Boston Scientific

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Charging System Patient Handbook

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℞ ONLY

CAUTION:
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

92195840-02

Guarantees

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Trademarks

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Labeling Symbols

For an explanation of labeling symbols, refer to the *Labeling Symbols* document.

Warranty

For device warranty information, visit (www.bostonscientific.com/warranty).

Product Model Numbers

Model Number	Description	Compatible System
SC-6414	Charging System Kit	• Precision™ Montage™ MRI • Precision Spectra™ • Spectra WaveWriter™ • WaveWriter Alpha™
SC-5314	Charger	
SC-6319	USB Power Supply	
SC-6359-S*	Charger Belt - Small 23 in to 37 in (58 cm to 94 cm)	
SC-6359-M*	Charger Belt - Medium 36 in to 51 in (91 cm to 130 cm)	
SC-6359-L*	Charger Belt - Large 50 in to 70 in (127 cm to 178 cm)	

*This component is not included in the Charging System Kit and is sold separately. Only one Belt will be provided depending on the appropriate size.

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Table of Contents

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1 The Charging System

Intended Use

The Charger is a medical device that is intended to charge the battery of the compatible Boston Scientific rechargeable Stimulator.

The Charger Belt is intended to aid in Charger placement while charging the battery of the compatible Boston Scientific rechargeable Stimulator.

Device Description

The Charger is a portable, rechargeable power source, that stores electrical energy. The stored electrical energy wirelessly charges the compatible Boston Scientific rechargeable Stimulator (also referred to as Implantable Pulse Generator or IPG within this manual).

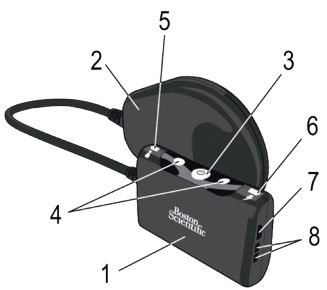


Figure 1 The Charger

1. Battery Pack
2. Charger Coil to charge the Stimulator
3. Power ON/OFF button/Alignment Indicator
4. Misalignment Indicators
5. Stimulator Battery Indicator
6. Charger Battery Indicator
7. USB port to plug in USB Power Supply
8. Speaker Port

The Charger Belt (Belt) is a cloth belt with a hook and loop fastener. The Belt holds the Charger and keeps it lined up with the Stimulator while charging. The Belt is provided in three sizes: small, medium, and large.

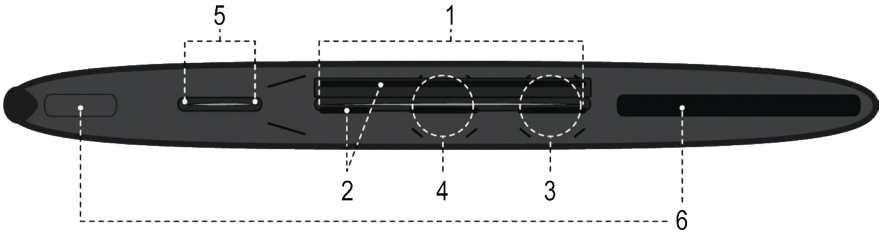


Figure 2 The Charger Belt

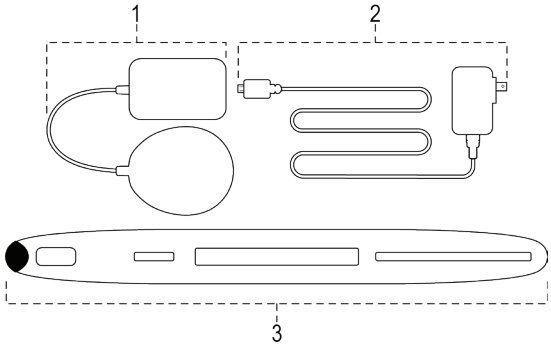
1. Charger Coil (Coil) Pocket
2. Hook and Loop Fastener for the Coil Pocket
3. Coil placement for the Stimulator implanted in the back
4. Coil placement for the Stimulator implanted in the abdomen
5. Pouch for the Battery Pack
6. Hook and Loop Fastener for the Belt

Charging System Components

Components of the Charging System are provided in a Charging System Kit (model number SC-6414). The Charging System Kit includes the Charger and a USB Power Supply. The Belt is provided separately from the Charging System Kit. Make sure you have received all components of the Charging System Kit. If any component is missing, contact Boston Scientific Customer Service: (866) 360-4747.

Table 1 includes a description of all Charging System components and accessories. Use only the Charging components and accessories that are listed in Table 1 and supplied by Boston Scientific.

The Charging System is not needed for Boston Scientific non-rechargeable Stimulators.



1. Charger
2. USB Power Supply
3. Belt

Figure 3 The Charger System

Table 1: Components of the Charging System

Model Number	Description	Quantity
SC-5314	Charger	(1)
SC-6319	USB Power Supply	(1)
SC-6359-S*	Charger Belt - Small 23 in to 37 in (58 cm to 94 cm)	(1)
SC-6359-M*	Charger Belt - Medium 36 in to 51 in (91 cm to 130 cm)	
SC-6359-L*	Charger Belt - Large 50 in to 70 in (127 cm to 178 cm)	

*This component is not included in the Charging System Kit and is sold separately. Only one Belt will be provided depending on the appropriate size.

Caring for the Charging System

Warnings

Unauthorized modification to the medical devices is prohibited. System integrity could be compromised and harm or injury to the patient could occur if the medical devices are subjected to unauthorized modification.

The Charging System is MR Unsafe and must not be taken into any MR environment such as the MRI scanner room.

Cautions

Keep the Charger and charging components dry. They should not be exposed to moisture.

Do not connect the Charger to any other device except to the USB Power Supply.

Keep the Charger and charging components away from pets, pests and children to avoid damage to the devices.

Charger device contains a non-replaceable battery. Contact Boston Scientific Customer Service for additional battery questions or concerns.

Precautions

Do not use if package is damaged or unintentionally opened before use.

Do not use if labeling is incomplete or illegible.

Do not expose the components of the Charging System to very hot or very cold conditions.

Do not leave the Charging System outdoors or in a car for extended periods of time. The Charging System may be damaged by extreme temperatures, especially high temperatures.

Ensure that the operating temperature of the Charging System is between 5 °C to 35 °C (41 °F to 95 °F).

Ensure that the storage temperature of the Charging System is between -20 °C to 60 °C (-4 °F to 140 °F).

Handle the Charging System components with care. Do not drop them on hard surfaces or submerge them in water. Avoid all sources of water which can come into contact with the Charging System components. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the Charging System.

Do not dispose of the Charger in a fire. The battery in the Charger may explode in a fire. Other external devices should be disposed of per local regulatory requirements. Please contact a healthcare professional for additional information.

Do not clean the Charger while it is connected to a power outlet.

As an operator of the Charging System, you should perform only the following service and maintenance tasks:

- Charging the Charger Battery
- Cleaning the Charger and Accessories

Ensure that the devices are not in use while performing service and maintenance tasks.

Do not use abrasive cleansers for cleaning.

Before washing the Belt, remove the Charger from the Belt.

The Charging System components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Remove residue from soapy detergents with a damp cloth and then wipe dry.

You can either hand wash the Belt or machine wash it using the gentle cycle. Air-dry the Belt after washing and store it in a dry location for the next use. See the instructions on the Belt label for additional information.

Adverse Effects

Potential risks are involved with use of the Charger. Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country.

The possible risks of using the Charger include the following:

- Burn
- Discomfort
- Pain
- Inadequate Stimulation - problems recharging the Stimulator can result in loss of stimulation and ineffective pain control

2 Charging the Charger

The Charger must be charged before using it to charge the Stimulator Battery. When you are not using the Charger, keep the Charger connected to the USB Power Supply, so that it is always ready to deliver a charge.

Charging the Charger

1. Find an electrical outlet that is next to a flat surface and that does not expose the Charging System to water or direct heat.
2. Plug the USB Power Supply into an electrical outlet.
   Any use of an electrical outlet has the risk of an electric shock. Be careful when plugging in the USB Power Supply.
3. Plug the other end of the USB Power Supply into the Battery Pack end of the Charger, see Figure 4.

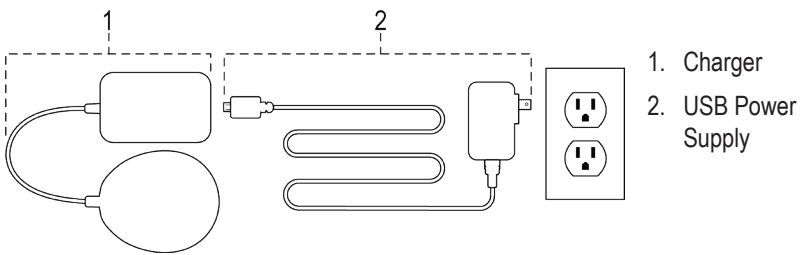


Figure 4 Charger plugged into the USB Power Supply

Charger Battery Indicator

The Charger Battery Indicator changes based on the Charger status.

	Blinking green = Charger Battery level is high and charging.
	Blinking yellow = Charger Battery level is medium and charging.
	Blinking red = Charger Battery level is low and charging.
	Solid green = Charger Battery is fully charged when the Charger Battery is charging.
	No light = Charger is not charging. Check the connection to Power Supply.

3 Charging the Stimulator

Warnings

- Do not charge the Stimulator while sleeping. This may result in a burn.
- Failure to use the Belt while charging may result in a burn. If you experience pain or discomfort while charging, stop charging and contact Boston Scientific.

Charging Routine

The programming software for the Stimulator System gives a healthcare provider a conservative recommendation for how often to charge. This estimate is based on 24 hours per day for 7 days per week at the programmed energy output level. You have the freedom to establish the charging routine that fits best based on the general recommendations from a healthcare provider. If you do not charge the Stimulator before it reaches the very low “hibernation” condition, stimulation will eventually stop until you charge the Stimulator Battery. Developing a charging routine that you are comfortable with will help to prevent you from losing stimulation due to a low battery. Developing a charge schedule involves balancing four things:

- How much battery power is needed in the Stimulator to have effective therapy.
- How often to charge the Stimulator.
- How long to charge the Stimulator.
- How to manage a personal schedule.

Checking the Battery Status of the Stimulator

Before charging the Stimulator, check the status of the Stimulator Battery using the Remote Control. The Remote Control displays the battery status of the Stimulator on the Home Screen. The Remote Control also displays messages about the battery condition of the Stimulator. Refer to the *Instructions for Use* provided for the Remote Control for additional information. The Stimulator will not communicate with the Remote Control during the charging session.

Charger Battery Indicator ⚡ while Charging the Stimulator

When the stimulator is charging, the Charger Battery Indicator shows the following charge levels.

	Solid green = Charger Battery level is high.
	Solid yellow = Charger Battery level is medium.
	Solid red = Charger Battery level is low.
	Blinking red = Charger Battery level is critically low. The Charger will shut off soon. **Note:** *The Charger beeps every 5 seconds as an initial indication to charge the Charger Battery. As a final indication, the Charger shuts off after 3 quick beeps.*
	No light = Charger is off.

Stimulator Battery Indicator while Charging the Stimulator

When the Stimulator is charging, the Stimulator Battery Indicator shows the following charge levels.

	Solid green = Stimulator is fully charged.
	Blinking yellow = Stimulator is charging.
	No light = Stimulator is not aligned. Charger is off. Charger Battery is charging.

Indicator Sounds

Chime: The Charger is turned on or turned off.

Steady Continuous Beep: The Charger is not aligned to the Stimulator. The Charger is not charging the Stimulator.

No Beep: The Charger is aligned to the Stimulator. The Charger is charging the Stimulator.

Continuous Double Beep: The Stimulator is fully charged when it continuously beeps for 1 minute.

Continuous 5 Second Interval Beep: Initial warning that the Charger Battery is depleted. Plug in the Charger.

3 Quick Beeps: The Charger Battery is fully depleted and shuts off.

For additional information regarding the Stimulator and its Battery status, see the *Instructions for Use* provided with the Stimulator System.

Charge Modes

The Charger has two charging modes:

- QuickCharge Mode (primary setting)
- Classic Mode (secondary setting)

QuickCharge Mode is the primary setting on the Charger. This mode charges faster than Classic Mode.

WARNING:

The Stimulator site may get warmer at the skin surface during QuickCharge Mode. If it becomes uncomfortably warm during charging, switch to Classic Mode. If the Stimulator site remains uncomfortably warm during charging, discontinue charging. Call a Boston Scientific representative or Customer Service for concerns.

Changing the Charge Mode

The Charge Mode can only be changed while charging the Charger.

Press and release the center button on the Charger, while the Charger is charging.

QuickCharge Mode = The Stimulator Battery Indicator blinks green and emits two beeps.

Classic Mode = The Stimulator Battery Indicator blinks red and emits a single beep.

Charging the Stimulator

When charging, you must use the Charger with the Belt to hold the Charger over the Stimulator.

1. Unplug the Charger from the USB Power Supply when the Charger Battery Indicator is green. Unplugging the Charger from the USB Power Supply turns off the Charger Battery Indicator, even if the Charger is fully charged.
2. Place the Belt on a flat surface.
3. Open the Hook and Loop Fastener for the Coil Pocket.
4. Place the Coil into the Belt.
5. Place the Battery Pack into the Belt.
6. Close the Hook and Loop Fastener for the Coil Pocket.

7. Wrap the Belt around the waist.
8. Press and hold the center button on the Charger until you hear a chime. The chime indicates that the Charger has successfully turned on. You will also see the Charger Battery Indicator ⚡ turn on.

   Note: *Pressing and holding the center button for 5 seconds resets the Charger.*
   To avoid accidental activation, the Charger will not turn on when you lightly tap the center button.

9. Move the Belt so that the Coil is over the implant area. The Charger beeps and the Misalignment Indicators blink in amber color, as the Charger searches for the Stimulator. The beeping stops and the center button turns green when the Charger has located the Stimulator. The beeping and blinking resumes if the Coil moves away from the Stimulator. The Charger turns off after 2 minutes, if the Stimulator is not aligned.

   Note: *For best charging results, ensure that the Charger is well ventilated and centered over the Stimulator. Covering the Belt and the Charger with any thick clothing material such as a jacket or blanket, could affect the Charger from being well ventilated.*

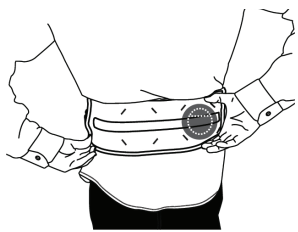


Figure 5 Ideal alignment of Charger (outlined in grey) over the Stimulator (dotted line).
This figure shows the implant location for the back only (not the abdomen).

10. Tighten the Belt to maintain alignment with the Stimulator. The Charger will not charge the Stimulator if there is misalignment. Refer to the instructions provided in “Troubleshooting” on page 15 for instructions if the Charger becomes unresponsive.

    Note: *Wearing the Belt loosely may cause the Charger to move. For best charging results, occasionally check the Charger to make sure that there is alignment with the Stimulator. If it moves out of alignment, it will start beeping again.*

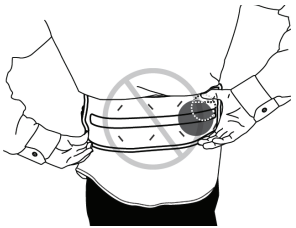


Figure 6 Poor alignment of Charger (outlined in grey) over Stimulator (dotted line).

11. Turn off the Charger after the Charger double beeps and the Stimulator Battery Indicator turns solid green. Turn off the Charger by pressing and holding the center button until you hear a chime.

    Note: *Pressing and holding the center button for 5 seconds resets the Charger.*

12. Unwrap the Belt from around the waist to remove the Belt.
13. Ready the Charger to charge the Stimulator again. See “Charging the Charger” section in this manual.

    Note: *The Charger can charge while inside the Belt. There is no need to remove the Charger from the Belt.*

Troubleshooting

Follow the steps below if the Charger becomes unresponsive.

1. Remove the Belt.
2. Plug the USB Power Supply into an electrical outlet.
3. Plug the other end of the USB Power Supply into the Battery Pack end of the Charger.
4. Once you see the blinking LED of the Charger Battery Indicator, the charge session with the Stimulator can resume.

4 Technical Information

Charger Battery Service Life

The Charger Battery has a typical service life of 300 charging cycles.

Wireless Charging Information:

Charging Frequency: 79 kHz – 85 kHz

The charging distance between the Charger and the Stimulator is between 0.25 cm to 2 cm (0.1 in to 0.8 in). Centering the Charger over the Stimulator ensures the shortest charging time. The Charger will beep as it searches for the Stimulator and will stop beeping when it is aligned with the Stimulator. Refer to the instructions provided in “Charging the Stimulator” on page 12 for instructions on aligning the Charger.

Essential Performance

Failure of the external electrical components will not result in an unacceptable risk to the user.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Charging System
The Charging System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Charging System can help prevent electromagnetic interference by maintaining a minimum distance of 30 cm (1 ft) between portable and mobile RF communications equipment (transmitters) and the Charging System.
Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Charging System is intended for use in the electromagnetic environment specified below. The customer or the user of the Charging System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Contact: ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. **Note:** *Applies to the external devices*
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Magnetic fields from common appliances are not expected to affect the device.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions - For All ME Equipment and ME Systems		
The Charging System intended for use in the electromagnetic environment specified below. The customer or user of the Charging System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guide
RF emissions CISPR 11	Group 1	The Charging System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Charging System 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.
Harmonic emissions IEC 61000-3-2	Class B	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Charging System is intended for use in the electromagnetic environment specified below. The customer or the user of the Charging System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m 80 MHz to 2,7 GHz	Professional healthcare facility environment and home healthcare environment. 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. Interference may occur in the vicinity of equipment marked with the symbol shown below: 
Note: *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 Charging System is used exceeds the applicable RF compliance level above, the Charging System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Charging System.			

Immunity Testing RFID Readers			
The Charging System has been tested for immunity to interference from RFID readers per the following specifications.			
RFID Spec Per AIM 7351731	**Frequency**	**Test Level (RMS)**	**Compliance Level**
ISO 14223	134.2 kHz	65 A/m	65 A/m
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m	7.5 A/m
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m	7.5 A/m
ISOAEC 15693 (ISO/IEC 18000-3 Mode 1)	13.56 MHz	5 A/m	5 A/m
ISO/IEC 18000-7	433 MHz	3 V/m	3 V/m
ISO/IEC 18000-63 Type C	860-960 MHz	54 V/m	54 V/m
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m	54 V/m

Enclosure Port Immunity to Proximity Magnetic Fields		
The Charging System has been tested for enclosure port immunity to proximity magnetic fields per the following specifications.		
Test Frequency	**Modulation**	**Immunity Test Level (A/M)**
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 kHz	Pulse modulation 50 kHz	7.5

5 Glossary

Battery Pack. Portion of the Charger that contains the battery, electronics, and user interface.

Belt. The Belt holds the Charger over the Stimulator while charging. The Belt has a reclosable pouch and adjustable straps to conveniently and easily use the Charger.

Charger. A portable device that charges the battery of the Stimulator.

Charger Battery Indicator. A signal light on the Charger that indicates the charge status of the Charger.

Charger Coil. Portion of the Charger on the end of the cable to charge the Stimulator.

Charging System. The Charging System is a medical device made up of components that support charging the battery of the compatible Boston Scientific Stimulator.

Charging System Failure. Inability of the Charger to deliver charge to the Stimulator.

Classic Mode. Reduced charge rate of the Stimulator.

Compatible Boston Scientific Stimulator. Boston Scientific rechargeable Implantable Pulse Generator (IPG).

Electromagnetic Interference (EMI). Electromagnetic signals that interfere with a variety of electrical signals including stimulation.

Implantable Pulse Generator (IPG). Medical Device, small implantable electrical pulse generator used to provide stimulation. Also called a Stimulator, implant, or electrical pulse generator.

Indicator Sound. A signal sound made by the Charger that indicates the charge status of the Stimulator.

Magnetic Resonance Imaging (MRI). The use of a nuclear magnetic resonance spectrometer to produce electronic images of tissues and organs.

Precaution. Generally, situations that you should be aware of in order to avoid potentially uncomfortable stimulation sensations and/or damage to the stimulation system.

QuickCharge Mode Primary charge rate of the Stimulator. It charges faster than Classic Mode.

Remote Control. A battery powered hand-held computer used to adjust stimulation. The Remote Control is a medical device.

Stimulation. When used as a therapy for pain, an artificially applied, low-level, pulsating electrical signal delivered to a nerve by a device.

Stimulator. Medical Device, small implantable electrical pulse generator used to provide stimulation. Also called an IPG, implant, or electrical pulse generator.

Stimulator Battery Indicator. A signal light on the Charger that indicates the charge status of the Stimulator.

Warning. Potential hazards that you must be aware of to avoid serious situations that may cause injury or death.

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