
# Altius® Direct Electrical Nerve Stimulation System
# Patient Manual

**Caution: Federal (US) law restricts this device to sale by or on the order of a physician**
LB-0196 Rev B

# ALTIUS SYSTEM PATIENT MANUAL

Neuros Medical (USA), Inc
26800 Aliso Viejo Parkway, Suite 250
Aliso Viejo CA 92656, USA
Support Phone Number: 833-240-4462



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).



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:
http://www.neurosmedical.com/patents

# ALTIUS SYSTEM PATIENT MANUAL

## Table of Contents


**1. Explanation of Symbols** ..... 5
**2. Introduction** ..... 7
**3. Indications for Use** ..... 7
**4. Contraindications** ..... 7
4.1. Altius System Contraindications ..... 7
**5. Warnings** ..... 7
5.1. Warnings ..... 7
5.2. Magnetic resonance imaging (MRI) Safety Information ..... 9
5.3. Warnings about Other Medical Treatments ..... 10
**6. Precautions** ..... 11
**7. Adverse events** ..... 12
7.1. Surgical risks ..... 12
**8. Altius System Overview** ..... 13
8.1. Altius System Altius System Implantable Pulse Generator & Cuff Electrode(s) ..... 13
8.2. Altius Patient Controller Overview ..... 14
8.3. Altius Battery Charger Overview ..... 15
8.4. Altius Programmer System Overview ..... 15
**9. Following Implantation Surgery** ..... 15
**10. Living with the Altius System** ..... 16
10.1. General Expectations ..... 16
10.2. Effect on Your Activities ..... 16
10.3. Medications ..... 17
10.3.1. Pain Relief Medications ..... 17
10.3.2. General Medications ..... 17
10.4. The Importance of Your Patient ID Card ..... 17
**11. Device Lifetime/Replacement** ..... 18
**Appendix I: Additional Electromagnetic Precautions** ..... 19
**Appendix II: Replaceable Parts & Cables** ..... 21
**Appendix III: Wireless Specifications of the Altius System** ..... 22
**Appendix V: Federal Communications Commission (FCC)** ..... 26

# ALTIUS SYSTEM PATIENT MANUAL

Information available for the Altius System:

The information for prescriber manual and patient manual provide information about indications, contraindications, warnings, precautions, adverse events, sterilization, patient selection, individualization of treatment, and component disposal.

Product manuals, such as the Patient Controller and Battery Charger guide, the programming guide, and implant manual provide device descriptions, package contents, device specifications, battery longevity and instructions for use.

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

# ALTIUS SYSTEM PATIENT MANUAL

## 1. Explanation of Symbols

| | |
|---|---|
|  | **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** |

| | |
|---|---|
| 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** |

# ALTIUS SYSTEM PATIENT MANUAL

## 2. Introduction

This manual is written for people who are considering or have received the Altius® Direct Electrical Nerve Stimulation System. The Altius System is designed to help adults living with lower limb loss who experience chronic intractable phantom and residual lower-limb post-amputation pain.

This manual discusses the Altius System and safety considerations. If you have any questions about this information, please contact your doctor.

To learn how to use your Patient Controller and Battery Charger, or review care and maintenance information, see the Patient Controller and Battery Charger User Guide (LB-0199).

## 3. Indications for Use

The Altius® Direct Electrical Nerve Stimulation System is indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees.

## 4. Contraindications

Contraindications describe situations in which a device should not be used, because the risks of use clearly outweigh possible benefits. Contraindications are determined by medical experts, clinical studies, and the Food and Drug Administration (FDA).

### 4.1. Altius System Contraindications

The Altius System is contraindicated for patients who are:

- Unable to operate the system.
- Unsuitable for the Altius implant surgery

## 5. Warnings

Warnings are statements about the safety of your device. You should take warnings very seriously. If you do not follow these warnings, it is possible you could be hurt, and or the Altius System could be damaged.

### 5.1. Warnings

The following are some warnings for the Altius System:

**Diathermy.** Diathermy should not be used on patients with the Altius System, or any of its components, either as a treatment for a medical condition or as part of a surgical procedure. The energy generated by diathermy can be transferred through the Altius System, possibly causing tissue injury, severe injury, or death. The Altius Implantable Pulse Generator (IPG), whether on or off, may be damaged. Ask your physician if you have additional questions.

**Electromagnetic Interference.** Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with the Altius System function. Altius includes features that provide protection from EMI. However, sources of strong EMI can result in the following:

- Serious patient injury or death, resulting from heating of the implanted components of the Altius System and damage to surrounding tissue.
- System damage, resulting in a loss of or change in symptom control, and requiring surgical replacement.
- Operational changes to Altius, causing it to reset and turn off, which may result in decrease in treatment effect.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation, 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 may fall down and be injured.

The Altius System IPG contains a magnetic reed switch which may be used in case of emergency to turn off therapy in order to defibrillate the patient. This switch may inadvertently stop therapy when around strong magnetic sources such as MRI/NMRI, electrical lines, electric motors, electric generators, transformers, strong handheld magnets, and arc welders if held too close to the IPG.

**WARNING:** Patients should be instructed to be cautious in the vicinity of equipment that generates electrical or electromagnetic fields and to seek medical advice before entering an area with posted warnings advising pacemaker patients (or patients with other types of implantable devices) not to approach.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Altius System, including cables specified by Neuros Medical. Otherwise, degradation of the performance of this equipment could result.

**WARNING:** Use of the Altius System adjacent to or stacked with other equipment should be avoided because it may result in improper operation. If such use is necessary, the Altius IPG and its accessories, and the other equipment it is used next to should be observed to verify that they are operating normally.

For Additional Information and Precautions, refer to Appendix III.

Refer to Table 1: Potential effects of EMI from equipment or procedures.

**Table 1: Potential effects of EMI from equipment or procedures**

| Equipment or procedure | Serious patient injury | Device damage | Device turns off/on | Momentary increase in stimulation | Intermittent stimulation |
|---|---|---|---|---|---|
| **Diathermy** | X | X | X | X | X |
| **Magnetic resonance imaging (MRI)** | X | X | X | X | X |
| **Electrocautery** | X | X | | X | X |
| **RF nerve lesioning** | X | X | | X | X |
| **Defibrillation cardioversion** | X | X | | X | X |
| **Radiation therapy** | | X | | | |
| **Lithotripsy** | | X | | | |
| **Transcutaneous electrical nerve stimulation (TENS)** | | | X | X | |
| **Household items** | | | X | X | |
| **Theft detectors** | | | X | X | X |
| **Industrial machinery** | | | X | X | X |
| **Transmitting devices** | | | X | X | X |
| **Cellular and mobile phones** | | | X | X | X |

**Patients with diabetes.** Some patients may be at higher risk of surgical complications, including those with diabetes. Discuss with your physician to better understand potential risks.

**Risk of Asphyxiation.** The Altius System utilizes several cables for power or data transfer. Ensure that you never wrap any of these around your neck to reduce the risk of strangulation or restriction of your airways. Be sure to keep these cables away from young children, or to be aware of what they are doing when in the same room.

5.2. Magnetic resonance imaging (MRI) Safety Information

The safety of having an MRI/NMRI with the Altius System has not been tested or evaluated. Patients must not have an MRI/NMRI without consulting the doctor who implanted the Altius System.

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 a MRI/NMRI is needed for any reason, the entire 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.

### 5.3. Warnings about Other Medical Treatments

Always tell your doctors, nurses or other health care providers (including dentists, physical therapists, prosthetists, and others) that you have the Altius System implanted in your body. There are some procedures that are not recommended for people with the Altius System. Receiving these procedures, medical therapies or diagnostics may damage your Altius IPG. This may require you to come in for a device check, or have your device surgically replaced.

**Caution:** If you are to undergo any of these procedures, have your healthcare professional call Neuros Medical for proper instructions.

The Following medical therapies or procedures may affect treatment or cause permanent damage to the Altius IPG (while on or off), particularly if used or performed in close proximity to the implanted components:

- lithotripsy — high-output sound or shock waves often used to treat gall stones and kidney stones
- electrocautery — the use of a heated electric probe to stop bleeding during surgery
- external defibrillation — the use of electrically charged paddles to restart the heart in an emergency
- radiation therapy — ionizing energy commonly used to treat cancer
- ultrasonic scanning — very high frequency sound waves used to produce images of internal organs or tissue for diagnostic purposes
- RF nerve lesioning/RF Ablation — use of radio frequency energy to interrupt nerve conduction as a treatment for chronic neck and spine pain
- high-output ultrasound — high frequency sound waves which may be applied as physical therapy to treat certain bone and muscle injuries, for muscle therapy, or to improve blood flow.
- TENS (Transcutaneous Electrical Nerve Stimulation) – Electrical current is applied through the skin to stimulate nerves as a treatment pain from various sources.
- Other implanted devices - The Altius System may impede the performance of other active implantable devices that employ signal sensing circuitry, including: Implanted cardiac pacemaker, implanted internal cardiac defibrillator, or other active implantable devices.

# 6. Precautions

Precautions are instructions you should follow to avoid damage to the Altius System or its components, so that it functions correctly and last longer.

Some precautions to follow when you have an Altius System:

**Altius IPG position and component manipulation.** Never attempt to change the orientation of the IPG or manipulate the implanted components. If the IPG flips over in your body, it cannot be charged. If you know that the IPG has turned, or if treatment cannot be turned on after charging, contact your physician to arrange an evaluation of the system.

Patients should avoid manipulating or rubbing the Altius IPG through the skin. Manipulation may cause component damage, cuff dislodgement, skin erosion, or stimulation at the implant site.

**Activities requiring excessive twisting or stretching**. Patients should avoid activities that may put undue stress on the implanted components of the Altius 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. Patients should avoid excessive bending of the torso.

**Massage Therapy**. Patients should avoid receiving massage therapy near the implanted Altius components. If patients receive massage therapy, inform the massage therapist about implanted device and show them where the IPG and cuff electrodes are located. These areas should be avoided during a massage.

**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 Altius System. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

**Walking or standing with prosthesis**. Do Not start or use treatment while walking or standing with prosthesis. Any sudden response to treatment may interfere or impair ability to stand or walk.

**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 turn off stimulation before engaging in activities that could be unsafe for themselves or others if they received an unexpected jolt or shock (eg, driving, operating power tools). Patients should discuss these activities with their physician.

# 7. Adverse events

As with any surgical procedure, the implantation of the Altius System Pulse Generator (IPG) involves some degree of risk. This section is intended to provide you with an explanation of the various potential complications associated with having a device implanted. None of these complications are unique to the Altius System IPG but can also occur during implantation of similar systems (like spinal cord stimulators (SCS)).

## 7.1. Surgical risks

Complications associated with medical device implantation reported in the medical literature include, but are not limited to:

- Infection or fever – This may require surgical correction or medical intervention.
- The skin over the device may break down (erode) exposing part of the device. This requires surgical correction.
- The device may move from its original location under the skin (migration) requiring that your doctor perform another surgery to secure it in position.
- You may bleed under the skin around the wound(s)or in the "pocket" created underneath the skin to hold the IPG (hematoma). This may require surgical correction.
- Fluid may accumulate in the "pocket" created underneath the skin to hold the IPG, which requires treatment.
- You may be sensitive to one or more of the materials used in the Altius System IPG that are exposed to the tissues of the body (histotoxic reaction). Though rare, this may require removal of the device.
- The device may suffer from an early life failure of the battery requiring device removal or replacement.
- An implanted lead may push through the skin requiring surgical correction.
- Stroke.
- Death.

Other Common surgical complications you may encounter are temporary swelling around the incision sites, local pain around the incision sites, abscess, fistula, atrophy (death of tissue), and potential side effects of general anesthesia.

The Altius System IPG uses the lead(s) to deliver direct electrical stimulation to your nerve for your therapy. Problems that can affect the lead's ability to perform this function may occur. These include:

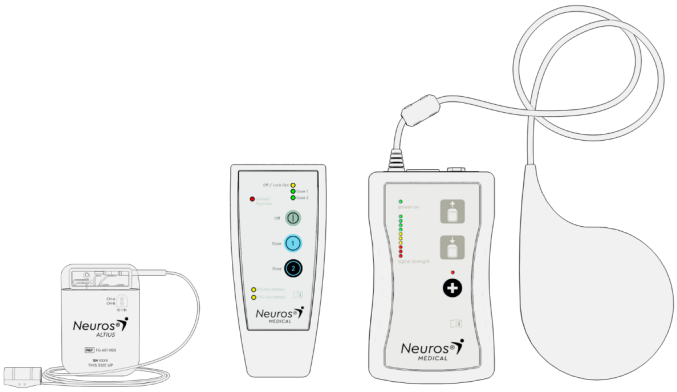
- A lead may dislodge from where it was placed during implantation, necessitating a surgical correction.
- A lead may fracture or break producing a poor electrical connection, necessitating re-operation.

The lead problems described above can occur at any time during the implant life of a lead. Surgical correction is typically required.

# 8. Altius System Overview

The Altius System is intended for the treatment of chronic intractable lower limb post-amputation pain, and is comprised of the following components for your use

- Altius System Implantable Pulse Generator and Cuff Electrode(s) (implanted)
- Altius IPG Battery Charger
- Altius Patient Controller

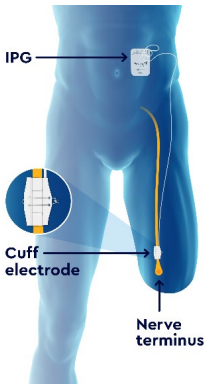



In addition to these components, there is a Programmer System that your Healthcare provider will use to communicate with the Altius IPG to set the parameters for your therapy doses and to ensure that your IPG is working as intended.

## 8.1. Altius System Altius System Implantable Pulse Generator & Cuff Electrode(s)

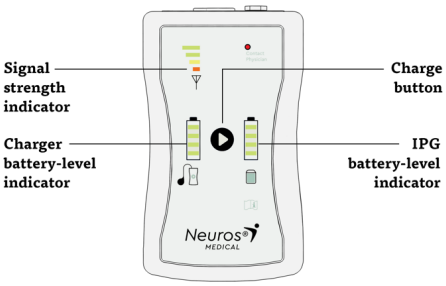
The Altius System Implantable Pulse Generator (IPG), sometimes called a stimulator, is a small, battery-powered electronic device that is implanted inside the body. The cuff electrodes connect the IPG to the nerves your HCP has targeted for treatment.

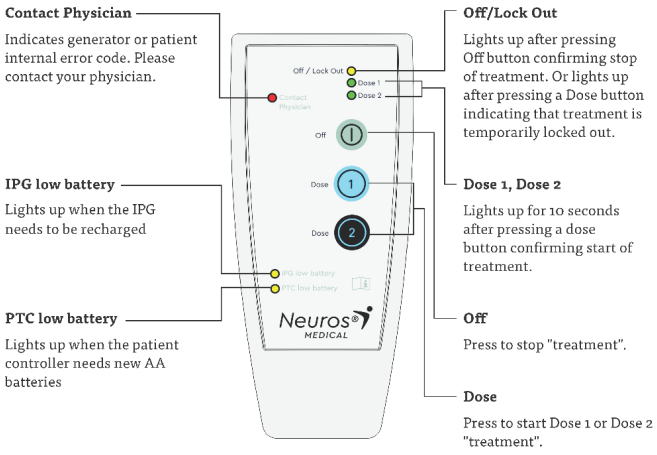
Depending on your doctor's individualized treatment plan one or two Nerve Cuff Electrodes can be connected to the Altius Implantable Pulse Generator. Your doctor who performed the procedure, implanted the Altius IPG and cuff electrode(s). In the case of an Above the Knee amputation (AKA), the patient typically receives one cuff electrode on the sciatic nerve. In the case of a Below the Knee amputation (BKA), the patient typically receives two cuff electrodes, one each on the common peroneal and tibial nerves. The Altius IPG will most likely be implanted in your left or right abdomen.




## 8.2. Altius Patient Controller Overview

The Altius System Patient Controller, or Altius Controller is powered by two replaceable AA batteries. The patient controller allows you to choose to activate the 30 minute therapy when you need it. You can press either dose 1 or dose 2, and then bring it over your implanted IPG to activate the therapy. If for any reason, you need to stop the therapy, you may press the off button and then hold it over your IPG.
See Patient Controller and Battery Charger Manual (LB-0199) for details on the proper operation of the Patient Controller.






8.3. Altius Battery Charger Overview

The Altius Battery Charger is used to recharge your IPG.

See Patient Controller and Battery Charger Manual (LB-0199) for details on the proper operation of the Battery Charger.

8.4. Altius Programmer System Overview

The Altius Programmer System allows the physician or clinical user to program your Altius IPG with custom therapy settings specific to you. The Altius programmer software runs on a laptop PC connected to the programming wand.

# 9. Following Implantation Surgery

It is important that you become actively involved in your own recovery by following your doctor's instructions carefully, including:

- Report any redness, swelling, or drainage from your incisions to your doctor.
- Avoid lifting heavy objects until instructed by your doctor.
- Avoid use of your prosthetic as instructed by your doctor as it may interfere with your incision wound on your residual limb.
- Exercise, and bathe according to your doctor's instructions.
- Be sure to contact your doctor if you develop a fever that lasts for more than two or three days.

- Ask your doctor any questions you may have about your device, pain management, or medications.
- Be sure to take all medications as directed by your doctor.
- Don't wear tight clothing that could irritate the skin over the device.
- Avoid rubbing the device or the surrounding abdomen area.
- If directed by your doctor, limit your leg movements that could affect the lead system.
- Avoid rough contact that could result in blows to the implant site. If you fall or are in an accident that results in a blow to the implant site, contact your doctor.
- Contact your doctor if you notice anything unexpected or unusual such as new symptoms.
- Inform your doctor if you plan long distance travel or if you plan to move to another city. Ask your doctor for a referral in the area.
- Your doctor may limit your driving, at least initially, to avoid putting undue strain on your wounds.
- Depending on level of physical exertion required by your job, your doctor may direct you to stay home and not return to work for a period. Ask your doctor about the timeline for returning to work.

# 10. Living with the Altius System

## 10.1. General Expectations

You will be able to feel the Altius IPG beneath the skin. Normal body movement will cause no harm to it or the attached lead(s). However, it is important that you not try to move or turn the IPG. It has been implanted with a specific orientation to the skin to ensure proper communication with your Battery Charger, Patient Controller, and the Programmer system which is used by your doctor to set and monitor the Altius System.

## 10.2. Effect on Your Activities

Once the wounds from your surgery are healed, you can expect to resume your normal activities, including sexual intimacy. Your implanted IPG and Cuff Electrode(s) are unaffected by walking, bending over or other normal daily activities.

You may notice that running a therapy session with your prosthetic on versus off, may result in a stronger or weaker sensation. This is normal and expected as the electrodes makes more or less direct contact with your nerve(s).

## 10.3. Medications

### 10.3.1. Pain Relief Medications

The Altius System is intended to treat lower limb post-amputation pain which results from both residual limb pain and phantom pain. Once your device is activated, you should consult your physician on how to manage your pain relief medication in relation to the Altius System and the therapy that it delivers.

### 10.3.2. General Medications

General Prescription medications, taken as directed, have no effect upon the proper operation of your Altius IPG. In general, the implantation of your Altius IPG should not require you to alter the use of any general medication.

## 10.4. The Importance of Your Patient ID Card

Each Altius Implantable Pulse Generator is supplied with a Patient ID card. This will be provided to you by your doctor following the implantation of your device. In addition, the information they provide to Neuros Medical allows the company to register you as a recipient of a device it manufactured so that your doctor may be properly and completely notified in the event a product advisory is issued.

It is important that you always carry your Patient ID card and a list of your medications with you. In the event of a medical emergency, the Patient ID card contains information of great importance to an attending physician and will assist in expediting any emergency medical care you may require. In addition, it is important to notify all of your health care providers that you have had an Altius device implanted.

Next time you visit your doctor or dentist, show them your Patient ID card so that a copy of it may be made for their records.

Front

Neuros MEDICAL

Patient name _____

Physician name _____

Physician facility _____

Physician phone number _____

**Contact physician for medical questions or emergency.**

Back

LB-0200 Rev A | June XX, 2022

**This person has an implanted Altius® medical device manufactured by Neuros Medical, Inc.**

**Warning information**

MRI, pacemaker implants or other active implantable devices and diathermy are unsafe. If you need to bypass devices with strong magnetic fields, such as store anti-theft systems and airport screening systems, you can present your implant card to the screening personnel.

For important safety information, contact Neuros Medical, or visit neurosmedical.com/manual.

**Neuros Medical, Inc.**
26800 Aliso Viejo Pkwy, Suite 250 | Aliso Viejo, CA 92656
NeurosMedical.com | 883.240.4462

NeurosMedical.com

**IMPLANT INFORMATION**

| | | | | |
|---|---|---|---|---|
| **MFG** | Neuros Medical | **Implant date** | | |
| **Product** | Altius System | MONTH | DAY | YEAR |

IPG

Place IPG label here

Cuff Electrode(s)

Place cuff electrode label here

Place cuff electrode label here

## 11. Device Lifetime/Replacement

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. Your specific situation and settings may result in shorter or longer battery life.

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.

IPG replacement or removal requires an additional surgery to open of the IPG's pocket in your abdomen. Replacement of the IPG typically requires 60 minutes or less. Contact your clinician to discuss removal or replacement of your IPG.

**Cuff lifetime, removal and replacement**

A cuff requires replacement when a break is suspected.

Contact your physician to discuss removal or replacement of your cuff electrode.

Caution: Significant impacts or falls, may lead to a cuff breaking.

# ALTIUS SYSTEM PATIENT MANUAL

## Appendix I: Additional Electromagnetic Precautions

EMI from the following equipment is unlikely to affect the Altius System if the guidelines below are followed. Consult other equipment manufacturer's product labeling for additional guidance.

**Environmental conditions**

**Household items.** Most household appliances and equipment that are working properly and grounded properly will not interfere with the Altius System. Many household items contain magnets or generate magnetic fields that are strong enough to activate the magnet switch inside the IPG, which can be programmed to start or stop therapy.

Home and commercial microwave ovens do not affect the operation of the Altius IPG, provided they are in good condition and used as intended. Even microwave energy from a severely defective microwave oven directly radiating onto the IPG should not damage the device, Patients with an implanted Altius IPG should be advised that some electric razors, electric power tools, and electric ignition systems, including those of gasoline powered engines, could cause interference. Generally, patients implanted with an Altius IPG may use gasoline powered engines, provided that protective hoods, shrouds, and other shielding devices have not been removed.

If interference is suspected, instruct the patient to move away or turn off the household item.

**Store Anti-Theft Systems/Airport Security Screening Systems**. Certain types of anti-theft systems, such as those installed at entrances/exits of stores, libraries and other facilities, as well as airport security systems can interfere with the Altius System IPG. Such interference would most often inhibit therapy signal delivery, if there is a therapy session in progress. Patients should be advised to proceed through such systems at a normal pace, i.e. not to slow down while passing through. Prior to passing through airport security systems, patients should notify the attendant security personnel that they carry an implant and should present their implant ID card.

**Industrial Machinery.** High voltage power lines, electric and arc welders, electric smelters, and power generating equipment can interfere with the operation of the Altius System IPG. For that reason, one needs to take into account the field strengths and modulation characteristics of all electromagnetic fields patients are exposed to in their workplaces or due to their lifestyle. Patients need to be specifically warned about these risks, and how they can minimize them by not running therapy treatment sessions when they are around these devices.

**Transmitting Devices**. Communication equipment such as radio and TV transmitters (including amateur ["ham radio"] transmitters, microwave, and CB radio transmitters with power amplifiers) as well as radar transmitters can interfere with the operation of the Altius System IPG. For that reason, one needs to take into account the field strengths and modulation characteristics of all electromagnetic fields patients are exposed to in their workplaces or due to their lifestyle. Patients need to be specifically warned about these risks, and how they can minimize them by not running therapy treatment sessions when they are around these devices.

**Cellular and Mobile Phones.** Cell phones and other mobile phones can affect the operation of the Altius IPG. These effects can be caused by the radio frequencies emitted by the phones or by the

phones' speaker magnets. Potential effects include inhibition of or inappropriate Altius System signal delivery if the phone is in very close proximity (within 30 cm / 12 in) of an Altius IPG and the corresponding leads. Because of the great variety of mobile phones as well as the significant physiologic differences between patients, it is impossible make generally applicable recommendations. As a general guideline, patients implanted with an Altius IPG who would like to use a mobile phone are advised to hold the phone to the ear that is contralateral to the implant site. Patients should not carry the phone in a breast pocket or on a belt closer than 25 cm (10 in) from the implanted IPG because some phones emit signals even when they are turned on but not in use.

Compared to smaller cell phones, portable (handbag) and mobile (permanent car or boat installation) phones will generally transmit at higher power levels. For phones with higher transmission power levels, it is recommended to maintain a minimum separation of 50 cm (20 in) between the antenna and the implanted IPG.

# ALTIUS SYSTEM PATIENT MANUAL

## Appendix II: 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) |

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 PATIENT MANUAL

## Appendix III: 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 pulse are 1.07ms for a 0 and 3.36 ms for a 1
- 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 pulse for a 0 is between 183µs, a 1 is 275µs
- Transmit Frequency: 19kHz
- Power: 1.8 mW

# ALTIUS SYSTEM PATIENT MANUAL

## Appendix IV: 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 establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| IEC 61000-4-5 Surge Immunity | 1 | ±0.5,1kV Line to Line; ±0.5,1,2kV Line to Ground | |
| 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. |

| Test Standard | Configuration | Compliance Level | Electromagnetic Environment Guidelines |
|---|---|---|---|
| IEC 61000-4-3 Radiated RF Immunity | 1,2,4 | 10V/m 80MHz – 2.7GHz<br>80% 1kHz AM | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| 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.<br><br>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<br>0% UT for 1 Cycle<br>70% UT for 30 Cycles<br>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.<br><br>**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<br>134.2kHz 2.1kHz PM 65A/m<br>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 PATIENT MANUAL

## 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 PATIENT MANUAL

## Appendix V: 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

**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.

**The Altius Battery Charger:**

# ALTIUS SYSTEM PATIENT MANUAL

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 f compliance could void the user's authority to operate this equipment.

**Formatted:** Font: (Default) Cambria, Ligatures: Standard + Contextual

**Formatted:** Normal, Indent: Left: 0.25", No bullets or numbering

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.