Clinician Programmer

User Manual

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

BlueWind MEDICAL

Preface

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 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.

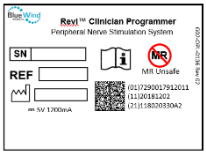


Figure 1 Revi Clinician Programmer - Label Location

Revi Wearable Device

The Revi Wearable Device has a safety compliance label affixed to the rear of the device (visible when the unit is removed from the Leg Band). See Table 1, for an explanation of the relevant symbols.

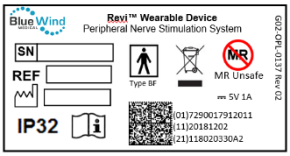


Figure 2 Revi Wearable Device - Label Location

Revi Implant

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

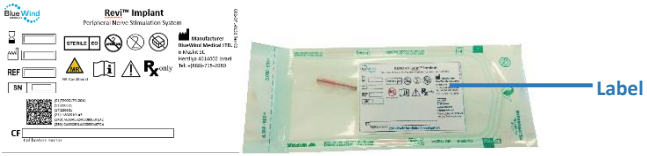


Figure 3 Revi Implant - Label Location

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)
REF	Catalog Number		Manufacturer
	Consult Instructions for Use		Dispose of properly after use
Rx Only	Prescription device		Type BF Applied Part
	Use by		Do not use if package is damaged
	Caution		Do not resterilize
CF	Calibration Factor	IP32	Ingress Protection
	Sterilized by Ethylene Oxide		MR Conditional
	Do not reuse		MR Unsafe
	USA Federal Communications Commission compliance		

Clinician Kit - Contents

The Revi Clinician Kit is supplied in a handy carrying case. Before use, check that it contains the items listed below:

- Clinician Programmer Tablet (with charger).
- Revi Wearable Device (with charger). See note below.
- Revi Clinician Programmer User Manual (this document).
- Revi Surgical Technique Guide.

Note: *The Revi Wearable Device supplied in this Kit is for use during surgical implantation of the Revi Implant and labeled accordingly. However, for treatment setup and during follow-up visits, the user uses the patient's individual Revi Wearable Unit (complete with Leg Band).*

Table of Contents

Glossary

Terms and Acronyms

Table 2 Terms and Acronyms Used in this Manual

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 electric current - applied locally with a metal instrument or needle - used for cutting or destroying tissue.
Revi Clinician Programmer (CP)	Tablet device running proprietary Clinician Programmer software. The CP is the Revi system's interface for treatment control, status evaluation, parameter programming and data acquisition.
Revi Implant	A battery-less, lead-less, miniature neurostimulator powered and controlled by the Revi Wearable Unit and/or Revi Wearable Device - see below.
Revi system	Peripheral nerve stimulation device intended for home use. The system comprises the **Revi Implant**, the **Revi Wearable Unit** (with battery charger) and the **Revi Clinician Programmer** (with battery charger).

Term/Acronym	Meaning
Revi Wearable Device	The external component of the Revi system that provides power to the Revi Implant and enables control over the Stimulation. The Wearable Device is used in this form (i.e., without the Leg Band) during implantation.
Revi Wearable Unit	Comprises the Revi Wearable Device and an adjustable Leg Band to hold the Wearable Device in place for the duration of treatment. The Wearable Device is used in this form (i.e., with the Leg Band) during treatment.
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 between half-an-hour and 2 hours, at the discretion of the clinician.
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 an overview of the Revi peripheral nerve stimulation therapy, together with explanations of the Revi system components, clinical considerations, warnings and precautions.

Also included are detailed instructions for operation and use of the Revi Clinician Programmer — a hand-held tablet device used during the implantation and to program the required stimulation parameters for a patient's Treatment Sessions and for follow-up and monitoring of compliance with the Revi Therapy.

The information in this manual is applicable to the Revi Clinician Programmer running software version 10.1.2, or higher.

Note: *For detailed information regarding the Revi Implant, together with general surgical guidelines for implantation, refer to the Revi Surgical Technique Guide.*

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 System.
- Are men who have Benign Prostatic Hyperplasia (BPH) or other lower urinary tract obstructions.
- Are implanted with any metallic implant, other than a BlueWind Implant, in the immediate area (8in/20cm 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. 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 known allergies to one of the implant materials (see implant specifications in Table 4 on page 72).

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.).

Summary of Clinical Evaluation

BlueWind Medical performed two clinical studies. The first study was the pilot trial which included both 6-months as well as long term (36-months) follow-up of 36 subjects to evaluate preliminary safety and effectiveness profile of the Revi System. The second study was the pivotal study, designed 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 included 6-months and 12-months follow-up. Full summaries of the clinical studies can be found in the Revi Surgical Technique Guide.

Safety Information

Prior to using the Revi system, the user should read and understand all instructions provided.

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 and instructions for the patient are also provided in the Revi Patient Therapy Guide. This is packed inside the Patient Kit containing the Revi Wearable Unit.*

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

Warnings

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

User Training

Users should be trained on use of the Revi System before performing Treatment Setup.

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 Unit 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 has not been verified with any other medical therapy / procedure and thus should be removed prior to any medical 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/precautions 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
- Exposure of the Wearable Unit to such devices and objects, may cause problems.

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

⚠ CAUTION

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.

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 Unit 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 Unit 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.

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.

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.

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 75.*

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.

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 Unit - 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.
- Avoid exposing the Revi System components to extreme temperatures, moisture or pressure. For recommended operating, storage and transportation conditions, see Environmental Specifications on page 74.
- 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 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 tablet 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 any 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 stimulator site, ankle discomfort, implant site infection, skin irritation, 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 change in voiding/bowel function, transient nausea.

Anticipated adverse events involved with the device include but are not limited to: spontaneous sensory response (not in association with stimulation), 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.

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 user 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, returning to the clinician periodically for follow-up visits.

The Revi System comprises the following:

- One implantable component - the Revi Implant
- Three 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 4 Revi System

Revi Implant

The Revi Implant provides the 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 5) through which the 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.

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

Figure 5 Revi Implant

Note: *For technical information, refer to System Specifications on page 72.*

Revi Wearable Unit

The Revi Wearable Unit comprises a Wearable Device and a Leg Band.

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

The Wearable Unit is designed for two purposes:

- **Use by the Surgeon** — for verifying the Implant's functionality and correct placement relative to the nerve during the implant procedure.

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

- **Use by the Patient** — for delivering routine treatments.

Wearable Device

The Wearable Device contains an electrical circuit board (which includes the user controls and indicators), 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 (30 mm).

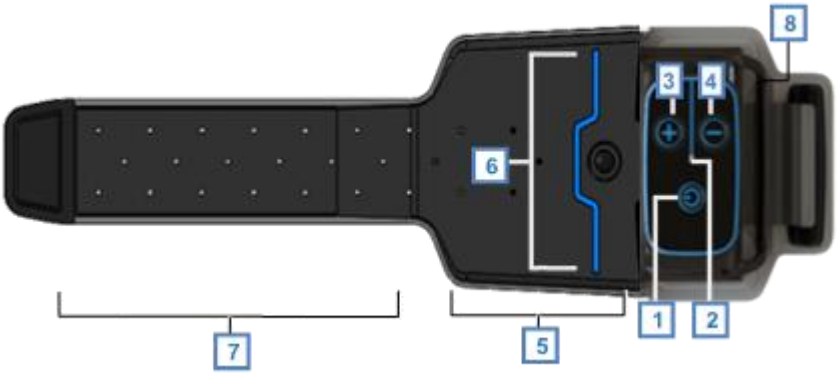


Figure 6 Revi Wearable Unit - Controls and Indicators

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 Revi 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.

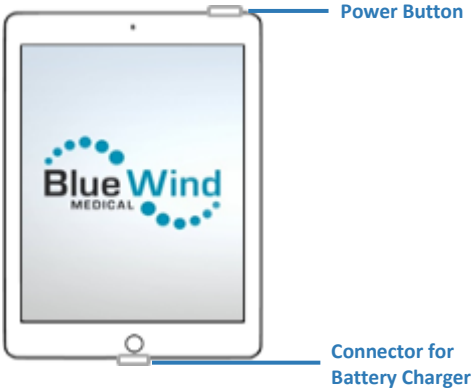


Figure 7 Revi Clinician Programmer (CP)

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

The Clinician Programmer, which is capable of transferring data to and from the Wearable Unit via a wireless connection, is designed for two purposes:

- **During the surgical procedure:**

  The CP monitors the Stimulation initiated by the surgeon to verify the Implant position.

- **During patient visits:**

  The CP is used for optimization of therapy for each patient by enabling the user to set 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 Implantation Procedure

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 Implantation Screens on page 26.

Revi First-Time Treatment Setup

The Clinician Programmer tablet provides a convenient workflow for the BlueWind Medical Representative, under the supervision of the treating clinician, for programming the Stimulation parameters of the Revi System for optimized therapeutic outcome for each patient.

For detailed instructions on first-time Treatment Setup of customized treatment parameters, see First-Time Treatment Setup on page 39.

Patient Training on Use of the Revi Wearable Unit

During the first-time Treatment Setup visit, the user will instruct the patient on the treatment guidelines and train the patient on how to operate the Wearable Unit for self-treatment sessions at home.

Refer to Patient Training on Use of the Wearable Unit on page 53.

Using the Treatment Monitor

The Clinician Programmer Treatment Monitor is a feature that enables the user to monitor a Treatment Session while the patient is receiving a Treatment, allowing the clinician to analyze potential problems.

For details, refer to Using the Treatment Monitor on page 54.

Instructions to the Patient After First-Time Treatment Setup

After the user has programmed the customized Stimulation parameters and trained the patient on how to operate their Revi Wearable Unit, the patient will receive additional information that is important to know before commencing therapy sessions at home.

Refer to the details provided in Instructions to the Patient After First-Time Treatment Setup on page 55.

End Session

On completion of the First-Time Treatment Setup procedure, the user is required to end the session for that patient. This ends the setup process and returns the CP display to the Treatment Management

Patient List screen.

Refer to the details provided in End Session on page 56.

Follow-up Visits

The BlueWind Medical Representative, under the supervision of the treating clinician, will conduct follow-up sessions to monitor patient compliance with the treatment schedule and evaluate treatment efficacy. In these sessions, the Clinician Programmer will be used as necessary to make any required adjustments to the treatment parameters.

Additionally, use of the Revi Reports feature enables the clinician to review the patient's treatment session history over a period of time.

Note: *During use, the Revi Wearable Unit records log files. As soon as the Wearable Unit and Clinician Programmer are paired, these files are automatically transferred to the CP. The user can view this data through the Reports.*

For full details, see Follow-up Visits on page 58.

Revi Clinician Programmer

Introduction to the Clinician Programmer

Important The Clinician Programmer tablet and its embedded proprietary BlueWind Medical software are intended for exclusive use with the Revi System.

Since the Clinician Programmer is designed for use in two different environments, the screens and controls are organized accordingly under two main modules - both accessible from the Home screen:

- **Implantation**
- **Treatment Management**

Information regarding the Settings and Instructions screens is included.

For easy reference, the following topics serve as an introduction to the Clinician Programmer:

Power ON and System Login on page 25
Home Screen on page 39
Implantation Screens on page 26
Treatment Management Screens on page 26
Patient List on page 27
Settings Screen on page 29
Logout Screen on page 29

Power ON and System Login

To Power On and Perform System Login

1. Press the Power On/Off button (top *right* corner; see Figure 7 on page 20).

   The tablet computer starts up; after a few seconds the Login Screen is displayed.

2. Tap the Login field, then use the virtual keyboard to type your Login Password:

Note: *Use the Login Password provided to you by BlueWind Medical Ltd. The field is case sensitive. Entering an incorrect password will trigger the display of a message prompting for the correct Login Password.*

⚠ CAUTION Repeated attempts to login using an incorrect Password will result in the Login screen becoming locked for several minutes.

3. Tap the Enter button.

   This will open the Home Screen Options (Figure 8).

Home Screen

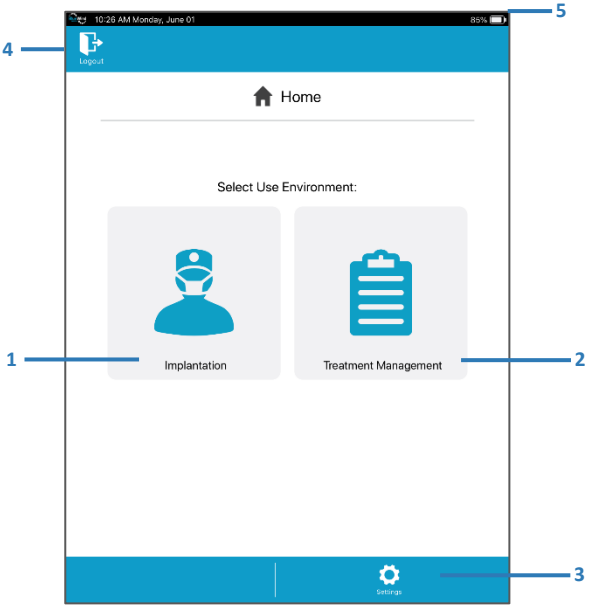


Figure 8 Home Screen

Legend

1	Access the Implantation module.
2	Access the Treatment Management module. See Treatment Management Screens on page 26.
3	Settings tab. Enables the user to change certain system settings. See explanations in Settings Screen on page 29.
4	Logout button; used to access the Logout dialog box (see Figure 12 on page 29) to perform system logout.
5	Battery status indicator

Implantation Screens

The Clinician Programmer Implantation module provides an interface for performing tasks related to the implantation procedure.

Treatment Management Screens

The Clinician Programmer Treatment Management module provides a convenient interface for performing treatment management tasks accessible from individual tabs at the bottom of the CP screen, as outlined below.

Note: *After entering the Treatment Management module, these four tabs are displayed continually at the bottom of each screen.*

Figure 9 Accessing Treatment Management Functions

Legend

Tab	Description
	Used to access the Patient List and manage Patient information. This includes adding or editing Patient information; assigning a Wearable Unit to a Patient; adding or replacing a Wearable Unit. See Patient List on page 27.
	Used to access the Treatment Management module. Allows the user to: configure Stimulation parameters (New Treatment Setup); view and

	adjust existing Stimulation parameters; view the Treatment Monitor during a Treatment Session.
	Used to view Revi Wearable Unit usage and monitor patient compliance with the treatment. See Viewing Reports on page 58.
	Used to End a Treatment Management session; returns to the Patient List.

Patient List

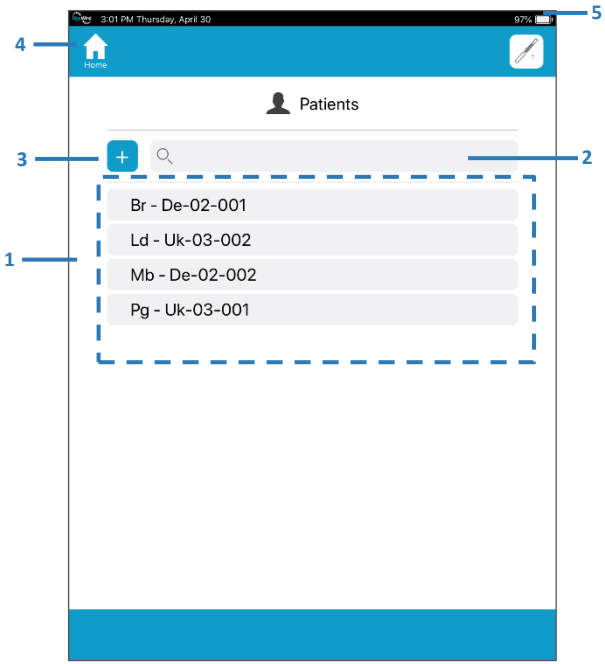


Figure 10 Treatment Management - Patient List

Legend

1	Patient List
2	Search Patient List - used to apply a filter to the search.
3	Add a New Patient to the List.
4	Home button; used to access the Home Screen.
5	CP Battery status indicator

Tapping a listed patient name expands the view, showing details of that specific Patient File (Figure 11).

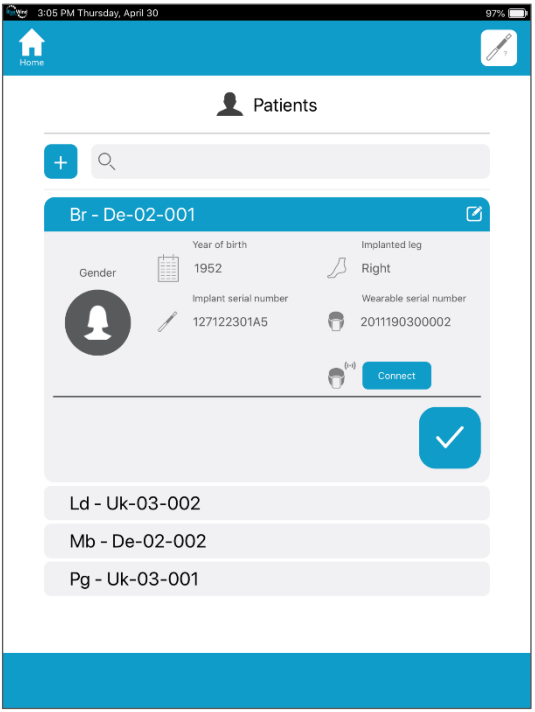


Figure 11 Patient File Currently Selected

Tasks that can be performed from a selected Patient File include:

Establishing communication between a patient's Revi Wearable Unit and the Clinician Programmer.

Refer to Pairing the Wearable Unit to the Clinician Programmer on page 41.

Accessing the Edit Patient functions – tap 

button.

From the Edit Patient dialog box, the user can:

- Edit patient details
- Enter a Wearable Unit serial number
  See Assigning a New Wearable Unit to the Patient on page 39.
- Replace a Wearable Unit, or Implant (if required)

Settings Screen

From the Home Screen, tapping the Settings tab at the bottom of the screen provides access to the Settings Screen. Here the user is able to view the currently defined CP settings (such as *language*, *manufacturer information*, *etc*.).

Logout Screen

The Logout screen is accessed from the Clinician Programmer Home Screen by tapping the Logout button (top *left* of the screen). This evokes the display of the Logout Screen, shown below.

Figure 12 Logout Screen

Note: *Only the Home Screen provides access to the Logout Screen. To perform Logout from the Treatment Management module, it is necessary to first End the Session. This will return the user to the Patient List display, from where use of the Home button* 

(top left) will enter the Home Screen.

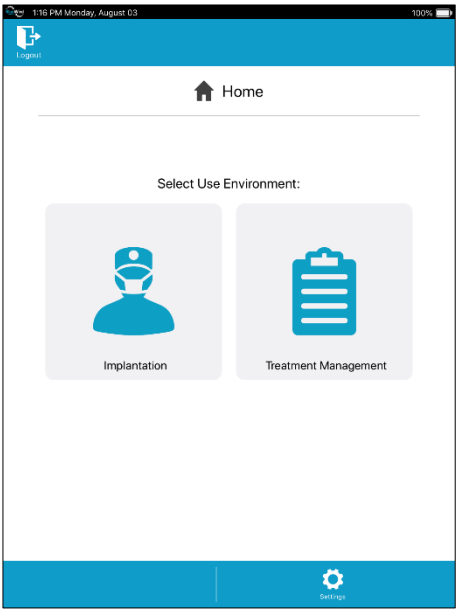
The CP is programmed with an *auto-logout-after-timeout* function. Therefore, in the event that the CP has been idle for a specific period of time, a message pop-up opens automatically providing the user with the option to cancel the Automatic Logout, if required.

Implantation with the Clinician Programmer

Procedure Preparation

Prior to surgery, prepare the Revi System by initiating an implantation session on the CP and verifying that the System is operable with the below listed steps:

1. Type your password and tap Enter.
2. Enter Implantation Mode.

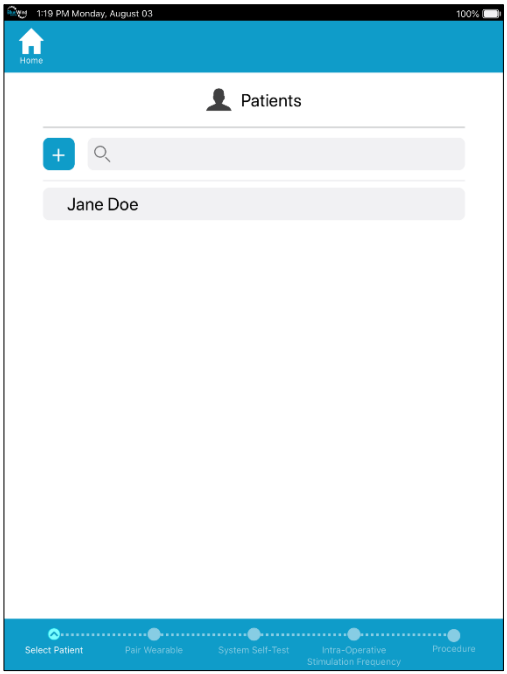


3. To select a patient that is already in the system tap the patient's ID and then "✓";

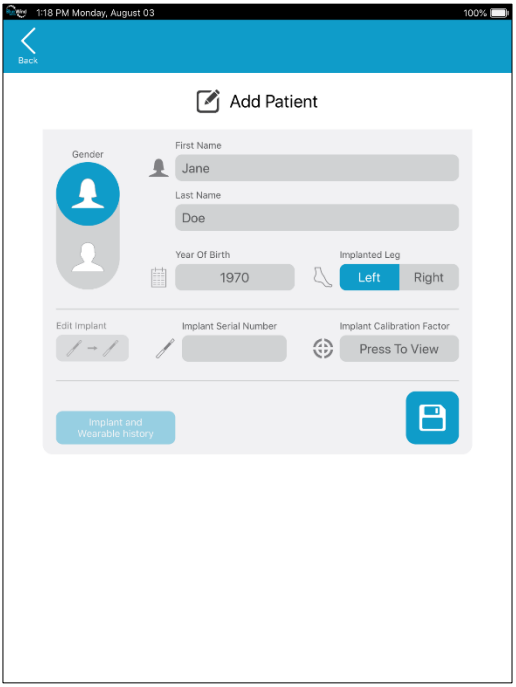
   OR

   To add a new patient:

   a. Tap the + button.

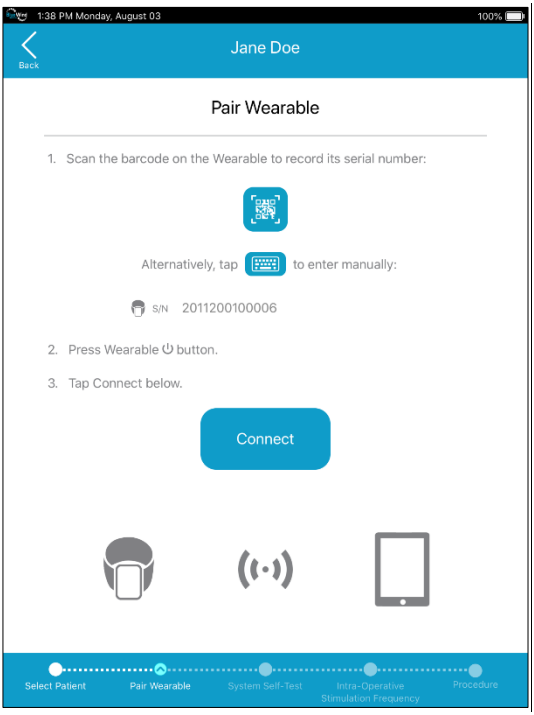

1:19 PM Monday, August 03
100%
Home
Patients
Jane Doe
Select Patient
Pair Wearable
System Self-Test
Intra-Operative Stimulation Frequency
Procedure

b. Enter all required data:



c. Tap “Save” 

4. Pairing Wearable Device to the CP: The next screen will guide you through the pairing of the Wearable Device to the CP.

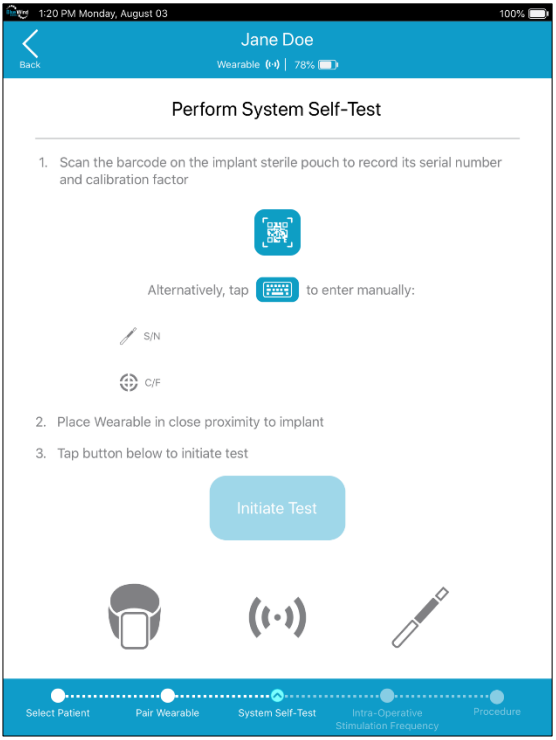


5. Scan the barcode of the Wearable Device to record the serial number (located on the label on the back side of the device).
6. Press the button on the Wearable Device to turn it on.

Note: *If the device does not turn on, connect it to the wall outlet using the charger. You will either:*
See the LED indicator 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.

7. Tap the “Connect” button on the CP.
8. The CP will now attempt to pair with the Wearable Device.
9. A message on the CP will either indicate that the Wearable is now connected to the CP or that the connection has failed and will instruct on how to continue.

10. Tap “Continue” to enter the System Self-Test. The following screen will appear:



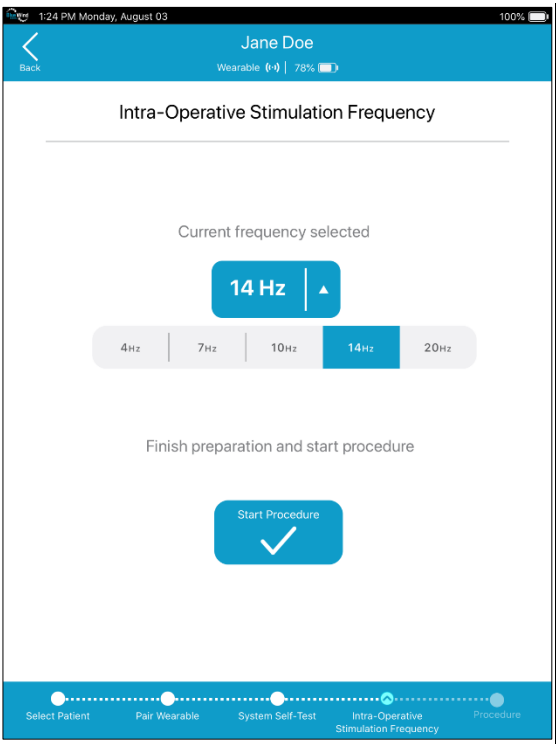
11. Scan the Implant barcode to record the serial number and calibration factor (located on the label on the back side of the Implant sterile pouch).

12. With the Implant still in its sterile pouch, place the Wearable Device antenna center (as indicated with the trapezoid shape marking the center of antenna mark), over the Implant and tap the "Initiate Test" button on the CP.

    A message on the CP will either indicate that Self-Test was completed successfully or that it failed and will instruct on how to continue.

***NOTE**: Avoid testing an implant 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.*

13. Once System Self-Test is complete, the following screen will appear:

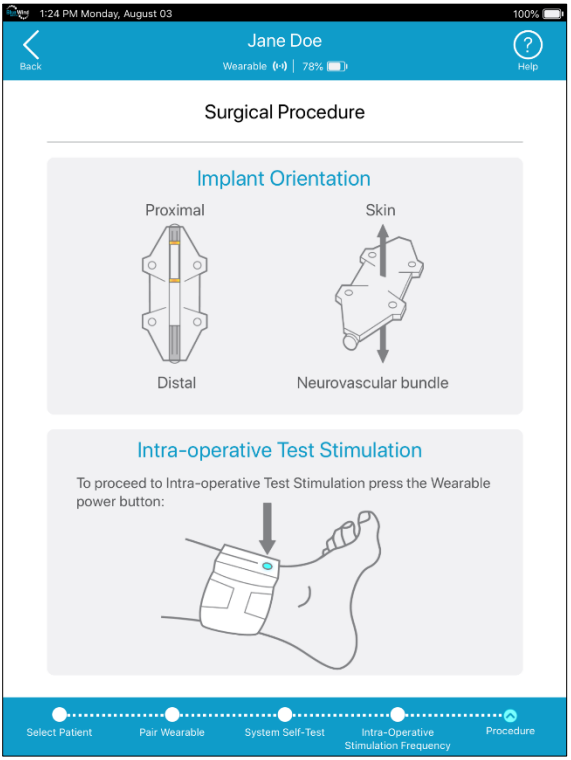


The Intra-Operative Stimulation Frequency is the frequency that will be used during the procedure to stimulate the nerve in order to verify correct Implant placement.

Setting stimulation frequency to the same frequency as treatment is recommended.

NOTE: *For patients who will require general or regional anesthesia, low frequencies (≤4 Hz) are recommended to enable easy detection of the motor response.*

14. Change the Intra-Operative Stimulation frequency if required, then tap the “Start Procedure” button. The following screen will appear:



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

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, you will need to repeat the preparation steps (i.e., choose a patient → System Self-Test → choosing Intra-Operative Stimulation Frequency) or, less preferable, proceed without the CP as monitor.*

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

Important Do not perform the test with the Implant on top of a metallic surface, as this may cause the test to fail.

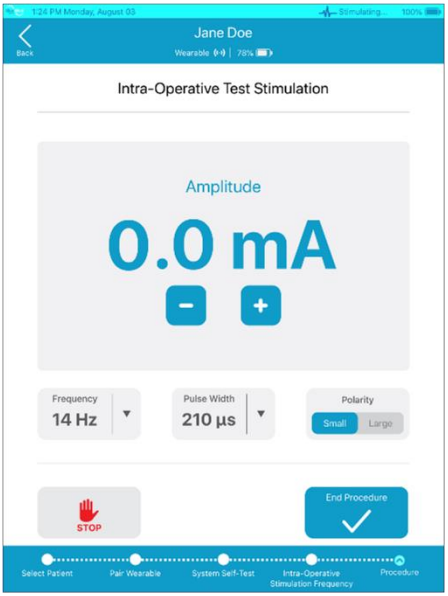
Surgical Implantation Procedure

Detailed instructions for the surgical implantation of the Revi Implant are provided in the Revi - Surgical Technique Guide US (Doc No: G02-CLU-0031).

Intra-Operative Test Stimulation

⚠ CAUTION The Clinician Programmer is intended to be used as a monitor during the procedure, outside of the sterile field.
Do not sterilize the Clinician Programmer, since sterilization may damage it.

After the surgeon has placed the implant in the patient's leg and once the Implant has been located by the Wearable, the following screen will appear:

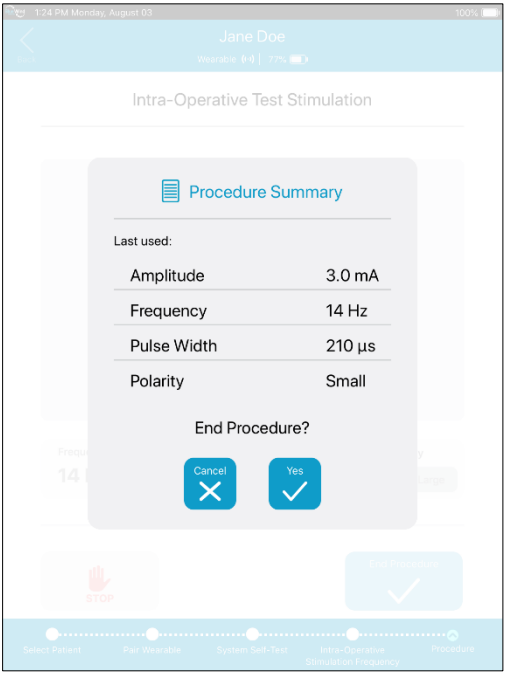


Important In the event of unexpected pain experienced by the patient, press stop button to stop stimulation immediately.

As an alternative to pressing the button on the Wearable to increase stimulation intensity, the plus button on the CP can be pressed.

Completing the Implantation Procedure

As an alternative to turning off the Wearable by pressing and holding the button, the End Procedure button on the CP can be tapped. The following screen appears:



Tap Yes to end procedure and return to the patient list.

Treatment Management with the Clinician Programmer

First-Time Treatment Setup

Assigning a New Wearable Unit to the Patient

❖ **To Assign a New Wearable Unit to the Patient**

1. From the Patient List, tap the required Patient File (or add a new patient if not registered on this CP).
2. From the selected file, tap the  button.
   The Edit Patient dialog box opens.

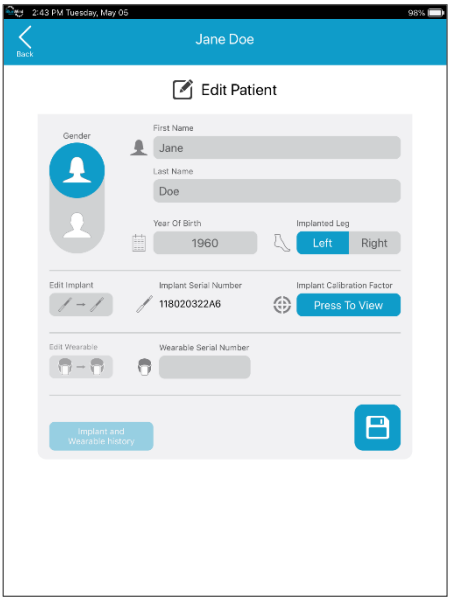


Figure 13 Edit Patient Dialog Box

Note: *At this stage, the display shows only Patient and Implant details. The Wearable serial number field is empty (pending entry).*

3. Take the new Revi Wearable Unit to be allocated to the patient, then expose the back of the unit in order to read the serial number located on the label.
4. Tap the empty Wearable Unit Serial Number text box.

The Edit Wearable dialog box opens:

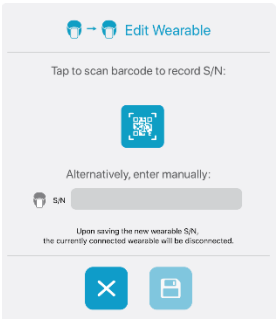


Figure 14 Edit Wearable Dialog Box

5. Proceed as follows:

   EITHER

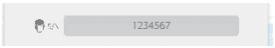
   Tap the Scan barcode icon.

   The CP camera opens.

   Capture an image of the exposed barcode on the back of the unit (refer to Step 3 above) to scan the barcode and record the Wearable Serial Number

   OR

   Tap the *Wearable serial number field*, then type the number exactly as it is shown on the label.



6. When done, tap  to save the details.

   The Edit Wearable dialog box closes, revealing the Edit Patient dialog box.

7. Tap  to save the details.

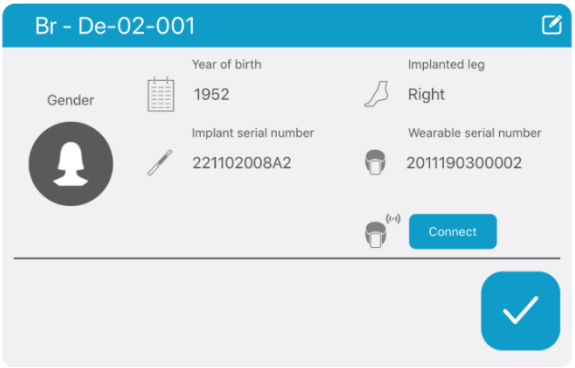


Figure 15 Patient File - Wearable Unit Assigned to Patient

The Edit Patient dialog box closes; the Patient File now shows that the Wearable Unit serial number has been saved and assigned to the patient - see Figure 13.

8. Proceed to the next instructions to establish communication between the patient's Revi Wearable Unit and the Clinician Programmer.

Pairing the Wearable Unit to the Clinician Programmer

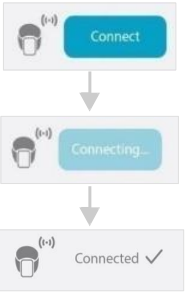
❖ **To Pair the Wearable Unit to the Clinician Programmer**

1. Press the Power button on the Wearable unit to turn it On.

Note: *If the device does not turn on, connect it to the wall outlet using the charger. You will either:*
See the LED indicator 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.

2. On the selected Patient File, tap the **Connect** button to establish communication between the Clinician Programmer and the patient's Revi Wearable Unit.

The screen display shows the connection progress, as follows:



Note: *Upon successful communication between the Clinician Programmer and the Wearable Unit, icons displayed at the top of the Patient List screen indicate active Bluetooth connection as well as Wearable Unit battery status.*

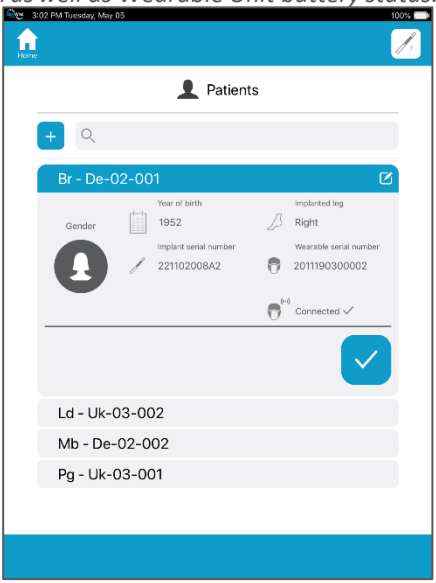


Figure 16 Successful Connection Indicated

3. When connected, observe the Procedure Summary details displayed on the *left* side of the screen (if available).

   When ready, tap the  button.

   A pop-up message opens asking for confirmation to continue to Treatment Setup.

4. Tap **Yes** to confirm.
   Since this is a first-time setup, the Patient list screen is now displayed in the background, behind the pop-up window.

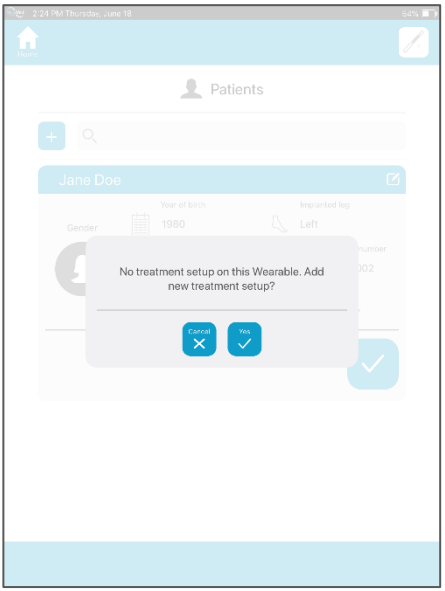
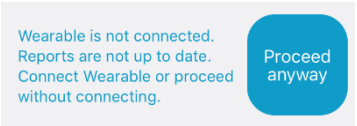


Figure 17 Treatment Screen - Initial Display

5. Proceed to the instructions for New Treatment Setup.

Note: *If there was no attempt to establish communication, or in the event that communication is unsuccessful, the following message will be displayed:*



Note: *Stimulation parameters can only be adjusted and saved when there is communication between the wearable and clinician programmer, but reports and active parameters can be viewed at all times by pressing "Proceed anyway".*

For communication troubleshooting, see Table 3 on page 67.

New Treatment Setup

The user sets and stores one or two treatment programs on the patient's Wearable Unit and activates one treatment program during the visit. The patient will perform treatment with the active program

until otherwise instructed.

New Setup

The New Treatment Setup Procedure requires the user to perform the following tasks, in the order shown below, according to the referred instructions:

Positioning the Wearable Unit on the Patient's Leg on page 44

Customizing Stimulation Parameters

- Stage 1 - Setting Minimum Sensation Level on page 46
- Stage 2 - Setting Maximum Tolerable Level on page 49
- Stage 3 - Setting Treatment Level on page 50

Saving Treatment Parameters on page 50

Positioning the Wearable Unit on the Patient's Leg

The strength of the communication signal between the Revi Wearable Unit and the Revi Implant — and therefore the accuracy of the unit's positioning — is indicated via blinking of the LED (Figure 18, **1**) and audible sounds.

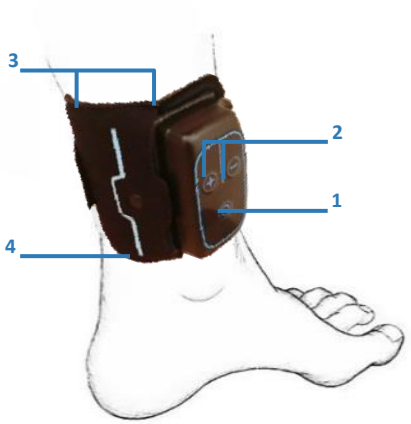


Figure 18 Revi Wearable Unit Positioned for Treatment

Note: *Figure 18 illustrates the position on the LEFT leg. For the RIGHT leg, the Power button (**1**) will be at the top.*

❖ **To Position the Revi Wearable Unit:**

1. Place the Revi Wearable Unit on the treated leg above the ankle, so that the control buttons (Figure 18, **2**) are oriented on the front of the leg and the Antenna (Figure 18, **3**) is positioned around the inner leg.
2. Wrap the Leg Band strap around the leg and through the loop, then close without tightening the strap.
3. Align the antenna marking on the bottom edge (Figure 18, 4) of the Wearable with the scar.

As the unit locates the Implant, you will hear a signal. The LED blinks yellow. On the CP, the Positioning Screen displays a visual indication of Position Quality (Figure 19).

The on-screen display represents the quality of the current positioning of the Revi Wearable Unit in relation to the Revi Implant.

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 beeping and flashing frequency achievable, you may do so by raising 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.

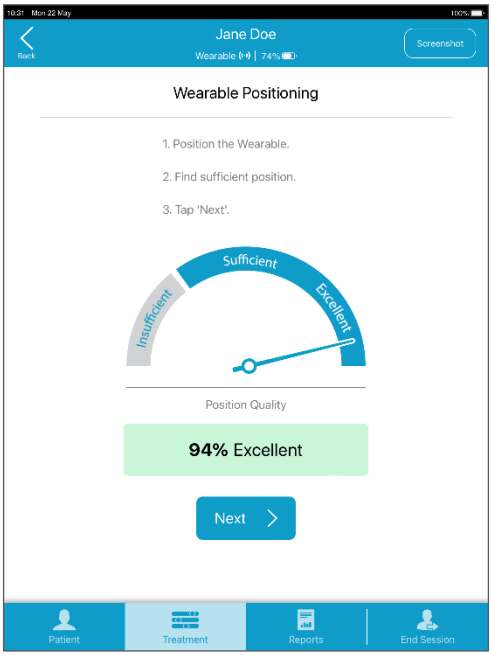


Figure 19 Wearable Positioning Screen

Customizing Stimulation Parameters

Customization of Stimulation parameters is performed in three stages, as described below.

Note: *For details of the range of Stimulation Parameter settings, see Table 4 on page 72.*

Stage 1 - Setting Minimum Sensation Level

Explain to the patient that the next steps are required to set the appropriate Minimum Sensation Level (i.e., the first time the patient feels a tingling sensation in the sole of the foot, heel or toes) and will require his/her cooperation.

Figure 20 Treatment Setup Screen - Initial Display

Start increasing the Stimulation level until the patient reports feeling a tingling sensation.

When using the slider, pressing the bottom at any time will stop the ramp up.

Note: *In the event that the patient does not feel a tingling sensation or experiences pain, the following parameters can also be adjusted: Frequency, Pulse Width or Polarity. Note the following:*

If Frequency and/or Pulse Width are increased, the Stimulation level will automatically be decreased to prevent the possibility of feeling of pain.

If Polarity is switched, the Stimulation level will be set to zero.

Once the patient reports feeling a tingling sensation, leave the stimulation level at this Minimum Sensation Level and tap the Set > button.

Note: *After setting the Minimum Sensation Level, the CP prompts the user to indicate where the sensation is being felt.*

Ask the patient where he/she feels a tingling sensation, then tap the appropriate button on the displayed areas of sensation options (Figure 21).

Figure 21 Areas of Sensation

Note: *A good response is when sensation is felt in the* ***Sole of the Foot Only****. In the event that any of the other areas of sensation indicators are tapped, the CP will guide you to change specific parameters (relevant to the selection) in order to set a new Minimum Sensation Level.*

Note: *If either the* ***Implantation Site Only*** *or* ***No Sensation*** *option is selected, you will not be able to proceed to Stage 2 (Setting the Maximum Tolerable Level). In this event, you are required to adjust parameters (Frequency, Pulse Width or Polarity) and set a new Minimum Sensation Level to ensure the patient experiences correct sensation.*

After setting the Area of Sensation, tap the 

button to proceed to Stage 2.

Note: *The Treatment Setup screen advances to Stage 2 – Setting Maximum Tolerable Level - see Figure 22.*

Stage 2 - Setting Maximum Tolerable Level

Figure 22 Maximum Tolerable Level

Start increasing the Stimulation level until the patient reports the maximum sensation, they are able to tolerate.

Leave the Stimulation level at this Maximum Sensation Level and tap the Set > button.

Note: *The system will immediately reduce the Stimulation level to the calculated default Treatment Level.*

Note: *If Frequency, Pulse Width or Polarity are changed at this stage, it is not possible to proceed directly to Stage 3 - and the user is now prompted to confirm the change. On doing so, the Treatment Setup screen returns to Stage 1 (see Figure 20) where the user is required to set a new Minimum Sensation Level.*

Stage 3 - Setting Treatment Level

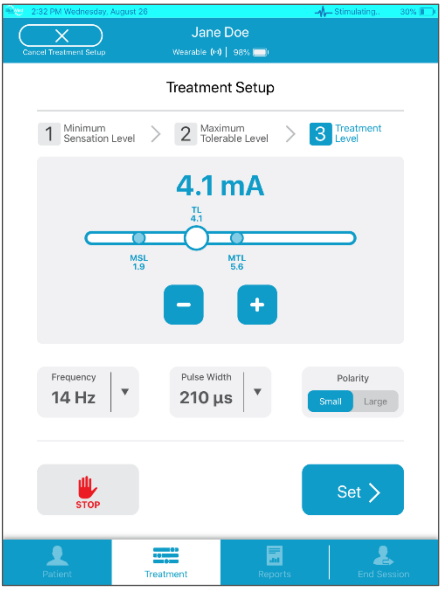
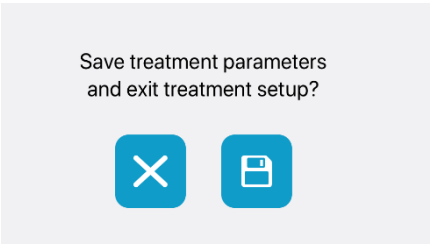


Figure 23 Treatment Level Screen

If necessary, the user may adjust the default Treatment Level set by the system. This level should be set to a high, yet comfortable, level that the patient can tolerate for the duration of an entire Treatment Session.

When done, tap the Set button, then proceed to Saving Treatment Parameters.

Saving Treatment Parameters



Tapping the Save button will automatically save the programmed Treatment parameters on the patient's Revi Wearable Unit. A pop-up message on screen and a beep sound by the Wearable Unit provide confirmation that the Save command was successful.

Note: *After saving the Treatment parameters, the Clinician Programmer exits Treatment Setup and the display switches to the patient's Existing Treatment Parameters screen - see Figure 24.*

Modifying Session Parameters

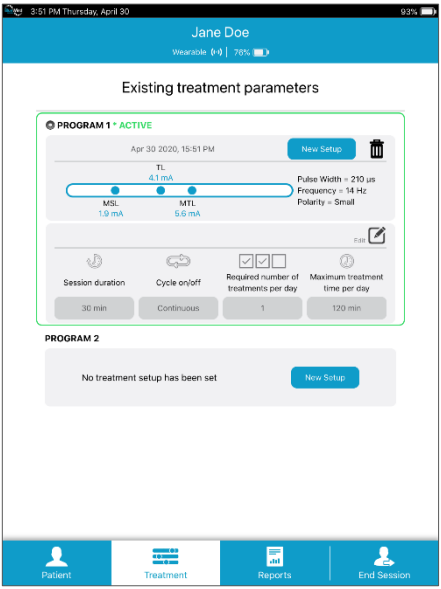


Figure 24 Existing Treatment Parameters Screen

Use the Edit button to edit any of the following parameters, as necessary:

- Session duration
- Cycle on/off
- Required number of treatments per day
- Maximum treatment time per day

Save changes

(Changes are saved on the Wearable Unit; A display of the changes on screen and a beep sound by the Wearable Unit provide confirmation that the Save command was successful.)

Cancel edits

(No changes are saved; display reverts to existing parameters).

The following parameters cannot be edited from the Existing

Treatment Parameters screen:

- Minimum Sensation Level
- Maximum Tolerable Level
- Treatment Level
- Frequency
- Pulse Width
- Polarity

Note: *To make adjustment to these settings, see Customizing Stimulation Parameters on page 46.*

Setting an additional Treatment Program to the Patient's Wearable

Tap the New Setup button on the screen entitled Existing Treatment Parameters in the Program 2 box and proceed as instructed in the New Treatment Setup section on page 43.

❖ **To select the active Treatment Program**

The currently active Treatment Program is highlighted with a green frame and its radio button appears selected (Figure 27). To activate the other Treatment Program, tap the desired Program's ○ button.

❖ **To delete a Treatment Program**

Tap the 🗑 button in the relevant Program's box and tap the Yes button on the pop-up window (Figure 28).

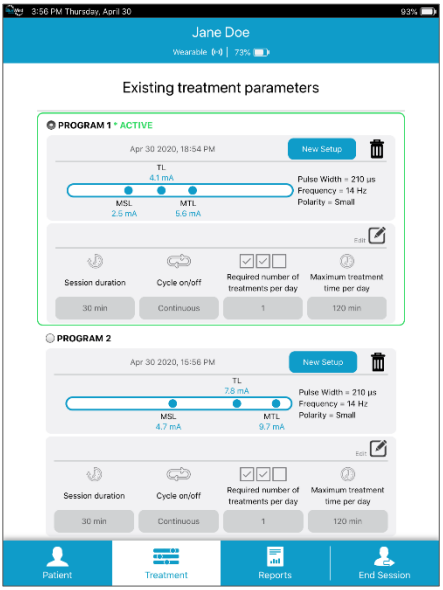


Figure 25 Existing Treatment Parameters, Multiple Treatment Programs

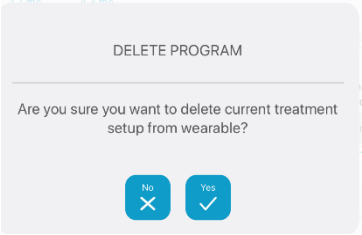


Figure 26 Delete Treatment Program from Wearable

Patient Training on Use of the Wearable Unit

Having customized the required treatment parameters, you should now instruct the patient, give treatment guidelines and train him/her to operate the Revi Wearable Unit for self-treatment sessions at home.

Practical guidance should include the following:

- Correct Positioning of the Wearable Unit on the leg.
- Turning ON the Wearable Unit.
- How often to perform Treatment (for example Daily, or other).
- Adjusting Stimulation levels (and expected results after adjustment).

- How to handle the unit if its position inadvertently shifts.
- Recharging the battery.
- Instructing the patient to read the Revi System Patient Therapy Guide at home.

Note: *After training the patient, it is recommended to ask the patient to commence a Treatment Session, while still in the clinic.*
Use of the Clinician Programmer Treatment Monitor can be helpful at this stage, to ensure the patient has fully understood the instructions and is comfortable during the full Treatment Session duration. See Using the Treatment Monitor.

Using the Treatment Monitor

The Treatment Monitor provides the user with the option of on-screen monitoring of a currently active Treatment Session.

Upon completion of a first-time Treatment Setup session and patient training on operation of the Revi Wearable Unit, this feature can be useful to ensure the patient has properly understood the training and is comfortable during the full duration of a Treatment Session.

Note: *The Treatment Monitor may also be used later during Follow-up visits, as described on page 58.*

Provided there is communication between the Revi Wearable Unit and the Clinician Programmer and the patient has initiated a Treatment Session, the Treatment Monitor can be viewed. See the example in Figure 27.

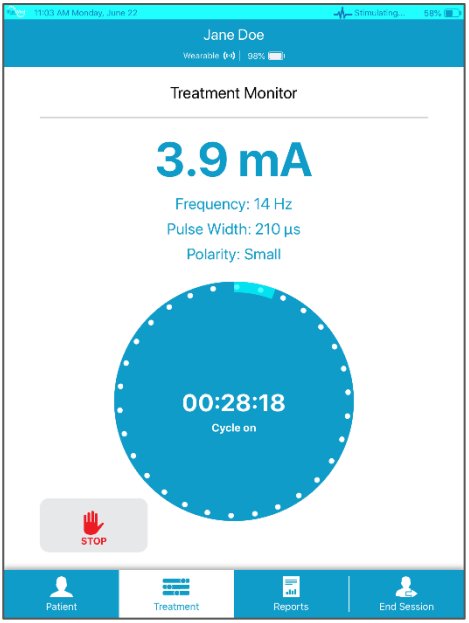


Figure 27 Treatment Monitor Screen

Note: *If necessary, the user can use the on-screen Stop*  *button to stop the currently active Treatment Session.*

If any adjustments to the currently defined Stimulation parameters are required, it is necessary to return to the Treatment Setup screen to make the changes (see Figure 20 on page 47).

Instructions to the Patient After First-Time Treatment Setup

In conclusion of the first-time Treatment Setup visit, the user should provide the patient with the recommendations and important information outlined below.

Important

Important for Patients to Know Before Home Treatment Sessions

- Always observe the Warnings and Precautions outlined in the Revi Patient Therapy Guide provided with the Revi Wearable Unit kit.
- Make sure that you fully understand how to use and care for your Revi Wearable Unit properly.
- If you have questions, ask your clinician.
- Keeping a voiding diary will help you track improvements in your symptoms over time.
- Adhering to the Treatment regimen prescribed by your treating

clinician/surgeon is very important. It will help you achieve optimal outcome.

- A patient identification card was given to you following implantation. It is recommended to carry the card at all times since this identifies you as a person with a Revi Implant and undergoing treatment with the Revi System and lists the MRI conditions.
- In the event that you require any other type of medical examination, treatment, surgical operation, *etc*. it is important to notify your doctor or relevant medical professional that you are using the Revi System. See specific precautions in the Revi Patient Therapy Guide.
- During Revi therapy, if you notice any unusual signs or symptoms, contact your clinician.

If two treatment programs were set, the user should also indicate:

- Two individual treatments are saved in your Wearable, but you will be using only one of them. In a few weeks we may contact you by phone and instruct you to switch to the other program. We will guide you through the process.

End Session

Tapping the End Session 

button exits the currently selected Patient and returns to the Treatment Management Patient List screen, as shown in Figure 10 on page 27.

Phone Instructions for Patient on Treatment Program Switch

In case program change is required, the BlueWind Medical representative should call the patient and provide the important information and instructions outlined below.
The BlueWind Medical representative should use a loud and clear voice and ask the patient to perform the tasks together with the BlueWind Medical representative and provide real-time feedback.

- Two treatment programs are saved on your Wearable. You have been using one and should now start using the other program.
- Connect the Wearable to the charger provided with your Revi system and make sure it is charging.

Important **The patient should only use the charger provided with the Revi System.**

- To check which treatment program is currently active, press and hold the Wearable plus button until 1 or 2 longer beeps sound (disregard the short beep immediately upon press of the plus button) and the LED blinks yellow once or twice, respectively: 1 beep/blink indicates program 1 is active, 2 beeps/blinks indicate program 2 is active
- To switch the active treatment program:
    a. Press and hold the Wearable minus button until 1 short beep sounds (disregard the short beep immediately upon press of the minus button) and the LED starts blinking yellow: program change mode is now enabled.
    b. While the LED blinks yellow, press and hold the plus button until a long beep sounds (disregard the short beep immediately upon press of the plus button) and the LED lights up steady yellow for a few seconds.
- To check if the treatment program was indeed switched, once the LED is not steady yellow anymore, press and hold the Wearable plus button until 1 or 2 long beeps sound (disregard the short beep immediately upon press of the plus button) and the LED lights up briefly once or twice, respectively: 1 beep/blink indicates program 1 is active, 2 beeps/blinks indicate program 2 is active.

Following the program switch, the BlueWind Medical representative should instruct the patient to disconnect the Wearable from the charger and start a treatment with the new program in order to make sure the patient does not experience any issues or discomfort.

Follow-up Visits

The user will conduct follow-up sessions to monitor patient compliance with the treatment schedule and evaluate treatment efficacy.

In these sessions, it is recommended that the user talk to the patient and also use the Clinician Programmer to view the patient's Reports, and maybe use the Treatment Monitor. This will enable the user to review the patient's treatment session history over a selected period of time and to gain an understanding of any difficulties the patient may be experiencing that require modification to settings, or further training.

Note: *The moment the patient's Revi Wearable Unit has been successfully paired with the Clinician Programmer, data on the Wearable Unit is automatically transferred to the CP where it is displayed as Reports or Alerts.*

When treatment parameter modifications are required, certain adjustments may be made from the Existing Treatment Parameters screen (see Modifying Session Parameters on page 51, Figure 24), without the need to enter Treatment Setup mode.

These include: *Session duration; Cycle on/off; Required number of treatments per day; Maximum treatment time per day.*

However, adjustments to Stimulation level, *Frequency, Pulse Width,* and/or *Polarity* require a New Treatment Setup.

Refer to the following, as applicable:

Viewing Reports on page 58

Modifying Session Parameters on page 51

Customizing Stimulation Parameters on page 61

Using the Treatment Monitor on page 61

End Session on page 61

Viewing Reports

The Clinician Programmer Reports main screen, with its scrollable calendar display, provides an overall view of device usage and patient compliance. Additionally, it provides access to detailed Reports featuring four categories of information:

- Time of Day
- Treatment Duration
- Stimulation Level Range
- Setup History

To access the Reports screens, first select the patient, then pair the Wearable Unit with the CP (see Pairing the Wearable Unit to the Clinician Programmer on page 41).

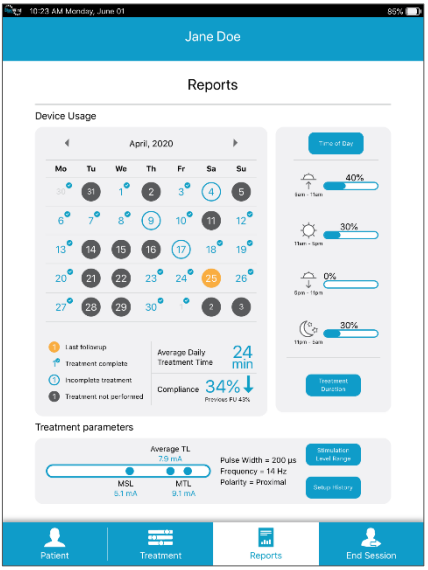


Figure 28 Reports Main Screen

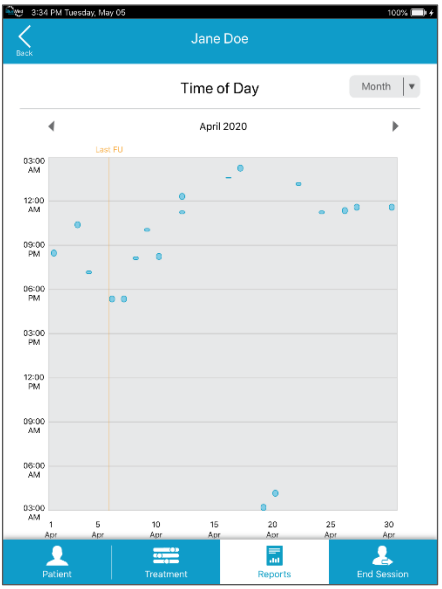


Figure 29 Report - Time of Day

Note: *Three viewing options are available: Week, Month, and 3 Months.*

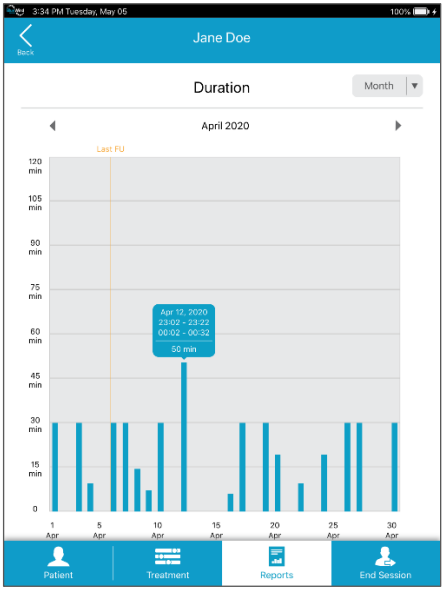


Figure 30 Report - Duration

Note: *Three viewing options are available: Week, Month, and 3 Months.*

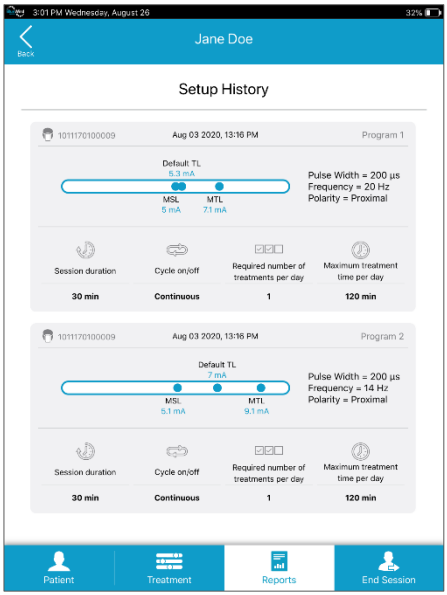


Figure 31 Report – Setup History

Customizing Stimulation Parameters

When parameters such as *Amplitude, Frequency, Pulse Width* or *Polarity* need to be changed, a New Treatment Setup must be performed.

On the Existing Treatment Parameters screen, tap the New Setup button.

Then, follow the instructions provided in New Treatment Setup on page 43.

Using the Treatment Monitor

During a follow-up session, if necessary, the user may use the Treatment Monitor to troubleshoot any technical problems presented by the patient, or evident in the Reports.

For more details, refer to Using the Treatment Monitor on page 54.

End Session

On conclusion of the follow-up session, tapping the End Session 

button exits the currently selected Patient and returns to the Treatment Management Patient List screen, as shown in Figure 10 on page 27.

Inquire Implant

The Inquire Implant function allows the user to read the serial number of any implant if the need arises.

❖ To Read the Implant Serial Number

1. On the Patient List Screen, tap the Inquire Implant button. The Inquire Implant pop-up window (Figure 32) opens.
2. Take a Revi Wearable Unit and expose the back of the unit in order to read the serial number located on the label.
3. *EITHER*

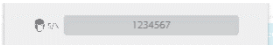
   Tap the Scan Barcode button.

   The CP camera opens.

   Capture an image of the exposed barcode on the back of the unit to scan the barcode and record the Wearable Serial Number

   OR

   Tap the Keyboard button, then type the number exactly as it is shown on the label.

4. Press the Wearable power button, then tap the Connect button to establish communication between the Clinician Programmer and the Revi Wearable Unit.
5. Upon successful connection, place the Wearable on the leg, with the antenna marking over the implantation site and tap the Read Implant S/N button.
6. Upon successful Implant inquiry the Implant's serial number is displayed at the bottom of the screen.

7. Tap X to close the Inquire Implant pop-up window.

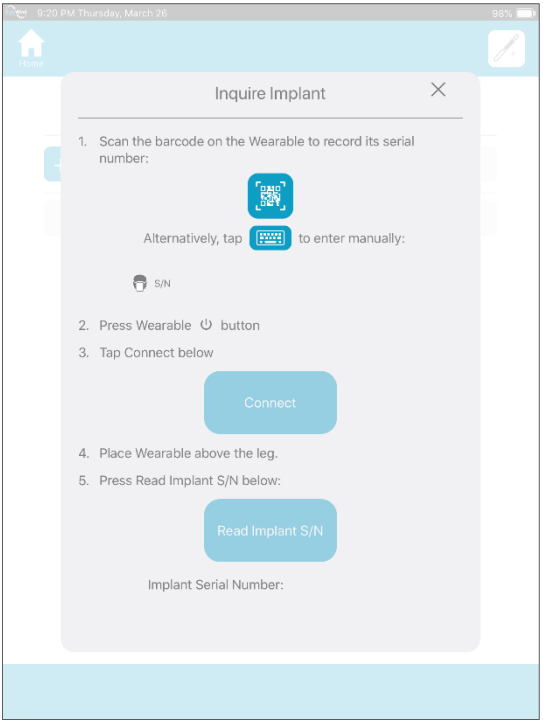


Figure 32 Inquire Implant

***Note**: In case Implant Serial Number is not read, follow the troubleshooting instructions on the screen (Figure 33).*

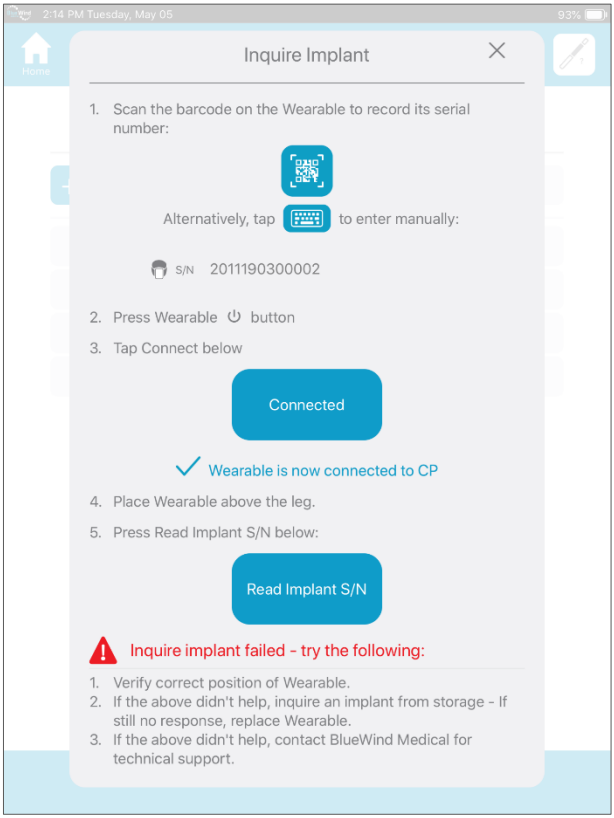


Figure 33 Inquire Implant failed

General Care & Maintenance

Revi Clinician Programmer

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

⚠ CAUTION Use only the charger and cable supplied in the Revi Clinician Therapy Kit.

Revi Wearable Unit

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.

Data Backup

Data backup is the responsibility of BlueWind Medical Ltd.

One of the company's Field Service Engineers will visit the site routinely to download the Clinician Programmer log files for this purpose.

Troubleshooting Guide

General Guidelines and Recommendations

The Revi Clinician Programmer has embedded troubleshooting in the form of pop-up windows displaying error messages with suggestions, where applicable.

Note: *For tablet hardware troubleshooting, follow the recommendations provided in the Apple iPad User Guide available at www.apple.com*

Note: *A backup Clinician Programmer should be available during each session in which the system is used*

This Troubleshooting Guide provides information to assist with issues that may be encountered when using the Revi Wearable Unit. Outlined in Table 3 are specific situations, their possible cause and the recommended corrective action.

Note: *When troubleshooting issues that the patient has encountered and for which he/she is asking for help, the patient can also perform a Treatment Session and the user can use the Treatment Monitor (described in Using the Treatment Monitor on page 54) or obtain additional information from the Reports (see Viewing Reports on page 58).*

Note: *A backup Wearable Unit should be available during each session in which the system is used.*

Revi Wearable Unit Troubleshooting

Table 3 Revi Wearable Unit - Troubleshooting Guide

General Note: For troubleshooting, ask the patient to start treatment while the CP is in monitoring state. This can provide you more information regarding the problem.

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 Device until the LED indicator turns steady 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 device is connected to the battery charger.	Disconnect the Wearable Device from the battery charger, then restart it.
The Revi Wearable Unit does not turn Off.	Power button was not pressed for long enough.	Press and hold the Power button for at least 5 seconds.
Cannot find the correct Position for the Revi Wearable Device. (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 Wearable Device unit is placed as shown in Figure 18 on page 44.
		Move the Wearable Device 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.
Cannot find the correct Position for the Revi Wearable Device. (Positioning beeps are not sounding; the LED indicator is YELLOW and blinking slowly).	A metal object, or something causing electromagnetic interference is located close to the Revi Wearable Device. Refer to: Metal Objects and Implants or Electromagnetic interference on page 10.	Move the object away from the Wearable Device (alternatively, move your leg away from the source of interference).

Situation	Possible Cause	Recommended Action
Cannot find the correct Position for the Revi Wearable Device. (Positioning beeps are not sounding; the LED is not illuminated).	The Wearable Device is turned Off.	Press the Power button once (short press). The LED indicator will turn YELLOW Sound and LED will indicate positioning
Beeping sound audible in the middle of stimulation.	Wearable Unit 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.
	A metal object, or something causing electromagnetic interference is located close to the Revi Wearable Unit. Refer to: Metal Objects and Implants or Electromagnetic interference on page 10.	Move the object away from the unit (alternatively, move the patient's leg away from the source of interference).
The Revi Wearable Unit feels excessively hot.	Technical problem.	Make sure the Wearable Device is not on the patient's leg while charging the battery.
		Stop using the Wearable Unit, then contact BlueWind Medical for technical support.
Revi Wearable Unit does not respond when pressing the + or - buttons.	Maximal / Minimal level has been reached (indicated by three consecutive short beeps).	Contact your clinician for a new Treatment setup.
	For patients for whom Stimulation Treatment parameters have been programmed by the user to have On-Off cycles: The + or - button has been pressed while the unit was in the Off phase.	Press the + or - button only while the unit is in the On phase.

Situation	Possible Cause	Recommended Action
	The + button has been pressed during the ramp-up stage.	Wait for the ramp-up stage to complete, 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.
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.

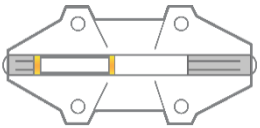
Tachyphylaxis Instructions

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 reprograming does not restore treatment effect, “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 4 Revi 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	
Stimulation Waveform	Biphasic charge - neutral	
Stimulation Polarity	Configurable	
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	
Essential performance Accuracy Limits	Pulse Amplitude: ±20% or ±0.15mA (whichever is greater) Pulse Width Accuracy: ±10% Pulse Frequency: ±10%	

Revi Wearable Unit	
Material	Polycarbonate and Silicone covered with fabric leg-band
Dimensions without Leg Band	5.5 [L] x 3.8 [W] x 1.4 [H] in 14 [L] x 9.6 [W] x 3.4 [H] cm
Dimensions with Leg Band	15.7 [L] x 4.5 [W] x 1.6[H] in 40 [L] x 11.3 [W] x 4 [H] cm
Weight without Leg Band	5.8 oz (165 g)
Weight with Leg Band	7.8 oz (220 g)
Leg Band material	Lycra+ Polyester+ Microfabric + Silicon
Battery	Li-ion Rechargeable, 1400 mAh
Battery operation	Battery operational voltage: 3.1 - 4.2 V 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
Revi Clinician Programmer	
Type	Tablet computer - iPad v.2017 and up
Software	Proprietary BlueWind Medical software version 10
Screen	Touch screen
Communication	BLE
Typical Stimulation Session Duration	
Duration	30 - 60 minutes
Stimulation Parameter Increments	
Amplitude	0.1 mA increments
Frequency	1 Hz increments
Pulse Width	20 µSec increments
Treatment Duration	5-minute increments

Environmental Specifications

Table 5 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 6 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 area at room temperature (typically 57 – 86 °F /14 – 30 °C)		70 - 200
	Transport	14 — 131 °F	≤ 85%	
		-10 — 55 °C		

Electromagnetic Specifications

Table 7 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 8 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 4) under the following conditions.

Table 9 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.

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 Unit in this manual. 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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