Altius® Direct Electrical Nerve Stimulation System
Prescriber Instructions for Use

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
LB-0195 Rev B

ALTIUS SYSTEM PRESCRIBER INSTRUCTIONS FOR USE

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

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

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

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

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

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

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Information available for the Altius System:

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

Product manuals, such as programming guide, patient user 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 PRESCRIBER INSTRUCTIONS FOR USE

1. Indications for Use, Contraindications, Warnings and Precautions

1.1. 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.

1.2. Contraindications

The Altius System is contraindicated for patients who are:

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

1.3. Operating Principle

The Altius System for Direct Electrical Nerve Stimulation is intended for the treatment of chronic intractable phantom and residual lower limb post-amputation pain. The system uses direct electrode-to-nerve contact via a nerve cuff electrode to directly administer electric stimulation on the nerve terminus of the amputated lower extremity to alleviate pain. Neuros Medical's unique Direct Electrical Nerve Stimulation technology holds the promise of providing an effective, mechanism-based yet non-destructive, treatment for managing chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. This technology was developed based on the findings from pre-clinical animal experiments that continuous application of high frequency alternating current (HFAC), with a relatively high amplitude, could result in a sustainable yet reversible electrical conduction block in a nerve. [1,2] Both computer simulation and animal experiments have shown this electrical block is local, predictable, sustainable, and reversible. The Altius System is intended to generate a HFAC electrical stimulus similar to the one used in the animal experiments.

While conventional nerve block by injection of local anesthetic, such as lidocaine, can often provide predictable and reliable relief of pain of peripheral origin, the short-lasting effect and the toxicity of these agents have prevented their long-term use.

The clinical benefit of Direct Electrical Nerve Stimulation technology results from its direct action on pain signals without toxicity. Specifically, the HFAC waveform may inactivate the target nerve and consequently block pain signal transmission. We hypothesize that this electrical conduction block is achieved through the inactivation of sodium channels by sustained depolarization of the cell membrane.

1.4. Warnings

1.4.1. Use as indicated and instructed

Only use compatible products for the indicated therapy and indicated populations. Failure to use compatible products per labeling indications and instructions may result in product damage, patient injury, or death.

[1] Kilgore, K.L. and Bhadra, N. (2004) Nerve conduction block utilizing high-frequency alternating current. *Medical & Biological Engineering and Computing* ***42****, 394-406*.

[2] Bhadra, N. and Kilgore, K.L. (2005) High-frequency Electrical Conduction Block of Mammalian Peripheral Motor Nerve. *Muscle & Nerve* ***32****: 782-790*.

1.4.2. 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. Refer to Appendix I: Electromagnetic interference for further information.

1.4.3. Electromagnetic Interference (EMI)

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 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 have fallen down and been injured.

This note applies to the Programmer Wand of the Altius System:

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Refer to

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Table **1**: Potential effects of EMI from equipment or procedures and Appendix I: Electromagnetic interference for information on sources of EMI, the effect of EMI on the patient and the neurostimulation system, and instructions on how to reduce the risk from EMI.

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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	
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

1.4.4. Case Damage

If the IPG case is ruptured or pierced due to outside forces, severe burns could result from exposure to the battery chemicals.

1.4.5. Packaging, Sterilization and Single Use

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

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

1.4.6. Effects on other implanted devices

Altius interaction with implanted cardiac devices - When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, anesthesiologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery.

The electrical pulses from the Altius System may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device. To minimize or prevent the cardiac device from sensing the Altius System output:

- Implant the devices on opposite sides of the body
- Consider using bipolar sensing on the cardiac device
- Careful programming and review of each system's performance is necessary to ensure safe cardiac system operation with effective neurostimulation therapy.
- See also "Programmer interaction with other active implanted devices."
- Programmer interaction with other active implanted devices - When a patient has an Altius and another active implanted device (eg, pacemaker, defibrillator, neurostimulator), the radio-frequency (RF) signal used to program these devices may reset or reprogram the other device.

To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital, and after each programming session of either device (or as soon as possible after these times).

Also, inform patients to contact their physician immediately if they experience symptoms that could be related to either device, or to the medical condition treated by either device.

Patient control devices may affect other implanted devices - Patients should not place a patient control device (eg, controller, charger) over another active implanted medical device (eg, pacemaker, defibrillator, another neurostimulator). The patient control device could unintentionally change the operation of the other device.

1.4.7. Use in pediatric patients

Safety and Effectiveness of Altius System for pediatric use have not been established.

1.4.8. Use in pregnant patients

Safety and Effectiveness of Altius System for pregnant patient use has not been established.

1.4.9. Use in diabetic patients

Surgical complications and adverse events may be more frequent and severe in diabetic patients - The following additional considerations should be made for diabetic patients including:

- A preoperative risk assessment should be performed for patients with diabetes who are at high risk for ischemic heart disease, those with autonomic neuropathy or renal failure, and patients with a Hemoglobin A1C (HbA1c) ≥ 8% (64 mmol/mol).
- Monitor the patient's blood glucose levels in the perioperative period and instruct the patient to continue to monitor levels as they may fluctuate as a response to surgery or to complications. Implanting physicians and/or anesthesiologists should consult practice guidelines for the intraoperative management of diabetic patients during surgery.
- Closely monitor patient for signs of infection or delayed wound healing, as the severity of these complications may be greater in diabetic patients.

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1.5. Magnetic resonance imaging (MRI) Safety Information

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

1.6. Precautions

1.6.1. Physician training

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

Prescribing physicians. Prescribing physicians should be experienced in the diagnosis and treatment of chronic post-amputation pain and should review prescriber information for Altius.

1.6.2. Storage and Operating Environments

The Altius IPG and the Cuff Electrode(s) are permanent implants, they are intended to be able to be used in the home and hospital and general environment while implanted in the patient. The Patient Controller and the Battery Charger are intended to be used in the home or general environment, while the programmer system, including the Programmer Wand is intended for use in the professional healthcare environment such as a hospital, clinic, or doctor's office.

Store the Altius IPG between -30° C and 60° C (-22° F and 140° F), and store the Cuff Electrode between -29° C and 60° C (-20° F and 140° F). Components of the Altius System should always be kept in temperature-regulated areas within the acceptable temperature range. The Altius IPG damage can occur at temperatures outside of this range. The IPG is designed to function between 17° C and 40° C (62.6° F and 104° F).

The Altius Battery Charger and Patient Controller is intended to be stored and transported between -25^{0}C and 70^{0}C (-13° F and 158° F).

The operational temperature range for use of the Battery Charger and Patient Controller is between 5^{0}C and 40^{0}C (41° F and 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 Altius Programmer Wand is designed to function normally after it has been exposed (While packaged for transport) to the following environmental extremes of -30° C and 60°

C (-22° F and 140° F), relative humidity between 20% and 75%; and atmospheric pressure between 500 hPa and 1060 hPa.

Recommended conditions for normal use of the Programmer wand is 10° C and 40° C (50° F and 104° F), relative humidity between 20% and 75%; and atmospheric pressure between 700 hPa and 1060 hPa.

The Altius PAPC is designed to function normally after it has been exposed (While packaged for transport) to the following environmental extremes of -20° C and 60° C (-4° F and 140° F), relative humidity between 20% and 75%; and atmospheric pressure between 500 hPa and 1060 hPa

Recommended conditions for normal use of the PAPC is 5° C and 35° C (41° F and 95° F), relative humidity between 20% and 75%; and atmospheric pressure between 700 hPa and 1060 hPa.

1.6.3. Component Handling

All system components and accessories should be handled with care. External devices should not be dropped, submerged in water, or operated in the rain. Avoid all sources of water that can come into contact with the external devices. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can cause permanent damage.

1.6.4. Patient Detoxification

Before conducting lidocaine injection screening, patients should be detoxified from narcotics. If patients are not detoxified, screening may not be properly assessed.

1.6.5. Effect on electrocardiograms (ECGs)

Ensure the IPG is not delivering therapy prior to initiating an ECG. If the IPG is delivering therapy during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Refer to "Appendix I: Electromagnetic interference" on page 16 for information about other medical procedures that may interact with the Altius System.

1.6.6. Charging system

Wound contact. DO NOT use the recharger on an unhealed wound. The charging system is not sterile and contact with the wound may cause an infection. Patients should have gauze and/or clothing between the charger to avoid direct contact with the wound or skin.

Recharger use. Check for skin irritation or redness near the Altius IPG during charging. Do not lie on the IPG or apply excessive pressure to the IPG during charging. Take periodic breaks during prolonged charging.

1.6.7. Information for the patient

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.

Component manipulation by patient. 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.

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 Altius treatment while walking or standing with prosthesis. Any sudden response to treatment may interfere or impair ability to stand or walk.

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.

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.

1.7. Component disposal

When explanting Altius System components (e.g., replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted component with completed Return Authorization documents to Neuros Medical for analysis and disposal.
- To allow for component analysis, do not autoclave the component or expose the component to ultrasonic cleaners.
- Dispose of any components not returned to Neuros Medical according to local environmental regulations;

Precautions:

- Follow appropriate biohazard controls for all explanted components or components coming into contact with bodily fluids. Only return such components to Neuros Medical in the appropriate packaging supplied by Neuros.
- Do not incinerate or cremate the Altius IPG because it may explode if subjected to these temperatures.

1.8. Patient selection

Best results of Altius System therapy are achieved when the patient is fully informed about the therapy risks and benefits, surgical procedure, follow-up requirements, and self-care responsibilities.

Maximum benefits from the Altius System require long-term postsurgical management.

The Altius System is not suitable for every patient with chronic intractable post-amputation pain. Suitable candidates for Altius have:

- Unilateral lower limb amputation.
- Moderate to severe chronic post-amputation pain, including residual limb and/or phantom limb pain.
- Adequate response to anesthetic injection for regional nerve block.
- Ability to operate the system.

The safety and effectiveness of the Altius System has not been established for:

- Pregnant women (including effects on a fetus, or during childbirth)
- Pediatric use (patients under the age of 22)

1.9. Long term effectiveness of Altius System

Long-term clinical data regarding the effectiveness of the Altius System is not yet available.

2. Adverse events summary

The implantation of the Altius System involves risks that are similar to other surgical implant procedures. In addition to those risks associated with surgery, the following adverse events may occur with implantation or use of the Altius System. Certain adverse events may necessitate surgical intervention.

- Undesirable response to electrical treatment, for example: pain, discomfort, undesirable sensation (incl. numbness, and tingling), and stimulation of surrounding tissue (incl. nerves and muscle)
- Heating pain or tissue injury during battery charging
- Falling or other unintentional response due to sudden change in treatment
- Infection, cellulitis, abscess, fever, and sepsis

- Immune or inflammatory response to any of the implanted materials or components, for example: rejection, skin irritation, rash or redness, allergic reaction, dermatitis, inflammation, granuloma, and itching
- Skin breakdown, for example: poor healing, wound reopening, pressure sores, and erosion at location of implanted components (IPG, Leads)
- Stiffness and decreased range of motion
- Pain, for example: pain near implanted components, phantom sensation or pain, and neuroma pain
- Malfunction of device which may result in loss of treatment, for example: dislodgement, breakage (incl. fragments), loose connections, electrical shunt, short or open circuits
- Early life failure of the IPG battery, necessitating removal or replacement.
- Nerve injury and neuropathy (numbness, pain and tingling) including compression injury
- Interference with prosthesis
- Radiation exposure if diagnostic x-rays are needed
- Adverse effects as a result of MRI or diathermy.
- Changes in blood glucose levels in response to any adverse effect.

NOTE: Patients with diabetes may have increased risks of infection, problems healing around the surgical site, and complications common to any surgical procedure. The severity of any surgical complication may be greater in patients with diabetes, particularly those with inadequate pre-operative glycemic control.

For adverse events observed in Altius clinical studies, refer to the Clinical Summary.

If a serious incident related to a patient's therapy occurs, immediately report the incident to Neuros Medical and the applicable competent authority.

3. Patient counseling information

Physicians should provide patients and caregivers with information about:

- The components of the Altius System: cuff, extension, and IPG.
- Instructions for using the Altius System, including use of the patient controller to initiate a 30-minute therapy session as needed to control pain, and use of the battery charger to recharge the IPG.
- The indications, contraindications, warnings, precautions, and adverse events for the Altius System.
- Physicians should also instruct patients to:
- Always inform any health care personnel that they have an implanted Altius System before any procedure is begun.
- Contact their physician if they notice any unusual symptoms or signs.

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Appendix I: Electromagnetic Interference for Information on Sources of EMI

Please review Electromagnetic interference (EMI) under "Warnings" in section 1.4 and Table 1: Potential effects of EMI from equipment or procedures on page 7.

Before any medical procedure is begun, patients should always inform any health care personnel that they have an implanted Altius System. The potential for the following effects results from an interaction of the Altius System and equipment —even when both are working properly.

Warnings

EMI from the following medical procedures or equipment may damage the device, interfere with device operation, or cause harm to the patient. If these procedures are required, follow the guidelines below:

Diathermy. Do not use short-wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy on patients implanted with the Altius System. Medical diathermy is generally contraindicated in patients with implanted devices. The effects of such intense energies on the Altius IPG cannot be predicted.

The energy generated by diathermy can be transferred through the Altius System, possibly causing tissue injury, severe injury, or death. The Altius IPG, whether on or off, may be damaged.

Although damage to the circuitry of the IPG appears unlikely, it nevertheless could occur. If diathermy is to be used notwithstanding the risk, it may not be applied in proximity of the Altius IPG and its leads, (i.e. as far away as possible is recommended). The risk of adverse effects can be decreased by ensuring that no therapy treatment session is in progress. The Altius IPG may revert into “Down” Mode, and it will have to be reset.

All patients should be advised to inform their healthcare professionals that they should not be exposed to diathermy treatment.

Electrocautery. High-voltage, high-frequency current used to stop bleeding during surgery or as a result of trauma. If necessary, bipolar electrocautery is recommended and to ensure no therapy treatment session is in progress.

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

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

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

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RF nerve lesioning. Radio frequency (RF) electromagnetic energy to interrupt nerve conduction as a treatment for chronic neck and spine pain.

If the procedure is required, it should be done as far from the Altius IPG as possible, and to ensure no therapy treatment session is in progress.

Use of RF Nerve lesioning may damage or cause unpredictable operation of the IPG. If the Altius IPG reverts to its "Down" mode, it will have to be reset.

Defibrillation Cardioversion. Defibrillation Cardioversion is where high voltage paddles to stabilize the heart rhythm during life threatening ventricular fibrillation or pulseless ventricular tachycardia in an emergency. Any implanted device can be damaged by external cardioversion or defibrillation. The defibrillation current can make the Altius IPG revert to its "DOWN" mode. The system can be damaged by exposure of high energies. No particular paddle placement can avoid such damage. To decrease the risk, it is recommended to position the paddles as far away from the Altius IPG as possible. In addition, paddle positions that would bring the Altius IPG into the direct path of the defibrillation current should be avoided. In the unlikely event of abnormal function, reprogramming of the IPG may be required. If the device is found to have reverted to its "DOWN" mode, it needs to be reset.

Radiation therapy. Can lead to a wide spectrum of effects, reaching from transient interference to permanent damage. It is therefore advisable to locally shield the Altius IPG against radiation if radiation therapy is to be used. If tissue in the vicinity of the implant has to be irradiated, it may be advisable to relocate the IPG.

WARNING: Therapeutic equipment generating ionizing radiation, such as linear accelerators and cobalt machines employed for treating malignant diseases, can damage the circuits used in most active implantable devices. Because the effect is cumulative, both dose rate and total dose determine if damage will occur and its possible extent. Please be aware of the fact that certain types of damage may not be immediately obvious. In addition, the electromagnetic fields generated by some types of radiation equipment for beam "steering" purposes can affect the function of the Altius IPG.

Lithotripsy. Lithotripsy is a therapy where high energy shock waves are used to treat stones in the kidney, bladder, ureter or gall bladder ultrasonic scanning. These very high frequency sound waves used to produce images of internal organs or tissue for diagnostic purposes.

WARNING: Direct exposure of the Altius System IPG to shock waves can damage the device. A device implanted outside the shock wave path presents no clearcut contraindication to lithotripsy. Before a lithotripsy is used, the patient should ensure that no therapy treatment session is in progress. If the device is found to have reverted to its "DOWN" mode, it will need to be reset.

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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. If therapeutic Ultrasound is to be used, it should not be applied in the region of the Altius IPG. If the patient cannot use therapy, then the IPG should be checked, as it may need to be reset.

WARNING: Direct exposure of the Altius System IPG to therapeutic ultrasound can damage the device. In addition, unexpected focusing of the ultrasound beam may harm the patient.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS is generally contraindicated in patients with implanted electrical devices. The high-voltage impulse delivered into the body by the TENS unit can impair the operation of the Altius System IPG. If a TENS unit is used nonetheless, the TENS electrodes have to be attached as far as possible from the Altius System IPG and the Cuff Electrodes. In addition, aiming for a limited current path, the TENS electrodes should be placed as close to each other as possible. Ensuring that a therapy treatment session is not in progress reduces the risk of adverse effects.

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.

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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 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 to 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.

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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.

ALTIUS SYSTEM PRESCRIBER INSTRUCTIONS FOR USE

The Altius Battery Charger:

This Device Complies with Part 18 of the FCC rules.

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

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

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

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

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