



Altius® Direct Electrical Nerve Stimulation System Implantable Pulse Generator Programmer Manual

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician
LB-0197 Rev B

VERIFY THE DOCUMENT PRINTED IS THE MOST CURRENT REVISION
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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"

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

For an up-to date list of relevant patents and patent applications, visit our patents page:
<http://www.neurosmmedical.com/patents>

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

This product manual covers programming instructions for Altius System, including information on the Clinician Programmer and Altius Programming Software. Refer to the Implant manual and Patient User manual for additional instructions for use, including device descriptions, package contents, device specifications, product-specific warnings and precautions, information on using the Patient Controller, and Battery Charger.

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



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1. Explanation of Symbols

REF	Model Number
SN	Serial Number
QTY	Quantity
UDI	Universal Device Identifier
	Consult Instructions for Use
	Refer to Instructions for Use
	Caution
	Do Not Use if Package is Damaged
	Temperature Limitations for Transport & Storage
	Humidity
	Atmospheric Pressure
	Prescription only
	Medical Device
	Type BF Applied Part
	Non- Ionizing Electromagnetic Radiation
	Keep Dry
	Keep Out of Sun
	Manufacturing Date
	Manufacturer

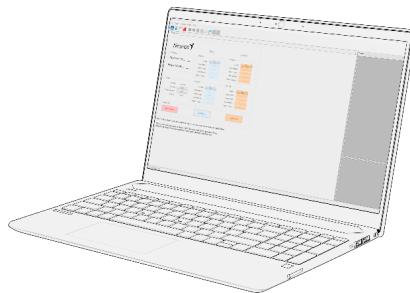
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2. Altius Programmer System Overview

2.1. Description of Altius Programmer System

The Altius Programmer System allows the physician or clinical user to interrogate and program the Altius IPG. The Altius programmer software runs on a laptop PC connected to the programming wand. Communication between the Programmer system and the Altius IPG is accomplished with the programmer wand placed directly over the implant site. The Programmer Wand communicates via magnetic induction telemetry with the Altius IPG implanted in the patient.

Understanding the instructions contained in this manual on how to operate the Altius Programmer System is essential to proper programming and operation of the Altius IPG. (Refer to the Altius Prescriber IFU for more information)



Warning: The Altius Programmer may be subject to interference from other electrical devices operated in the vicinity. Portable and mobile RF equipment is especially likely to impair the normal function of the programmer. If the Altius Programmer is not operating as expected, consider whether such interference is the cause. Other Equipment, even if performing per the specifications and within emission limits, may interfere with the Altius Programmer.



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2.2. Programmer Functions

The programmer can perform the following functions:

- Read (Interrogate) Altius IPG parameters as currently programmed
- Modify Altius IPG parameters
- Retrieve the on-board log file from the Altius IPG
- Record the list of commands that are sent to the Altius IPG from the programmer
- Order the IPG to measure the Impedance of the Cuff Electrode(s) and the nerve cuff interface
- Set the onboard clock of the Altius IPG
- Single pulse - For use in determining sensory threshold for a patient
- Start and stop therapy

2.3. Programmer Components

The Altius Programmer System consists of:

- Altius Programmer Wand
- Altius Programmer Application PC
 - Altius Programmer Application installed on a Laptop PC (PAPC)
 - Laptop PC power supply

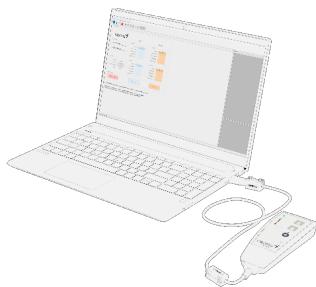
Note: The manual for the laptop PC is also provided

Warning: Use of items other than those identified above or in a manner not in accordance with these instructions may cause damage to the Altius Programmer.

2.4. Interconnecting the Programmer components for Operation

- Unplug the Programmer Application PC (PAPC) from its power supply
- Plug the USB connector of the Programmer Wand into a USB port on the PAPC

Warning: Do not attempt to connect any line-powered device (such as a cable-connected printer) to the Altius Programmer. This may create an electrical safety hazard for the patient.



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2.5. Programmer Wand

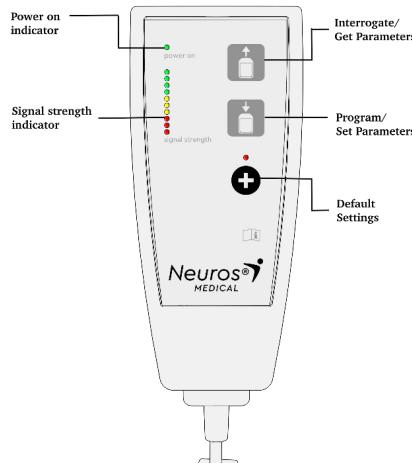
The programmer wand has three buttons:

- Interrogate
- Program
- Default Settings – Set the parameters to default off settings

The programmer wand also has three different sets of indicator lights:

- The power indicator light, located above the text “power on”, is illuminated when the programmer wand is powered.
- The bar graph indicator lights display the strength of the telemetry signal between the Programmer Wand and the Altius IPG

The Default Settings indicator light, located above the Default Settings program button, flashes a few times after the Reset programming has been successfully completed.



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2.6. Charging the Battery of the Altius PAPC

Warning: Only charge the Altius PAPC with the supplied power supply. Do not attempt to recharge the PAPC's battery with any other power supply.

To charge the battery of the Altius PAPC:

Note: The Power Supply main come in two separate sections 1) AC power cord and 2) AC/DC power supply and DC output connector. If this is the case, plug the two in together before starting

- Plug the DC output connector of the supplied power supply into the input power connector of the PAPC.
- Plug the other end of the power supply into AC mains wall receptacle. Be sure that the mains voltage is in the range of 100-240VAC, 50/60Hz and that the receptacle is properly grounded.

Warning: Do not plug the Power Supply into an extension cord or other such device, only plug the power supply into a wall receptacle. Doing so may result in an electrical hazard to the device or the user.

- When charging the battery of the Altius PAPC, allow the internal battery a minimum of a 4 hour charging session before attempting to use the Altius PAPC at implant. It is recommended that the Altius PAPC battery of the Programmer System be routinely charged between uses.

2.7. Operating the Altius Programmer System

Warning: The Altius Programmer shall not be used on board aircraft without prior consent from the aircraft's crew.

Note: Consult local regulations if using the Altius Programmer outside of the country where it was obtained.

Caution: The Altius Programmer must be operated as a battery-powered device, as there may be a risk of electrical shock to the patient from the AC mains.

Note: Connect it to the AC mains only when charging of the PAPC is required. The Altius PAPC should be positioned such that disconnecting it from the power supply is not impeded.

Note: It is recommended that you have an Altius Patient Controller on hand during programming sessions as a back-up to terminating therapy.

2.8. Using the Altius PAPC Touch Screen (If Available)

Some base laptop PC models used for the Altius PAPC may be equipped with a touchscreen. Selections on the screen may be made by touching the screen with one's finger or a stylus (may be supplied with the Altius PAPC).

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Caution: Using sharp items or regular writing equipment (pen or pencil) may damage the touch screen.

2.9. Buttons and Symbols on the Altius PAPC

The base laptop PCs which are used for the Altius PAPC come with a Windows QWERTY keyboard layout.

There will also be a separate power button.

2.10. Altius PAPC Battery Replacement

The Altius PAPC is powered by a battery that may need to be replaced if it fails to properly recharge. Contact your local Neuros Medical representative if a replacement battery is needed.

Warning: Proper disposal of the used battery is essential. Dispose of the used battery in accordance with local environmental laws and regulations.

Warning: Never puncture or incinerate a used battery.

2.11. Routine Cleaning

Warning: DO NOT attempt to sterilize an Altius Programmer Wand or Altius PAPC because any sterilization method could severely damage the equipment.

Warning: DO NOT submerge any part of the Altius Programmer Wand or Altius PAPC in water. Damage to the unit may result. The Altius Programmer System is not protected against ingress of water, and may have limited humidity ingress protection (IPX0).

Warning: Always turn off and unplug the Altius PAPC and Altius Programmer Wand prior to cleaning.

Following each use, it is recommended that a soft cloth dampened with a germicidal cleaning solution be used to wipe the exterior of the Programmer Wand, and the Altius PAPC. Do not use solvents or cleaning cloths impregnated with chemical cleaning agents.

2.12. Storage, Handling and Usage

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 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.

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 15% and 90%; and atmospheric pressure between 500 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),



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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.

Warning: When using the Programming Wand in an environment that is 40°C (104°F), the Programming Wand may warm up to 43.3°C (110°F). Ensure to inform the patient of this. If you or the patient feel any part of the system getting to hot, stop using the Programming Wand and wait for it to cool down.

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.

Warning: The Altius Battery Charger and Patient Controller shall not be used on an Aircraft without consent from the crew

2.13. Additional Notes

In general, contact between the patient's skin and the Altius Programmer wand should be avoided due to risk of cross-contamination. Programmer wand should always be separated from the patient's skin with their clothing, or sheet or drape.

Warning: 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. When not using or charging the Programmer System, ensure that all cables are wound and stored securely.

Note: The Altius Programmer System does not contain any user serviceable parts.

Warning: DO NOT discard the Altius Programmer wand in the trash. The Altius programmer contains electrical non-RoHS components. If disposal is necessary properly consult local environmental laws and regulations governing the disposal of such material.

Caution: At this time the Altius PAPC is not intended to be connected to a network, either an internal hospital network or a public network. Doing so is a cybersecurity risk and not recommended.

The Altius PAPC is classified as Class II equipment when connected to the supply mains, Internally Powered ME equipment when the laptop power supply is not connected to mains.

The PAPC is powered by an AC/DC power supply rated at 100-240VAC, 50/60Hz with a maximum output of 65W. The PAPC may have several different power connectors depending on the model. The PAPC's are all rated for power input of 20VDC and 3.25A, for a maximum power of 65W.

The Programmer Wand is classified as a Type BF applied part. The Programmer Wand is a USB powered device with a rating of 5VDC, and 0.5A.

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2.14. Cautions and Warnings

The following discussion on potential hazards from the environment focuses on maintaining the utmost patient safety. Although the Altius System IPG was designed to provide the highest possible protection against such hazards, complete immunity against these risks cannot be guaranteed.

For further information check the Prescriber Manual (LB-0195)

2.14.1. Implanted components and MRI scans

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

2.14.2. Electromagnetic Interference

The Altius IPG, and Accessories can be affected by interference from magnetic, electrical, and electromagnetic signals, provided these are sufficiently strong. Most interference will lead to inhibition of communication with the IPG by the patient controller, the Battery Charger or the Programmer System. In rare cases, an interfering signal could trigger inappropriate therapy signal delivery. In addition, interfering signals exceeding a certain threshold may couple enough energy into the IPG to damage the IPG circuits and/or the abdominal tissue and/or in the vicinity of the Cuff Electrode. In other rare cases during a programming visit, incorrect parameter values may be programmed to the IPG from the programmer system.

The patient manual (LB-0196) also covers these factors, and these risks should be disclosed in the discussion with the patient. The susceptibility of a particular device is dependent on the location of the IPG pocket, the type of interfering signal, and on the programmed therapy parameters. Because of the diversity of the potential causes of electromagnetic interference, Neuros Medical cannot characterize and describe all sources of interference and their effects in this manual.

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.

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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.

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.

2.14.3. Surgical Cautions and Warnings

For a list of surgical cautions and warnings, see Prescriber Manual (LB-0195), and Implant Manual (LB-0198).

3. Altius Programmer Software Overview

Note: please contact Neuros Medical with any questions, concerns, or issues at 1-833-240-4462.

The Altius Programmer Software contains the commands that are used to read and modify the parameters that control the settings of the Altius IPG.

3.1. Altius Programmer Start-up

After having followed the steps to setup the hardware of the Programmer system in section 2.4 Interconnecting the Programmer components, follow these steps to start the software:

1. Turn on the Altius PAPC
2. Login to Altius user with the appropriate credentials.
3. Start the Altius Programmer Application by doubling clicking on the Altius icon on the desktop.

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Once the Altius Programmer Application has started you will see this screen:

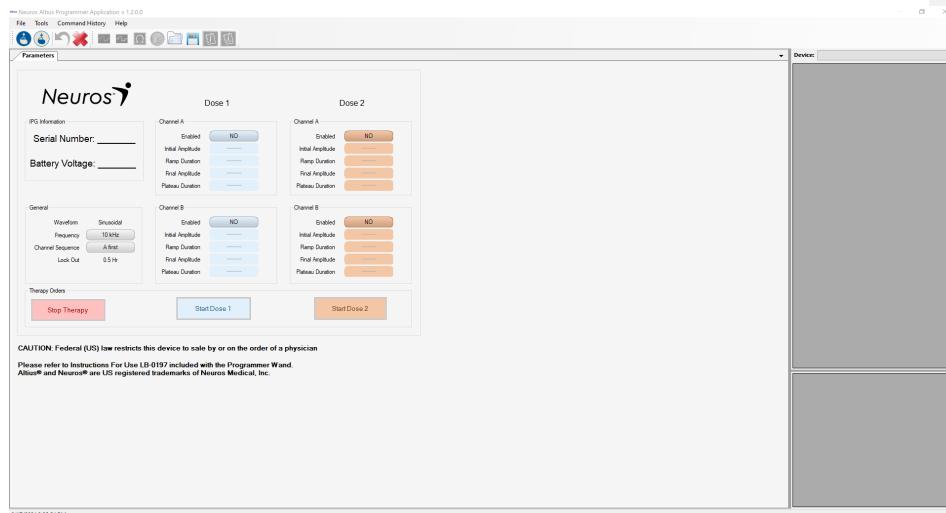


Figure: Altius Programmer on initial Start

Note: The toolbar is grayed out except for the **Interrogate** and **Cancel** commands for now.

Note: If the Altius Programmer Wand is not connected to the PAPC prior to starting the Altius Programmer software, an error message will display.



3.2. Basic Operation of the Altius Programmer Application

Once the Altius Programmer Application has been started, this offers various commands for communicating, interrogating, and programming the Altius IPG.

3.2.1. Communicating with the Altius IPG

The Clinical user can obtain data from the Altius IPG by means of the Programmer wand, which must be placed over the patient's implant site.



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Caution: The Programmer wand should be thoroughly cleaned between uses and draped, when necessary to prevent patient skin irritation or contamination.

3.2.2. Interrogation and Programming

The Altius IPG has a set of parameters that control the therapy doses available to the patient. These values are referred to as the *device (therapy/dose) values (parameters)*.

The Altius Programmer Software can read the device values by means of the **Interrogate (Get Parameters)** command. This must be the first action carried out by the physician/clinical user in order to access the data from Altius PG. If the interrogation process is successful, the device values are loaded and displayed on the screen of the Altius Programmer. The values displayed on the screen may be referred to as the parameter values.

The clinical user can review and modify the parameter values using the Altius Programmer. The modified parameter values can then be transmitted to the Altius IPG by means of the **Set Parameters (Program)** command.

Note: The modified Parameter values displayed on the programmer screen are NOT set on the IPG until the **Set Parameters** command is sent.

The **Undo (Set Previous Parameters)** command may be used to revert the device values to those previously programmed.

The **Default Settings** command programs the Altius IPG with standard safe parameter values (All Channels Disabled). The **Default Settings** command may be initiated by clicking the **Default Settings** in the Tools drop down menu, or pressing the **Default Settings** button on the Altius Programming Wand.

Useful parameter combinations can be stored as **basic** files (may also be referred to as "user presets"). The file extension for these are ".mip". After the creation of a particular basic file, the basic file can be loaded for patients who may use similar set of programmed values.

The **Save** and **Load** commands of the Altius Programmer software read and write data to and from the basic (.mip) files. As such the Altius Programmer software can also be used as an editor of the basic files (See Section 16).

3.2.3. Monitoring Tools

The Altius Programmer system can be used to review the commands sent to the Altius IPG during programming and review the Altius IPG log file.

- The Altius Programmer software keeps a log (Command History) of all the interactions with the Altius IPG.
- The Altius IPG keeps a log (record) of all the events and conditions that have occurred. These records can be downloaded from the Altius IPG to the Altius Programmer system.



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- The Altius Programmer software can be used to measure the impedance of the cuff electrode(s) (see Section 6).

3.2.4. Closing the Altius Programmer Application

To exit the Altius Programmer Application use of these two ways:

1. Clicking the "X" in the top right corner of the Altius Programmer software screen.
2. Go to the Menu bar, selecting File, in the drop-down menu click exit.

4. Altius Programmer Software Description

The Altius Programmer Software once started and has successfully interrogated the Altius IPG will show the toolbar no longer grayed out, and will show the current parameter values of the Altius IPG.

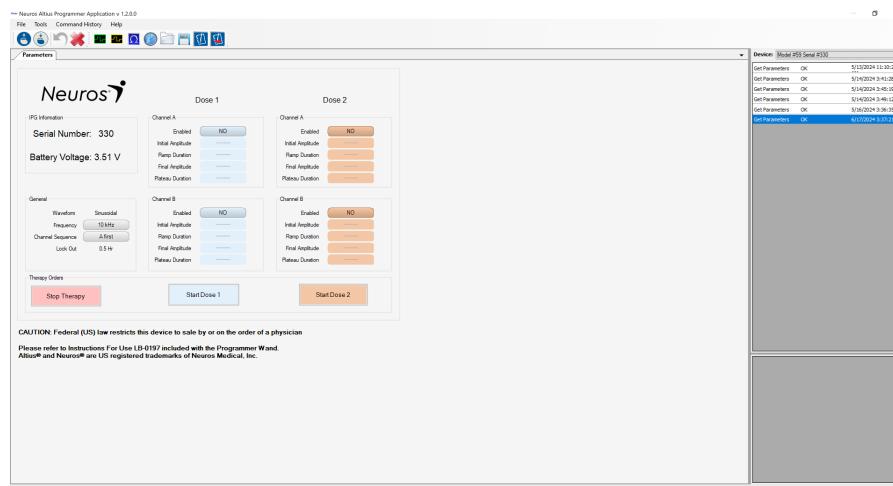


Figure: Altius Programmer Software after interrogating an Altius IPG

4.1. Menu Bar

The Altius Menu Bar has four (4) menus with drop down options File, Tools, Command History, and Help.

These next few sections may not describe what each function does, and is only intended to show where the various functions are.

Figure: Altius Programmer Software Menu Bar

Altius Neuros Altius Programmer Application v 1.2.0.0

File Tools Command History Help

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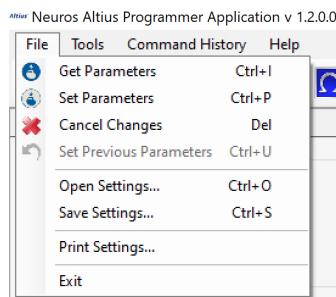
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4.1.1. File Menu

The File Menu dropdown allows the user to execute the following functions:

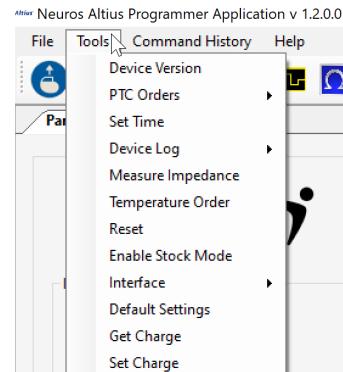
- **Get Parameters**
- **Set Parameters**
- **Cancel Changes**
- **Set Previous Parameters**
- **Open (Load) Settings – Base Files**
- **Save Settings – Base Files**
- **Print Settings**
- **Exit**



4.1.2. Tools Menu

The tools menu contains the following set of Commands:

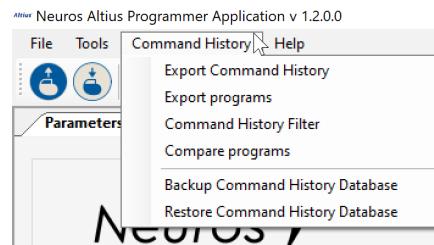
- **Device Version** command
- PTC Orders – Contains the button commands on the Altius Patient Controller
- **Set Time** command
- Device Log – Contains the **Read Device Log** and **Clear Device log** commands
- **Measure Impedance** command
- **Temperature Order** command
- **Reset** command
- **Enable Stock Mode** command
- Interface – Shows the Interface Version information
- **Default Settings** command
- **Get Charge** command
- **Set Charge** command



4.1.3. Command History Menu

The Command History menu contains the following set of commands:

- **Export Command History**
- **Export programs**
- **Command History Filter**
- **Compare Programs**
- **Backup Command History Database**
- **Restore Command History Database**



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4.1.4. Help Menu

The Help Menu contains the **About** command. **About** will display the Altius Programmer Software files and their version information.



4.2. Toolbar

The Toolbar of the Altius Programmer contains some of the most common commands used in the Altius Programmer.



The List of Symbols and commands from left to right are:

- Get Parameters (Interrogate)
- Set Parameters
- Set Previous Parameters
- Cancel Changes
- Single Pulse Dose 1
- Single Pulse Dose 2
- Measure Impedance
- Set Time
- Load Settings
- Save Settings
- Read Device Log
- Export Command History

4.3. Parameters tab

The parameters tab of the Altius Programmer Software shows the device settings, Serial number of the Altius IPG, and the Battery voltage of the Altius IPG. This tab also has the following command buttons at the bottom of the screen: Stop Therapy, Start Dose 1, Start Dose 2.

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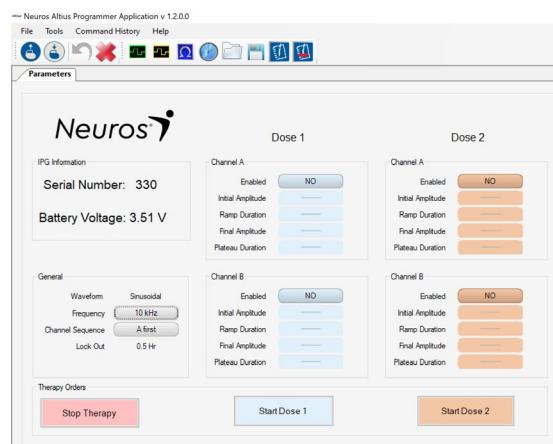


Figure: Default Parameters in the Altius Programmer Parameters Tab

4.4. Altius Parameter Settings

The Altius IPG can be programmed by the Altius Programmer Application with the following set of values for clinical use:

Altius IPG Parameter Ranges		
General Parameters	Specifications	Increment
Waveform	Sinusoidal	-
Frequency (High)	5khz, 10khz	-
Channel Sequence	A First, B First	-
Lockout	0.5hr	-
Dose/Channel Parameters	Specifications	Increment
Enabled	Yes/No	-
Initial Amplitude	0-8Vp	0.1Vp
Ramp Duration	0**.5, 10, 15 min	-
Final Amplitude	0**-16Vp	0.1Vp
Plateau Duration*	10, 15, 20, 25, 30 min	-

Table: Altius IPG Clinical Parameters

*Plateau Duration is automatically calculated based on the Ramp duration selected, If Channel A and B are enabled/disabled, and channel sequence

**Some default values must be changed before attempting to Set Paramaters

At the Patient's initial activation and programming visit, to find the patient's response to Direct Electrical Nerve Stimulation their parameter settings will be determined using a 15-minute Ramp Duration which will involve the voltage will start at 0Vp and over the 15 minutes be

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increased to 15Vp. Using the patient's responses the parameters will then be set to achieve a sensation that is strong, but tolerable transient sensation for the patient.

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

4.5. Altius IPG Parameter Tab Information

The Altius IPG Serial Number displayed in the Parameters tab is a unique number to the specific device.

Battery Voltage displayed in the Parameters tab shows the current voltage of the Altius IPG. This voltage can be used to infer how well charged the implanted device is. If the Altius IPG is below 3.3 volts, it will have to be charged prior to interrogating and programming. A full charge is at approximately 4.10 volts. For more information on the IPG battery and charging see the Altius Clinician Guide (LB-0195)

5. Interrogation

5.1. Communicating with the implanted Altius IPG

After having followed the steps in section 3.1, place the Altius Programming Wand over the implant site, at a distance of no more than 3.5cm (1.4 in) from the Implanted Altius IPG. A blinking green or yellow light on the signal strength indicator indicates that the IPG is within communications range of the Programmer Wand. A blinking red light indicates that the distance is too great, or it is not properly aligned and communications may be difficult, but not impossible. No light at all means that the Programmer Wand and Altius IPG are out of communication range or that the battery of the Altius IPG is discharged below the minimum charge for communication, and thus incapable of communicating with the Programmer Wand.

5.2. Interrogating the Altius IPG

To read the parameters of the Altius IPG:

1. Ensure that the Programming Wand is placed over the implant site and there is a green or yellow blinking light.
2. Interrogate the Altius IPG using one of the three options:
 - a. Select **Interrogate (Get Parameters)** button on the toolbar
 - b. Select File then Select **Interrogate (Get Parameters)** button on the toolbar
 - c. Press the Keyboard shortcut <Ctrl+I>
 - d. Press the **Interrogate (Get Parameters)** button on the Programming Wand

If the Interrogation is successful, the Altius Programmer Application will display the message "Get Parameters OK" in the Command History

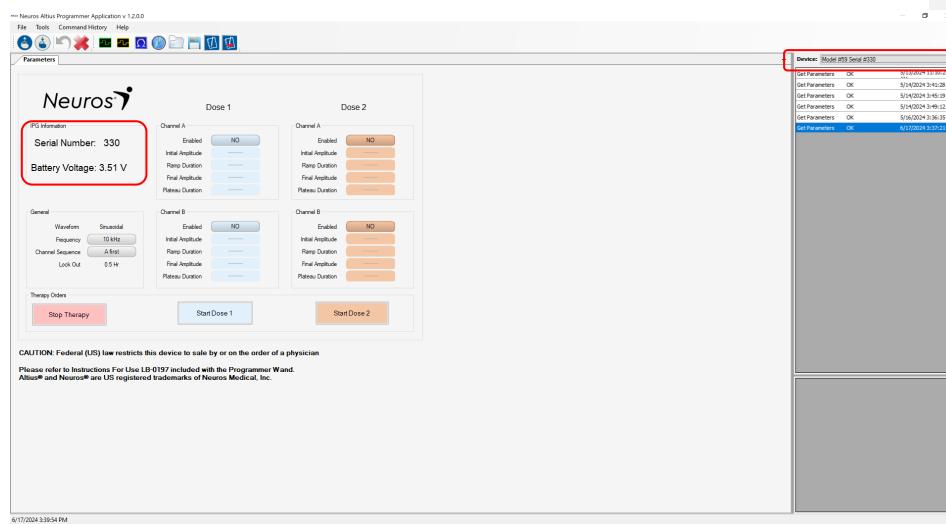
The IPG Model, Serial Number, Battery Voltage, and Therapy parameters will appear on screen. Also, any previous Command History will be displayed on the right side of the screen.

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However, if the Programmer Wand is not well positioned or is moved out of position the **Get Parameters** may fail and the Programmer Application will display the “Get Parameters error” in the Command History and a pop-up window may show:



If this error occurs, close the error window, and ensure that the Programmer wand is in the correct position and attempt **Get Parameters** again following the steps above.

6. Measuring Cuff Electrode Impedance

The impedance of the Cuff Electrode(s) is used as an integrity check. The Impedance check is essential to ensure the device is both connected and working properly. If the impedance measurement results in unusual readings it could indicate an issue with the device continuity.

The Impedance for a Cuff Electrode will have a natural variability based on each patient and size of Cuff Electrode used.

The Altius Programmer Application will display 4 distinct Impedance ranges:

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- $>180\ \Omega$
- $180\ \Omega - 3,000\ \Omega$
 - This is the only range where a number will be given.
 - The accuracy of this range is 10%.
- $>3,000\ \Omega$
 - Indicates a range $3,000 - 20,000\ \Omega$
- High Impedance
 - Indicates a range of $20,000\Omega$ or greater

The typical expected range is:

Nerve Diameter (mm)		≤ 5	6 - 8	$9 \leq$
Cuff Size		Small	Medium	Large
Impedance Ω	Good	500 - 1400	200 - 800	
	OK	180 - 2000	180 - 1200	
	Bad	< 180 or > 2000	< 180 or > 1200	

Note: If impedance measurements are outside of these ranges, check with the patient to determine if they are still feeling the therapy. If they are not feeling therapy, then something may be wrong and further troubleshooting may be required.

To Measure Impedance:

1. Place (or replace, if necessary) the Programmer Wand over the Altius IPG.
2. To get the Impedance:
 - a. Press the **Measure Impedance** button on the toolbar
 - b. Select Tools on the menu bar and then select **Measure Impedance**
3. View the Impedance values and compare to the Impedance Values above and determine if any additional action is required.



Figure: Impedance Measurement pop-up Window, Channel A only

4. Once done reviewing the measurement values, close the window.

Note: The Impedance Measurement Values are stored in the Command History

5. To repeat, follow steps 1-4.

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7. Single Pulse Testing

Single Pulse is used as another device integrity check. This test ensures that the Altius IPG and Cuff Electrode(s) are working properly, and that the patient can feel the pulse. If the Single pulse results in an unusual result it could indicate an issue with the device continuity. The single pulse used is a biphasic 100 μ s pulse width.

Single Pulse Dose 1 and **Single Pulse Dose 2** execute the Single Pulse based on the Final Amplitude Parameter for Channel A and/or Channel B.

Warning: The Single Pulse Dose 1 and Dose 2 commands will send a Single Pulse of energy to both Channel A and Channel B at the Final Amplitude voltage, if both are enabled. It is strongly recommended that when using Single Pulse, the test is only executed on one channel at a time.

The steps to execute the Single Pulse Dose 1 or Dose 2 are:

1. Ensure that the programming wand is in place.
2. Set the Dose and Channel Final Amplitude to the value to be tested.
3. Disable the Channel that the Single Pulse test is not being used for.
4. **Set Parameters** by one of the following methods:
 - a. Click the **Set Parameters** button on the toolbar
 - b. Go to File menu and select **Set Parameters**
 - c. Press the keyboard shortcut <Ctrl+P>
 - d. Press the **Set Parameters** button on the Programming Wand
5. Check that the Parameters were set in the Command History
6. Click the Single Pulse Dose button being tested.
7. To repeat this process, follow steps 1-6.

8. Setting the Clocks on the Altius IPG and Altius PAPC

The PAPC and the Altius IPG are not connected to any networks for cybersecurity reasons. The clocks on both devices will drift from the current time, as such they should be regularly reset. The PAPC clock should reset to the current time, or a standard time zone. The IPG can get its time from the PAPC, but a manual time may also be entered.

The time on the PAPC and the IPG are used to log the events as they occur on the Programmer Application in the Command History and on the Altius IPG in the Log File.

8.1. Setting the PAPC Clock

The PAPC runs Windows 10. To reset the clock, follow these steps:

1. Start the PAPC.
2. Login to the PAPC.
3. Right Click on the lower left of the screen where the time and date are.
4. Click on the Adjust Time/Date, this will open a settings window for Date & Time.

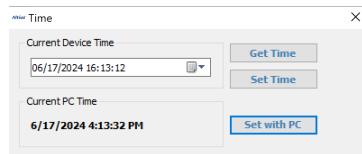
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5. Click on the Change button under the Set the Date and Time Manually.
6. Enter the current Date and Time.
7. Close the settings window.

8.2. Setting the Altius IPG Clock

To reset the clock on the Altius IPG follow these steps once the Programmer Application is running and **Get Parameters** has successfully retrieved the parameters from the IPG:

1. To start Select Time by:
 - a. Clicking the **Set Time** button on the toolbar
 - b. Going to Tools menu and clicking **Set Time**
2. A pop-up window will display the Current Device Time and the Current PC Time



3. Setting IPG Time
 - a. If the PAPC is has already been reset, Click the **Set with PC** button.
 - b. If setting the time manually, enter the desired current device time. The format followed is: MM/DD/YYYY HH:MM:SS, then click **Set Time**.

Note: MM is the two digit number for the Month, DD is the two digit day of the month, YYYY is the four digit year, HH is the hour expressed in 24 hours, MM is the two digit minute, SS is the two digit second.

4. Once the IPG time is set, click the **Get Time** button to get the latest Altius IPG time.
5. Compare this time to the current PAPC time displayed.

9. Modifying and Setting Parameter Values

Modifying and Setting Parameter Values should always be based on patient feedback.

To use the Programmer Application Software to Modify and set Parameter values follow the steps below, ensuring that the Programmer Application is running, and **Get Parameters** has successfully retrieved the parameters from the IPG:

Caution: Ensure that the parameters set, are appropriate to the patient prior to programming.

Note: All Parameter Values are modified by clicking the value to be modified, which will open the value window for the specific parameter. The Plateau Duration is set automatically.

Warning: Use of any non-clinical setting has not been tested or proven to work to reduce pain for the intended use with the patient population.



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1. Select the General Parameter Value to be modified:
 - a. Waveform
 - i. Waveform is the shape of the wave used for the therapy.
 - ii. Sinusoidal is the waveform that can be programmed
 - b. Frequency
 - i. Frequency is the setting which selects the electrical frequency used to deliver the therapy voltage.
 - ii. 5kHz and 10kHz (default) are the two frequencies available
 - c. Channel Sequence:
 - i. Channel Sequence is the sequence for which Channel goes first.
 - ii. A first is the default value, B first is also valid if determined by the clinician
 - d. Lockout
 - i. Lockout is the amount of the patient is unable to begin another therapy session
 - ii. 30 min is the only value that can be programmed
2. Modifying and Setting Dose 1 & Dose 2, Channel A & Channel B Parameter Values:
 - a. Enabled
 - i. Yes – The rest of the Parameters are available for programming
 - ii. No – The Parameter programming is disabled for the rest of the parameters.
 - b. Initial Amplitude
 - i. Initial Amplitude is the voltage that Dose 1 Channel A will start at.
 - ii. This value can be set from 0 to 8 Volts and an increment of 0.1 Volts.
 - iii. This value must be less than the Final Amplitude Voltage Parameter Value.
 - c. Ramp Duration
 - i. Ramp duration is the amount of time that the voltage will ramp up until it reaches the final amplitude voltage.
 - ii. This value can be set to 5, 10 or 15 min.
 - iii. 0 min is default value, that must be changed if programming that dose and channel
 - d. Final Amplitude
 - i. Final Amplitude is the voltage amplitude reached once the Ramp has completed.
 - ii. This value can be set from 0 to 16 volts, with increments of 0.1 volts.
 - iii. This value must be greater than the Initial Amplitude Parameter Value.
 - e. Plateau Duration
 - i. Plateau Duration is the amount of time that the Final Amplitude Voltage runs.
 - ii. Plateau Duration is automatically selected based on the ramp duration, channel sequence and if the other channel is enabled or disabled
 - iii. Plateau Duration is set automatically to 10, 15, 20 or 25 minutes
 - iv. 30min is a default value that will be changed automatically

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3. If any values appear in **Red** text this indicates that two parameter values conflict with each other, and that one of the values needs to be corrected.
 - a. In addition to appearing in red, the conflict will appear in the conflict window in the lower right-hand corner of the Programmer Application.
 - b. Some conflicts will result in a pop-up window to alert the clinician to review the values that they selected.
 - c. It is recommended, that Dose 1 have the stronger therapy, and that Dose 2 has the lower, or back-up therapy.
4. Ensure that the Programming wand is placed over the implanted IPG.
5. Once all conflicts have been resolved, all changed parameter values should appear in **Blue** text. Select the **Set Parameters** command.
6. The Programmer Application will send the new parameters to the IPG, and the "Set parameters Ok" will appear in the Command History Window.

10. Starting and Stopping Therapy Session with the Programmer System

To ensure that the programmed parameter values are acceptable for the patient to use, it is important that the settings be run in the clinical setting. The following instructions assume that the Programmer Application has been started, and Programmer wand is in place over the IPG, and that any parameters that need to be modified have been, per Section 9.

Caution: When starting a therapy session in Clinic, it is important to remind the subject to keep the Programmer Wand in place over the Implanted IPG in the event that the therapy needs to be quickly stopped.

Caution: The clinician should also have available a Patient Controller, to turn off therapy in the event the programmer wand stops working

10.1. Starting Therapy Session

1. Check to ensure that the Programmer is in place over the Altius IPG.
2. Check to ensure that the desired Parameter Values have been sent to the IPG by using the **Get Parameters** command.
 - a. Correct any values. Refer to Section 9.
3. Start the therapy session by executing the **Start Dose 1** or **Start Dose 2** command by one of the following ways:
 - a. Click the start **Dose 1** or **Dose 2** blue or orange buttons under the respective Dose 1 or Dose 2 Parameter Value sets.
 - b. Click Tools on the menu bar, click the PTC orders menu, and Select **Start Dose 1** or **Start Dose 2**
4. The order will then be transmitted to the device and the Start Dose 1 OK or Start Dose 2 OK will appear in the Command History.

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10.2. Stopping Therapy

1. Ensure that the Programmer Wand is in place over the implanted Altius IPG.
2. Stop the therapy by executing the **Stop Therapy** command by one of the following
 - a. Click the **Stop Therapy** button under the therapy orders section
 - b. Click Tools on the menu bar, click the PTC orders menu, and Select **Stop Therapy**
3. The order will then be sent to the Altius IPG and Stop Therapy Ok will appear in the command history.

11. Device Log File

The Device Log file can be a useful tool to assess changes in programming, frequency in charging, or the frequency in device use among other uses.

11.1. Reading Device Log File

To Read the Device Log file from the IPG follow these steps, assuming the Programmer Application has been started and the programmer wand is in place:

1. Ensure that the programmer wand is in place over the IPG.
2. Execute the **Read Device Log** command by one of the following methods:
 - a. On the toolbar select **Read Device Log** icon
 - b. On the menu bar select Tools, in the drop down menu select Device Log, and Select **Read Device Log**
3. The Device log will open in a Pop-up window displaying the most recent event in the log will appear first and with the oldest event appearing last.

Note: The IPG log has a limited memory and will only be able to store a minimum of 300 events and the date and time they occurred according to the IPGs on board clock.

11.2. Device Log File storage and Data

An event can be described as any external command the IPG is given, or any internal event recorded for its safe operation, such as:

- Starting or ending therapy
- Starting a charging session including recording temperature values
- Receiving new parameter values
- Starting and ending the lock out period

The Device Log, once downloaded onto the PAPC is stored in the following directory:

C:\Neuros Altius Programmer 1.2.0.0\Log

The device log file names follow the naming convention "LogFile_<IPGSN>", where IPGSN is the serial number of the IPG.

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The Device log is stored as a .csv file and can be accessed by opening it in notepad or Microsoft excel. It is strongly recommended to copy the log file to an external USB drive and review it on a different computer.

If the same IPG and PAPC are used throughout a patient's set of programming visits, the log file stored on the PAPC will be updated with the new data from the IPG in the order from oldest data to newest data.

11.3. Clearing Device Log

The Device log can also be cleared.

Warning: Clearing the Device Log if it has not been downloaded onto the PAPC means that data is no longer available and is irrecoverable.

Follow these steps to clear the Device log:

1. Ensure that the programmer wand is in place over the IPG.
2. On the menu bar select Tools, in the drop down menu select Device Log, and Select Clear Device Log
3. The Clear Device Log OK will appear in the command History

12. Command History

The Command History stores the list of commands that the PAPC sends to a specific Altius IPG. It is displayed in the middle right hand corner of the screen.

12.1. Saving and Exporting the Command History

The Command History can be backed up and exported by following these steps:

1. Open the Programmer Application
2. On the Command History Box on the right side of the screen select the IPG Serial Number of Interest from the Drop down, if the IPG has not already been selected.
3. Select Export Command History by one of the following methods:
 - a. On the Tool Bar Select the **Export Command History** Icon
 - b. On the Menu Bar select Command History, select **Export Command History**

This will bring up a File Save box for the default file location which is C:\Neuros Altius Programmer 1.2.0.0\Log. Enter the name of the file you would like to save the Command History as.

Note: The recommended file format to use is CmdHist_<IPGSN>, where IPGSN is the serial number of the IPG. Variations to include date, and the clinician performing the programming are encouraged.

4. Save the file.

The Command History File will be saved as a .txt file. It is recommended to transfer the file via USB jump drive to another computer.

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12.2. Compare Programs

Compare Programs can be accessed by going to the Menu Bar and selecting Command History. In the Command History menu, select Compare Programs.

This will open a screen that will show the Get Parameter and Set Parameter Values sent to an Altius IPG. Once the Window is open, double click a Set Parameter command other than the latest one, and it will show the parameter values that are different between the current programmed parameters values and the parameter values from the selected Set parameters command. If nothing shows up, then there is no difference between the two parameter value sets.

The Window also shows a button with **First of Today**. This button will show the first programmed command of the day.

The **Print** Button will open a print window where it can be saved.

Once done, click the **x** button in the top right corner of the screen, or click the **Close** button on the bottom right of the screen.

12.3. Export Programs

The export Program command can be used to export all the Set/Get parameter commands with all programmed parameters in the current IPG log information on the PAPC.

To Export Programs, go to the menu bar, select Command History, Select Export programs. This will open a dialog box to save the file as .txt. The file will be saved in the C:\Neuros Altius Programmer 1.2.0.0\Log folder.

12.4. Command History Filter

Caution: Changing the Command History Filter may inadvertently hide useful information about the list of commands sent to the IPG from the PAPC.

The Command History Filter may be accessed by going to the Menu Bar, selecting Command History, and clicking on Command History filter. This will open a window where the commands shown in the Command History Window can be filtered in or out.

12.5. Backup/Restore the Command History File Database

Warning: Exporting or Importing the Command History File Database should only be done at the direction of Neuros Medical personnel.

If a Backup Command History Database or Restore Command History Database needs to be done, it should be executed by Neuros Medical personnel, or under their supervision.

13. Default Settings

Default Settings will set the IPG to the default settings of Doses and Channels disabled.

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Caution: **Default Settings** will clear the current programmed parameter values when executed.

To use Default Settings:

1. Ensure that the Altius Programmer Application has executed the **Get Parameters** command successfully.
2. With the Programmer Wand still over the Altius IPG, execute **Default Settings** by one of the following methods:
 - a. Clicking the **Default Settings** button on the Programming Wand
 - b. Going to the menu bar, selecting Tools, and clicking on **Default Settings**

14. Resetting the Altius IPG

The Altius IPG is designed to protect itself if an internal fault occurs by going into a safe mode (down mode), where all therapy is disabled, and the ability to turn on therapy from the Programmer Application, or the Patient controller is disabled until the IPG is Reset. The IPG will go into Safe Mode if it detects an internal fault, or if it is exposed to certain conditions such as, but not limited to electrocautery or defibrillation, or strong magnetic fields that trigger safe mode.

If the Altius IPG goes into safe mode the patient will know if they attempt to activate Dose 1 or Dose 2, or to charge the Altius IPG, the Patient Controller and the Battery charger will activate the Contact Physician light. The patient must come in for a programming visit to reset the Altius IPG and reactivate therapy.

To Reset the IPG:

1. Interrogate the Altius IPG with Programming Wand positioned over the implant site
2. An error screen will come up stating that the IPG is in down mode.
3. On the Menu Bar select Tools
4. In Tools, click **Reset**
5. The Reset will order will be sent to the IPG, and the IPG will reset itself to the default settings of Dose 1 & 2, Channels A & B off, the Reset OK will appear in the Command History.
6. If executed and the default settings appear the reset was successful, the user parameter values may now be modified to the patient's previously programmed values, or modified if desired by the patient.

Caution: If This does not work, the clinician may have to contact Neuros and have Neuros field staff see the patient

15. Magnet Mode

The Altius IPG contains a magnet activated reed switch in case of emergency where the therapy needs to be turned off.

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If a Magnet with a strength of 10 to 25 gauss is used close to the Implanted location of the IPG, a Dose disabled by magnet event will be logged by the IPG, and if therapy is active, the dose will be disabled and the lockout period will begin.

16.Using Base Files

Base files may also be referred to as Settings or Setting Files. They are stored as .mips files. A base file may be used to save or load common starting parameter values.

The default file storage location for Base/Settings file is C:\Neuros Altius Programmer 1.2.0.0\Log folder

16.1. Save Base File

To Save a Base/Settings file:

1. Open the Programmer Application
2. Change the Parameters to the desired value, ensure that show up in **Blue** text
3. Save the Base/Settings file by one of the following methods:
 - a. Click the **Save Settings** Button on the Toolbar
 - b. On the Menu Bar go to File, and in the dropdown, Click **Save Settings**
 - c. Use the Keyboard command <Ctrl+s>
4. This will open the save file window, enter the name for the file, and click Save.

16.2. Load Base file

To Load a Base/Settings file:

1. Open the Programmer Application
2. Ensure that the Programmer Wand is placed over the IPG.
3. Execute the **Get Parameters** command
4. Load the Base/Settings file by one of the following methods:
 - a. Click **Load Settings** button on the Toolbar
 - b. On the Menu Bar go to File, and in the dropdown menu, Click **Load Settings**
 - c. Use the Keyboard command <Ctrl+0>
5. This will open the Open Settings file window, select the file to load, and click Open, or double click on the file name.
6. The file is now loaded, and the parameter differences will appear in **Blue** text

17.Print Settings

The Print Settings function allows the user to Print the Settings currently displayed to an Adobe pdf file.

To use Print Settings:

1. Go to the Menu Bar, select File, Click **Print Settings**

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2. This will open a Print preview window, with the Adobe pdf symbol will be displayed in the top right of the screen.

Warning: It is not recommended to attempt to connect the Programmer Application PC to an external Printer.

3. Once the file has been saved it may should be transferred to a USB jump drive for review off of the PAPC.

18. Device Temperature

The **Temperature Order** command will have the Altius IPG communicate the temperature of the IPG in degrees Celsius.

To execute the **Temperature Order** command, follow these steps:

1. Ensure that the Programmer Application has been started, and that the Programmer Wand is in place over the Implanted Altius IPG.
2. Execute the **Get Parameters** command.
3. Go to the Menu Bar, select Tools, in the drop-down menu click **Temperature Order**.
4. If executed correctly, the Temperature will display in a pop-up window.

GetTemperature OK will appear in the Command History Window.



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Appendix I: Replaceable Parts & Cables

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

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

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

Non-Implantable replaceable Components:

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

Implantable replaceable Components

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

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

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Appendix II: Wireless Specifications of the Altius System

Communication/Telemetry and Wireless Charging:

Patient Controller and Programming Wand to the IPG(Communication)

- Modulation: ASK (Amplitude Shift Keying)
- The Amplitude is 0 and a 1 is 305 μ s 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 183 μ s, a 1 is 275 μ s
- Transmit Frequency: 19kHz
- Power: 1.8 mW



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Appendix III: Electromagnetic Interference Information

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

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

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

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

Test Standard	Configuration	Compliance Level	Electromagnetic Environment Guidelines
CISPR 11 Radiated Emissions	1,2,3	Group 1 Class B	The Altius System uses RF energy only for its internal function; therefore, its RF emission are low and are 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.



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



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

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

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Appendix IV: Federal Communications Commission (FCC)

The Altius Patient Controller and the Altius IPG:

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

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

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

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

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

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



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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.

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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.