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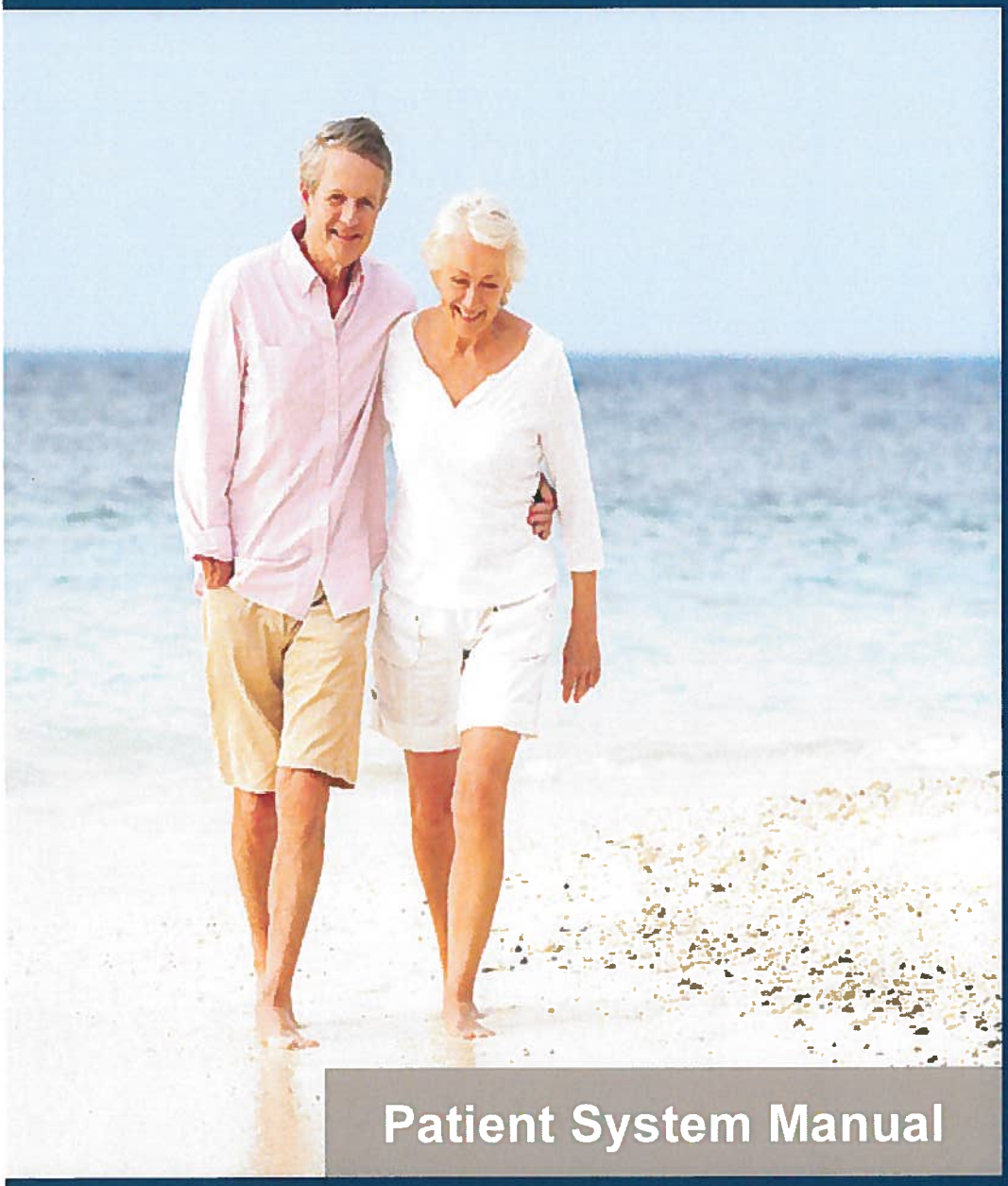

Algovita™ Spinal Cord Stimulation System

Programmer Charger
Model 4200

Pocket Programmer
Model 4100

Patient System Manual

ALGOSTIM, LLC

CE 0123

℞ ONLY

2014

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FCC Information (US Only)
The following is communications regulation information about the Algovita Programmer Charger and Pocket Programmer.
Programmer Charger FCC ID: 2ABU84200
Pocket Programmer FCC ID: 2ABU84100

These devices comply with part 15 of the FCC Rules. Operation is subject 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.

Safety and Compatibility Standards Conformity

Algovita Programmer Charger Model 4100 and Pocket Programmer Model 4200 comply with the following standards:

- IEC 60601-1, Medical Electrical Equipment Safety
- IEC 60601-1-2, Electromagnetic Compatibility
- EN 45502-1, Safety, Marking and Information of Medical Devices

Electromagnetic Compatibility

The Federal Communications Commission (FCC) and various international agencies have rules and regulations meant to minimize interference created by electronics. The Programmer Charger and Pocket Programmer meet US and European regulatory limits for Electromagnetic Compatibility (EMC). EMC is the ability of electronic devices, including computers, to function properly together in the electronic environment.

However, there is no guarantee, depending on the specific circumstances that the Programmer Charger or Pocket Programmer will not interfere with other electronics. Should this equipment cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by doing one or more of the following:

- Relocate the Programmer Charger or Pocket Programmer away from the device being affected.
- Plug the equipment and the Programmer Charger into a different electrical outlet circuit if the Programmer Charger is being used while it is being recharged.

Electromagnetic Compatibility Declaration Tables

This section lists the EMC Declaration tables. The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer should assure that they are used in such an environment. The Programmer Charger and Pocket Programmer contain RF transmission and receiving capabilities; consequently, it is

possible that other portable and mobile RF communications equipment may interfere with the Programmer Charger and Pocket Programmer.

The power supply cables (maximum length 188 cm [74 in]) and charging paddle (maximum cable length 101 cm [40 in]) were 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 Programmer Charger and Pocket Programmer.

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

Table 9. Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Programmer Charger and Pocket Programmer 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 B	The Programmer Charger and Pocket Programmer are 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 10. Guidance and manufacturer's declaration – electromagnetic emissions			
The Programmer Charger and Pocket Programmer are intended for use in the electromagnetic environment specified below. The customer or the user of the Programmer Charger and Pocket Programmer 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	± 8 kV contact ± 15 kV	The Programmer Charger and Pocket Programmer are portable devices intended for use in hospital or home environments as well as being carried by ambulatory patients.
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% UT (30% dip in U_T) for 25 cycles <5% UT (>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 Programmer Charger and Pocket Programmer requires continuous operation during power mains interruptions, it is recommended that the Programmer Charger and Pocket Programmer 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 11. Guidance and manufacturer's declaration – electromagnetic emissions

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Programmer Charger and Pocket Programmer, 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. 

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 Programmer Charger and Pocket Programmer are used exceeds the applicable RF compliance level above, the Programmer Charger and Pocket Programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Programmer Charger and Pocket Programmer.

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

Table 12. Recommended separation distances between portable and mobile RF communications equipment and the Programmer Charger and Pocket Programmer

The Programmer Charger and Pocket Programmer are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Programmer Charger and Pocket Programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Programmer Charger and Pocket Programmer 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 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 13. Wireless Specifications and Safety	
Programmer wireless technology operating characteristics	The Programmer Charger and Pocket Programmer interact 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 Programmer Charger and Pocket Programmer interact 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.

Note: 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 or more 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.

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 (ie, 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 basis 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 transmission from this transmitter will be free from interference.