NUVECTRA™

Virtis™ Sacral Neuromodulation System
Information for Prescribers

Physicians / prescribers should read this document in full prior to using the Virtis™ Sacral Neuromodulation System

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2022

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Packaging Symbols Glossary

Symbol	Explanation
	**Title:** Catalog Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.6[1] **Description:** Indicates the manufacturer's catalog number so that the medical device can be identified.
	**Title:** Batch Code **Standard:** ISO 15223-1 **Reference Number:** 5.1.5[1] **Description:** Indicates the manufacturer's batch codes so that the batch or lot can be identified.
	**Title:** Use by date **Standard:** ISO 15223-1 **Reference Number:** 5.1.4[1] **Description:** Indicates the date after which the medical device is not to be used.
	**Title:** Date of Manufacture **Standard:** ISO 15223-1 **Reference Number:** 5.1.3[1] **Description:** Indicates the date when the medical device was manufactured.
	**Title:** Manufacturer **Standard:** ISO 15223-1 **Reference Number:** 5.1.1[1] **Description:** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	**Title:** Authorized representative in the European Community **Standard:** ISO 15223-1 **Reference Number:** 5.1.2[1] **Description:** Indicates the Authorized representative in the European Community.
	**Title:** Packaging unit **Standard:** ISO 7000 **Reference Number:** 2794[2] **Description:** Indicates the number of pieces in the package.
	**Title:** Consult instructions for use **Standard:** ISO 15223-1 **Reference Number:** 5.4.4[1] **Description:** Indicates the need for the user to consult the instructions for use.
	**Title:** Caution **Standard:** ISO 15223-1 **Reference Number:** 5.4.4[1] **Description:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Symbol	Explanation
	**Title:** Do not reuse **Standard:** ISO 15223-1 **Reference Number:** 5.4.2[1] **Description:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	**Title:** Do not resterilize **Standard:** ISO 15223-1 **Reference Number:** 5.2.6[1] **Description:** Indicates a medical device that is not to be resterilized.
	**Title:** Sterilized using ethylene oxide **Standard:** ISO 15223-1 **Reference Number:** 5.2.3[1] **Description:** Indicates a medical device that has been sterilized using ethylene oxide.
	**Title:** Do not use if package is damaged **Standard:** ISO 15223-1 **Reference Number:** 5.2.8[1] **Description:** Indicates a medical device that should not be used if the package has been damaged or opened.
	**Title:** Keep away from sunlight **Standard:** ISO 15223-1 **Reference Number:** 5.3.2[1] **Description:** Indicates a medical device that needs protection from light sources. This symbol can also mean keep away from heat.
	**Title:** MR Conditional **Standard:** ASTM F2503 **Reference Number:** 7.3.2[3] **Description:** An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.
	**Title**: MR Unsafe **Standard**: ASTM F2503 **Reference Number:** 7.3.3[3] **Description**: An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	**Title:** Temperature limit **Standard:** ISO 15223-1 **Reference Number:** 5.3.7[1] **Description:** Indicates the temperature limits to which the medical device can be safely exposed.
	**Title:** Rx Only **Standard:** 21 CFR Part 801.109 paragraph (b)(1) **Description:** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Explanation
CE	**Title:** European Conformity **Standard:** 93/42/EEC Annex XII **Description:** Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

1. ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements
2. ISO 7000:2019 Graphical symbols for use on equipment-Registered symbols
3. ASTM F 2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Contents

Virtis System Overview

The Nuvectra™ Virtis™ Sacral Neuromodulation System is an MR conditional, rechargeable, 8-channel, 2x4 electrode sacral neuromodulation system for the treatment of overactive bladder or urinary retention (Figure 1).

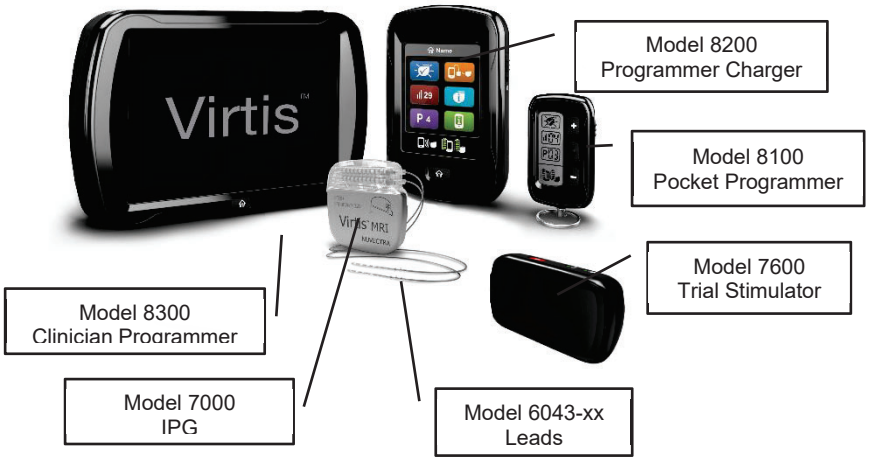

Figure 1. Virtis System components

A Virtis System is implanted in two stages: stage 1 stimulation trial and stage 2 system implant. In stage 1, the physician places the lead. When placing the lead, the physician uses the trial stimulator to deliver intraoperative test stimulation while using the Clinician Programmer to control the stimulation and record patient responses. The trial stimulator emulates the implantable stimulator.

After placing the lead, the physician externalizes an extension and programs the trial stimulator with programs appropriate for a stimulation trial. During the stimulation trial, the patient controls stimulation using the Pocket Programmer.

After a successful stimulation trial, during the stage 2 procedure, the externalized extension is removed, the lead is connected to the implantable stimulator, which is then implanted. If additional lead length is needed, a new extension is used. After implanting the stimulator, the physician uses the Clinician Programmer to program the stimulator and set the options and limits available to the patient on the Programmer Charger and Pocket Programmer.

With an implanted Virtis System, the patient uses the Programmer Charger or the Pocket Programmer to control stimulation. The patient also uses the Programmer Charger to charge the stimulator.

Implanted Components

The implanted components deliver stimulation to the sacral nerve.

Virtis Stimulator Model 7000

The stimulator is an 8-channel, rechargeable stimulator. The stimulator has two 4-channel connector ports. Each channel corresponds to an electrode on a lead. The 4-electrode lead can be inserted into either connector port. If two leads are used, the Virtis System allows stimulation on only one lead at a time.

The stimulator battery is a deep discharge recovery battery with CoreGuard™ technology. Even if the patient allows the battery to completely discharge, the patient can recharge the battery with the Programmer Charger.

The stimulator battery is expected to last 10 years. Actual battery life depends on the stimulation settings used. Once the battery no longer provides a sufficient amount of time between recharges, the stimulator needs to be surgically replaced.

Virtis Lead Model 6043-xx

The lead has four electrodes with 3-mm electrode spacing. The lead is available in 30 and 40-cm lengths.

Virtis Extension Model 6612-xx

For a stimulation trial, an extension is externalized and connected to the trial stimulator. For a system implant, an extension is used when additional length is needed between the lead and the stimulator. The extension is available in 20, 40, and 60-cm lengths.

Warning: The Virtis Extension is MR Unsafe.

1 Denotes length in centimeters

External Components

The clinician uses the external components to program stimulation. The patient uses the external components to control stimulation and charge the stimulator.

Warning: The Virtis External Components are MR Unsafe.

Virtis Trial Stimulator Model 7600

The trial stimulator is an external stimulator that emulates the implantable stimulator. The physician uses the trial stimulator during intraoperative test stimulation. The patient uses the trial stimulator during the stimulation trial.

Virtis Clinician Programmer Model 8300

The clinician uses the Clinician Programmer to program the stimulation delivered by the trial stimulator and implantable stimulator, and to set the stimulation options and limits available to the patient on the Programmer Charger and Pocket Programmer.

The Clinician Programmer wirelessly communicates with the implantable stimulator and trial stimulator, which keeps the programmer outside the sterile field during the implant procedure.

Virtis Programmer Charger Model 8200

The patient uses the wireless Programmer Charger to turn stimulation on and off, adjust stimulation strength within the limits set by the clinician, change programs, monitor the implantable or trial stimulator battery level, and charge the implantable stimulator.

Virtis Pocket Programmer Model 8100

The Pocket Programmer is a wireless, key fob-sized patient programmer used to turn stimulation on or off, adjust stimulation strength, change programs, and monitor the implantable or trial stimulator battery level.

Labeling Overview

The following clinician and patient documents are part of the Virtis System labeling. Refer to the appropriate document for instructions for use.

Table 1 - Virtis System Labeling

Clinician Documents	
Information for Prescribers	• Virtis System description and labeling overview • Indications, contraindications, warnings, precautions, adverse events summary, clinical summary
MRI Procedure Guidelines	• Warnings, precautions, and instructions for MR conditions of use

Clinician Documents	
Stage 1: Implant Manual for Leads	• Procedures for placing a lead for a stimulation trial • Procedures for explanting and placing a lead for a lead revision • Stimulation trial instructions
Stage 2: Implant Manual for Stimulator	• Procedures for implanting a stimulator after a stimulation trial • Procedures for explanting and replacing an implantable stimulator
Implant Manual for Extensions	• Procedures for implanting or replacing an extension
Clinician Programming Manual	• Instructions for using the Clinician Programmer to perform intraoperative stimulation for lead placement and create stimulation programs • Instructions for additional clinician tasks not related to implant procedures
Clinician Programmer Quick Reference	• Descriptions of the most commonly used Clinician Programmer functions

Patient Documents	
Patient System Manual	• Implanted Virtis System description • Indications, contraindications, warnings, precautions, and adverse events • Information on recovering from Virtis System implant surgery and living with a Virtis System • Instructions on how to use, charge, troubleshoot, and care for the Programmer Charger and Pocket Programmer
Patient Stimulation Trial Manual	• Virtis Trial System description • Indications, contraindications, warnings, precautions, and adverse events • Information on recovering from a lead placement procedure • Information on patient activities during a stimulation trial • Instructions for how to use, charge, troubleshoot, and care for the Pocket Programmer
Programmer Charger Quick Reference	• Instructions for the most commonly used Programmer Charger functions
Pocket Programmer Quick Reference	• Instructions for the most commonly used Pocket Programmer functions
Magnet Insert	• Instructions for using the optional magnet to turn stimulation off and on

Indications for Use

The Virtis Sacral Neuromodulation System is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

Contraindications

Implantation of a Virtis Sacral Neuromodulation System is contraindicated for the following patients:

- Patients who have not demonstrated an appropriate response to test stimulation; or
- Patients who are unable to operate the Virtis SNM System.

MRI Safety Information

Under certain conditions, some fully implanted Virtis Systems are magnetic resonance (MR) Conditional. Virtis Trial Systems are MR Unsafe.

Virtis Trial System

Warning: Patients with a Virtis Trial System must not be exposed to MRI scans. The electromagnetic field generated by an MRI scanner may forcefully dislodge the leads, damage the trial stimulator electronics, induce heating of the tissues near the lead, and induce voltage through the leads that may cause an uncomfortable or jolting sensation or serious injury. The Virtis Trial System components have not been tested for heating or migration in the MR environment. Introducing a patient with a Virtis Trial System into an MRI scanner may result in severe patient injury or component malfunction.

Virtis System

A Virtis System is MR Conditional for an MRI examination of the head only, if a stimulator and lead are fully implanted in approved locations and all other Virtis System, patient, and MRI system conditions are met. Failure to follow all conditions for safe MR scanning may result in severe patient injury or component malfunction. See the Virtis Sacral Neuromodulation System MRI Procedure Guidelines for complete warnings, precautions, and instructions for MR conditions of use.

Warnings

Diathermy

Diathermy, shortwave, microwave, and/or therapeutic ultrasound diathermy must not be used on Virtis System patients. The energy generated by diathermy can be transferred through the Virtis System, causing tissue damage at the lead site, which may result in severe injury or death.

Ablation

Ablation safety has not been established for radiofrequency (RF) or microwave ablation in patients who have a Virtis System. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

MR Safety Information

The Virtis extension is MR Unsafe because it has not been evaluated for use in an MR environment.

Do not take the Clinician Programmer, Programmer Charger, Pocket Programmer, or programmer accessories (for example, a charging paddle or power cord) into an MR environment, such as an MRI scanner room. Virtis programmers, chargers, and programmer accessories are MR Unsafe.

Virtis System lead, stimulator, and port plugs are MR Conditional only when implanted in approved locations:

- Lead— Implanted in the sacrum
- Stimulator—Implanted in the buttocks, below the iliac crest
- Port plugs—Inserted in the stimulator connector port

Virtis System leads, stimulators, and port plugs implanted in other locations, and other Virtis System components are untested for an MR environment.

Mechanical Obstruction

This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, urethral stricture, or other causes.

Electrocautery

Electrocautery devices should not be used in close proximity to implanted Virtis System components. Contact between an active electrode and an implanted Virtis System component may cause direct stimulation of the sacral nerve, which may damage the Virtis System or cause severe injury.

Electromagnetic Interference (EMI)

Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from electromagnetic interference, and the Virtis System should not be affected by common sources of EMI. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of

a neurostimulator. However, sources of strong electromagnetic interference can result in the following:

- **Serious injury or death**, resulting from heating of the implanted components of the neurostimulation system and damage to surrounding tissue
- **System damage**, resulting in loss of or change in symptom control, which may require surgical replacement
- **Operational changes** to a stimulator or trial stimulator, which may cause stimulation to turn on or off, or stimulation settings to reset to default clinician settings, resulting in loss of stimulation, return of symptoms, or requiring reprogramming by a clinician
- **Unexpected changes** in stimulation, causing a momentary increase in stimulation which may cause an uncomfortable or jolting sensation, which some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation may feel uncomfortable, it does not damage the device or injure the patient directly. In rare cases, as a result of the unexpected change in stimulation, patients have fallen down and been injured.
- **Loss of communication** during programming, which may result in incorrect or incomplete programming
- **Uncomfortable warmth** or burning from heating of the implanted components

If any system components (stimulator, leads, lead fragments, or extensions) remain implanted in the patient after a partial system explant, the patient is still susceptible to the adverse effects listed above.

Table 2 - Potential effects of EMI from devices or procedures

Medical procedure	Patient injury	Device damage	Momentary increase in stimulation	May turn device on or off	Intermittent stimulation	See guidelines
Bone growth stimulators		X	X		X	page 13
Defibrillation/ cardioversion	X	X	X		X	page 9 page 10 page 11 page 13
Dental drills and probes		X				page 13
Therapeutic Diathermy[a]	X	X			X	Page 6
Electrocautery	X	X				page 6
Electrolysis		X			X	page 13
Electromagnetic field devices (e.g., arc welding, power stations)			X	X	X	page 8

Medical procedure	Patient injury	Device damage	Momentary increase in stimulation	May turn device on or off	Intermittent stimulation	See guidelines
High-output ultrasonics		X				page 13
Household items			X	X		page 8
Laser procedures		X				page 13
Lithotripsy		X				page 13
Magnetic resonance imaging (MRI)	X	X	X	X	X	page 5
Psychotherapeutic procedures	X	X	X	X	X	page 13
Radiation therapy		X				page 13
Radio-frequency (RF) / microwave ablation	X	X			X	page 11
Theft detector	X			X		page 8
Therapeutic magnets				X		page 6
Therapeutic ultrasound[a]	X	X			X	page 6
Transcutaneous electrical nerve stimulation (TENS)			X	X		page 13

[a] Warning: Diathermy, shortwave, microwave, and/or therapeutic ultrasound diathermy must not be used on Virtis System patients. See page 6 for more information.

The Most Common Sources of EMI

Hospital or Medical Environment

Advise patients to inform healthcare personnel that they have a Virtis System (US patients show their patient identification card) before any procedure is performed. Many diagnostic procedures, such as x-rays and ultrasounds, may be performed without affecting the Virtis System. However diagnostic and therapeutic equipment with higher energy levels may interfere with the Virtis System. See contraindications, warnings, and precautions for specific therapies and procedures.

Home, Work, or Public Environment

Advise patients to avoid or exercise caution when in the presence of the following sources of EMI:

- Theft detectors or security screeners such as those used at entrances or exits of stores, libraries, and other public places, and airport security screening devices. Advise patients to

exercise caution when approaching these devices and request assistance to bypass the device. If the patient must proceed through the device, advise the patient to turn their stimulator or trial stimulator off and move carefully and quickly through the center of the screener.

- Power lines and transmission towers
- Electric substations, power generators, and large transformers
- Portable and mobile RF communications equipment
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters
- Electric fences
- Body fat measurement scales

Equipment that should not affect the operation of the implanted or trial stimulator:

- Cell phones and Bluetooth devices
- Electric toothbrushes, electric shavers, and hair trimmers
- Microwave ovens
- Appliances such as washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors
- Electric blankets and heating pads
- Personal computers and tablets, copiers, and fax machines
- Televisions, AM/FM radios, stereos, and personal music players
- Vacuum cleaners and electric brooms

Advise patients to move away from the EMI source if they suspect EMI is disrupting Virtis System operation.

For additional information about equipment that generates electromagnetic interference, contact Cirtec Medical Corporation Customer Service.

Heat Due to Charging

Advise patients not to charge their stimulator while they are sleeping. While charging, the charging paddle may become too warm, which may result in a burn. Failure to use the adjustable belt or an adhesive patch as shown in the charging instructions may also result in a burn.

Magnet

Do not use the optional magnet near implanted medical devices such as pacemakers, cardioverter defibrillators (ICDs), or other neurostimulation systems. The magnet may interfere with the operation of these implanted devices.

Modification

Do not modify the trial stimulator, Clinician Programmer, Programmer Charger, Pocket Programmer, or charging accessories. Modification of any Virtis System component may result in damage to the system, compromised system integrity, or patient injury.

Other Active Implanted Medical Devices

The neurostimulation system may affect the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps. Physical proximity may cause sensing problems and inappropriate device responses. Clinicians involved with both devices should evaluate any potential interference problems before surgery. Careful programming of each system may be necessary to optimize the patient's benefit from each device. The effects of a Clinician Programmer, Programmer Charger, or Pocket Programmer interacting with other active implantable medical devices

(e.g., pacemakers, defibrillators, implanted spinal cord and peripheral nerve stimulators, deep brain stimulators, and implantable infusion pumps) are unknown. Exercise caution when other implanted devices are operating concurrently with the Virtis System. Possible effects include sensing problems and unwanted device responses.

Neurostimulator interaction with implanted cardiac devices

When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (e.g., pacemaker, defibrillator), clinicians involved with both devices (e.g., neurologist, neurosurgeon, cardiologist, electrophysiologist, urologist, urogynecologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery. To minimize or prevent the effects described below, implant the devices on opposite sides of the body and follow any additional instructions.

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from cardiac devices and could result in an inappropriate response of the cardiac devices. Minimize or prevent the cardiac device from sensing the neurostimulator output by:
    - » programming the neurostimulator therapy output to a bipolar configuration
    - » consider using bipolar sensing on the cardiac device
    - » checking for interactions

Programmer Interaction with Other Implanted Devices

Do not charge the stimulator, use the Clinician Programmer, or use the Programmer Charger or Pocket Programmer to change program settings when near a person who has an implanted device such as a pacemaker, defibrillator, implanted spinal cord stimulator, peripheral nerve stimulator, deep brain stimulator, implanted infusion pump, or other implanted device. The effects of the Virtis programmers on other implanted devices are unknown.

Radio-Frequency or Microwave Ablation

Safety has not been established for radiofrequency (RF) or microwave ablation in patients who have a Virtis System. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage.

Stimulator Case Damage

If the stimulator case is ruptured or pierced from outside forces, exposure to the battery chemicals may result in severe burns.

Precautions

Clinician Training

Implanting clinicians should be trained on the implantation and use of the Virtis Sacral Neuromodulation (SNM) System.

Prescribing clinicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms and should be trained on the use of the Virtis SNM System.

Patient Populations

Use in Special Populations. Safety and effectiveness of sacral neuromodulation has not been established for pediatric patients (under the age of 16), pregnant or nursing patients, or patients with neurological disease origins (such as multiple sclerosis or diabetes), or for bilateral stimulation.

Virtis System Considerations

Allergic Reaction to Product Materials

Before implanting a Virtis System, determine if a patient may have an allergic reaction to implanted or external component materials, including the charging paddle and optional adhesive patches.

Implanted Stimulator Location

When determining the stimulator pocket location, do not select a pocket location that is close to bony structures or areas of pressure or restriction. Creating a pocket in these areas may cause patient discomfort or lead migration.

Ensure the implant location is:

- On the opposite side of the body from another active implanted device (e.g., pacemaker, defibrillator) to minimize possible interaction between the devices.
- Away from areas of restriction or pressure to minimize the potential for skin erosion, patient discomfort, or damage to components.

- In an area accessible to the patient for proper operation of the Programmer Charger.

Patients Who Are Poor Surgical Risks

Do not implant a Virtis System if a patient is considered a poor surgical risk. Implanting a Virtis System has risks similar to other surgical procedures such as bleeding.

Bleeding risk - Patients should be assessed preoperatively for the risk of increased or uncontrolled bleeding. Clinicians should consider all factors that may increase the risk for bleeding such as antithrombotic agents, vascular abnormalities, and coagulation disorders. Fatal retroperitoneal hematoma in the postoperative period has been reported for similar devices following implant of the chronic lead in patients who were on anticoagulation therapy.

Clinician Training

Implanting clinicians should be trained on the implantation and use of the Virtis SNM System.

Prescribing clinicians should be experienced in the diagnosis and treatment of lower urinary tract symptoms, incontinence, and retention and should be trained on the use of the Virtis SNM System.

Preoperative Considerations

Antibiotics. To help prevent infection, use prophylactic antibiotics. An infection may require removal of the Virtis System.

Care and Handling of Components. Before implanting, handle system components with care. Excessive heat, traction, bending, twisting, or the use of instruments that may cut, crush, or damage a component may cause component failure.

Charging Stimulator Before Implant.

- Do not place the charging paddle directly on an unhealed wound. The charging paddle is not sterile. Contact with an unhealed wound may result in an infection.
- To help prevent infection, make sure the Implanted Stimulator Battery icon displays four bars (75–100%) before implanting. A sufficiently charged stimulator allows the surgical wound more time to heal before the stimulator needs charging.

Package and Component Damage. Do not use or implant a component if:

- The package is damaged or open. If a component is damaged, the system may not function properly. Using a damaged charging paddle or power cord may cause an electrical shock.
- The sterile package is punctured or damaged, which may have compromised component sterility.
- The implantable stimulator was dropped on a hard surface, which may cause the implantable stimulator not to function properly.

Single-Use, Sterile Device. Implantable Virtis System components are single use only. Do not resterilize a system component or reimplant an explanted system component because of risk of infection or device malfunction.

Trial Cable. The trial cable is a single-use component. Do not resterilize the trial cable because of risk of infection.

Use-By Date. Do not implant a Virtis System component if the use-by date has expired. The use-by date is on the sterile package and the shelf carton. Return expired components to Cirtec Medical Corporation.

Other Medical Procedures and Therapies

System Interaction with Other Medical Treatments and Procedures. A Virtis System may interact with the following therapies or procedures:

- Diagnostic ultrasound (e.g., carotid and Doppler scans) has no adverse effect on an implanted stimulator, lead, or extension. The stimulator may interfere with the scan by deflecting the ultrasonic beam.
- Diagnostic x-rays. The effects of diagnostic x-rays on an implanted or trial stimulator are typically transient because interference occurs only during the time of x-ray exposure. In some cases, the implanted or trial stimulator may need to be reprogrammed.
- CT procedures. If stimulation is on, a CT scan may damage an implanted or trial stimulator. A CT scan is unlikely to damage an implanted or trial stimulator if stimulation is off.
    - » Disconnect a trial stimulator or turn off an implanted stimulator.
    - » Minimize x-ray exposure to the Virtis System by:
        - Using the lowest possible x-ray tube current consistent with obtaining the required image quality
        - Make sure the x-ray beam does not dwell over the stimulator for more than a few seconds

        Note: For CT procedures that require scanning over the stimulator continuously for more than a few seconds, as with CT perfusion or interventional exams, attending staff should be ready to take emergency measures to treat adverse reactions.
    - » If stimulation was turned off before the CT procedure, turn stimulation on.

After a procedure, advise patients to contact their healthcare provider if they have questions or suspect their Virtis System is not functioning properly.

The following therapies or procedures may turn stimulation off or damage an implanted or trial stimulator, particularly if used in close proximity. Using these therapies or procedures may result in loss of therapy and additional surgery to remove or replace system components.

- Radiotherapy
- Lithotripsy
- External defibrillation
- Radiation therapy
- Ultrasonic scanning
- High-output ultrasound
- Transcranial magnetic stimulation (TMS)
- Electroconvulsive therapy (ECT)
- Transcutaneous electrical nerve stimulation (TENS)
- Magnetic Resonance Imaging (MRI) (Conditional for fully implanted system only)

The Virtis system has not been tested for the compatibility with the following medical procedures.

- Electrolysis
- Dental drills and probes
- Electrolysis
- Laser procedures
- Psychotherapeutic procedures

If any of the therapies or procedures listed above are required:

- For MRI, scans all conditions in the Virtis Sacral Neuromodulation System MRI Procedure Guidelines must be met, and all instructions must be followed.
- For other therapies or procedures listed above:
    - » Put the implanted stimulator in storage mode using the Clinician Programmer or by holding the Virtis Model 4900 Magnet over the stimulator for more than five seconds.
    - » All equipment, including ground plates and paddles, must be used as far away from the implanted stimulator as possible.
    - » If possible, keep fields, including current, radiation, or high-output ultrasonic beams, away from the implanted stimulator.
    - » Set equipment to the lowest energy setting clinically indicated.
    - » Following treatment, see the Patient System manual or Virtis Magnet insert for instructions on how to bring the implanted stimulator out of storage mode.
- Verify Virtis System function.

- Advise patients to contact their healthcare provider if they have questions or suspect their Virtis System is not functioning properly.

External Components

Charging With an Unhealed Wound. Do not place the charging paddle on an unhealed wound. The charging paddle is not sterile, and contact with an unhealed wound may result in an infection.

Component Compatibility. Use only the programmers and accessories in the Virtis System to program the implanted or trial stimulator, charge the implanted stimulator, charge the programmers, or adjust stimulation. The effects of non-Virtis components on a Virtis System are unknown.

Flammable Atmospheres

- Avoid using the trial stimulator, Clinician Programmer in flammable or explosive environments (e.g., flammable anesthetic mixtures or environments with greater than 25% oxygen). Using a battery powered device near flammable or explosive atmospheres can produce a spark which may cause injury.
- Advise patients to avoid using the trial stimulator, Programmer Charger, or Pocket Programmer in flammable or explosive environments (e.g., during vehicle refueling). Using a battery-powered device near flammable or explosive environments can produce a spark, which may cause injury.

Programmer Storage. If you store a Clinician Programmer, Programmer Charger, or Pocket Programmer for an extended period of time, make sure to fully charge the battery before storing, and periodically charge the battery every 6 months. The programmers use a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

Patient Activities

Activities requiring excessive twisting or stretching

Patients should avoid activities that may put undue stress on the implanted components of the Virtis SNM system. Activities that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component. Examples of such activities include gymnastics, mountain biking, and other sports or equipment that involve the movements described above. Ask your patients about the activities they are involved in and inform them of activity restrictions.

Patient Programmer Charger (PPC) recharge coil

If swelling or redness occurs near the contact site, advise the patient to contact the clinician before using the PPC again. Swelling or redness may indicate an infection or an allergic reaction to the antenna.

Component manipulation by patient (twiddler's syndrome)

Patients should avoid manipulating or rubbing the neurostimulation system through the skin. Manipulation may cause component damage, lead dislodgement, skin erosion, or uncomfortable stimulation at the implant site.

Scuba diving or hyperbaric chambers

Patients should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA).

Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their clinician.

Skydiving, skiing, or hiking in the mountains

High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. Patients should be aware that during skydiving, the sudden jerking that occurs when the parachute opens may cause lead dislodgement or fractures, which may require surgery to reposition or replace the lead.

Unexpected changes in stimulation

Electromagnetic interference, postural changes, and other activities may cause a perceived increase in stimulation, which some patients have described as uncomfortable stimulation (jolting or shocking sensation); therefore, patients should reduce the amplitude to the lowest setting or turn off the neurostimulator before engaging in activities that could be unsafe for themselves or others if they received an unexpected jolt or shock (e.g., driving, operating power tools). Patients should discuss these activities with their clinician.

Patient programming and patient control devices

Patient access to a control device

Patients must carry the PoP or the PPC at all times to have the capacity to adjust and/or turn off the neurostimulator.

Patient magnet control feature disabled

If the magnet control feature has been disabled, the patient must carry their PoP or PPC with them at all times so that they can turn the neurostimulator on or off.

Patient magnet may damage items

Patients should not place the patient magnet on or near computers, computer monitors, magnetic storage disks or tapes, televisions, cellular phones, electronic personal information managers,

credit cards, or other items affected by strong magnetic fields. If the patient magnet is too close, these items may be damaged.

Patient control device handling

To avoid damaging the patient control device, patients should not immerse them in liquid, clean it with bleach, nail polish remover, mineral oil, or similar substances; and should not drop it or mishandle it in a way that may damage it.

Patient control device use

When operating the PoP or PPC, patients should use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the control device could occur. The consequences of using a battery-powered control device near flammable or explosive atmospheres has not been tested. The PoP and PPC are not designed for use in explosive environments

PPC use

Check for skin irritation or redness near the neurostimulator during recharging. Do not sit or lie on, or apply excessive pressure to the recharger coil. Take periodic breaks during prolonged recharging. Although no direct cause and effect has been established, some patients have reported heating sensation, discomfort, blistering not caused by heating, skin irritation, or redness near the implanted neurostimulator during or after recharging. Contributing factors may include excessive pressure on the recharger, prolonged recharging periods, or individual patient physiological factors. A soft cloth may be placed between the recharge coil and skin for comfort.

Component Return and Disposal

Explanted Components

If a complaint is filed, all explanted leads, extensions, and explanted stimulators associated with the complaint must be returned to Cirtec Medical Corporation. Explanted components that are not associated with a complaint may be returned at the discretion of the customer. Do not autoclave the components or expose them to ultrasonic cleaning.

Contact Cirtec Medical Corporation Customer Service for instructions about returning explanted components. If you are returning components to Cirtec Medical Corporation, also return the associated components and accessories needed to make a full evaluation.

Explant the stimulator before cremation. The cremation process may cause the implanted stimulator battery to explode. Dispose of unreturned components according to local environmental regulations.

Programmers

Nuvectra programmers contain rechargeable lithium batteries. Do not incinerate or dispose of the programmers in general household trash. When no longer needed, return the programmers to Cirtec Medical Corporation or consult local regulations for proper disposal of electronic devices.

Individualization of Treatment

Patients achieve the best results when they are informed about the surgical procedure, therapy risks and benefits, self-care responsibilities, and follow-up requirements. Maximum benefits from the neurostimulation system require long-term postsurgical management.

Patient Selection

Select patients carefully to ensure that:

- Their symptoms are of physiological origin
- They demonstrate the ability to properly operate the Virtis System, including recharging the system on a recurring basis
- They are appropriate candidates for surgery
- They received satisfactory results from a stimulation trial

Patient Counseling Information

Patient counseling information - Clinicians should:

- Provide patients with the following:
  - » Information about the components of the SNS system.
  - » Instructions for using the PoP and PPC.
- For trials, give the patient the Patient Stimulation Trial Manual at a minimum, review these sections with the patient:
  - » Living with your InterStim system
  - » Information for your doctors
- For permanent implant, give the patient the Virtis SNM System Patient System Manual, Programmer Charger Quick Reference, and Pocket Programmer Quick Reference at a minimum, review these sections with the patient:
  - » Contact your doctor section of the introduction
  - » Using your Pocket Programmer
  - » Using your Programmer Charger
- Instruct patients to always do as follows:

» Always inform health care professionals, such as clinicians and dentists, that they have an implanted SNM system. Patients should bring their Virtis Patient System Manual to all medical and dental appointments to help them answer questions that the health care professional may have regarding medical procedures and potential device interactions.
» Always carry a PoP or PPC to be able to adjust and/or turn off the neurostimulator.
» Always bring their PoP or PPC to Virtis SNM system related appointments.
» Contact their clinician if they notice any unusual symptoms or signs.

Adverse Events Summary

Potential risks resulting from a Virtis System implant procedure are similar to other sacral neuromodulation implant procedures. All known potential adverse events are described in this section. The data are derived from literature review of published clinical study data for similar therapies.

- Temporary pain at the implant site or infection
- Seroma, hematoma, or blood clot
- Patient use of anticoagulation therapies may increase the risk of procedure-related complications such as a hemorrhage

Risks of using an implanted Virtis System include, but are not limited to the following:

- Negative change in urinary or bowel function.
- Change in stimulation, painful stimulation, or problem with the operation of the system due to electromagnetic interference from other electrical devices, medical equipment, or medical procedures
- Pain at the stimulator site
- Lead migration.
- Seroma or hematoma at the stimulator site
- Skin erosion at the stimulator site
- Uncomfortable or painful stimulation related to a system issue caused by random failure of a system component or battery, change in electrode position, loose electrical connection, lead or extension insulation breach or fracture
- Infection at the site of a Virtis System component
- Therapy failure caused by random failure of a system component (e.g., battery drain, lead or lead insulation break, loose connection, or electrical short)
- Allergic response or tissue reaction to the implanted system materials

For a comprehensive summary of adverse events, refer to the clinical summary.

Virtis System Clinical Summary

Introduction

The safety and effectiveness of the Virtis SNM System for urinary control was based on a systematic review of published clinical studies that evaluated the safety and/or effectiveness of the fully implantable Medtronic InterStim SNM System.

The Virtis SNM System is similar in design, technology, performance, indications for use, output characteristics, and patient population to the InterStim system evaluated in the studies. The literature review strategy was conducted according to the guidelines and methods suggested by Egger[2], Smith, and Altman in their book "Systematic Reviews in Health Care."[2]

The result of the systematic review and meta-analysis included seven articles, representing a total of 1,277 patients implanted with SNM systems. Safety data were reported in a total of 1,111 patients that had SNM system implants, and effectiveness data were reported in a total of 1,075 implanted patients that had SNM system implants. The articles included in the systematic review and meta-analysis included patients with urinary retention (UR) and OAB. The OAB patients had symptoms of urinary urgency- frequency (UF) and/or urinary urgency incontinence (UUI).

Based on nonclinical studies that demonstrated that the Virtis SNM system has comparable output characteristics to the InterStim system reported in the literature, the objective of the systematic literature review was to use published clinical literature to provide clinical evidence of the safety and effectiveness of the device for the improvement of UUI, UF, and UR symptoms.

Safety of the Virtis SNM system was demonstrated by a review of incidence of complications of the InterStim System from seven literature articles for urinary dysfunction indications. These consisted of two review articles and five original clinical research articles, which totaled 1,111 patients.

Effectiveness of the Virtis SNM system was evaluated using the responder rate endpoint (obtained from the literature specific to the improvement of urinary dysfunction with the use of SNM systems. Responder rate is defined as:

- For UUI: Proportion of patients that obtained at least a 50% reduction in the number of leaks per day (analyses included all leaks or only urgency leaks)
- For UF: Proportion of patients that obtained at least a 50% reduction in the number of voids per day or less than 8 voids per day
- For UR: Proportion of patients that obtained at least a 50% reduction in the volume per catheterization

Summary of Literature Search Strategy

The objective of the literature review was to systematically identify, select, collate and review relevant studies to support the marketing application of the Virtis SNM System. A summary of the literature search strategy and inclusion/exclusion criteria is provided below.

The scientific literature database Medline/PubMed was used by Cirtec Medical Corporation and duplicated by FDA to perform a search for published data relevant to the clinical evaluation of the Virtis SNM System. The search was conducted for literature published through January 15, 2019.

All articles from the published literature were triaged for inclusion based on their suitability prior to full review. Studies were selected for inclusion in this review if the methods section clearly indicated that the equivalent SNM system (InterStim) was used in the treatment of urinary dysfunction. These studies were initially selected by Cirtec Medical Corporation based on the study endpoints and the safety and effectiveness criteria selected. Systematic meta-analysis reviews, randomized clinical trials, and prospective clinical studies were included by Cirtec Medical Corporation because these were deemed to be of the highest data quality. Individual cohort studies published less than 15 years ago were included, or if the cohort studies were published over 15 years ago and had more than 100 patients, the studies were also included in this search.

The literature search strategy from Cirtec Medical Corporation, and duplicated by FDA, consisted of the following three steps. FDA added one more step to select articles focused on urinary dysfunction that had a clearly defined study design:

1. The Medline database was searched for indexed articles using 21 MeSH terms (Medical Subject Headings, National Library of Medicine) and broad relevant terms for pelvic neurostimulation systems and treatment of urinary incontinence. After eliminating duplicates, there were 923 articles.
2. The abstract of each article was reviewed and categorized according to the same rigorous inclusion/exclusion criteria used by Cirtec Medical Corporation. Exclusions eliminated 896 articles, resulting in the selection of 27 articles for full review.

Exclusions included: n < 100 pts non-randomized (42 articles), n < 100 pts, > 15 years (83 articles), > 10 years, non-randomized (1 article), animal data (3 articles), technical note/clinician technique (66 articles), case report/series (38 articles), cost assessment (20 articles), disease state (17 articles), dissimilar medical area (7 articles), dissimilar patient population (64 articles), dissimilar device (e.g., tibial) (151 articles), dissimilar indication (53 articles), excluded study type (e.g., bench, retrospective study) (123 articles), intra-device comparison (2 articles), medicinal substance (16 articles), no abstract (53 articles), no author (4 articles), no clinical data (98 articles), no device evaluation/no device identification (32 articles), patient care management (30 articles), and articles that only included patient physiology/anatomy/demographics (54 articles). Of note, the exclusion numbers above add to 957, because some excluded articles fit in more than one category.

1. Three additional articles were selected from other sources including two articles identified from meta-analysis reviews and one more that was found by cross reference (i.e., it was cited in the most current study publication). This step brought the review to a total of 30 articles for full assessment.
2. FDA performed an additional step to exclude articles that focused on bowel dysfunction. FDA also excluded articles on urinary dysfunction that either reported results in a study cohort already included in the literature review or articles that did not have adequate details on study design methodology. In the case of the InSite study, two articles were included (Siegel 20155, and Siegel 20187), which reported on two phases of this study. Phase 1 was a randomized, controlled trial (RCT) comparing SNM to standard medical therapy (SMT) at 6 months. Phase 2 was a prospective evaluation of the safety and effectiveness of SNM for 5 years. Overall, a total of seven articles were deemed appropriate for inclusion by the FDA. Out of the seven included articles, all seven had endpoints appropriate for the assessment of safety, and six of seven articles provided long-term effectiveness endpoints appropriate assess improvements in urinary dysfunction.

Safety and Effectiveness Results

Safety Results

FDA evaluated the safety of the Virtis SNM System based on the published articles on the use of the InterStim System for urinary dysfunction.

A total of seven published articles on urinary dysfunction were evaluated. These consisted of two review articles (Herbison 2009[3] and Siddiqui 2010[4]) and five original clinical research articles (Amundsen 2018[1], Siegel 2015[5], Siegel 2018[7], White 2009[10], van Kerrebroeck 2007[9]). Since patients from Siegel 2015[5] (InSite Phase 1) were rolled over to Siegel 2018[7] (InSite Phase 2), only the number of patients from Siegel 2018[7] are used for calculations of the total number of implanted patients. These articles presented safety data in a total of 1,111 patients that had SNM system implants.

Safety Results from Literature Sources

The literature provided strong evidence to support low serious AE (SAE) rates for the use of the InterStim System to treat urinary dysfunction. A total of 1,111 patients had SNM system implants.

All AEs and SAEs reported per article are provided in Table 3.

Table 3 - Adverse Events Reported in the Literature for the InterStim System

Article Reference	Follow up duration	Adverse Events	SAE
Amundsen 2018[1] (139 subjects)	2 years	Device revision 3% Device removal 8.6% Infection 2.9% Pain 1.4% Procedural pain 6.0%	NR Ł
Herbison 2009[3*] (219 subjects)	12 months	Pain at implant site 15.3% Pain, new 9% Suspected lead migration 8.4% Infection 6.1% Transient sensation of electrical shock[**] 5.5% Pain, lead site 5.4% Surgical revision 33.3%	NR Ł
Siddiqui 2010[4***] (Spinelli 2005[8]: 127 subjects)	13.8 months	Lead migration 7% Lead revision performed 3%	NR Ł
Siegel 2015[5€] (InSite study – Phase 1) (59 subjects with test stimulation, 51 subjects with full system implant)	6 months	Change in stimulation, undesirable 10.2% Pain, implant site 8.5% Lead migration/dislodgement 3.4% Infection, implant site 3.4% Surgical intervention[†] 3.9%	0%
Siegel 2018[7] (InSite study – Phase 2) (272 subjects)	5 years	Surgical intervention related to tined lead 22.4% (primary safety endpoint) Undesirable change in stimulation 22% Implant site pain 15% Therapeutic product ineffective 13% Implant site erosion 0.4% Other AEs 6% Surgical interventions [****] Due to AE 30.9% Due to Battery replacement 33.5% Due to Lack or loss of effectiveness33.5% Permanent explant 19.1%	Implant site erosion 0.4% §

Article Reference	Follow up duration	Adverse Events	SAE
van Kerrebroeck 2007[9] ¥ (152 subjects)	5 years	New pain/undesirable change in stimulation 28.3% Pain at neurostimulator site 19.8% Pain at lead site 7.9% Infection at lead or neurostimulator site 7.9% Sensation of electric shock** 7.9% Undesirable change in voiding function 7.2% Lead migration 8.6% Technical problems during implant (surgery) 5.3% Device problem 10.6% Other AE 33.6% Surgical intervention 39.5% Device explant 10.5% Device exchange 23.7%	NR Ł
White 2009[10] € (221 subjects with test stimulation, 202 subjects with full system implant)	36.9 months	Pain, implant site 2.9% Device malfunction, secondary to trauma 8.9% Infection 3.5% Post-operative hematoma requiring intervention 1.5% Lead migration 5.9% Explant due to lack of effectiveness 3.5% Revision due to battery depletion 2% Elective removal 5% Overall surgical intervention 30.3%	NR Ł

NR Ł Rates are not reported by the authors or not meaningful due to small sample size (n < 30).

* Only AEs with > 5% occurrence rate were reported by the authors.

** Typically classified as Uncomfortable sensation or stimulation.

*** Review article referencing multiple original clinical articles; Only one original article (Spinelli 20058) met the inclusion/exclusion criteria set for literature review, and data from this article is provided.

**** The sub-categories of Surgical interventions are not mutually exclusive.

€ Authors reported AE rates in subjects receiving SNM test stimulation.

Ŧ Authors reported this AE rate in subjects with full system SNM implant.

§ This SAE occurred in 1 subject and was resolved.
¥ Device- and therapy-related AE rates are combined and are not mutually exclusive.

As stated earlier, the Siegel 2015[5] and Siegel 2018[7] articles reported results from the InSite study. The InSite study was Medtronic's post-approval study as required by the FDA at the time of approval of a Premarket Approval (PMA) to help assure continued safety and effectiveness of the approved device. Post-approval studies (PAS) are conditions of device approval.

More information on the InSite study for P970004 can be found on FDA's website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=101911&c_id=335

The enrollment across 38 sites included a total of 571 subjects with a diagnosis of OAB as demonstrated by greater than or equal to eight voids per day and/or a minimum of two involuntary leaking episodes on a 3-day voiding diary. Subjects must have failed or were not candidates for more conservative medical treatments and were 18 years of age or older. Additional inclusion/exclusion criteria can be found in Siegel (2015[5]).

As stated above, the InSite study was conducted in two phases. Phase 1 was a prospective, multicenter RCT comparing SNM to SMT at 6 months. Phase 2 of the InSite study was a prospective evaluation of the safety and effectiveness of SNM for 5 years. Siegel (2015[5]) reported results on Phase 1 of the InSite study, and Siegel (2018[7]) reported results on Phase 2 of the InSite study.

The InSite Phase 1 study (Siegel et al, 2015[5]) included 147 randomized subjects (70 to SNM and 77 to SMT). Adverse event data from a total of 59 subjects assigned to the SNM group were available at the 6-month follow-up. There were no unanticipated adverse device effects. Device-related AEs (related to surgery, therapy, device, or implant site) occurred in 30.5% (18/59) of subjects. None of the device-related AEs was serious. The most common device-related AEs in SNM subjects were undesirable change in stimulation 10.2% (6/59), implant site pain 8.5% (5/59), lead migration/dislodgment 3.4% (2/59), and implant site infection 3.4% (2/59). For the 51 SNM subjects with full system implant, the 6-month post-implant surgical intervention rate was 3.9% (2/51).

The InSite Phase 2 study (Siegel et al, 2018[7]) included 340 subjects who completed the test stimulation, of which 272 received a full system implant. The primary safety objective of the study was to demonstrate that the upper bound of the 95% confidence interval for the cumulative 5-year rate of AEs related to the tined lead requiring surgery was less than 33%. The 5-year cumulative rate of surgical intervention related to tined lead was 22.4% (95% CI 16.6-27.7), which fulfilled the primary safety objective. There were no unanticipated device-related AEs. In subjects with a fully implanted system, an undesirable change in stimulation was the most common AE, which occurred in 60 of 272 subjects (22%), followed by implant site pain in 40 subjects (15%) and therapeutic product ineffectiveness in 36 subjects (13%). All other device

related AEs, which developed upon or after implantation, were reported in fewer than 6% of subjects. One event, implant site erosion, was classified as serious but it resolved. Surgical interventions were also reported, including revision, replacement, and permanent explant of any device component. A subject could have experienced multiple types of surgical interventions and an intervention could have been due to multiple reasons, such as an AE, subject request, lack or loss of effectiveness or battery replacement. Surgical intervention was performed in 84 subjects (30.9%) due to an AE and 91 (33.5%) underwent a surgical intervention due to battery replacement. In all 272 implanted subjects, the permanent explant rate was 19.1% (95% CI 14.1-23.9) at 5 years. The top reason reported by investigators for permanent explant was an AE in 30 of the 272 subjects (11.0%), which was most often an ineffective therapeutic product (7 of 272 or 2.6%). Other reasons included subject need for magnetic resonance imaging, lack or loss of effectiveness and withdrawal of subject consent. Of the permanent explants, 23 (8.5%) were associated with a lack or loss of effectiveness. Surgical intervention was performed in 91 subjects (33.5%) due to lack or loss of effectiveness after full system implantation.

van Kerrebroeck et al (2007[9]) conducted a prospective, single-arm, multicenter study initiated after FDA approval of InterStim therapy. A total of 163 subjects were enrolled and 152 subjects received the full system implant. Safety data through 5- year follow-up were presented in all implanted subjects, and relatedness to device or therapy was provided. Table 3 provides AE rates combined across device- related and therapy-related AEs, and as such, an AE may be either device-related or therapy-related or both. There were 102 (67%) subjects who had at least one device- or therapy-related AE. Of the AEs, 31 were device-related (24 subjects, 15.8%) and 240 were therapy-related (97 subjects, 63.8%). Most AEs (96%) were resolved by the time the data were analyzed. A total of 60 (39.5%) subjects experienced an AE requiring surgical intervention, with 36 (23.7%) requiring device exchange. The system was explanted from 16 subjects due to adverse event or lack of effectiveness.

Amundsen et al (2018[1]) conducted a multicenter, open-label, RCT in 386 women with more than six episodes of UUI over 3 days and inadequately managed by medications. Subjects were assigned to the SNM arm (n=194) or the Botox arm (n=192). Of the 194 subjects assigned to SNM, 139 received full implants, and safety data are reported in these subjects. At 2 years, device revisions occurred in 4/139 (3%) because of decreased effectiveness. Device removal occurred in 12/139 (8.6%) (infection 2.8%, decreased effectiveness 2.8%, subject desire 1.4%, and pain 1.4%). One participant was re-implanted after a resolved surgical site infection. Post-procedure pain was reported in 6% of subjects. Additional analysis compared all AEs between Botox and SNM groups, and the only observed clinical difference was an increased rate of urinary tract infections in subjects treated with Botox.

White et al (2009[10]) conducted a prospective, longitudinal study in 221 subjects who received test stimulation, of which 202 received full system SNM implants. Subjects had refractory urinary urgency and frequency (n=121), urge incontinence (n=63), or urinary retention (n=37). At a mean follow-up of 36.9 months, 67 subjects (30.3%) had experienced AEs that required surgical interventions at the lead and neurostimulator site. The complications included pain at the

site of the neurostimulator in six subjects (2.97%), device malfunction secondary to trauma in 18 (8.9%), infection in seven (3.5%), postoperative hematoma requiring re- exploration in three (1.5%), and lead migration in 12 subjects (5.9%). An additional seven subjects (3.5%) underwent device removal for lack of effectiveness, four subjects (2.0%) required revision secondary to battery expiration, and 10 subjects (5.0%) underwent elective removal.

Herbison et al (2009[3]) reported safety data from three articles (Hassouna 2000; Jonas 2001; Schmidt 1999) with 219 implanted subjects at 12 months. Only AEs with more than 5% prevalence were reported by the authors. These AEs included pain at the implant site (15.3%), new pain (9.0%), suspected lead migration (8.4%), infection (6.1%), transient sensation of electric shock (5.5%), and pain at the lead site (5.4%). Surgical revision of the implant or leads had to be carried out in 33.3% of the subjects.

Siddiqui et al (20104) was a review article that summarized safety data from six original articles (five full-text, one abstract only). Only one of the articles (Spinelli 20058) met Axonics' literature review inclusion/exclusion criteria, and AE data from this study are summarized in Table 3. This article reported AEs in 127 subjects followed up for an average duration of 13.8 months. Lead migration rate as reported at 6 months was 7%, and lead revision was performed in 3% of the cases.

Effectiveness Results

The analysis of effectiveness for the treatment of urinary dysfunction was based on a review of six of the seven articles discussed above for safety. The study by White et al (2009[10]) was excluded from the effectiveness evaluation since that study did not provide data on long term effectiveness results. Since subjects from Siegel 2015[5] (InSite Phase 1) were rolled over to Siegel 2018[7] (InSite Phase 2), only the number of subjects from Siegel 2018[7] are used for calculations of the total number of implanted subjects. The six articles encompassed 1,075 subjects with SNM system implants.

The articles included in the systematic review and meta-analysis included subjects with UR and OAB. The OAB subjects had symptoms of UUI and/or UF.

Key effectiveness outcomes from the published literature on the InterStim System are presented in Table 4.

Table 4 - Effectiveness Outcomes Reported in the Literature for the InterStim System

Article Reference	# Subjects Receiving Test Stimulation	# Subjects Receiving Permanent Implant (% of subjects receiving test stimulation)	Follow up Duration with Permanent Implant # subjects at follow up (% of subjects receiving permanent implant)	Effectiveness Endpoint (Responder Rate)
Amundsen 2018[1]	169 (UUI)	139 (82%)	2 years 122 subjects (88%)	50%*
Herbison 2009[3**]	NR	278 (NR)	NR	Details in text
Siddiqui 2010[4***]	NR	234 (OAB) (52-77%¥)	6 months-29 months	45% of subjects reported a lack of daily incontinence episodes
Siegel 2015[5] (InSite study – Phase 1)	59 (OAB) 29 (UUI) 19 (UF)	51 (86%)	6 months 51 subjects (100%)	76% (OAB) 71% (UUI) § 61% (UF) Complete continence in 39% of UUI subjects
Siegel 2018[7] (InSite study – Phase 2)	340 (OAB) 202 (UUI) 189 (UF)	272 (80%)	5 years 150 subjects (OAB)(55%) 118 subjects (UUI) 109 subjects (UF)	82% (OAB) 76% (UUI) § 71% (UF) Complete continence in 45% of UUI subjects
van Kerrebroeck 2007[9]	163 103 (UUI) 28 (UF) 31 (UR)	152 (93%) 96 (UUI) 23 (UF) 31 (UR)	5 years 105 subjects (69%) 65 subjects (UUI) 27 subjects (UF) 13 subjects (UR)	58% (UUI) § 40% (UF)† 71% (UR)

* Responder rate estimated from graph provided in the article.

** Number of subjects with the full system implanted was not provided in the review article and was calculated by Axonics based on data in original clinical research articles.

*** Authors reported effectiveness data based on three most representative studies.

¥ This rate was reported in the article.

§ Analysis performed on all leak episodes.

† Responder rate was calculated using only one of the two standard criteria used for UF effectiveness. Only criterion of ≥50% reduction in voids as

compared to baseline was used; the criterion of reduction to less than 8 voids was not used.

NR Not reported.

As stated in the Safety Section above, two articles (Siegel 2015[5] and Siegel 2018[7]) presented results of the InSite study. Siegel (2015[5]) reported results on Phase 1 of the InSite study and Siegel (2018[7]) reported results on Phase 2 of the InSite study.

Phase 1 was a prospective, multicenter RCT comparing SNM to SMT at 6 months. Phase 2 of the InSite study was a prospective evaluation of the safety and effectiveness of SNM for 5 years.

Siegel, et al (2015[5]) included 147 randomized subjects (70 to SNM and 77 to SMT). Fifty-nine (59) subjects received SNM test stimulation, of which 51 received the full SNM implant and were available at the 6-month follow-up. Seventy-three (73) subjects received SMT and were available at the 6-month follow-up. Results are reported as the proportion of subjects with both UUI and UF that had a minimum of a 50% reduction in urinary incontinence episodes or voids per day or a return to eight voids (normal voiding). Two types of analyses were performed – an Intent to Treat (ITT) analysis was performed based on subject assignment to the randomized group; and an as treated analysis was performed based on the treatment received, and in subjects who had both baseline and follow-up visit data. The ITT OAB responder rate at 6 months was 61% in SNM subjects and 42% in SMT subjects. The as treated OAB responder rate at 6 months was 76% in the SNM group and 49% in the SMT group. In the SNM group, 39% of subjects achieved complete continence. The responder rate in UUI subjects was 71% and in UF subjects was 61%. This study provided level 1 evidence of the objective and subjective superiority of SNM over standard medical therapy in subjects with OAB.

Siegel, et al (2018[7]) reported results on Phase 2 of the InSite study, which included a larger cohort and longer follow-up duration. The 2018 study had an initial enrollment of 340 subjects with OAB that underwent test stimulation, of which 202 had UUI and 189 had UF. Among these subjects, 272 (80%) received a full system implant of the SNM device. Of the 272 OAB subjects that received a full system implant, 150 completed the 5-year follow-up visit, of which 118 were UUI subjects and 109 were UF subjects. Responder rates at 5 years were analyzed using two methods. The Modified completers analyses included all subjects who received a full system implant and completed a baseline and 5-year follow-up visit or were exited prior to 5- years due to device-related AE or lack of effectiveness (n=183). The Completers analyses comprised all subjects who received an implant and completed a baseline and 5-year follow-visit (n=150). Using the Modified completers analysis, the 5-year responder rate was 67% in OAB subjects, 64% in UUI subjects and 57% in UF subjects. Complete continence was achieved in 38% of the UUI subjects. Using the Completers analysis, the 5-year responder rate was 82% in OAB subjects, 76% in UUI subjects and 71% in UF subjects. Complete continence was achieved in 45% of the UUI subjects.

Amundsen, et al (2018[1]) reported results from the ROSETTA trial which included randomized subjects with UUI (194 to SNM and 192 to Botox (BTX)). One hundred sixty-nine (169) subjects received SNM test stimulation and subjects who reported ≥ 50% reduction from baseline in UUI episodes continued to the SNM implant stage. Of the 169 test stimulation subjects, 139 (82%) underwent full SNM system implant. One hundred and fifty-nine (159) subjects were BTX clinical responders following one-month injection and continued to be followed for effectiveness. Follow-up duration was 2 years, and 122 SNM subjects and 138 BTX subjects provided diary data at the 2-year visit. Intent to treat responder rate at 2 years for SNM treatment was reported as 50%. The low responder rate in this study may be due use of ITT analysis, which is the most conservative type of analysis. Overall, the authors concluded that both SNM and BTX treatments resulted in similar improvement of UUI episodes at 2 years.

van Kerrebroeck, et al (2007[9]) included 163 subjects enrolled with urinary dysfunction. Of these subjects, 103 had UUI, 28 had UF, and 31 had UR. The majority of these subjects (129) had been implanted with the SNM device as part of a previous clinical trial (MDT-103) and were crossed over to this long-term follow-up study. The remaining 34 subjects were newly enrolled in this study, of which 23 received the full SNM system implant. A total of 152 subjects with full implants were followed for a duration of 5 years. One hundred five (105) subjects (69%) completed the 5-year follow-up visit, of which 87 reported voiding diary results. SNM therapy success was measured by ≥ 50% improvement from baseline in voiding diary variables. At 5 years, UUI subjects demonstrated a responder rate of 58% (for leaks per day), and UF subjects achieved a responder rate of 40% (for voids per day). UR subjects had a responder rate of 58% (for catheterizations per day) and 71% (for volume per catheterization). Note that even though the standard literature-based criteria for UF responder rate is defined as ≥ 50% reduction in voids as compared to baseline or reduction to less than eight voids per day (normal voiding), this article used only the criterion of ≥ 50% reduction in voids as compared to baseline for calculating responder rate. This may explain the lower responder rate for UF subjects in this study as compared to other studies.

Herbison, et al (2009[3]) includes a review of eight articles reporting effectiveness of SNM treatment for urinary dysfunction. Seven of the eight articles reported results from studies that randomized subjects to an immediate SNM implant group and delayed SNM implant group, and results from the immediate implant group were provided by the authors. Effectiveness results were reported in a total of 278 implanted subjects across the eight articles. Seven of the eight studies reported a subject follow-up duration of 6 months, with the remaining one study reporting follow-up results from 12 months. The review article reported highly significant changes in all reported effectiveness outcomes.

Siddiqui, et al (2010[4]) reviewed literature pertaining to effectiveness of SNM treatment for OAB subjects. Seven studies met the criteria of "good" quality. Three of these studies were designated as most representative by the authors and were included in the effectiveness reporting in Table 4. In these three studies, 234 (52- 77%) subjects received full implants following a successful test

stimulation period. Follow-up duration ranged from 6 months to 29 months. At the follow-up visits, approximately 45% of subjects reported a cure or lack of UUI episodes.

Results

Effectiveness Conclusions

The results compiled from the literature available for the approved Medtronic InterStim SNM System show that SNM therapy provides a clinically meaningful benefit in a significant proportion of patients with urinary retention and the symptoms of OAB who have failed or could not tolerate more conservative treatments and have demonstrated at least a 50% improvement (reduction) in urinary symptoms during a trial period.

Effectiveness, as measured by clinically meaningful improvements in urinary symptoms (including reduction in urgency leak episodes, reduction in urgency episodes, reduction in daily voiding frequency, reduction in catheterization volume, reduction in catheterization frequency, and/or improvement in health-related quality-of-life scores), was demonstrated in the referenced articles involving the use of the InterStim SNM System.

Given the similarities in design, technological characteristics, non- clinical performance, indications for use, methods and conditions of use, and intended patient population between the InterStim SNM System and the Virtis SNM System, it is reasonable to conclude that the Virtis SNM System will have similar clinical performance to that of the InterStim SNM System.

Safety Analysis

Risks associated with the device are based on the nonclinical laboratory and animal studies. Additional risk information, including long-term safety data, was leveraged from a systematic literature review of the similar InterStim System.

Of the InterStim safety articles discussed above, the Siegel (2018[7]) article (InSite Phase 2 study) had the longest duration of follow-up and the greatest number of implanted subjects. That study collected up to 5 years of follow-up data on 272 subjects implanted with the InterStim System. An undesirable change in stimulation was the most common AE, which occurred in 60 of 272 subjects (22%), followed by implant site pain in 40 subjects (15%), and therapeutic product ineffectiveness in 36 subjects (13%). All other device related AEs, which developed upon or after implantation, were reported in fewer than 6% of subjects. One event, implant site erosion, was classified as serious but it resolved. Surgical interventions were also reported, including revision, replacement, and permanent explant of any device component. Surgical intervention was performed in 84 subjects (30.9%) due to an AE, 91 subjects (33.5%) underwent a surgical intervention due to battery replacement, and 91 subjects (33.5%) underwent a surgical intervention due lack or loss of effectiveness after full system implantation. In all 272 implanted subjects, the permanent explant rate was 19.1% (95% CI 14.1-23.9) at 5 years. In the other referenced studies of the InterStim System that provided safety information, there were reported

occurrences of additional AE types including infection, lead migration, and transient sensation of electrical shock.

References

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10. White WM, Mobley JD III, Doggweiler R, et al. Incidence and predictors of complications with sacral neuromodulation. Urology. 2009 Apr;73(4):731-5.

Cirtec Medical Corporation Customer Service

If you have any questions about the Virtis System, call Cirtec Medical Corporation Customer Service at 1 763 493 8556 within the United States.

Outside of the United States, call your product distributor for assistance. If additional assistance is needed, contact Cirtec Medical Corporation Customer Service at +1 763 493 8556.

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Part Number
0300-000171-001 Rev 09

2023-01

Cirtec MEDICAL

NUVECTRA™

Virtis™ Sacral Neuromodulation System
Clinician Programming Manual

Clinician Programmer
Model 8300

CE 0123

2022

℞ ONLY

Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, clinical summary, and related information.

FCC Information (US Only)

The following is communications regulation information about the Virtis Clinician Programmer:
Clinician Programmer FCC ID: 2ABU84500 contains FCC ID: U9R-W2CBW003

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

Important: Changes and modifications to the products not authorized by Cirtec could void the FCC certification and negate your authority to operate these products.

Contents

Packaging Symbols Glossary

Symbols	Details
REF	**Title:** Catalog Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.6[1] **Description:** Indicates the manufacturer's catalog number so that the medical device can be identified.
SN	**Title:** Serial Number **Standard:** ISO 15223-1 **Reference Number:** 5.1.7[1] **Description:** Indicates the manufacturer's serial number so that the medical device can be identified.
	**Title:** Date of Manufacture **Standard:** ISO 15223-1 **Reference Number:** 5.1.3[1] **Description:** Indicates the date when the medical device was manufactured
	**Title:** Manufacturer **Standard:** ISO 15223-1 **Reference Number:** 5.1.1[1] **Description:** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
EC REP	**Title:** Authorized representative in the European Community **Standard:** ISO 15223-1 **Reference Number:** 5.1.2[1] **Description:** Indicates the Authorized Representative in the European Community.
	**Title:** Packaging unit **Standard:** ISO 7000 **Reference Number:** 2794[2] **Description:** Indicates the number of pieces in the package.
	**Title:** Refer to instruction manual/booklet **Standard:** ISO 7010 **Reference Number:** M002[3] **Description:** To signify that the instruction manual/booklet must be read.
	**Title:** Do not use if package is damaged **Standard:** ISO 15223-1 **Reference Number:** 5.2.8[1] **Description:** Indicates a medical device that should not be used if the package has been damaged or opened.
	**Title:** Keep dry **Standard:** ISO 15223-1 **Reference Number:** 5.3.4[1] **Description:** Indicates a medical device that needs to be protected from moisture.
	**Title:** Temperature limit **Standard:** ISO 15223-1 **Reference Number:** 5.3.7[1] **Description:** Indicates the temperature limits to which the medical device can be safely exposed.
	**Title:** Humidity limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.8[1] **Description:** Indicates the range of humidity to which the medical device can be safely exposed.
	**Title:** Atmospheric Pressure limitation **Standard:** ISO 15223-1 **Reference Number:** 5.3.9[1] **Description:** Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	**Title:** Fragile, handle with care **Standard:** ISO 15223-1 **Reference Number:** 5.3.1[1] **Description:** Indicates a medical device that can be broken or damaged if not handled carefully.
MR	**Title:** MR Conditional **Standard:** ASTM F 2503 **Reference Number:** 7.2.2[3] **Description:** An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.
MR	**Title:** MR Unsafe **Standard:** ASTM F 2503 **Reference Number:** 7.2.34 **Description:** An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

Packaging Symbols Glossary

Symbol	Details
	**Title:** Non-ionizing electromagnetic radiation **Standard:** IEC/TR 60878 **Reference Number:** 5140[5] **Description:** To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	**Title:** Class II equipment **Standard:** IEC/TR 60878 **Reference Number:** 5172[5] **Description:** To identify equipment meeting the safety requirements specified for class II equipment according to IEC 61140.
	**Title:** WEEE Waste of Electrical and Electronic Equipment **Standard:** BS EN 50419[6] **Description:** Indicates that when end user wishes to discard this product it must be sent to separate collection facilities for recovery and recycling in the EU.
	**Title:** Rx Only **Standard:** 21 CFR Part 801.109 paragraph (b)(1) **Description:** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
	**Title:** European Conformity **Standard:** 93/42/EEC Annex XII **Description:** Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety, and environmental protection legislation.

1. ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements
2. ISO 7000:2019 Graphical symbols for use on equipment-Registered symbols
3. ISO 7010:2019 Graphical symbols - Safety colours and safety signs - Registered safety signs
4. ASTM F 2503-20: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
5. IEC/TR 60878:2015 Graphical symbols for electrical equipment in medical practice
6. BS EN 50419:2006 Marking of Electrical Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

Terminology

Autotune	A programmer function that re-tunes the radio communication between the Clinician Programmer and the Stimulator, Programmer Charger, or Pocket Programmer. It has no impact on stimulator settings, see Autotuning a Stimulator on page 28.
EPG	External Pulse Generator. Non-implantable Pulse Generator used in trialing.
IPG	Implantable Pulse Generator. Implantable Pulse Generator used in the permanent implant.
Pairing	A programming step that locks the patients Pocket Programmer to their IPG or EPG. Assures a Pocket Programmer does not communicate with a different patient's IPG or EPG.
Sacral Model	Main Clinician Programmer screen that is used to define the implanted system configuration. See section 5, "Configuring Components and Verifying Lead Location", page 17
Stage 1 Implant Procedure	Trial stage or phase of a Virtis System implant, see the Model 7000 Stage I Implant Manual
Stage 2 Implant Procedure	Permanent stage or phase of a Virtis System implant, see the Model 7000 Stage II Implant Manual

1 Introduction

The Virtis™ Clinician Programmer Model 8300 is part of the Virtis Sacral Neuromodulation System. The Virtis System is an MR conditional, rechargeable, 8-channel, 2x4 electrode sacral neuromodulation system for the treatment of overactive bladder or urinary retention (Figure 1).

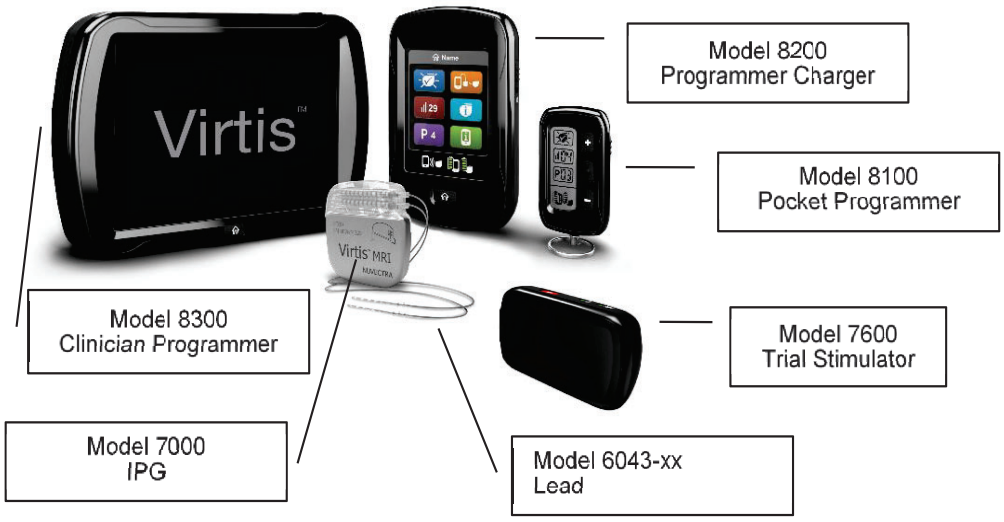


Figure 1.Virtis System components

The implanted Virtis System components are an implantable stimulator and lead with an optional extension. A trial stimulator provides stimulation by emulating the implantable stimulator during intraoperative test stimulation and during the stimulation trial. The clinician uses the Clinician Programmer during intraoperative test stimulation and to program the Virtis System. The patient uses the Programmer Charger or the Pocket Programmer to control stimulation. The patient also uses the Programmer Charger to charge the implantable stimulator.

During the stage 1 and stage 2 implant procedures, the clinician uses the Clinician Programmer to control intraoperative test stimulation and to record responses to stimulation. The Clinician Programmer wirelessly communicates with the trial stimulator or the implantable stimulator, allowing the clinician to keep the Clinician Programmer outside of the sterile field during the implant procedure.

After the stage 1 or stage 2 implant procedure, the clinician uses the Clinician Programmer to program a trial or implantable stimulator and to make adjustments to programming.

The following (Figure 2) illustrates the typical Clinician Programmer activities by treatment stage.

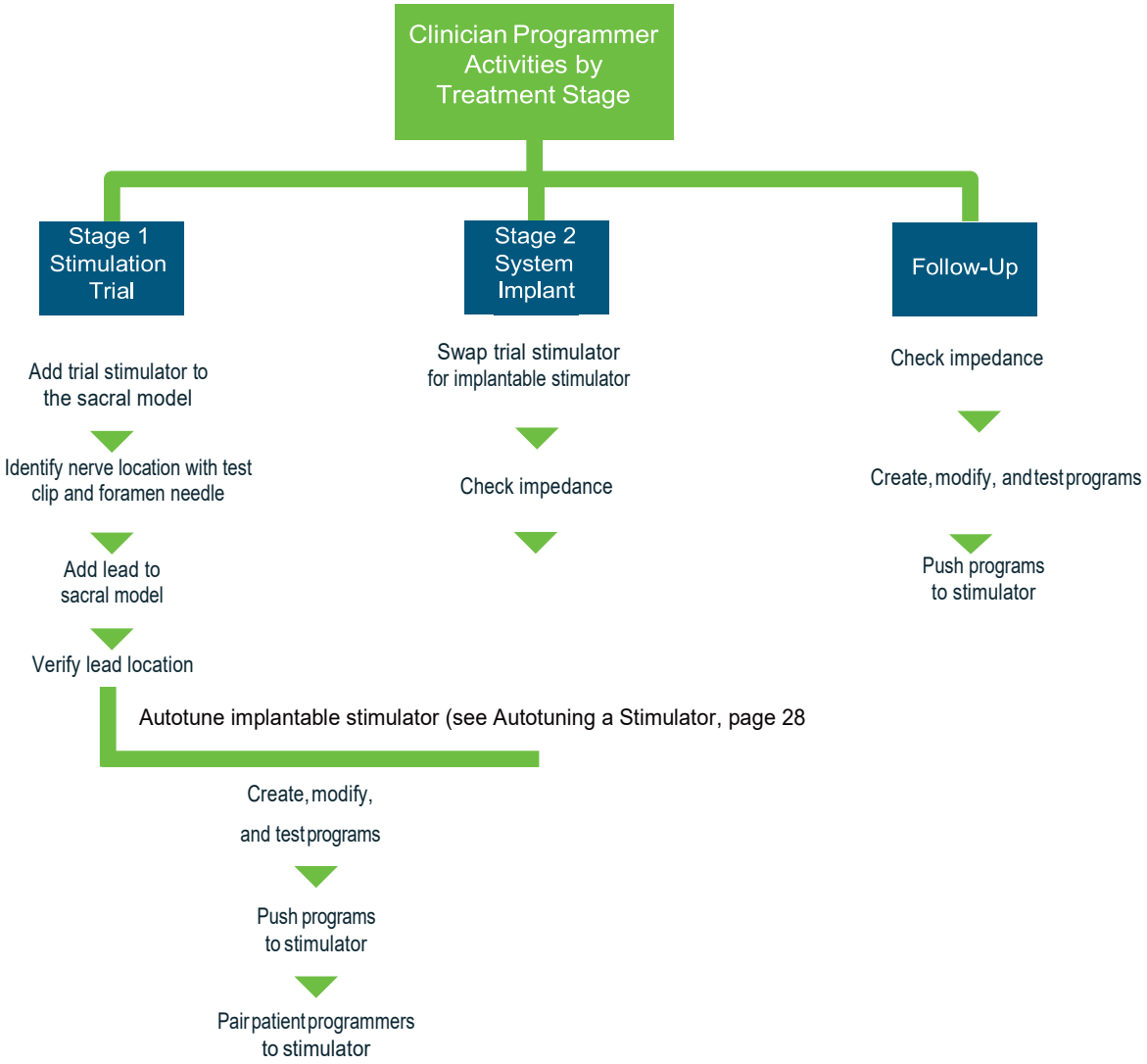


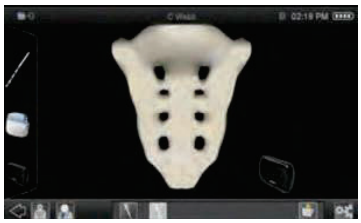
Figure 2. Typical Clinician Programmer activities by treatment stage

Stimulation Trial

Place the foramen needle and connect the trial cable, then...

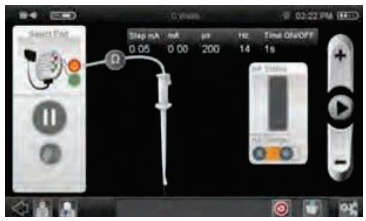
add a trial stimulator to the sacral model.

See Configuring Components on page 18.



identify the nerve location with the test clip and foramen needle.

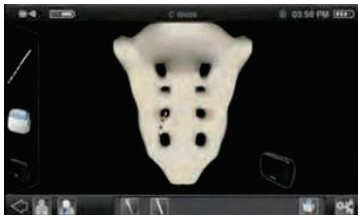
See Identifying the Nerve Location with a Test Clip and Foramen Needle on page 20.



Place the lead, then...

add a lead to the sacral model.

See Configuring Components on page 18.



verify lead placement.

See Verifying Lead Location on page 22.

Secure the externalized extension and trial cable, then...

create, modify, and test programs.

See Creating a Program and Subprogram on page 34 and Verifying Programming on page 37.

push programs to the stimulator.

See Pushing and Pulling Programs on page 38.

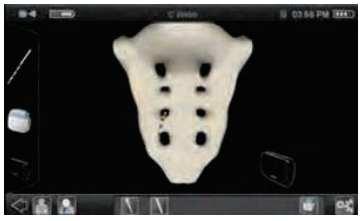
pair patient programmers to the stimulator.
See Pairing on page 43.

System Implant

Prepare the implantable stimulator, then...

swap the trial stimulator for the implantable stimulator.

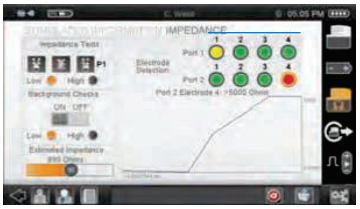
See Swapping a Swapping a Trial Stimulator for an Implantable Stimulator on page 26.



Connect the lead to the stimulator, then...

check impedance.

See Impedance on page 42



Implant the stimulator, then...

autotune the implantable stimulator.

See Autotuning a Stimulator, page 28.

Complete the Stage 2 procedure, then ...

create, modify, and test programs.

See Creating a Program and Subprogram on page 34 and Verifying Programming on page 37.

push programs to the stimulator.

See Pushing and Pulling Programs on page 38.

pair patient programmers to the stimulator.

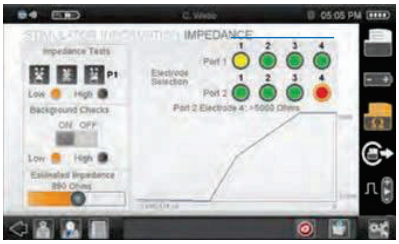
See Pairing on page 43.

Follow-Up

Review therapy results with the patient, then...

check impedance.

See Impedance on page 42.



create, modify, and test programs.

See Creating a Program and Subprogram on page 34 and Verifying Programming on page 37.

push programs to the stimulator.

See Pushing and Pulling Programs on page 38.

2 Important Safety Information

Warnings

Clinician Programmer Interaction with Other Implanted Devices. Do not use the Clinician Programmer to change program settings when near a person who has a pacemaker or other implanted devices. The effects of the Virtis System programmers on other implanted devices are unknown.

Modification. Do not modify the Clinician Programmer or the associated charging accessories. Modification of any Virtis System component may result in damage to the system, compromised system integrity, and harm or injury to the patient.

Precautions

Adjusting Program Settings. Avoid adjusting stimulator program settings to levels far above the motor and sensory response threshold. High settings may cause discomfort and increase the need for more frequent charging.

Component Compatibility. Use only the Clinician Programmer and accessories in your Virtis System to charge the Clinician Programmer or adjust stimulation. The effects of non-Virtis components on a Virtis System are unknown.

Electromagnetic Interference. Do not attempt to program near equipment that may generate electromagnetic interference (EMI) as it may interfere with the Clinician Programmer communication with other Virtis System components. If EMI disrupts programming, move the Clinician Programmer away from the source of EMI. Examples of sources of EMI are Magnetic Resonance Imaging (MRI), lithotripsy, computer monitors, cellular and cordless telephones, motorized wheelchairs, x-ray equipment, and other monitoring equipment. Interrupting programming may result in incorrect or incomplete programming.

Flammable Atmospheres. Avoid using the Clinician Programmer in flammable or explosive environments (e.g., flammable anesthetic mixtures or environments with greater than 25% oxygen). Using a battery- powered device near flammable or explosive atmospheres can produce a spark which may cause injury.

Power Failures. Power failures (without battery backup) during use will reinitialize the Clinician Programmer. Any unsaved information is lost; saved information is retained.

Magnetic Resonance Imaging (MRI). Do not take the Clinician Programmer or power cord into an MR environment, such as the MRI scanner room. The Clinician Programmer and power cord are MR Unsafe.

3 About the Clinician Programmer

The Clinician Programmer (Figure 3) is a hand-held, rechargeable device used to program the stimulation delivered by the trial stimulator and implantable stimulator, and to set the stimulation options and limits appropriate for each patient when the patient uses their patient programmers.

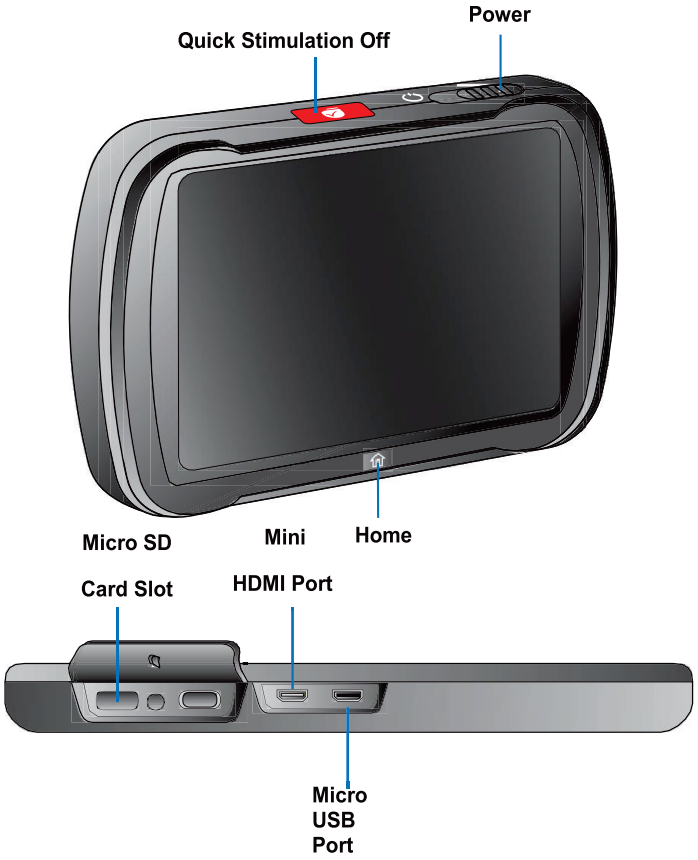


Figure 3. Clinician Programmer

Quick Stimulation Off	Stops stimulation for a connected stimulator.
Power	Turns the Clinician Programmer on and off.
	**Home**. Returns to the Patient Home screen, Patient Select screen, or Login screen.
Micro SD Card Slot	Contains the SD card required for operation. Do not use the card in another device, including another Clinician Programmer. Other devices cannot access the information on the card.
Mini HDMI Port	Use with a commercially available cable to connect to an IEC 60950-1 certified external monitor for viewing. Control still occurs via the Clinician Programmer, and not through the connected monitor.
Micro USB Port	Use to connect the provided power cord to recharge the Clinician Programmer.

Turning the Clinician Programmer On and Off

To turn on the Clinician Programmer:

- Slide and hold **Power** until an image displays on the screen. To turn off the Clinician Programmer:
- Slide and hold **Power** for five seconds.

Logging In to the Clinician Programmer

Use the Login screen (Figure 4) to access the normal operation and demo modes. Both modes require a user name and password. The initial user name is *admin* and the password is *admin*. After the initial log in, reset the password for the administrator user, and create accounts for each additional user. See User Administration on page 51.

Note: Demo mode includes sample patient information you can view and edit. The Clinician Programmer does not save changes you made in demo mode after you log out.

Figure 4. Login screen

Using the Navigation Bar and the Patient Home Screen

The navigation bar (Figure 5) displays at the bottom of the Clinician Programmer screen when viewing a patient. The navigation bar contains menus and submenus for accessing functionality and screens.

Note: The navigation bar displays on all screens except for the Patient Home screen. To access Clinician Programmer functionality:

1. Tap a menu on the navigation bar. A submenu displays.
2. Tap a submenu. The screen associated with the submenu displays.

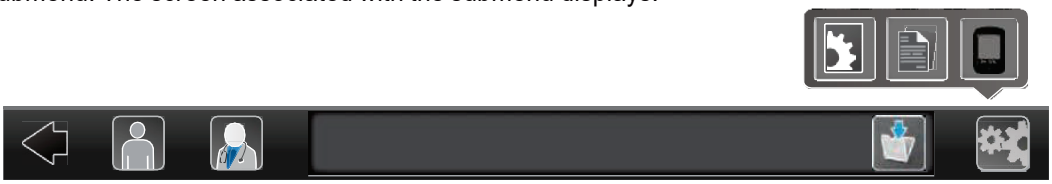


Figure 5. Navigation bar with submenu displayed

	Patient Many
	Patient Information. View and edit patient information, such as name and date of birth.
	Picture Gallery. View pictures taken with the Clinician Programmer camera.
	Patient Select. Exit the current patient record to view and select from a patient list.
	Clinician Menu
	Implants. Conduct intraoperative test stimulation and configure a Virtis System on the sacral model for programming
	Program Management. Create and edit programs and subprograms. Push and pull (transfer) programs between the stimulator and the Clinician Programmer.
	Stimulator Information. Configure and manage a stimulator, including pairing patient programmers and autotuning the stimulator.
	Camera. Take pictures with the Clinician Programmer camera.
	Tools Menu
	Settings. Configure the Clinician Programmer.
	Reports. View and print a patient report.
	Emulators. View virtual interfaces of the patient programmers.
	Save Changes. Displays an orange arrow when there are unsaved changes and a blue arrow when there are no changes to save. Tap to save changes.
	Back. Returns to the previously viewed screen.

The Patient Home screen (Figure 6) displays after selecting a patient, or when you press (Home) when viewing a patient.

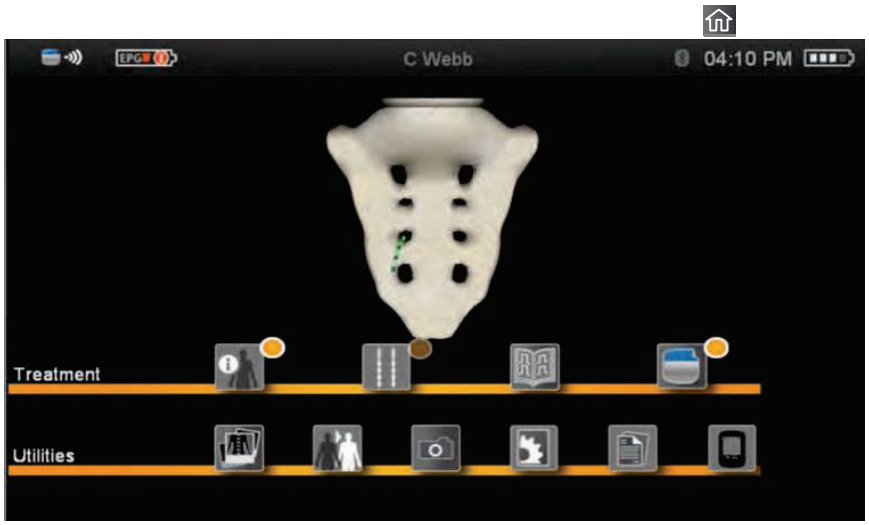


Figure 6. Patient Home screen

The Patient Home screen illustrates the typical order in which you complete treatment activities in the Treatment bar. The Patient Home screen also displays the current completion state of those activities. Use the completion state as a guide when determining your next activity. Activity completion states are performed, in progress, and not performed.

The Utilities bar provides quick access to other Clinician Programmer functionality.

Using the Status Bar

The status bar (Figure 7) displays at the top of the screen when viewing a patient and contains status icons for the Clinician Programmer and the stimulator.

Note: All icons, except for the Stimulator Connection icon, within the status bar are informational only; they do not result in an action when touched.

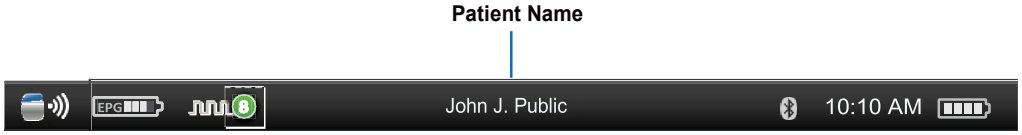


Figure 7. Status bar

Stimulator Connection. The connection status of the Clinician Programmer to the displayed patient's stimulator. Tap the icon to manually connect to or disconnect from the stimulator.

Note: The Clinician Programmer automatically attempts to connect to the patient's stimulator when you navigate from the Patient Home screen to another patient screen.

Stimulator Battery Status. The battery level of the patient's stimulator. Displays EPG for a trial stimulator and IPG for an implantable stimulator. Displays red if the battery is low.

Running Program. Stimulation indicator. Displays a T when stimulating using a test program or during intraoperative test stimulation. Displays a program number when stimulating using a patient program.

Bluetooth Connection. The connection status of the Clinician Programmer to a printer

Clinician Programmer Battery Status. The battery level of the Clinician Programmer.

Stopping Stimulation

The Clinician Programmer includes a **Quick Stimulation Off** icon (Figure 8) on stimulation screens, as well as a **Quick Stimulation** Off button at the top of the Clinician Programmer (Figure 3 on page 9).

Figure 8. Quick Stimulation Off

If the Clinician Programmer is connected to a stimulator, tap the **Quick Stimulation Off** icon or press the button to immediately stop stimulation.

To stop stimulation for a patient not in the Clinician Programmer:

1. Tap (Quick Stimulation Off) on the Select Patient screen (*Figure 9 on page 14*). A list of nearby stimulators displays.
2. Select the stimulator from the list of nearby stimulators.

   Identify the patient's stimulator by viewing the serial number on the back of their trial stimulator, or by reading their Cirtec patient ID card for their implantable stimulator.

   Note: If the patient's stimulator does not display in the list, make sure it is on and nearby. If it is connected to another Clinician Programmer, Programmer Charger, or Pocket Programmer, press the Quick Stimulation Off button on the other programmer.
3. Tap **Confirm**. Stimulation stops.

If program adjustment is needed, add the patient to the Clinician Programmer. See Adding a Patient on page 15.

4 Managing Patients

To deliver and program stimulation for a patient, you must first add the patient to the Clinician Programmer. For a new patient, you manually add the patient to the Clinician Programmer. For a patient with an existing stimulator, you pull (transfer) the patient's Virtis System information from their stimulator.

Note: Virtis System information stored on the stimulator includes programs and patient demographic information. The stimulator does not store patient responses to intraoperative test stimulation.

Once you add a patient, the Clinician Programmer stores the patient for future use. After you update the patient's Virtis System information on the Clinician Programmer, you push (transfer) the updated information back to the stimulator. At a future visit, if you or another clinician do not have the Clinician Programmer previously used with the patient, you can pull information from the patient's stimulator. See Pushing and Pulling Programs on page 38.

Note: Patient information on a Clinician Programmer is information from the last time you used that Clinician Programmer to update patient information. Whenever viewing patient information, consider pulling information from the patient's stimulator, as the patient's stimulator may have been updated using a different Clinician Programmer.

Using the Select Patient Screen

Add patients and select patients using the Select Patient screen (Figure 9)

To access the Select Patient screen:

- Log in to the Clinician Programmer.

–or–

Tap (Patient Select).

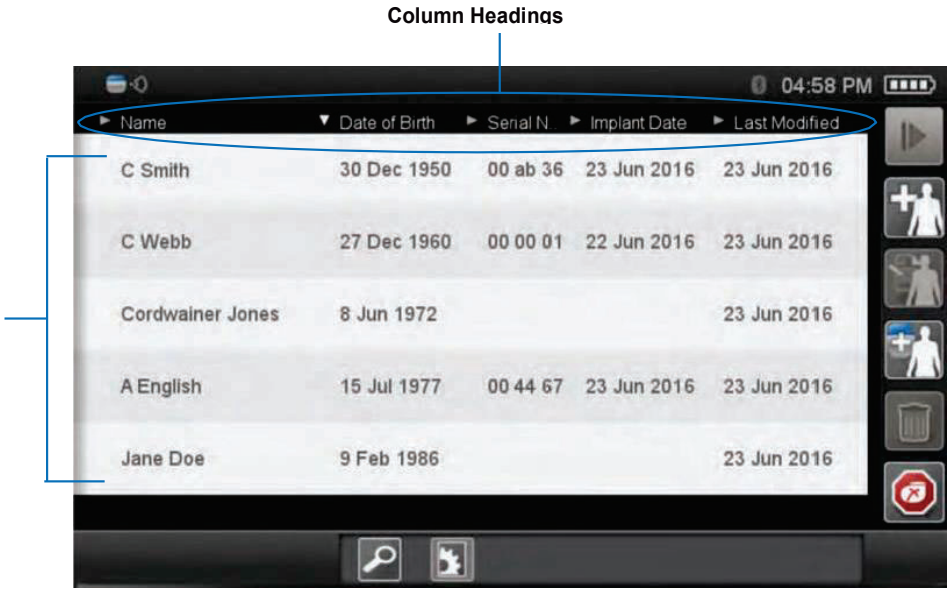


Figure 9. Select Patient screen

	Column Headings. Tap to sort by the column and to reverse the sort order.
	Patient List. Drag up or down in the patient list to view additional patients. Tap to select a patient.
	Continue. Displays the Patient Home screen for the selected patient.
	Manually Add Patient. Adds a new patient to the Clinician Programmer through manual input.
	Patient Information. Displays the Patient Information screen for the selected patient.
	Add Patient from Stimulator. Adds a patient to the Clinician Programmer using information stored on the stimulator.
	Delete Patient. Deletes the selected patient from the patient list.
	Quick Stimulation Off. Stops stimulation for the selected patient. Queries and displays a list of stimulators in range if no selected patient.
	Filter. Displays a list to filter the patient list by a physician.
	Settings. Provides access to Clinician Programmer information and settings.

Adding a Patient

For patients with an existing stimulator, add a patient by pulling information from their stimulator. For new patients, manually add the patient by entering information about the patient.

Note: When you add a patient with an existing stimulator, the Clinician Programmer pulls programs, patient information, and component configuration.

To add a patient from a stimulator:

1. Move the Clinician Programmer within 1 meter (3 feet) of the stimulator.
2. Tap (Add Patient from Stimulator). A list of nearby stimulators displays.

   Note: If a stimulator does not display in the list, make sure it is on, nearby, and not connected to another Clinician Programmer, Programmer Charger, or Pocket Programmer by turning the programmers off or moving them out of range.
3. Select a stimulator.
4. Tap **Confirm**. The Patient Information screen displays (Figure 10).

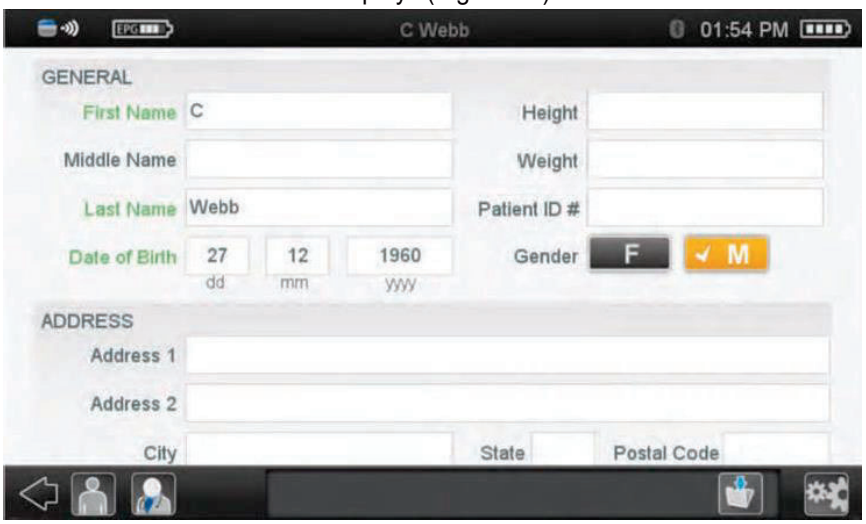


Figure 10. Patient Information screen

5. Verify patient information.

To manually add a patient:

1. Tap (Manually Add Patient). The Patient Information screen displays (Figure 10).
2. Enter patient information.

   The required fields are First Name, Last Name, and Date of Birth.

   Note: To associate a physician with a patient, the physician must already exist on the Clinician Programmer. See Pushing and Pulling Programs on page 38 to add a physician to the Clinician Programmer.

Selecting a Patient

To select a patient:

1. Tap a column heading to sort by the column.

   –or–

   Tap (Filter), select a physician, and tap Accept.

   Note: Tap (Filter) to remove a filter.
2. Drag up or down in the patient list to view additional patients.
3. Tap a patient to select the patient.
4. Tap (Continue) to access the Patient Home screen.

Deleting a Patient

To delete a patient:

1. Tap a patient in the Select Patient screen.
2. Tap  (Delete Patient).
3. Tap **Accept** on the popup confirmation screen to confirm removal of the patient from the patient list.
4. Tap **Accept** again to confirm the removal of the patient from the SD card.

5 Configuring Components and Verifying Lead Location

The Clinician Programmer Implants screen (Figure 11) includes a model of the sacrum to represent a patient's Virtis System. You must add components (a stimulator and leads) to a patient's Virtis System on the sacral model before stimulating (intraoperative test stimulation or programs).

Once you configure the Virtis System on the sacral model, perform intraoperative stimulation to determine optimal lead location.

As needed, update the sacral model to reflect changes to the patient's Virtis System, such as swapping a trial stimulator for an implantable stimulator.

To access the Implants screen:

Tap (Clinician Menu) > (Implants) in the navigation bar

-or-

Tap (Implants) from the Patient Home screen.

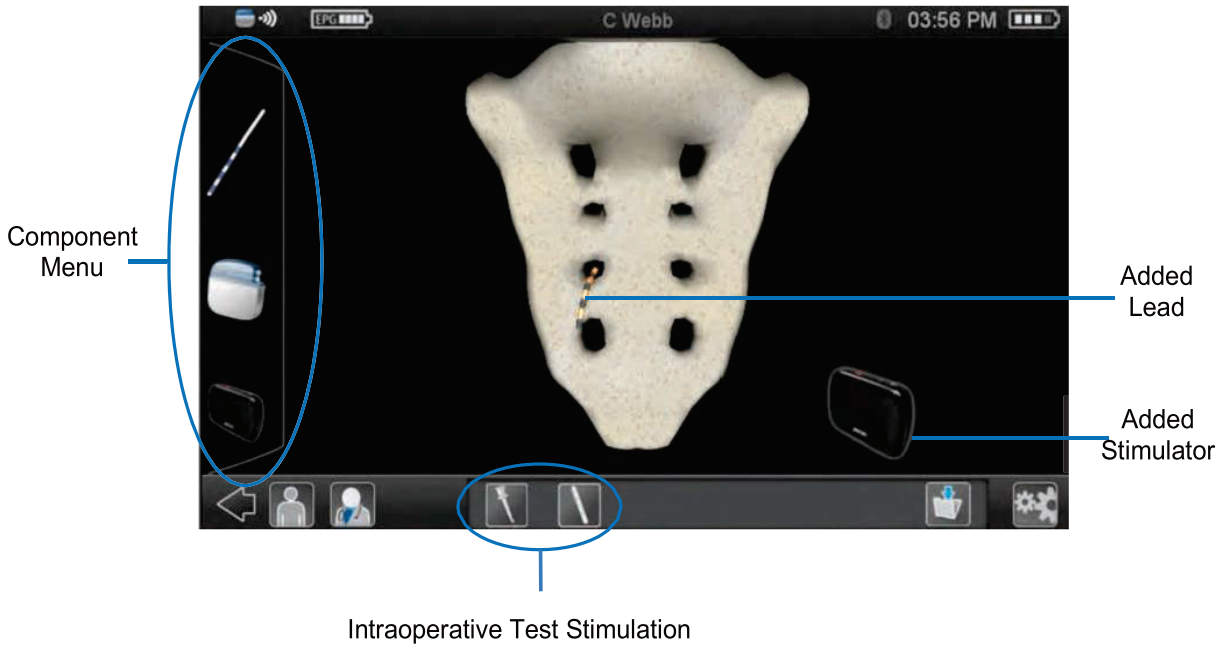


Figure 11. Implants screen

	Lead	The sacral model can have up to two leads.
	Implantable Stimulator	
	Trial Stimulator	
	Test Clip Intraoperative Test Stimulation	Tap to identify the nerve location using a test clip and foramen needle. Available when the sacral model has a trial stimulator with at least one open port (not connected to a lead).
	Lead Intraoperative Test Stimulation	Tap to verify lead location. Available when the sacral model has a stimulator with at least one connected lead.

Configuring Components

Configure components on the sacral model to perform intraoperative test stimulation or to program. To configure components on the Implants screen:

1. Add a stimulator.
   a. Tap a stimulator on the component menu; a trial stimulator for a trial and an implantable stimulator for a permanent implant. A list of stimulators in range displays.
   b. Tap the serial number for the patient's stimulator.
   c. The trial simulator serial number is on the label on the back of the stimulator. The implantable stimulator packaging material and the front of the stimulator includes the serial number.

      Note: If the stimulator does not display in the list, verify the stimulator is on, nearby, and not connected to another programmer. Tap **Query** to refresh the list.

      –or–

      Tap Other to add a stimulator that is not in range. Before stimulating, provide the serial number for the stimulator. See Replacing a Stimulator on page 27.
   d. Tap **Accept**.
2. Conduct intraoperative test stimulation with a test clip and a foramen needle to locate the nerve. See Identifying the Nerve Location with a Test Clip and Foramen Needle on page 20.
3. Add a lead.
   a. Tap the lead on the components menu. The lead displays on the sacral model.
   b. Drag the lead to the desired location.
4. [Optional step] Configure lead information.
   a. Tap the lead on the sacral model. The Lead Edit menu displays (Figure 12).

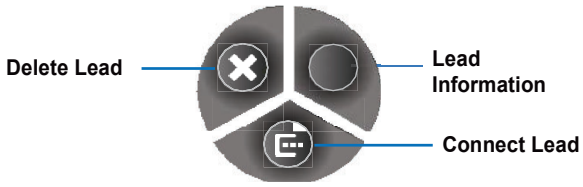


Figure 12. Lead Edit menu

   b. Tap  (Lead Information). The Lead Information popup displays (Figure 13).

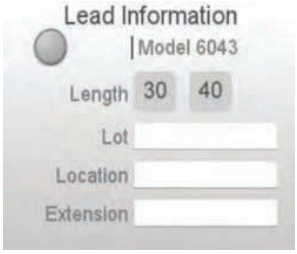


Figure 13. Lead Information popup

   c. Complete the lead and extension information.
   d. Tap outside of the popup to close the popup.

5. Connect the lead.
   a. Tap the lead on the sacral model. The Lead Edit menu displays (Figure 12).
   b. Tap (Connect Lead). The Trial Stimulator Information popup displays (Figure 14).

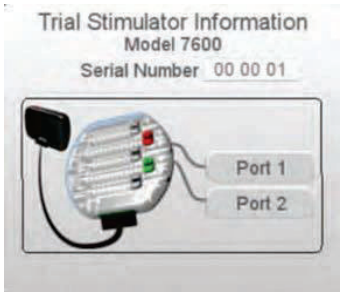


Figure 14. Trial Stimulator popup

   c. Tap the port to connect the lead.

   d. Tap outside of the popup to close the popup.
6. Conduct intraoperative test stimulation to verify lead location. See Verifying Lead Location on page 22.

Conducting Intraoperative Test Stimulation

Perform intraoperative test stimulation when implanting the Virtis System to identify and verify the optimal lead location. First, perform intraoperative test stimulation with a test clip and foramen needle to identify the nerve location. Then place the lead and perform intraoperative test stimulation to verify the lead placement and record the patient's responses for each electrode and each cognitive state. After verifying lead location, you can view recorded responses by electrode and cognitive state.

During intraoperative test stimulation, the Clinician Programmer stimulates for 1 or 3 seconds, stops stimulation for 1 or 3 seconds, then increments the amplitude by a step increment that you configure. The Clinician Programmer repeats the process until the amplitude reaches the limit you set.

You can pause the automatic increments of amplitude using the Clinician Programmer.

Note: If you are tapping the test clip to the lead to verify lead location:

- Use (Test Clip Intraoperative Test Stimulation).
- Configure the Clinician Programmer for manual amplitude adjustment (Time on/Off).
- Make sure the sacral model has one open port.
- You cannot record responses using (Test Clip Intraoperative Test Stimulation).

Identifying the Nerve Location with a Test Clip and Foramen Needle

Conduct intraoperative test stimulation with a test clip and foramen needle to identify the nerve location.

To access the Test Clip Intraoperative Test Stimulation screen (Figure 15):

- Tap (Test Clip Intraoperative Test Stimulation) in the navigation bar on the Implants screen.

  Note: (Test Clip Intraoperative Test Stimulation) is only available when the sacral model has a trial stimulator with at least one open port (a port not connected to a lead).

Figure 15. Test Clip Intraoperative Test Stimulation screen

	Selected Port	The selected port is orange. Tap to change ports. **Note:** You can change ports if the trial stimulator on the sacral model does not have a connected lead.
	Pause Incrementing	Tap while stimulating to hold stimulation at the current amplitude. When paused, the button is orange, stimulation continues, but the amplitude does not automatically increment. Tap again to resume incrementing.
Ω	Impedance Results	The results of the test that was automatically executed when starting stimulation. • Gray – Impedance test not executed • Yellow – Low impedance (≤ 2000 ohms) • Green – Normal impedance (2001-5000 ohms) • Red – High impedance (> 5000 ohms)
Step mA		The rate at which the amplitude changes with each increment or decrement.
mA		Amplitude. Limited by mA Range.

µs		Pulse width. 20-440 µs.
Hz		Frequency. 2-130 Hz.
Time On/Off		The amplitude cycle time: 1 second, 3 seconds, or manual. The Clinician Programmer automatically increments the amplitude every 1 or 3 seconds, stops stimulation for 1 or 3 seconds, then increments the amplitude by the value in Step mA. The Clinician Programmer repeats the process until the amplitude reaches the limit set for the amplitude range, then stimulation stops. **Note:** You can configure the Clinician Programmer for manual amplitude adjustment if you are tapping the test clip against the foramen needle stylet eyelet.
mA Status		An indicator of the amplitude level during stimulation.
mA Range		The highest and lowest amplitude values allowed during stimulation. 0-15 mA.
	Start	Tap to start stimulation. Stimulation ramps to the set amplitude, and the icon switches to Stop.
	Stop	Displays and flashes when stimulating. Tap to stop stimulation. Stimulation ramps down to 0, and the icon switches to Start.
	Increment/ Decrement	Increments or decrements the selected stimulation parameter.

To identify the nerve location:

1. Tap the port connected to the test clip.
   Note: You can only change ports if the trial stimulator does not have a connected lead.
2. Set the stimulation parameters.
   a. Adjust the mA Range.
   b. Tap a stimulation parameter.
   c. Tap **Increment** or **Decrement**.
3. Tap (Start) to start stimulation, then tap **Accept** to confirm the start of stimulation.
   An impedance test executes, impedance results display, and stimulation starts.
   Note: If the impedance result is red (high), stop stimulation, verify the test clip is attached or touching the foramen needle, and restart stimulation. If the result is sill red (high), consider reinserting the foramen needle. You can conduct intraoperative test stimulation regardless of the impedance test results.
4. Monitor the patient for responses (*Table 1*) and adjust parameters as needed (*Table 2* - Amplitude recommendation for observed motor responses*)*.

	Motor Response		
Foramen	**Pelvic Floor**	**Leg Foot**	**Sensory Response**
S2	May have clamp[a]	Leg/hip rotation, heel rotation, foot planter flexion, contraction of the calf	Generally none, possible genital, penile, clitoral, foot, leg
S3	Bellows[b, c]	Plantar flexion of great toe, sometimes flexion of other toes	Pulling in or near the perineum, extending forward to scrotum or vagina
S4	Bellows[b, c]	None	Pulling in rectum

a. Clamp—Look for anterior-posterior shortening of the perineal structures, which is seen as a twisting of the anal sphincter. In males, a retraction at the base of the penis may be seen.
b. Bellows—Movement of the perineum from the contraction of the levator ani. Look for deepening and flattening of buttock groove from lifting and dropping of pelvic floor.
c. If the anus is visualized, see pulling in of anal sphincter.

Table 1. Typical patient responses to intraoperative test stimulation

Amplitude	Future Lead Placement Recommendation
Less than 2 mA	Desired Range
2 to 3 mA	If the lead is placed in this location, more frequent stimulator charging may be required. Consider repositioning the foramen needle to achieve the desired amplitude.
Greater than 3 mA	Consider repositioning the foramen needle to achieve the desired amplitude.

Table 2 - Amplitude recommendation for observed motor responses

5. Tap (Stop) once you identify the nerve location.
   Note: The Clinician Programmer automatically shuts off stimulation once it reaches the top of the amplitude range.

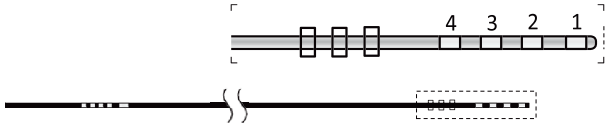
Verifying Lead Location

Conduct intraoperative test stimulation with a lead to verify optimal lead location. When conducting intraoperative test stimulation, you identify a patient's cognitive state and stimulate on only one electrode at a time. During stimulation, you can record a patient's responses to stimulation.

To access the Lead Intraoperative Test Stimulation screen (Figure 16):

- Tap (Lead Intraoperative Test Stimulation) in the navigation bar on the Implants screen.
  Note: (Lead Intraoperative Test Stimulation) is available when the sacral model has a lead connected to the stimulator.

Figure 16. Lead Intraoperative Test Stimulation screen

	Selected Port	The selected port is orange. If the sacral model contains two connected leads, tap to select a different lead and port.
	Responses	Tap while stimulating to hold at the current amplitude, and to record patient responses. When paused, stimulation continues cycling on and off at the rate set in Time ON/OFF, stimulation continues, the amplitude does not automatically increment, and the Responses Type popup displays. For each electrode and each cognitive state, a patient can have up to three pairs of responses; one motor and one sensory response per pair. If you indicate more than three pairs of responses, the Clinician Programmer overwrites the oldest response. You can record the following responses: • Motor: Foot, Heel, Leg, Bellows, Great Toe, Bottom Foot, Other (user entry) • Sensory: Genitals, Perineum, Tailbone, Rectal, Low Extremity, Butt Cheek, Other (user entry) When not stimulating, tap to view previously recorded responses for the electrode and cognitive state selected. When starting stimulation, the Clinician Programmer deletes the existing responses for the electrode and cognitive state.
	Cognitive State	Tap to select prior to stimulation or to view previous responses. The cognitive state of the patient: Awake Sedated (default) Under general anesthesia
Selected Electrode		The selected electrode is orange. Tap an electrode to select the electrode. **Note:** The numbering of electrodes is 1 to 4, with 1 being on the distal end of the lead. 
Ω	Impedance Results	The results of the test that was automatically executed when starting stimulation. • Gray – Impedance test not executed • Yellow – Low impedance (≤ 2000 ohms) • Green – Normal impedance (2001-5000 ohms) • Red – High impedance (> 5000 ohms)
Step mA		The amount at which the amplitude changes with each increment or decrement.

mA		Amplitude. Limited by mA Range.
µs		Pulse width. 20-440 µs.
Hz		Frequency. 2-130 Hz.
Time On/Off		The amplitude cycle time: 1 second, 3 seconds, or manual. The Clinician Programmer automatically increments the amplitude every 1 or 3 seconds, stops stimulation for 1 or 3 seconds, then increments the amplitude by the value in Step mA. The Clinician Programmer repeats the process until the amplitude reaches the limit set for the amplitude range, then stimulation stops. **Note:** You can configure the Clinician Programmer for manual amplitude adjustment if you are tapping the test clip against the lead.
mA Status		An indicator of the amplitude level during stimulation.
mA Range		The highest and lowest amplitude values allowed during stimulation.
	Start	Tap to start stimulation. Stimulation ramps to the set amplitude, and the icon switches to Stop.
	Stop	Displays and flashes when stimulating. Tap to stop stimulation. Stimulation ramps down to 0, and the icon switches to Start.
	Increment/ Decrement	Increments or decrements the selected stimulation parameter.
	Create Program	Creates a subprogram with the currently set stimulation parameters; the selected electrode as a cathode and the implantable stimulator or trial stimulator ground pad as an anode. See Creating a Program and Subprogram on page 34. **Note:** During a trial, do not send the patient home with a program that uses the trial stimulator as an anode or cathode when the patient does not have a ground pad.
	Clear Responses	Clears responses for all electrodes in all cognitive states. **Note:** The Clinician Programmer also clears responses for the selected electrode when you start intraoperative test stimulation on that electrode.

To conduct intraoperative test stimulation with a lead:

1. Tap a port to select a lead if the sacral model contains two connected leads.
2. Tap the electrode on which you want to stimulate.
   Note: The numbering of electrodes is 1 to 4, with 1 being on the distal end of the lead.
3. Tap the patient's cognitive state. Default is  (Sedated). Any previous responses for the selected electrode display.
4. Set the stimulation parameters.
   a. Adjust the mA Range.
   b. Tap a stimulation parameter.
   c. Tap **Increment** or **Decrement**.
5. Tap  (Start) to start stimulation, then tap **Accept** to confirm the start of stimulation.
   The Clinician Programmer clears existing responses for the selected electrode and cognitive state, executes an impedance test, displays the impedance results, and starts stimulation.
   Note: You can conduct intraoperative test stimulation regardless of the impedance test results.

6. Monitor the patient for responses (Table 1 on page 21) and adjust stimulation parameters as needed (Table 2 - Amplitude recommendation for observed motor responses on page 22).
7. Indicate a patient response.
   a. Tap (Responses).

      The response screen displays (Figure 17). Stimulation holds at the current amplitude, continuously cycling on and off at the time set in Time ON/OFF, but the amplitude does not automatically increment.

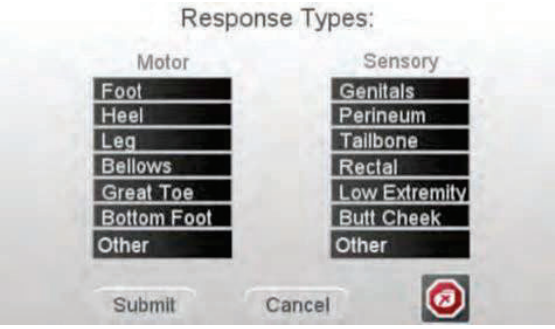


Figure 17. Response Types popup

   b. Indicate up to one motor response and one sensory response in the Response Types popup, and tap **Submit**. Stimulation resumes incrementing.
8. Tap (Stop) once you verify the lead location.

   Note: The Clinician Programmer automatically shuts off stimulation once it reaches the top of the amplitude range.
9. [Optional step] Tap (Create Program) to create a program with the current parameters. The Select Program Destination popup displays.

Figure 18. Select Program Destination popup

   a. Indicate where to create the program.
   b. Tap **Accept**.

      The Programming screen displays with the selected electrode as a cathode and the implantable stimulator, or trial stimulator with a connected ground pad, as an anode. See Creating a Program and Subprogram on page 34.

      Note: During a trial, do not send the patient home with a program that uses the trial stimulator as an anode or cathode when the patient does not have a ground pad.

Managing Stimulators

Update the sacral model whenever a patient's stimulator changes. On the sacral model, you can complete the following:

- Swap a trial stimulator for an implantable stimulator
- Replace a trial stimulator with a trial stimulator, or an implantable stimulator with an implantable stimulator
- Delete a stimulator

Note: If you are swapping a trial stimulator for an implantable stimulator or are replacing an implantable stimulator, make sure to autotune the implantable stimulator when instructed to do so in the Stage 2: Implant Manual for Stimulator. For information on autotuning a stimulator, see Autotuning a Stimulator, page 28.

Swapping a Trial Stimulator for an Implantable Stimulator

Swapping copies programs, patient information, and component configuration from the trial stimulator to the implantable stimulator.

To swap a trial stimulator for an implantable stimulator:

1. [Optional step] Pull the programs from the trial stimulator to the Clinician Programmer. See Pushing and Pulling Programs on page 38.

   Complete if the trial stimulator has the most recent programs. Do not complete if you have made changes to the programs using the Clinician Programmer and you want the implantable stimulator to have the changed programs.
2. Tap (Clinician Menu) > (Implants) in the navigation bar.
3. Tap the connected trial stimulator on the sacral model. The Trial Stimulator Information popup displays (Figure 19).

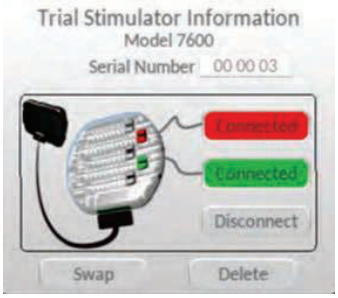


Figure 19. Trial Stimulator Information popup

4. Tap **Swap**.
5. Tap **Accept** to confirm the change. A list of stimulators in range displays.
6. Select the serial number for the implantable stimulator.

   The implantable stimulator packaging material and the front of the stimulator includes the serial number.

   Note: If the stimulator does not display in the list, verify the stimulator is on, nearby, and not connected to another programmer. Tap **Query** to refresh the list.
7. Tap **Accept**.

   The Clinician Programmer automatically attempts to push programs to the implantable stimulator. If you receive a notification to manually push programs, see Pushing and Pulling Programs on page 38.

Autotune the implantable stimulator when instructed to do so in the Stage 2: Implant Manual for Stimulator. For information on autotuning, see Autotuning a Stimulator, page 28.

Replacing a Stimulator

You can replace a trial stimulator for another trial stimulator or an implantable stimulator for another implantable stimulator.

To replace a stimulator or edit the serial number for a stimulator:

1. [Optional step] If replacing a stimulator, pull programs from the stimulator.
   Complete if existing stimulator has the most recent programs. Do not complete if you have made changes to the programs using the Clinician Programmer and you want the new stimulator to have the changed programs. See Pushing and Pulling Programs on page 38.
2. Tap (Clinician Menu) > (Implants) in the navigation bar.
3. Tap the connected stimulator on the sacral model. The Stimulator Information popup displays (Figure 20).

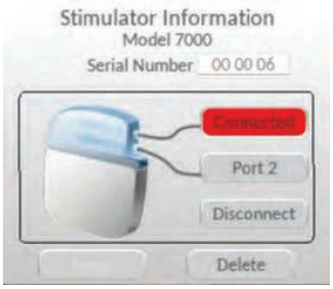


Figure 20. Stimulator Information popup

4. Enter the serial number for the stimulator.
   The trial simulator serial number is on the label on the back of the stimulator. The implantable stimulator packaging material and the front of the stimulator includes the serial number.
5. Tap **Hide** on the success message that displays.
6. Manually push programs from the Clinician Programmer to the stimulator. See Pushing and Pulling Programs on page 38.

If replacing an implantable stimulator with another implantable stimulator, autotune the implantable stimulator when instructed to do so in the Stage 2: Implant Manual for Stimulator. For information on autotuning a stimulator, see Autotuning a Stimulator on page 28.

Deleting a Stimulator

Deleting a stimulator from the sacral model deletes the patient's programs on the Clinician Programmer.

To remove a stimulator on the sacral model:

1. Tap (Clinician Menu) > (Implants) in the navigation bar.
2. Tap the connected stimulator on the sacral model. The Stimulator Information popup displays (Figure 20).
3. Tap **Disconnect** to disconnect any connected leads.
4. Tap **Accept** to confirm the deletion of the leads and all associated programs.
5. Tap **Delete** from the Stimulator Information popup.

Autotuning a Stimulator

Autotune the stimulator after implant or if you or the patient experience reduced communication between the stimulator and the Programmer Charger, Pocket Programmer, or Clinician Programmer. This may happen when the tissue surrounding the stimulator changes, such as after healing from surgery or a significant weight change.

The programmer re-tunes the radio communication between the Clinician Programmer and the stimulator, Programmer Charger, or Pocket Programmer. This may improve the reliability of the communication. It has no impact on stimulator settings.

To tune a stimulator:

1. Tap (Clinician Menu) > (Stimulator Information) in the navigation bar.

   –or–

   Tap (Stimulator Information) from the Patient Home screen.
2. Tap (Autotune Stimulator).

6 Programming

Use the Clinician Programmer to create and edit programs. A program provides stimulation. Patients can have up to 10 programs. A program is made of one to four subprograms. Running a program runs the subprograms consecutively.

Note: You can run subprograms or programs using the Clinician Programmer, but patients only run programs.

Within a subprogram you program the electrodes to stimulate, the amplitude allocation for each electrode, the stimulation values (frequency, pulse width, and amplitude), and the range in which patients can increase and decrease the strength (amplitude) of their stimulation.

If a patient already has programs on their stimulator, a clinician can pull the programs from the stimulator for adjustments. After configuring and testing programs, the clinician pushes the programs to the stimulator for patient use.

Note: Programs or changes to programs are not available to the patient until you push the programs to the stimulator.

Using the Clinician Programming Screens

Use the following programming screens (Figure 21) to view, configure, and run programs.

- **Program Management screen.** Displays when first accessing a patient's programs. Includes information for all of a patient's programs. Use to create new programs, change the order of programs, and push and pull programs between the Clinician Programmer and the stimulator. See Using the Program Management Screen on page 30.
- **Program screen.** Accessible from the Program Management screen or the Subprogram screen. Use to create a new subprogram, modify program settings, and run a program or subprogram before pushing the programs to the stimulator. See Using the Program Screen on page 31.
- **Subprogram screen.** Accessible from the Program screen. Use to configure the electrodes and stimulation parameters for a subprogram, and to run a subprogram. See Using the Subprogram Screen on page 32.

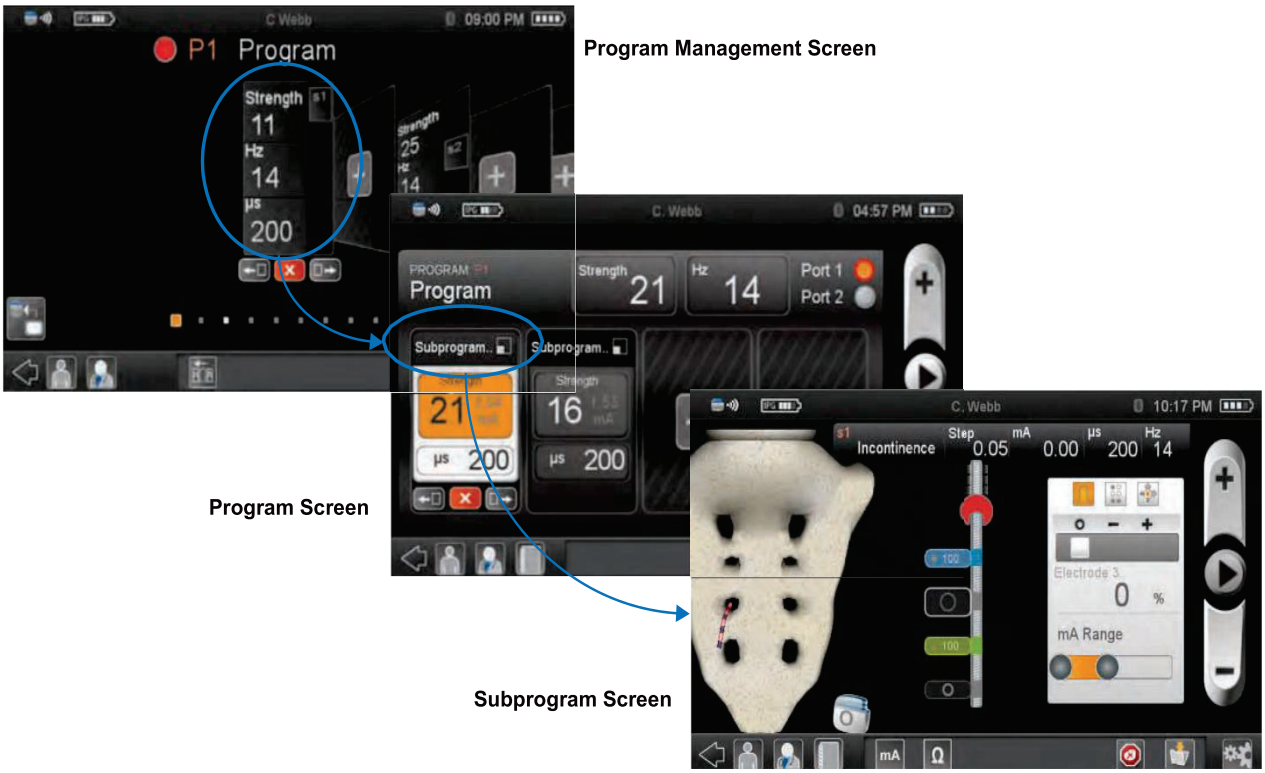


Figure 21. Programming screens

Using the Program Management Screen

To access the Program Management screen (Figure **22**):

- Tap (Clinician Menu) (Program Management) in the navigation bar.

-or-

Tap (Program Management) from the Patient Home screen.

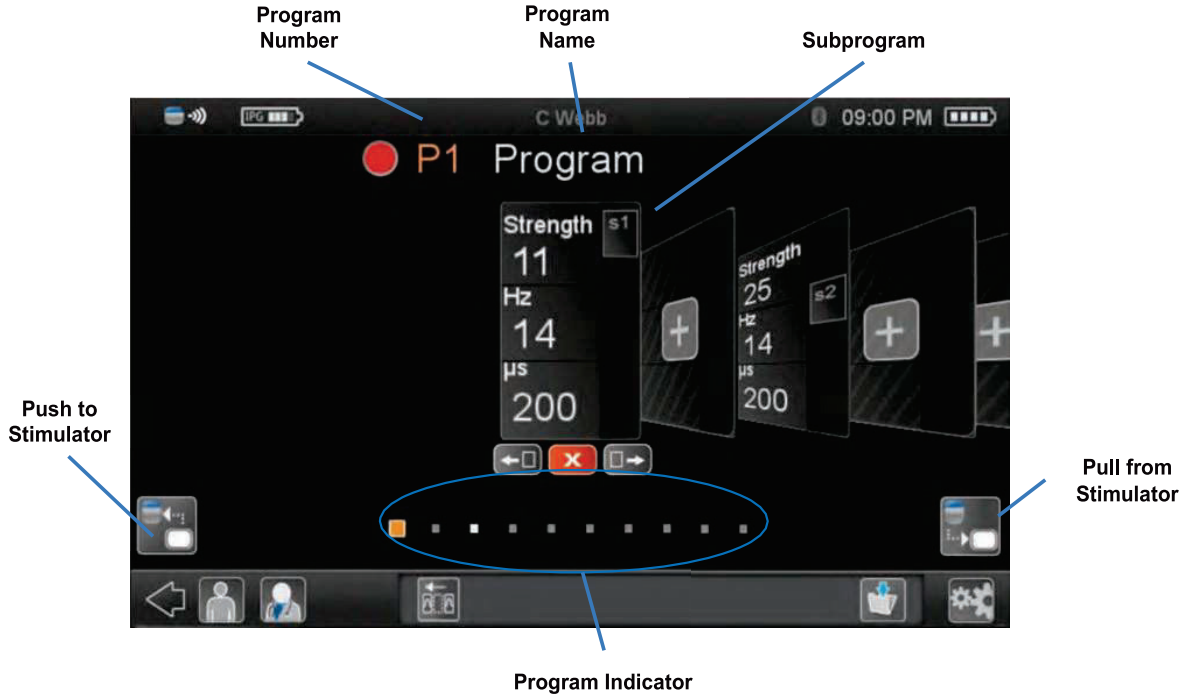


Figure 22. Program Management screen

Program Number	The number assigned to the program by the Clinician Programmer that indicates the display order on the patient programmers.
	Add. An empty program. Tap to add a program. Drag let or right in the middle of the screen to select a program.
	Compact Program. Compacts programs so there are no empty programs between configured programs. Compacting programs displays programs on the patient programmers successively, without gaps in program numbers, once you push programs to the stimulator.
	Delete. Deletes the program, including the subprograms.
	Move. Changes the program order. Moving programs adjusts the program number and display order on the patient programmers once you push programs to the stimulator.
	Pull from Stimulator. Pulls programs from the stimulator to the Clinician Programmer.
	Push to Stimulator. Pushes programs from the Clinician Programmer to the stimulator.
	Port Indicator. The port (lead) on which the program stimulates. Red is port 1. Green is port 2. Stimulation is unilateral; a program stimulates on only one port (lead). **Note:** Colors indicate port location and may not match flags used during the implant procedure.
Program Indicator	Gray boxes are blank programs. White boxes are populated programs. An orange box is the selected program. Drag left or right in the middle of the screen to select a program.

Strength	A representation of amplitude. The patient programmers display strength, not amplitude. A program's strength is derived from the strength of its subprograms. Each subprogram has a strength range of 1-50. The program strength will display 51-99 when incrementing a subprogram that has not reached its maximum strength while another subprogram is at its maximum strength.
Hz	Frequency. Applies to all subprograms within the program.
µs	Pulse width. Does not display when the subprograms of a program have different pulse widths.

Using the Program Screen

To access the Program screen (Figure 23):

- Tap a program on the Program Management screen. If patient stimulation is on, the Clinician Programmer shuts off stimulation.

Figure 23. Program screen

Program Number	The number assigned to the program by the Clinician Programmer that indicates the display order on the patient programmers.
	**Port Indicator**. The port (lead) on which the program stimulates. Stimulation is unilateral; a program stimulates on only one port (lead). External ring: red is port 1, green is port 2. Interior: gray when not selected, orange when selected.
	**Add**. An empty subprogram. Tap to add a subprogram.
	**Configure Subprogram**. Displays the Subprogram screen.
	**Move**. Changes the subprogram order. Moving subprograms adjusts the subprogram number. **Note:** The Clinician Programmer compacts subprograms when pushing programs to a stimulator so that there are no empty subprograms between configured subprograms.
	**Delete**. Deletes the subprogram.

Strength	A representation of amplitude for a program and subprogram. The patient programmers display strength, not amplitude. A program's strength is derived from the strength of its subprograms. Each subprogram has a strength range of 1-50. The program strength will display 51-99 when incrementing a subprogram that has not reached its maximum strength while another subprogram is at its maximum strength.
Hz	Frequency. Applies to all subprograms within the program.
mA	Amplitude. The amplitude a subprogram ramps up to upon starting stimulation. Subprograms within a program can have different amplitudes.
µs	Pulse width. Subprograms within a program can have different pulse widths.
	**Start**. Displays when not stimulating. Tap to start stimulation. Stimulation ramps to the set amplitude, and the icon switches to Stop.
	**Stop**. Displays and flashes when stimulating. Tap to stop stimulation. Stimulation ramps down to 0, and the icon switches to Start.
	**Increment/Decrement**. Increments or decrements the selected parameter.

Using the Subprogram Screen

To access the Subprogram screen (Figure 24):

Tap a subprogram name or  (Add) on a subprogram on the Program screen.

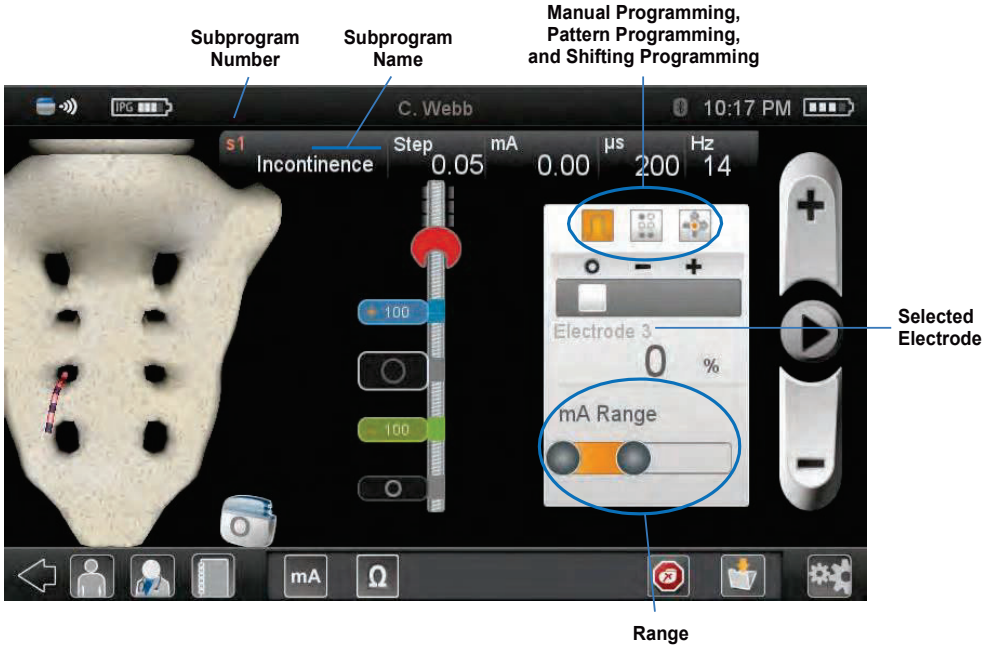
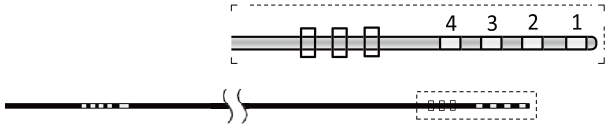


Figure 24. Subprogram screen

Subprogram Number	The number assigned to the subprogram by the Clinician Programmer that indicates order. Moving a subprogram adjusts the subprogram number.
Step	The rate at which the amplitude changes with each tap of **Increment** or **Decrement**.
mA	Amplitude. The amplitude a subprogram ramps up to upon starting stimulation. Limited by the amplitude range. Increments based on the Step parameter.
µs	Pulse width. Limited by the pulse width range.
Hz	Frequency. Limited by the frequency range. Changing the frequency for a subprogram changes the frequency for all subprograms within the program.
Selected Electrode	The selected electrode is orange. Tap an electrode to select the electrode. **Note:** The numbering of electrodes is 1 to 4, with 1 being on the distal end of the lead. 
Range	Displays the range for the selected parameter. The range restricts incrementing and decrementing of the parameter for the subprogram. Adjust the range to constrict or expand adjustment capabilities. The amplitude range sets the range in which a patient can adjust their stimulation strength. Available ranges: • Amplitude: 0-15 mA per channel and 0-30 mA total for the IPG or EPG • Pulse width: 20-440 µs • Frequency: 2-130 Hz
	**Manual Programming**. Manual electrode configuration. See Configuring Electrodes on page 34.
	**Pattern Programming.** Preconfigured electrode patterns. See Configuring Electrodes on page 34.
	**Shifting Programming.** Shifting of amplitude allocation up and down a lead. See Configuring Electrodes on page 34.
	**Amplitude Toggle.** Press and hold to display the amplitude value of an electrode, instead of the allocated percentage of the total amplitude for a subprogram.
	**Impedance Check.** Tap to conduct an impedance check from the implantable stimulator or trial stimulator ground pad to each electrode. Impedance results display for approximately one minute. Tap anywhere on the screen to dismiss the results.
	• Gray – Impedance test not executed • Yellow – Low impedance (≤ 2000 ohms) • Green – Normal impedance (2001-5000 ohms) • Red – High impedance (> 5000 ohms)
	**Start**. Displays when not stimulating. Tap to start stimulation. Stimulation ramps to the set amplitude, and the icon switches to Stop.
	**Stop**. Displays and flashes when stimulating. Tap to stop stimulation. Stimulation ramps down to 0, and the icon switches to Start.
	**Increment/Decrement.** Increments or decrements a selected parameter.

Creating a Program and Subprogram

To create a program and subprogram:

1. Drag left or right in the Program Management screen (Figure 22) to select a program.
2. Tap (Add Program). The Program screen displays (Figure 23).
3. Tap the name of the program and select a predefined name or edit the existing name.

Notes:

- » To change the program number (P1-P10), move the program on the Program Management screen.
- » The program number and program name are both visible to the patient on the Programmer Charger.

4. If two leads are connected to the stimulator, tap or to select the lead to program.
5. Tap (Add) to add a subprogram.
6. Tap New to create a subprogram.

   –or–

   Tap Copy if additional subprograms exist for the patient, and tap a subprogram to copy.

   The Subprogram screen displays (Figure 24).
7. Tap the name of the subprogram and select a predefined name or edit the existing name.
8. Adjust subprogram parameters. See Adjusting Subprogram Parameters on page 34.
9. Configure the electrodes. See Configuring Electrodes on page 34.
10. Verify programming. See Verifying Programming on page 37.
11. Push program changes to the stimulator. See Pushing and Pulling Programs on page 38.

Adjusting Subprogram Parameters

To adjust a parameter value (Amplitude [mA], Pulse Width [µs], or Frequency [Hz]):

1. Set the subprogram range for the parameter.
   a. Tap the value on the subprogram header to display the range slider.
   b. Tap the left-most slider to set the minimum value.
   c. Tap the right-most slider to set the maximum value.

   Note: The amplitude range sets the range in which a patient can adjust their stimulation strength.
2. Adjust the subprogram value.
   a. Tap the value on the subprogram header.
   b. Tap **Increment** or **Decrement**.

Configuring Electrodes

Configure electrodes for a subprogram via the Subprogram screen. A subprogram requires at least one anode and one cathode. You can also configure the implantable stimulator or a trial stimulator with a connected ground pad.

Note: During a trial, do not send the patient home with a program that uses the trial stimulator as an anode or cathode when the patient does not have a ground pad.

The Clinician Programmer automatically balances the amplitude allocation for the configured electrodes so that each configured electrode has the same amount of amplitude. You can manually adjust the allocation for each configured electrode if there are at least two configured electrodes of the same polarity. Adjusting the allocation for a configured electrode locks the electrode percentage; the Clinician Programmer does not change a locked electrode when balancing the amplitude allocation. The Clinician Programmer ensures that the amplitude allocation is always 100% of the set amplitude.

Note: If you remove an electrode from the subprogram while stimulating, the amplitude of the remaining electrodes stays the same and the amplitude value of the subprogram adjusts to reflect the removal of the electrode.

Modify programming by:

- Manually configuring each electrode (manual programming)
- Using preconfigured electrode patterns to assign the polarity of electrodes (pattern programming)
- Incrementally shifting amplitude allocation between electrodes (shifting programming)

Manual Programming

To manually configure electrodes:

1. Tap (Manual Programming) on the Manual Programming screen (Figure 25). The manual programming options display to the right of the lead.

Figure 25. Manual Programming screen

2. Tap an electrode or the stimulator in the lead model.

   Notes:

   » The trial stimulator represents the ground pad on the Subprogram screen.

   » The numbering of electrodes is 1 to 4, with 1 being on the distal end of the lead.

3. Change the polarity to positive (anode) or negative (cathode) using the polarity slider. The electrode changes color to blue for positive (anode) and green for negative (cathode).
4. Add additional electrodes.
5. [Optional step] If there is more than one electrode of the same polarity, increase or decrease the amplitude allocation for the selected electrode using Increment and Decrement.

   Adjusting the amplitude locks the electrode. You can also press and hold the electrode to lock the amplitude. To unlock the electrode for balancing by the Clinician Programmer, press the electrode until the lock symbol no longer displays.

Pattern Programming

To use patterns:

1. Tap (Pattern Programming) on the Pattern screen. The patterns display to the right of the leads (Figure 26).
   Note: Selecting patterns deletes any configured electrodes for the subprogram.

Figure 26. Pattern screen

2. Tap a pattern.
3. Tap (Manual Programming) to switch to manual programming to make adjustments.

Shifting Programming

To shift amplitude allocation:

1. Tap (Shifting Programming) on the Shifting screen. The shifting options display (Figure 27).

Figure 27. Shifting screen

2. Slide **Shifting Rate** to set the rate of shifting.
3. Tap the up or down triangles to shift the amplitude allocation in increments to the other electrodes.
   Note: Taping (Revert) reverts the electrode configuration to the original settings.

Verifying Programming

Verify programming changes by running the subprograms and programs. After verifying subprograms and programs, push program changes to the stimulator. See Pushing and Pulling Programs on page 38.

Caution: Use the lowest stimulation values possible that provide effective treatment. High values may cause patient discomfort and may increase the charging frequency of the stimulator.

To run a subprogram on the Subprogram screen:

1. Verify the patient name in the status bar matches the patient you are treating.
2. [Optional step] Tap Ω (Impedance Check) on the navigation bar to check impedance.
3. Tap (Start).
4. Tap **Accept** in the verification message.

   Stimulation ramps to the set amplitude, (Start) switches to (Stop), then (Stop) flashes to indicate stimulation is on.
5. Adjust parameters as needed.

   Note: If you remove an electrode from the subprogram while stimulating, the amplitude of each remaining electrode stays the same, but the total amplitude of the subprogram adjusts to reflect the removal of the electrode.
6. Press (Stop) when finished programming.

To run a program or subprogram on the Program screen:

1. Verify the patient name in the status bar matches the patient you are treating.
2. Tap a parameter in the program header to run a program.

   –or–

   Tap a parameter in the subprogram tile to run a subprogram.
3. Tap (Start).
4. Tap **Accept** in the verification message.

   Stimulation ramps to the set amplitude, (Start) switches to (Stop), then (Stop) flashes to indicate stimulation is on.
5. Adjust parameters as needed.
   a. Tap the value on the subprogram header.
   b. Adjust the amplitude, frequency, and pulse width range.
   c. Tap Increment or Decrement.
6. Press (Stop) when finished verifying.

Note: While stimulating a subprogram on the Program screen, selecting a different subprogram or program ramps down stimulation on the active subprogram then ramps up stimulation for the new selection.

Pushing and Pulling Programs

You can pull programs from the stimulator to copy them to the Clinician Program, or push programs from the Clinician Programmer to copy them to the stimulator.

Pushing or pulling programs updates the patient's programs with any new, modified, or deleted programs. Pushing and pulling programs also updates patient information and component configuration.

Pushing a modified program to the stimulator resets the run time for that program. If the program has not changed, the run time for the program remains the same after a push. See Patient Stimulation on page 44.

Note: Make sure to push program so they are available on the stimulator. To push or pull programs:

1. Tap  (Clinician Menu) >  (Program Management) in the navigation bar.
   –or–
   Tap  (Program Management) from the Patient Home screen.
2. Tap  Push to Stimulator) or  Pull from Stimulator).
3. Tap Accept.

7 Stimulator Information

Use the Stimulator Information Screens (Figure 28) to pair programmers to the stimulator, configure the stimulator, perform impedance checks, and view information about the stimulator.

1. To access the Stimulator Information screens:
   Tap (Clinician Menu) > Stimulator Information).
   –or–
   Tap (Stimulator Information) from the Patient Home screen.
2. Tap a selection from the Stimulator Information menu.

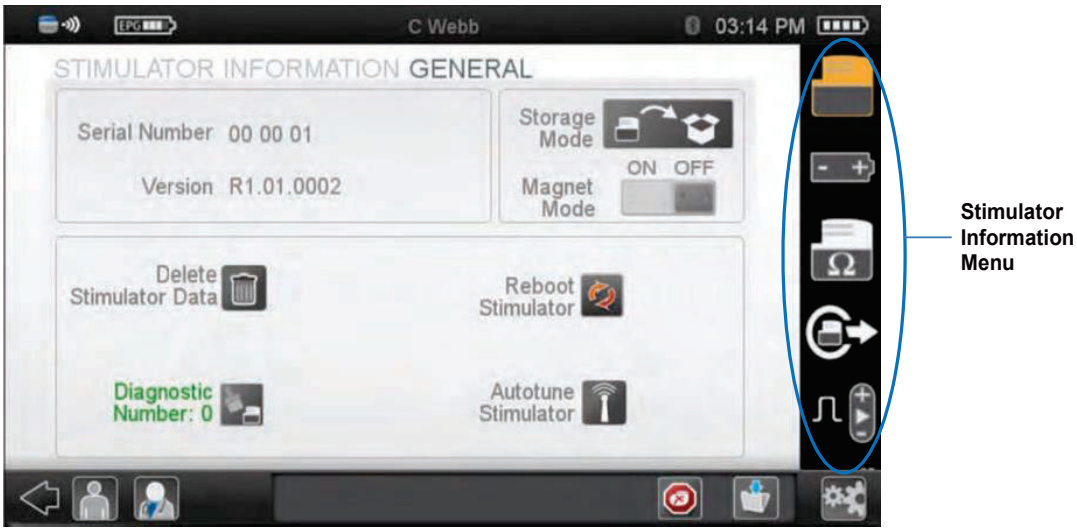


Figure 28 Stimulator Information Screens

	General. View general stimulator information and configure stimulator settings.
	Battery & ERI. View battery and Elective Replacement Interval (ERI) information.
	Impedance. Execute on-demand impedance checks and configure impedance check settings. Pairing. Pair a Programmer Charger and Pocket Programmers to the stimulator.
	Patient Stimulation. Stimulate using patient programs and view the run time of programs.
	An Advanced Features function is available. This feature is only Accessible when instructed to do so by Cirtec Customer Service.

General

To access the General screen (Figure 29):

- Tap (Stimulator Information) > (General).

Figure 29. General screen

Serial Number	The serial number of the stimulator.
Version	The version of the stimulator.
	Storage Mode. Tap to turn the stimulator off. For instructions on waking up the stimulator, see the Stage 2: Implant Manual for Stimulator.
Magnet Mode	Slide to set the magnet mode. When on, the patient can use the optional Virtis System Magnet Model 8900 to turn stimulation off and on. See the magnet insert for information. **Note:** Regardless of this setting, you can always use a magnet to place an implantable stimulator into storage mode.
	Delete Stimulator Data. Tap to remove programs and data residing on the stimulator.
	Reboot Stimulator. Tap to reboot the stimulator, which stops stimulation and reinitializes the internal settings. **Note:** This does not affect the patient information or programs on the stimulator.
	Autotune Stimulator. Tap to notify the stimulator to optimize communication. Autotune the stimulator after implant or if you or the patient experience reduced communication between the stimulator and the Programmer Charger, Pocket Programmer, and Clinician Programmer. This may happen when the tissue surrounding the stimulator changes, such as after healing from surgery or a significant weight change.
	Diagnostic Number. Tap to clear the displayed diagnostic number on the stimulator. If there is more than one diagnostic number, repeat to clear additional numbers.

Battery & ERI

Use the Battery & ERI screen (Figure 30) to view information on the implantable stimulatory battery and Elective Replacement Interval (ERI).

To access the Battery & ERI screen:

- Tap (Stimulator Information) > (Battery & ERI).

Figure 30. Battery & ERI screen

Battery Charges	The number of full battery chargers of the implantable stimulator.
Storage Mode Exits	The number of times the implantable stimulator exited storage mode.
Battery Depletions	The number of times the implantable stimulator battery depleted.
Implantation	The date when the stimulator was implanted. **Note:** The Clinician Programmer uses its current date to set the implant date of the implantable stimulator when you add the stimulator to the sacral model.
ERI Expiration	The expected replacement date of the implantable stimulator. The date is ten years from the implantation date.

Impedance

Use the Impedance screen (Figure 31) to perform on-demand impedance checks, set background impedance checks, and set the estimated impedance value for stimulation.

To access the Impedance screen:

- Tap (Stimulator Information) > (Impedance).

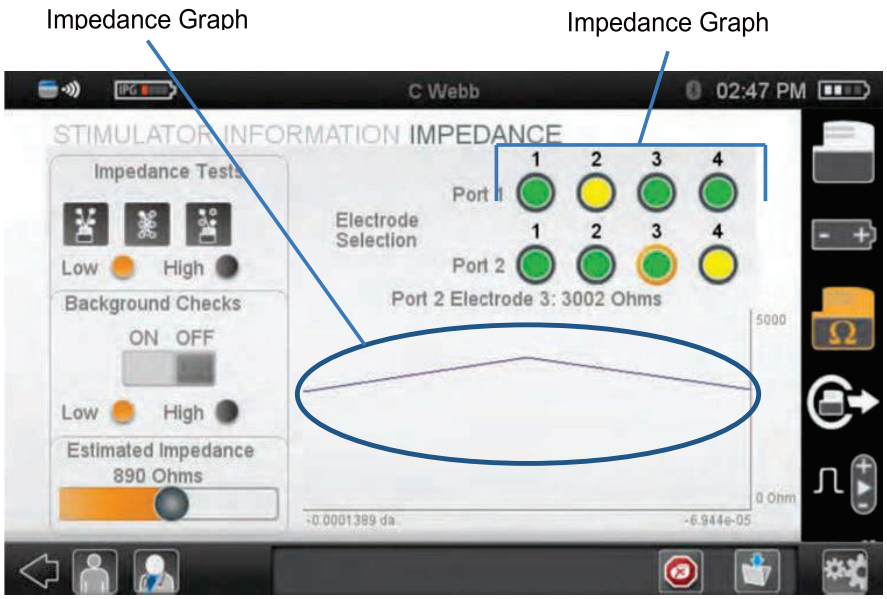
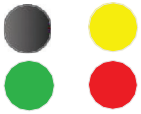


Figure 31. Impedance screen

Impedance Tests: Low/High	Tap to set the amplitude at which the stimulator executes the impedance check; Low is 0.2 milliamps and High is 0.5 milliamps. Always execute an initial impedance check using the low setting. If the impedance results are low (yellow) or high (red) and the patient did not feel stimulation, execute another test using the high setting. Contact Cirtec Customer service when results are low (yellow) or high (red) for either an impedance check using the high setting or an impedance check using the low setting where the patient feels stimulation.
	**Electrode to Can**. Tap to check the impedance between each electrode and the implantable stimulator or trial stimulator ground pad.
	**Electrode to Electrode**. Tap to check the impedance between a selected electrode and the other electrodes.
	**Program Electrode to Can**. Tap to check the impedance between the implantable stimulator or trial stimulator ground pad and the electrodes configured in the most recently viewed program, indicated to the right of the icon.
Background Checks	Tap to set if the stimulator checks the impedance for the electrodes of the running program. When enabled, the implantable stimulator checks impedance each time stimulation stops and the trial stimulator checks impedance each time stimulation starts. If the stimulator detects high impedance for an electrode, the stimulator disables the program. If enabled, set the amplitude for the background impedance checks; Low is 0.1 milliamps and High is 0.2 milliamps. **Note:** A patient cannot run a disabled program. A patient may have a disabled program if background checks were on and they unplugged their trial stimulator while the stimulator was performing a background check.

Estimated Impedance	This is an advanced feature. Contact Cirtec Customer Service for more information.
	Displays the results of the most recent impedance check. • Gray – Impedance test not tested • Yellow – Low impedance (≤ 2000 ohms) • Green – Normal impedance (2001-5000 ohms) • Red – High impedance (> 5000 ohms)
Impedance Graph	Tap an electrode to display impedance results for an electrode over multiple impedance checks.

Pairing

To use a Programmer Charger or a Pocket Programmer to control stimulation, you must pair the Programmer Charger or Pocket Programmer to the stimulator. Use the Pairing screen (Figure 32) to pair a Programmer Charger or Pocket Programmer to the stimulator.

To pair the programmers, you need the serial number located on the label on the back of the programmer. The programmers need not be present when pairing with the stimulator.

To access the Pairing screen:

- Tap (Stimulator Information) > (Pairing).

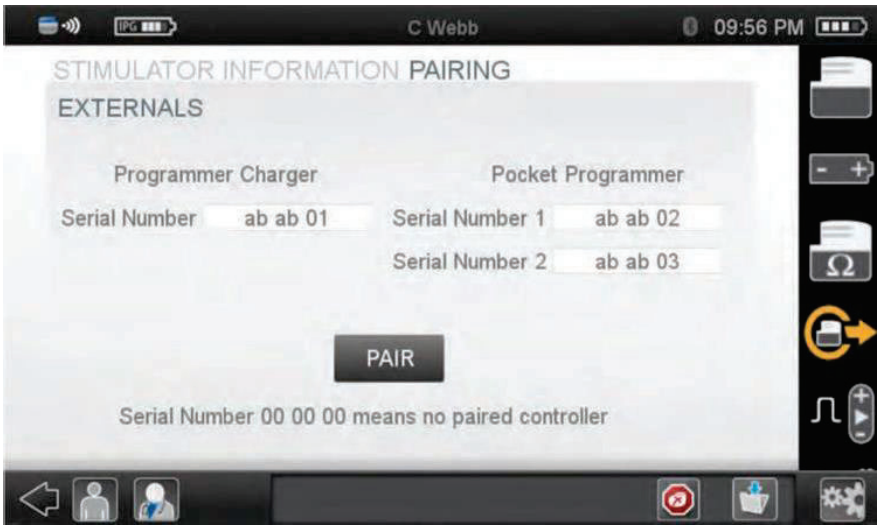


Figure 32. Pairing screen

Serial Number	Tap to enter the serial number located on the label on the back of the programmer, then tap **Pair**.
Pair	Tap to send the stimulator the serial numbers for the paired Programmer Charger and Pocket Programmer.

Patient Stimulation

Use the Patient Stimulation screen (Figure 33) to view the run time of a program and run patient programs.

Note: Patient programs are programs that reside on the stimulator. Programs on the Programming screen are trial programs that need pushed to the stimulator to become patient programs.

To access the Patient Stimulation screen:

- Tap (Stimulator Information) > Patient Stimulation).

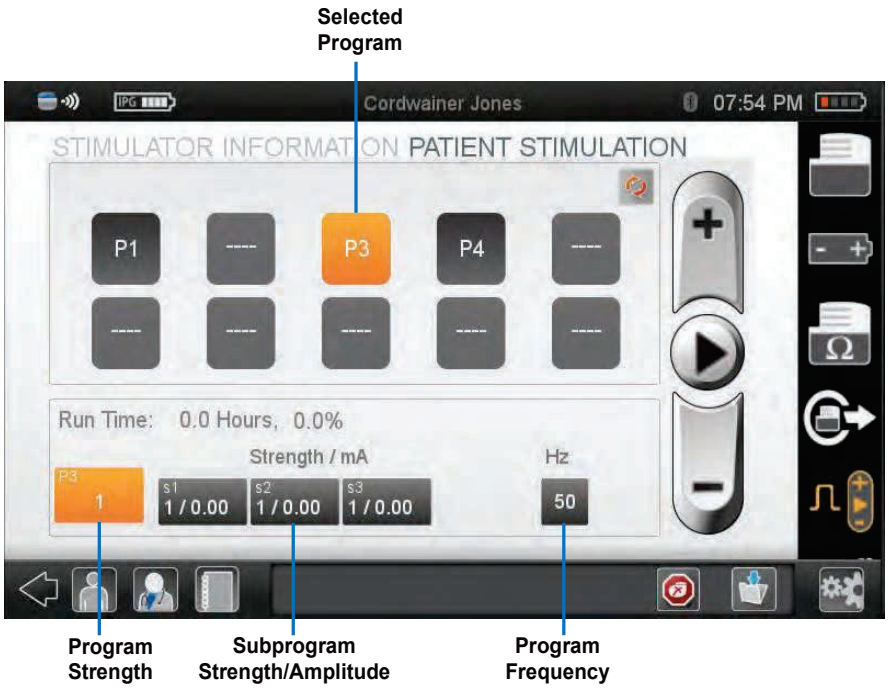


Figure 33. Patient Stimulation screen

	Tap to reset the run time of the selected program or of all programs. **Note:** Pushing a changed program from the Clinician Programmer to the stimulator resets the run time of the changed program.
	Tap to select the program to view the program run time and stimulation settings.
Run Time	The run time of the selected program. Run time does not include test stimulation ran on the Program screen and Subprogram screen. The percentage next to the run time is the run time of the program in relation to the total run time for all programs on the stimulator.
	Start. Tap to start stimulation for the selected program. Stimulation ramps to the set amplitude, and the icon switches to Stop.
	Stop. Tap to stop stimulation for the selected program. Stimulation ramps down to 0, and the icon switches to Start.
	Increment/Decrement. Tap to increment or decrement the selected parameter.

8 Pictures

Use the Clinician Programmer camera to take pictures related to a patient or a patient procedure.

To take pictures with the Clinician Programmer:

1. Tap (Clinician Menu) (Camera).

   –or–

   Tap (Camera) from the Patient Home screen.

   The Camera screen (Figure 34) displays with the picture preview.

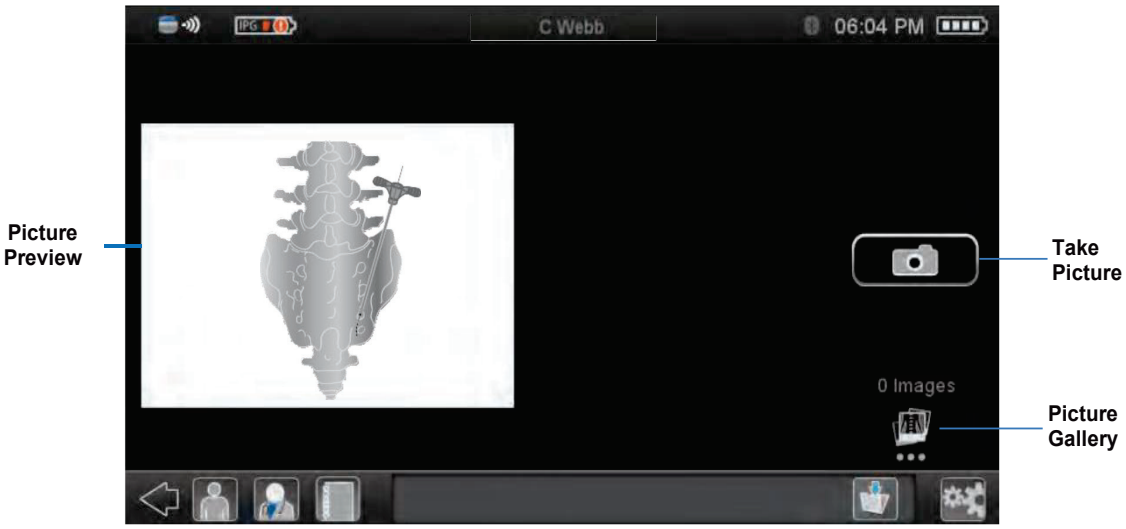


Figure 34. Camera screen

2. Tap (Take Picture) to take the picture.
3. Tap **Keep** to save the picture in the gallery.

   –or–

   Tap **Discard** to dispose of the picture and return to the picture preview.

To view pictures:

1. Tap (Patient Menu) > (Picture Gallery).

   –or–

   Tap (Picture Gallery) from the Patient Home screen.

   The Gallery screen (Figure 35) displays.

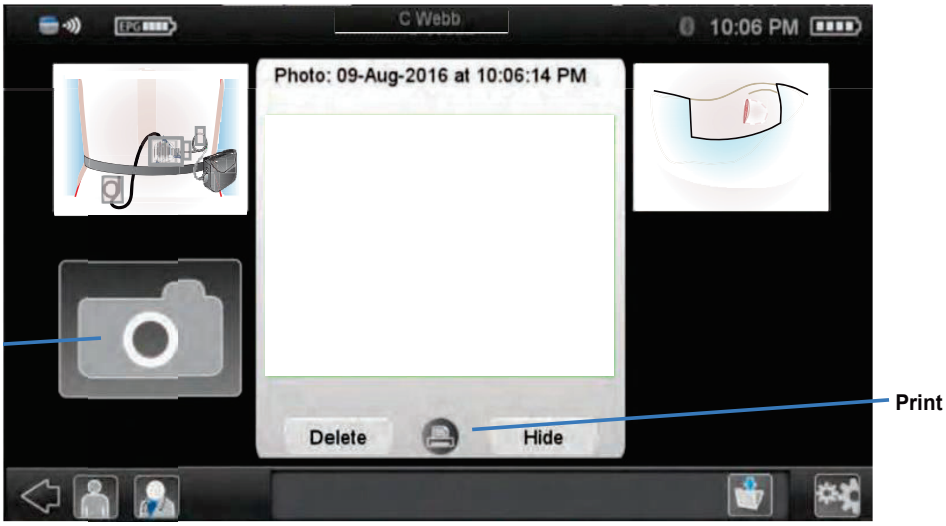


Figure 35. Gallery screen

2. Tap a picture to enlarge the picture.
3. Tap (Print) to mark the picture for printing on reports.

   Note: A report can have up to four pictures.

9 Clinician Programmer Settings

Use the Settings screens (Figure 36) to adjust the display and defaults of the Clinician Programmer.

To access the Settings screens:

1. Tap (Tools Menu) > (Settings).

   –or–

   Tap (Settings) from the Patient Home screen.

2. Tap a selection from the Settings menu.

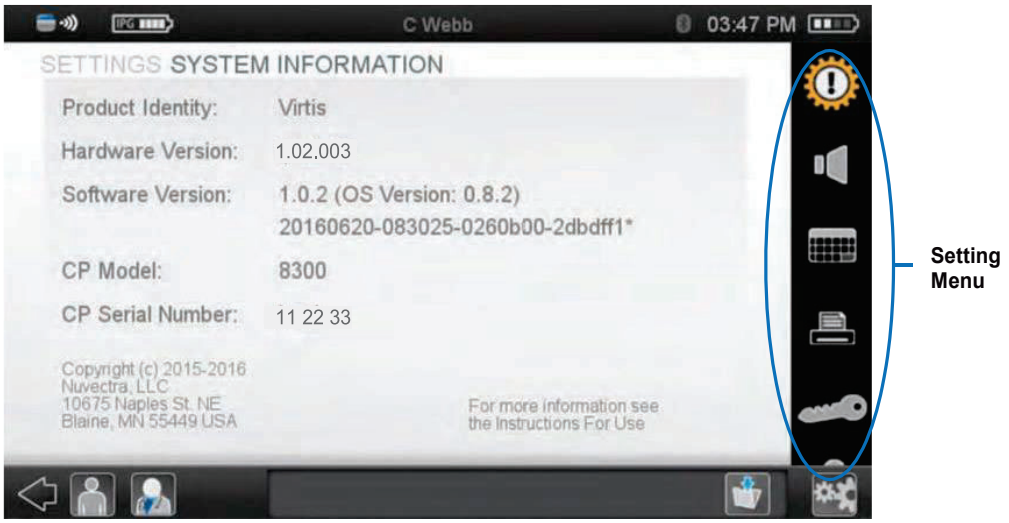


Figure 36. Settings screens

	System Information. View information about the Clinician Programmer, including version, model, and serial numbers.
	Display. Set display settings for the Clinician Programmer, including screen brightness and calibration.
	Time & Date. Set the time and date settings for the Clinician Programmer.
	Printer Management. Perform a printer test.
	User Administration. Configure user accounts for the Clinician Programmer.
	Physician Administration. Configure physician and medical facility information.
	Programming Defaults. Set Clinician Programmer default settings for new programs for the current user.

Display

The Display screen (Figure 37) includes setting options that affect the display of the Clinician Programmer.

To access the Display screen:

- Tap (Settings) > isplay).

Figure 37. Display screen

Brightness	Slide to adjust the brightness of the screen. **Note:** The screen brightness affects the rate at which the battery discharges.
Power Saving Timeout	Slide to adjust the time at which the Clinician Programmer shuts down. **Note:** The Clinician Programmer screen dims after two minutes with no use
Sound	Tap to turn on or off the click sound that occurs when tapping the screen.
Cursor	Tap to turn on or off the cursor indicator that displays when tapping the screen. Tap to reset the display settings to the factory defaults
	Tap to start a calibration test to recalibrate the screen.
	You may need to recalibrate the screen if you touch an image on the screen and the Clinician Programmer does not react as expected

Time & Date

The Time & Date screen (Figure 38) provides setting options that affect the date and time of the Clinician Programmer. The date displays on the status bar of the Clinician Programmer screens.

Note: The Clinician Programmer uses its current date to set the implant date of the implantable stimulator when you add the stimulator to the sacral model.

To access the Time & Date screen:

- Tap (Settings) > (Time & Date).

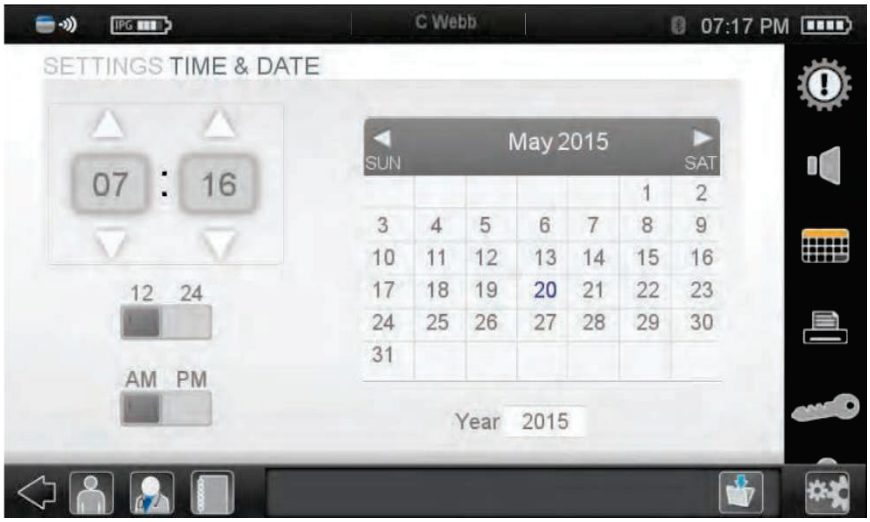


Figure 38. Time & Date screen

Calendar	Tap a day to set the month and day.
Year	Tap to enter a year.
Hour & Minute	Tap to change the hour and minute.
12/24	Tap to set the display of time to a 12-hour or 24-hour clock.
AM/PM	Tap to set the time to AM or PM. Displays when 12/24 is set to 12.

Printer Management

The Printer Management screen (Figure 39) provides the ability to print a test page to help troubleshoot issues with printing.

Note: Make sure to turn on the printer and to move the printer in range of the Clinician Programmer prior to printing a test page.

To access the Printer Management screen:

- Tap (Settings) > (Printer Management).

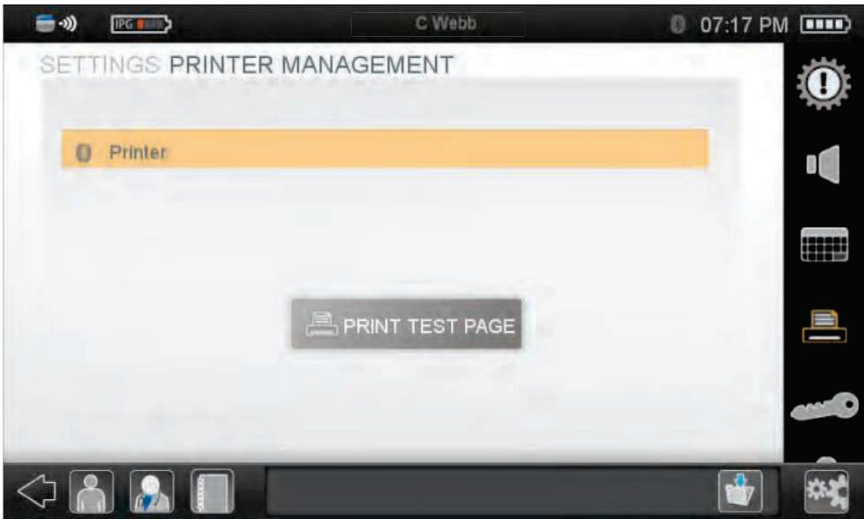


Figure 39. Printer Management screen

User Administration

The Clinician Programmer is shipped with administrator access. The initial user name is admin and the password is admin. After the initial log in, reset the password for the administrator user, and create accounts for each additional user using the User Administration screen (Figure 40).

The Admin user can add or delete users. Other users can change their information and password. To access the Settings User Administration screen:

- Tap (Settings) > (User Administration).

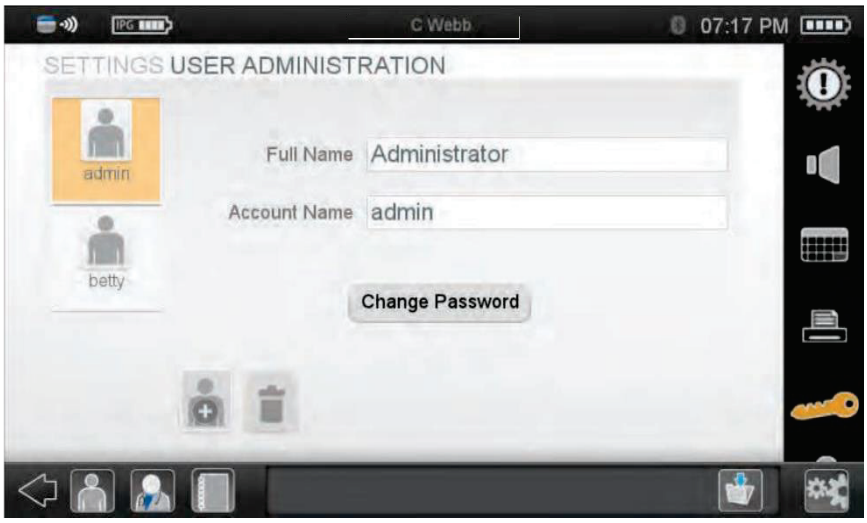


Figure 40. User Administration screen

	Tap to change the indicated user information and password. Scroll to view additional users
	Tap to add a user.
	Note: Only the Admin user can add a user. Tap to delete a user. **Note**: Only the Admin user can delete a user.

Physician Administration

Add a physician and their medical facility information on the Physician Administration screen (Figure 41). After adding a physician, you can add the physician to one or more patients on the Patient Information Screen. Deleting a physician removes the physician from all patients.

To access the Physician Administration screen:

- Tap (Settings)(Physician Administration).

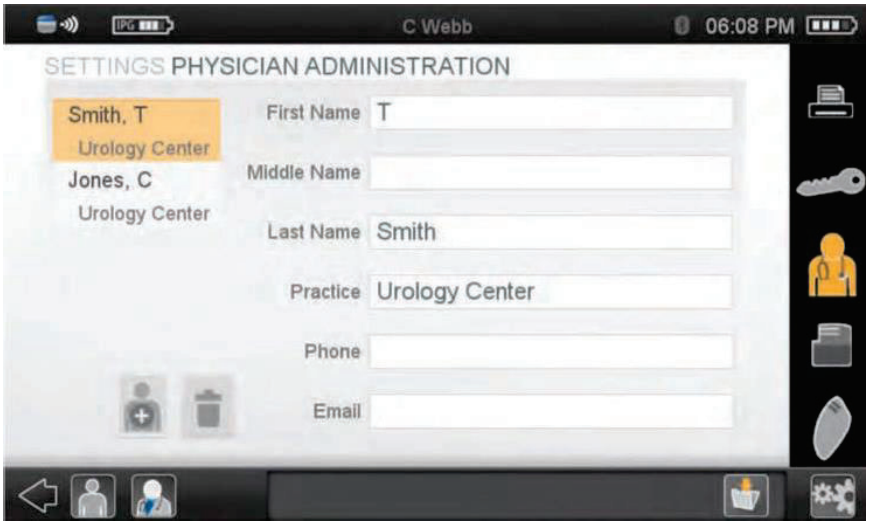


Figure 41. Physician Administration screen

Physician Name	Tap to edit the information for the physician. Scroll to view additional physicians.
	Tap to add a physician.
	Tap to delete a physician.

Programming Defaults

Use the Programming Defaults screen (Figure 42) to set the defaults for frequency and pulse width for when you create new programs on the Clinician Programmer. Changing the defaults does not affect previously created programs.

Note: Use the lowest settings possible that provide effective treatment. High settings may cause discomfort and decrease the time between changing batteries for a trial stimulator and increase the charging frequency of the implantable stimulator.

To access the Programming Defaults screen:

- Tap (Settings) > (Programming Defaults).

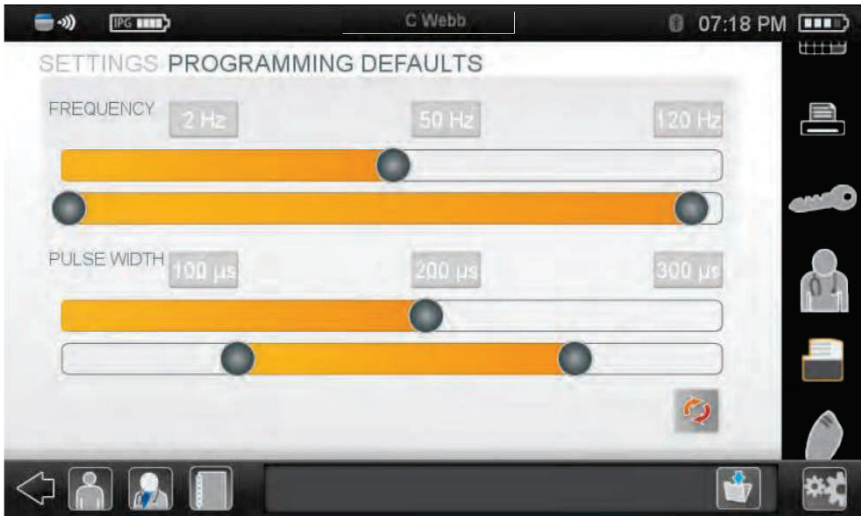


Figure 42. Programming Defaults screen

Frequency	Top slider: Slide to set the default frequency for a new program. Bottom slider: Slide to set the default frequency range (minimum and maximum) for a new program.
Pulse Width	Top slider: Slide to set the default pulse width for a new subprogram. Bottom slider: The default pulse width range (minimum and maximum) for a new subprogram.
	Tap to reset the program defaults to the system factory defaults.

10 Reports

The Clinician Programmer has a report you can print using a Zebra EM220 strip printer or a compatible replacement. To view and print reports:

1. Move a printer that is on and in range of the Clinician Programmer.
2. Tap (Tools Menu) > (Reports) in the navigation bar.

   –or–

   Tap (Reports) from the Patient Home screen.

   The Reports screen (Figure 43) displays with general information about the patient and the stimulator.
3. Tap one or more selections from the Report menu to add the information to the displayed report. The selection is highlighted in the Report Menu.
4. Tap (Print) to print the report. The report prints the information displayed on the Reports screen.

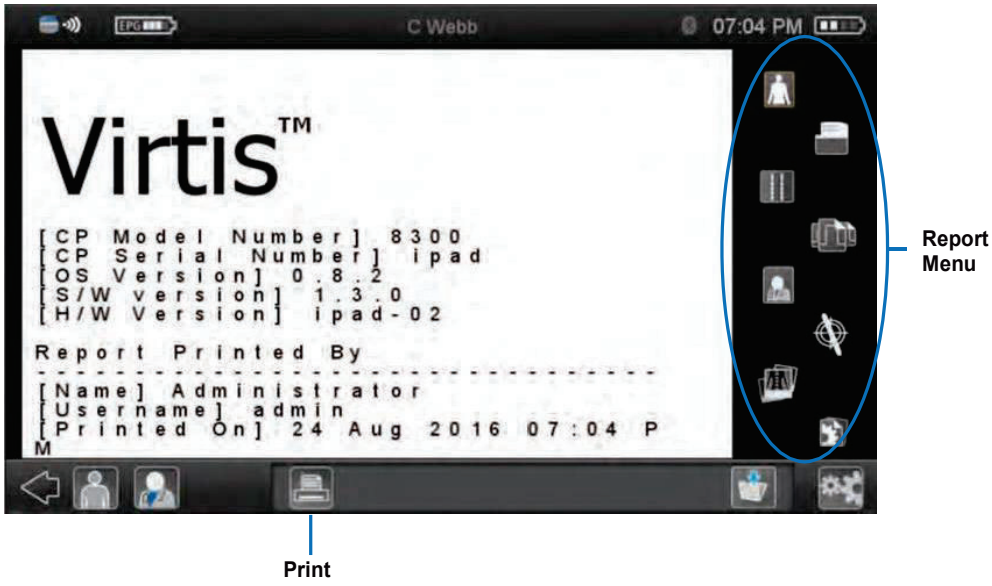


Figure 43. Reports screen

	General Information. Displays on every report. Clinician Programmer version and model information, current date, and information from the Patient Information screen. Company information displays at the end of the report.
	Stimulator. Stimulator information, including stimulator to lead port connections and the serial number of paired Programmer Chargers and Pocket Programmers.
	Lead. Lead information, including model and lot number.
	Program. Program and subprogram information, including modification information, program configuration information, electrode assignments, and program runtime.
	Physician. Information about the physician and medical facility.
	Intraoperative Test Stimulation. Intraoperative test stimulation results.
	Pictures. Pictures selected from the gallery. See Pictures on page 45.
	Stimulator Diagnostics. Battery information and impedance check results.

11 Emulators

The Clinician Programmer includes emulators for the Programmer Charger and Pocket Programmer that you can use to become familiar with the interface without starting stimulation or affecting the settings in the Emulators screen (Figure 44). See the Patient System Manual for information on the Programmer Charger and Pocket Programmer.

Figure 44. Emulators screen

To access the emulators:

1. Tap (Tools Menu) (Emulators).
   –or–
   Tap (Emulators) from the Patient Home screen.
2. Tap an emulator button to demonstrate the Programmer Charger or Pocket Programmer functionality.

Note: The programs that display in the emulator mimic the programs the Clinician Programmer has for the patient. Make sure to push the programs to the stimulator so they are available for the patient.

12 Charging the Clinician Programmer Batteries

Charging the Clinician Programmer

The Clinician Programmer battery status displays in the status bar of the Clinician Programmer battery status (Figure 45).

Figure 45. Clinician Programmer battery status

If storing the Clinician Programmer for an extended period of time, fully charge the Clinician Programmer, then charge the Clinician programmer every six months. The Clinician Programmer uses a small amount of charge while off and may become non-rechargeable if not periodically charged.

If the Clinician Programmer charge drops below 15%, the Clinician Programmer stops controlling stimulation. If the Clinician Programmer shuts down from a low charge, connect the Clinician Programmer to the power cord and restart the Clinician Programmer. If you were programming when the Clinician Program shut down, view programs to verify they are complete.

Note: You can use the Clinician Programmer while the Clinician Programmer is charging.

To charge the Clinician Programmer:

- Insert the power cord to the micro USB port on the bottom of the Clinician Programmer and power cord (Figure 46).

Figure 46. Clinician Programmer and power cord

For more information, see the instructions packaged with the Programmer Power Cord Model 8010.

13 Care, Handling, and Disposal

Care and Handling

Handle the Virtis System components and accessories with care. Do not drop them or submerge them in water. Avoid all sources of water that can come into contact with the devices. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. See the Limited Warranty for additional information.

Cleaning the Clinician Programmer

The Clinician Programmer and power cord are not waterproof. Do not immerse them in liquid or allow moisture to get inside the cases.

If the Clinician Programmer is dirty, clean the outside with a slightly damp cloth. Do not clean your Clinician Programmer with bleach, nail polish remover, or similar substances.

Clean the Clinician Programmer screen with a household glass cleaner that does not contain ammonia.

Cleaning the Trial Stimulator Battery Contacts

Clean the trial stimulator battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.

Caution: Do not leave depleted batteries in the trial stimulator. The batteries may corrode and cause damage to the electronic components. If you will not use the trial stimulator for several weeks, remove the batteries.

Storage

Caution: If you store the Clinician Programmer for an extended period of time, make sure to fully charge the battery before storing, and periodically charge the battery every 6 months. The Clinician Programmer uses a very small amount of battery charge while turned off and may become non-rechargeable if not periodically charged.

The sensitive electronics of the Clinician Programmer can be damaged by temperature extremes, particularly high heat.

- Do not expose the Clinician Programmer to excessively hot or cold conditions, including leaving the Clinician Programmer in your car or outdoors for extended periods of time.
- If storing the Clinician Programmer for an extended period of time, the temperature should not exceed -4° F to 140° F (-20°C to 60°C).

Repair

The Clinician Programmer does not have any user-serviceable parts. Do not attempt to open or repair the device. Unauthorized repairs will void the warranty. If unforeseen service is required, only Cirtec should service or repair the Clinician Programmer.

If you have any questions about a Virtis System, call Cirtec Customer Service.

When contacting Cirtec, have the Clinician Programmer serial numbers available, which are located on the label on the back of each device.

Note: The Limited Warranty does not cover loss or theft of the Clinician Programmer or damage caused by misuse. For additional information, see the Limited Warranty.

Accessory Replacement

Contact Cirtec if you lose a power cord or other accessory.

Disposal

The Clinician Programmer contains rechargeable lithium batteries. Do not incinerate or dispose of the Clinician Programmer in general household trash. When no longer needed, return the Clinician Programmer to Cirtec or consult local regulations for proper disposal of electronic devices.

14 Troubleshooting

If the instructions in this chapter do not solve your problem, contact Cirtec Customer Service.

Cirtec Customer Service

If you have any questions about the Virtis System, call Cirtec Customer Service at 763 493 8556 within the United States.

Outside of the United States, call your product distributor for assistance. If additional assistance is needed, contact Cirtec Customer Service at +1·763·493·8556.

Clinician Programmer Troubleshooting

Problem	Possible Cause and Solution
Patient is not experiencing stimulation.	The Clinician Programmer is not connected to the stimulator. Disconnect the stimulator from any nearby Programmer Chargers, Pocket Programmers, or Clinician Programmers, then tap the stimulator in the status bar to establish a connection.
	The stimulator battery is depleted, as indicated by the stimulator battery level on the status bar of the Clinician Programmer. Note: Pocket Programmers and Programmer Chargers also display the battery level of a connected stimulator. Charge the stimulator.
	Stimulation is not in an optimum location. Adjust the assignment of the electrodes for the subprograms. Using the Subprogram Screen on page 32.
	Stimulation is off. Although unlikely, EMI from security gates or other electronic devices may have turned off stimulation. Restart stimulation.
	The impedance at the stimulation site increased. Conduct an impedance test and review the results. If necessary, adjust the estimated impedance. See General on page 40.
Patient is noticing changes (increases or decreases) in stimulation strength.	A change in body position is affecting stimulation strength. Patients should keep their Programmer Charger or Pocket Programmer with them to adjust the strength or to select a new program.
Cannot start stimulation.	The battery of the Clinician Programmer is too low. Charge the Clinician Programmer. See Charging the Clinician Programmer on page 56.
Stimulation stopped unexpectedly.	
The Clinician Programmer does not turn on.	
After tapping an icon, an incorrect screen appears.	The Clinician Programmer touch screen is out of calibration. Calibrate the touch screen. See Display on page 48.
Cannot increase or decrease the strength, amplitude, frequency, or pulse width for a program.	Incrementing or decrementing the value is outside the allowed range. Adjust the maximum value for the range. Using the Subprogram Screen on page 32.
Cannot add pictures to a report.	The report already contains the maximum number of four pictures. Deselect a picture from the picture gallery. See Pictures on page 45.
Tapping the Pocket Programmer or Programmer Charger emulator on the Clinician Programmer does not result in stimulation changes.	The emulator screens are for reference only. Run programs from the Patient Stimulation screen. See Patient Stimulation on page 44.

Problem	Possible Cause and Solution
The programs on the stimulator (visible via the patient programmers) do not display on the Clinician Programmer.	The programs were not pushed or pulled to the Clinician Programmer. Pull the programs from the Programmer Charger to the Clinician Programmer, or push the programs to the Programmer Charger to the Clinician Programmer. See Pushing and Pulling Programs on page 38
Diagonal lines display in a program on the Program Management screen.	The stimulator has disabled the program. Execute an impedance check and adjust the patient's programs. See Impedance on page 42.
A red outline displays on the subprogram number on the Subprogram screen.	The subprogram amplitude is not balanced. Make sure there is at least one anode and one electrode for the subprogram.
Cannot change the amplitude on an electrode.	The electrode is locked or there are not two electrodes of the same polarity. Change the electrode configuration. See Using the Subprogram Screen on page 32.
Cannot shift amplitude in certain configurations.	The Clinician Programmer does not shift amplitude if the shifting would result in less than 100% allocation of the amplitude. Change the electrode configuration. Using the Subprogram Screen on page 32.
Implant date not correct.	The Clinician Programmer is not set to the current time or the stimulator implant was programmed before surgery. Contact Customer Service.
Trouble communicating with a stimulator.	Environmental conditions for the stimulator changed. Autotune the stimulator. See General on page 40.
Patient cannot turn stimulation on or off with a magnet.	Magnet mode is not on. Turn magnet mode on. See General on page 40.

Clinician Programmer Messages

Some messages may include a reference number. If provided, note the reference number when contacting Cirtec Customer Service.

Message	Description/Possible Action
Unable to communicate with stimulator. Try again.	Verify the stimulator is in range of the Clinician Programmer. Reconnect by tapping the stimulator icon in the status bar.
Stimulation stopped. Connection to stimulator interrupted.	
Unable to pull/push programs. Try again.	
Unable to create patient record from stimulator. Create patient record manually.	
Unable to communicate with stimulator. Manually push programs when able to connect.	
Start stimulation and try again. If message persists, contact support.	
Unable to connect. Clinician Programmer battery too low.	Plug the power cord into the Clinician Programmer to ensure uninterrupted usage.
Battery level is at 10%. Charge Clinician Programmer.	
An existing patient record is associated with the selected stimulator (MICS ID).	The Clinician Programmer contains a patient with the same serial number. Identify the patient with the same stimulator by sorting patients by the serial number on the Patient Select screen.
That stimulator already exists on this CP. Use it anyway?	
The model type in the patient record does not match the model type for the stimulator.	Verify the model and serial number for the patient.
Unable to automatically push programs. Manually push programs.	Manually push the programs from the Program Management screen.
Unable to clear data from trial stimulator. Manually clear data before reusing.	Clear the data from the Stimulator Information General screen.

Message	Description/Possible Action
Stimulator programs do not match Clinician Programmer programs.	The programs on the stimulator do not match those on the Clinician Programmer. Push or pull the programs.
CP Patient Record's model type does not match the stimulator's reported model type.	Verify the stimulator model number and type and update the information.
Four images already marked for printing. Remove one before proceeding.	A report can have up to four pictures. Deselect a picture from the picture gallery to add a different picture.
Unable to find a powered on compatible printer within range.	Verify the printer is on. Move the printer closer to the Clinician Programmer.
Create a valid subprogram to shift current.	Verify the program has at least one anode and one cathode.

Charging a Fully Discharged Implantable Stimulator

A patient may need assistance to charge a fully discharged implantable stimulator.

To charge a fully discharged implantable stimulator:

1. Move the Programmer Charger within 1 meter (3 feet) of the implantable stimulator and turn on the Programmer Charger. The Not Able to Connect screen displays.
2. Tap Cancel to display the Home screen.
3. Connect the charging paddle to the Programmer Charger.
4. Align the charging paddle over the implantable stimulator. Use either the adjustable belt or an adhesive patch to hold the charging paddle in place.
5. Tap  (Charge Status). The Charge Status screen displays.
6. Tap OK on the Charge Status screen.
7. Wait until charging completes.
8. Tap OK on the Charging Complete screen.
9. Tap  (Communication) to connect to the implantable stimulator.

Setting the Implantable Stimulator Depth

Adjust the depth setting if an implantable stimulator is implanted deeper than 1.5 cm (0.59 in) or if the patient has trouble charging the implantable stimulator.

To set the implant depth:

1. Tap  (Programmer Settings) on the Home screen of the Programmer Charger.
2. Tap Advanced Settings on the Programmer Settings screen.
3. Enter the last two digits of the serial number located on the back of the Programmer Charger and tap OK.
4. Tap Implant Depth on the Advanced Settings screen.
5. Select Deep.

15 System Specifications

Clinician Programmer Specifications

Clinician Programmer Specifications	
Operating temperature	0° C to 40° C (32° F to 104° F)
Storage temperature	-20° C to 60° C (-4° F to 140° F)
Operating/storage humidity	10% to 95%
Operating/storage atmospheric pressure	70 kPa to 106 kPa (20.7 inHg to 31.3 inHg)
Size (approximate)	213.4 x 127 x 23 mm (8.4 x 5 x 0.904 in)
Weight including battery (approximate)	450 grams (15.9 ounces)
Battery	Rechargeable lithium-ion battery
Mode of operation	Continuous

Table 3 Clinician Programmer Specifications

Safety and Compatibility Standards Conformity

Virtis Clinician Programmer Model 8300 complies with the following standards:

- IEC60601-1, Medical Electrical Equipment Safety
- IEC60601-1-2, Electromagnetic Compatibility
- ISO 14708-1, Safety, Marking and Information of Medical Devices

Electromagnetic Compatibility Declaration Tables

This section lists the EMC Declaration tables. The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer should assure that they are used in such an environment. The Clinician Programmer contains RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with the Clinician Programmer.

The power supply cable (maximum length 188 cm) and an HDMI cable (200 cm) was included in the Virtis System testing to demonstrate compliance with the requirements of IEC 60601-1-2 2007. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the Clinician Programmer.

The Clinician Programmer should not be used adjacent to or stacked with other equipment.

If adjacent or stacked use is necessary, the Clinician Programmer should be observed to verify normal operation in the configuration in which it will be used. The essential performance of the Clinician Programmer is that it cannot cause the stimulator or trial stimulator to exceed stimulation limits set by the clinician.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Clinician Programmer uses RF energy primarily for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Clinician Programmer is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 4 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic immunity			
The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Clinician Programmer requires continuous operation during power mains interruptions, it is recommended that the Clinician Programmer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the A.C. mains voltage before application of the test level.			

Table 5 ***Guidance and manufacturer's declaration - electromagnetic immunity***

Guidance and manufacturer's declaration - electromagnetic immunity			
The Clinician Programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Clinician Programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinician Programmer is used exceeds the applicable RF compliance level above, the Clinician Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Clinician Programmer.			

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

Table 6 ***Guidance and manufacturer's declaration - electromagnetic immunity***

Recommended separation distances between portable and mobile RF communications equipment and the Clinician Programmer			
The Clinician Programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clinician Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clinician Programmer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Table 7 Recommended separation distances between portable and mobile RF communications equipment and the Clinician Programmer

Wireless Information Table

Wireless Specifications and Safety	
Programmer wireless technology operating characteristics	The Clinician Programmer interacts with the stimulator using MedRadio Band: 402-405 MHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 301 839-2 USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219
	The Clinician Programmer interacts with the stimulator using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 300 328 USA: FCC part 15.24
Stimulator wireless technology	The stimulator complies with emissions requirements per R&TTE Standard EN 301 839-2 v13.1 (402MHz to 405MHz).
Wireless integrity	The Virtis System employs mechanisms to ensure integrity of the communication area. The stimulator will not respond to any device to which it is not linked.

Table 8 Wireless Specifications and Safety

Compliances and Authorizations

The Clinician Programmer has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instruction manual, may cause harmful

interference to radio communications. Operation of this equipment in a residential area may cause harmful interference in which case the user will be required to correct the interference at his own expense.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth.

Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary bases in the 2360-2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmissions from this transmitter will be free from interference.

16 Glossary

Term	Definition
Balancing	The automatic allocation of the total amplitude for a polarity of a program to equal 100%.
EPG	External Pulse Generator. Also known as the trial stimulator.
IPG	Implantable Pulse Generator. Also known as the implantable stimulator.
Patterns	Predefined stimulation patterns for each lead used to quickly program patient stimulation.
PG	Pulse Generator. Term used by the Clinician Programmer to represent either a trial stimulator or an implantable stimulator.
Pocket Programmer	A patient programmer used to control stimulation.
Program	A combination of stimulation settings used to deliver stimulation to one or more sites in a patient. A program consists of one or more subprograms.
Programmer Charger	A patient programmer used to adjust stimulation. Includes a charging paddle to charge the implantable stimulator.
Shipping	Moves amplitude allocation on a lead to identify optimal stimulation.
Step	The rate of increase or decrease when adjusting amplitude.
Strength	Amplitude increments based on the amplitude of a program. For the patient, strength is the intensity of their stimulation.
Subprogram	A combination of stimulation settings. A program consists of one or more subprograms.

Table 9 Glossary

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OpenSSL includes cryptographic software written by eric young (eay@cryptsoft.com). This product includes software written by Tim Hudson (tjh@cryptsoft.com).

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