



SetPoint System Patient Instructions for Use

Read all instructions, warnings and cautions carefully. Failure to follow them could lead to damage to your SetPoint System, cause it to malfunction, degrade its performance and/or result in harm.

Contact your doctor or SetPoint Medical with any questions about the information contained in the **SetPoint System Patient Instructions for Use** (Patient IFU). Copies of all SetPoint System Instructions for Use (IFUs) are available on the SetPoint Medical website. Any SetPoint System-related incident or problem, which is believed to represent a safety issue, should be reported to SetPoint Medical, Inc. immediately.

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Caution: Federal law restricts this device to sale by or on the order of a physician.

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Patient Quick Reference Guide

This page is a summary that explains the important points about using the SetPoint System. In addition, you should also watch the training video by clicking this [link](#) or scanning this QR Code with your mobile device:



SetPoint System Use & Care

Charging



- Keep your Charger on your Docking Station when you are not wearing it to keep it charged.
- You will know your Charger is fully charged when its LED is **solid green**, or when your Docking Station's LED is **solid blue**.
- Make sure your Charger is fully charged when you bring it to the clinic.

Cleaning



- Use a dry, lint-free cloth to clean your Charger, avoiding the magnetic latch.
- If needed, use isopropyl alcohol (IPA) wipes to clean lotion and oils off your Charger and to clean the magnetic latch area.
- Never spray your Charger with any substance or put it in any liquid.
- Keep lint and dirt out of your Charger's magnetic latch area.

Implant Charging



- Wear your Charger around your neck and make sure the magnetic latch closes properly.
- Charging begins when your Charger's LED **blinks green**, or **orange** and you hear **three beeps that go up in tone**.
- You will know charging is done when your Charger's LED is **solid green**, and you hear **four beeps (three beeps that go up in tone and a fourth beep that is a repeat of the last tone)**.
- It is recommended that you establish a routine to charge your Implant on the same day and time every week.

Travel



- Always carry your Charger in its Carrying Case when taking it somewhere.
- Do not use your Charger while traveling in cars, trains, boats, planes, or other vehicles.
- Provide your Patient ID card to security personnel when going through airport security if they have any questions or concerns about your SetPoint System.



Do not go into places with signs that warn about radio frequency (RF) safety.



Contact the clinic right away if you start to feel any pain or discomfort.



Charge your Implant weekly.

The information contained herein is not intended to serve as a substitute for a complete and thorough understanding of all the instructions presented in the Patient IFU. Please refer to the relevant sections in the Patient IFU for all pertinent information concerning use of the SetPoint System, and safety and efficacy information.



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Introduction

This **SetPoint System Patient Instructions for Use** (Patient IFU) describes how your SetPoint System works and gives you important safety tips for using it. Remember this guide does not replace advice given by your doctor. You should always talk to your doctor for individual health needs. You should read and understand this document to ensure that you can use the SetPoint System appropriately.

The table below shows the SetPoint System model numbers for the parts of the system that are described in this IFU.

Device Name	Model Number
Implant	M01
Charger	E04
Docking Station	C01

Table 1 - Device Names and Model Numbers

Indication for Use

The SetPoint System is indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response, loss of response or intolerance to one (1) or more biological or targeted synthetic DMARDs.

Pediatric Use

The SetPoint System is not intended for use in the pediatric population.

SetPoint System Description

The SetPoint System includes:

- The Implant (A) which is placed within a Pod (B) and implanted on the left vagus nerve in the neck (C)
- A Charger (D) with a Docking Station (F)
- A Programmer (E)

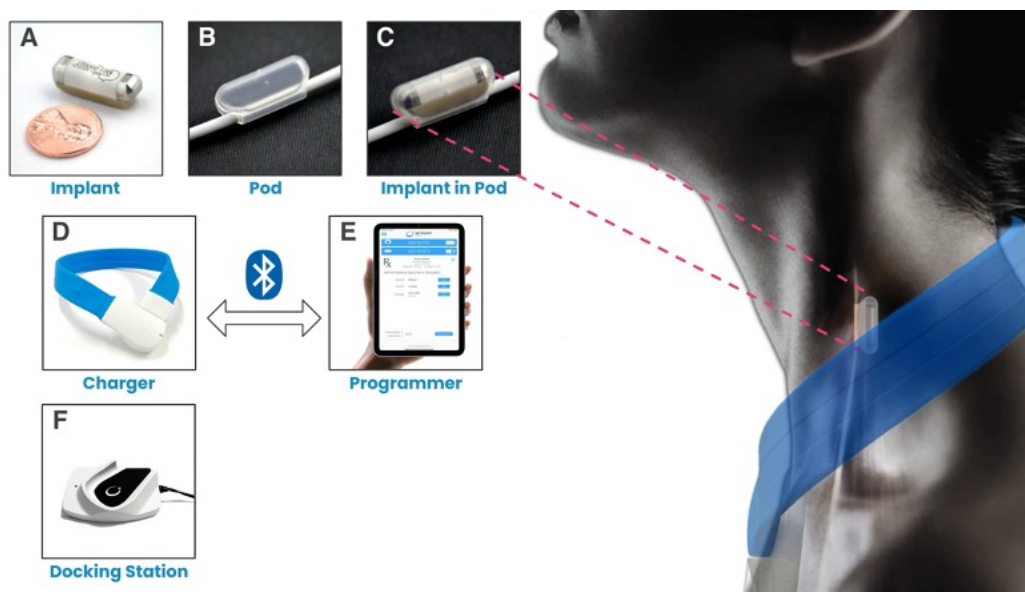


Figure 1 – SetPoint System and Components

Implant and Pod

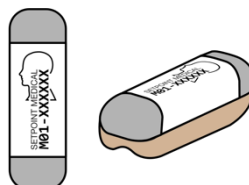


Figure 2 - Implant

The Implant is an integrated neurostimulation device. It is used to electrically stimulate the vagus nerve for 1 minute, every day. It is about 1 in (2.5 cm) long and weighs about 0.1 oz (3 g). An experienced surgeon implants it next to the vagus nerve on the left side of the neck. The Implant is placed inside a Pod, which is a flexible cover made of silicone. The Pod helps hold the Implant in place.

Automatic Stimulation

Your doctor, or someone from their team, will program your Implant with the information that describes the strength and timing of stimulation. Once programmed, the Implant uses a built-in timer to deliver therapy at the scheduled time every day.



What to Do if the Stimulation is Uncomfortable

You may or may not feel a sensation when the Implant is stimulating your vagus nerve. If this sensation becomes uncomfortable, you should contact your doctor as soon as possible. Your doctor may require you to visit the clinic to adjust the programming based on your comfort level.

Suspending Therapy

If you and your doctor determine it is necessary to temporarily pause receiving doses, visit the clinic to have your automatic treatment suspended or subsequently resumed.

Charger

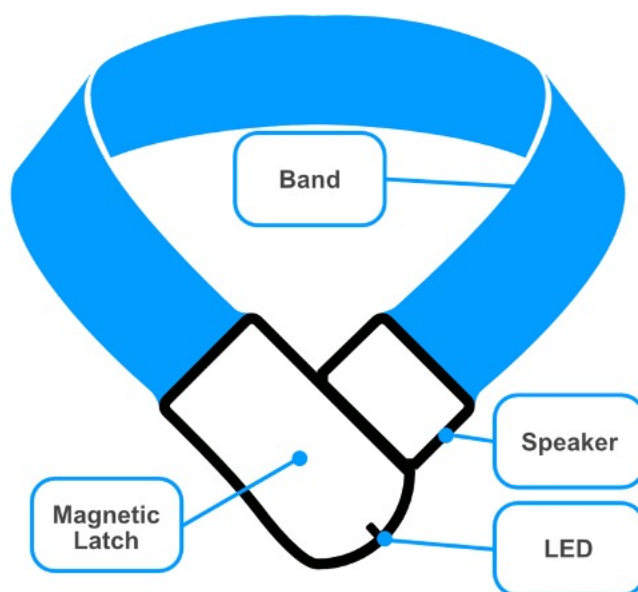


Figure 3 – The Charger

The Charger is a device worn around your neck. It is used for charging your Implant at home and for programming the Implant at the clinic. It is recommended to be worn once a week to charge the Implant.

The Charger is about 24 in (61 cm) long and 1.5 in (3.8 cm) wide, when unlatched and laid flat, and weighs about 9 oz (270 g). The Charger does not have any buttons or switches, but it does have an LED and a speaker.

The Charger only comes in one size that is meant to fit most people, forming a circular ring about 21 in (53 cm) in circumference when latched. Before the implant procedure, your doctor will perform a fit and tolerability test. This makes sure it fits comfortably around your neck and that the magnetic latch closes.



Docking Station

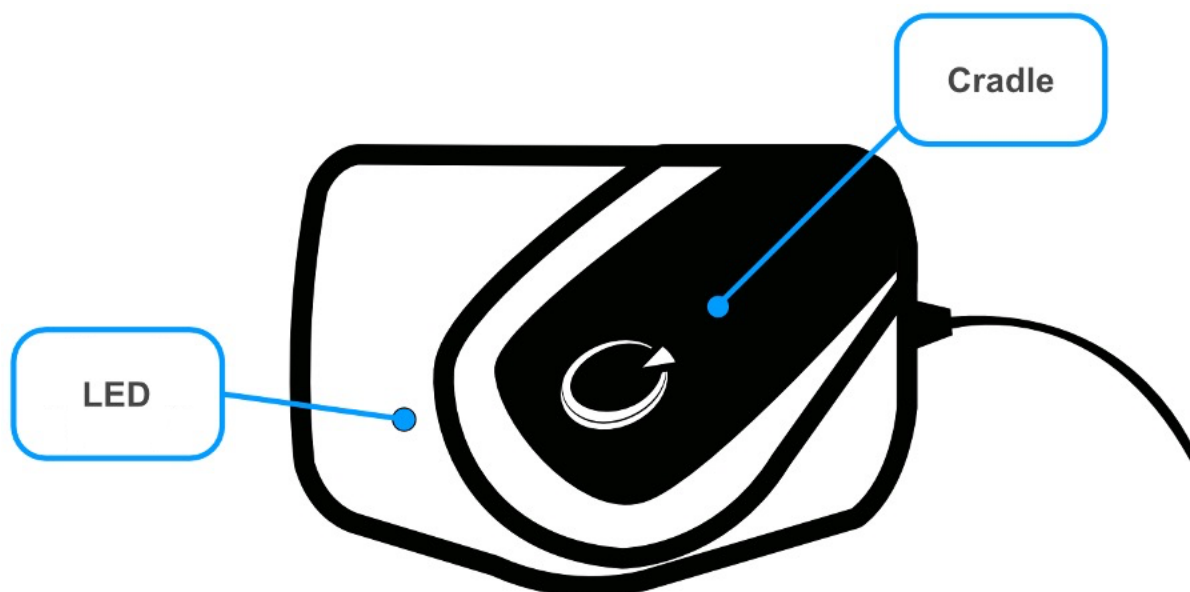


Figure 4 – The Docking Station

The Docking Station is provided with the Charger. The Docking Station is for charging and storing the Charger. Only the Docking Station provided in the Carrying Case should be used to charge the Charger. Use of any other wireless power supply may damage the Charger, the wireless power supply, or both.

The Docking Station is about 4.5 in (11.4 cm) wide, 3 in (7.6 cm) deep, and 2 in (5.0 cm) tall, and weighs about 10 oz (290 g). The Docking Station does not have any buttons or switches, but it does have an LED. The Docking Station has a cradle for placing the Charger on and a power cord that must be plugged into an electrical outlet. The Docking Station cannot be serviced at home. The Docking Station is meant to be used indoors and should always stay plugged in at home.

Programmer

Programmer is an app installed on an Apple iPad® that is only used by a trained healthcare professional. They use it with the Charger to program the Implant or to turn off or resume stimulation, if necessary. Additionally, it gives the healthcare professional information about the use of the Implant and Charger, such as how many doses have been delivered or missed, and Implant battery charge levels.

Patient Identification (ID) Card

The Patient ID Card, shown in Figure 5, is completed by your healthcare professional and given to you following surgery. This card serves as proof of an implanted medical device within your body. It is important to always have your Patient ID Card on hand and present it during security screenings, such as at airports. Additionally, the QR code on the card provides access to critical information regarding your Implant, which is necessary to ensure that any treatments are compatible with it. Always present the Patient ID card to healthcare professionals, dentists, or estheticians before pursuing any additional medical, medical imaging or beauty treatments. Neglecting to inform these professionals about the Implant may cause harm to the SetPoint System and/or may lead to complications with the treatment. If you change doctors, or lose your card, contact SetPoint Medical for a replacement card.

<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  </div> <div>PRODUCT NAME</div> </div> <p>Patient ID Card It is important to keep this card with you at all times.</p> <div style="display: flex; align-items: center; margin-top: 10px;">  <p>This individual is implanted with a vagus nerve stimulation device, which is MR Conditional.</p> </div> <p>Please refer to https://spm.care/A2rL34z or scan the QR Code for up-to-date information regarding MR Conditional labeling, operational instructions for this device and manufacturing contact information.</p> <div style="text-align: center; margin-top: 10px;">  https://spm.care/A2rL34z </div> <div style="margin-top: 20px;"> <div style="border: 1px solid #ccc; padding: 5px; display: inline-block; width: 80%;"> Patient Name </div> </div>	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <small>Please register your vagus nerve stimulation device at https://spm.care/Wa92aM7</small> </div> <div style="width: 80%;"> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;">Physician Name</div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;">Physician Phone #</div> <div style="border: 1px solid #ccc; padding: 5px;">Procedure Date</div> </div> </div> <div style="margin-top: 10px;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <small>Physician Contact</small>  <p>SetPoint Medical +1 661-750-6140 25101 Rye Canyon Loop Valencia, CA 91355 USA</p> </div> <div style="width: 50%;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px;"># M01</div> <div style="border: 1px solid #ccc; padding: 2px;">SN XXXXXX</div> <div style="border: 1px solid #ccc; padding: 2px;">UDI</div> <div style="border: 1px solid #ccc; padding: 2px;">UDI Data Matrix Placeholder</div> </div> </div> </div> </div>
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Figure 5 – Sample Patient ID Card (Front and Back)



Important Safety Information

Read all instructions, warnings and cautions carefully. If you have any questions consult with your doctor. If you do not follow these guidelines, your SetPoint System could get damaged, not work correctly, and/or result in harm.

Contraindications

There are certain situations in which the SetPoint System should not be used because the risk(s) are greater than the potential benefit(s).

You should not use the SetPoint System:

- If you have had certain health procedures that would interfere with how the device works, for example,
 - If you have had surgery to remove the vagus nerve (vagotomy).
 - If you have had your spleen removed (splenectomy).
- If your doctor determines that it might not be safe for you to have the surgery, for example,
 - If you have spine disease in your neck that makes it risky to place a breathing tube (intubate).
 - If you cannot be safely given anesthesia for surgery.
- If you cannot safely use SetPoint Charger, for example,
 - If your neck is too large to wear SetPoint Charger.
 - If you have a pacemaker or a defibrillator implanted.

Warnings & Precautions

It is important to use the SetPoint System safely to avoid injury or damage to the SetPoint System or other devices. Here are some key safety tips:

- Always present the Patient ID card to healthcare professionals, dentists, or estheticians before pursuing any additional medical, medical imaging or beauty treatments. If you do not, the treatment may cause harm to the SetPoint System and/or may lead to complications with the procedure.
- Do not scuba dive or enter a hyperbaric chamber after receiving the Implant. The safety of high pressure has not been established and these conditions could damage the device.
- Do not use the SetPoint Charger while it is covered (e.g., with a scarf or similar material), in direct sunlight, or in air temperatures exceeding 90 °F (32 °C). If you do, it may cause the Charger to overheat rapidly and shut down prematurely.
- Do not continue to use the SetPoint Charger or Docking Station beyond their expected service life (5 years for the Charger and 10 years for the Implant). If you do, it can lead to additional risks associated with deterioration of the device over time. Signs of performance degradation include incomplete Implant charging during the weekly session.
- Do not use third-party wireless chargers with the SetPoint Charger or try to charge other devices with the SetPoint Docking Station. Using incompatible accessories with the SetPoint System could lead to device damage or malfunction.
- Do not position the SetPoint Charger around the neck if there are any unhealed wounds. If you do, it increases the risk of infection.
- Do not apply excessive force or rough handling to the SetPoint Charger. If you do, it may damage its internal electrical components, potentially causing malfunction.
- Do not use any cleaning product other than isopropyl alcohol (IPA) wipes to clean the SetPoint Charger. If you do, it could damage the Charger or leave behind harmful or irritating residues.

- Do adhere to local e-waste regulations when disposing of any part of the SetPoint System. If you do not, it can result in environmental contamination with hazardous substances.
- Do not modify or tamper with the SetPoint Charger or Docking Station. If you do, it could alter their function or bypass safety features and result in harm.

Medical Imaging Warnings

There are various types of medical imaging technologies in common use. Although X-rays, computed tomography (CT), ultrasound imaging (sonography), positron emission tomography (PET) are all safe to perform after you receive your Implant, it is vital that you always show your Patient ID card to any healthcare professional performing these procedures. Specifically for magnetic resonance imaging (MRI), although you can have scans 2 weeks after implantation, they can only be performed under certain conditions as outlined in **SetPoint System Magnetic Resonance Imaging (MRI) Safety Information Manual**. This is referred to as MR Conditional and must be discussed with your MRI technician.



Figure 6 - MR Conditional

The SetPoint Charger and SetPoint Docking Station should never be brought near MRI machines because they are not safe for use in that environment. This is referred to as MR Unsafe.



Figure 7 - MR Unsafe

Medical Procedure Warnings

Use caution with any medical procedure that introduces electrical current, electromagnetic radiation, or thermal energy into tissues in the neck area. The Implant may absorb, intensify, or reflect these energy sources, resulting in localized heating that could damage the device or nearby nerves and vascular structures. This damage may result in pain or discomfort, loss of vocal cord function, or even possibly life-threatening injury if there is damage to blood vessels. Note that these risks are present whether the Implant is active or suspended. It is vital that you always show your Patient ID card to any healthcare professional performing these procedures so that they can carefully evaluate potential interactions and risks. Before proceeding with any procedure that delivers energy to the tissues surrounding the Implant, they should consider alternatives that avoid energy transfer. Specific examples of higher risk procedures around the implantation site that need to be avoided because they could damage the Implant, cause it to malfunction, and/or result in harm including severe injury:

- Shortwave diathermy, microwave diathermy, ultrasound diathermy or other procedures that induce heat in internal tissues. This does not include diagnostic ultrasound which is permitted.
- Electrosurgery/electrocautery, and ablation techniques that utilize any form of electromagnetic radiation or electrical current to cut, coagulate, or thermally destroy tissues. For electrocautery, do not use within 2 cm of the Implant. If using monopolar electrocautery, place the return pad such that the current path is not across the Implant.
- Transcutaneous electrical nerve stimulation (TENS), electroconvulsive therapy or other procedures that apply electrical current through skin surface electrodes.
- Extracorporeal shock wave lithotripsy or other procedures that use pressure waves or induce mechanical forces to break up internal structures.

- Radiation therapy, including forms of photon beam radiation therapy such as x-rays, gamma rays, proton beam therapy, brachytherapy, stereotactic radiosurgery, cobalt machines, and linear accelerators.

Radio Frequency (RF) Warnings

The SetPoint System uses radio frequency (RF) fields for communication between different parts of the system or when charging the Implant or Charger. These RF fields could disrupt the functioning of similar frequency-utilizing devices. Do not use the Charger for charging the Implant near devices sensitive to RF interference, while travelling in vehicles such as cars, trains, boats, airplanes, or during any medical treatments, or in proximity to other medical devices. The SetPoint System has not been tested with, and may affect the operation of, other implanted devices, such as cardiac pacemakers and implanted defibrillators. Possible effects include, but are not limited to, sensing problems and inappropriate device responses. The RF signals from the Charger could theoretically interfere with or be concentrated by other implanted devices such as neural stimulators or insulin pumps.

The Charger and Docking Station are vulnerable to electromagnetic interference from devices that emit RF fields, like cellphones and security scanners. Portable RF communications equipment (including peripherals such as antenna cables and external antennas), RFID scanners and card readers (including animal identification tag scanners) should be used no closer than 12 inches (30 cm) to any part of the Charger and Docking Station. Otherwise, degradation of the performance of this equipment could result. If it is suspected that the Charger or Docking Station are not functioning correctly due to electromagnetic interference, try changing your location, waiting until a later time, or turning off the suspected source of interference if possible. Use of the Charger or Docking Station adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Charger and Docking Station should be observed to verify they are operating normally.

The Charger and Docking Station are intended for use indoors, for example in the home or clinic. They should not be used in environments where the intensity of electromagnetic disturbances is known to be high, such as near high-frequency surgical equipment or radio transmitters. They should also not be used in any environment with a posted FCC Notice, Caution or Warning sign indicating the presence of high-intensity radio frequency (RF) fields that surpass normal public exposure limits. These areas are typically indicated by restricted environment signs like those in Figure 8. After receiving the implant, do not enter these areas without seeking medical guidance first. Exposure to high levels of RF could cause the Implant to malfunction or lead to tissue damage in the vicinity of the device.



Figure 8 - Restricted Environment Signage



Other Help Using Your SetPoint System

In addition to reading this guide, you can watch the training video by clicking this [link](#) or scanning the QR Code in Figure 9 or by looking at the **Patient Quick Reference Guide** for help on how to use your SetPoint System. If you still need more training, you can ask your doctor.



Figure 9 – Scan to Watch Training Video



Using Your SetPoint System

The table below shows the conditions for transport, storage, and use of the Charger and Docking Station.

Use	Temperature	Humidity	Altitude
Transport: In Carrying Case	50 to 104 °F (10 to 40 °C)	15 to 93 %RH	Up to 98,425 ft (30,000 m)
Storage: Charger on Docking Station			Up to 9,843 ft (3,000 m)
Use: Charging the Implant	50 to 90 °F (10 to 32 °C)		

Table 2 – Transport, Storage, and Use Conditions

⚠ Warning: Do not scuba dive or enter a hyperbaric chamber after receiving the Implant. The safety of high pressure has not been established and these conditions could damage the device.

⚠ Warning: Do not use the SetPoint Charger while it is covered (e.g., with a scarf or similar material), in direct sunlight, or in air temperatures exceeding 90 °F (32 °C). If you do, it may cause the Charger to overheat rapidly and shut down prematurely.

The Charger normally heats up during use, potentially reaching up to 118 °F (48 °C). To prevent overheating and premature shutdown, the Charger needs to be at or below 90 °F (32 °C) before being used to charge the Implant. If the Charger has been stored above 90 °F (32 °C), it must be allowed to cool down to this temperature, which can take up to 10 minutes.

⚠ Warning: Do not continue to use the SetPoint Charger or Docking Station beyond their expected service life (5 years for the Charger and 10 years for the Implant). If you do, it can lead to additional risks associated with deterioration of the device over time. Signs of performance degradation include incomplete Implant charging during the weekly session.

The rechargeable battery in the Charger is rated to last for at least 5 years. If you cannot complete the weekly Implant charging session with a fully charged Charger, the entire Charger may need to be replaced as its battery cannot be replaced or serviced at home. Contact your doctor if you believe there are any issues with your Charger.

The rechargeable battery in the Implant is rated to last for at least 10 years. The Implant may need to be replaced if it can no longer deliver daily stimulation as the Implant's battery cannot be replaced. Your doctor will be able to determine this by looking at information provided by the Programmer during a clinic visit. Contact your doctor if you believe there are any issues with your Implant.

Unpacking and Setting Up Your Charger and Docking Station

Your Charger and Docking Station will be provided to you in a Carrying Case. This Carrying Case should be used whenever you are transporting the Charger. When not being transported, your Charger and Docking Station should be unpacked from the Carrying Case, the Docking Station should be plugged into an electrical outlet, and the Charger should be placed on the Docking Station.



Figure 10 – Unpacking Charger and Docking Station

1. Place your Carrying Case on a flat surface with the logo on top and the handle facing away from you.
2. Unzip the Carrying Case and flip the top open.
3. Remove your Charger from the Carrying Case and set it aside.
4. Remove your Docking Station from the Carrying Case.
5. Uncoil the power cord and plug your Docking Station into an electrical outlet.
6. Place your Docking Station on a flat surface, like a dresser, with enough room to accommodate the Charger once placed on the Docking Station and where you can ensure that the Docking Station is at least 8 in (20 cm) away from you during use.
7. Confirm that your Docking Station has a **solid pink** LED before placing the Charger on the Docking Station. If the LED is not showing a **solid pink** light, see **Appendix D – Troubleshooting**.

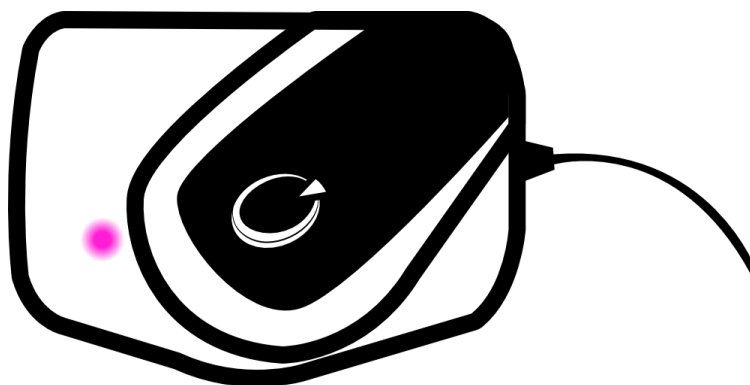


Figure 11 – The Docking Station shows a **pink** LED when it is plugged in, but not charging the Charger.

Charging Your Charger

⚠ Warning: Do not use third-party wireless chargers with the SetPoint Charger or try to charge other devices with the SetPoint Docking Station. Using incompatible accessories with the SetPoint System could lead to device damage or malfunction.

Your Charger should be placed on the Docking Station whenever it is not being transported or used to charge your Implant (whenever you are not wearing it).

1. Place your Charger on the Docking Station's cradle as shown, making sure that the latch is closed. The Charger must be latched while charging.

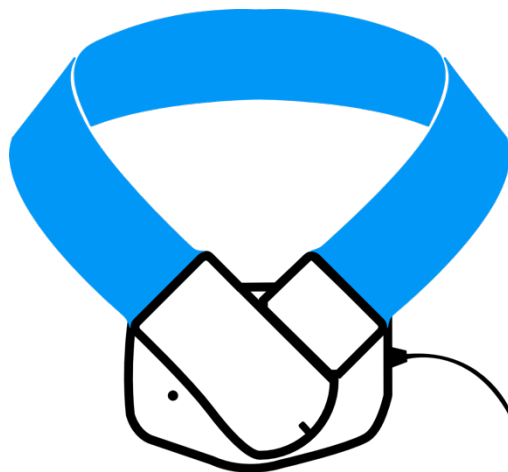
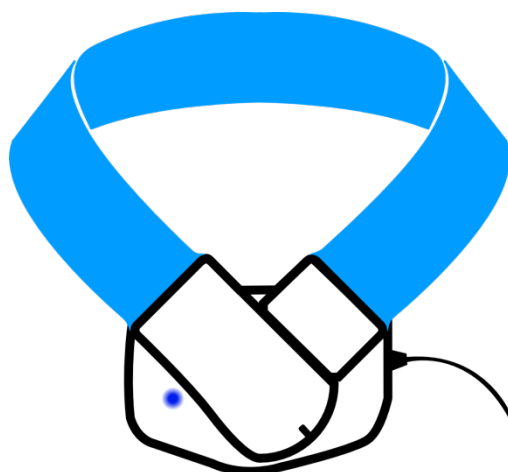


Figure 12 – The Charger must be latched closed when placed on the Docking Station's cradle.

2. The Docking Station's LED will begin **blinking blue** to show that it is charging. Once the Charger is fully charged, the Docking Station's LED will display **solid blue**. If the Docking Station does not show a **blinking** or **solid blue** LED, see **Appendix D – Troubleshooting**.



*Figure 13 – The Docking Station's LED **blinks blue** when charging or shows **solid blue** when charging is complete.*

3. While the Charger is placed on the Docking Station's cradle, tapping on the Charger logo will show its battery level. If the Charger's LED shows **solid green**, it is fully charged. If the Charger LED shows **blinking green**, it has enough charge to charge the Implant. If the Charger LED shows **blinking orange**, it is charging but not ready yet to charge the Implant.



Figure 14 – Tapping on the Charger while it is on the Docking Station will show its battery level.

Even if the Charger is done charging, there is no need to take it off the Docking Station. Leaving the Charger on the Docking Station ensures that it is always fully charged.

Before visiting the clinic or charging your Implant, you should make sure that your Charger has a full charge by tapping on the Charger logo while it is on the Docking Station and looking for a **solid green** LED.

Charging Your Implant

SetPoint Medical recommends that you charge your Implant each week using your Charger.

⚠ Warning: Do not position the SetPoint Charger around the neck if there are any unhealed wounds. If you do, it increases the risk of infection.

The Charger is only to be placed on skin without cuts or wounds. If the Charger needs to be used on an open wound, the wound should be covered in sterile gauze or bandage first.

For ease of use, the Charger has both an LED and a speaker for showing charge status. If needed, you can use a mirror to look at the Charger LED.

1. Tap on your Charger logo while it is on the Docking Station and look for a **green** LED. If the LED is **orange**, leave the Charger on the Docking Station until it turns **green**.
2. Remove your Charger from the Docking Station.
3. Unlatch your Charger by pulling or twisting the two halves of the magnetic latch apart. Do not touch the pins on the inside of the magnetic latch.
4. Carefully lift your Charger over your head or bring it around your neck. The magnetic latch should rest on the front of your neck with the SetPoint logo half on the right side.
5. Take both halves of the magnetic latch and press them together. The magnets in the Charger should snap into place and latch easily. If the Charger is hard to latch, it is likely twisted or upside down. You might need to use a mirror to see better or ask someone to help if it is tricky.
6. Make sure the latch is securely closed so your Charger will not fall off. Adjust it so it sits comfortably on your neck.

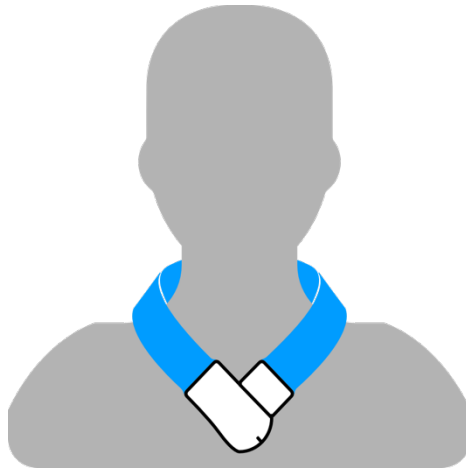


Figure 15 – The Charger should rest comfortably around your neck as shown.

7. The Charger's LED will begin to **slowly pulse white** while it is trying to connect to your Implant. Once it has connected to your Implant, the Charger will play **two beeps that go up in tone**. If at any time after connecting it plays **two beeps that go down in tone**, it means the Charger has lost connection with your Implant.
8. The Charger will play **three beeps that go up in tone** when it begins charging the Implant and will then show an **orange** or **green** LED.
9. It is recommended that you charge your Implant for approximately 5 minutes each week or until the battery is full, whichever comes first. The Charger's LED shows **solid green** and plays **four beeps (three beeps that go up in tone and a fourth beep that is a repeat of the last tone)** when your Implant battery is full. After your Implant has reached full charge, the beeps will repeat every 30 seconds until you take your Charger off.
10. Once charging is completed, unlatch your Charger and remove it from your neck.
11. Latch your Charger and place it back on the Docking Station.

Following a Routine

Creating a routine can make it easier to remember when to charge your Charger and Implant. SetPoint Medical recommends the following routines:

1. You should wear your Charger to charge your Implant for about 5 minutes on the same day each week. For example, you may choose to charge your Implant every Sunday morning or right before going to bed every Saturday night. Less frequent charging may require longer time to fully charge the Implant.
2. When you are not wearing your Charger, it should be placed on your Docking Station. This makes sure that the Charger always has a full charge when you need it for charging the Implant or for a clinic visit.

Traveling With and Packing Your Charger and Docking Station

⚠ Warning: Do not apply excessive force or rough handling to the SetPoint Charger. If you do, it may damage its internal electrical components, potentially causing malfunction.

When at home, it is important to follow the recommended routine outlined above to maintain your devices' batteries. When traveling, you should consult with your doctor on what equipment you should take with you depending on the length of your trip. If you need to bring your Charger or Docking Station, always use your Carrying Case.



You should bring your Charger to your rheumatologist visit as it may be needed to adjust the programming on your Implant. If you are planning a long trip that requires your Docking Station, bring a standard plug adapter if traveling internationally. Please contact your doctor if any issues arise during travel.

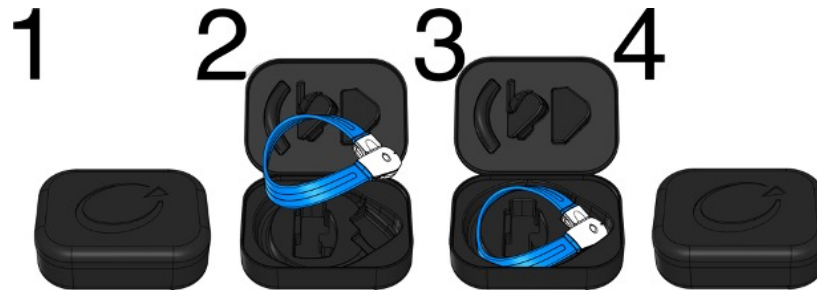


Figure 16 – Packing the Charger in the Carrying Case

1. Place your Carrying Case on a flat surface with the logo on top and the handle facing away.
2. Unzip your Carrying Case and flip the top open.
3. Place your latched Charger in the Carrying Case.
4. Zip your Carrying Case shut.

The Charger cannot be turned off, but it switches to low power mode by itself after about 1 minute of inactivity. Opening or closing the Charger or removing the Charger from the Docking Station will wake it up, and it will begin looking for an Implant.

Pack your Carrying Case in your carry-on luggage when traveling in an airplane. Provide your Patient ID card to security personnel when going through airport security if they have any questions or concerns about your SetPoint System. See <https://www.tsa.gov> for more information about traveling with medical equipment.

Cleaning

⚠ Warning: Do not use any cleaning product other than isopropyl alcohol (IPA) wipes to clean the SetPoint Charger. If you do, it could damage the Charger or leave behind harmful or irritating residues.

- Use a dry, lint-free cloth to clean your Charger avoiding the magnetic latch.
- If needed, use isopropyl alcohol (IPA) wipes to clean lotion and oils off your Charger and to clean the magnetic latch area.
- Never spray your Charger with any substance or put it in any liquid.
- Keep lint and dirt out of your Charger's magnetic latch area.

Replacement and Disposal

⚠ Warning: Do adhere to local e-waste regulations when disposing of any part of the SetPoint System. If you do not, it can result in environmental contamination with hazardous substances.

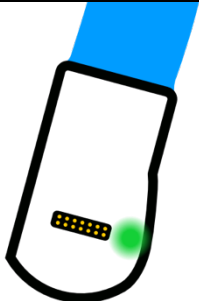
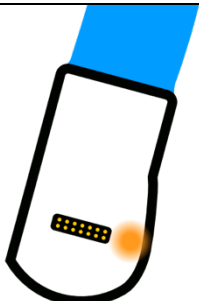
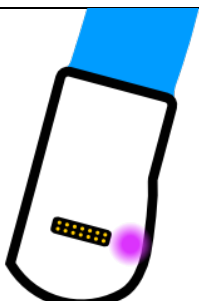
To reorder the Charger or Docking Station, contact your doctor. You may need to return the old Charger and Docking Station to your doctor, but if instructed to dispose of it please follow local e-waste regulations.



Appendix A - Charger LED Status

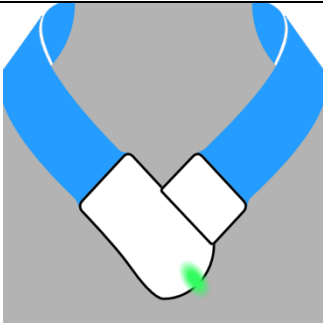
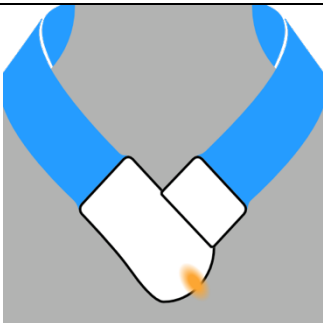
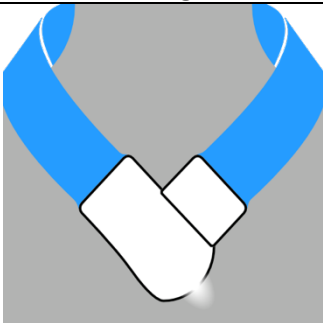
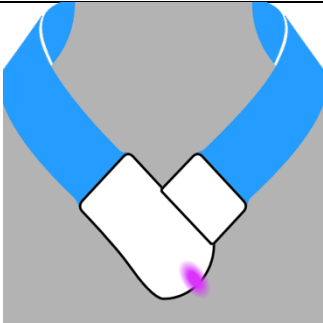
The LED on the Charger will show different things based on how it is being used.

While Unlatched

LED Color	Status
 <p>Green</p>	<p>Solid: The Charger has enough charge to charge the Implant.</p>
 <p>Orange</p>	<p>Solid: The Charger does not have enough charge to charge the Implant.</p> <p>Blink: The Charger needs to be charged before it can be used, or it will turn off.</p>
 <p>Pink</p>	<p>Slow Blink: This is a warning. The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight.</p> <p>Rapid Blink: The Charger has an error that cannot be fixed. Stop using it and call your doctor.</p>

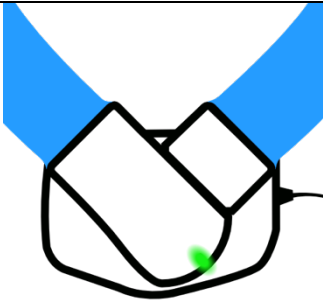
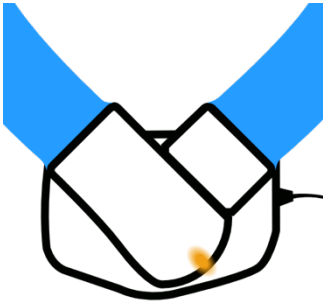
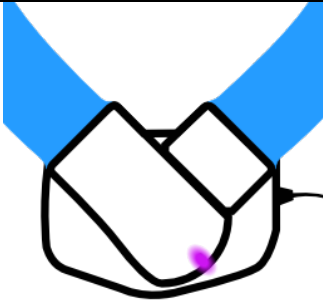


While Being Worn

LED Color	Status
 Green	<p>Solid: The Implant is fully charged.</p> <p>Blink: The Implant has enough charge.</p>
 Orange	<p>Solid: The Implant is not fully charged and has not started charging yet.</p> <p>Blink: The Implant is charging but is not full yet.</p>
 White	<p>Slow Pulse: The Charger is trying to connect to your Implant.</p> <p>Rapid Blink: The Implant is delivering a dose and charging will start once it is complete.</p>
 Pink	<p>Solid: The Implant is suspended and will not deliver doses.</p> <p>Slow Blink: This is a warning.</p> <ul style="list-style-type: none"> • The band of the Charger might be twisted or bent. Make sure to wear it correctly. • The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. • There might be dirt or lint on the Charger's magnetic latch. Look at the Cleaning section in the guide for how to clean the latch. <p>Rapid Blink: The Charger has an error that cannot be fixed. Stop using it and call your doctor.</p>



While on the Docking Station

LED Color	Status
 <p>Green</p>	<p>Solid: The Charger is fully charged.</p> <p>Blink: The Charger has enough charge to charge the Implant.</p>
 <p>Orange</p>	<p>Blink: The Charger is charging, but not full enough to charge the Implant.</p>
 <p>Pink</p>	<p>Slow Blink: This is a warning.</p> <ul style="list-style-type: none"> • The Charger may not be closed properly. The Charger cannot charge if it is not latched. • The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. <p>Rapid Blink: The Charger has an error that cannot be fixed. Stop using it and call your doctor.</p>


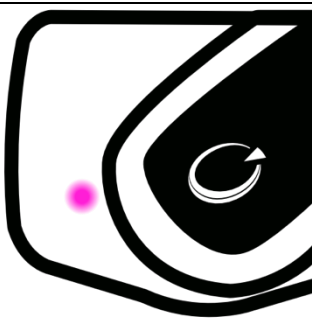
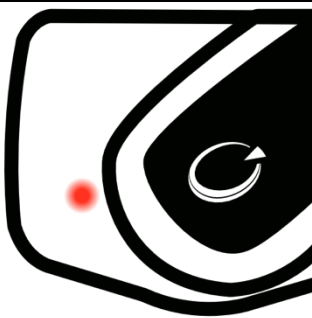


Appendix B – Charger Speaker Status

Sound Pattern	Status
Two Beeps That Go <i>Up</i> in Tone	The Charger is now connected to your Implant.
Two Beeps That Go <i>Down</i> in Tone	The Charger has lost its connection with your Implant.
Repeating Beep	The connection between the Charger and your Implant is not strong enough to start charging.
Three Beeps That Go <i>Up</i> in Tone	The Implant has started charging.
Four Beeps, Three Beeps That Go <i>Up</i> in Tone and a Fourth Beep That is a Repeat of the Last Tone	The Implant has finished charging.



Appendix C – Docking Station LED Status

LED Color	Indicator Status
 Blue	<p>Solid: The Charger is fully charged.</p> <p>Blink: The Charger is charging.</p>
 Pink	<p>Solid: The Docking Station is ready for use, but the Charger is not charging.</p>
 Red	<p>Blink: The Docking Station has an error.</p> <ul style="list-style-type: none"> • Remove the Charger from the Docking Station. • Check that there are no metal objects on or around the Docking Station. • Place the Charger on the Docking Station again. • Check that the Charger is closed. <p>If the error continues, stop using the Docking Station, and contact your doctor.</p>



Appendix D – Troubleshooting

Docking Station











Event	Cause and Resolution
The Docking Station does not show a pink LED when plugged in.	The Docking Station is not getting power. Check if the outlet it is plugged into is working (it is turned on, the GFI is not tripped, and the wall switch is on). If the outlet is fine but the problem continues, contact your doctor.
The Docking Station is blinking red on its LED.	<p>This is a warning.</p> <ul style="list-style-type: none"> • Check that the Charger is closed. • Check that there are no metal objects on or around the Docking Station. The Docking Station cannot charge if there are metal objects present. • The Charger and/or Docking Station might be too hot and cannot charge. Make sure to keep them in a cool place and away from direct sunlight. • Take off the Charger for a few seconds, then put it back on the Docking Station cradle. Sometimes, if it wasn't placed or seated correctly, it can stop the Charger and Docking Station from charging. <p>If the error continues, stop using the Docking Station, and contact your doctor.</p>
The Docking Station shows a pink LED when the Charger is placed on it.	If this persists and the LED never turns blue , the connection between the Charger and your Docking Station cannot be established. This could be caused by electromagnetic interference. Try changing your location, waiting until a later time, or turning off the suspected source of interference if possible. If using portable RF communications equipment, make sure they are no closer than 12 inches (30 cm) to any part of the Charger or Docking Station.
















Charger


Event	Cause and Resolution
The Charger is slowly blinking pink on its LED.	<p>This is a warning.</p> <ul style="list-style-type: none"> The Charger may not be closed properly. The Charger cannot charge if it is not latched. The Charger might be too hot. Make sure to keep it in a cool place and away from direct sunlight. The band of the Charger might be twisted or bent. Make sure to wear it correctly. There might be dirt or lint on the Charger's latch. Look at the Cleaning section in the guide for how to clean the latch. <p>If the Charger continues to slowly blink pink, contact your doctor.</p>
The Charger is rapidly blinking pink on its LED.	The Charger has an error that cannot be fixed. Stop using it and call your doctor.
The Charger shows a solid pink LED.	The Implant is suspended and will not deliver doses. Contact your doctor to restart therapy.
The Charger sounds a repeated beeping tone when worn.	<p>The connection between the Charger and your Implant is not strong enough to start charging. The band of the Charger might be twisted or bent. Make sure to wear it correctly.</p> <p>If the Charger continues the repeated beeping pattern, contact your doctor.</p>
The Charger slowly pulses white on its LED when worn.	If this persists and the connection beeps never play, the connection between the Charger and your Implant cannot be established. This could be caused by electromagnetic interference. Try changing your location, waiting until a later time, or turning off the suspected source of interference if possible. If using portable RF communications equipment, make sure they are no closer than 12 inches (30 cm) to any part of the Charger.

Appendix E – Explanation of Symbols Used on Packaging and Devices

Symbol	Title	Reference	Description
21 CFR 801.109: Prescription Devices			
	Prescription Only	(b) (1)	Caution: Federal law restricts this device to sale by or on the order of a physician
47 CFR 2.1074: Identification			
	FCC Declaration of Conformity	(b)	The product complies with the applicable FCC requirements
ASTM F2503			
	Magnetic Resonance (MR) Conditional	Fig. 5	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields
	Magnetic Resonance (MR) Unsafe	Fig. 9	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment
WEEE Directive 2012/19/EU			
	Symbol for the marking of EEE	Annex IX	Separate collection for electrical and electronic equipment
IEC 60417			
	Non-ionizing Electromagnetic Radiation	5140	To indicate elevated, potentially dangerous, levels of non-ionizing radiation
	Class II Equipment	5172	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	For Indoor Use Only	5957	To identify electrical equipment designed primarily for indoor use
IEC 60529			
IP21	Degree of Protection	N/A	Protected against solid foreign objects of 0.5 in (12.5 mm) Ø and greater; Protection against vertically falling water drops.
IP22	Degree of Protection	N/A	Protected against solid foreign objects of 0.5 in (12.5 mm) Ø and greater; Protection against vertically falling water drops when enclosure is tilted up to 15°.
International Efficiency Marking Protocol for External Power Supplies			
	International Efficiency Marking Level VI	N/A	Mark indicating EPS meets the level VI requirements at both 115 V/60 Hz and 230 V/50 Hz
ISO 15223-1: 5.1. Manufacture			
	Manufacturer	5.1.1	Indicates the medical device manufacturer

	Date of Manufacture	5.1.3	Indicates the date when the medical device was manufactured
	Use-By Date	5.1.4	Indicates the date after which the medical device is not to be used
	Catalog Number	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified
	Serial Number	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Model Number	5.1.10	Indicates the model number or type number of a product
ISO 15223-1: 5.2. Sterility			
	Do Not Use If Package Is Damaged and Consult Instructions for Use	5.2.8	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
ISO 15223-1: 5.3. Storage			
	Temperature Limit	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity Limitation	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed
	Atmospheric Pressure Limitation	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
ISO 15223-1: 5.7. Others			
	Unique Device Identifier	5.7.10	Indicates a carrier that contains unique device identifier information
ISO 7010			
	Refer to Instruction manual/booklet	M002	To signify that the instruction manual/booklet must be read
	General Warning Sign	W001	To signify a general warning
UL Solutions Marks and Label Hub			
	UL Recognized Component Mark for US and Canada	N/A	Tested and certified in accordance with applicable US and Canadian electrical safety and performance standards
Electrical Appliances and Materials Safety Act			



	TÜV SÜD PSE Diamond Mark	N/A	Tested and certified in accordance with applicable Japanese electrical safety and performance standards for Specified Electrical Appliances and Materials
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Applicable Standards and Regulations

21 CFR 801 Medical Devices – Labeling

47 CFR 2 Frequency Allocations and Radio Treaty Matters: General Rules and Regulations – Equipment Authorization Procedures

ASTM F2503 – 23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Electrical Appliances and Materials Safety Act Statutory Operations and Implementation Guide (ver. 4.0)

IEC 60417:2024 Graphical Symbols for use on Equipment

IEC 60529:1989/AMS2:2013/COR1:2019 Degrees of protection provided by enclosures (IP Code)

International Efficiency Marking Protocol for External Power Supplies Version 3.0, September 2013

ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

ISO 7010:2019 Graphical symbols – Safety colors and safety signs – Registered safety signs



Appendix F – SetPoint System Technical Description

Implant

Power Source

The Implant is internally powered by a rechargeable battery.

Characteristic	Value
Type	Secondary (Rechargeable)
Chemistry	Lithium-ion (Li-ion)
Form Factor	Cylindrical
Voltage	4.0 V (Nominal)
Capacity	3.0 mAh
Safety Features	Zero-Volt Technology

Table 3 – Implant Battery Characteristics

The rechargeable battery is rated to last for 10 years, and this duration is not impacted by any Implant settings, (e.g., the strength or timing of stimulation).

Charger

⚠ Warning: Do not modify or tamper with the SetPoint Charger. If you do, it could alter its function or bypass safety features and result in harm.

Classification

Per IEC 60601-1, the Charger does not meet the definition of an Applied Part, only of an Accessible Part. Per clause 4.6, and per risk assessment, it was, however, tested to the more rigorous Applied Part requirements. The table below shows the relevant technical classifications for the Charger per IEC 60601-1 and collateral standards.

Classification	Value
Accessibility	Type BF, Applied Part
Power Source	Internally Powered
Mode of Operation	Continuous
Operating Environment	Home Healthcare
Transportability	Body-Worn
Transit Operability	Transit-Operable
Ingress Protection	IP22

Table 4 – Charger As-Tested Classifications

Per IEC 60601-1, the user is classified as a Patient only while the Charger is latched around their neck, and as an intended Operator while placing or removing the Charger around their neck or onto or from the Docking Station.

Power Source

The Charger is internally powered by a non-replaceable, rechargeable battery.

Characteristic	Value
Type	Secondary (Rechargeable)
Chemistry	Lithium-ion (Li-ion)
Form Factor	Pouch

Voltage	3.7 V (Nominal)
Capacity	1.0 Ah
Safety Features	Over Charge, Over Discharge, and Over Current Detection

Table 5 – Charger Battery Characteristics

On a full charge, the rechargeable battery can power the Charger for 20 to 60 minutes depending on the placement of the Charger around the neck and how optimally it is communicating with the Implant. The rechargeable battery is rated to last for 5 years, and this duration is not impacted by how the Charger is used.

Radios

The Charger contains a Bluetooth Low Energy (BLE) radio receiver that receives RF electromagnetic energy in the frequency range 2.400 GHz to 2.4835 GHz. The Charger also contains two radios, one BLE and one inductive, that transmit electromagnetic energy as follows:

Characteristic	Value	
	BLE Radio	Inductive Radio
Frequency Range	2.400 GHz – 2.4835 GHz	127.6 kHz – 134.4 kHz
Modulation Type	GFSK, 1Mbps	AM 2400 bps
EIRP	2.5 mW (+4 dBm)	Not Defined, Total Power ≤ 6 W

Table 6 - Radio Transmit Details

Product Markings

All Charger product markings are contained on the Charger label shown below (artwork shown is for reference only).

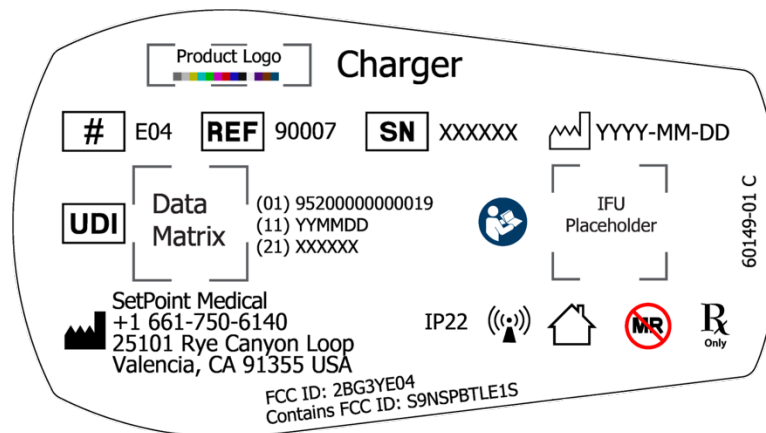


Figure 17 – Charger Label

Docking Station

Warning: Do not modify or tamper with the SetPoint Docking Station. If you do, it could alter its function or bypass safety features and result in harm.

Classification

The table below shows the relevant technical classifications for the Docking Station per IEC 60601-1 and collateral standards.



Classification	Value
Accessibility	Accessible Part
Power Source	Externally Powered Class II
Mode of Operation	Continuous
Operating Environment	Home Healthcare
Transportability	Portable
Transit Operability	Non-Transit-Operable
Ingress Protection	IP21

Table 7 – Docking Station Classifications

Per IEC 60601-1, the user is classified as an intended Operator while placing or removing the Charger onto or from the Docking Station.

Power Source

The Docking Station is externally powered through a power supply cord to a power supply with a mains-plug that can be removed from the mains socket-outlet to provide supply mains isolation. This non-detachable power supply cord is not replaceable.

Characteristic	Value
Input Type	AC
Input Voltage	100-240 VAC
Input Frequency	50-60 Hz
Input Max Current	1.0-0.5 A
Output Type	DC
Output Voltage	5 V
Output Max Current	2.4 A

Table 8 – Docking Station Power Supply Performance Characteristics

Product Markings

All Docking Station product markings are contained on the Docking Station and power supply labels shown below (artwork shown is for reference only).

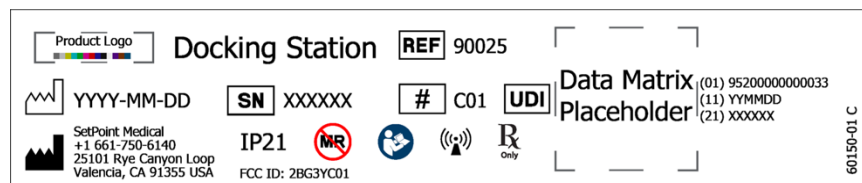


Figure 18 – Docking Station Label

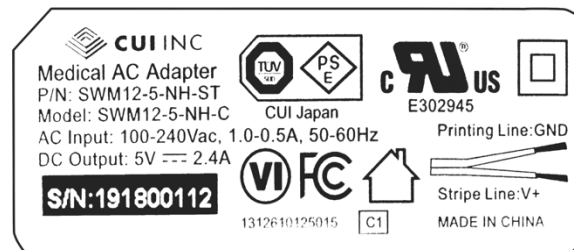


Figure 19 – Docking Station Power Supply Label



Charger and Docking Station

Emissions and Immunity Testing

The Charger and Docking Station are classified as CISPR 11 Class B Group 2 emitters. Both devices were tested with immunity test levels for use in a home healthcare environment. They were found to comply with the following immunity test standards at the specified test levels:

IEC 61000-4-2 – Charger and Docking Station Electrostatic Discharge

Device	Contact Discharge (\pm kV)	Air Discharge (\pm kV)
Charger	8	2, 4, 8, 15
Docking Station	N/A	

Table 9 - IEC 61000-4-2 Test Details

IEC 61000-4-3 – Charger and Docking Station Radiated RF EM Fields and Proximity Fields from RF Wireless Communications Equipment

- Radiated RF EM Field Exposures: 10 V/m from 80 MHz – 2.7 GHz w/80% Amplitude Modulation @1 kHz
- Proximity Field Exposures:

Test Frequency (MHz)	Modulation	Immunity Test Level (V/m)
385	Pulse, 18 Hz	27
450	Pulse, 18 Hz	28
710, 745, 780	Pulse, 217 Hz	9
810, 870, 930	Pulse, 18 Hz	28
1720, 1845, 1970, 2450	Pulse, 217 Hz	28
5240, 5500, 5785	Pulse, 217 Hz	9

Table 10 - IEC 61000-4-3 Test Details (Pulse = 50% Square Wave Duty Cycle)

IEC 61000-4-4 – Docking Station EFT/Burst

- \pm 2 kV @100 kHz Repetition Frequency

IEC 61000-4-5 – Docking Station Line to Line Surge

- \pm 0.5 kV and \pm 1 kV

IEC 61000-4-6 – Docking Station Conducted Disturbances

- 3 V_{rms} from 150 kHz – 80 MHz
- 6 V_{rms} from 150 kHz – 80MHz for ISM and Amateur Radio Bands w/80% Amplitude Modulation @1 kHz

IEC 61000-4-8 – Charger and Docking Station Rated Power Frequency Magnetic Field

- 30 A/m @60Hz

IEC 61000-4-11 – Docking Station Voltage Dip and Interruption

- 100 VAC and 240 VAC @60 Hz

Voltage Level	Duration (cycles)	Phase Angle
0% of U _t	0.5	0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°



0% of U_t	1	0°
70% of U_t	30	0°
0% of 120 V	300	0°

Table 11 - IEC 61000-4-11 Test Details ($U_t = 100\text{ V}$ or 240V)

IEC 61000-4-39 – Charger and Docking Station Proximity Magnetic Field

Test Frequency	Modulation	Immunity Test Level (A/m)
30 kHz	CW	8
134.2 kHz	Pulse, 2.1 kHz	65
13.56 MHz	Pulse, 50 kHz	7.5

Table 12 - IEC 61000-4-39 Test Details (Pulse = 50% Square Wave Duty Cycle)

FCC Compliance

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.

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 to 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.

Changes or modifications not expressly approved by SetPoint Medical could void your authority to operate the equipment.

To maintain compliance with the FCC's RF exposure guidelines, the Docking Station should be installed and operated with a minimum distance of 8 in (20 cm) between it and your body.



Appendix G – Clinical Studies Safety

Adverse Events

Adverse events are side effects, complications, or discomforts related to a procedure or treatment. This Appendix describes adverse events associated with the SetPoint system that may occur during the surgery to insert or remove the Implant or associated with stimulating the vagus nerve (referred to as vagus nerve stimulation or VNS)

Clinical Studies

The SetPoint System has been evaluated in two U.S. clinical studies enrolling 257 patients (the pilot study enrolled 15 patients and RESET-RA enrolled 242 patients). Adverse events reported by the study doctor as related to either the surgery or stimulation associated with the SetPoint System are summarized below.

At the time of FDA review for the SetPoint System, patients on average had been living with the Implant and receiving stimulation for longer than 1 year, with some patients, those enrolled in the pilot study, receiving treatment for over 5 years.

Nearly all adverse events reported during the clinical studies were mild to moderate in severity, and nearly all adverse events were considered non-serious by the study doctor (98% non-serious). No patients during the study experienced a life-threatening complication related to the SetPoint System, and no deaths were reported for any cause. During the clinical studies, no new safety issues were identified.

Surgery (Insertion of the Implant)

- Symptoms at incision site (such as pain, redness, swelling, numbness, rash, and tingling) occurred in about 6 out of 100 patients (about 6%).
- Vocal cord paresis (impaired motion of the vocal cord) occurred in about 5 out of 100 patients (about 5%). It was typically experienced as mild to moderate hoarseness, but it also included difficulty breathing or difficulty swallowing in two cases. Some patients elected to have additional treatment with speech therapy or injections of bulk fillers to the vocal cords.
- Hoarseness occurred in about 3 out of 100 patients (about 3%).
- Eye symptoms (eyelid swelling or drooping of upper eyelid) occurred in about 1 out of 100 patients (about 1%).
- Difficulty swallowing occurred in about 1 out of 100 patients (about 1%).

The following occurred in less than 1 out of 100 patients (less than 1%), all were non-serious:

- Headache or migraine
- Wound infection
- Complication with suture
- Cough
- Sore throat
- Difficulty breathing
- Diarrhea
- Rash
- Scar pain
- Inflammation and blood clot at intravenous (IV) site



Stimulation Therapy

Stimulation therapy was well-tolerated by patients. When patients reported symptoms considered related to stimulation, the symptoms either self-resolved over time or resolved with an adjustment to the strength of stimulation. The most common complaint was mild to moderate pain or discomfort related to stimulation, occurring in about 3 out of 100 patients (about 3%). Other symptoms, occurring in less than 1 out of 100 patients (less than 1%), are listed below.

- Toothache
- Retching
- Nausea
- Metallic taste
- Choking sensation
- Cough
- Sore throat
- Near fainting
- Poor quality sleep
- Spasm near device
- Jaw pain (TMJ)

Charger

One patient reported a rash after wearing the Charger.

Surgery (Removal of the Implant)

In one patient, the larynx (voice box) was accidentally injured. It was successfully repaired during the surgery and did not require hospitalization. Antibiotics and a drainage tube in the neck were required until the injury healed.



Appendix H – Cybersecurity

IT Configuration

A guide for more advanced IT configuration of the SetPoint System can be found on the SetPoint Medical Website at <https://spm.care/it-guide>. The IT guide contains the following information:

- Detailed technical descriptions of minimum networking requirements
- Diagrams for the home and healthcare use environment
- A list of all addresses and ports the SetPoint System uses for its connectivity
- Recommended networking encryption protocols
- Recommendations for IT-related cybersecurity hardening
- Details on data integrity and backup procedures
- Troubleshooting related to IT issues

Cybersecurity Software Updates

Known cybersecurity vulnerabilities found in the SetPoint System will be published as advisories on the SetPoint Medical website. Any advisories can be found at <https://spm.care/cybersecurity-advisories>. Software and firmware updates that remediate cybersecurity vulnerabilities can be obtained by bringing your SetPoint Medical devices to your healthcare professional.

Data Integrity, Backup, and Recovery

A fundamental tenet of the SetPoint System's data strategy is about what data is *not* collected or stored. Every effort is made to avoid collecting, transmitting, or storing data unless it is necessary to the functionality of the system. For example, none of the following pieces of information are ever stored on the Implant or Charger:

- Patient Names
- Usernames or Emails
- Location or Address Information
- Clinic Information
- Phone Numbers
- Date of Birth
- Race or Gender Information

Implant Integrity and Backups

The Implant ensures the integrity on all its non-volatile memory. In certain critical spaces, such as therapy parameters, redundant copies of data are kept. Where redundant data is available, and corruption or tampering is detected, an attempt will be made to restore a known-valid copy of the data. If corruption is detected on non-volatile program memory, the device will return to its bootloader – a state which is displayed on the Charger so that the user is made aware (see Appendix A - Charger LED Status).

Integrity checks are performed routinely, including every time an Implant is charged and every time an Implant powers up to perform autonomous stimulation. Therapy parameters are kept safe with redundant copies on the Implant. They are also preserved in the Cloud. Should all therapy parameters on the Implant be corrupted or erased, they will be automatically restored by Programmer fetching the data from the Cloud during the next clinic visit.



Charger Integrity and Backups

The Charger also ensures the integrity of all its non-volatile memory. In certain critical spaces, redundant copies of data are kept. Where redundant data is available, and corruption or tampering is detected, an attempt will be made to restore a known-valid copy of the data. If corruption is detected on non-volatile program memory, the device will return to its bootloader – a state which is displayed on the Charger so that the user is made aware (see the Appendix A - Charger LED Status). Integrity checks are performed routinely, including every time the Charger is placed on the Docking Station.

Decommissioning and Sanitizing the Charger's Data

The Charger stores the following Implant information in its non-volatile memory:

- A cached Implant Event Log, including the last-connected Implant's Model ID and Serial Number
- Key information for encryption with the Implant

This data is erased when connected to a new Implant. Only authorized and authenticated healthcare professionals are allowed to issue commands to read this data. The Charger leverages chip Readout Protection (RDP) modes to prevent any debuggers from accessing this data. Attempts to access this data with a debugger will result in erasing all memory on the device. No explicit steps are needed to sanitize or decommission a Charger.

Decommissioning and Sanitizing the Implant's Data

The Implant does not support deleting its data. Contact SetPoint Medical to request a return merchandise authorization (RMA) for the explanted Implant, if removed.

Responding to Cybersecurity Events

If you suspect a cybersecurity event has occurred, contact SetPoint Medical. SetPoint Medical has a team that monitors for cybersecurity events and will promptly respond to any cybersecurity threats. If you believe you have discovered a cybersecurity vulnerability in a SetPoint Medical product, please follow SetPoint Medical's Coordinated Vulnerability Disclosure process which can be found at <https://spm.care/security>.

Software Bill of Materials

An up-to-date Software Bill of Materials (SBOM) can be found on the SetPoint Medical Website at <https://spm.care/sbom>.

Cybersecurity End-of-Support

Cybersecurity support is offered through the expected operating duration of the devices (i.e., 5 years for the Charger and 10 years for the Implant). During this time, patients and healthcare professionals can expect cybersecurity updates to the Implant and Charger to address any vulnerabilities that may be discovered.