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

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 PATIENT MANUAL

Table of Contents

ALTIUS SYSTEM PATIENT MANUAL

List of Figures

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

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 PATIENT MANUAL

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**

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).

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.

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.

5.1. 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.

5.2. 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.

ALTIUS SYSTEM PATIENT MANUAL

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

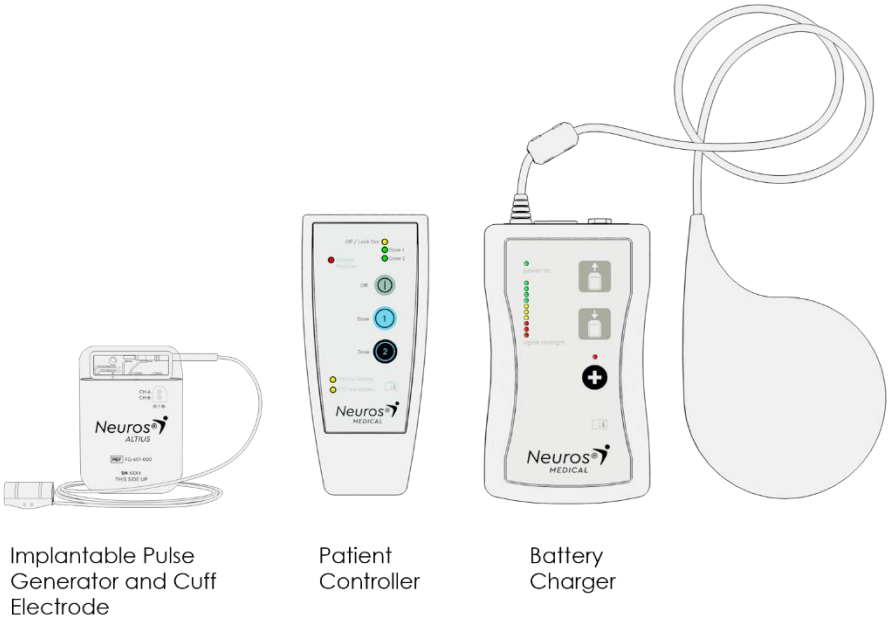

Figure 1: Neuros Altius System

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 implanting doctor's individualized treatment plan, one or two Nerve Cuff Electrodes can be connected to the Altius Implantable Pulse Generator. If you have one Cuff electrode it will typically be wrapped around your sciatic nerve in the residual limb, and if you have two cuff electrodes, they will be wrapped around the Common Peroneal nerve and the tibial nerve below where the sciatic nerve splits. The Altius IPG will most likely be implanted in your left or right abdomen.

ALTIUS SYSTEM PATIENT MANUAL

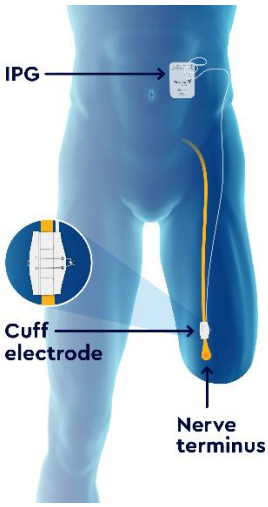

Figure 2: Altius System Implanted

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.

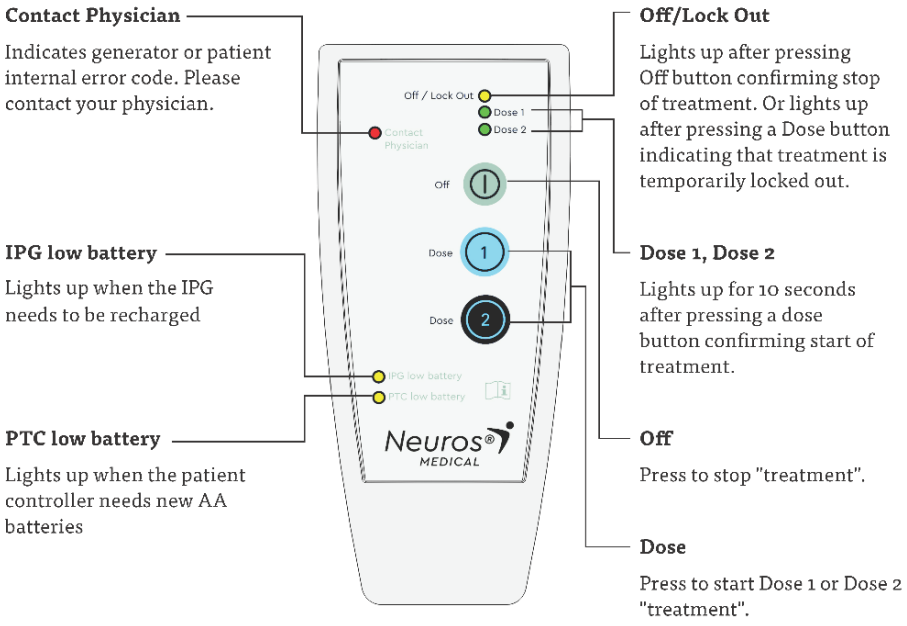

Figure 3: Altius Patient Controller

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.

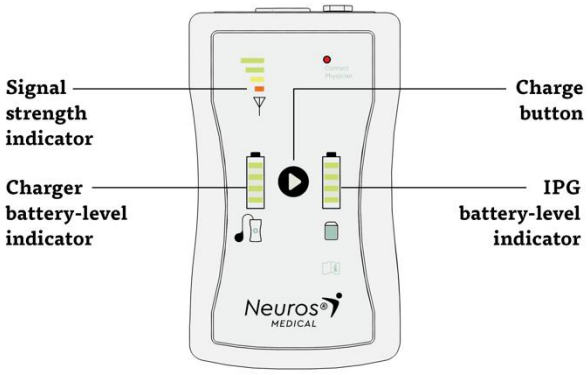

Figure 4: Altius Battery Charger

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.

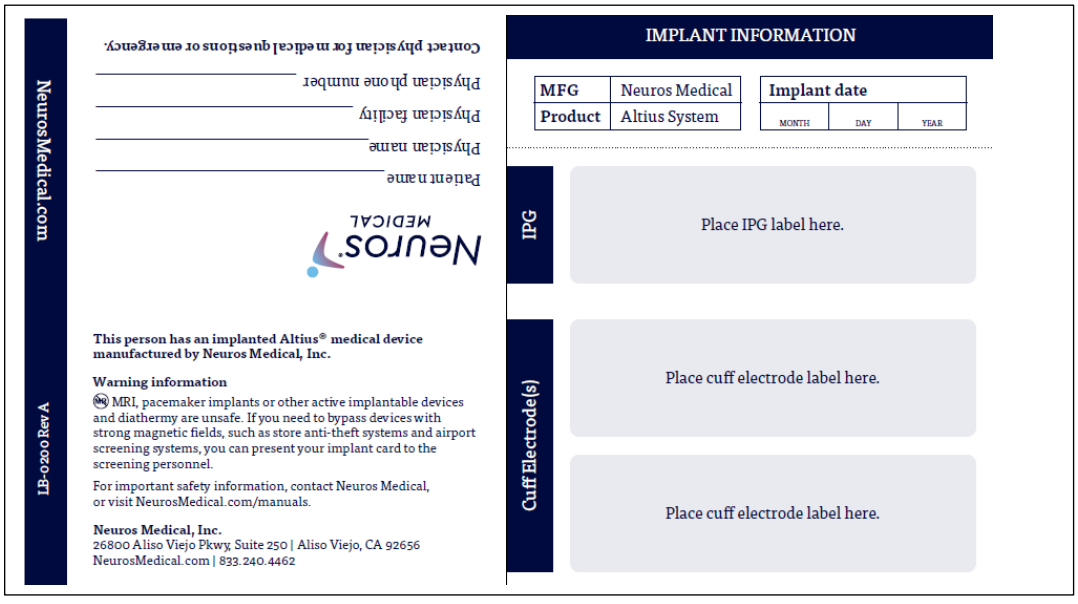

Figure 5: Altius Patient Implant Card

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 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
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 PATIENT MANUAL

Table 9 from IEC 60601-1-2 ed 4.1 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 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.

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.

Altius® Direct Electrical Nerve Stimulation System - Patient Controller and Battery Charger Manual

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

LB-0199 Rev B

Altius System Patient Controller and Battery Charger 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).

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 Patient Controller and Battery Charger Manual

Table of Contents

List of Figures

Altius System Patient Controller and Battery Charger Manual

Information available for the Altius System:

The information for prescribers 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 this 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 Controller and Battery Charger Manual

1. Explanation of Symbols

Symbol	Symbol Meaning
REF	Model Number
QTY	Quantity
SN	Serial Number
UDI	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
Rx Only	Prescription only
MD	Medical Device
	Non- Ionizing Electromagnetic Radiation
	Humidity
	Atmospheric Pressure
	Keep Dry
	Keep Out of Sun

Altius System Patient Controller and Battery Charger Manual

Symbol	Symbol Meaning
	**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 Controller and Battery Charger Manual

2. Introduction

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

This manual is designed to help you understand the operation of the Altius System components intended for patient use, the Patient Controller and Battery Charger.

For information on indications, contraindications, warnings, and precautions, please see the Patient Manual (LB-0196). If you have any questions about this information, please contact your doctor.

The Altius Patient Controller and Altius Battery Charger are type BF Applied Parts.

3. 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.

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.

3.1. 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.

3.2. Caution and Warnings Associated With Battery Charger and Patient Controller Operation

- The Altius System IPG may not properly detect a Dose on signal and fail to deliver therapy due to a software or hardware problem, necessitating replacement.
- The Altius System IPG may not properly detect a Dose off signal and fail to turn therapy off due to a software or hardware problem, necessitating replacement.
- An Altius System IPG may detect environmental interference and inappropriately deliver therapy. See Patient Manual (LB-0196) for more information on Electromagnetic Interference.
- An Altius Patient Battery Charger may not function as designed due to a software or hardware problem and not charge the IPG as intended. A replacement Battery Charger will be required.
- An Altius Patient Controller may not function as designed due to a software or hardware problem and not activate the IPG as intended. A replacement Controller will be required.
- Heat due to charging. The implanted IPG may become warm while charging. If you experience discomfort, please stop charging and contact your physician immediately.

4. Altius Patient Controller and Battery Charger Overview

4.1. Altius Patient Controller Overview

You may receive your Patient Controller from your health care provider following your implant procedure. Please note, your Patient Controller will not be operational until after your initial programming visit. If you attempt to use it prior to your initial programming, therapy will not activate, and the Contact Physician light may illuminate. Discuss this with your physician during the initial programming visit.

The patient controller allows you to choose to activate 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. Dose 1 is intended to be your primary therapy, and Dose 2 is intended to be an alternate therapy that is a lowered therapy compared to Dose 1. Your physician or clinical staff programming your device should go over this with you.

If for any reason, you need to stop the therapy, you may press the off button and then hold it over your IPG.

Altius System Patient Controller and Battery Charger Manual

The Altius System Patient Controller, or Altius Controller, is powered by two replaceable AA batteries.

See Section 6 of this manual for details on the proper operation of the Patient Controller.

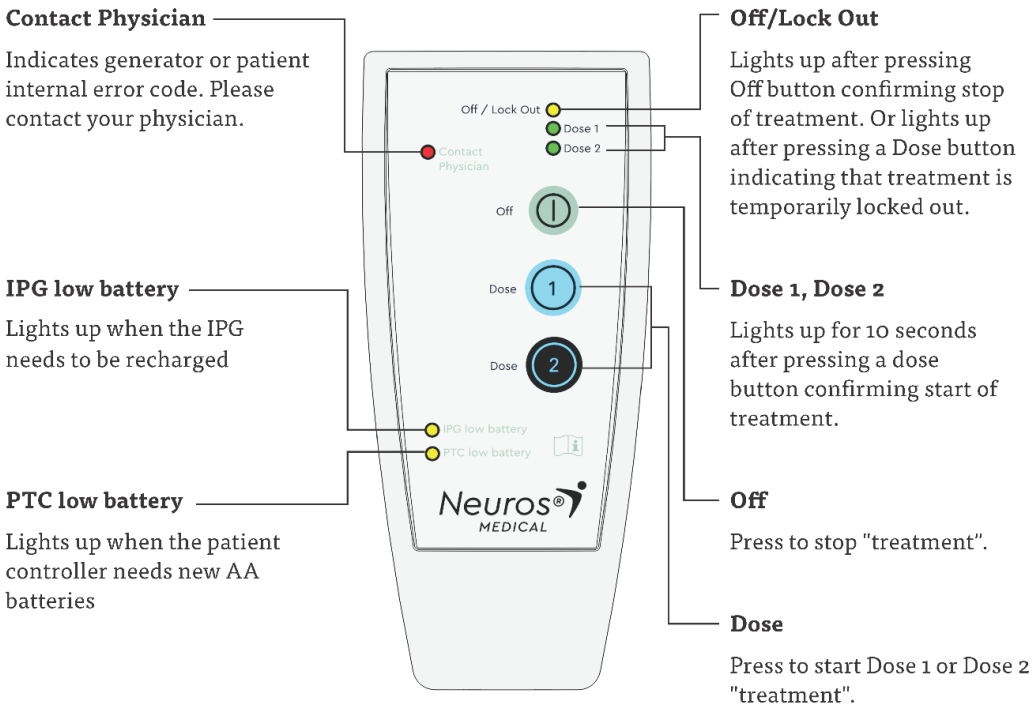

Figure 1: Altius Patient Controller

4.2. Altius Battery Charger Overview

The Altius Battery Charger is used to recharge your IPG.

Please refer to Section 7 of this manual for details on the proper operation of the charger.

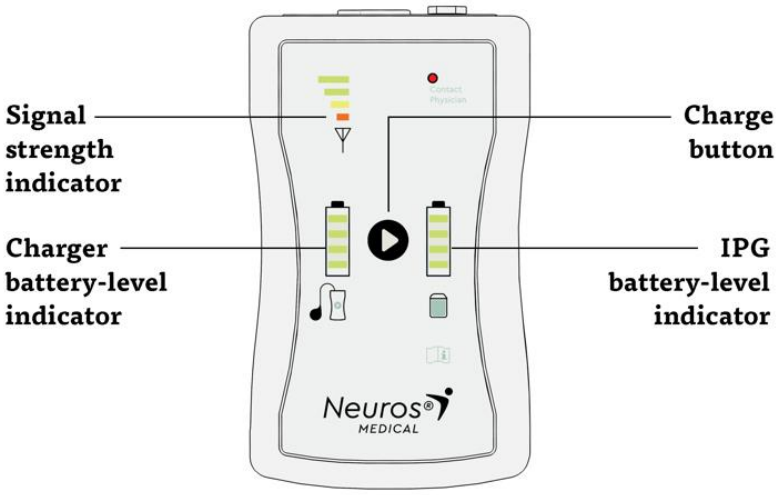

Figure 2: Altius Battery Charger

Altius System Patient Controller and Battery Charger Manual

5. Living with the Altius System

5.1. 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.

5.2. 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).

5.3. Medications

5.3.1. 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.

5.3.2. 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.

5.4. The Importance of Your Patient ID Card

Each Altius Implantable Pulse Generator (IPG) 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.

Altius System Patient Controller and Battery Charger Manual

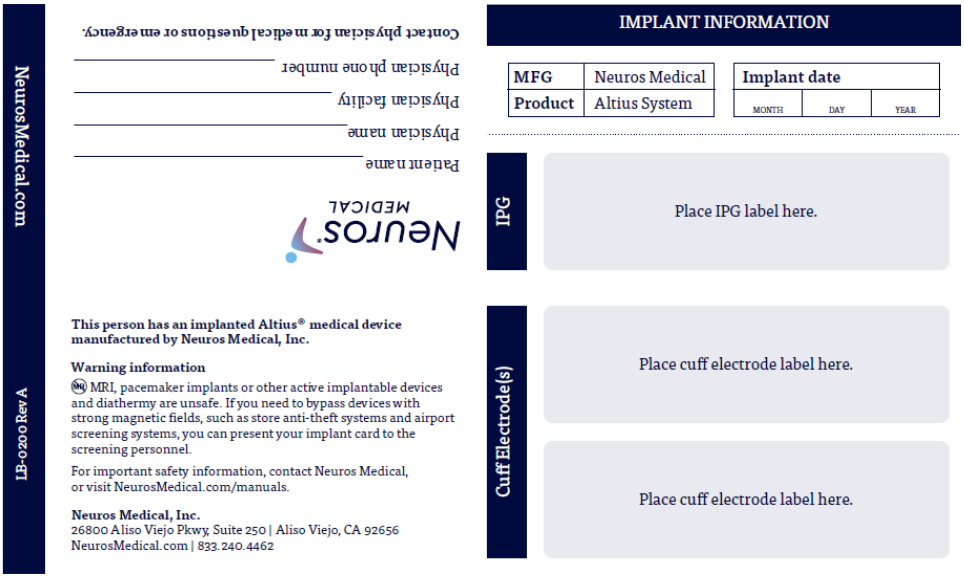

Figure 3: Altius Patient Implant Card

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.

6. Using Your Altius System - Patient Controller

6.1. Using Your Patient Controller

The Altius Patient Controller has three buttons and several light indicators.

Each Button on the patient controller initiates a function as described in detail on the following pages of this section.

Buttons and Basic Operation

To use the patient controller and functions, you will simply press a button as you would on any typical remote and then hold it over your Altius IPG to transmit the button command.

The following figure describes the buttons and lights of the patient controller:

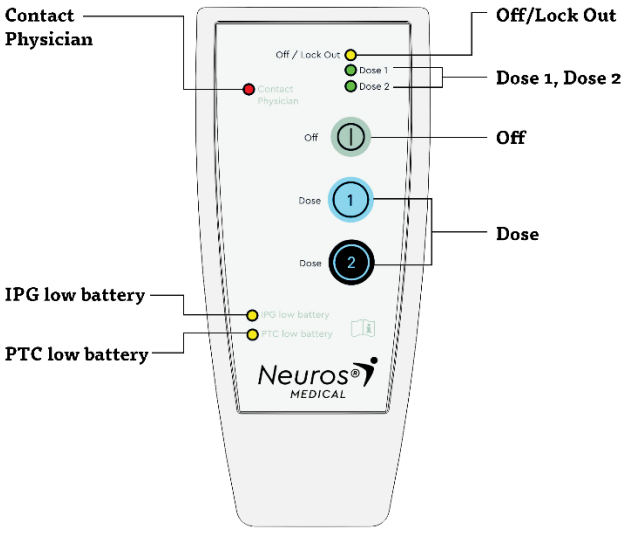

Figure 4: Altius Patient Controller

6.2. Communicating with the Altius IPG

Effective communication between your IPG and the patient controller is necessary. To establish communication with your IPG:

1. Press the button,  or  or  you intend to activate. Please note, the Patient Controller provides audible signals (sounds) to confirm the status of the IPG each time a button is pressed. See section 6.7 below for details.
2. Place the controller over the IPG, over your lightweight clothing
   a. The patient controller should not contact your skin directly.
3. The distance between IPG and the patient controller should be less than 2 inches.

   The patient controller is your direct link to choose available treatment. You cannot turn on your IPG without the patient controller.

Warning: When using the Patient Controller in an environment that is 40˚C (104˚F) or hotter, the Patient Controller may warm up to 43.4˚C (110.1˚F). If you feel any part of the system getting too hot, stop using the Patient Controller and wait for it to cool down.

6.3. About Your Altius IPG Battery

When the patient controller detects that your IPG battery is low, the “IPG low battery” indicator will light up and stay on until the IPG is recharged. See “Charging the Altius IPG”

Warning: Failure to consistently charge your Altius IPG Battery may result in a failure of the device to deliver therapy. If the IPG battery is too low, the device may need to be replaced.

6.4. Turning Treatment Off

The patient controller has a dedicated Treatment off Button.

You may press ⏻ at any time to turn treatment off.

After pressing the ⏻ button, the patient controller "Off/Lock Out" indicator briefly lights up confirming the off status

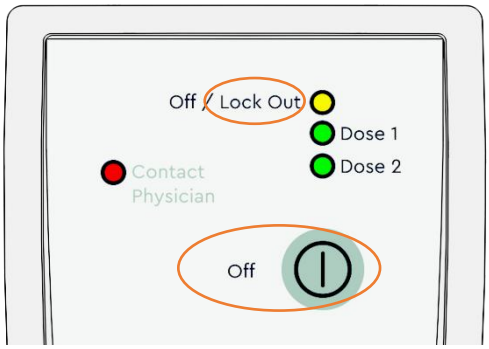

Figure 5: Altius Patient Controller Lock Out and Off Buttons

6.5. Starting a Treatment Session

Your Altius IPG has been programmed with two therapies: "Dose 1" or "Dose 2"

To start a treatment session:

1. Make sure that you are in a stationary, comfortable position, sitting or reclining (Couch, Sofa or Armchair, etc.).

   Warning: Walking or standing with prosthesis. Do not start or use treatment while walking or standing with your prosthesis. Any sudden response to treatment may interfere or impair your ability to stand or walk.

2. Press and release the ① or ② button to start a treatment session. Pressing any button after that will change it to that button/dose command to the IPG.
3. The green Dose 1 or Dose 2 indicator light will briefly light up confirming which treatment was started.

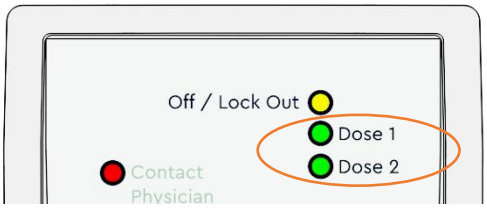

Figure 6: Altius Patient Controller Dose Buttons

4. The treatment will automatically turn off after the prescribed duration of time.
5. Once you have started a treatment dose, you will have a short window where you can turn off the dose and restart it if you pressed the wrong button. If you miss this window, you cannot switch to another dose until after the Lock Out period has ended. (See Next section "Lock Out")
6. If the yellow Off/Lock Out indicator light turns on after pressing the 1 or 2 button, the IPG is momentarily "locked out" and a new treatment session cannot be started at this time.

   Note: The treatment session can be turned off at any time by pressing the off button.

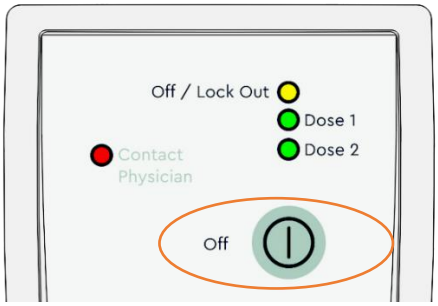

Figure 7: Altius Patient Controller Off Button

6.6. Lock Out

After a treatment session has started, there is a 30-minute prescribed "lock out" during which a new treatment session cannot be started.

For example, after pressing 1, pressing 2 will cause the "Off / Lock Out" indicator to light up. The next treatment cannot be started until after the first treatment turns off and the prescribed lockout has passed.

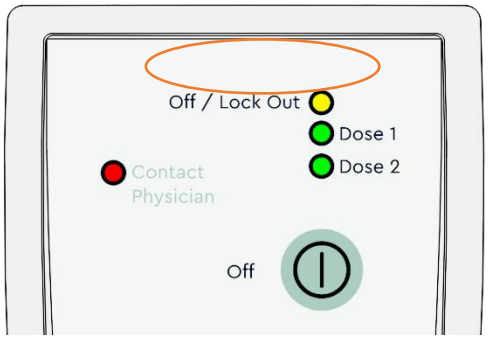

Figure 8: Altius Patient Controller Lock Out Button

6.7. Audible Signals from your Patient Controller

The patient controller provides audible signals (sounds), to confirm the status of the IPG, each time a button is pressed.

One beep. The command was accepted by the IPG.

Two beeps. The command is not allowed. For example, the IPG is momentarily locked out and a treatment session cannot be started (see "Lock out").

Steadily repeating beeps. The patient controller is out of range of the IPG and needs to be better aligned to establish communication. This beeping will continue for roughly 10 seconds to give you time to better align the patient controller with the IPG. If during this time communication is established, the command will be sent to the IPG and either one beep or two beeps confirming the status of the IPG will occur (see One beep or Two beeps above).

Three quick beeps. The controller could not establish communication with the IPG and has stopped trying. You will only hear three quick beeps after the conclusion of the slow repeated beeps if communication was not established. The Patient Controller should be moved closer to the IPG and the button command should be attempted again.

Figure 9: Altius Patient Controller

6.8. Understanding Battery Status

About the Patient Controller Batteries lights

As a user of the Altius System for amputation pain, it's essential that you understand the importance of battery power. The replaceable batteries in your patient controller and the rechargeable battery in your IPG work together to provide you with dependable treatment. Always pay attention to the battery status indicator described in this section.

When the patient controller batteries need to be charged, the "PTC low battery" indicator will light up. If the patient controller battery is not replaced before draining completely, your patient controller will not communicate with your IPG to start treatment sessions. Replace the patient controller batteries as soon as possible after the indicator light comes on to maintain patient controller function.

Note: Make a habit of replacing the patient controller batteries when you first see the "PTC low battery" indicator light up. See "Patient controller battery replacement".

6.9. Altius Patient Controller Battery Replacement

Caution: Small parts such as the AA battery could be hazardous if swallowed or cause choking if ingested or inhaled. Keep small parts and accessories out of the reach of children.

To replace batteries in your patient controller:

1. On the rear of the patient controller, slide down the battery compartment lock.
2. Lift off the battery cover by grabbing the cover near the middle of the Patient Controller and lifting up.
3. Remove the old batteries.

   Caution: when removing the old batteries, be careful that the bottom metal contact plate does not come out. If it does come out, contact your physician for a replacement controller.
4. Place two new AA batteries in the slots, matching the positive (+) and negative (-) markings in the compartment.

   Warning: If the batteries are not placed correctly according to the positive (+) and negative (-) markings, the patient controller may heat up. If this happens it is recommended to remove the batteries, and let the patient controller cool down, before putting the batteries back in. If you have any concerns that the patient controller may be damaged, contact your physician.
5. Align the battery compartment cover on the case starting at the bottom of the patient controller.
6. Slide up the battery compartment lock.

Altius System Patient Controller and Battery Charger Manual

7. Using Your Altius System - Battery Charger

7.1. Battery Charger Description

The charging system for your Altius IPG consists of the charger unit, a charging paddle (coil), and an AC Adapter power supply. When it is not being used, keep the charger connected to the power supply so it is always ready to recharge your IPG.

The Battery Charger is powered by two (2) 18650 Li Ion battery cell with a nominal capacity of 2600mAh and is used to charge the battery of the Altius IPG. The device is supplied with an AC Adapter power supply (Cell-Con Battery Charger AC Adapter; Input: 100–240VAC, 50-60Hz, 0.3A; Output: 8.4V, 1.3A) to charge the Battery Charger from a standard wall outlet. US and European plug adapters are included.

Warning: If the Altius IPG is not charged regularly, it will not be able to deliver therapy, or may stop delivering therapy during a treatment session.

Caution: The Altius Battery Charger is subject to, and/or could be the cause of, potential electromagnetic or other interference from other electrical devices operated in the vicinity. Portable and mobile RF equipment is especially prone to impair the normal function of the charger.

7.2. A Typical Therapy Example

The Altius System utilizes voltage and frequency with a 30-min time duration to provide your 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.

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

Figure 10: Altius Battery Charger with AC adapter Power Supply

7.3. Importance of Charging Your Altius IPG

Your Altius IPG uses a rechargeable battery to provide treatment. How often you charge your Altius IPG depends on how frequently you use the treatment. Charging frequency is determined by usage frequency. The low battery Indicator will light if battery is low in the IPG. Low battery can interrupt treatment. Developing a charging routine rather than waiting to charge until the low battery indicator light comes on will help avoid treatment interruptions due to low battery.

Charging your Altius IPG should be done at least once a week. The need and frequency for charging sessions is be determined by how frequently you use your device, and how short or long you would like an individual charging session to last. In general, if you are regularly using your Altius IPG, you should run at least one charging session a week.

WARNING: Throughout the service life of your device it is recommended that you recharge at least once per month. Failure to charge the device for a long period of time, such as months or years, may make the device impossible to recharge, and the treatment will no longer be available.

WARNING: The Altius IPG Charger shall not be used on board aircraft. The Altius Charger shall not be used on board a ship without prior consent from the ship's crew.

NOTE: Consult local regulations if using the Charger outside of the country where it was purchased.

WARNING: Do not attempt to connect any equipment to the I/O port of the Altius Charger. This port is solely for factory or service personnel use.

7.4. Altius Battery Charger Features

Your Altius IPG Battery Charger has several features which have the following significance:

- IPG-Charger Coupling Signal Strength Indicator: Bar graph display depicting connection between the charger and the Altius IPG
- If there is an issue with the Battery Charger or the IPG, the Contact physician light will turn on. If this happens, contact your physician, and you may need to come to your doctor's office to have the issue resolved.
- Charger Battery Status Indicator: Bar graph display depicting the state-of-charge of the Altius Battery Charger.
- Start Button: Start button for the Altius Battery Charger.
- IPG Battery Status Indicator: Bar graph display depicting the current state-of-charge of the Altius IPG battery.

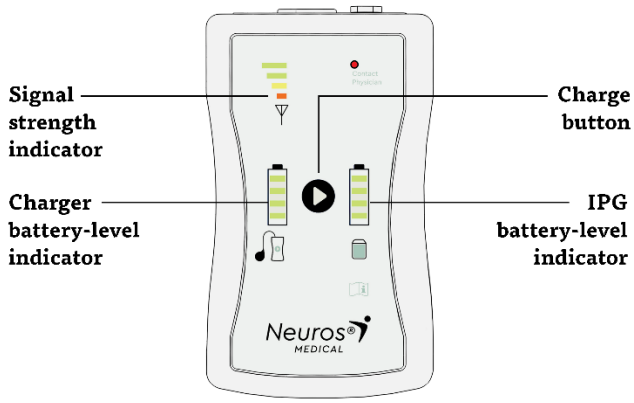

Figure 10: Altius Battery Charger

7.5. To Prepare the Charger

Charging the internal battery of the Altius Battery Charger consists of two steps:

1. Plug the AC Adapter power supply into a standard AC wall outlet

   WARNING: Only use the AC Adapter Power Supply provided with the Altius Battery Charger to charge the Battery in the Charger.

   CAUTION: Do not touch the DC contacts of the Battery Charger. However, it poses no significant risk if inadvertent contact is made.

2. Plug the other end of the AC Adapter power supply into the Battery Charger

   The battery-level lights on the charger will cycle indicating that the charger is actively being charged. Once the charger is fully charged, the battery-level lights will stop cycling and remain continuously on.

NOTE: The charging process is fully automatic, and so can be left to charge unattended.

The charger is completely ready and able to fully charge your Altius IPG when all 4 battery level lights are continuously on and no longer cycling.

If the battery lights are still cycling, the charger may only partially charge the Altius IPG. Battery Charger may be used, but it may not be able to return your Altius IPG to a full charge and you may need to charge again sooner than you normally would.

Figure 11: Altius Battery Charger

7.6. Charging Your Altius IPG

The Battery Charger used to charge the battery of the Altius IPG. It is especially designed to properly control the charging process with minimal intervention and to ensure your safety.

Note: Inspect the Battery Charger for any damage before each use. Contact your physician if a replacement Battery Charger is needed.

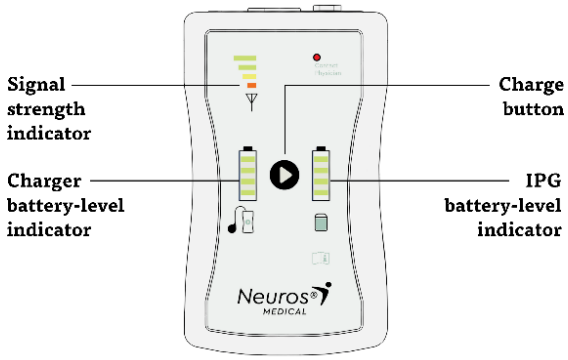

Figure 12: Altius Battery Charger Battery Level

1. When the charger battery level indicator is solid with four green bars, disconnect the charger from the power supply. A long audible beep will confirm the adapter is no longer connected to the charger.

   Note: Charging the internal battery of your Charger and charging your Altius IPG CANNOT be done at the same time. You FIRST have to charge the battery of your Charger and THEN you can charge your Altius IPG.

2. Make sure that you are in a stationary, comfortable position, sitting or reclining (Couch, Sofa or Armchair, etc.).

3. Place the charging coil (paddle) over your Altius IPG, over your clothing. You may use an accessory belt to hold the charging paddle in place.

   Warning: When Charging in an environment that is 40˚C (104˚F) or hotter, the Charging paddle may warm up to 42.7˚C (108.8˚F), and the Charger case may also warm up to 42.8˚C (109˚F). If you feel any part of the system getting too hot, stop charging and wait for the battery charger to cool down.

   Note: The Altius IPG cannot be charged if a treatment session is in progress

   Note: The charger should not be operated close to other electronic equipment. If sufficient spatial separation cannot be maintained, the charger needs to be monitored to ensure normal function.

4. Turn on the charger by pressing-and-holding the button for 3 seconds and then release. Once the button is released, you should hear repeated short beeps confirming that the charger is ON but the charging coil is not in the correct position.

   Note: The Battery Charger will beep for 10 seconds, if it has not been positioned correctly at the end of the 10 seconds, then it will stop attempting to couple with the Altius IPG.

5. Use the signal strength indicator to adjust the position of the charging coil. Move the charging coil until one or two green indicators light up. The short beeps will stop when the charging coil is placed in the correct position and the IPG is being charged.

   Note: If moving the Paddle (Charging Coil) does not light up the green indicators, charging can still be done with only a yellow indicator light on.

6. Once the Charging Coil has established a link with the Altius IPG, the charger will begin the charging process.

   Note: If the charging Coil positioning is poor or if the charging paddle has been displaced, the Charger will display a decreasing number of illuminated bars on the IPG-Charger Coupling Signal Strength Indicator. In addition, you will hear an audio signal sounding approximately once per second. If this occurs, please move the charging paddle back into the correct position.

   Note: If the position of the charging paddle with respect to the Altius IPG remains poor, the charging process is automatically suspended. When this occurs, a new charging session must be initiated by pressing the Button again.

7. The IPG Battery Status Indicator depicts how the charging process of your Altius IPG is progressing.

Note: Depending on how long since the last charging session, and how much you have used the device, the charging may take anywhere between 30 minutes to up to approximately 6 hours. If you cannot fully charge your Altius IPG in one session, you may need to increase your charging frequency.

8. When the charger emits a long beep, charging is complete. If all 4 battery level indicators light up, the IPG is fully charged. The charger will automatically shut off. If you need to end a charging session you can either remove the charging paddle from over the IPG, and the Battery Charger will shut off after 10 seconds, or you may press the Button and hold for 3 seconds to turn off the charger.

   Caution: Do not confuse the end-of-charge signal (one long distinct beep) with the steadily repeating misalignment beep.

   The charger monitors the temperature of your implanted Altius IPG so that its temperature rises only minimally. If you wish to resume the charging session after a pause, please wait for approximately 10 minutes before initiating a new charging session to allow the temperature of your implanted Altius IPG to return to normal.

   It is estimated that the rechargeable IPG battery will provide you with 10 years of service under typical settings usage, and weekly charging. Under higher than typical settings and usage, your IPG may require more frequent charging and may last less than 10 years of service.

   Audible Signals from the Altius Battery Charger

   One Beep. Charging is complete and the charger stopped automatically, or the charger was stopped by pressing and holding the button for 3 seconds

   Three Beeps. Charger battery level is too low to continue to charge the IPG and charging has stopped. You will need to charge the charger before you can start recharging the IPG.

   Steadily Repeating Beeps. The charging coil is not in the correct position and cannot start charging the IPG. Move the position of the charging coil until a yellow or green indicator lights up.

8. HELP Section

8.1. Help with Treatment

If you are unable to start treatment:

1. Press the desired dose button and listen for a single beep.
2. If you hear a single beep but do not see a dose indicator light up, look to see if the “IPG low battery” indicator lights up.
3. If the “IPG low battery” indicator lights up, charge the IPG. When charging is complete, try to start treatment.
4. If treatment still will not start, call your physician.

8.2. Treatment Session Increases or Decreases on its Own

The level of sensation you feel during treatment may change over time. The amount of sensation you feel from treatment may also change depending on body position (lying down, standing, or bending), and also if you are wearing, or not wearing your prosthetic.

8.3. Treatment Shuts Off before Completing a Treatment Session

When the IPG battery needs to be recharged, it will stop treatment. Check the battery status with the patient controller and recharge if necessary, then turn treatment back on. If the IPG regularly stops treatment before you charge, you can charge more often.

The Altius IPG is also equipped with a magnetic switch for use in cases where a physician in an ED (Emergency Department) may need to ensure that your device is off.

Although unlikely, anti-theft screeners such as those at the entrance of stores, can turn treatment off. If you cannot turn the IPG back on with your patient controller, you may need to recharge the IPG.

8.4. There is No Feeling From Treatment

If you no longer feel therapy, it may be due to your body is adapting to the sensation, in which case the treatment is still being delivered but you may no longer feel it.

Caution: If you experience a full session, but do not feel the therapy for any part of it you may need to visit your doctor.

8.5. Help with Your Patient Controller

"IPG low battery" lights up on the patient controller

The batteries in your implanted IPG are low and should be charged soon. See "Charging your Altius IPG" Section 7.5.

"PTC low battery" lights up on the patient controller.

The batteries in your patient controller need to be replaced with two fresh AA batteries. See "Altius Patient Controller Battery replacement" Section 6.9.

"Contact physician" lights up on the patient controller.

The Altius IPG or patient controller has generated an internal error code. This may indicate a system failure that prevents treatment from being delivered by the IPG. Please contact your physician.

No response from patient controller.

After pressing a dose button, watch for one of the indicators to light up and listen for an audible sound. If none of the indicators light up and you cannot hear

any beeps, the batteries in your patient controller may need to be replaced with two fresh AA batteries. See "Altius Patient Controller Battery replacement." Section 6.9.

If after pressing a dose button you see a dose indicator light up and hear one beep, the IPG has received the command and will begin a treatment session.

If you do not feel the sensation, it may be due to nerve accommodation to the sensation in which the treatment is still being delivered but you may no longer feel it. If you do not feel the sensation for the whole treatment session, contact your physician.

If you see the Off / Lockout Out indicator light and hear two beeps, you are unable to deliver treatment at this time. See “Lock out” Section 6.6.

8.6. Help with Your Battery Charger

“Contact Physician” lights up on the charger.

The implantable IPG or charger has generated an internal error code. This may indicate a system failure that prevents treatment from being delivered by the IPG. Please contact your physician.

Charger not charging.

Make sure charger is unplugged from power supply as shown in the picture below.

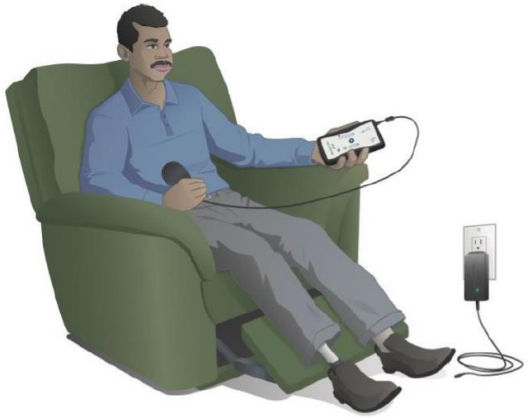

Figure 13: Altius System Charger

8.7. Contact Physician Indicator

The Altius Charger was designed to provide you with certain warnings regarding the status of the Altius IPG as well as the Charger device itself. If the charger detects a situation that requires action, the “Contact Physician” indicator will illuminate and you should contact your doctor to schedule a prompt Altius IPG check-up. Your IPG may not respond to therapy activation using the patient controller until the situation is resolved.

NOTE: Remember you should always conduct a recharge session to ensure that your device is working.

Altius System Patient Controller and Battery Charger Manual

9. Altius Patient Controller & Battery Charger Cleaning

CAUTION: DO NOT use solvents or cleaning cloths impregnated with chemical cleaning agents

WARNING: DO NOT attempt to clean the electrical connectors of the Battery Charger or the AC adapter

WARNING: DO NOT submerge the Patient Controller, Battery Charger or the AC adapter in water or any other liquid. Damage to the devices may result.

Cleaning the Patient Controller

Once a month the Altius Patient Controller is recommended to be cleaned using a mild detergent applied with a damp cloth. Do not use abrasive cleansers.

Use a dry cloth to dry the Patient Controller to remove any excess moisture.

Cleaning the Battery Charger

WARNING: Before and After cleaning the Battery Charger and AC Adapter Power Supply, ensure that it is disconnected from the Charger's AC adapter, and the AC Adapter is unplugged from the AC mains.

Once a month the Battery Charger and AC Adapter is recommended to be cleaned using a mild detergent applied with a damp cloth. Do not use abrasive cleansers.

Use a dry cloth to dry the device to remove any excess moisture, and let it air dry before plugging everything back together.

10. Altius Patient Controller & Battery Charger Maintenance

The Altius Patient Controller only requires periodic replacement of the replaceable AA batteries. There are no other User replaceable parts.

The Altius Battery Charger & AC Adapter do not have any user replaceable parts.

WARNING: No modification of this equipment is allowed.

The Altius Patient Controller and the Altius Battery Charger with AC Adapter are expected to have a useful life of at least 5 years.

Warranty: If you experience an issue with your Altius Patient Controller or Battery Charger within 3 years from date of issue, contact your medical provider or Neuros Medical for a replacement.

10.1. Power Ratings

The Altius Patient Controller is powered by two standard AA alkaline batteries. Each battery should be a standard AA alkaline battery with an operating voltage of 1.5V new, and a max Amp-hour rating of ~2 amp-hours.

The Battery Charger AC adapter has the following power ratings:

Input Voltage: 100-240VAC 50-60Hz

Input Current: 0.3A max.

Output Voltage: 8.4V

Output Current: 1.3A max.

Altius System Patient Controller and Battery Charger Manual

11. Altius Patient Controller & Battery Charger Storage and Handling

Once you receive your Patient Controller & Battery Charger do not expose them to extreme temperatures. They should be stored in a cool and dry place. Do not leave the devices in your car or outdoors for extended periods of time. The electronics in both units are sensitive, and can be damaged by these extreme conditions, particularly high heat.

The Patient Controller should be able to be used to activate therapy in most temperatures.

Use of the battery charger should try to be avoided in temperatures above 80˚F (27˚C). If possible, try to move to a cool location prior to starting a charging session.

Your Patient Controller & Battery charger should be kept at normal room temperature, humidity, and pressure conditions.

Temperature Usage range of 5˚C- 40˚C (41˚F - 104˚F)

Relative Humidity range of 15% - 90%

Atmospheric Pressure of 700 hPA – 1060 hPA, or from 10,000 ft above sea level (Pressurization of a commercial aircraft) to 1,300 ft below sea level (the lowest elevation of dry land on earth)

The Patient Controller and Battery when not being used should be stored between -25˚C - 70˚C (13˚F - 158˚F)

When moving the Altius Patient Controller and/or Altius Battery Charger from very cold or very hot storage areas (such as your car), wait at least an hour to use either device. The devices require time to return to a safe operating temperature.

12. Altius Patient Controller & Battery Charger Disposal

If the Altius Patient Controller & Battery Charger is no longer needed, you may return them to your doctor's office.

WARNING: DO NOT discard the Charger in the trash. The Charger contains Lithium batteries as well as environmentally unfriendly (Lead Solder) components. If disposal of the Altius IPG Charger is necessary, properly dispose of it in accordance with local regulations governing the disposal of such material.

13. Device Lifetime/Replacement

IPG 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. The IPG replacement does not, in of itself, require cuff replacement unless a cuff break is suspected.

The 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 Controller and Battery Charger Manual

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.

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 Patient Controller and Battery Charger Manual

Appendix II: 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.

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.