry their Patient Identification Card with them when traveling.

As a precaution, if patients encounter security or theft detectors, they should walk far away from the sides of them when passing through and avoid performing their Revi therapy sessions around them. Patients should make sure security staff are informed that they have an implanted stimulator and carry their patient identification card with them for verification.

Revi Wearable Unit Placement Site

The Revi Wearable Unit is Non-Sterile and not to be sterilized and should not be applied to an open wound. Contact with an open wound could cause an infection.

The Revi Wearable Unit should not be used if the skin in the area surrounding the implant site is inflamed, infected, or otherwise compromised.

Swelling along with pain, warmth and excessive redness in the implantation site could be a sign of infection, Implant rejection or an allergic reaction to the Leg Band material.

If patients experience these symptoms near the Wearable Unit's placement site, they should contact their clinician before using the device.

Travel and International Use

Important When traveling, it is important the patient continues adhering to their Revi Treatment regimen.

⚠ CAUTION It is possible that airport security devices may affect communication between the patient's Revi Wearable Unit and the Revi Implant.

For more details, refer to Theft Detectors and Security Screeners on page 11.

During flight, electromagnetic interference can impact the communication between the Revi Wearable Unit and the Revi Implant, causing the Stimulation to either stop, or be uncomfortable.

⚠ CAUTION In addition, communication between the Revi Wearable Unit and the Revi Implant may cause interference with the navigation or communication system of the aircraft.

As a precaution, performing a Treatment Session during a flight should be avoided.

Note: *Use of a power adapter may be necessary when using the battery charger in different countries.*

Sterilization, Handling and Storage

- Labels on system components:
  - Safety labels and their location are illustrated as follows:

    Revi Clinician Programmer - see **Figure 1**

    Revi Wearable - see **Figure 2**

    Revi Implant – see **Figure 3**
  - Do not use the product if the labeled “Use by” date has passed.
  - Do not use if labeling is incomplete or illegible.
- Handle the Revi System components with care. Dropping system components on hard surfaces, or other rough handling, can damage it.
- Do not use system components if package has been dropped on a hard surface from a height of more than 24 in (60 cm).
- Avoid exposing the Revi System components to extreme temperatures, moisture or pressure. For recommended operating, storage and transportation conditions, see Section Environmental Specifications on page 67 below.
- Do not use any component that shows sign of damage.
- Use only Revi System components with the device. No modification of this equipment is allowed. Use of components from other systems or modified components may damage the system or cause injury.
- Only BlueWind Medical's trained and authorized service engineers shall be permitted to service the system.

- The Revi Implant:
  - The Revi Implant is sterilized by ethylene oxide. Inspect the condition of the sterile package before opening the package and using the contents. Do not use the contents if the package is broken or torn, or if contamination is suspected due to a defective sterile package seal.
  - The Implant is for single use only. Do not reuse. Reprocessing of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
  - Do not re-sterilize the package or its contents. Re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness, or death.
- The Revi Wearable Device:
  - The Revi Wearable Device is not sterile and should not be sterilized by any means. For delivering stimulation during the surgical procedure the Wearable Unit should be placed inside a sterile sleeve or drape.
  - The Revi Wearable Device is water resistant, but not waterproof. Do not use the device in or around water.
- The Revi Clinician Programmer:
  - The Revi Clinician Programmer is not sterile and should not be sterilized by any means.
  - The Clinician Programmer is intended for use as a monitor during the procedure, outside of the sterile field.

Water Resistance

The Revi Wearable Unit is water resistant, but not waterproof (i.e., water can be repelled to some degree but not completely). The device should not be used in or around water.

Using the wearable device while / after it has been immersed in water could lead to electrocution or damage to the device.

If the device has been damaged, contact your BlueWind Medical for replacement.

Device Components

Please do not tamper or modify the Revi Wearable Unit. No modification of this equipment is allowed.

Use of components from other systems or modified components may damage the system or cause injury.

Service Life

The Revi Wearable Device service life is 1 year.

The Revi Implant lifetime is 10 years from implantation.

The Revi Clinician Programmer lifetime is limited only by the hardware (for details see iPad User Guide at www.apple.com).

The system can fail due to random component failure, or loss of battery functionality.

In the case where one of the system components is damaged or stops working, the component should not be used and returned to BlueWind Medical. There are no user serviceable system components.

If the Revi Implant reaches its end of life, contact BlueWind Medical to arrange a removal or replacement for continued therapy as needed.

Component Disposal

Revi System components should not be disposed as unsorted municipal waste.

Contact BlueWind Medical Ltd. (see last page of this guide for contact details) for instructions on returning the system component to the manufacturer.

Disposal of the battery chargers should be in accordance with local municipal guidelines.

Possible Adverse Events

Potential risks are associated with any implantation surgery, or use of a neurostimulation system.

Anticipated adverse events involved with the *surgery* include, but are not limited to: bleeding, pain at implantation site, ankle discomfort, implant site infection, skin irritation, nerve injury, skin erosion, seroma, formation of thrombosis and pulmonary embolism, potential temporary or permanent mobility impairment and nerve injury.

Anticipated adverse events involved with the stimulation include, but are not limited to: undesirable changes in stimulation such as sensation of transient electric “shock”/sudden radiating sensation/sporadic sensory response, uncomfortable heating effect, discomfort, or transient muscular spasm induced by stimulation.

Anticipated adverse events involved with the *treatment* include, but are not limited to: adverse changes in voiding/bowel function, or transient nausea.

Anticipated adverse events involved with the *device* include, but are not limited to: spontaneous sensory response (not in association with simulation), implant migration or displacement, allergic reaction and technical device problems.

Adverse events that were reported in a previous study included 4% device related Adverse Events, all of which were reported as pain associated with the device (i.e., treatment/stimulation), and 10.6% procedure related AEs, of which 6.6% were related to the surgical wound.[2]

Most adverse events resolve within a few days to a few weeks on their own or with medication.

[2] G02-CLT-0019: OASIS 12M Clinical Study Report (IDE G200013). May 2023. On file at BlueWind Medical.

Summary of Clinical Evaluation

OPTIMIST Pilot Study

Study Design:

A 6-month multi-center prospective, single arm, interventional pilot study was conducted to collect preliminary data on BlueWind system's safety and performance in patients. Thirty-Six (n=36) subjects were implanted (31 women and 5 men). Thirty-four (n=34) subjects continued to system activation, home treatment and follow-up visits.

The primary endpoint was incidence of serious adverse events (SAE) (system or procedure related), and the secondary endpoints assessed the performance of the system using parameters collected from 3-day voiding diary and a quality-of-life questionnaire (OAB-q).

Male subjects enrolled in this study demonstrated similar safety and effectiveness outcomes for the Revi System compared to the female subjects.

Twenty-patients, out of 34 who completed the pilot study, agreed to participate in a long term, 36 months extension study and attended at least one long term follow-up visit (at 18, 24 or 36 months). No SAEs were reported during the extended follow-up period. The 3 year pilot study data provided preliminary support of the durability of the Revi System and demonstrated no reduction in device effectiveness over time (tachyphylaxis).

OASIS Pivotal Study

BlueWind Medical performed a clinical study to determine the safety and efficacy of the Revi System in the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency and/or urinary frequency. The study was conducted in 23 centers, 16 of which were in the U.S., and evaluated 151 patients. A summary of the clinical study is presented below.

Study Design

BlueWind Medical conducted an interventional, prospective, multi-center, single arm open label pivotal study of the Revi System for the treatment of females diagnosed with urge urinary incontinence alone or in combination with urinary urgency and/or urinary frequency. Across 23 sites, 151 subjects were enrolled. The study evaluated changes in baseline UUI episodes as measured by voiding diaries and patient reported outcomes through one year of Revi

therapy. A long-term follow-up extension is being performed every six months after the 12-month visit up to 3 years, which subjects had the option of consenting to.

Patients who achieved at least a 50% improvement in the number of UUI episodes as measured in a 7-day voiding diary were considered therapeutic successes ("responders"). The secondary effectiveness endpoints were 1) the proportion of subjects with ≥10 points (MID) improvement in Health Related Quality of Life (HRQL; based on OAB-q) at 6 months post system activation with a performance goal of 50%, 2) the proportion of responders at 12 months post system activation as demonstrated by ≥50% improvement in either average number of urgency related incontinence episodes or average number of severe/large urgency related incontinence episodes, as measured by 7-day Patient Voiding Diary, with a performance goal of 50%, and 3) the proportion of responders at 6 months post system activation as demonstrated by ≥50% improvement in the average number of moderate-severe urgency episodes (Patient Perception of Intensity of Urgency Scale) PPIUS degree 3, 4 or <8 voids/day, with a performance goal of 45%. This endpoint is defined only for patients with baseline number of voids per day of at least 8 and baseline number of urgent episodes (PPIUS 3 or 4) of at least 9 per 7-day diary.

The primary safety endpoint for the study was to quantify the incidence of adverse events from implantation to one year after activation. The potential risks related to this study are the known risks of surgical procedures and electrical stimulation, including but not limited to bleeding, pain, infection, skin irritation, mobility impairment, nerve injury, uncomfortable or sporadic electric "shock" or radiating sensations, uncomfortable heating, discomfort or burn.

The BlueWind Medical Revi implant was surgically placed subfascially (underneath the fascia) in the right or left leg of subjects with UUI. After a recovery period of 4-weeks ±2 weeks post implantation, system activation based on sensation and motor assessment was conducted. Subjects underwent an acute stimulation session of the tibial nerve to evaluate their sensory/motor reaction to stimulation. Thereafter, subjects underwent parameters' setting, and were trained for system home use. Tailored patient therapy parameters were adjusted based upon patient tolerability, patient sensation and motor threshold. Stimulation parameters were modified for each patient in a stepwise process, until a sensory response (tingling sensation in the ankle, foot, toes and sometimes a radiation sensation in the leg and/or genital area) or a sensory response in combination with a motor response (flexion of the big toe, fanning out of digits 2-5, extension of the foot) was elicited.

Parameter settings were individually set for each patient. Patients were instructed to administer daily stimulation of a minimum of 30 minutes and a

maximum of 2 hours, per clinician discretion. Patients were able to adjust the amplitude within a range customized to the patient. Stimulation parameter settings were re-evaluated at each follow-up visit and sensory and motor thresholds assessed. Treatment parameters (frequency, pulse width, polarity and amplitude) were adjusted according to the individual patient sensations. After six months, the primary effectiveness and safety endpoint were assessed.

An independent Data and Safety Monitoring Board (DSMB) monitored the study to evaluate safety, study conduct, scientific validity, and data integrity of the study. The DSMB was used to assess the progress of the clinical study and to provide determinations and recommendations regarding the study conduct.

Clinical Inclusion and Exclusion Criteria

Inclusion Criteria

1. Signed written informed consent.
2. Female aged 18 or greater (21 or greater in the US), with no plans to become pregnant during the trial; if of bearing potential, negative pregnancy test and if sexually active, using acceptable contraception.
3. Subject who is mentally competent with the ability to understand and comply with the requirements of the study.
4. Diagnosis of UUI demonstrated on a 7-consecutive days voiding diary defined as a minimum of nine (9) leaking episodes associated with urgency, with at least one episode per day for 5 days.
5. More than or equal to 6 months history of UUI diagnosis
6. Subject with inadequate response to any of the following conservative treatments (i.e. dietary restriction, fluid restriction, bladder training, behavioral modification, pelvic muscle training, biofeedback, etc.) and pharmacologic treatment.
7. If used, subjects should be on stable dose of antimuscarinics and/or beta-3 adrenergic agonists for at least 3 months prior to baseline and agree to remain on stable medication consumption until the 12-month follow-up visit.
8. If used, subjects should be on a stable dose of tricyclic antidepressants, Selective Serotonin Reuptake Inhibitors (SSRI) and Serotonin-Norepinephrine Reuptake Inhibitors (SNRI) for at least 3 months prior to baseline.
9. Subjects with positive tibial nerve motor or sensory response tested via physical/neurological examination.

10. Subjects with normal renal function defined by GFR of 50 ml/min or more
11. Leg circumference of no less than 20 cm and no more than 30 cm at implantation site (i.e. 5cm above the medial malleolus).
12. Subject agrees to attend all follow-up evaluations and is willing and capable to completely and accurately fill out voiding diaries and questionnaires and is willing to complete required exams and tests.

Exclusion Criteria

1. Previous participation in another study with any investigational drug or device within the past 90 days.
2. Subjects who are unable to operate the Revi System
3. Deemed unsuitable for enrollment by the investigator based on history or physical examination
4. Subjects at high surgical risk with multiple illnesses or active general infections that expose them to excessive bleeding or delayed or non-healing wounds. This includes patients who need anticoagulation therapy that cannot be temporarily stopped for the implantation procedure
5. Any significant medical condition that is likely to interfere with study procedures, device operation, or likely to confound evaluation of study endpoints
6. Subject has morbid obesity (>50 BMI)
7. Any psychiatric or personality disorder at the discretion of the study physician
8. PHQ-15 Patient Somatization Score ≥ 20
9. Any metal or other implant in the area of Revi implantation site (20cm distance).
10. Variation in diuretics consumption within the last 6 months.
11. Subjects who have received botulinum toxin injections within the past 12 months.
12. Failure to respond to previous neuromodulation therapy for overactive bladder.
13. Subjects who have received neurostimulation in the last 3 months.
14. Previous urinary incontinence surgery or prolapse surgery using graft material within the last 12 months.
15. Any spinal or genitourinary surgery within the last 6 months.

16. Previous abdominoperineal resection of the rectum or previous radical hysterectomy.
17. Skin, peripheral edema, orthopedic or neurologic anatomical limitations that preclude implantation or/and use of the device.
18. Diagnosis of interstitial cystitis or bladder pain syndrome as defined by either American Urological Association (AUA) or European Association of Urology (EAU) guidelines.
19. More than minimal level of suspected stress incontinence or mixed incontinence with stress component likely to confound study outcome, based on a 7-day voiding diary or medical history, or when stress incontinence score in the MESA incontinence questionnaire is higher than the urgency incontinence score
20. Subjects with suspected urinary retention and/or PVR>150ml.
21. Any neurological disease or disorder including Alzheimer's, Parkinson, MS, stroke (CVI), neuropathy or injury resulting in neuropathy and/or suspected neurogenic bladder.
22. Current or recurrent urinary tract infection (3 or more infections in the last 6 months), or presence of urinary fistula, or urinary tract obstruction such as cancer, urethral stricture or presence of urinary stone.
23. History of chemotherapy or pelvic radiotherapy that might have affected bladder control or caused neuropathies (i.e. peripheral neuropathy).
24. Diabetes with peripheral nerve neuropathy or severe uncontrolled diabetes (with HbA1C > 7%). Note: patients with HbA1C in the range of 7.1-7.5% may be considered eligible based on their complete medical record.
25. Uterine prolapse, cystocele, enterocele or rectocele with pelvic prolapse to or beyond the hymen.
26. Subjects with a documented history of allergic response to Platinum iridium, Titanium, Zirconia, Gold, Silicone or Parylene.
27. Other active implantable electronic device/s regardless of whether stimulation is ON or OFF.
28. Have a life expectancy of less than 1 year.
29. Subjects who are breastfeeding
30. History of drug or alcohol abuse.

Follow-Up Schedule & Subject Accounting

Subjects were seen at baseline, implantation procedure, device activation (which occurred 4 weeks ±2 weeks after implantation), and then at 1-month, 3-months, 6-months, and 12-months post activation. Adverse events and complications were recorded at all visits. A long-term follow-up extension is being performed every six months after the 12-month visit up to 3 years, which subjects had the option of consenting to.

Overall, 282 patients consented and were screened for the study, with 151 patients implanted. Of the eleven subjects who prematurely terminated the study, seven participants were terminated from trial participation prior to the 6-month visit. One participant (0.7%) terminated due to an adverse event (cardiac condition which necessitated a cardiac pacemaker), 1 (0.7%) terminated due to compliance to attend visits, 3 (2%) were lost to follow-up and two (1.3%) withdrew consent after implant.

Each of the remaining 144 participants (100%) completed the 6-month visit. Additional 4 subjects terminated the study before the 12-month visit. A flow-chart summarizing the flow chart of the follow-up schedule and subject accounting can be found in **Figure 4** below.

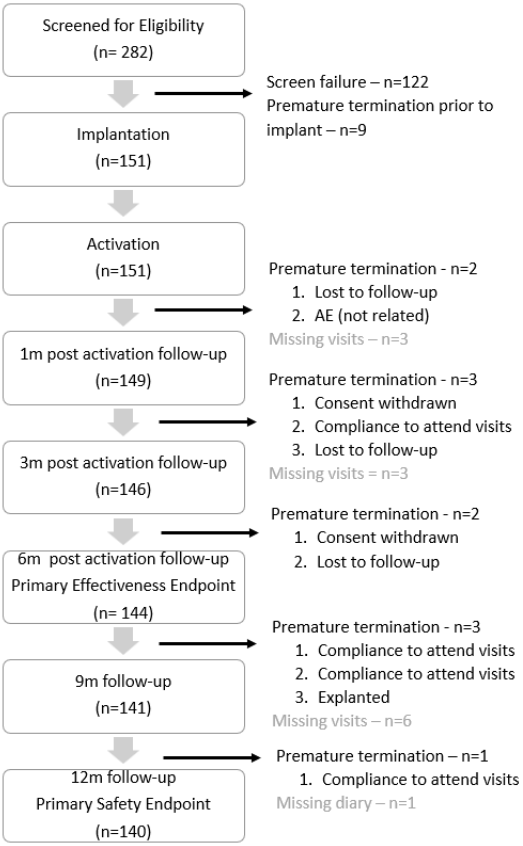


Figure 4: Flow Chart of Follow-Up Schedule & Subject Accounting

Clinical Endpoints

Primary effectiveness and safety endpoints are described below.

Safety – The primary safety endpoint for the study was to assess incidence of adverse events from implantation to 12-months post-activation.

Effectiveness – The primary effectiveness endpoint was to determine the proportion of responders at 6 months post system activation as demonstrated by ≥50% improvement in average number of urgency related incontinence episodes as compared to baseline, measured by 7-day Patient Voiding Diary.

Secondary effectiveness endpoints were to determine the following:

• Proportion of subjects with ≥10 points (MID) improvement compared to baseline in HRQL (based on OAB-q) at 6 months post system activation

• Proportion of responders at 12 months post system activation as demonstrated by ≥50% improvement in either average number of urgency related incontinence episodes or average number of "large" (severe) urgency related incontinence episodes, as measured by 7-day Patient Voiding Diary.

• Proportion of responders at 6 months post system activation as demonstrated by ≥50% improvement in the average number of moderate-severe urgency episodes PPIUS degree 3,4 or <8 voids/day

All Primary and Secondary effectiveness endpoints were hypothesis tested.

Study Population Demographics and Baseline Parameters

One-hundred and fifty-one (151) female subjects of mean age of 58.8 years (SD: 12.5),mean BMI of 30.2 (SD: 6.9) and mean baseline UUI/day and mean average of urgent episodes/day of 4.8/day (SD: 2.9) and 6.7/day (SD: 3.3), respectively were implanted in the OASIS study (Table 3). Race and ethnicity data was collected only from the US cohort where the majority of the subjects were white (n=83, 95.4%), not Hispanic or Latino (n=81, 93.1%) (Table 4).

The distribution of OAB related medical history is presented inTable 5. One-hundred and forty-seven subjects (97.4%) received first line therapy in the past, and 84 of them were continuing with some kind of first line therapy at baseline. All but one subject (99.3%), had tried at least one type of OAB medication historically, and 49 (32.7%) were still receiving OAB medication at baseline. Of those who received OAB medication, 123 (60.6%) received Antimuscarinics, 71 (35.0%) received Beta-3 Adrenergic Agonists and 3 (1.5%) received Tricyclic Antidepressants (some subjects reported more than one type of OAB medication).

Table 3: Descriptive Statistics of Demographic Characteristics (ITT Analysis Set)

Parameter	Mean	Std	Min	Median	Max	n
Age (Years)	58.8	12.5	24.0	61.0	81.0	151
Height (cm)	165.4	6.6	152.0	165.0	180.3	151
Weight (kg)	82.7	20.6	49.0	78.7	152.0	151
BMI (kg/m2)	30.2	6.9	18.3	28.6	49.8	151
UUI	4.8	2.9	1.0	4.0	17.7	151
Urgent episodes	6.7	3.3	1.6	6.1	22.0	151

Table 4: Distribution of Race and Ethnicity (ITT-US Analysis Set)

Characteristic / Result		N	%
Race	Black or African American	3	3.4
	White	83	95.4
	Other - Hispanic	1	1.1
	All	87	100.0
Ethnicity	Hispanic or Latino	6	6.9
	Not Hispanic or Latino	81	93.1
	All	87	100.0

Table 5: Frequency Distribution of OAB Related Medical History (ITT Analysis Set)

Medical History	Any								Ongoing?					
	Yes		No		Unknown		All		Yes		No		All	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Lifestyle Modification, Pelvic Muscle Training, Biofeedback	147	97.4	4	2.6	0	0.0	151	100.0	84	57.1	63	42.9	147	100.0
Botulinum Toxin Injections	18	11.9	132	87.4	1	0.7	151	100.0	0	0.0	18	100.0	18	100.0
PTNS	29	19.2	121	80.1	1	0.7	151	100.0	0	0.0	29	100.0	29	100.0
OAB Medication	150	99.3	1	0.7	0	0.0	151	100.0	49	32.7	101	67.3	150	100.0

Safety and Effectiveness Results

The safety and effectiveness endpoints were evaluated under principles of Intent to Treat (ITT). The analysis set consists of all subjects for whom the implantation of the BlueWind Revi system was attempted. Specifically, the analysis set consists of all subjects for whom skin incision time was not missing. The intent-to-treat (ITT) analysis of effectiveness is based on the 151 subjects who had an implant attempted.

The results of the study showed improvement in UUI episodes, HRQL, number of moderate to severe urgency episodes, and average number of "large" (severe) urgency related incontinence episodes. The analyses performed on the ITT population demonstrate a statistically significant improvement on both the primary and secondary endpoints when compared to the pre-determined performance goals.

Safety Results

The primary safety endpoint for the study was to assess incidence of adverse events from implantation to 12-months post-activation. The potential risks related to this study are the known risks of surgical procedures and electrical stimulation, including but not limited to bleeding, pain, infection, skin irritation, mobility impairment, nerve injury, uncomfortable or sporadic electric "shock" or radiating sensations, uncomfortable heating, discomfort or burn.

Among 151 implanted subjects, 117 (77.5%) had at least 1 AE with a total of 286 AEs, including one adverse event that was adjudicated as normal wound healing process and not an AE by the CEC. There were no procedure/device related SAE in the safety (ITT) population, and there were no unanticipated device/procedure related AEs. Ten AEs were adjudicated as surgical wound related events, with seven classified as surgical wound complication, two as wound infection and one as wound dehiscence (**Table 7**). The rest of the surgical procedure related AEs (n=6, 4.0%) were also classified as either mild or moderate (i.e., numbness after surgery, swollen foot, allergic reaction, skin rash, cellulitis, pain). Six patients (4.0%) experienced device related adverse events, all of which were reported as pain associated with the treatment/stimulation. Most of the device and/or procedure related adverse events were transient in nature and mainly concentrated around the first several weeks post implantation procedure. All device or procedure related AEs were anticipated and were either mild or moderate in severity.

Table 6: Rate of Device and Procedure Related Treatment Emergent Adverse Events by Severity as Determined by the CEC (ITT Analysis Set)

AEs adjudicated	Device Related Mild AE	Device Related Moderate AE	Procedure Related Mild AE	Procedure Related Moderate AE
285	5 (3.3%)	1 (0.7%)	7 (4.6%)	9 (6%)

Table 7: Rate of Procedure and Device Related Adverse Events as Determined by the CEC (ITT analysis set)

			N	%
Device	Pain associated with device	TOTAL	6	4
Procedure	Surgical Wound related	Complication	7	4.6
		Infection	2	1.3
		Dehiscence	1	0.7
		TOTAL	10	6.6
	Non surgical wound related	Numbness after surgery	1	0.7
		Swollen foot	1	0.7
		Pain	1	0.7
		Erythroderma/skin rash	1	0.7
		Cellulitis	1	0.7
		Allergic reaction to pre-op antibiotic	1	0.7
		TOTAL	6	4.2

Primary Effectiveness Endpoint

The primary effectiveness endpoint was defined as the proportion of subjects with ≥50% improvement in average number of urge related incontinence episodes at 6 months post system activation. The Revi therapy demonstrated clinically meaningful improvement in urgency incontinence episodes marked by a 76.4% (CI: 68.7%-82.6%) responder rate, where a responder was defined as a subject improving at least 50% in their UUI episodes compared to baseline. Although the primary endpoint was specified for the 6-month follow-up duration, an additional analysis was performed to determine the 12-month response rate on the ITT population at 12 months. Here too, the analysis demonstrates a similar response rate of 78.4%.

Table 8: Primary Effectiveness Endpoint Analysis

Primary Endpoint	Responders	Lower 95% CL	Upper 95% CL	P-Value
≥50% reduction in UUI at 6m (PG: 50%)	76.4%	68.7%	82.6%	<.0001
≥50% reduction in UUI at 12m (PG: 50%)*	78.4%			

*12-month data are considered post-hoc and no statistical inference can be made from these data.

Secondary Effectiveness Endpoints

Clinical improvement was also demonstrated by a secondary endpoint demonstrating improvement in Health-Related Quality of Life (HRQL) with a response rate of 83.6% (CI: 76.7%-88.7%) and 84.6% at 6- and 12-months post activation, respectively. Another secondary endpoint was specified to address the broader spectrum of OAB symptoms, including frequency and urgency. This secondary endpoint also demonstrated improvement in frequency and urgent episodes (PPIUS degree 3,4) with response rate of 74% (CI: 65%-81.3%) and 80.1% at 6- and 12-months post activation, respectively. Lastly, since the large volume UUI episodes are considered the most debilitating symptom for wet OAB patients, a composite secondary endpoint - including not only UUI episodes, but also large UUI episodes - was assessed, with a statitically significant response rate of 88% (CI: 81.6%-92.4%) at 12 months.

Table 9: Secondary Effectiveness Endpoint Analysis

Secondary Endpoints	Follow-up	Responders	Lower 95% CL	Upper 95% CL	P-Value
≥10 points (MID) in HRQL (OABq) at 6m (PG: 50%)	6m	83.6%	76.7%	88.7%	<.0001
	12m*	84.6%			
Improvement in urgency episodes and voids at 6m (PG: 45%)	6m	74%	65%	81.3%	<.0001
	12m*	80.1%			
≥50% reduction in UUI or large volume UUI at 12m (PG: 50%)	12m	88%	81.6%	92.4%	<.0001

*12-month data are considered post-hoc and no statistical inference can be made from these data.

Additional Endpoints:

At 12-months 95% (124/130) of the patients indicated they are satisfied with the therapy and 50% (69/139) were dry on 3-consecutive diary days. Additionally, a 92% compliance rate was observed at 12-months.

Concomitant Medication Subgroup Analysis:

Concomitant OAB medication at baseline was shown to have an affect on response

rate. Subjects using OAB medication had a higher responder rate (89%) than those not using OAB medication concomitantly (70%) (p=0.012) after 6-months of device activation. Nevertheless, the subgroup of 98 subjects not taking concomitant OAB medication still demonstrated a clinically meaningful benefit regardless of OAB medication status.

Revi System Description

The Revi System has an implantable wireless neurostimulation component which is intended to be placed in the vicinity of the tibial neurovascular bundle.

The Revi Implant has no battery; the Revi Wearable Unit transmits energy to the Implant, which sends electrical pulses to the tibial nerve. These electrical pulses stimulate the nerve along the leg, reaching the sacral plexus - which also contains nerves innervating the bladder, urinary sphincter and pelvic floor. This stimulation has the power to modulate nerve function, calming the bladder and relieving symptoms of urgency incontinence alone or in combination with urinary urgency

The Revi Wearable Unit is programmed with customized stimulation parameter settings, set by the clinician at an initial Treatment Setup visit, having been determined according to the patient's tolerability, sensations and motor thresholds. The patient then receives the personalized Wearable Unit and continues Treatment Sessions at home, only returning to the clinician for follow-up visits.

The Revi System comprises the following:

- One implantable component - the Revi Implant
- Two non-implantable components:
  - Revi Wearable Unit (with battery charger).
  - Revi Clinician Programmer (CP) (with battery charger).
  - HealthGo Micro (Hub).

Note: Each component should have a backup available during each relevant session in which the system is used.

Figure 5 Revi System

Revi Implant

The Revi Implant provides stimulation current to peripheral nerves in vicinity of the Implant.

The Implant consists of an electronic assembly within a hermetically-sealed encapsulation. On the outer surface of the encapsulation there are two ring electrodes (see Figure 6) through which stimulation current is delivered to the tissue.

The Implant is covered by a silicone membrane with suture holes, allowing the surgeon to anchor the Implant to the fascia by suturing.

Since the Implant contains no battery, it is powered and controlled by an external Wearable Unit. Having an external power source (see **Revi Wearable Unit/Wearable Device**, below) increases the implant lifetime and output capability while allowing for a smaller Implant size.

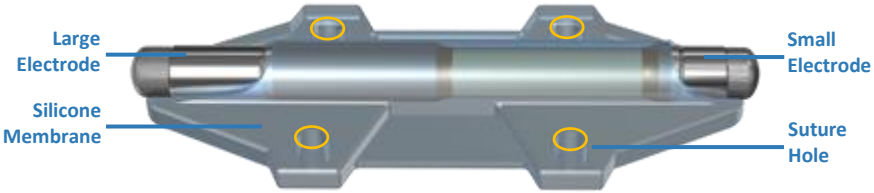


Figure 6 Revi Implant

Revi Wearable Unit/Wearable Device

The Revi Wearable Unit/Wearable Device wirelessly powers the Implant and controls stimulation parameters.

The Wearable Unit/Wearable Device is designed for two purposes:

- **Use by the Surgeon** — for verifying the Implant's functionality and correct placement relative to the nerve.
- **Use by the Patient** — for delivering routine treatments.

Wearable Unit

The Wearable Unit comprises of a Wearable Device and a Leg Band, and is used during treatment.

Note: *During implantation, the device is used without the Leg Band.*

Wearable Device

The Wearable Device contains an electrical circuit board (which includes the user controls and indications), a flexible antenna and a rechargeable battery. In addition, it has a dedicated charger (supplied with the Wearable Device).

The Wearable Device communicates with the Clinician Programmer (CP) via Bluetooth Low Energy (BLE). This communication enables the CP to program the Wearable Device and also to download the recorded log files, indicating patient usage of the Wearable Device.

The Wearable Device can be paired to any specific Implant. Once paired, the Wearable Device transmits power and can only communicate (through magnetic coupling) with the Implant to which it is paired. Magnetic coupling is strong enough to enable full range, uninterrupted stimulation and communication for implantation depth of up to 1.18 in (30mm).

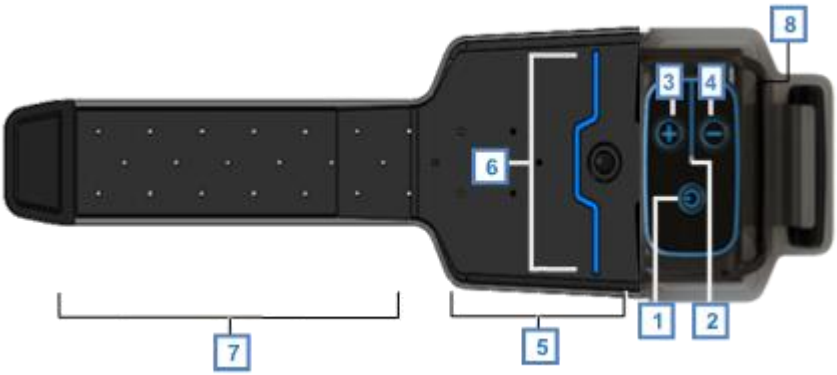


Figure 7 Revi Wearable Unit - Controls and Indicators

Legend

1	Power Button
2	Led Indicator
3	"+" Button
4	"-" Button
5	Antenna
6	Antenna center marking
7	Fabric strap
8	Charging Connector

Revi Clinician Programmer (CP)

The Clinician Programmer (CP) is the system's interface for treatment control, status evaluation, parameter programming and data acquisition.

The Clinician Programmer comprises proprietary software that is embedded into a commercially-available tablet in a single-app mode i.e., the tablet runs only the Revi software.

Access to the Clinician Programmer is password protected to allow access only to authorized users.

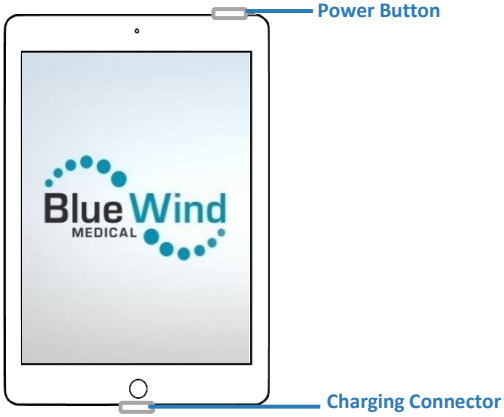


Figure 8 Revi Clinician Programmer (CP)

Note: The Clinician Programmer is supplied with its own dedicated battery charger.

Note: The Clinician Programmer is capable of transferring data to and from the Wearable Device via a wireless connection (via Bluetooth Low Energy) and is designed for two purposes:

- **During the surgical procedure**:
  The CP monitors the stimulation used by the surgeon to verify the Implant position.
- **For optimization of therapy for each patient**:
  The CP is used to optimize therapy for each patient by enabling the user to set and/or adjust the stimulation parameters as required, as well as to receive treatment logs from the Wearable Unit and present them as usage reports.

HealthGo Micro (Hub)

The HealthGo Micro is a hub that communicates with the Wearable device using BLE and acquires and transmits data to the Cloud. It is provided to the patient for use at home.

Revi Therapy

Overview

Before deciding whether or not Revi therapy is appropriate, it is important for the clinician to discuss and assess the benefits and risks with the patient, in order that they may both make an informed decision. The patient should receive a copy of the patient therapy guide to help determine if they want to receive the Revi System. The following information explains the benefits, and possible risks, and also describes what to expect from Revi Treatment.

Revi Treatment

Revi therapy is neurostimulation (neuromodulation) treatment that can relieve symptoms of of urgency incontinence alone or in combination with urinary urgency . The Revi System uses mild electrical pulses to stimulate the tibial nerve located in the lower leg.

Revi Treatment does not provide a cure for the patient's condition. However, the Treatment is likely to reduce symptoms to a tolerable, or even normal, level and allow the patient to resume many of their normal daily activities.

Surgery

The first step toward receiving the treatment is a surgical procedure to place the miniature stimulator (Revi Implant) in the patient's leg, near the tibial nerve. As with any surgical implantation, there are risks related to the surgery itself and almost all of them are resolved on their own, or with medication, within a period of days to weeks. Since the Revi Implant is very small and implanted peripherally (in the lower leg), the risks are relatively low (see Possible Adverse Events on page 15).

For a small number of patients, the treatment will not improve the symptoms (or more rarely, the device may fail). If the clinician decides to remove the implant, or in the event of a complication requiring implant removal, additional surgery will be required.

The advantage of having a neurostimulator implanted is that the patient can perform daily treatments at home, tailored to their individual needs.

Stimulation

For each Treatment Session (typically, 30-60 minutes), the Revi Wearable Unit is placed around the leg, strapped into position over the Implant site, then activated.

The unit transmits energy to the Implant, which sends electrical pulses to the tibial nerve. For the patient, this will feel like a tingling sensation in the sole of the foot and/or toes. These electrical pulses stimulate the nerve along your leg and reach the nerves in the pelvis that control the bladder, urinary sphincter and the pelvic floor. This Stimulation has the power to modulate the function of nerves (i.e., neuromodulation), calming the bladder and relieving the symptoms.

Neuromodulation/neurostimulation therapy is an alternative for people with urinary control problems who did not respond to, or could not tolerate other treatments - such as, a change in diet, medication, biofeedback, or catheterization.

There are additional risks related to the Stimulation itself (see Possible Adverse Events on page 15). The majority of adverse events are resolved either on their own or by adjusting the Stimulation settings. Clinicians should remind patients that they are in control of their own Treatment and can adjust the Stimulation at any time within a predetermined range of stimulation levels.

Clinical Therapy

Revi therapy has been tested in a Clinical Trial on patients suffering from urgency incontinence alone or in combination with urinary urgency.

Almost 80% of implanted patients demonstrated ≥50% reduction in urge urinary incontinence episodes at 12-months. In addition, 50% of the patients who reached 12-months follow-up experienced complete alleviation of their urinary leaking episodes (assessed on 3 consecutive diary days).

Clinical improvement was also supported by significant improvements in Health Related Quality-of-Life.

Possible Risks

Potential risks are associated with any surgery, implantation, or use of a neurostimulation system.

When considering the suitability of a patient for Revi therapy, the possible risks for performing the implantation procedure and neurostimulation are described in Possible Adverse Events on page 15. Caution should also be used when applying certain other medical therapies to patients implanted with the Revi Implant. For a detailed list, see Medical Therapies/Procedures on page 55.

The clinician should discuss any implications of the above with the patient and afford them the opportunity to address any concerns or questions.

Potential Changes to Lifestyle to Accommodate Therapy

When assessing Revi therapy as a suitable form of treatment, it is recommended that the clinician ask the patient about activities in which they're typically involved. If these include extreme sports or similar strenuous pursuits, potential activity restrictions and/or changes to lifestyle may be required once the patient is implanted with the Revi Implant. Please refer to the Warnings and Precautions in the Safety Information on page 4.

Clinical Workflow

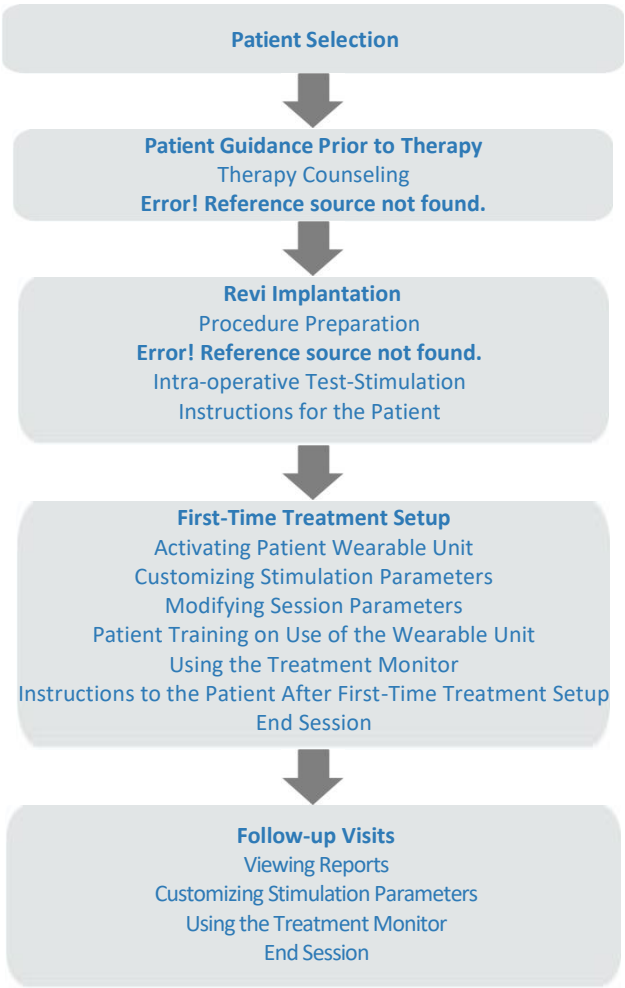


Figure 9 Clinical Workflow

Patient Selection

In determining the suitability of a patient for Revi therapy for the treatment of urgency incontinence alone or in combination with urinary urgency, criteria that should be taken into consideration are outlined in the following:

- Indications for Use on page 3.
- Contraindications on page 3.

- Use in Specific Populations on page 4.

Patient Guidance Prior to Therapy

Therapy Counseling

Prior to receiving Revi therapy, the treating clinician/surgeon plays an important role in providing guidance to the patient. This should include discussing the benefits and risks of the therapy (as previously described - see the Overview on page 34 and Possible Risks on page 35), as well as the implications of having a permanent Implant.

The discussion should also include possible restrictions affecting lifestyle as referred to in Potential Changes to Lifestyle to Accommodate Therapy on page 36.

The patient should receive a copy of the patient therapy guide to help determine if they want to receive the Revi System.

Once the patient and clinician have decided that Revi treatment is appropriate, the clinician should ensure that the patient is scheduled for a consultation session (to take place prior to the day of surgery) with the surgeon who will be performing the Implantation procedure. For details of this session, see Prior to Surgery on page 38.

Prior to Surgery

Prior to the day of surgery, patients should receive a consultation session which will include the following:

1. Measure the patient's leg circumference at a level 2 in (5 cm) above the Medial Malleolus. This measurement has good correlation to the tibial nerve depth (i.e., distance from the skin). The system was tested to support patients with circumference of 8 – 12 in (20 – 30 cm) and implantation depth of 0.2 – 1.2 in (5 – 30 mm) from the skin.
   The Revi Implant should not be used for patients with measurements outside these ranges.
2. The patient should receive a detailed explanation regarding the surgical procedure, anesthesia, potential adverse events and implications of having a permanent implant - including relevant restrictions as described in the patient therapy leaflet (contained in the Implant package) under Warnings and Precautions.
3. The patient should be instructed to perform a scrub of the

surgical site with antiseptic soap, at home, before surgery (e.g., in the evening before and morning of surgery).
In a study by Brueseke T, et al. (2015)[a] on risk factors for surgical site infection in patients undergoing sacral nerve modulation therapy, it was demonstrated that the use of a Chlorhexidine gluconate (CHG) scrub the night before and the morning of surgery reduced surgical site infection from 7.4% to 1.7%.

[a] Brueseke T, Livingston B, Warda H, et al. Risk factors for surgical site infection in patients undergoing sacral nerve modulation therapy. Female Pelvic Med Reconstr Surg 2015;21:198–204.

Implantation Procedure

Surgical approach and techniques for inserting the Revi Implant are detailed in the instructions provided below.

The Clinician Programmer tablet provides a convenient workflow for preparing the Revi System by initiating an implantation session on the Clinician Programmer and verifying that the System is operable. For detailed instructions on using the Clinician Programmer before, during and after the implantation procedure, see Revi Clinician Programmer User Manual.

Important Surgeons should be experienced with similar surgical procedures and should be trained prior to performing this procedure.

⚠ CAUTION Do not charge the Clinician Programmer (CP) or Wearable Device during the procedure. Charging the CP and Wearable Device should be completed prior to the procedure.

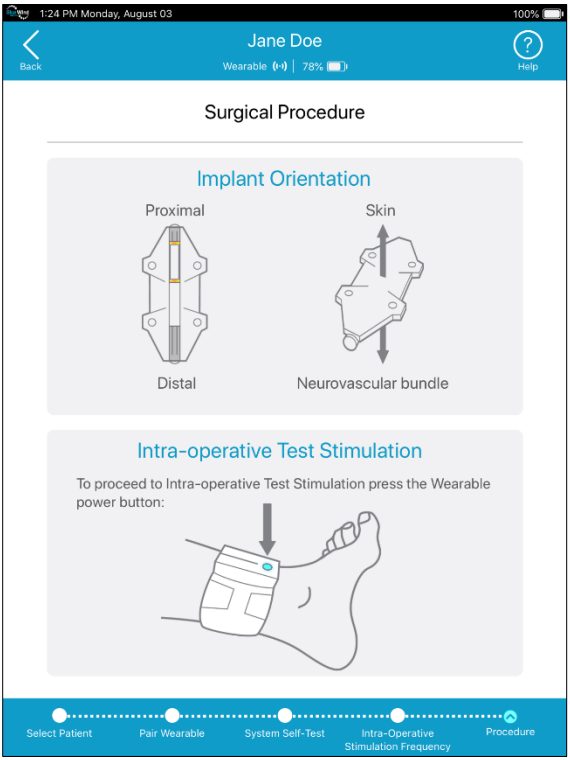
Important Do not open the Implant sterile pouch until after the System Self-Test is performed.

It is recommended to postpone opening the pouch to the time just before the surgeon needs to place it, in order to reduce the risk of contamination.

Revi Clinician Programmer (CP) Activation and System Self-Test

Prior to surgery, the BlueWind Medical representative prepares the Revi System by initiating an implantation session on the CP and verifying that the System is operable (System Self-Test) (see Revi Clinician Programmer User Manual).

The following screen will appear on the CP:



Important **Do not shut down the Wearable Device.**

NOTE: *If the CP shuts down (after 2 hours of inactivity) or has been actively shut down before proceeding to the Intra-Operative Test Stimulation, the preparation steps performed by BlueWind Medical Representative will have to be repeated; or, less preferable, proceed without the CP as monitor.*

⚠ CAUTION Do not use Revi System components that fail the System Self-Test.

Preparations and Draping

1. Prepare essential equipment including:
   - Basic surgical kit and anatomy forceps.
   - Sutures (recommended 3-0 PROLENE®/3-0 ETHIBOND®, 4-0 VICRYL® and 3-0 Nylon/4-0 Monocryl).
   - Sterile sleeve for the Wearable Device.
   - Make sure the Wearable Device and CP batteries are fully charged.
   - Revi System preparation – enter patient information, System Self-Test and choosee the Intra-Operative Stimulation frequency (as described above).
2. Patient preparation:
   - Prophylactic analgesia and intravenous antibiotics should be administered 15-60 minutes before skin incision.
   - Patient positioning: Place the patient in a supine position. For better visualization of the medial aspect of the ankle, it is recommended to apply a support (e.g. sandbag) under the contralateral buttock and raise the leg intended for implantation for separation from the contralateral leg.
   - Mark the leg for the appropriate surgical incision site as follows (Figure 10):
     - Mark the most prominent point of the medial malleolus.
     - Measure 0.8 in (2 cm) proximally and mark one transverse line.
     - Measure additional 2 in (5 cm) proximally and mark a second transverse line.
     - Measure 0.8 in (2 cm) posterior to the edge of the tibia and mark a longitudinal line across the points.

   ***NOTE**: Check that the longitudinal line lays half way between the tibia and Achilles tendon.*

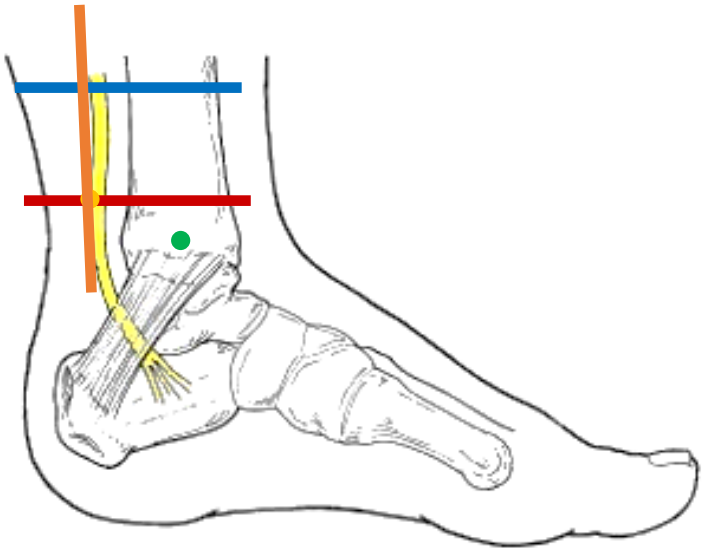


Figure 10 Location of Incision Site

NOTE: *Avoid hair removal at the surgical site. If hair must be removed use single-patient use clippers and not razors.*

- Wipe with alcohol and infiltrate local anesthesia along the marked incision line. Avoid penetrating the fascia with a deep injection and infiltrating the local anesthesia under the fascia.
- Prepare the skin at the surgical site immediately before incision using an antiseptic preparation (i.e., chlorhexidine scrub for 10 minutes, in outward circular motions followed by an alcohol wipe and drying off).

Important **Thorough skin antiseptic preparation must be performed**, in order to minimize the risk of post-operative infections.

- If using electrocautery, ensure that antiseptic skin preparation is dried thoroughly.
- Drape the patient in the usually accepted manner. The foot is a highly contaminated area, make sure it is draped tightly.

NOTE: *If a need arises during the procedure, general and/or regional anesthesia may be added.*

Anatomy of the lower leg

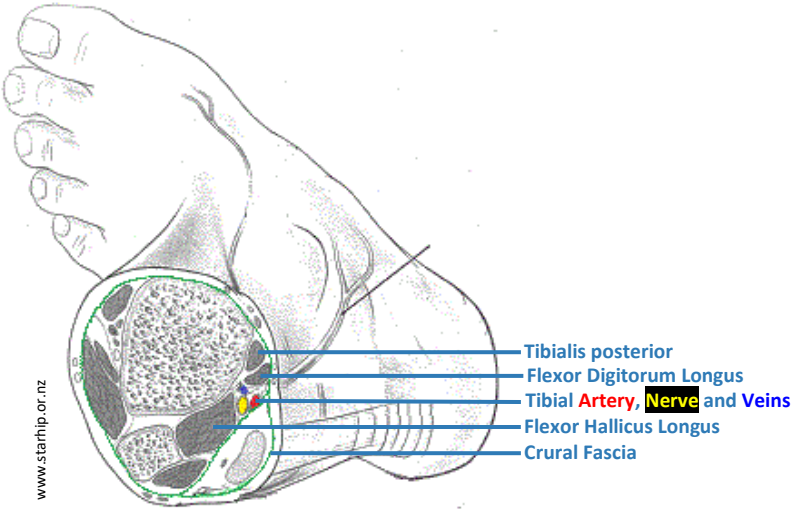


Figure 11 Anatomy of the Lower Leg

Surgical Incision

⚠ CAUTION When using sharp instruments near the Revi Implant, be extremely careful to avoid nicking or damaging the Implant casing, insulation or electrodes. Damaging the Implant may affect its functionality and could lead to the need for surgical replacement.

Redo marking if needed with a sterile marker and a ruler. Make an incision, extending 2 in (5 cm) along the previously-marked incision line (refer to step 3 in Preparations and Draping).

Surgical Dissection

Deepen the incision by blunt dissection of the underlying fat tissue until the crural fascia (deep fascia of the leg) is exposed.

⚠ CAUTION Before proceeding - extra care should be taken to protect the tibial neurovascular bundle when dissecting the crural fascia. Throughout the procedure, do not use a electrocautery on cut setting**.** Once the crural fascia is exposed avoid using any type of electrocautery .

1. Use a guarded dissection technique to divide the crural fascia.
2. Identify the posterior tibial neurovascular bundle.

3. Irrigate and dry the surgical opening thoroughly before placing the Implant.

NOTE: *If the tibial neurovascular bundle is obscured by a second fascia or an overlaying muscle, identify the bundle by following these guidelines:*

a. *You should consider dissecting through a second fascia when encountering another layer of fascia above the neurovascular bundle ..*

b. *If you cannot verify location of the neurovascular bundle, count 2 tendons posterior to the tibia (Tibialis Posterior & Flexor Digitarum Longus) and look for the neurovascular bundle.*

c. *If needed, consider extending the surgical incision distally, as the neurovascular bundle becomes more superficial towards the distal area.*

NOTE*: In the event that the crural fascia was not dissected directly above the tibial neurovascular bundle, continue dissecting the crural fascia to align the opening and the tibial neurovascular bundle (Figure 12).*

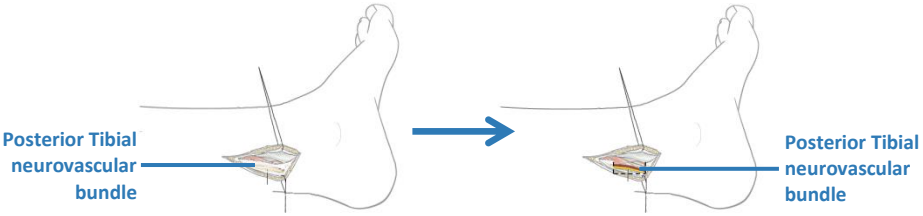


Figure 12 Surgical Dissection Illustration

Implant Placement

⚠ CAUTION Do not use a sharp object to manipulate the Revi Implant; the Implant is covered with a thin layer of Parylene and can be damaged by sharp objects, including tissue forceps.

1. Using plastic forceps or anatomy forceps, hold the Implant by the silicone membrane (Figure 13)

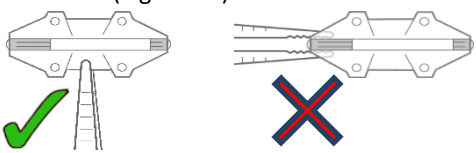


Figure 13 Correct Implant Handling

2. Place the Revi Implant into the surgical opening over the neurovascular bundle (Figure 14).

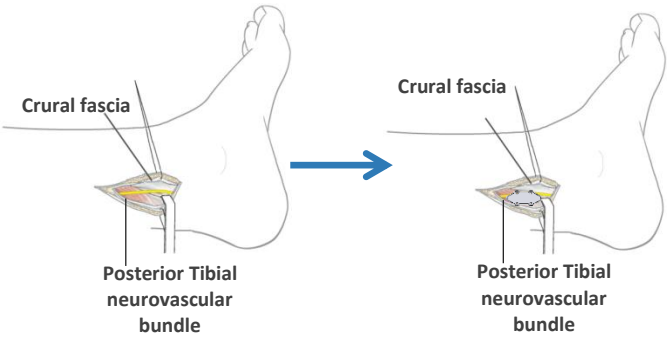


Figure 14 Implant Placement

3. Position the Implant so that the larger electrode is oriented distally; ensure the smooth silicone surface of the implant is facing upward (i.e., superficially), see Figure 15.

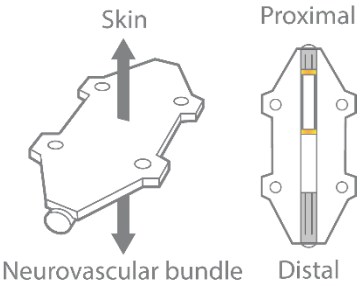


Figure 15 Implant Orientation

⚠ CAUTION

Observe the following precautions:

- Ensure that the Implant is placed no deeper than 1.2 in (3 cm) below the skin and is parallel to the skin. If the Implant is too deep or is not parallel to the skin incision, energy transfer may be inefficient or unsuccessful.
- Once the Implant is in place, avoid using electrosurgical cautery as this may damage the Implant and/or conduct heat through it.

Intra-Operative Test Stimulation

⚠ CAUTION

To use the non-sterile Wearable Device in a sterile field, place a sterile barrier / sleeve between the patient and the Wearable Device in order to prevent contamination. Do not sterilize any part of the Wearable Device, since sterilization may damage it.

⚠ CAUTION

The Clinician Programmer is intended to be used as a monitor during the procedure, outside of the sterile field. If use of the touch screen is required during the procedure, it should be handled by a non-sterile OR staff member.
Do not sterilize the Clinician Programmer, since sterilization may damage it.

1. Instruct the patient regarding the sensation he/she is about to feel and ask his/her cooperation in giving feedback.
2. Press the Wearable Device button to start positioning (i.e., communication with implant).

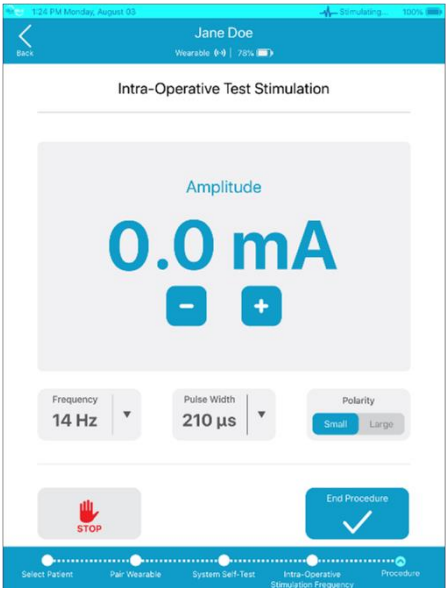
The Wearable is ready for positioning when the LED blinks orange and the buzzer beeps slowly (Figure 16; item #1).

3. Place the Wearable Device antenna center (marked by a white trapezoid sticker) over the Implant.

Figure 16 Wearable Device Positioned for Test

4. Once the Implant has been located, the system will automatically move to Stimulation mode

The LED will glow green and the following screen will appear on the CP:



Important In the event of unexpected pain experienced by the patient, move the Wearable Device away from the Implant or press the stop button to stop stimulation immediately.

5. Press the + button on the Wearable to increase stimulation intensity.

The LED blinks green as the Wearable ramps up the stimulation level, then shows steady green, indicating the target level has been reached and that the + button can be pressed again if needed.

6. Increase the stimulation intensity until the patient reports paresthesia in the heel, sole of the foot or toe area.

NOTE: *For patients who received general or regional anesthesia, continue*

until motor response is achieved by observing the patient's toes for flexion of the big toe or fanning of all toes.

⚠ CAUTION

The surgeon must be aware of sterility issues during motor response checking. Ask the attending nurse to watch for motor response without touching the foot. Setting the frequency to a low level (≤4Hz) will facilitate a pulsating motion which will make recognizing the response easier.

An optimal result is paresthesia or motor response achieved at a low or moderate level of stimulation (≤ 5 mA). If results are non-satisfactory, it may be necessary to re-position the Implant closer to the tibial nerve and then repeat the test.

***NOTE**: If needed, a non-sterile assistant may change the following stimulation parameters on the CP:*

- *Polarity – toggle between the small and large electrode as being the cathode.*
- *Pulse width*
- *Frequency – it is recommended to test intra-operative stimulation at the same frequency as treatment.*

***NOTE:** For patients who received general or regional anesthesia, a low frequency (4Hz) is recommended to facilitate easier detection of the motor response.*

Implant Anchoring and Incision Closure

1. Once the Intra-Operative Test Stimulation provides satisfactory results, secure the Implant to the fascia using non-absorbable suture material (such as 3-0 PROLENE® or 3-0 ETHIBOND®) to minimize long-term movements or migration of the Implant.
2. Repeat the Intra-Operative Test Stimulation once the Implant is secured.

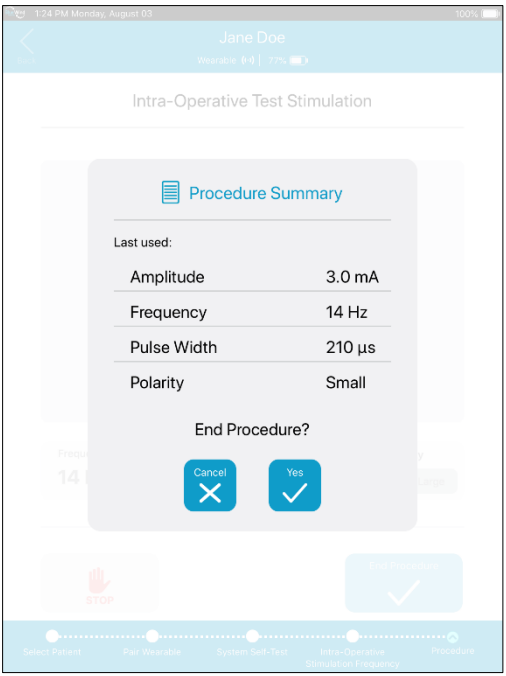
Important **Do not suture the incision in the fascia layer**
(Do not close the fascial incision)

3. Close the subcutaneous tissue using an absorbable poly-filament suture (such as 4-0 VICRYL®).
4. Close the skin outer layer with an interrupted pattern using a non-absorbable mono-filament suture material (such as 3-0 Nylon) or a continuous intradermal pattern using an absorbable monofilament (such as 4-0 Monocryl).
5. Repeat the Intra-Operative Test Stimulation sequence (as described on page 46), to ensure successful stimulation within acceptable parameters .
6. Cover the surgical incisions with a sterile wound dressing prior to removal of drapes.

Completing the Implantation Procedure

1. Turn off the Wearable by pressing and holding the button until:

The LED turns off accompanied by a beep, and the following screen appears:



2. Gently apply a compressive dressing.
3. Antibiotic and analgesics shall be prescribed for the first 24 hours and may be dispensed for longer, at the clinician's discretion.
4. Complete the Patient Registration Form (inside the Implant package insert) and send it to BlueWind Medical by Fax or Email (see contact details in the Implant package insert or the last page of this manual).
5. Complete and provide the patient with a Revi Implant ID card.
6. Explain the instructions outlined below to the patient.

Instructions for the Patient

Instruct the patient regarding the natural healing process of the wound, how to treat the wound and what are considered unusual signs and symptoms that warrant contacting the medical center.

During the two weeks following surgery, it is important to take extra care so as not to interfere with the healing process. Patients should be instructed to comply with the following instructions:

- Keep the leg elevated (above waist level) as much as possible during the first 3 days.
- Do not engage in rigorous physical activity such as running, cycling, dancing or climbing until cleared by your clinician.
- Keep the dressing and general area dry and undisturbed until your follow-up appointment to remove the stiches. Sponge bath only for first 72 hours. Take extra care not to wet the incision when taking showers.
- Do not rub or manipulate the location of the Implant.
- In some cases, your clinician will advise you to wear compression stocking to support the incision healing.

Relevant restrictions applicable to patients implanted with a Revi Implant should be explained; instruction should also be given regarding Warnings and Precautions.

Important **For this, a patient leaflet with the relevant information is provided in the Revi Implant package and should be given to the patient before discharge.**

The patient should return to the clinic for suture removal 10-14 days following the implantation procedure and again for a first-time treatment setup session after the surgical wound has healed

and at least 2 weeks after surgery.

During this session, the stimulation parameters will be optimized for the patient's individual needs and the patient will receive his/her own customized Wearable Unit - along with training on how to operate it.

Explantation or Replacement of the Revi Implant

Specific surgical approach and techniques for removing or replacing the Revi Implant are detailed in the instructions provided below.

It is recommended not to explant the device unless there is a specific medical need or otherwise deemed necessary by the treating clinician.

Prior to Surgery

Prior to the day of surgery, patients should receive a consultation session, similar to the one described on page 38.

Preparations and Draping

1. Prepare essential equipment including:
   - ❑ Surgical instruments and sutures
   - ❑ For Implant replacement:
     - Sutures (recommended 3-0 PROLENE®/ETHIBOND®, 4-0 VICRYL® and 3-0 Nylon/4-0 Monocryl).
     - Sterile sleeve for the Wearable Device.
     - Make sure the Wearable Device and CP are fully charged.
     - Revi System preparation– enter patient information, complete System Self-Test and choose the Intra-Operative Stimulation Frequency (as described on page 41).
2. Patient preparation:
   - ❑ Prophylactic analgesia and intravenous antibiotics should be administered 15-60 minutes before skin incision.
   - ❑ Patient positioning: Place the patient in a supine position. For better visualization of the medial aspect of the ankle, it is recommended to apply a support (e.g., sandbag) under the contralateral buttock and raise the operated leg, for separation from contralateral leg.

NOTE: *Avoid hair removal at the surgical site. If hair must be removed use single-patient use clippers and not razors.*

- Prepare the skin at the surgical site immediately before incision using an antiseptic preparation (i.e., chlorhexidine scrub for 10 minutes in outward circular motions followed by alcohol wipe and drying off).

Important **Thorough skin antiseptic preparation must be performed**, in order to minimize the risk of post-operative infections.

- Drape the patient in the usually accepted manner. The foot is a highly contaminated area, make sure it is draped tightly.
- For this procedure local anesthesia is required.

NOTE: *General and/or regional anesthesia may be used if the clinician finds it is warranted*

Surgical Sequence

⚠ CAUTION **Electrosurgery device use -** Do not use monopolar cautery. Use extreme caution when using bipolar cautery in the area near the Implant as it may conduct heat through the Implant.

1. Make a 2 in (5 cm) long incision over the previous surgical scar.
2. Deepen the incision by blunt dissection of the underlying fat tissue until the crural fascia and Implant are identified. The Implant is likely to be encapsulated by tight fibrous tissue.

⚠ CAUTION Extra care should be taken to protect the tibial neurovascular bundle when dissecting the fibrous tissue encapsulating the Implant. Loupe magnification may be helpful.

3. Carefully dissect the encapsulating fibrous tissue until the entire Implant is exposed.
4. To cut the anchoring sutures, start by placing a fine instrument between the suture wing and tissue, then cut the fibrous tissue.
5. Irrigate and dry the surgical opening thoroughly before closing the incision.
6. For Implant replacement, continue by placing a new Implant in accordance with the instructions for Implant Placement on page 45.

Incision Closure

NOTE: *In cases of infection, the clinician should not attempt to place a new Implant and should consider leaving the incision open for second-intention healing or plastic surgery.*

Important Do not suture the incision in the fascia layer .(Do not close the fascial incision).

1. Close the subcutaneous tissue using an absorbable poly-filament suture (such as 3-0 VICRYL®).
2. Close the skin outer layer with either an interrupted pattern using a non-absorbable mono-filament suture material (such as 3-0 Nylon) or a continuousintradermal pattern using an absorbable monofilament (such as 4-0 Monocryl).
3. Gently apply a compressive dressing
4. Antibiotics and analgesics shall be prescribed for the first 24 hours and may be dispensed longer according to the clinician discretion.
5. Provide patient with post-operative instructions (see Instructions for the Patient on page 51).
6. For Implant replacement, also:
   - Complete patient registration card (inside package insert) and send it to BlueWind Medical by Fax or Email (see details on the last page of this manual).
   - Complete and provide patient with a new Revi Implant ID card.

Implant Handling Post Explantation

Return the explanted Implant to BlueWind Medical for inspection and safe disposal.

1. Rinse the Implant thoroughly in water. Do not autoclave or use ultrasonic cleaners.

   Place the Implant in secure biohazard labeled bag, pad it with absorbent material and place it in second biohazard sealable bag per the institution protocol.
2. Contact BlueWind Medical (see details on the last page of this guide) for courier service details.

NOTE: *Shipping costs are fully covered by BWM.*

The Implant is for single use only. Do not reuse. Reprocessing of single-use devices may cause contamination and/or patient infection or cross infection.

Recharging the Revi Wearable Device

The Revi Wearable Device is powered by a rechargeable battery, sealed inside the Device.

Important Charge the battery before each implantation in order to ensure functionality throughout the procedure.

When the Revi Wearable Device is connected to the battery charger, the LED illumination color and (blinking or steady) light indicates the present battery power status. See illustration in Figure 17.

⚠ CAUTION The battery inside the Revi Wearable Device could become excessively hot during the battery-charging process, handle with care.

As a safety precaution, the Revi Wearable Device is programmed to disable stimulation while the Device is connected to the battery charger. As an additional precaution, follow these guidelines:

- Do not attempt to charge the battery while the Wearable is on the leg.
- Only use the charger provided with the Revi System.

Important Use only the AC adapter and USB cable designed exclusively for the Revi System to connect to the USB port.

To Charge the Battery

1. Make sure the Revi Wearable Device is turned Off (If currently On, press and hold the Power button to turn Off).
2. Connect the battery charger cable to the Revi Wearable Device power input socket.
3. Plug the battery charger into the main power wall outlet. Battery charging will begin.

During the charging process the LED indicator will blink, changing colors from red to green according to charged status.
When fully-charged, blinking stops and LED illumination shows steady green.

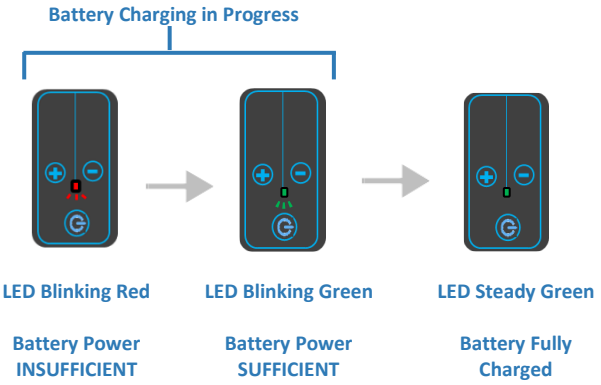


Figure 17 Charging the Battery

Cleaning the Revi Wearable Device

For cleaning of the Revi Wearable Device, follow the recommendations of the manufacturer outlined below.

⚠ CAUTION Do not immerse the Device in water or allow liquids to seep into the components.

Do not use abrasive scouring powders or pads, caustic detergents, ammonia, or acid-based cleaning solutions.

Use of these materials may cause irreparable damage to system components.

1. Ensure the Device is turned Off and the battery charger is disconnected.
2. Clean the Device surfaces using a damp wipe, moistened with water or alcohol.
3. Dry with a soft, clean cloth.

Verifying Revi Implant Functionality

You may wish to verify the Implant's functionality while in storage. Directions below guide you through this test using the Wearable Device.

1. Press the Wearable button to turn it On.

   The Device is in testing mode when the LED blinks orange

2. With the Implant still in its package, place the Wearable antenna center (as indicated with a mark on the antenna in *Figure 16; item #2*) over the Implant.
3. Once the Implant has been located, the system will indicate the result of the functionality test:

   LED illuminated green
   Test passed - implant functional.

   LED illuminated red.
   NOTE: Make sure you are close enough to the implant.
   Test failed - Implant should not be used.

1. You may repeat the test with additional Implants by repeating steps 1- 3.
2. Press and hold the button to turn Off the Wearable.

NOTE: *Avoid testing an implant on top of a metallic surface or in the immediate proximity of other implants. Make sure there is >20in/50cm distance between tested implant and other implants or other operated wearable devices.*

⚠ CAUTION Do not use the Implant if it has failed the functionality test.

Safety and Handling of Revi Clinician Programmer

For information regarding Safety and Handling of the Revi Clinician Programmer, including charging and cleaning instructions, follow the recommendations provided in the Apple iPad User Guide available at www.apple.com.

Troubleshooting Guide

Table 10 Troubleshooting Guide

Situation	Possible Cause	Recommended Action
The Revi Wearable Device does not turn On.	Insufficient battery power.	Check the battery status by connecting it to the battery charger. If the battery indicator is blinking red, charge the Wearable until the LED indicator turns GREEN.
	Device is in deep sleep state	Connect device to the wall outlet using the charger. LED will blink green and beeps will sound. Disconnect from charger then restart it.
	The Wearable is connected to the battery charger.	Disconnect the Wearable from the battery charger, then start again.
The Revi Wearable Device does not turn Off.	Power button was not pressed long enough.	Press and hold the Power button for 5 seconds.
Cannot find the correct Position for the Revi Wearable Device. (The LED indicator is ORANGE and blinking slowly).	The Wearable is not positioned in the correct location.	Make sure the Wearable is placed as shown in Figure 16 on page 47.
		Move the Wearable around slowly until you start hearing the Positioning beeps and frequency of the LED blinking increases.
		Move the unit to a higher location. Rotate the unit so that the buttons move from a side orientation to a more frontal orientation.
	A metal object, or device causing electromagnetic interference (refer to page 69), is located close to the Revi Wearable Device.	Move the object away from the Wearable (alternatively, move the patient's leg away from the source of interference).

Situation	Possible Cause	Recommended Action
Cannot find the correct Position for the Revi Wearable Device (the LED indicator is not illuminated).	The Wearable is turned Off.	Press the Power button once (short press). The LED indicator will turn ORANGE. Sound and LED will indicate positioning.
Beeping sound audible in the middle of stimulation.	Wearable is dislocated from position.	Re-position the device, then press the Power button once (short press). Or- wait at least 5 seconds Try positioning the Wearable Unit as high on the leg as possible, while still maintaining a good positioning signal.
	Electromagnetic interference or metal object near the Wearable Device.	Move away from the interference or move the object away from Wearable.
The Revi Wearable Device feels excessively hot.	Technical problem.	Make sure the Wearable is not on the patient's leg while charging the battery.
		Contact BlueWind Medical for technical support.
Revi Wearable Device does not respond when pressing the + or - buttons.	Maximal / Minimal level has been reached (indicated by three consecutive short beeps).	To change amplitude, press – button if maximal level has been reached or press + button if minimal level has been reached.
	The + button has been pressed during the ramp-up stage (LED blinking GREEN).	Wait for the ramp-up stage to Complete (LED illuminating steady GREEN), then press the + button.
Revi Wearable Unit does not start or continue requested action (the LED indicator is RED).	Any system error.	Retry performing the requested action.

Note: *The CP will offer real-time troubleshooting guidance if an error occurs.*

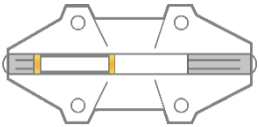
Tachyphylaxis Instructions

Since the Revi therapy does not require constant stimulation and stimulation sessions are recommended for between 30 minutes to 2 hours per day, the likelihood of loss or deterioration in efficacy due to tachyphylaxis or neural tolerance is low. Nevertheless, similar to other neuromodulation therapies, where tachypylaxis has been reported, further programming/reprogramming can result in improvement of symptoms and higher patient satisfaction. Since the Revi implant is battery-less, eliminating the concern of preserving the battery lifetime, the device can provide a wide range of stimulation parameters, including high energy demanding parameters (i.e., amplitude – up to 10mA, pulse width – up to 790mSec, frequency – up to 30Hz). If loss of efficacy does occur, all of the above range in parameters can be programmed/reprogrammed as frequently as needed. In addition, as done with neuromodulation therapies that provide 24/7 stimulation, if reprogramming does not restore treatment effect, a “stimulation holiday” can also be considered and the patient should be instructed to cease therapy for a period of time.

Technical Information for the Revi System

System Specifications

Table 11 System specifications

Revi Implant		
Overall Weight	0.03 oz (0.9 g)	
Length	1.2 in (30 mm)	
Capsule Diameter	0.11 in (2.7 mm)	
Dimensions with Silicone	1.2 x 0.51 x 0.14 in (30 x 13 x 3.5 mm)	
Material	Zirconia ceramic, titanium and gold capsule, coated with Parylene; platinum-iridium electrodes, and silicone suture wings	
Electrodes		
Material	Platinum /Iridium	
Insulation	Zirconia ceramic	
Length	Small electrode: 0.06 in (1.7 mm); Large electrode: 0.15 in (4.0 mm)	
Diameter	0.11 in (2.7 mm)	
Number of electrodes	2	
Stimulation Parameters		
Essential performance	System shall generate the essential stimulation parameters above within the allowed accuracy limits	
Stimulation Waveform	Biphasic charge-neutral	
Pulse Repetition Frequency	Up to 30 Hz	
Pulse Amplitude	Up to 14 mA (may vary according to software version)	
Pulse Width	Up to 790 µsec	
Stimulation Polarity	Configurable	
Typical Treatment duration	30-60 minutes	

Essential performance Accuracy Limits	Pulse Amplitude: ±20% or ±0.15mA (whichever is greater) Pulse Width Accuracy: ±10% Pulse Frequency: ±10%
Stimulation Parameter Increments	
Amplitude	0.1 mA increments
Frequency	1 Hz increments
Pulse Width	20 µSec increments
Treatment Duration	5 minutes increments
Wearable Device	
Material	Polycarbonate and Silicone covered
Dimensions without Leg Band	5.5 [L] x 3.8 [W] x 1.3 [H] in 14 [L] x 9.6 [W] x 3.2 [H] cm
Weight	5oz (165g)
Battery	Li-ion Rechargeable, 1400mAh
Battery operation	Battery operational voltage: 3.1 -4.2V. Battery charging: up to 1 week of Treatment on a single charge. It is recommended to charge the Wearable unit after each treatment. Maintenance time: 1 year
Logging Capacity	365 Treatment days
Battery Charger	Manufacturer: FRIWO Gerätebau GmbH (Ostbevern, Germany) Model number: FW8002.1MUSB/05 Power rating: 6W
Communication	Bluetooth Low Energy (BLE)
Clinician Programmer (CP)	
Type	Tablet computer – iPad v.2017 and up
Software	Proprietary BlueWind Medical software version 10
Screen	Touch screen
Communication	Bluetooth Low Energy (BLE)

Environmental Specifications

Table 12 Environmental Conditions – Revi Wearable Device

System Component	Condition	Ambient Temperature	Relative Humidity (non-condensing)	Pressure (KPa)
Revi Wearable Device	Operation	50 — 90 °F	≤ 85%	70 - 106
		10 — 32 °C		
	Transport/Storage	14 — 131 °F		
		-10 — 55 °C		

Table 13 Environmental Conditions - Revi Implant

System Component	Condition	Ambient Temperature	Relative Humidity (non-condensing)	Pressure (KPa)
Revi Implant	Storage	The implant should be stored in a cool/dry room temperature (typically 57 – 86 °F; 14 – 30 °C)		70 - 200
	Transport	14 — 131 °F	≤ 85%	
		-10 — 55 °C		

Electromagnetic Specifications

Table 14 Revi Wireless Power Transfer Electromagnetic Specifications

Parameter	Specifications
Operating frequency	The Revi System operates at 6.78 MHz, centered at the 6.765-6.795 MHz.
Transmission coil average input power	< 1.4W during treatment (assumptions: loaded Wearable device antenna coil resistance 1.35 Ohm, pulse frequency=30Hz, 15% added margin).
Operating distances between the Wearable device and its intended communication companion (Implant)	The Wearable device wraps around the leg (via a leg band) at the Implant site.
Wireless functions and specific wireless technology	**Wireless Power Transfer:** The Implant receives radiated power from the battery-powered Wearable device via weak magnetic coupling between the Implant coil antenna and the Wearable device antenna. The Implant uses that power to inject electrical current pulses into the leg tissue to stimulate the tibial nerve for treatment of symptoms of urgency incontinence alone or in combination with urinary urgency. **Communication and modulation:** The Wearable and the Implant communicate by modulating the 6.78 MHz power carrier using On-Off Keying (OOK) for the Wearable device to Implant communication and load modulation for Implant to Wearable device communication.
Effective RF radiated power output	Effective RF radiated power is relevant in the far field, however the System uses near field wireless power transfer for which the coil average input power cited above is more appropriate.
Bandwidth of receiving section (Wearable device)	Rx 3dB BW 22.5kHz

Table 15 Revi Bluetooth Low Energy Specification

Parameter	Specification
Wireless technology	Bluetooth™ 4.2 standard
Operating frequency	Frequency range: 2402-2480 MHz Number of channels: 40 Channel bandwidth: 2MHz
Transmitter power (wearable device)	-1dBm
Operating distances between the Wearable device and its intended communication companion	Bluetooth™ is a short distance communication technology. Clinician Programmer: Should be in the same room as the Wearable device. It is recommended that the distance will not exceed 30 feet (10 meters). HealthGo Micro Hub: Should be in the same room as the Wearable device while it is charging.
Wireless functions	Commands from Clinician Programmer to Wearable device and command acknowledgement and data transfer from Wearable device to the Clinician Programmer during implantation and treatment programming. Wearable status inquiry by the hub HealthGo Micro hub and log data transfer from the Wearable device to the hub upon request (during Wearable device charging). The HealthGo Micro hub is not capable of controlling any parameter of the Wearable device.
Modulation	Networking standard IEEE 802.15.1 Single frequency or frequency hopping according to standard

Electromagnetic Compatibility

The System was tested to meet its essential performance (see **Table 11**) under the following conditions.

Table 16 Compliance with EN 60601-1-2 (Edition 4.0 2014)

Test	Standard	Compliance level
Emission (IEC 60601-1-2 sections 7.1- 7.2)		
Conducted emission Freq. range:150 kHz - 30 MHz	CISPR 11	Group 2 Class B 230 & 120 VAC mains (PS)
Radiated emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 2 Class B
Harmonic current emission test	IEC 61000-3-2	Not applicable
Voltage changes, Voltage fluctuations and Flicker test	IEC 61000-3-3	Suitable for use in all establishments, including domestic establishments.
Immunity (IEC 60601-1-2 sections 8.9 & 8.10)		
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges
Immunity from radiated electromagnetic fields	IEC 61000-4-3	10.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m PM (18 Hz or 217 Hz), FM 1 kHz
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2 kV on AC mains (PS), Tr/Th – 5/50 ns, 100 kHz
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM on AC mains (PS), Tr/Th – 1.2/50 (8/20) μs
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0 & 6.0 VRMS on AC mains (PS): 0.15÷ 80 MHz, 80% AM, 1 kHz
Immunity from power frequency magnetic field	IEC 61000-4-8	30 A/m @ 50 Hz & 60 Hz
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	230 & 120 VAC mains (PS); 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles

Certifications

Revi™ Wearable Device MA-1004-0500
FCC ID: 2BAXD-E02-0

Part 15: This device has been tested and found to comply with part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This 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 this device 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

Users are not permitted to modify this device. Any changes or modifications not expressly approved by BlueWind Medical may cause harmful interferences and void the FCC authorization to operate this device.

This product is not end-user serviceable.

In order to comply with FCC RF Exposure requirements, this device must be used in accordance with the instructions provided in this manual.

Revi™ Wearable Device MA-1004-0500

Part 18: This device has been tested and found to comply with part 18 of the FCC Rules. This equipment 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 this device does cause harmful interference to radio or television reception, or interference with other particular devices is noted during use of the Revi Wearable:

- Try separating the distance between the two devices during use
- Consult BlueWind Medical's responsible party

This product is not end-user serviceable. If the product does not function, please contact BlueWind Medical.

Users should clean the device according to the instructions provided in section Cleaning the Revi Wearable Device in this guide. Make sure the device is dry after cleaning.

In order to comply with FCC RF Exposure requirements, this device must be used in accordance with the instructions provided in this manual.

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