Revi™

Patient Therapy Guide

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

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 using the Wearable device.

Safety Compliance Label

The Revi Wearable Unit has a safety compliance label affixed to the back side of the device (visible when the unit is removed from the leg band). Do not use the device if the label is missing. See explanation of the symbols below.

Table 1 Safety Label - Explanation of Symbols

Symbol	Description	Symbol	Description
SN	Serial Number		Date of Manufacture (YYYY-MM-DD)
REF	Catalog Number		Manufacturer
	Consult Instructions for Use (consult accompanying documents)		Dispose of properly after use
Rx Only	Prescription device (Caution: U.S. Federal law restricts this device for sale by or on the order of a physician)		Type BF Applied Part

Table 1 Safety Label - Explanation of Symbols (Continued)

Symbol	Description	Symbol	Description
	Magnetic Resonance (MR) Conditional		Caution
IP32	Ingress Protection		MR Unsafe

The Revi Patient Kit Contains

The Revi Wearable Unit is supplied in a handy carrying case.
Before use, check that this contains the items listed below:

- Revi Wearable Unit
  (comprises a wearable device inside a Leg Band)
- Battery charger and cable
- Revi Patient Therapy Guide (this guide)
- Revi Wearable Unit Quick-Start Guide

Revi Patient Kit

Wearable Unit (with leg band)

Wearable Device (without leg band)

Manual Contents

Glossary

Terms and Acronyms

Table 2 Terms and Acronyms Used in this Guide

Term/Acronym	Meaning
BlueWind Medical Representative	The BlueWind Medical Representative is responsible for programming the device as well as training the patient on home use of the device with oversight of the treating clinician/surgeon
Diathermic therapy	A medical procedure producing heat in the applied body tissue by use of electrical current.
Electrosurgery	A surgical instrument using electrical current for cauterizing of blood vessels.
External defibrillation	An electronic device sending an electric shock to the heart to restore normal heart rhythm.
Lithotripsy	A medical procedure involving the application of ultrasonic waves in order to destruct hardened masses such as stones in the kidney, gastrointestinal system, or gall bladder.

Table 2 Terms and Acronyms Used in this Guide (Continued)

Term/Acronym	Meaning
LED	Light-Emitting Diode: an electrical component that emits light.
Leg Band	An adjustable leg band used to place and hold the wearable device over the implantation site for the duration of therapy session.
MRI	Magnetic Resonance Imaging. A non-invasive diagnostic procedure for imaging tissues of high fat and water content that cannot be seen with other radiologic techniques.
Neurostimulator	A medical device, producing mild electrical signals for nerve stimulation. The Revi Implant is a Neurostimulator.
OAB	Over-Active Bladder – a group of complex symptoms that is characterized by urinary urgency, with or without urgency-associated urinary incontinence.
Revi System	Peripheral nerve stimulation device intended for home-care use. The system comprises the **Revi Implant** and the **Revi Wearable Unit** (with leg band and battery charger).

Table 2 Terms and Acronyms Used in this Guide (Continued)

Term/Acronym	Meaning
Revi Implant	The Revi Implant (or "Implant") is the implantable wireless neurostimulation component that is placed by your surgeon in the vicinity of your tibial neurovascular bundle. During the therapy session, the implant sends electrical pulses to the tibial nerve using energy received by the Revi Wearable unit.
Therapy Session	Therapy delivered by the Revi System for a duration of between half-an-hour and 2 hours, at the discretion of the clinician.
Wearable Unit	The external component of the Revi System, comprising a **Leg Band** holding the **Wearable device**, that provides power to the Revi Implant and enables control over the therapy session.

Introduction

This user manual contains important information regarding your Revi therapy and is designed to help you use and understand the operation of the Revi Wearable Unit for your optimal management of Therapy Sessions.

Important **Prior to using your Revi Wearable Unit for the first time, make sure you fully understand the training you have been given by the BlueWind Medical Representative and your clinician and the contents of this manual.**

Purpose of the Revi System (Indications)

The Revi System is intended for peripheral nerve stimulation.

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

When Should the Revi Wearable Unit Therapy Not be Used (Contraindications)?

The Revi Wearable Unit is contraindicated for the following patients:

- Cannot properly operate the Revi Wearable Unit, or do not have the necessary assistance, to operate the Revi Wearable Unit.
- Are implanted with any metallic implant within the immediate area (8 in/20 cm distance) of the intended site for the Revi implant implantation.
- Have nerve damage that could impact the therapy session.

Some medical treatments are contraindicated or need special consideration when you have the Revi implant implanted.

Refer to Medical Therapies/Procedures on page 16 for complete information.

Use in Specific Populations

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

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

Warnings

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

Driving/Operating Machinery

Do not operate automobiles, potentially-dangerous machinery or heavy equipment during the Stimulation Therapy Session.
If sudden Stimulation changes occur, they may distract you while operating the

vehicle or equipment.

Flammable Fuel, Chemicals, or Environmental Hazards

Do not commence or continue Stimulation Therapy Session while at a petrol-filling station, or in the presence of flammable fuel, fumes or chemicals (including when in an oxygen-rich environment). When the wearable unit is turned ON, or in use, it could potentially ignite the chemicals or fumes, causing severe burns, injury or death. When entering a flammable environment, turn the Revi wearable unit OFF.

Medical Therapies/Procedures

Some medical procedures could damage your Revi Implant and may cause you injury. Talk to your clinician about your Revi Implant before having any of the following medical conditions as these may affect your Revi Implant and should not be used in the implant area:

- Diathermic therapy (deep heating therapy)
- Electrosurgery (only bipolar cautery may be used)

- 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 (oxygen therapy)

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

Diathermy

Diathermy is a medical and surgical technique that involves the production of heat in a part of the body by high-frequency electric currents. Shortwave, microwave or therapeutic ultrasound diathermy should not be used on patients implanted with the Revi Implant as diathermy can transmit energy through the

implanted system, potentially causing tissue damage at the location of the implanted electrodes, resulting in severe injury.

Electromagnetic Interference

Energy from common household items and equipment found at home, work, or in public can potentially interfere with the Revi System. This is called electromagnetic interference (EMI).

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.

Magnetic Resonance Imaging (MRI)

The Revi Implant is an MR conditional device. It is not safe to have your area of implantation with the Revi Implant placed in an MRI machine. Please consult with your clinician so that they may refer to the Revi Surgical Technique Guide for more information.

You should present your Patient Identification Card to MRI staff prior to having an MRI.

The Revi system should not be activated during the MRI procedure.

The Revi Wearable Unit (and accessories) is MR Unsafe and should never enter an MRI room or facility. The Clinician Programmer (CP) is also MR Unsafe and should never enter an MRI room or facility. The Revi Implant has not been tested simultaneously with other devices in the MRI environment.

Active Implantable Devices

Do not wear or place the Revi Wearable Unit over implanted devices other than the Revi Implant. Other implanted devices such as pacemakers, cardioverter defibrillators, implanted drug pumps, etc., could be adversely affected.

The effect of active implantable devices on your Revi Implant and Therapy Session is unknown.

Consult your clinician if you need to be implanted with this kind of system.

Effects on Other Implantable Devices

The effect of the Revi System on the operation of other implanted devices, such as cardiac devices, 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

When you are in need of both a Revi System and an implanted cardiac device (for example, a pacemaker, defibrillator/cardioversion), interactions between the two devices should be discussed by the patients' physicians involved with both devices (such as the cardiologist, electrophysiologist, urologist, and urogynecologist) before surgery as these devices can

damage your Revi Implant. To reduce potential interference, the devices should be implanted on opposite sides of the body and as far away from each other as practical. 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.

If you do receive implantation of external defibrillation, your clinician should confirm that the Revi system is working as intended.

Precautions

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

Metal Objects and Implants

External and implanted metal objects can impact the communication between the Revi Wearable Unit and Implant when placed near the system. This may prevent or reduce the system's therapy session.

As a precaution, follow these guidelines:

- If you need a metal implant inserted in the vicinity of the Revi Implant, consult with your clinician regarding the impact.
- Keep metal items at least 8 in (20 cm) away from the Revi Wearable Unit while performing the Stimulation therapy session.

Strenuous Activities and Excessive Force

You 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 your Revi Implant: Running, Jogging, Road biking, Swimming.

SCUBA Diving or Hyperbaric Chamber

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

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.

Do not use the Revi Wearable Unit 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 you experience these symptoms near the Wearable Unit's placement site, contact your clinician before using the device.

Electromagnetic Interference

The Revi System has features to protect from electromagnetic interference (EMI) and most common household items and equipment you encounter on a daily basis are unlikely to affect your Revi therapy. However, EMI and/or radiofrequency from electrical devices may

disrupt the communication between the Revi Wearable Unit and the Implant in certain situations, causing the Stimulation to either stop or be uncomfortable.

Keep your distance from powerful electrical items to reduce the risk of potential problems. 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 stereo speakers.
- Short-wave or microwave therapy equipment.

Note: *For more details, refer to Electromagnetic Specifications on page 86.*

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 your Implant. Airport authorities advise patients to carry their Patient Identification Card with them when traveling.

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

Storage and Handling

Handle the Revi Wearable Unit with care. Dropping the device on hard surfaces, or other rough handling, can damage it. Please contact your clinician if you think your unit is not functioning properly to get it evaluated.

It is recommended to store your Revi Wearable Unit in a dry and room-temperature environment.

Avoid exposing the device to extreme temperatures or moisture. For example, do not leave the Revi Wearable Unit in your car or outdoors for extended periods of time.

Note: *See Table 13 on page 85 for recommended storage temperatures.*

Water Resistance

The Revi Wearable Unit is water resistant, but not waterproof. Do not use the device in or around water.
Using the wearable device while / after it has been immersed in water could damage the device.

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

Device Components

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

Your Revi Wearable Unit is intended to be used only by you. Use of components from other systems or modified components may damage the system or cause injury.

Service Life

The Revi Wearable Unit 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).

Nevertheless, stimulators can fail due to random component failure, or loss of battery functionality.

In any case where one of the system components is damaged or stops working, the component should not be used.

If the Revi Wearable Unit has been damaged or stops working, contact your clinician for evaluation and/or replacement.

If the Revi Implant reaches its end of life, contact your clinician.

Component Disposal

The Revi System must not be disposed of in municipal waste.

Contact your clinician or BlueWind Medical Ltd. (see back cover of this guide for contact details) for instructions on returning the unit to the manufacturer.

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

What is Revi Therapy?

Before deciding whether or not Revi therapy is appropriate for you, it is important to discuss and assess the benefits and risks with your clinician, in order to make an informed choice. The following information explains the benefits and risks and describes what to expect from the Revi System Therapy.

Revi Therapy Session

The Revi System is intended to provide neurostimulation (neuromodulation) therapy that can relieve symptoms of Overactive Bladder (OAB). The Revi system uses mild electrical pulses to stimulate the tibial nerve located in the lower leg.

Revi therapy does not provide a cure for your OAB condition. However, the therapy session is likely to reduce your symptoms to a tolerable, or even normal, level and allow you to resume many of your normal daily activities.

Surgery

The first step toward receiving the therapy session is a minor surgical procedure to place the miniature stimulator (Revi Implant) in your leg, near the tibial nerve. As with any surgical implantation, there are risks related to the surgery itself and almost all of them are expected to resolve 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 49).

For a small number of patients, the therapy session will not improve the symptoms (or more rarely, the device may fail). If you are among them, and you and your clinician decide 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 you can perform daily therapy session in the comfort of your own home, tailored to your individual needs.

Stimulation

For each Therapy 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. This will feel like a tingling sensation in the heel, sole and/or toes. These electrical pulses stimulate the nerve along your leg and reach the nerves in your pelvis that control the bladder, urinary sphincter and the pelvic floor. This Stimulation has the power to modulate (adjust) the function of nerves (therefore called Neuromodulation), calming the over-active bladder and relieving your symptoms.

Neuromodulation/Neurostimulation therapy has helped thousands of 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 49). The majority of events are resolved either on their own or by adjusting the Stimulation settings. Remember, you are in control of your own therapy session, you can adjust the Stimulation at any time.

Summary of Clinical Evaluation

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 (1) 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 principal safety endpoint for the study was to quantify the incidence of material surgical procedure and device-related adverse events from implantation to one (1) 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

Women aged 18 or greater (21 or greater in the U.S.) with a diagnosis of urge urinary incontinence (UUI) demonstrated on a 7-consecutive day voiding diary defined as a minimum of nine (9) leaking episodes associated with urgency, with at least one episode per day for 5 days. Individuals had to have a history of UUI diagnosis for more than or equal to 6 months with inadequate response to conservative treatments (i.e. dietary restriction, fluid restriction, bladder training, behavioral modification, pelvic muscle training, biofeedback, etc.) and pharmacologic treatment. If used, individuals were required to be on stable dose of antimuscarinics, beta-3 adrenergic agonists, tricyclic antidepressants, Selective Serotonin Reuptake Inhibitors (SSRI) and/or Serotonin-Norepinephrine Reuptake Inhibitors (SNRI) for at least 3 months prior to baseline and agree to remain on stable medication consumption until the 12-month follow-up visit. In

addition, individuals must have a positive tibial nerve motor or sensory response tested via physical/neurological examination and a leg circumference of no less than 20 cm and no more than 30 cm at the implantation site (i.e. 5cm above the medial malleolus).

Exclusion Criteria

Individuals were excluded if they had more than a minimal level of suspected stress urinary incontinence base on a 7-day voiding diary, medical history, or when stress incontinence scores in the MESA incontinence questionnaire were higher than the urgency incontinence score. Individuals with a diagnosis of interstitial cystitis or bladder pain syndrome and those with suspected urinary retention and/or post void residual (PVR) of >150ml were also excluded. Other exclusion criteria included those at high surgical risk, those on anticoagulation therapy that could not be temporarily stopped for the procedure, morbid obesity (>50 BMI), a metal or other implant within 20cm distance of the implant site, botulinum toxin injections within the past 12 months, neurostimulation in the last 3 months, failed previous neuromodulation therapy for overactive bladder, previous urinary incontinence surgery or prolapse surgery using graft material within the last 12 months, any spinal or genitourinary surgery within the last 6 months, previous abdominoperineal resection of the rectum or previous radical hysterectomy. Individuals with any neurological disease, neuropathy or injury resulting in neuropathy and/or suspected neurogenic bladder,

current or recurrent urinary tract infection (3 or more infections in the last 6 months), presence of urinary fistula, urinary tract obstruction such as cancer, urethral stricture or presence of urinary stone were also excluded. Other exclusions included history of chemotherapy or pelvic radiotherapy, diabetes with peripheral nerve neuropathy or severe uncontrolled diabetes (with HbA1C > 7%), pelvic organ prolapse to or beyond the hymen, documented history of allergic response to Platinum iridium, Titanium, Zirconia, Gold, Silicone or Parylene, other active implantable electronic devices and those who are breastfeeding.

Follow-Up Schedule & Subject Accounting

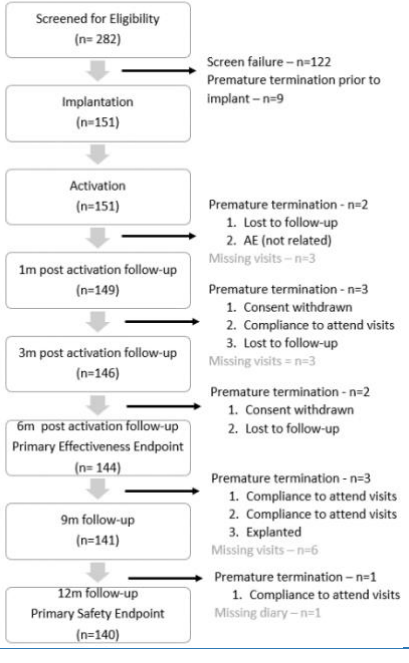
Subjects were seen at baseline, implantation procedure, device activation (which occurred 4 weeks ±2 weeks after implantation), and then at 1-month, 3-months, 6-months, and 12-months post activation. Adverse events and complications were recorded at all visits. A long-term follow-up extension is being 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 1 below.

Figure 1: 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, measured by 7-day Patient Voiding Diary.

Study Population Demographics and Baseline Parameters

One-hundred and fifty-one (151) female subjects of mean age of 58.8 years (SD: 12.5) and mean BMI of 30.2 (SD: 6.9) 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 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

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 5). 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). Only 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 4 Frequency Distribution 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 5 Frequency Distribution of Surgical Wound Related AEs

Surgical wound complication	Surgical wound infection	Wound dehiscence	Total
7 (4.6%)	2 (1.3%)	1 (0.7%)	10 (6.6%)

The additional surgical procedure related AEs (n=6) are specified in the table below (Table 6).

Table 6 Frequency Distribution of non-surgical wound, procedure related AEs

Numbness after surgery	Swollen foot	Pain	Erythroderma/ skin rash	Cellulitis	Allergic reaction to pre-operative meds	Total
1 (0.7%)	1 (0.7%)	1 (0.7%)	1 (0.7%)	1 (0.7%)	1 (0.7%)	6 (4.0%)

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.

Table 7 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

Secondary Effectiveness Endpoints

Clinical improvement was also demonstrated by a secondary endpoint demonstrating significant improvement in Health-Related Quality of Life (HRQL) with a response rate of 83.6% (CI: 76.7%-88.7%) at 6-months post activation. Another secondary endpoint was specified to address the broader spectrum of OAB symptoms, including frequency and urgency. This secondary endpoint also demonstrated statistically significant improvement in frequency and urgent episodes (PPIUS degree 3,4) with response rate of 74% (CI: 65%-81.3%) at 6-months post activation. 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 clinically meaningful response rate of 88% (CI: 81.6%-92.4%) at 12 months.

Table 8 Secondary Effectiveness Endpoint Analysis

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

Potential Adverse Events

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

Risks associated with the Revi Implant Procedure:

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

Risks associated with the use of the Revi Wearable Unit:

Anticipated adverse events involved with the stimulation include: undesirable changes in stimulation such as sensation of transient electric "shock"/sudden radiating sensation, sporadic sensory response, uncomfortable heating effects, discomfort, or burn.

Anticipated adverse events involved with the therapy session include: adverse changes in voiding/bowel function, transient nausea.

Anticipated adverse events involved with the device include: spontaneous sensory response (not in association with stimulation), implant migration or displacement, allergic reaction and

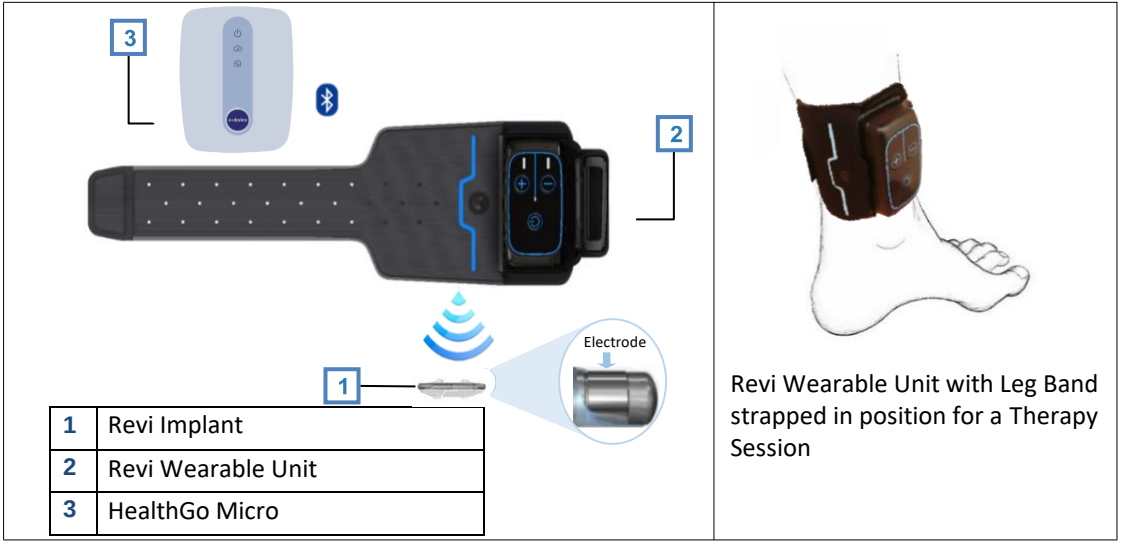
technical device problems.
Most adverse events resolve within a few days to a few weeks on their own or with medication.

Revi System

Revi System is a peripheral nerve stimulation system intended for home-care use. The system comprises the following components (illustrated in **Figure 2**):

- **Revi Implant** - a small neurostimulator device that generates mild electrical stimulation, similar to a pacemaker. The implant was placed within your lower leg by your surgeon, using a minimally-invasive surgical technique.
- **Revi Wearable Unit** - an external wearable device used to control therapy. This device acts like a wireless 'power supply' to your Revi Implant, enabling you to control and manage your therapy session by starting and stopping your therapy sessions, adjusting the strength of the Stimulation pulses, and maintaining a comfortable level of Stimulation.
- **HealthGo Micro (Hub)** – a hub for use at home, which transfers data from the Wearable Unit to the cloud for the purpose of remote support.

Note: *An additional component (a hand-held tablet device) will be used by the BlueWind Medical Representative during your clinic visits, to communicate with your Revi Wearable Unit via a wireless (Bluetooth) connection.*



1	Revi Implant
2	Revi Wearable Unit
3	HealthGo Micro

Revi Wearable Unit with Leg Band strapped in position for a Therapy Session

Figure 2 Revi System Components and Communication

Revi Wearable Unit

You will be provided with the Revi Wearable Unit which is supplied within its own carrying case, together with a Leg Band and a battery charger. Also included is this *Patient Therapy Guide* and a *Quick-Start Guide*. **Figure 3** shows the unit in the Leg Band ready for use and illustrates the controls and indicators.

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

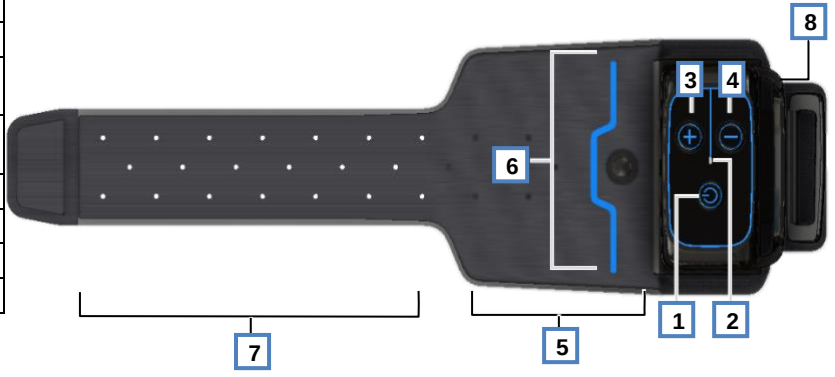


Figure 3 Revi Wearable Unit - Controls and Indicators

Your Revi Wearable Unit will be programmed so that it provides the therapy that is most suitable for you.

After programming your therapy session parameters, you will be trained to use your unit to perform your own Revi therapy sessions. You will be told about the precautions and warnings to be aware of. If you have any questions or problems with your wearable unit, ask your clinician for more training or information.

Important **If you have not received training, contact your clinician before using your Revi Wearable Unit for the first time.**

For easy reference, see these guidelines and recommendations for optimal use of the Revi system:

- Important to Know - Page 55
- Receiving Other Medical Treatment - Page 56
- Charging the Battery - Page 56
- Revi Therapy Session - Page 59
- Cleaning Instructions – Page 70

Important to Know

Important **In addition to observing the safety information provided in Warnings on page 17 and Precautions on page 23, it is important to know the following:**

- Keeping a voiding diary will help you track improvements in your symptoms over time.
- Adhering to the therapy session regimen prescribed by your clinician is very important. It will help you achieve the best results.
- A patient identification card was given to you by your clinician that contains basic information about you and your Revi System.
  You should carry the card with you at all times since this identifies you as a person with a Revi Implant and undergoing therapy session with the Revi system. If you lose your patient Identification card, please contact your clinician for a new card.

Receiving Other Medical Therapy or Treatment

In the event that you require any other type of medical examination, therapy, treatment, surgical operation, *etc*. it is important to notify your clinician or relevant medical professional that you are using the Revi system.

Make sure your attending medical professionals know that you are implanted with the Revi Implant and are aware of the associated warnings. See Medical Therapies/Procedures on page 18.

Charging the Battery

Your Revi Wearable Unit is powered by a rechargeable battery, sealed inside the Wearable unit.

The length of the battery power will depend on your Stimulation settings. Like any battery-powered device, the more it is used and the higher the settings, the faster the battery power becomes depleted. While recharging the battery could be required only once per week, or as often as once per day, it is recommended to charge the Wearable unit after each

therapy session, so it is ready for your next therapy session.

When the Revi Wearable Unit is connected to the battery charger, the LED light color and state (*blinking* or *steady*) indicates the current battery power status. See the illustration in **Figure 4**.

⚠ **CAUTION** **The battery inside the Revi Wearable Unit could become excessively hot during the battery-charging process.**
As a safety precaution, the Revi Wearable Unit is programmed to prevent you from starting Therapy Session, while the unit is connected to the battery charger.
As an additional precaution, follow these guidelines:

- Do not charge the battery while the Wearable Unit is on the leg.
- Use only the charger provided to you with the Revi system.
- During the battery-charging process, the charger may become warm - handle with care.

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

To Charge the Battery

1. Make sure the Revi Wearable Unit is turned Off. (If it is On, press and hold the power button to turn Off).
2. Connect the battery charger cable to the Revi Wearable Unit power input socket (see **Figure 3**, 8).
3. Plug the battery charger into a wall outlet.
   Battery charging starts.

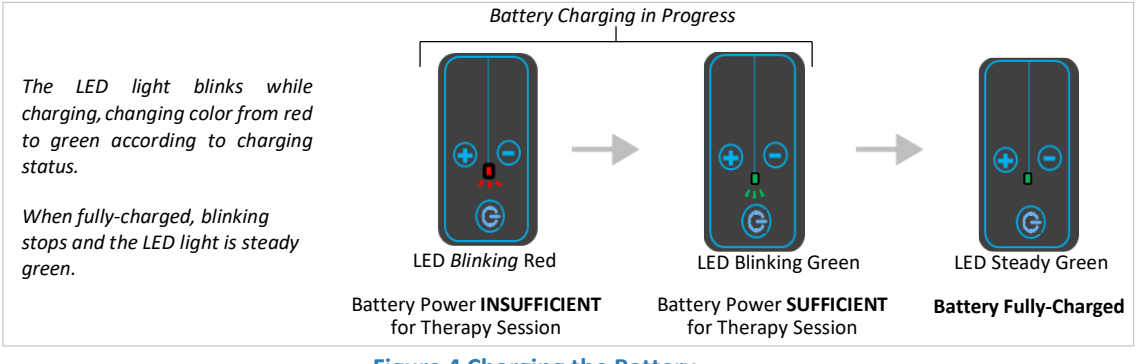


Figure 4 Charging the Battery

Revi Therapy Session - Before You Start

1. Make sure the Revi Wearable Unit is secured inside the Leg Band.
2. Press the Power button to turn the unit On.

The unit is ready for positioning when the LED blinks orange

Proceed to Positioning the Revi Wearable Unit.

Note: *It will not be possible to initiate a Therapy Session if the battery is not sufficiently charged to complete an entire session.*

If the battery does not have enough charge, when you turn the unit on, you will hear a sound, the LED will light up red, and then the unit will turn off.

Recharge the battery - see Charging the Battery *on page 56*.

Note: *If the wearable unit does not turn on, connect it to the wall outlet using the charger. You will either:*

See the LED blinking red - the wearable needs to be charged, OR:

See the LED blinking green and hear three beeps - you may continue by disconnecting from charger and pressing the Power button again.

Note: *While the unit is connected to the charger, the unit will not respond to Power button press.*

Positioning the Revi Wearable Unit

The strength of the signal between the Revi Wearable Unit and the Revi Implant is indicated via blinking of the LED (**Figure 5**, **1**) and audible sounds. This corresponds to the accuracy of the unit's position.

As the unit locates the Implant, you will hear a beeping sound.
The LED blinks orange.

Indicators for Correct Positioning:

Indicators for better positioning are:

- Faster beeping sound
- Faster LED blinking

The indicators mark good positioning over a range of locations. The best positioning is achieved in the highest point of this range.

❖ Positioning the Revi Wearable Unit for Therapy

1. The Wearable unit box (**Figure 5**, 4) should be at the front of the leg and the rest of the Wearable Unit should be on inner part of the leg.
2. Pass the strap through the loop without tightening.
3. Align the antenna marking (**Figure 5**, 3) of the Wearable with the scar.

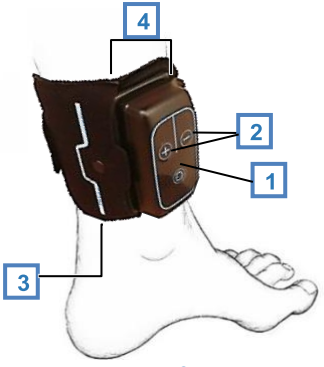


Figure 5 Positioned for Therapy

Position of Wearable Unit shown on the LEFT leg. For the RIGHT leg, Power button (1) will be at the top.

4. Adjust the height according to the beeping and flashing frequency – Place the Wearable as high as possible on the leg while maintaining the fastest possible beeping and flashing frequency. To do this, raise the Wearable slowly until you hear the signal slowing down, then bring it back down slightly to the last point (-highest point) with fast signals.
5. Tighten the strap to a secure, yet comfortable, level.

✓ *You are now ready to start a Revi Therapy Session.*

Note: *If you do not start the Therapy Session within 5 minutes of positioning, the Revi Wearable Unit will turn Off automatically.*

Starting a Therapy Session

❖ **To Start a Therapy Session**

1. Make sure the Revi Wearable Unit is correctly positioned, as described previously.
2. Press the Power button once - just a short press - to start Therapy Session.

You will hear a sound; the LED will blink green.
The unit will slowly ramp up the Stimulation level that you set during the previous Session (or for the first Therapy Session, to the customized level set by the BlueWind Medical Representative and your clinician).

Note: *During this stage, you may start sensing the Stimulation in your leg, as a tingling sensation in the bottom of your foot and/or toes. This is normal.*

Once the unit reaches the Stimulation level, the blinking stops and the LED shows a steady green light.
This indicates the desired level has now been reached.

3. If necessary, you may adjust the Stimulations to make them stronger or weaker (using the **+** or **-** buttons as shown below), until a strong, yet comfortable, level is reached.

INCREASING the Stimulation Level

To ***INCREASE*** Stimulation by one level:

Press this button once.

You will hear a beep; the green LED will blink for a few seconds (to indicate ramp-up of the Stimulation level), then will show a steady green light. Steady green indicates the increased level has been reached.

To further ***INCREASE*** Stimulation:

Wait until ramp-up is complete, then press this button again for as many times as necessary until you reach the required stronger Stimulation level.

At each button press, you will hear a sound; the green LED will blink for a few seconds (to indicate ramp-up of the Stimulation level), then will show steady green. This indicates the level has been increased.

DECREASING the Stimulation Level

To ***DECREASE*** Stimulation by one level:

Press this button once.

You will hear a beep; LED will blink once, and then will remain steady green.

To further ***DECREASE*** Stimulation:

Press this button again for as many times as necessary until you reach the intended weaker Stimulation level.

At each button press, you will hear a beep; the LED will remain steady green.

Note: *If you are trying to INCREASE or DECREASE the Stimulation level when the maximal (or minimal) level has already been reached: The unit will indicate that this is not possible by sounding three consecutive beeps.*

What Should I do if Stimulation Turns On and Off at Regular Intervals?

Your Revi Therapy Session may have been programmed so that Stimulation is turned On and Off at regular intervals.

During the Off phase, the green LED will blink slowly.

If you are not sensing Stimulation and are not sure if the Therapy Session is ongoing, check if the LED is blinking. If the LED is Off, then the Therapy Session has ended.

What Should I do if the Unit Loses Communication with the Implant?

In some cases, the Revi Wearable Unit may move out of position and lose communication with the Implant. For example, when the unit is not securely fastened around your leg or when it is accidentally bumped into another object.

If this occurs during a Therapy Session, the unit will sound an alert and the LED will blink orange.

Proceed as follows:

1. Loosen the strap on the Leg Band.
2. Move the Revi Wearable Unit over the Implant area until optimal positioning is reached, indicated by rapid blinking and beeping.
3. Refasten the strap, then press the Power button once – just a short press - to restart your Therapy Session.

Note: *The Therapy Session will automatically restart from the point at which it previously stopped.*

Ending a Therapy Session

The Revi system continues Therapy for the duration set. Once the Session ends, the unit will turn Off automatically.

The LED light will be a steady red for a few seconds.
A sound will indicate the Therapy Session has ended.

Important **When the session has ended, unfasten the Leg Band and remove from your leg. Store the Revi Wearable Unit in the carrying case.**

Can I End a Session Before Therapy is Completed?

Yes. Your clinician defines the duration of the Therapy Session — however, if you find it **necessary**, you can end the session before Therapy completion:

Press and hold the Power button until the Revi Wearable Unit indicates it is shutting down.

The LED light will be a steady red for a few seconds.
A sound will indicate the Therapy Session has ended.

Can I Simply Remove the Unit to Stop a Therapy Session?

Yes. You can unfasten the Leg Band and remove the Revi Wearable Unit from your leg, without pressing the Power button.

As you move the unit away from your leg, the Implant will no longer receive energy from the Wearable Unit and you will no longer receive Stimulation pulses.

Therapy Programs

Your clinician will decide to provide you with either one or two Therapy programs. If your Wearable Unit was set up with two Therapy programs, a BlueWind Medical Representative will guide you through the process of changing it if and when a program change is required.

Important **Do not attempt to change the therapy program on your own.**

⚠ **CAUTION** **For the purpose of therapy program change, use only the charger provided to you with the Revi System.**

Cleaning Instructions

The Revi Wearable Unit is provided Non-Sterile and not to be sterilized.

Cleaning the Leg Band

Hand wash the leg band approximately every 4 weeks according to the following instructions:

1. Remove the Revi Wearable Device from the Leg Band.
2. Fill a sink or a bowl with lukewarm water at a temperature of 95°F ± 41°F (35°C ± 5°C).
3. Add 2 teaspoons of mild liquid hand-washing detergent based on the ionic properties of anionic, sodium sulfate.
4. Submerge the Leg Band in the soapy water and soak for 15 minutes. With the hands, work the suds into the leg band.
5. Use gentle movements to swish the Leg Band through the sudsy water. Avoid

scrubbing or twisting which can stretch or damage the fabric.

6. Remove the Leg Band from the water.
7. Hold the leg band under a faucet and let lukewarm water run over it, rinsing out any soapy water. Be sure to rinse until the leg band no longer releases any suds.
8. Lay the leg band flat on a towel and lay another towel over top and press to remove water.
9. Hang the leg band to dry at room temperature – do not tumble-dry or use heat.

Cleaning the Revi Wearable Unit

If cleaning of the Revi Wearable Unit is required, follow the recommendations of the manufacturer outlined below.

CAUTION

Do not immerse the unit 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!

- Ensure the unit is turned Off and the battery charger is disconnected.
- Clean the unit's surfaces using a damp wipe, moistened with water or alcohol.
- Dry with a soft, clean cloth.

Travel and International Use

Important **When traveling, it is important to continue adhering to your Revi Therapy regimen. You should carry your Patient Identification Card when traveling.**

⚠ **CAUTION** **It is possible that airport security devices may affect the communication between your Revi Wearable Unit and your Revi Implant.**
For more details, refer to the precautions provided in Theft Detectors and Security Screeners on page 26.

⚠ **CAUTION** **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.**
In addition, the 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, avoid performing a Therapy Session during flight.

Note: *You may need a power adapter when using the battery charger in different countries.*

Troubleshooting Guide

General Guidelines and Recommendations

Table 9 provides a troubleshooting guide to assist you with difficulties when using the Revi Wearable Unit.

> ***Note:*** *If any problem remains unresolved, contact your clinician so that your Revi system can be evaluated.*

Who to contact for help?

Please contact your clinician if you have questions about your health or the Revi Wearable Unit.

Revi Wearable Unit Support:

For questions regarding the Revi Wearable Unit, additional information, and product manuals, visit our website or contact your clinician.

Table 9 Troubleshooting Guide

Situation	Possible Cause	Recommended Action
The Revi Wearable Unit 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 unit until the LED light turns GREEN.
	Daily Therapy was completed. (The unit has already been activated for the maximum activation time for today).	Wait until tomorrow, then try again.
	The device is connected to the battery charger.	Disconnect the device from the battery charger, then start again.
The Revi Wearable Unit does not turn Off.	Power button was not pressed long enough.	Press and hold the Power button for at least 5 seconds.

Table 9 Troubleshooting Guide (Continued)

Situation	Possible Cause	Recommended Action
Cannot find the correct Position for the Revi Wearable Unit. (Positioning beeps are not sounding; the LED indicator is YELLOW and blinking slowly).	The unit is not positioned in the correct location.	Make sure the unit is placed as shown in Figure 4 on page 61.
		Move the unit 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 the side of your leg to the front of your leg.
	A metal object, or something causing electromagnetic interference is located close to the Revi Wearable Unit. Refer to Electromagnetic Interference on page 23 and Metal Objects and Implants on page 21.	Move the object away from the unit (alternatively, move your leg away from the source of interference).

Table 9 Troubleshooting Guide (Continued)

Situation	Possible Cause	Recommended Action
Cannot find the correct Position for the Revi Wearable Unit. (Positioning beeps are not sounding; the LED indicator is not illuminated).	The Wearable Device is turned Off.	Press the Power button once (short press). The LED light will turn ORANGE. Sound and LED will indicate positioning
Beeping sound audible in the middle of Therapy.	Device moved out of position.	Re-position the device, then press the Power button once (short press).
	Electromagnetic interference or metal object near the Wearable Unit.	Move away from the interference, or move the object away from unit.
The Revi Wearable Unit feels excessively hot.	Technical problem.	Make sure you are not wearing the unit while charging the battery.
		Contact your clinician for technical support.

Table 9 Troubleshooting Guide (Continued)

Situation	Possible Cause	Recommended Action
Stimulation sensation is lower than usual.	The unit is not in the correct location.	Follow the positioning instructions on page 61.
		Choose the most optimal position achievable, then start the Therapy Session.
	Maximum Therapy Session level has not been reached.	Press the '+' button to increase Stimulation level.
	Your unit may need reprogramming with new parameters.	Contact your clinician for a new Therapy setup.

Table 9 Troubleshooting Guide (Continued)

Situation	Possible Cause	Recommended Action
Revi Wearable Unit does not respond when pressing the + or - buttons.	Maximal / Minimal level has been reached (indicated by three consecutive short beeps).	You may need to contact your clinician for a new Therapy setup.
	For patients for whom Stimulation parameters have been programmed to have *On-Off* cycles: The + or - button has been pressed during time the unit was in the *Off* phase.	Press the + or - button only during time the unit is in the *On* phase.
	The + button has been pressed during the ramp-up stage (LED blinking GREEN).	Wait for the ramp-up stage to complete, then press the + button (LED light is steady GREEN).

Table 9 Troubleshooting Guide (Continued)

Situation	Possible Cause	Recommended Action
Revi Wearable Unit does not start or continue requested action (the LED light is RED).	Any system error.	Retry performing the requested action.
Feel a change in stimulation when standing up, walking, or changing positions.	Moving the body can affect how the stimulation feels, even though the stimulation level does not change.	Contact your clinician if the stimulation feels unpleasant while sitting. The stimulation may need to be adjusted.

Note: *Your clinician is your primary source for all questions and requests regarding your Revi System. As an additional resource, you may contact the manufacturer, BlueWind Medical Ltd. - see the back cover of this guide for details.*

System Specifications and Technical Data

System Specifications - Technical Information

Stimulation Parameters

Table 10 Revi System Specifications - Stimulation Parameters

Parameter	Details
Essential performance	System shall generate the essential stimulation parameters below within the allowed accuracy limits
Stimulation Waveform	Biphasic charge - neutral
Pulse Repetition Frequency	Up to 30 Hz
Pulse Amplitude	Up to 14 mA
Pulse Width	Up to 790 µSec
Essential performance Accuracy Limits	Pulse Amplitude: ±20% or ±0.15mA (whichever is greater) Pulse Width Accuracy: ±10% Pulse Frequency: ±10%

Technical Data

Table 11 Technical Data - Revi Implant

Parameter	Details
Revi Implant capsule Dimensions [L], [Diameter]	1.2 x 0.11 in
	3 x 0.27 cm
Revi Implant with silicone Dimensions [L], [W], [H]	1.2 x 0.51 x 0.14 in
	3 x 1.3 x 0.35 cm
Revi Implant - Weight	0.03 oz (0.9 g)
Material	Zirconia ceramic, titanium and gold capsule, coated with Parylene; platinum-iridium electrodes, and silicone suture wings.

Table 12 Technical Data - Revi Wearable Unit

Parameter	Details
Revi Wearable Device Dimensions [L], [W], [H]	5.5 [L] x 3.8 [W] x 1.4 [H] in
	14 [L] x 9.6 [W] x 3.4 [H] cm
Revi Wearable Unit – Device with Leg Band Dimensions [L], [W], [H]	15.7 [L] x 4.5 [W] x 1.6[H] in
	40 [L] x 11.3 [W] x 4 [H] cm
Revi Wearable Device - Weight	5.8oz (165 g)
Revi Wearable Unit – Device with Leg Band - Weight	7.8 oz (220 g)
Leg Band material	Lycra+ Polyester+ Microfabric +Silicon
Logging Capacity	365 Therapy days

Table 12 Technical Data - Revi Wearable Unit (Continued)

Parameter	Details
Revi Wearable Device - Battery	Li-ion Rechargeable, 1400mAh
	Battery operational voltage: 3.1 - 4.2 V. Battery charging: up to 1 week of Therapy on a single charge. It is recommended to charge the Wearable unit after each therapy.
Battery Maintenance Time	1 year
Battery Charger	Manufacturer: FRIWO Gerätebau GmbH (Ostbevern, Germany) Model number: FW8002.1MUSB/05 Power rating: 6W

Environmental Specifications

The table below details the recommended environmental conditions required for the Revi Wearable Unit.

Table 13 Environmental Conditions Required

System Component	Condition	Ambient Temperature	Relative Humidity (non-condensing)	Pressure (kPa)
Revi Wearable Unit	**Operation**	60 — 90°F	≤ 85%	70 - 106
		10 — 32°C		
	Transport/Storage	14 — 131°F		
		-10 —55°C		

Electromagnetic Specifications

Table 14 Revi System 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.

Table 14 Revi System Electromagnetic Specifications (Continued)

Parameter	Specifications
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 OAB symptoms. **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.

Table 14 Revi System Electromagnetic Specifications (Continued)

Parameter	Specifications
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.

Table 15 Revi Bluetooth Low Energy Specification (Continued)

Parameter	Specification
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 4) 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

Test	Standard	Compliance level
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

HealthGo Micro Hub

You will be provided with a HealthGo Micro Hub to use at home and transfer data on a weekly basis. The HealthGo Micro is intended as an adjunct to the Revi System for the remote download of the Wearable Unit log data for the purpose of remote support.

What you need to do:

Simply plug the Hub into a power outlet in the same room in which you usually charge the Revi Wearable Unit (ideally close to a window or a door for better communication) and leave it plugged in. While the Wearable Unit charges, the Hub will automatically download the log data, without any action required from you.

Please refer to your HealthGo Micro Hub User Manual for specifications, operating and troubleshooting instructions, warnings, precautions, FCC and other compliance notifications.

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Trademarks

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Patient Therapy Guide

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