Altius® Direct Electrical Nerve Stimulation System - Implantable Pulse Generator and Cuff Electrode Lead Implant Manual and Instructions for Use

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

LB-0198 Rev C

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

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The information provided in this document may change without prior notice.

Please read the complete documentation provided before you use the device.

Although FDA has determined that the probable benefits outweigh the probable risks, there remains some uncertainty regarding the manufacturer's human factors engineering (HFE) and usability engineering (UE) analysis and validation testing. As a condition of approval, FDA is requiring the manufacturer to provide an HFE/UE analysis and validation testing and recommending that this analysis and testing is designed using the FDA's 2016 guidance document "Applying Human Factors and Usability Engineering to Medical Devices" (https://www.fda.gov/media/80481/download).

This manual can also be found at: www.neurosmedical.com

The Altius® System is protected by several U.S. Patents.

For an up-to date list of relevant patents and patent applications, visit our patents page: https://www.neurosmedical.com/patents

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Table of Contents

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Table of Figures

Refer to the Prescriber manual for indications, contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, and component disposal.

This product manual covers implant instructions for Altius. Refer to the Programming manual and Patient User manual for additional instructions for use, including information on using the Programming Wand, Patient Controller, and Battery Charger.

For information that supports the clinical use of the Altius System, refer to the clinical summaries manual.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

1. Explanation of Symbols

Symbol	Symbol Meaning
	**Model Number**
	**Quantity**
	**Serial Number**
	**Unique Device Identifier**
	**Consult Instructions for Use**
	**Refer to Instructions for Use**
	**Caution**
	**Magnetic Resonance (MR) unsafe**
	**Do Not Use if Package is Damaged**
	**Temperature Limitations for Transport & Use**
	**Prescription only**
	**Medical Device**
	**Non- Ionizing Electromagnetic Radiation**
	**Humidity**
	**Atmospheric Pressure**
	**Keep Dry**
	**Keep Out of Sun**
	**Type BF Applied Part**

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Symbol	Symbol Meaning
IP22	**Liquid Ingress Protection**
	**Manufacturing Date**
	**Manufacturer**
	**Battery Charger Data Port – Not for Patient Use**
	**Battery Charger Power Port**
	**Battery Charger Symbol**
	**IPG Symbol**
	**Battery Charger Signal Strength Indicator**

2. Altius System Overview

2.1. Description of Altius Direct Electrical Nerve Stimulation System

The Altius System consists of an Implantable Pulse Generator (IPG), Cuff Electrode(s) with two bands of circumferential contacts, surgical tools and accessories, Programmer Application Software, and Programmer Wand; The patient will be supplied with a Patient Controller, and Battery Charger with charging paddle.

The Altius System IPG, Cuff Electrodes and accessories are intended to be used as on-demand therapy to aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees, as detailed in the Altius Prescriber manual (LB-0195). Refer to the Altius Prescriber manual for indications, contraindications, warnings and precautions, as well as other important device and patient care information.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

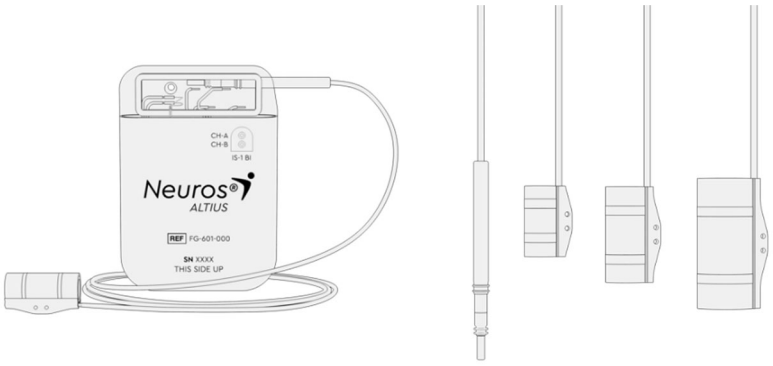

Figure 1: IPG and Cuff Electrode Connector and Three Cuff Sizes

The *implantable components* of the Altius System are:

- Implantable Pulse Generator (IPG)
- Implantable Cuff Electrodes

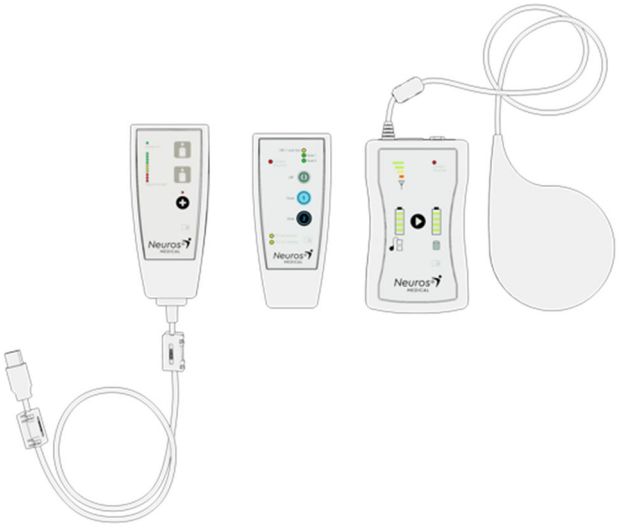

Figure 2: Non-Implantable Altius Components

The *non-implantable components* of the Altius System are:

- Battery Charger
- Patient Controller
- Programmer Wand
- PAPC Programmer Application Personal Computer (not shown in figure 2. Refer to Programmer Manual))

2.2. Altius System IPG Physical Characteristics

The Altius IPG is designed to deliver electrical stimulation to nerves. The electrical signals travel from the IPG, through the lead wire, to Cuff Electrodes placed circumferentially around the nerve(s). The physical characteristics of the Altius IPG are outlined in the table below:

Description	Value[a]
Height	68.5 mm
Width	47.0 mm
Thickness	11.0 mm
Volume	34 cm^3
Mass	60 g
Number of connector ports	2
Lead connectors	3.2 mm; IS-1 Bi-polar
Battery life	10 years[b]
Power source	Lithium ion rechargeable battery[c]
Radiopaque identification (ID) code	NRS AXX[d]
Materials in contact with human tissue[e]	Titanium, Epoxy resin, Silicone rubber
Exposed metallic surface[e]	59.28 cm^2
Exposed Epoxy surface[e]	19.44 cm^2

a. All measurements are approximate.

b. For battery life see section 2.5

c. Model Contego 325mAh Lithium-ion battery (li-Ion) manufactured by Resonetics (Formerly Eagle-Picher). The battery provides a usable capacity of 325 mAh, and a Recharge rate of C/2.

d. The Altius IPG contains a unique radio-opaque identifier within the hermetically sealed case allowing X-rays to identify information about the implant. The radio-opaque identifier is 7x6 mm (roughly 0.25 inches square) and contains the acronym "NRS" for Neuros plus alphanumeric characters identifying the version and year during which the IPG was manufactured (e.g. "A12" indicates Alpha 2012).

e. Tests have revealed that these materials are biocompatible. The Altius System IPG does not cause any temperature elevation capable of damaging the surrounding tissue.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

2.3. Altius System Nerve Cuff Electrode Physical Characteristics

The physical characteristics of the Altius Cuff Electrode are outlined in the table below:

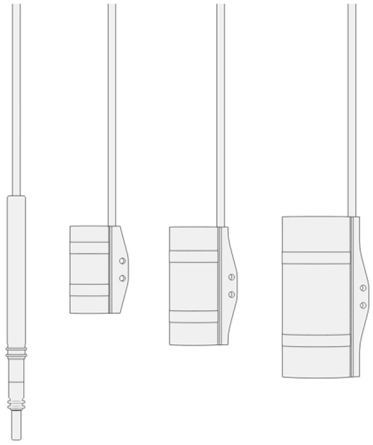

Figure 3: Connector and The three Cuff Sizes

Description	Value
Cuff Sizes (minimal diameter)	4 mm, 6 mm, 9 mm
Inner Diameter Ranges	4-6 mm, 6-9 mm, 9-13 mm
Cuff Lengths – nominal	15 mm, 20 mm, 28 mm
Number of Contact-Bands[a]	2
Contact-Band Spacing (inner edge to inner edge)	5 mm, 7 mm, 11 mm
Cable Length[a] (not incl. distal Cuff)	100 cm
IS-1 Connecter diameter – nominal	3.2 mm
Materials in contact with human tissue[a] – Platinum, MP-35N, Silicone	
[a] Tests have revealed that these materials are biocompatible.	

2.4. Altius System IPG Rechargeable Battery Behavior

The battery voltage of the Altius IPG, when its battery is fully charged, is approximately 4.1 V. When the battery voltage falls to 3.3V, the device enters RTC only, an operating mode where all circuits are disconnected except for the on board clock, battery voltage monitoring, and battery recharge signal monitoring.

If the battery drops below 3.0V, the device enters a low-power mode where the device is only listening for the battery recharge signal.

The device will return to normal behavior once the battery voltage rises above 3.3 V

It is therefore recommended to charge the IPG at least once a week. Recharging is also recommended if the device is interrogated, and the battery level is at or below 3.5V.

Additionally, patients who use the Altius IPG more frequently will require more frequent charging. Neuros Medical recommends a recharge schedule that fits the patient's personal lifestyle, while maintaining sufficient charge to deliver a complete treatment session.

Developing a patient's IPG recharge schedule involves finding the right balance between how frequently the patient wants to recharge and how long the patient wants to spend during each recharge session. Recharge time can range from between 30 minutes to approximately 6 hours. Patients should be instructed to charge until the Charger emits an end-of- charge, one-beep signal.

2.5. Altius System IPG Battery Life

The anticipated life of the IPG battery varies, depending on the IPG settings and utilization patterns over time. At typical settings, and usage and with weekly charging, the battery is predicted to last 10 years. A patient's specific utilization and settings may result in shorter or longer battery life. The Altius System utilizes voltage and frequency with a 30-min time duration to provide therapy. Based on Altius IPG's battery capacity and power requirements, a patient with a single Cuff Electrode connected to the Altius IPG, with typical values from the Table below, and running two therapy sessions a day, will use approximately 19.5 mAh over 24 hours. Over a 7-day period the IPG would consume 136.7 mAh of battery capacity, or about 40% of battery capacity, when new. The following Table provides the values for a typical use example.

Parameter	Value
Voltage	7.5 (peak voltage)
Frequency	10 kHz
Therapy Duration	30 min
Cuff Electrode Impedance	600 Ω
Therapy Current Consumption	19 mA
24-Hour IPG Battery Capacity Consumption	19.5 mAh

All Altius IPGs eventually require surgical replacement as a result of battery depletion. When the battery is depleted, communication with the IPG or continued treatment will not be possible. IPG replacement does not, in of itself, require cuff replacement unless a cuff break is suspected.

2.6. Altius System programming settings

The Altius IPG has 2 channels, Channel A and Channel B. Each Cuff Electrode, that is implanted on separate nerves, is assigned to either Channel A or Channel B respective to the IPG connector port into which it was inserted, CH-A or CH-B (see table 2). Therapy is delivered to each nerve through these channels independently.

The Altius IPG can be programmed with up to 2 doses, called Dose 1 and Dose 2, allowing patients to select and use the dose they prefer. Each dose can be programmed to deliver a programmed therapy on Channel A only, or just Channel B only, or simultaneously on Channel A and Channel B. Some parameters are in common across all Doses (1 & 2) and Channels (A & B). The range of values for these parameters is shown below:

Altius IPG Parameter Ranges		
General Parameters	**Specifications**	**Increment**
Waveform	Sinusoidal	-
Frequency (High)	5khz, 10khz	-
Channel Sequence	A First, B First	-
Lockout	0.5hr	-
Channel Delay	0 min	-
Dose/Channel Parameters	**Specifications**	**Increment**
Enabled	Yes/No	-
Initial Amplitude	0-8Vp	0.1V
Ramp Duration	0-15 min	1 min
Final Amplitude	0-16Vp	0.1V
Plateau Duration	0-30 min	1 min

At the Patient's initial activation and programming visit, to find the patient's response to Direct Electrical Nerve Stimulation their parameter settings will be determined using a 15-minute Ramp Duration which will involve the voltage will start at 0Vp and over the 15 minutes be increased to 15Vp. Using the patient's responses the parameters will then be set to achieve a sensation that is strong, but tolerable transient sensation for the patient.

Subsequent adjustment visits will be made based on the patient's ability to handle the therapy with either an increase or decrease of that therapy.

2.7. Implanted components and MRI scans

WARNING: Safety of MRI/NMRI with an implanted Altius System has not been evaluated. Patients implanted with the Altius System, or any of its components, should not be subject to MRI/NMRI. MRI exposure may result in dislodgement of the Altius IPG or Cuff Electrode(s), heating of the Altius IPG, injury to the nerve, and increased voltage through the Cuff Electrodes or Altius IPG. If MRI/NMRI is needed for any reason, the Altius System must be explanted prior to the diagnostic MRI/NMRI. For patients implanted with the Altius IPG, receiving an MRI/NMRI diagnostic scan, without first explanting the IPG may result in severe patient injury, death or device malfunction.

2.8. When explanting components

CAUTION: If permanently explanting an IPG, be sure to also explant all cuffs, leads, extensions, and accessories. Abandoned components may prevent the patient

from being allowed MRI scans in the future due to concerns of cuff electrode heating that can result in tissue damage.

3. Experience and Training

Implanting surgeons should be familiar with lower limb surgical procedures and should review the procedures described in the implant manual before surgery.

4. Handling

4.1. General

All system components and accessories should be handled with care. External devices should not be dropped, submerged in water, or operated in the rain. Avoid all sources of water that can come into contact with the external 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 cause permanent damage.

4.2. Handling during Surgical Implant

Care must be taken to avoid damaging the Cuff Electrode or the Altius IPG with sharp instruments or excessive force during surgical implant. The following guidelines will help to ensure the longevity of components:

- Do not implant the Altius IPG if it has been dropped. Dropping can cause latent damage to components, loss of sterility, loss of hermeticity, or other damage. Replace the dropped Altius IPG with a new, sterile Altius IPG prior to implantation.

WARNING: If the Altius IPG case is pierced or ruptured, severe burns could result from exposure to battery chemicals.

- Do not sharply bend or kink any segment of the Cuff Electrode.
- Avoid applying excessive tensile forces in any direction and to any segment of the Cuff Electrode. During insertion of Cuff Electrode connectors into the Altius IPG header; a damaged connector may result in failure to deliver therapy
- Avoid pulling an implanted Cuff Electrode lead taut; strain relief loops may help to minimize tension on the Cuff Electrode.
- If anchoring of the strain relief loops is necessary, do not tie the anchoring sutures overly tightly as they may cut through the silicone tubing.
- Avoid handling the Cuff Electrode with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments, such as hemostats or scalpels to prevent damage to the Cuff Electrode.

4.3. Storage and Handling

The Altius IPG can be stored between -30° C and 60° C (-22° F and 140° F). Neuros recommends storing the Altius IPG below 24° C (75° F). Store the Cuff Electrode between -29° C and 60° C (-20° F and 140° F. Components of the Altius System should always be kept

in temperature-regulated areas within the acceptable temperature range. Altius IPG damage can occur at temperatures outside of this range.

The Altius IPG is intended to be used between 17° C and 40° C (63° F and 104° F).

4.4. Packaging Information

Read the label on the product package before opening to ensure you have the right product. The Altius System IPG and Cuff Electrode are single use, single patient products and are supplied in a shelf box containing a literature pack and the sterile package. The sterile packs have been sterilized with ethylene oxide gas. Both the IPG and Cuff Electrode consist of an outer TYVEK/PET blister pack containing an inner TYVEK/PET blister. For products that are provided STERILE, introduce the contents into a sterile field: (1) Peel the Tyvek lid from the outer tray, (2) use a sterile handling technique to put the inner tray into sterile field, and (3) peel the Tyvek lid from inner tray to expose the contents. Before opening the sterile package, check for any signs of damage suggesting that the sterility of the package or its contents might have been compromised. Damaged packages need to be returned to Neuros Medical.

IPG Kit Contents:

Shelf box contains:

- Altius System Patient Implant Card
- Peel-off labels for use with implantation documents
- Sterile inner blister pack contains:
  - One (1) Altius System IPG
  - One (1) Allen Torque Wrench [Size - 0.035in (0.9mm), Torque - 11oz-in (77.68 mNm)]
  - One (1) Port Plug

Cuff Electrode Kit Contents:

- Shelf box contains:
- Peel-off labels for use with implantation documents
- Sterile inner blister pack contains:
  - One (1) Cuff Electrode

4.5. Re-sterilization and Reuse

The Altius IPG, Cuff Electrodes, and kit contents were sterilized with ethylene oxide prior to shipment. Check the expiration date on the package before opening the sterile package and using the contents. Do not use the contents after the expiration date, if the sterile barrier is breached, or if contamination is suspected because of a defective sterile package seal.

- Do not use any component that shows signs of damage.
- Do not use if “Use Before” date has expired.
- Do not attempt to re-sterilize the contents of the sterile package that has been damaged or in any way compromised. Return any unopened devices to Neuros Medical.
- The Altius IPG, Cuff Electrode, port plug, are single-use only devices. Do not re-implant for any reason.

- An Altius System IPG that has been explanted for any reason may not be reimplanted in another patient.

5. Device Implantation

5.1. General Considerations

This section describes the recommended procedures for implanting the Altius System for the treatment of Post-amputation Pain. Procedures discussed include Cuff placement, IPG placement, and lead wire tunneling.

Cuffs are designed for permanent implant. In single Cuff procedures, the Cuff is wrapped around the sciatic nerve 1 to 3 cm proximal to the nerve end or neuroma, if present. Single Cuff procedures are typically performed with patients who have an above the knee amputation (AKA). In two Cuff procedures, one Cuff is wrapped around the tibial nerve, and one Cuff is wrapped around the common peroneal nerve, 1 to 3 cm distal to the branch of the sciatic nerve. Two Cuff procedures are typically performed with patients who have a below the knee amputation (AKA). See section 5.2.1, Cuff Electrode Placement for additional details.

The lead wire (one Cuff procedure) or wires (two Cuff procedure) are tunneled subcutaneously from the Cuff placement site to the IPG pocket, an access incision may be used to transition and tunnel to the IPG pocket.

The IPG is placed in a subcutaneous pocket in a location in the abdomen as deemed appropriate by the implanting physician, considering the patient's ability to reach the IPG location for initiation of Direct Electrical Nerve Stimulation with the Patient Controller. It is recommended that an appropriate location be used to minimize tensile forces on the lead wire during subject movement. The patient should also be consulted to ensure that the IPG is placed such that it does not cross their belt-line.

WARNING: The IPG uses a transcutaneous wireless charging system which may result in heating. When implanting the IPG be aware of and avoid any thermally sensitive tissues.

WARNING: Use of surgical electrocautery devices, high-voltage, high-frequency current, can induce Altius IPG signal inhibition or can make the IPG revert to its "DOWN" mode, with no delivery of therapy. The device can be damaged if high energies are coupled into the system.

Use of electrocautery in close proximity to an implanted Altius System IPG can also couple radio frequency energy directly through the leads into the abdominal tissue, producing burns.

If electrocautery is used, it is recommended that bi-polar electrocautery is used, not mono-polar electrocautery. If the Altius IPG reverts to its "Down" mode, it will have to be reset.

5.1.1. Patient Pre-operative preparation

The patient should undergo a nasal swab to test for *Staphylococcus* and application of mupirocin to nares in patients who test positive.

The day before and the day of the procedure the patient should bathe with antimicrobial soap (such as Phisohex or Hibiclens).

Follow institutional protocols for pre-operative IV antibiotics.

5.1.2. Patient Preparation

- The patient is preferably placed in the Lateral Decubitus Position with the amputated limb up.
- Using standard sterile techniques, carry out the appropriate skin prepping, draping, and injection of local anesthetic to perform the implant procedure for Cuff or Cuffs.
    - Drape the patient's contralateral limb (that is in the down position) before draping the surgical site.
    - This will allow the sterile field to be maintained later in the surgery when the amputated limb is flexed at the hip to ensure there is enough slack in the lead.
- The patient should be anesthetized as per the physician's discretion.

PRECAUTIONS FOR INFECTION PREVENTION

Note: In addition to standard operating room (OR) sterile-field procedures and strictly excluding candidates with a history of surgical infections, the following steps are strongly recommended:

1. Double gloving by surgeons and Operating Room (OR) personnel.
2. Use of bio-occlusive dressings for incisions.
3. Additional recommendations throughout this section.

5.2. Cuff Electrode Implantation

WARNING: As a preventative measure, the nerve should be visualized using ultrasound and target incision location where the diameter is less than 13 mm. Ensure proper handling during dissection, measurement, and cuff placement and anchoring to prevent nerve damage.

5.2.1. Cuff Electrode Placement

- Expose and mobilize the target nerve(s) using the standard technique for a nerve sparing gentle dissection. As a general rule, the following Table is representative of standard cuff placement.

	1 Cuff Electrode	**2 Cuff Electrodes**
Nerve(s)	Sciatic	Tibial and common peroneal

NOTE: Implanting physicians may elect to place two cuffs on a bifurcated sciatic, and in some cases, a single cuff on a BKA subject (e.g., very distal tibial common peroneal bifurcation). Final decisions regarding Cuff Placement are made at the time of the surgical procedure.

- Measure the diameter of the nerve using Maquet graft sizers, vessel loops or comparable tool and select the appropriately sized Cuff.
- Soak cuff electrode(s) in antibiotic solution.
- Orient Cuff Electrode such that the lead wire from the Cuff is routed superior from Cuff.
- Protrude angled forceps out from under nerve. Gently clasp Cuff edge that has a suture anchor and pull Cuff under nerve.
- With forceps, being careful not to clasp the metal contacts, carefully wrap the Cuff edge that does not have a suture anchor around the nerve.
- Overlap the Cuff edge that has a suture anchor over top the Cuff edge without a suture anchor. Ensure there is circumferential coverage of the nerve, and that the platinum contacts are touching the nerve. After circumferentially wrapping the Cuff, both suture anchors should be accessible.

WARNING: If the cuff electrode overlaps itself, ensure that both electrode tracks are in contact with the nerve, and not in contact with each other; and that the overlapping section of the cuff is just silicone.

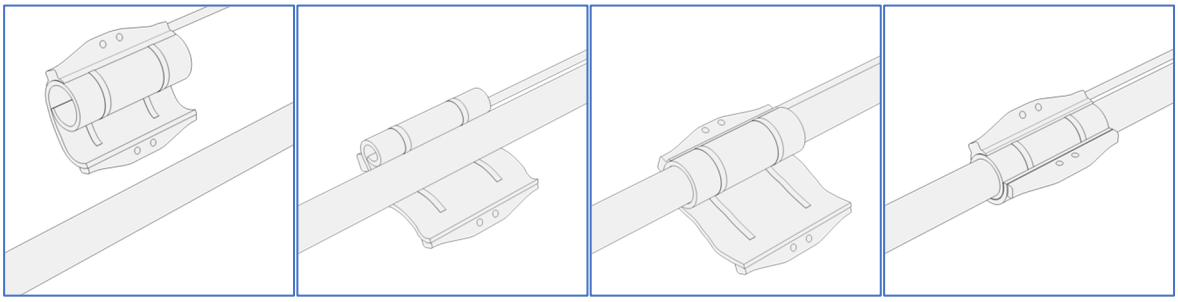

Figure 4: Wrapping Cuff Around Nerve

5.2.2. Anchoring the Cuff Electrode

- Secure the Cuff Electrode by tying a suture through the suture anchors with non-absorbable suture. Tie sutures such that the loop between the anchors remains loose. The suture is only intended to prevent unexpected unwrapping and should not be tight.

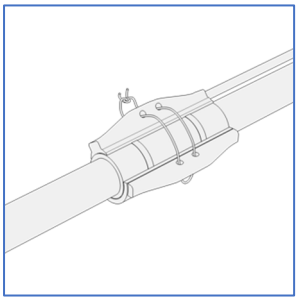

Figure 5: Secured Cuff Around Nerve

WARNING: Do not overly tighten the suture. The Cuff is self-sizing and sutures need to allow for postoperative inflammation and swelling.

WARNING: Do not suture directly through the Cuff because it may damage the Cuff Electrode.

- Flex/Extend leg to full range of motion to form slack along the cable length as necessary.
- Within the Cuff Electrode incision site, create a strain-relief loop 2-5 cm in diameter with the cable from Cuff Electrode.
- If necessary, anchor the strain-relief loop by loosely suturing through fascia and around the cable.

5.3. IPG Implantation and Cuff Electrode Connection

- Select and mark the intended Altius IPG site and create an incision at the top of the Altius IPG site. The primary location for the subcutaneous pocket is the anterolateral abdominal wall. Secondary location at surgeon discretion.
- Create a subcutaneous pocket no larger than the Altius IPG outline at a depth of no more than 2.5 cm (1 inch) from the surface.

WARNING: Shallow implant depth may lead to increase in risk of wound dehiscence leading to infection.

NOTE: It is important to keep the pocket small to reduce the chances of the IPG flipping or moving and to discourage patient manipulation. The recommended maximum depth of implant for proper device interrogation and charging is not more than 2.5cm.

NOTE: The Altius IPG device interrogation and charging could become ineffective at depths greater than 2.5cm (1 inch).

- Identify anterior superior iliac crest margin and place IPG medially to avoid the iliac crest.
- Create a small pocket beneath the left incisional border to accommodate the exiting lead from the IPG header.

5.3.1. Tunneling Cuff Electrode Lead Cable to IPG Pocket

- Mark the desired tunneling route from the Cuff Electrode incision, along the midaxillary line to the lateral abdominal wall, and then transverse to the IPG pocket.

NOTE: Avoid tunneling routes through areas that are subject to flexion to minimize the stress on the lead.

- Make a tunneling access incision in the lateral abdominal wall, where tunneling route transitions from longitudinal to transverse.
- Bend the tunneling tool to conform to the patient's body.
- Create a subcutaneous tunnel that begins inside the Cuff Electrode incision site and extends to the tunneling access incision site.

NOTE: Deep tunneling should be avoided to prevent potential injury to other tissue in the body.

Pass the Cuff Electrode connector through the sheath (or tunneling sheath), with attention to avoid reducing the diameter of the strain relief loop at the Cuff Electrode incision site. Withdraw the sheath (or tunneling sheath).

- Flex/Extend leg to full range of motion to form slack along the cable length as necessary.
- Create a subcutaneous tunnel that begins inside the tunneling access incision site and extends to the IPG pocket.
- Within tunnel access incision site, make a strain-relief loop 2-5 cm in diameter with the lead from Cuff Electrode.
- Pass the Cuff Electrode connector (proximal end) through the sheath (or tunneling sheath), with attention to avoid reducing the diameter of the strain relief loops. Withdraw the sheath (or tunneling sheath).

5.3.2. Connecting and Implanting the IPG

- Do not pre-soak the IPG in any fluid. Ensure the IPG cavity (channel port) is dry.
- Ensure the Cuff Electrode Connector is dry.
- Fully insert the Cuff Electrode connector by hand into the Altius IPG port, using the table below as reference for one vs. two Cuff Electrodes. When the connector is properly inserted, it will extend to the end of the port which can be visually confirmed through the clear epoxy header.

CH A	Sciatic	Tibial
CH B	Port Plug	Common Peroneal

- Pass the torque wrench through the septum seal into the setscrew and turn clockwise until the torque wrench "clicks," indicating the screw has been fully tightened. The wrench is torque-limited and cannot be over tightened.
- For single Cuff Electrode procedures, place a silicone Altius Port Plug into the Altius IPG port unoccupied channel (typically channel B). Check that the Port Plug is secure, but do not over tighten the set screws as they may perforate the silicone.

- Place the programmer wand in a sterile ultrasound sleeve so that the system integrity may be confirmed.
- Test impedances using the Programmer Wand and the Altius Programmer Application. Verify impedances are within expected ranges.

WARNING: A wet (blood, saline, antibiotic solution…) IPG cavity or Cuff Electrode Connector could result in erroneous impedance measurement checks. Remove any fluid from these areas and ensure a dry connection.

WARNING: Observe necessary precautions when inserting the Cuff Electrode connector in the IPG. Do not use surgical tools to insert Cuff Electrode Connector. This should be done by hand.

NOTE: If the port plug is used in CH-B, it is not necessary to tighten the setscrew as described.

- Coil any excess cable from Cuff Electrode behind the Altius IPG.
- Place the Altius IPG in the subcutaneous pocket with "THIS SIDE UP" facing towards the skin.
- Secure the Altius IPG in the pocket by suturing through the hole in the IPG header and the underlying fascia.

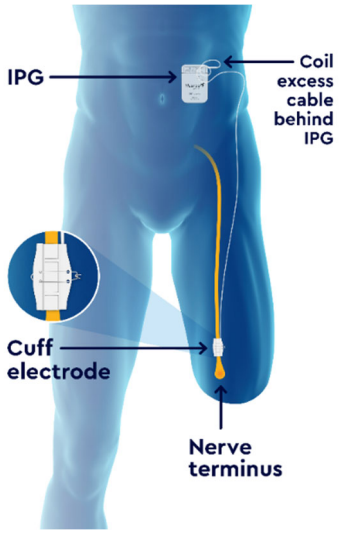

Figure 6: Implanted Altius System

5.3.3. Completing the Implant Procedure

- Lavage all surgical wound beds thoroughly with antibiotic solution.
- An antibiotic powder may be applied topically to incision sites prior to surgical wound closure.
- Close and dress all surgical wounds. Close the incisions in a transverse manner using 2 layers. The deep layer may be closed with a running 3-0 non-absorbable suture followed by an imbricating layer of absorbable 3-0 suture. Apply bio-occlusive dressing after closure.

Note: You may use either staples or suture for wound closure. If you elect to use staples, wait to activate the Altius IPG until after the staples have been removed.

5.3.4. Post-op patient care & Antibiotics

- Prescribe anti-biotics for the patient for no longer than 24-48 hours post-operatively
- If staples were used to close the incisions, ensure that the staples are removed prior to the patient's activation visit.
- Physician should discuss proper post-operative wound care with patient prior to discharge.

6. Device Explantation

In the event that the system needs to be explanted for any reason, the procedure described below is recommended to remove all implanted components. The procedure can be modified as necessary, for example to remove just the IPG in the event of IPG replacement at end of battery life.

6.1. Explanting or Replacing the Altius IPG

Turn off the Altius IPG to ensure a treatment session is not active.

Create an incision through the existing scar over the Altius IPG. The incision should extend down to the level of the Altius IPG.

CAUTION: Use bipolar electrocautery, monopolar electrocautery may damage the Altius IPG.

Withdraw the Altius IPG from the pocket.

Using a sterile Allen wrench (torque wrench), unscrew the connector setscrews to release and remove the Cuff Electrode connector(s) from the Altius IPG. While holding the IPG in one hand, grasp each Cuff Electrode silicone lead connector between thumb and forefinger. Pull the lead IS-1 connectors from the terminal by cautious application of constant traction. Grasping the plugs with a sterile pad can help improve traction. Never apply excessive traction to the actual Cuff Electrode lead body, which could damage the leads and cause lead failure.

NOTE:

- When tightening or loosening a set screw, always insert the tip of the torque wrench fully into and in line with the set screw. Do not insert the torque wrench into the set screw at an angle.
- Prior to inserting the IS-1 lead connectors, verify visually that none of the set screws protrudes into any of the IPG header cavities. Back off any set screw found protruding beyond the wall into the header cavity by turning it back in a counterclockwise direction with the Allen wrench. Turn the set screw just enough so that its tip is no longer inside the header cavity. Do not back the set screw completely out of the terminal block.
- Observe that the tips of the lead contacts are inserted beyond the respective lead tip terminals. Tighten the set screws using the sterile torque wrench included in the Altius IPG package. Turn the Allen wrench clockwise until you can clearly hear and feel the clicking that limits excessive torque on the set screw. Carefully apply traction to the strain relief of each lead to make sure that the leads are securely anchored in the terminal.

  For Altius IPG replacement, connect the new Altius IPG. Reference above section 5.3.2: Connecting and Implanting IPG.

  For the Altius System removal, continue to section 6.2: Explanting or Replacing the Cuff Electrode.

6.2. Explanting or Replacing the Cuff Electrode

Note: If the entire Altius System (Altius IPG and Cuff Electrodes) is to be removed, then the Altius IPG should be removed first (as described above) followed by the Cuff Electrodes.

- If the Altius IPG has just been explanted, cover the Altius IPG wound bed with sterile gauze moistened with normal saline while the Cuff Electrodes are explanted.
- Expose and mobilize the nerve and the electrode using the standard technique for a nerve-sparing dissection.
- Cut any sutures used to secure the Cuff Electrode.
- If two Cuff Electrodes were implanted, repeat steps 2 – 5 for the other nerve.
- Detach the Cuff Electrode from the nerve bundle by gently unwrapping the Cuff.
- Remove the Cuff Electrode using gentle traction at the distal free end of the Cuff.
- For Cuff Electrode Replacement: Prior to leaving the surgical suite, impedance should be checked and ensure the IPG is not enabled. The IPG will be enabled at the Day 14 postoperative visit.
- Close and dress all incisions.
- Note: As is required by regulation in most countries, all explanted components should be decontaminated, and returned in a sealed pouch to Neuros Medical for returned device analysis.

  All explanted Altius System IPGs should be returned to Neuros Medical Inc. for testing and analysis, which can provide valuable information on how to further improve device quality and reliability.

WARNING: Never incinerate an Altius System IPG. The battery in these devices can explode if placed in fire.

WARNING: The IPG must be explanted before a deceased patient is cremated.

WARNING: Implantable parts are not to be reused if they have previously been implanted in another patient.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Appendix I: Replaceable Parts & Cables

The Altius System is fully replaceable, there are no User serviceable parts.

For replacement of any part of the Altius System please contact your Neuros Medical Representative.

WARNING: Use of accessories, and cables other than those specified or provided by Neuros Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Non-Implantable replaceable Components:

Neuros Medical Part Name	Expected Service Life	Neuros Medical Part Number	Cable Length (If Applicable)
Altius Patient Controller	5 Years	FG-604-000	N/A
Altius Battery Charger	5 Years	FG-603-000	61cm (24in) (Charger to Paddle)
AC Adapter for Altius Battery Charger	5 Years	PC-200-044	170cm (66 in)
Altius Programmer Wand	5 Years	FG-606-000	305cm (10ft)
Programmer Application PC (PAPC)	5 Years	FG-608-000	N/A

Implantable replaceable Components

Neuros Medical Part Name	Neuros Medical Part Number	Cable Length (If Applicable)
Altius IPG*	FG-601-000	N/A
Cuff Electrode Small	FG-600-001	100cm (39 in)
Cuff Electrode Medium	FG-600-002	100cm (39 in)
Cuff Electrode Large	FG-600-003	100cm (39 in)

*The battery in the Altius IPG has undergone simulated bench tests to demonstrate battery longevity at nominal settings and usage is 10 years.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Appendix II: Wireless Specifications of the Altius System

Communication/Telemetry and Wireless Charging:

Patient Controller and Programming Wand to the IPG(Communication)

- Modulation: ASK (Amplitude Shift Keying)
- The Amplitude is 0 and a 1 is 305µs signal
- Transmit Frequency: 20kHz
- Power: 0.27 Watts (W)

Battery Charger to Altius IPG (Charging)

- Modulation: PWM (Pulse Width Modulation) (Only for limited communication)
- The pulses are 1.07ms for a 0 and 3.36 ms for a 1 (Only for limited communication)
- Transmit Frequency (386kHz – 490kHz)
- Transmitter Power is 0.52 W

Altius IPG to the Patient Controller and Programming Wand (Communication)

- Modulation: PPM (Pulse Position Modulation)
- The position between two pulses for a 0 is 183µs, a 1 is 275µs
- Transmit Frequency: 19kHz
- Power: 1.8 mW

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Appendix III: Electromagnetic Interference Information

The Altius System can be used in 4 main configurations and used accordingly as listed below:

1) The Battery Charger Being Charged by AC Mains
2) The Battery Charger Being Used to Charge the IPG Battery
3) The Patient Using the Controller to turn the IPG On/Off*
4) The Programmer System Being Used to Program the IPG

*Due to practical limitations of testing, configuration 3 and configuration 4 were determined to be equivalent to each other as the Patient Controller and Programmer Wand use the same circuitry for transmitting and receiving telemetry data.

The Altius System was found to be complaint following the testing listed below for the specified configurations and environments as specified below:

Test Standard	Configuration	Compliance Level	Electromagnetic Environment Guidelines
CISPR 11 Radiated Emissions	1,2,3	Group 1 Class B	The Altius System uses RF energy only for its internal function; therefore, its RF emission are low and ae not likely to cause any interference in nearby electronic equipment. The Altius IPG, Battery Charger and Patient Controller is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
CISPR 11 Radiated Emissions	4	Group 1 Class A	The Altius Programmer System 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.
CISPR 11 Conducted Emissions	1	Group 1 Class B	The Altius Battery Charger is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 Harmonics	1	Harmonics Class A	
IEC 61000-3-3 Flicker	1	4% max	
IEC 61000-4-2 ESD Immunity	1,2,3,4	±8kV Contact; ±2,4,8,15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be 30% or higher. The operator may have to reset the system if the communication between the Programmer Wand and the PAPC is interrupted.
IEC 61000-4-4 EFT Immunity	1	±2kV 100kHz repetition frequency	The Battery Charger is suitable for use in all establishments. Including domestic

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Test Standard	Configuration	Compliance Level	Electromagnetic Environment Guidelines
IEC 61000-4-5 Surge Immunity	1	±0.5,1kV Line to Line; ±0.5,1,2kV Line to Ground	establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-4-6 Conducted RF Immunity	1,2,4	3Vrms 0.15 – 80MHz; 6Vrms in ISM and Amateur Radio Bands; 80% 1kHz AM	Portable and mobile RF communications equipment should not be used at levels as tested per the compliance levels listed in the table below.
IEC 61000-4-3 Radiated RF Immunity	1,2,4	10V/m 80MHz – 2.7GHz 80% 1kHz AM	
IEC 61000-4-8 Power Frequency Magnetic Field Immunity	1,2,3,4	30A/m 50/60Hz	The Altius Programmer System 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. The Altius IPG, Battery Charger and Patient Controller is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-4-11 VDI Immunity	1	0% UT for 0.5 Cycle at 0,45,90,135,180,225,270,315 degrees 0% UT for 1 Cycle 70% UT for 30 Cycles 0% UT for 300Cycles	The Battery Charger is suitable for use in all establishments. Including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. **Note:** If the user of the Altius Battery Charger requires uninterrupted operation during power mains interruptions, it is recommended to power the Altius Battery Charger from an uninterruptible power supply or battery.
IEC 60601-1-2 ed4.1 Proximity Radiated RF Immunity (Table 9)	1,2,4	See Table 9 Compliance Levels on next page	The separation distance between an interfering RF transmitter and any Altius System Device should be greater than 0.3m (12in) and the maximum power from the RF transmitter should not exceed 2 W or 28V/m at a distance of 0.3m.
IEC 60601-1-2 ed4.1 Proximity Magnetic Field Immunity (Table 11)	1,2,3,4	30kHz CW 8A/m 134.2kHz 2.1kHz PM 65A/m 13.56MHz 50kHz PM 7.5A/m	The separation distance between an interfering magnetic field and the Altius System should be greater than 15cm, unless intentionally activating the magnetic reed switch of the IPG to deactivate therapy.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Table 9 from IEC 60601-1-2 ed4.1 Compliance Levels:

Test Frequency (MHz)	Immunity Test Level (V/m)
385	27
450	28
710	9
745	9
780	9
810	28
870	28
930	28
1720	28
1845	28
1970	28
2450	28
5240	9
5500	9
5785	9

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

Appendix IV: Federal Communications Commission (FCC)

The Altius Patient Controller and the Altius IPG:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

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

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

The Altius Programmer Wand:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment 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 is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

ALTIUS SYSTEM IPG AND CUFF ELECTRODE IMPLANT MANUAL AND INSTRUCTIONS FOR USE

The Altius Battery Charger:

This Device Complies with Part 18 of the FCC rules.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.