algovita™

Algovita™ Spinal Cord Stimulation System

Clinician Programmer
Model 4500

Patient Feedback Tool
Model 4520

Clinician Programming Manual

ALGOSTIM, LLC

℞ ONLY

CE 0123

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Refer to the Information for Prescribers Manual for indications, contraindications, warnings, precautions, adverse events, clinical study results, and related information.

FCC Information (US Only)
The following is communications regulation information about the Algovita Clinician Programmer and Patient Feedback Tool:
Clinician Programmer FCC ID: 2ABU84500 contains FCC ID: U9R-W2CBW003
Patient Feedback Tool FCC ID: contains X3ZBTMOD5

These devices comply with part 15 of the FCC rules. Operation is subect to the following two conditions: (1) These devices may not cause harmful interference, and (2) These devices must accept any interference received including interference that may cause undesired operation.

Important: Changes and modifications to the products not authorized by Algostim, LLC could void the FCC certification and negate your authority to operate these products.

19. System Specifications

Clinician Programmer Specifications

Table 18. Clinician Programmer Specifications	
Operating temperature	32° F to 122° F (0°C to 50°C)
Storage temperature	-4° F to 185° F (-20°C to 85°C)
Operating/storage humidity	10% to 95%
Operating/storage atmospheric pressure	20.7 in. Hg to 31.3 in. Hg (700 kPa to 1060 kPa)
Size (approximate)	8.4 x 5 x 0.904 in^3 (213.4 x 127 x 23 mm^3)
Weight including battery (approximate)	450 grams (15.8 ounces)
Battery	Chargeable lithium-ion battery
Mode of operation	Continuous

Safety and Compatibility Standards Conformity

Algovita Model 4500 Clinician Programmer and Model 4250 Patient Feedback Tool comply with the following standards:

- IEC60601-1, Medical Electrical Equipment Safety
- IEC60601-1-2, Electromagnetic Compatibility
- EN45502-1, Safety, Marking and Information of Medical Devices

Electromagnet Compatibility Declaration Tables

This section lists the EMC Declaration tables. The Clinician Programmer and Patient Feedback Tool are intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer and Patient Feedback Tool should assure that they are used in such an environment. The Clinician Programmer and Patient Feedback Tool contain RF transmission and receiving capabilities; consequently, it is possible that other portable and mobile RF communications equipment may interfere with the Clinician Programmer and Patient Feedback Tool.

The power supply cable (maximum length 188 cm) was included in the system testing to demonstrate compliance with the requirements of IEC 60601-1-2 2007. Use of accessories and cables other than those specifically listed may result in increased emissions or decreased immunity of the Clinician Programmer and Patient Feedback Tool.

The Clinician Programmer and Patient Feedback Tool should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Clinician Programmer and Patient Feedback Tool should be observed to verify normal operation in the configuration in which it will be used.

Table 19. Guidance and manufacturer's declaration - electromagnetic emissions

The Clinician Programmer and Patient Feedback Tool are intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer and Patient Feedback Tool should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Clinician Programmer and Patient Feedback Tool use RF energy primarily for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Clinician Programmer and Patient Feedback Tool are 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 20. Guidance and manufacturer's declaration - electromagnetic immunity

The Clinician Programmer and Patient Feedback Tool are intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer and Patient Feedback Tool should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Clinician Programmer and Patient Feedback Tool requires continuous operation during power mains interruptions, it is recommended that the Clinician Programmer and Patient Feedback Tool be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the A.C. mains voltage prior to application of the test level.

Table 21. Guidance and manufacturer's declaration - electromagnetic immunity

The Clinician Programmer and Patient Feedback Tool are intended for use in the electromagnetic environment specified below. The customer or the user of the Clinician Programmer and Patient Feedback Tool should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Clinician Programmer and Patient Feedback Tool, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\ \sqrt{P}$ $d=1.2\ \sqrt{P}$ 80 MHz to 800 MHz $d= 2.3\ \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clinician Programmer and Patient Feedback Tool are used exceeds the applicable RF compliance level above, the Clinician Programmer and Patient Feedback Tool should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Clinician Programmer and Patient Feedback Tool.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 22. Recommended separation distances between portable and mobile RF communications equipment and the Clinician Programmer and Patient Feedback Tool

The Clinician Programmer and Patient Feedback Tool are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clinician Programmer and Patient Feedback Tool can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clinician Programmer and Patient Feedback Tool as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80 MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Wireless Information Table

Table 23. Wireless Specifications and Safety

Programmer wireless technology operating characteristics	The Clinician Programmer interacts with the stimulator using MedRadio Band: 402-405 MHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 301 839-2 USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219
	The Clinician Programmer interacts with the stimulator using 2.45 GHz. The effective radiated power is below the limits as specified in: Europe: EN ETSI 300 328 USA: FCC part 15.24
Stimulator wireless technology	The stimulator complies with emissions requirements per R&TTE Standard EN 301 839-2 v13.1 (402MHz to 405MHz).
Wireless integrity	The Algovita SCS System employs mechanisms to ensure integrity of the communication area. The stimulator will not respond to any device to which it is not linked.

Compliances and Authorizations

The Clinician Programmer 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 may cause harmful interference in which case the user will be required to correct the interference at his own expense.

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth

Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary bases in the 2360-2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmissions from this transmitter will be free from interference.