# Prospera Spinal Cord Stimulation System

Patient Guide for the Trial System

**Technical Manual**

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Rx only



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# Table of Contents

# 1 About This Technical Manual

## Objective

This technical manual provides information for the patient on how to use the Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System, with an external stimulator during a trial spinal cord stimulation period.

You'll find:

- Safety related information
- System description
- Description of the usage of the patient programmer MyHomeStream TR with software version 2.0 or higher
- Activity guidelines during the temporary trial

This technical manual does not contain any information about the implantation of leads or stimulator programming. These activities are carried out by physicians or other health care technicians.

## Technical Manuals

The technical manual will be given to you by your physician or by an authorized representative of your physician after implantation.

1. Consult all relevant technical manuals.
2. Keep the technical manuals for future reference.

To ensure safe operation, in addition to this technical manual, please also consult the following technical manuals:

- Smartphone manufacturer's information on the patient programmer MyHomeStream TR

## Conventions

### Marking of Safety Messages

The following symbol indicates potential hazards:

⚠

Follow all safety messages indicated by this symbol to avoid serious or even fatal injury or damage to the system.

Safety messages are also indicated by a classification to indicate severity.

| Classification | Meaning |
|---|---|
| **Danger** | Non-compliance **may immediately lead to severe injury or death.** |
| **Warning** | Non-compliance leads to a potentially dangerous situation that **can cause severe injuries or death.** |
| **Caution** | Non-compliance leads to a potentially dangerous situation that **can cause moderate injuries.** |
| **Attention** | Non-compliance leads to a potentially dangerous situation that **can cause minor injuries or material damage.** |

## Typographical Conventions

### Instructions

The individual steps of the user manual are numbered. Prerequisites, intermediate results and results may be specified.

### Prerequisite

- This is a prerequisite.

1. First step
2. Second step
   - ▶ Intermediate result
3. Third step

### Result

This is the final result.

### Elements of the User Interface

Elements that are displayed on the user interface, such as buttons or menu items, are indicated by square brackets and bold font. Example: **[Button]**.

### Navigation paths

The elements of a navigation path are shown in bold and separated by ">".

Example: **[Main menu]** > **[Sub-menu]** > **[Item]**

### Highlights

Text that needs to be emphasized is shown in **bold font.**

### Cross References

Cross references are indicated using "see" or "see also".

## Notes

Notes are indicated using the word "Note" in bold font.
They indicate useful information and may be placed anywhere in the text. Example:

**Note**

Useful information is indicated using the word "Note" in bold font. The information itself is given in regular font.

## Figures

Figures that show the product or the user interface are used for illustration purposes only. The details shown in the figure may differ from that of the delivered product or your software version.

## Abbreviations

The following abbreviations are used in this technical manual.

| Abbreviation | Meaning |
|---|---|
| CoC | Certificate of Conformity |
| FCC | Federal Communications Commission |
| HF | High frequency |
| IP | International Protection |
| MRI | Magnetic Resonance Imaging |
| NRTL | Nationally Recognized Test Laboratory |
| RF | Radio frequency |
| SCS | Spinal Cord Stimulation |
| TENS | Transcutaneous Electrical Nerve Stimulation |
| WPA2 | Wi-Fi Protected Access, Version 2 |

## Gender

Personal designations are used in the male or female form in order to facilitate the flow of reading. This form is intended to include all gender identities.

# 2 Safety

This chapter contains safety messages referring to the handling of the Prospera SCS System and transport and storage of the system components.

## Warnings

**WARNING**

**Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment**

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 12 inches (30 cm) from this device, this can result in a reduction in its performance.
This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennae), keep such devices at a distance of at least 12 inches (30 cm) from the external stimulator.

## Precautions

⚠ **Caution**

**Damage to the External Stimulator due to Contact with Water**

The external stimulator might get damaged if it is directly exposed to liquids. The affixation pouch that is used to attach the external stimulator to your body provides limited protection against exposure to liquids.

- **Do not remove the external stimulator from its affixation pouch or bandages**.
- Do not shower with the external stimulator.
- Do not bathe with the external stimulator.

## Further Safety Notes

⚠ **Attention**

**Product Damage due to Maintenance Activities**

Do not perform any maintenance activities on the external stimulator, as this may damage the external stimulator and impair its function.

- **Do not remove the device from the affixation pouch**.
- Do not change the device batteries by yourself.

**Attention**

**Risk of Electromagnetic Interference through the Use of Unauthorized Accessories**

The use of accessories, transducers or cables not listed by BIOTRONIK or of accessories other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- **Only use accessories authorized by BIOTRONIK**.

**Attention**

**Product Damage and Risk of Injuries due to Modification of External Stimulator**

Any modification of the external stimulator might lead to a device malfunction and result in injuries.

- **Do not modify the external stimulator**.

**Attention**

**Undesirable Therapy Possible with TENS Use**

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver too much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

**Attention**

**Risk of Electromagnetic Interference**

The use of the external stimulator adjacent to or stacked with other devices should be avoided, as this may lead to the external stimulator operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor the external stimulator and the other device(s) being used with it in order to ensure that they are all working correctly.

## Transport and Storage

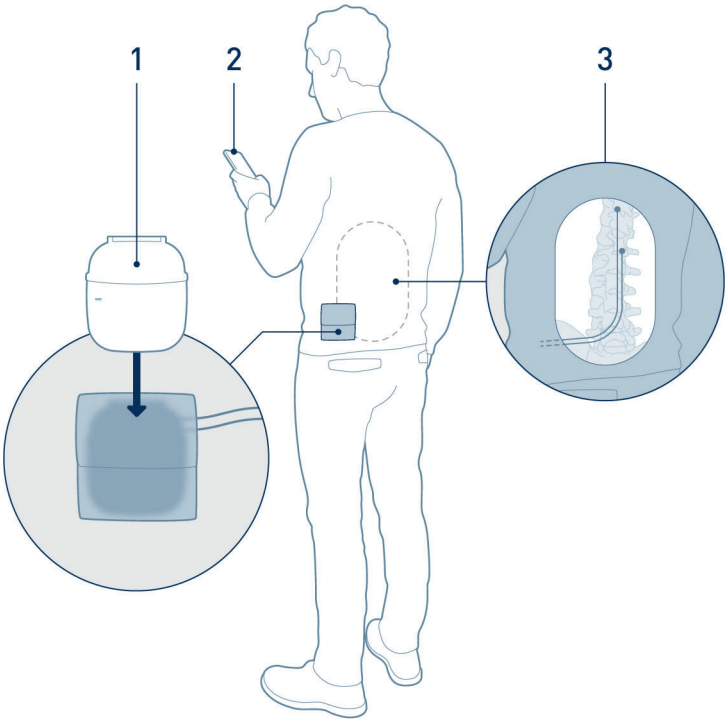
### Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

When traveling by airplane, the patient programmer should be put into airplane mode.

# 3 Product and System Description

## Overview of the System Components




| | |
|---|---|
| 1 | External stimulator |
| 2 | Patient programmer |
| 3 | Implanted leads |

You have received a trial spinal cord stimulation system. This system delivers electrical pulses to the spinal cord to relieve pain.

The system is comprised of an external stimulator, which is used to generate electrical pulses, and one or two implanted leads, which are used to deliver the electrical pulses.

This trial spinal cord stimulation system is used in a temporary trial intended to determine if the spinal cord stimulation therapy adequately manages your chronic pain symptoms.

For this purpose, one or two leads were implanted near your spinal cord and connected to the external stimulator. The external stimulator is fixed outside your body using bandages. The external stimulator has been programmed according to your medical condition and paired with a patient programmer. This temporary trial can last from a few days to several weeks, depending on your medical condition and the judgement of your physician.

You and your physician will use results of this trial, along with other factors, to determine if a fully implanted spinal cord stimulation system is appropriate for you.

For personally controlling your therapy, your physician has given you the patient programmer. This is used to change the therapy program and increase or decrease the program strength according to what works best for you.

## External Stimulator

The external stimulator is used during the temporary trial and has the following characteristics:

- It has the same therapy functions as the stimulator that will be implanted if the temporary trial is successful.
- It is externally attached to the body.
- It operates on non-rechargable batteries.

The external stimulator continuously delivers pulses when stimulation is turned on. This stimulation therapy is programmed according to your medical condition. You can adjust the stimulation based on your daily habits by using your patient programmer.

The external stimulator and the patient programmer communicate wirelessly.

The external stimulator operates on batteries, which in most cases will last for the duration of your trial. You can monitor the battery status using the patient programmer. If the batteries are low, they should be replaced only by your physician.

## Leads

Depending on your medical condition, up to two leads may be implanted and connected to the stimulator. The leads are implanted near the spinal cord to deliver electrical pulses intended to have a pain relieving effect. The leads are made of a very flexible material to adapt to your movements.

## Patient Programmer

As part of your spinal cord stimulation system, you have received a patient programmer. The patient programmer is used to change which stimulation program you are using, as well as to increase or decrease the strength of the stimulation. The general operation of the patient programmer is no different from that of a standard smartphone. However, you will not be able to perform typical phone functions on it, such as making phone calls or installing other apps.

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

# 4 First Steps

## Package Contents

Your physician has given you the following items for the temporary trial:

- This technical manual
- The patient programmer with the following components:
  - Patient programmer
  - Smartphone manufacturer's information for the patient programmer
  - Charging cable
  - Power plug adapter

## Unpacking the Items

1. Unpack all items.
2. Check if you have received all listed items.
3. Contact your physician if items are missing to replace them.
4. Check the items for any visible damage.
5. Do not use the items if there is any visible damage. Contact your physician to exchange the damaged items for new ones.
6. Safely store the packaging in a dry place until the temporary trial is completed.

# 5 Using the Patient Programmer

## General Notes about the Device

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

**Note**

Unauthorized access to the patient programmer may result in insufficient or excessive stimulation.

- Protect your patient programmer against unauthorized access.
- Lock the patient programmer when you are not using it.
- To unlock the patient programmer, use a secure password that cannot be guessed. Refer to the smartphone manufacturer's information on how to create a secure password.
- When unlocking the patient programmer, ensure you are not in a location where someone could see your password.
- Keep the patient programmer in a secure place and do not disclose your password.
- If your patient programmer is lost or stolen, contact your physician.

The patient programmer comes with cellular network connectivity enabled. You should also connect the patient programmer to a wireless network (WiFi), such as those found in most homes. This can be done in the same way that you would connect your personal devices to your wireless network. This is recommended for ensuring app updates occur.

The patient programmer is designed for daily use.

If the battery capacity reduces over time and becomes unsuitable for daily use, please contact your physician to get a replacement.

### Note

Misuse of the patient programmer may result in insufficient or excessive stimulation.

- Only run applications on the patient programmer that are associated with the patient programmer app. Do not install or run any other app on the patient programmer.
- Do not manipulate the operating system of the patient programmer, in order to not compromise the built-in protection provided by the hardware or software manufacturer.
- If you suspect security issues, contact your physician.

## Notes on Daily Use

### Environment

The patient programmer is a standard smartphone and should only be used in places where the use of a smartphone is permitted. Before using the patient programmer, make sure that its use is not prohibited in your location.

## Communication with Stimulator

The patient programmer and the stimulator communicate wirelessly. For a reliable connection between the patient programmer and stimulator, please ensure the following:

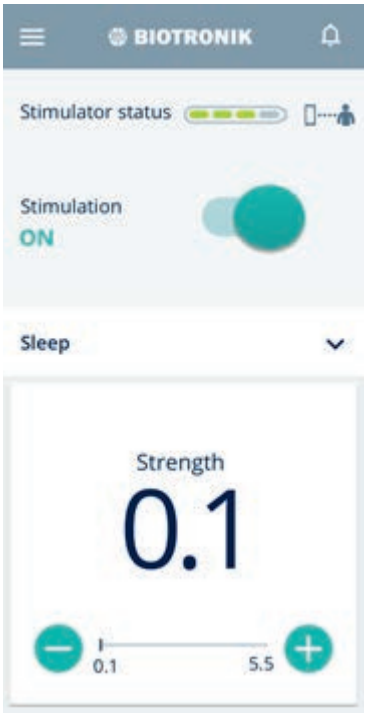
- Regularly charge the patient programmer.
- Charge the patient programmer nightly by your bedside or other location where you will be near the patient programmer on a daily basis.
- The distance to the stimulator should not exceed 5 ft (1.5 m) while in use.
- The Bluetooth function of the patient programmer should always be turned on.
- When the patient programmer is not in use, it is recommended that you leave it plugged in at your bedside or other location you are regularly near each day. This will allow your stimulator to transfer data to your patient programmer on a daily basis, even if you do not need to use your patient programmer for stimulation adjustments.
- Avoid restarting the patient programmer or the patient programmer app unless needed. In the event the patient programmer app is restarted, there will be some delay before communication with the stimulator is available again.

### Airplane Mode and other Settings

The patient programmer device can be put into airplane mode. In airplane mode, it can continue to be used for stimulation adjustments as long as the Bluetooth function is enabled. It is recommended to disable the airplane mode when it is no longer needed.
To access settings associated with the smartphone, use the **[Additional Information]** menu outside of the patient programmer app, and refer to the smartphone manufacturer's information.

## Understanding the User Interface and Menu

Main screen



The following elements are available on the main screen:

| Element | Explanation |
|---|---|
| Menu  | Opens the menu. |
| Notifications  | Opens the **[Notifications]** screen. |
| Unread Notifications  | Indicates that unread notifications are present and opens the **[Notifications]** screen. The number indicates the number of notifications. |
| Connected  | Indicates that the stimulator is in communication with the patient programmer. |
| Disconnected  | Indication that the stimulator is not able to communicate with the patient programmer due to range or interference issues. |
| Battery Status  | Indicates the battery status of the stimulator. |

| Element | Explanation |
|---|---|
| Stimulation on  | Indicates that the stimulation **is turned on** and turns the stimulation off when selected. |
| Stimulation off  | Indicates that the stimulation **is turned off** and turns the stimulation on when selected. |
| Therapy Programs  | Opens the list of programs that can be selected.<br>The currently selected program is displayed on the left. |
| [Strength] | Displays the current value of the program strength. |
| Adjusting the Program Strength  | Decreases or increases the program strength. |

## Selecting the Stimulation Program

### Note

The selected program or the settings may not be optimal for you and may not fully relieve your pain or may cause side effects.

1. Read the following instructions carefully.
2. Ensure that you understand the instructions and that you can operate the device properly.
3. If in doubt, ask your physician.

Depending on the therapy and your daily habits, your physician has configured various programs. You can select them on the patient programmer.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the ⌄ button to open the list of programs that can be selected.
2. Select the desired program.

### Result

The desired program is selected, activated on the stimulator, and the stimulation starts.

## Turning the Stimulation on/off

Under certain circumstances it may be necessary to turn the stimulation on or off.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. **For turning on:** 
   When the stimulation is in this turned off state, select the switch to turn it on.

   **For turning off:** 
   When the stimulation is in this turned on state, select the switch to turn it off.

### Result

The stimulator starts or stops the stimulation.

## Setting Program Strength

The program strength can be increased or decreased, depending on your daily habits, using the patient programmer.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The stimulation is turned on.
- The patient programmer app is open and the main screen is displayed.

1. **Increase** the program strength:
   Select the + button.
   **Decrease** the program strength:
   Select the − button.

### Result

The stimulation continues with the adjusted program strength.

For possible errors when changing the program strength, see Troubleshooting while Using the Patient Programmer [Page 39].

## Displaying Notifications

### Note

Notifications from the stimulator or from your physician will be displayed in the patient programmer app. Messages from other sources, like the operating system of the smartphone, are displayed in other locations on the screen.

In all cases, follow the instructions on the screen carefully. If in doubt, ask your physician.

To view the notifications in the patient programmer app, proceed as follows.

### Prerequisite

- The patient programmer is adequately charged and is connected to the cellular network or wireless network (WiFi).
- The patient programmer app is open and the main screen is displayed.

1. Select the  button.

### Result

All notifications are displayed.

## Saving Default Strength

If you have more than one stimulation program available, every time you select a different stimulation program, the program strength will begin at a specific default strength. If you have adjusted the strength of a stimulation program, you have the option to save a new default strength so the program will always start at this value in the future.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the desired program.
2. Adjust the desired stimulation strength.
3. Select the button for the menu.
4. Select the **[Save default strength]** menu item.
5. Confirm the new default strength for the current program selecting the **[Update]** button.

### Result

The new default strength is saved and, whenever the program is selected, it starts with the new program strength.

## Updating the Patient Programmer App

BIOTRONIK periodically updates the software of the patient programmer app when the patient programmer device is not actively being used. The updates are executed automatically. An active WiFi connection is required for the update. Connect the patient programmer to the WiFi to ensure updates occur. Additionally, plug in the patient programmer device when it is not in use. Do not turn the patient programmer device off overnight, so that the updates can be installed.

**Note**

Additionally, updates for the operating system of the patient programmer will be available periodically. Make sure you do not need to make stimulation adjustments for a few minutes before proceeding.

- Keep the operating system of the patient programmer device up-to-date to ensure that you can perform stimulation adjustments without interruption.
- You may see a notification on the patient programmer device that an operating system update is available. Select the notification and follow the prompts to install the update. For more information, refer to the smartphone manufacturer's information on how to update the operating system.
- Make sure you do not need to make stimulation adjustments for a few minutes before proceeding.

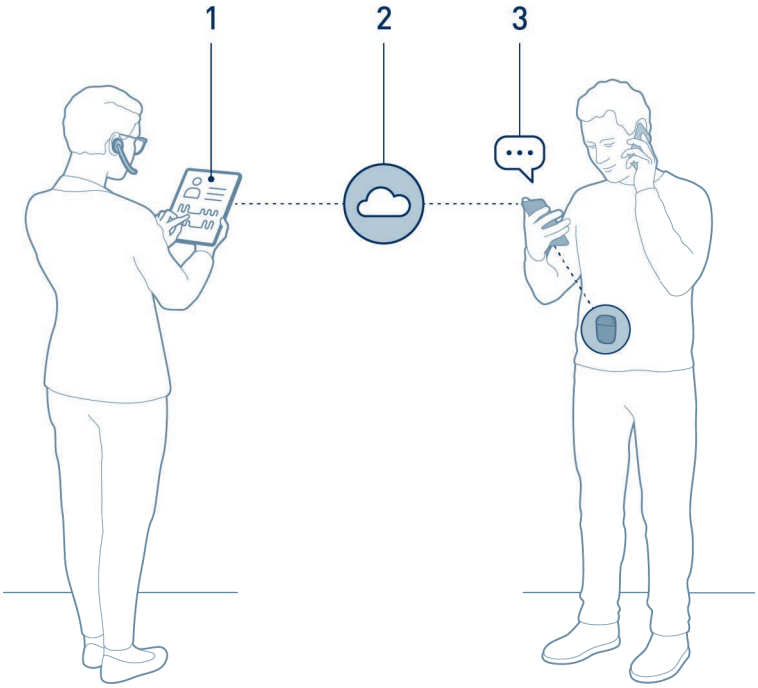
Please note the following information on data security for the patient programmer when using a network connection:

- Wireless communication between the clinician programmer, the stimulator, the patient programmer, and the BIOTRONIK server includes multiple levels of encryption to protect patient and clinician data.
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).

# 6 Remotely Receiving a New Program

## Overview

Receiving a new program remotely is a convenient way to receive a new stimulation program without having to visit your physician's office. You and your physician will decide during an in-office visit whether to turn this capability on in your stimulator.




| | |
|---|---|
| 1 | The physician will discuss and send the new program. |
| 2 | The transmission is sent in a secure and encrypted manner. |
| 3 | Program is sent to patient programmer where a confirmation box will be displayed. |

Receiving a new program happens in the following steps which are described in more detail in the following sections:

1. Your physician will call you to discuss your status and new program options.
2. The new program will be sent to your patient programmer remotely. To ensure your privacy and safety, the transmission is sent in a secure and encrypted manner.
3. Once received, a confirmation box will be displayed on the patient programmer for you to accept or reject the program.
4. If you accept the new program, it will be automatically installed on your stimulator.
5. The new program always starts with the minimum strength, 0.1. Increase the program strength as directed.

**Note**

You have to explicitly agree to participate in the remote service. No new program will be sent without your agreement.

## Preparing to Receive the Program

The following preparations must be made to receive a new program:

- You will need at least 15 minutes.
- Have a working phone on, so your physician can reach you.
- Go to a room where you will not be disturbed and where you can have a telephone conversation with your physician.
- Ensure the patient programmer is ready, adequately charged and the signal strength of the cellular or wireless network (WiFi) connection shows at least 2 bars. Shift your position or choose a different room if the signal strength is not sufficient.
- Ensure that the wireless communication between the patient programmer and the stimulator is working and the distance between them is less than 5 ft (1.5 m). The patient programmer main screen shows the active connection:

- Ensure that the battery status of the stimulator on the patient programmer shows at least 2 bars: 

## Installing the New Program

### Prerequisite

- The patient programmer app is active and the patient programmer is connected to the cellular network or the wireless network (WiFi). Your physician will establish a remote connection to your patient programmer and will check your spinal cord stimulation system status. The new program will then be sent to your patient programmer.

1. A confirmation box is displayed on the patient programmer indicating that the new program has been received. Accept the installation of the new program selecting the **[ACCEPT]** button.
   - ▶ Once the installation is successful, the **[Update successful]** confirmation box is displayed.
2. Select the **[CLOSE]** button to acknowledge this confirmation and return to the patient programmer **[Home]** screen.
   - ▶ The new program will be displayed as the currently selected program. The program strength will begin at 0.1.
3. Increase the stimulation selecting the + button.

### Result

The stimulation is started. The new program can be used like any other program on the patient programmer.

# 7 Everyday Life

## Risky Therapeutic and Diagnostic Procedures

The use of certain medical diagnosis and treatment procedures poses a risk to you as a patient or may damage the spinal cord stimulation system. Therefore, certain procedures must be avoided. Other procedures may be performed with special precautions.

The following procedure should not be carried out during the temporary trial:

- Diathermy
- MRI scans

Special precautions should be taken when using the following procedures:

- Lithotripsy (kidney stone fragmentation)
- Ablation (tissue sclerotherapy)
- Radiation therapy
- High frequency surgery
- External defibrillation
- Transcutaneous electrical nerve stimulation (TENS)

⚠ **Attention**

**Undesirable Therapy Possible with TENS Use**

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver too much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

## Dos and Don'ts

### Interactions with Electromagnetic Fields and other Environmental Influences

Certain factors, such as electromagnetic fields or other environmental influences may pose a risk to you as a patient or damage your spinal cord stimulation system. Please pay attention to the following points:

⚠ **Caution**

**Damage to the External Stimulator due to Contact with Water**

The external stimulator might get damaged if it is directly exposed to liquids. The affixation pouch that is used to attach the external stimulator to your body provides limited protection against exposure to liquids.

- **Do not remove the external stimulator from its affixation pouch or bandages**.
- Do not shower with the external stimulator.
- Do not bathe with the external stimulator.

- If using therapy that generates sensations with stimulation (paresthesia), do not operate vehicles or machinery while the stimulation is on.
- Do not use wireless chargers in the vicinity of the external stimulator.
- Do not pass through the metal detector at security checks. **Do not remove the external stimulator.** Use an alternate security check method. Consider showing your patient ID card to the security personnel.
- Magnetic fields near the stimulator may deactivate the therapy function of the stimulator.
  Do not bring your stimulator close to strong magnetic fields.

## Operating Conditions

Certain conditions may pose a risk to your spinal cord stimulation system. Please pay attention to the following points:

⚠ **Attention**

**Product Damage and Risk of Injuries due to Modification of External Stimulator**

Any modification of the external stimulator might lead to a device malfunction and result in injuries.

- **Do not modify the external stimulator**.

- Only use the external stimulator at an ambient temperature between +59 °F and +99 °F (+15 °C and +37 °C).
- Only use the external stimulator at a relative humidity of 15% to 90%.
- Only use the external stimulator at altitudes below 9842 ft (3000 m).
- Only use the external stimulator at an atmospheric pressure of 700 to 1060 hPa.

## Physical Activities

Certain physical activities may pose a risk to your spinal cord stimulation system. Please pay attention to the following points:

### Note

As the leads are not firmly ingrown during your temporary trial, there is risk that the leads may shift during physical activity, which could make the therapy less effective.

Your physician will provide you with instructions for limiting your physical activities for the duration of the temporary trial. In general, this includes:

- Do not bend your upper body.
- Do not rotate your upper body.
- Do not stretch your upper body.
- Do not lift weights over 5 lbs (2 kg).
- Do not lift your arms overhead.

### Note

A wrong movement may cause the leads to become detached from the external stimulator. This can lead to an insufficient therapy and may cause damage to the leads.

If the leads become dislodged from the external stimulator:

- Cover the exposed ends of the leads with a bandage.
- Contact your physician.

## Care

**Attention**

**Product Damage due to Maintenance Activities**

Do not perform any maintenance activities on the external stimulator, as this may damage the external stimulator and impair its function.

- **Do not remove the device from the affixation pouch**.
- Do not change the device batteries by yourself.

Do not remove the external stimulator from the affixation pouch, in order to keep it out of the reach of children, pets, and pests.

### Cleaning the Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

# 8 Troubleshooting

## Troubleshooting Stimulation

### Note

If an error occurs that is not described below, contact your physician.
If an error persists after you have tried the proposed solution, contact your physician.

**The stimulation turns off during use.**

- The stimulator battery is very low.
  Contact your physician to have the batteries replaced.
- The stimulator came in contact with a strong magnet for longer than 1 minute.
  Use the patient programmer to confirm in notifications and then turn stimulation back on.
- A stimulator problem occurred.
  Use the patient programmer to check notifications for more information.

## Troubleshooting while Using the Patient Programmer

### Note

If an error occurs that is not described below, contact your physician.
If an error persists after you have tried the proposed solution, contact your physician.

**I don't understand the meaning of the symbols on the patient programmer.**

| Symbol | Meaning |
|---|---|
|  | The Disconnected symbol is displayed on the patient programmer.<br>**Cause:** The patient programmer is not connected to the stimulator.<br>**Proposed solution:**<br>• Ensure that the distance to the stimulator does not exceed 5 ft (1.5 m) during use.<br>• Ensure that the Bluetooth function of the patient programmer is always turned on.<br>• Remove any sources of interference such as power cables, microwave oven, fluorescent lights, or other wireless devices. |
| – or + | The button on the patient programmer is grayed out and the stimulation strength cannot be decreased or increased.<br>**Cause:** The minimum or maximum value for the program strength was reached.<br>**Proposed solution:** Contact your physician to change the strength limits of the existing program if a higher strength is desired. Alternatively, try changing to a different program. |
|  | The Battery Error symbol is displayed.<br>**Cause:** An error has occurred with the stimulator.<br>**Proposed solution:** Contact your physician. |

### The patient programmer cannot identify the stimulator.

If the patient programmer is not compatible with your stimulator hardware or software, no identification of the stimulator can take place during remote programming.
Contact your physician to arrange an update for your patient programmer.

# 9 Appendix

## Technical Data

### Service Life of the Stimulator

| Category | Design |
|---|---|
| Battery life | 7 days (with 3 disposable LiFeS2 AAA batteries) |
| Service life of the external stimulator | 2 years |

## Symbols on the External Stimulator

| Symbol | Meaning |
|---|---|
|  | Manufacturer |
|  | Manufacturing date |
|  | BIOTRONIK order number |
|  | Serial number |
|  | Observe the technical manual |
|  | Store in a dry place |
|  | Type BF applied part |
|  | MR unsafe |
| GTIN | Global Trade Item Number |
|  | Regulatory compliance mark (for Australia) |

## Radio Frequency Parameters

### Communication between the External Stimulator and Patient Programmer or Clinician Programmer

| Category | Design |
|---|---|
| Frequency band | 2.4 GHz ISM Band |
| Operating frequency | 2400 MHz ... 2483.5 MHz |
| Operating range | 0 - 2 m |
| Numbers of channels | 40 |
| Bandwidth | 2 MHz / channel |
| Max. transmission power (EIRP) | Class 1: 8 dBm (6.3 mW) |
| Modulation | GFSK |
| Robustness | Frequency Hopping |

## Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

## Data Security

Please note the following information on data security for the patient programmer:

- Security settings within the patient programmer are automatically set and remotely managed including user login settings, device lockdowns, device firewall, and anti-virus.
- Wireless communication between the clinician programmer, the stimulator, the patient programmer, and the BIOTRONIK server includes multiple levels of encryption to protect patient and clinician data.
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).
- Only accept remotely sent programs when directed by your physician.

## Note

Unauthorized access to the patient programmer may result in insufficient or excessive stimulation.

- Protect your patient programmer against unauthorized access.
- Lock the patient programmer when you are not using it.
- To unlock the patient programmer, use a secure password that cannot be guessed. Refer to the smartphone manufacturer's information on how to create a secure password.
- When unlocking the patient programmer, ensure you are not in a location where someone could see your password.
- Keep the patient programmer in a secure place and do not disclose your password.
- If your patient programmer is lost or stolen, contact your physician.

**Note**

Misuse of the patient programmer may result in insufficient or excessive stimulation.

- Only run applications on the patient programmer that are associated with the patient programmer app. Do not install or run any other app on the patient programmer.
- Do not manipulate the operating system of the patient programmer, in order to not compromise the built-in protection provided by the hardware or software manufacturer.
- If you suspect security issues, contact your physician.

**Note**

Notifications from the stimulator or from your physician will be displayed in the patient programmer app. Messages from other sources, like the operating system of the smartphone, are displayed in other locations on the screen.

In all cases, follow the instructions on the screen carefully. If in doubt, ask your physician.

## Quality of Service for Wireless Technology

2.4 GHz GFSK wireless technology is used for the communication between the stimulator and the clinician programmer or the patient programmer.

The quality of wireless communication will vary depending on the operating environment such as outdoors, home, operating room, or a recover room. The quality of service should be sufficient to transfer more than 8 kbps with latency depending on the type of transaction. Interrogation of 32 kB of data may take up to 20 s whereas 2 kB of data will require less than 5 s.

In the case of interference, the system will retry communication to ensure reliable data transfer resulting in longer durations for user transactions. In very high interference cases, you could lose the connection to the device.

To resolve communication issues, do the following:

1. Move the clinician programmer or the patient programmer closer to the stimulator.
2. Ensure there is a direct line of sight between the clinician programmer or the patient programmer and the stimulator.
3. Turn off or move away from other devices that may be operating in the 2.4 GHz band. Such devices include wireless home networks, mobile phones, wireless consumer devices, etc. For information on wireless security, see above, Data Security.

## Open Source and Commercial Software

A list of hardware and software components used is available upon request.

## Disclaimer, Warranty, and Warranty Conditions

https://www.biotronik.com/warranty-booklet-neuro/

## Country-Related Information

### International Radio Certification

#### Telemetry Information for Australia

This device is in compliance with the Australian "Radiocommunications Act 1992" and, therefore, it is labeled according to the "Radiocommunications (Compliance labeling – Devices) Notice".

#### Telemetry Information for the USA

The stimulator will be registered with the Federal Communications Commission under the following number:

- External stimulator:
  FCC ID: QRI-SCSTS

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## Electromagnetic Compatibility

The external stimulator is suitable for use in all home care and professional healthcare establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The external stimulator maintains safe levels of stimulation in the presence of electromagnetic interference. The devices are intended for use in the electromagnetic environment specified in the following tables. The user should ensure that they are used in such an environment.

The following tests were performed according to IEC 60601-1-2: 2014:

| Section | Test | Test Level |
|---|---|---|
| 7.1 | CISPR 11<br>RF Radiated emission | • Group 1<br>• Class B |
| 8.9 / 8.10 | IEC 61000-4-2<br>Electrostatic discharge (ESD) | • ± 8 kV contact discharge<br>• ± 2/4/8/15 kV air discharge |
| | IEC 61000-4-3<br>Radiated RF EM fields | • Modulation 1 kHz<br>• 10 V/m, 80 MHz ... 2.7 GHz<br>• Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9 V/m ... 28 V/m) |
| 8.9 | IEC 61000-4-6<br>Conducted disturbances induced by RF fields | • 3 Vrms<br>• 6 Vrms in ISM + Amateur Radio Bands<br>• 150 kHz ... 80 MHz |
| | IEC 61000-4-8<br>Power frequency magnetic fields | • 30 A/m<br>• 50/60 Hz |

**WARNING**

**Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment**

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 12 inches (30 cm) from this device, this can result in a reduction in its performance.
This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennae), keep such devices at a distance of at least 12 inches (30 cm) from the external stimulator.

**Attention**

**Risk of Electromagnetic Interference**

The use of the external stimulator adjacent to or stacked with other devices should be avoided, as this may lead to the external stimulator operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor the external stimulator and the other device(s) being used with it in order to ensure that they are all working correctly.

**Attention**

**Risk of Electromagnetic Interference through the Use of Unauthorized Accessories**

The use of accessories, transducers or cables not listed by BIOTRONIK or of accessories other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- **Only use accessories authorized by BIOTRONIK**.

## Legend for the Label

The label icons symbolize the following:

| Symbol | Meaning |
|---|---|
| MD | Medical device |
|  | Manufacturing date |
| REF | BIOTRONIK order number |
| SN | Serial number |
| UDI | Unique device identifier |
|  | Temperature limit |
|  | Humidity limit |
|  | Acceptable atmospheric pressure range for storage |
|  | Consult the instructions for use! |
|  | Contents |
|  | Manufacturer |
|  | Distributor |

| Symbol | Meaning |
|---|---|
|  | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. |
|  | Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK. |
|  | Patient programmer |
|  | Wall adapter |
|  | Power plug adapter |

# Index

## T



## U



## W

# Prospera Spinal Cord Stimulation System

Patient Guide for the Implanted System

**Technical Manual**

BIOTRONIK
excellence for life

Rx only



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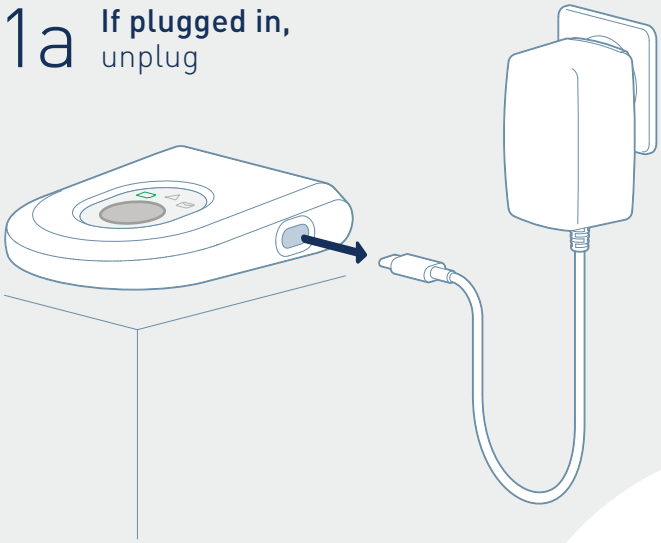
BIOTRONIK
excellence for life

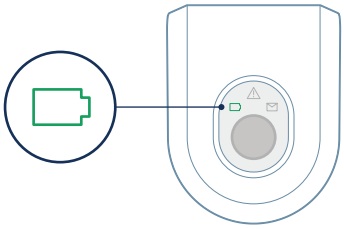
# Table of Contents

# Charger Quick Guide

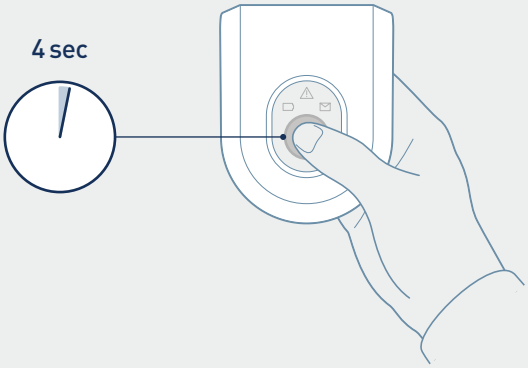
## 1a **If plugged in,** unplug



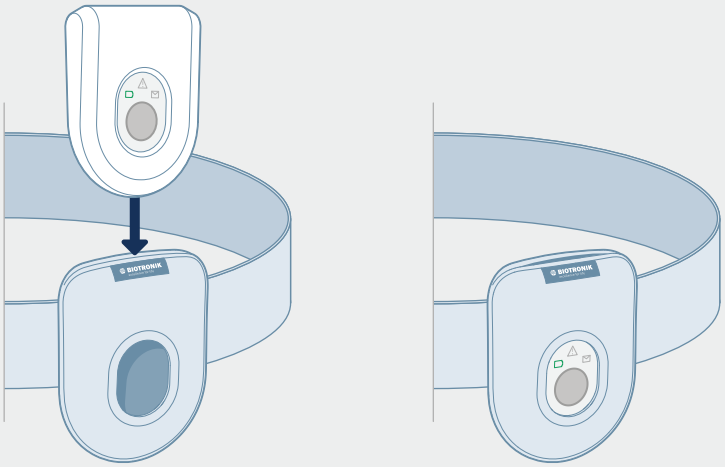
## 2 Battery symbol is green



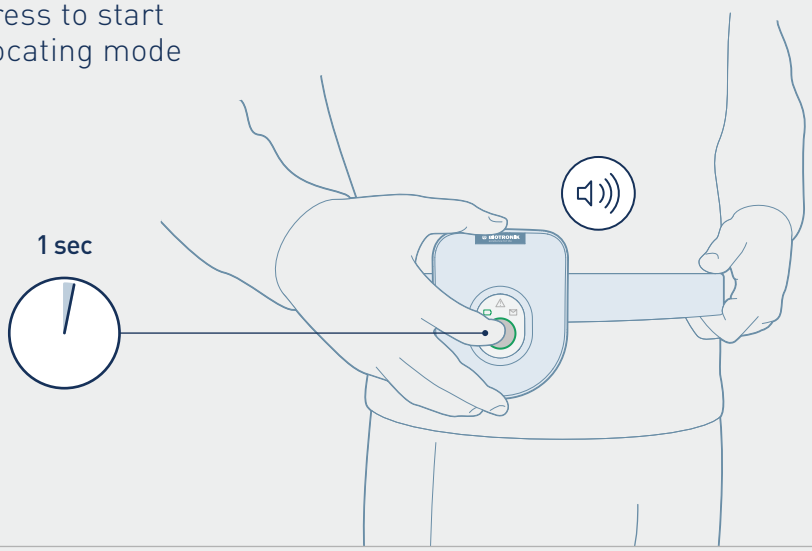
## 1b **If unplugged,** press and hold



## 3 Put the charger in the belt and put on the belt



## 4 Press to start Locating mode

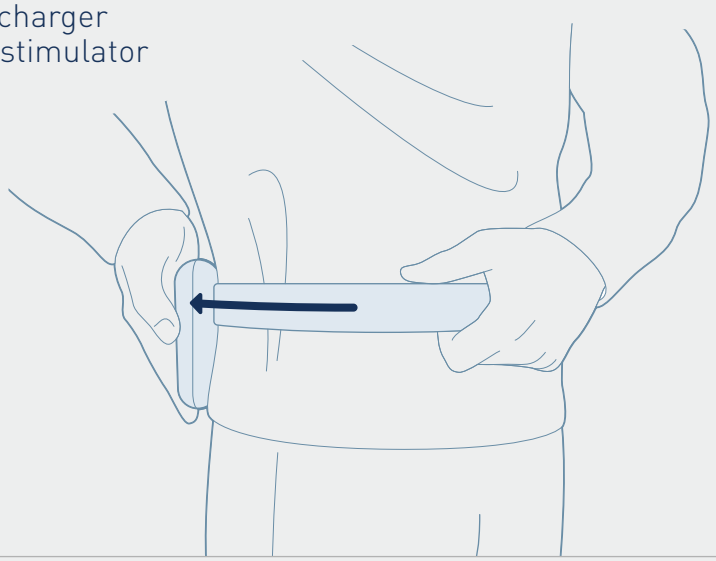



Locating mode signal
75 sec

Sound

Light

## 5 Move the charger over your stimulator

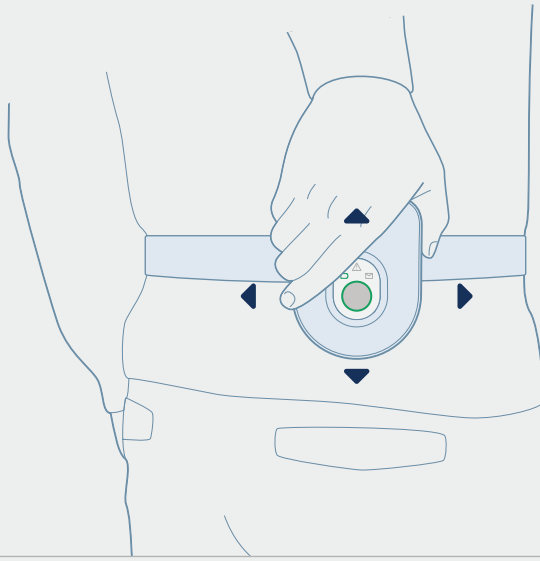


Locating mode signal
75 sec

Sound

Light

## 6 Slowly adjust the position

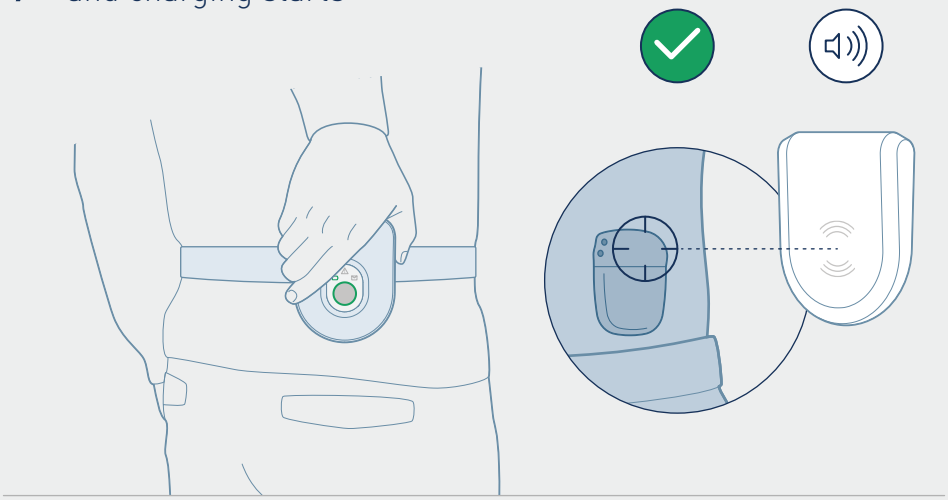


Locating mode signal
75 sec

Sound

Light

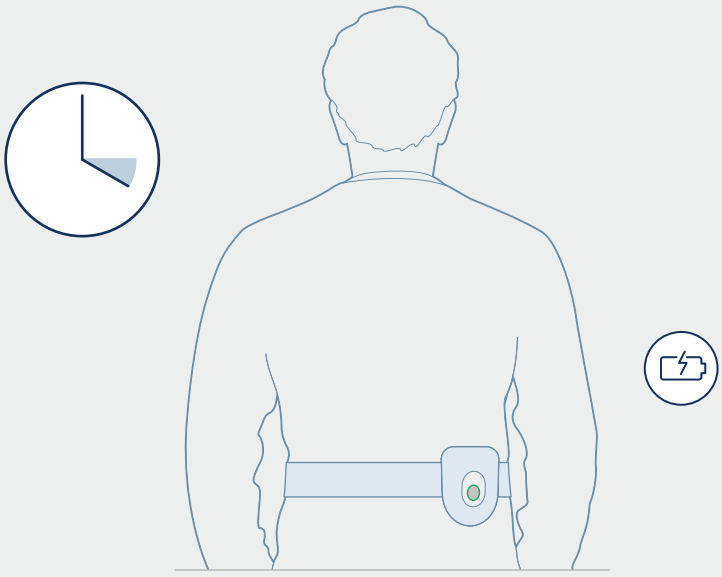
## 7 Confirmation signal sounds and charging starts



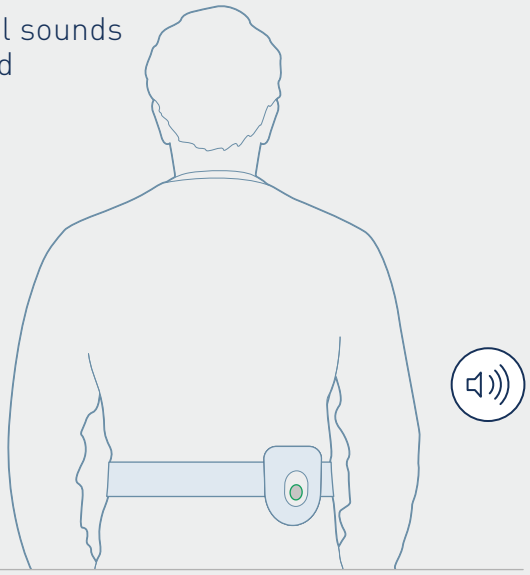
Confirmation signal

Sound

## 8 Wait until charging is completed



9 Charging complete signal sounds when charging completed

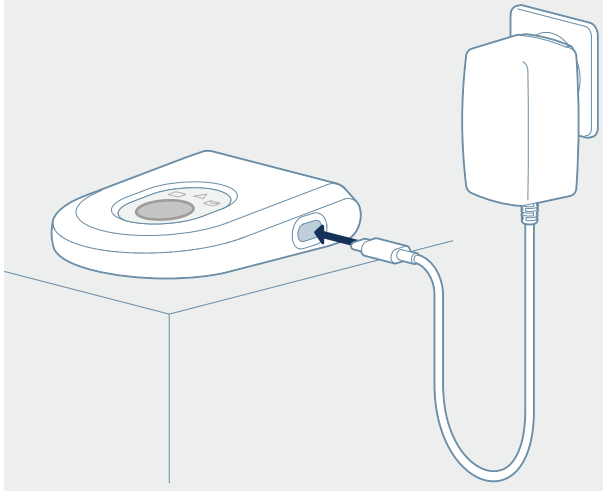


Charging complete signal

Sound

10 Remove charger

11 Plug in charger



# 1 About This Technical Manual

## Objective

This technical manual provides information for the patient on how to use the Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System, with an implantable stimulator.

You'll find:

- Safety related information
- System description
- Description of the usage of the patient programmer MyHomeStream with software version 2.0 or higher
- Description of the usage of the charger, Prospera CHG
- Activity guidelines in specific situations

This technical manual does not contain any information about the implantation procedure or stimulator programming. These activities are carried out by physicians or other health care technicians.

## Technical Manuals

The technical manual will be given to you by your physician or by an authorized representative of your physician after implantation.

1. Consult all relevant technical manuals.
2. Keep the technical manuals for future reference.

To ensure safe operation, in addition to this technical manual, please also consult the following technical manuals:

- Smartphone manufacturer's information on the patient programmer MyHomeStream

## Conventions

### Marking of Safety Messages

The following symbol indicates potential hazards:

⚠

Follow all safety messages indicated by this symbol to avoid serious or even fatal injury or damage to the system.

Safety messages are also indicated by a classification to indicate severity.

| Classification | Meaning |
|---|---|
| **Danger** | Non-compliance **may immediately lead to severe injury or death.** |
| **Warning** | Non-compliance leads to a potentially dangerous situation that **can cause severe injuries or death.** |
| **Caution** | Non-compliance leads to a potentially dangerous situation that **can cause moderate injuries.** |
| **Attention** | Non-compliance leads to a potentially dangerous situation that **can cause minor injuries or material damage.** |

## Typographical Conventions

### Instructions

The individual steps of the user manual are numbered. Prerequisites, intermediate results and results may be specified.

### Prerequisite

- This is a prerequisite.

1. First step
2. Second step
   - ▶ Intermediate result
3. Third step

### Result

This is the final result.

### Elements of the User Interface

Elements that are displayed on the user interface, such as buttons or menu items, are indicated by square brackets and bold font. Example: **[Button]**.

### Navigation paths

The elements of a navigation path are shown in bold and separated by ">".

Example: **[Main menu]** > **[Sub-menu]** > **[Item]**

### Highlights

Text that needs to be emphasized is shown in **bold font.**

### Cross References

Cross references are indicated using "see" or "see also".

### Notes

Notes are indicated using the word "Note" in bold font.
They indicate useful information and may be placed anywhere in the text. Example:

**Note**

Useful information is indicated using the word "Note" in bold font. The information itself is given in regular font.

## Figures

Figures that show the product or the user interface are used for illustration purposes only. The details shown in the figure may differ from that of the delivered product or your software version.

## Abbreviations

The following abbreviations are used in this technical manual.

| Abbreviation | Meaning |
|---|---|
| CoC | Certificate of Conformity |
| FCC | Federal Communications Commission |
| HF | High frequency |
| IP | International Protection |
| MRI | Magnetic Resonance Imaging |
| NRTL | Nationally Recognized Test Laboratory |
| RF | Radio frequency |
| SCS | Spinal Cord Stimulation |
| TENS | Transcutaneous Electrical Nerve Stimulation |
| WPA2 | Wi-Fi Protected Access, Version 2 |

## Gender

Personal designations are used in the male or female form in order to facilitate the flow of reading. This form is intended to include all gender identities.

# 2 Safety

This chapter contains safety messages referring to the handling of the Prospera SCS System and transport and storage of the system components.

## Warnings

⚠ **WARNING**

**Heat Generation Resulting from Use of Non-BIOTRONIK Charger**

If you use a charger made by another manufacturer, the stimulator surface may become hot and cause injury.

- Only use a **BIOTRONIK-provided charger** to charge your stimulator.

⚠ **WARNING**

**Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment**

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 12 inches (30 cm) from this device, this can result in a reduction in its performance.
This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennae), keep such devices at a distance of **at least 12 inches (30 cm) from the charger**.

## Precautions

**⚠ Caution**

**Heating of Metallic Objects like Surgical Staples by the Charger**

The charger can heat up nearby metallic objects like surgical staples when turned on.

- Do not position the charger over your stimulator if there are **metallic surgical staples** between the stimulator and the charger.
- Do not turn on or use the charger near metallic objects like keys or clothing zippers.

**⚠ Caution**

**Injuries due to Heat Generation while Charging**

The charger or the stimulator may heat up while charging. Causes for this include: excessive charge time, charger poorly aligned with stimulator, high ambient temperature, or malfunction of the charger.

- **Stop the charging process** if you feel uncomfortable heat near the charger or the stimulator.
- **Stop the charging process** if the Alert symbol on your charger lights up and the charger emits a sharp beep sequence.
- Do not use the charger if the ambient temperature is above +95°F (+35°C).

## Further Safety Notes

⚠ **Attention**

**Product Damage and Risk of Injuries due to Modification of Charger**

Any modification of the charger might lead to a device malfunction and result in injuries.

- **Do not modify the charger**.

⚠ **Attention**

**Risk of Electromagnetic Interference through the Use of Unauthorized Accessories**

The use of accessories, transducers or cables not listed by BIOTRONIK or of accessories other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- **Only use accessories authorized by BIOTRONIK**.

**Attention**

**Interrupted or Delayed Charging due to Wrong Operating Conditions**

If you operate the charger outside of the specified conditions, the charger may be damaged and the charging process may be delayed until you receive a new charger.

- **Do not use the charger in water or in the vicinity of water.**
- Do not shower or bathe while wearing the charger.
- Only use the charger at an ambient temperature between +50°F and +104°F (+10°C and +40°C).
- Only use the charger to charge the stimulator at an ambient temperature between +50°F and +95°F (+10°C and +35°C).
- Only use the charger at an atmospheric pressure between 700 hPa and 1060 hPa.
- Only use the charger up to 9,843 ft above sea level (3,000 m).

**Attention**

**Interrupted Charging due to Electromagnetic Interference**

Electronic devices may interfere with the functionality of the charger.

- Avoid using the charger near sources of electromagnetic interference such as other wireless chargers, electronic anti-theft systems or metal detectors.

**Attention**

**Infection through Contamination of Wounds**

The charger is not sterile. If the charger comes into contact with skin injuries, wounds may become infected.

- Do not place the charger on **open wounds**.
- Do not place the charger on the implant site after implantation until your physician has directed you to do so.

**Attention**

**Undesirable Therapy Possible with TENS Use**

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver too much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

**Attention**

**Impaired Charging due to Wrong Position of the Stimulator**

If the implanted stimulator is rotated or twisted in its pocket, the charger may not be able to establish a connection to the stimulator. As a result, the charging process may be prolonged or the stimulator may not be charged at all.

- **Do not rotate or twist the stimulator**.

**Attention**

**Interference with the Stimulation Therapy due to Electromagnetic Interference**

Electromagnetic fields may affect the spinal cord stimulation system. The stimulation therapy may be disturbed temporarily.

- Turn the stimulation off temporarily.
- Avoid situations with especially risky electromagnetic impacts and choose alternatives if possible.
- Note that effects from electromagnetic interference may not be obvious but could lead to a malfunction of the system.
- Clear up any suspicion of a malfunction by contacting your physician to schedule a follow-up of the system.

**Attention**

**Undesired Therapies or Loss of Therapies due to Wrong Operating Conditions**

When you operate the implantable stimulator outside of the specified conditions it may be damaged.

- Only use the stimulator at altitudes below 9843 ft (3000m).
- Only use the stimulator at an atmospheric pressure of 700 hPa to 1060 hPa.

**Attention**

**Product Damage due to Maintenance while the Charger is in Use**

If you perform any of the activities described in the chapter Care [Page 78] while the charger is in use, the charger may be damaged and the function impaired.

- Only perform the activities when the charger is not in use.

**Attention**

**Risk of Electromagnetic Interference**

The use of the charger adjacent to or stacked with other devices should be avoided, as this may lead to the devices operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor the charger and the other device(s) being used with it in order to ensure that they are all working correctly.

## Transport and Storage

### Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

When traveling by airplane, the patient programmer should be put into airplane mode.

The charger contains a battery. Pay attention to the following while transporting and storing the charger:

- Keep the charger away from water, chemicals, and food items.
- Protect the charger from becoming damaged or soiled.
- Protect the charger from heat. Do not leave the charger in a vehicle at high temperatures and do not put it in the microwave.
- Do not transport or store the charger in air-tight containers.
- Store and transport the charger out of the reach of children, pets, and pests. Do not leave children or pets unattended with the charger.

Ensure the following ambient conditions for storage and transport:

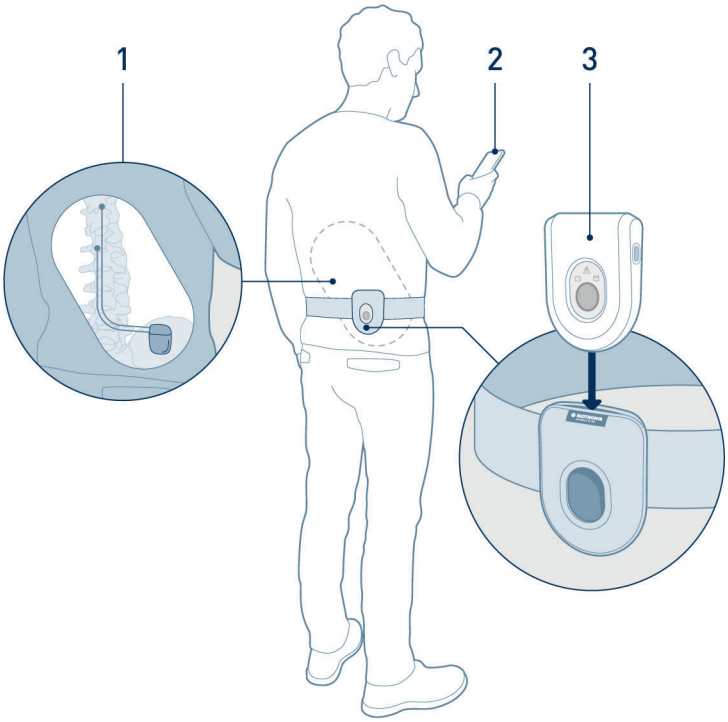
| | |
|---|---|
| Temperature range | +14°F ... +113°F<br>(-10°C ... +45°C) |

Only use an undamaged charger. If you notice any changes (irregular coloration, strong smell, etc.) in the charger during storage, handling, charging, or normal use, stop using the damaged charger immediately. Contact your physician for further assistance.

If the charger is leaking any fluid, stop using the charger. Rinse any leaking fluid with plenty of clean water. If leaking fluid comes into contact with your eyes, rinse them with plenty of clean water and consult a physician.

# 3 Product and System Description

## Overview of the System Components




| | |
|---|---|
| 1 | Implanted stimulator and leads |
| 2 | Patient programmer |
| 3 | Charger with charger belt |

You have received an implanted spinal cord stimulation system. The system delivers electrical pulses to the spinal cord to relieve pain.

For this purpose, one or two leads were implanted near your spinal cord. A stimulator has been implanted under the skin of your lower left or right back.

The system is comprised of the implanted stimulator, which is used to generate electrical pulses, and one or two implanted leads, which are used to deliver the electrical pulses. The implanted stimulator must be charged regularly (daily or weekly). To help you do this, your physician has given you a charger.

For personally controlling your therapy, your physician has given you the patient programmer. This is used to change the therapy program and increase or decrease the program strength according to what works best for you.

## Implantable Stimulator

The implantable stimulator is typically implanted in the lower back. It has the same therapy functions as the external stimulator previously used during your temporary trial.
The implantable stimulator has been programmed according to your medical condition and paired with a patient programmer.

The implantable stimulator consists of a can and a header.
The can houses the rechargeable battery and electronic circuits.
The header contains the connectors for the leads and a battery charging coil.

You can adjust therapy based on your individualized daily needs using the patient programmer. During the charging process, the charger is placed over the header of the implantable stimulator to efficiently charge the battery. You can check the battery status of the implantable stimulator using the patient programmer and conveniently charge it with the charger.

## Leads

Depending on your medical condition, up to two leads may be implanted and connected to the stimulator. The leads are implanted near the spinal cord to deliver electrical pulses intended to have a pain relieving effect. The leads are made of a very flexible material to adapt to your movements.

## Patient Programmer

As part of your spinal cord stimulation system, you have received a patient programmer. The patient programmer is used to change which stimulation program you are using, as well as to increase or decrease the strength of the stimulation. The general operation of the patient programmer is no different from that of a standard smartphone. However, you will not be able to perform typical phone functions on it, such as making phone calls or installing other apps.

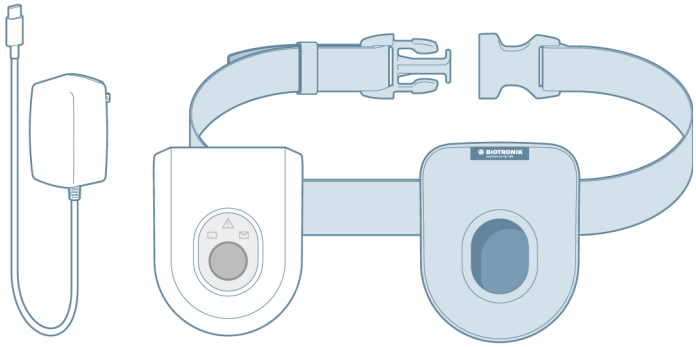
For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

## Charger

The implanted stimulator uses a rechargeable battery and must be charged regularly. To help you do this, your physician has given you a charger with the corresponding charger belt.

The charger itself has a rechargeable battery. The transfer of energy from the charger to the stimulator takes place wirelessly.

In order to charge the stimulator efficiently, the charger must be held in alignment with the stimulator for the entire charging session. Using the charger belt, the charger is held on the body, over the stimulator, to charge it.



# 4 First Steps

## Package Contents

After successfully implanting the spinal cord stimulation system, your physician has given you the following items:

- This technical manual
- The charger with the following components:
  - Charger
  - 2 charger belts of different lengths
  - A wall adapter with USB connector and power plug adapters
- The patient programmer with the following components:
  - Patient programmer
  - Smartphone manufacturer's information for the patient programmer
  - Charging cable
  - Power plug adapter

## Unpacking the Items

1. Unpack all items.
2. Check if you have received all listed items.
3. Contact your physician if items are missing to replace them.
4. Check the items for any visible damage.
5. Do not use the items if there is any visible damage. Contact your physician to exchange the damaged items for new ones.

# 5 Operating the Charger

## General Notes about the Device

Please always follow the listed safety messages when using the charger:

⚠ **Attention**

**Product Damage and Risk of Injuries due to Modification of Charger**

Any modification of the charger might lead to a device malfunction and result in injuries.

- **Do not modify the charger**.

**Attention**

**Interrupted or Delayed Charging due to Wrong Operating Conditions**

If you operate the charger outside of the specified conditions, the charger may be damaged and the charging process may be delayed until you receive a new charger.

- **Do not use the charger in water or in the vicinity of water.**
- Do not shower or bathe while wearing the charger.
- Only use the charger at an ambient temperature between +50°F and +104°F (+10°C and +40°C).
- Only use the charger to charge the stimulator at an ambient temperature between +50°F and +95°F (+10°C and +35°C).
- Only use the charger at an atmospheric pressure between 700 hPa and 1060 hPa.
- Only use the charger up to 9,843 ft above sea level (3,000 m).

**Attention**

**Interrupted Charging due to Electromagnetic Interference**

Electronic devices may interfere with the functionality of the charger.

- Avoid using the charger near sources of electromagnetic interference such as other wireless chargers, electronic anti-theft systems or metal detectors.

## Design and Function

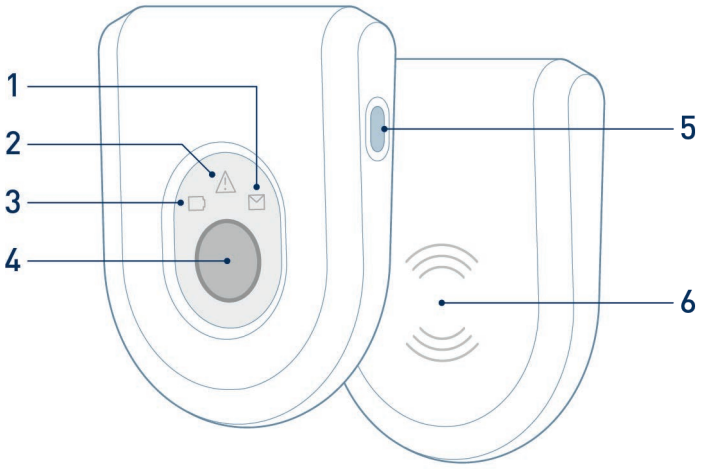
### Charger

The charger has 1 illuminated control button and 3 illuminated symbols.

The control button and the symbols draw your attention to the charger battery status, state changes, malfunctions, and notifications of the patient programmer through the following signals:

- Lighting up in different colors, blinking, and pulsing
- Single or multiple beeps

The meaning of these signals can be found in the respective instructions and descriptions.

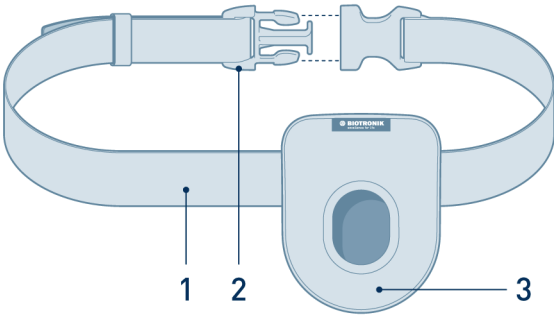



| | | | |
|---|---|---|---|
| 1 | See Patient Programer | 4 | Control button |
| 2 | Alert | 5 | USB connector |
| 3 | Charger Battery Status | 6 | Position indicator |

| Control Button / Symbol | Function |
|---|---|
|  Control button | • Button for turning the charger on/off (press for 4 seconds)<br>• Button for initiating the search for the stimulator to start charging (press for 1 seconds when charger is on.)<br>• Lights up green, blinks green, lights up amber or blinks amber: Indicates the status of the connection to the stimulator and the status of the charging process. |
|  Charger Battery Status | Lights up green, blinks green, lights up amber or blinks amber: Indicates the state of charge of the charger battery. |
|  Alert | Lights up amber or blinks amber: Alert. |
|  See Patient Programmer | Lights up amber: Connect your stimulator to the patient programmer for more details. |

For more information about the symbols, see also Light Signals [Page 49].

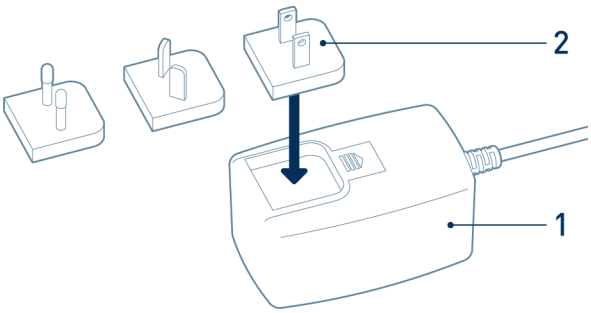
## Charger Belt




| | | | |
|---|---|---|---|
| 1 | Charger belt | 3 | Pocket for the charger |
| 2 | Clasp | | |

## Wall Adapter

The package contents include several country-specific power plug adapters.




| | | | |
|---|---|---|---|
| 1 | Wall adapter | 2 | Power plug adapter |

## Symbols on the Back of the Charger

| Symbol | Meaning |
|---|---|
|  | Manufacturer |
|  | Manufacturing date |
| REF | BIOTRONIK order number |
| SN | Serial number |
|  | Observe the technical manual |
|  | Type BF applied part |
|  | MR unsafe |
| IP22 | • Protection against the ingress of solid foreign bodies with a ⩾ 12 mm diameter<br>• Protection against dripping water falling at an angle up to 15° |
| GTIN | Global Trade Item Number |
|  | NRTL certification mark |
|  | Federal Communication Commission |
|  | Regulatory compliance mark (for Australia) |

## Selecting a Suitable Location for Charging the Charger

To connect the charger to the wall outlet, select a location that fulfills the following criteria:

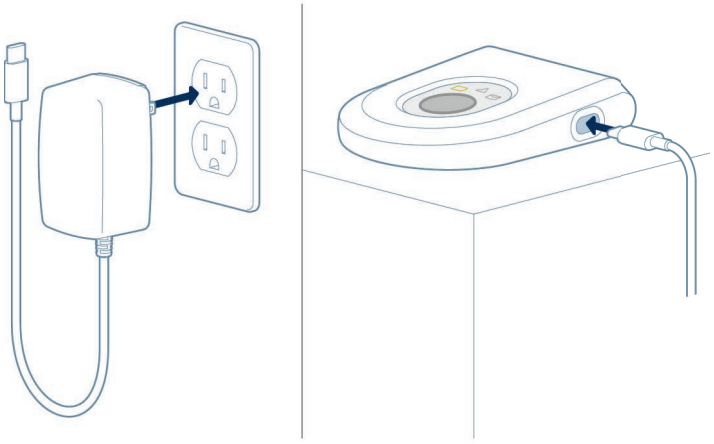
- Even, dry and non-metal surface
- The charger cannot slip, even while the cables are connected
- No danger of tripping
- The cable will not be under tension
- The charger is protected against liquids and moisture
- The power plug is freely accessible and can be pulled out at all times
- The wall outlet is not connected to a light switch
  This way, you prevent the charging from being accidentally interrupted.
- The charger must not be charged on an airplane

## Preparing the Wall Adapter

If the pre-installed power plug adapter is not appropriate for your region, follow the instructions below:

1. Remove the pre-installed adapter.
2. Insert the appropriate power plug adapter into the wall adapter.
   ▶ The power plug adapter audibly snaps into place.

## Charging the Charger



1. Connect the wall adapter to the wall outlet.
   Only use the power cord supplied with the product. Other power cords can damage the charger.
2. Insert the USB connector of the wall adapter into the USB port of the charger.
   - ▶ All the symbols on the charger light up for 1 second.
   - ▶ The Charger Battery Status symbol then indicates the current state of charge of the charger battery, see Light Signals [Page 49].
3. Charge the charger until the Charger Battery Status symbol lights up solid green.
   - ▶ The charger is fully charged.

## Recommendations for Charging the Charger

Always charge your charger fully to ensure that you are able to fully charge your stimulator at any time. Leave the charger plugged into a wall outlet when it is not being used to charge the stimulator.

The Charger Battery Status symbol and the beeps of the charger provide you information on the current charger battery status.

Once the charger has been charged, then you can charge the stimulator.

# 6 Charging the Stimulator

## Charging Intervals

Charge your stimulator regularly so it can reliably deliver therapy. Select fixed, regular times for charging the stimulator, for example, same day of the week, every week. This way you can ensure that the stimulator is always adequately charged.

How frequently you need to charge your stimulator depends on your individual therapy settings.

The current battery status of your stimulator will be indicated on your patient programmer. If the charge on your stimulator is so low that it needs to be charged to prevent loss of stimulation, you will also receive a notification on your patient programmer.

If the stimulator battery charge gets too low, stimulation will turn off and therapy will stop. Several days after stimulation stops due to low battery, you will no longer be able to communicate with the stimulator using your patient programmer until you have charged your stimulator.

If the stimulator is not charged for multiple months after the stimulation has turned off due to low battery, it is possible the long-term performance of the stimulator battery could be affected.

## Dos and Don'ts for Charging the Stimulator

While charging the stimulator, the charger must be placed directly over your stimulator. This is the only way the stimulator can be charged. Using the charger belt, the charger is held on the body, over the stimulator.

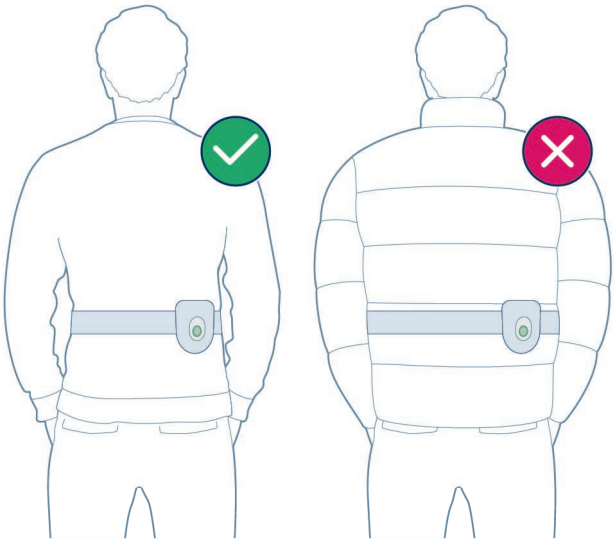
**Attention**

**Infection through Contamination of Wounds**

The charger is not sterile. If the charger comes into contact with skin injuries, wounds may become infected.

- Do not place the charger on **open wounds**.
- Do not place the charger on the implant site after implantation until your physician has directed you to do so.

- Equipment for charging the stimulator
  - Only use the charger for charging your **own stimulator**.
  - Only charge your stimulator with a **BIOTRONIK-supplied charger**.
  - Do not use a **damaged charger or charger belt**.
- Physical conditions for charging the stimulator
  - Do not use the charger when you are **tired or sleeping**.
- Location for charging the stimulator
  - Do not use the charger in an airplane.
- Clothing type for charging the stimulator
  - Ensure that the charger is **adequately ventilated** during the charging. Over the charger, do not wear any clothing or only wear thin clothing.
  - Only wear a **thin layer of clothing** or nothing between the charger belt and your skin.



- Position while charging the stimulator
  - Do not make any **movements** that cause the charger to move away from its position above the stimulator while charging.
  - Minimize resting on pillows, cushions or other objects that could **cause heat** to build up around the charger while charging.
- Metallic objects near the charger
  - Do not place the charger on **metallic objects**.
  - Do not position the charger over your stimulator if there are metal **surgical staples** present between the stimulator and the charger.
- Use of charger during the charging process
  - Do not attempt to charge the stimulator while **charging the charger**. The charger will not perform stimulator charging while plugged in to wall power.

## Positioning the Charger and Charging the Stimulator

⚠ **WARNING**

**Heat Generation Resulting from Use of Non-BIOTRONIK Charger**

If you use a charger made by another manufacturer, the stimulator surface may become hot and cause injury.

- Only use a **BIOTRONIK-provided charger** to charge your stimulator.

⚠ **Caution**

**Heating of Metallic Objects like Surgical Staples by the Charger**

The charger can heat up nearby metallic objects like surgical staples when turned on.

- Do not position the charger over your stimulator if there are **metallic surgical staples** between the stimulator and the charger.
- Do not turn on or use the charger near metallic objects like keys or clothing zippers.

**Caution**

**Injuries due to Heat Generation while Charging**

The charger or the stimulator may heat up while charging. Causes for this include: excessive charge time, charger poorly aligned with stimulator, high ambient temperature, or malfunction of the charger.

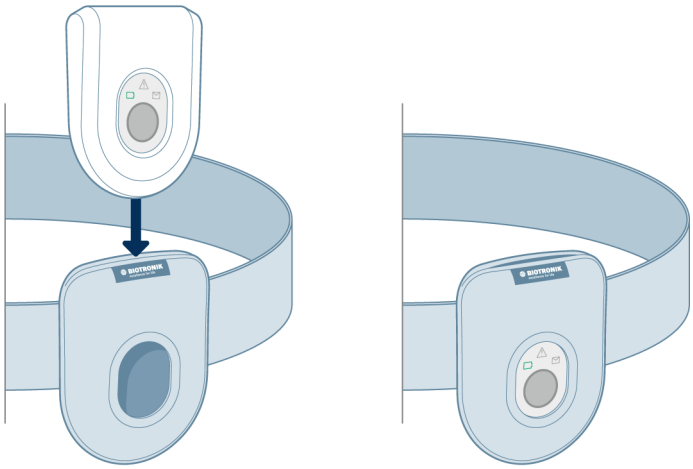
- **Stop the charging process** if you feel uncomfortable heat near the charger or the stimulator.
- **Stop the charging process** if the Alert symbol on your charger lights up and the charger emits a sharp beep sequence.
- Do not use the charger if the ambient temperature is above +95°F (+35°C).

## Procedure for Positioning the Charger and Charging the Stimulator

### Prerequisite

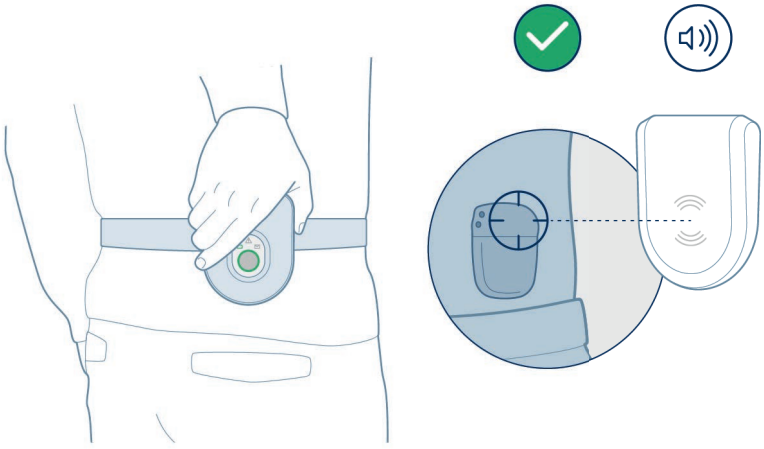
- The charger is adequately charged and unplugged.
- Any thick clothing which could interfere with charging has been removed.

1. Put the charged charger in the charger belt pocket.
   The symbols and control button on the charger must be visible.



2. Press the control button of the charger for at least 4 seconds.
   - ▶ All the symbols light up briefly.
   - ▶ The charger is turned on.
3. Place the charger belt at the height of the stimulator around your body and close the clasp.
   The symbols on the charger must be visible.
4. Fasten the charger belt in such a way that you can change the belt position easily.

5. Press the control button of the charger for 1 second.
   - ▶ Short repeating beeps are emitted.
   - ▶ The control button blinks green.
   - ▶ The charger is in the locating mode and attempts to establish a connection with the stimulator for 75 seconds.
6. Position the charger over the stimulator by moving the charger belt. Slowly adjust the position over the stimulator.



   - ▶ The confirmation signal (long beep) indicates that the charger has established a connection with the stimulator.
   - ▶ The charging begins.
7. Tighten the charger belt around your body.
   The belt should not move during the charging process.

**Note**

If the charger cannot establish a connection with the stimulator after 75 seconds, the control button illumination is turned off, the beeps stop and the charger terminates the locating mode.
Press the control button again for 1 second.
The charger enters the locating mode again and reattempts to establish a connection with the stimulator.

For more information about the symbols on the charger, see Signals of the Charger [Page 46].
For possible errors while charging the stimulator, see Troubleshooting while Using the Charger [Page 80].

Always fully charge the stimulator to ensure that the stimulator can reliably deliver therapy for as long a period as possible.

**Note**

If you have to interrupt the charging process before the stimulator is fully charged, wait for locating mode to begin, and then press and hold the control button for 4 seconds to disable locating mode. Then press the control button for another 4 seconds to turn off the charger.

### Procedure for Ending Charging

As soon as the stimulator is fully charged, the control button of the charger blinks green and a three beep ascending tone sequence is emitted twice.

1. Open the clasp of the charger belt and take off the charger belt.
2. Take out the charger from the pocket on the charger belt.
3. Prepare the charger for the next charging process.
   This way, you ensure that you are ready to charge the stimulator at any time.
   See Charging the Charger [Page 35]

# 7 Signals of the Charger

## Audio Signals

### Turn-on Signal

A single low beep is emitted if you press the control button for 4 seconds or if you connect the charger to a wall outlet with the charging cable. All symbols briefly light up. Then the **Charger Battery Status** symbol lights up or blinks.
The charger is turned on.

### Locating Mode


The charger emits short repeating beeps if you press the **control button** for 1 second while the charger is turned on. This signal indicates that the charger is trying to connect to the stimulator. The **control button** simultaneously blinks **green**. Position the charger over the stimulator by moving the charger belt. As soon as the connection between charger and stimulator is established, the confirmation signal sounds.
If no connection can be established after 75 seconds, the charger stops beeping (without confirmation signal) and terminates the locating mode. Check whether thick clothing is interfering with the connection between charger and stimulator. Press the control button for one second to restart the locating mode.

### Connection Established/Confirmation

Long beep indicates that the connection between charger and stimulator is established and charging begins.
The **control button** lights up **green**.
The connection is preceded by the locating mode, which is activated by pressing the control button.

### Pairing Lost/Locating

A short signal combination followed by short repeating beeps indicates that the charger has lost connection to the stimulator and is in locating mode again. This may happen if the charger belt gets out of place. Reposition the charger over the stimulator. As soon as the connection is re-established, this is signaled by the confirmation signal (long beep).

### Charging Complete

A three beep ascending tone sequence during the charging process signals that the charging of the stimulator is completed. The **control button** blinks **green** for 20 seconds and then turns off. Remove the charger belt.

### Alert

 4 x

A signal combination of high and low tones is repeated four times.

The alert signal is always combined with one or more **blinking light signals**. The alert signal indicates one of the following status:

- Charger battery too low
- Overheating or charger error
- Stimulator battery can no longer be charged

Please refer to the description of the light signals, see Light Signals [Page 49].

### Alert

 2 x

A signal combination of high and low tones is repeated twice if you press the control button while the charger is connected to the charging cable. It is not possible to charge the stimulator and the charger at the same time. Disconnect the charging cable before you start the locating mode.

## Light Signals

### All Symbols Briefly Light Up

You have turned on the charger or connected it to a wall outlet. All symbols briefly light up. Then the Charger Battery Status symbol lights up or blinks. The charger is turned on.

### Locating Mode


The control button blinks green if you press it for 1 second while the charger is turned on. This signal indicates that the charger is trying to connect to the stimulator. The **locating mode signal** (short repeating beeps) is emitted simultaneously.
Place the charger over the stimulator by moving the charger belt. As soon as the connection between charger and stimulator is established, the confirmation signal sounds and the control button lights up green.
If no connection is established in 75 seconds, the charger stops beeping (without confirmation signal) and terminates the locating mode. Check whether thick clothing is interfering with the connection between charger and stimulator. Restart the locating mode.

### Charging the Stimulator

The charger is connected to the stimulator. The control button lights up green. The stimulator is charging.

### Charging Complete


When the stimulator is fully charged, the control button blinks for 20 seconds and then turns off. The charger simultaneously emits the **charging complete signal** (a three beep ascending tone sequence). Remove the charger belt.

### Pairing Lost/Locating

The control button blinks amber for 2 seconds and the charger simultaneously emits the **pairing lost signal** (a short signal combination). The charger has lost connection to the stimulator. It immediately starts the locating mode again and emits the **locating mode signal** (short repeating beeps). The control button blinks green.

This may happen if the charger belt gets out of place due to excessive movement. Reposition the charger over the stimulator.

### See Patient Programmer

The See Patient Programmer symbol lights up amber.

There is a notification for you on the patient programmer. Read and confirm the notification.

### Overheating or Charger Error

The Alert symbol blinks amber while the stimulator is charging. In addition, the charger emits the **alert signal** (a signal combination of high and low tones that is repeated 4 times).
The charger has overheated. Abort the charging process. Allow the charger to cool down for at least 60 minutes; until then, it is not possible to start the charging process.
If further charging is desired, after 60 minutes, start charging the stimulator again. Make sure not to cover the charger with pillows or blankets to prevent it from becoming overheated again.
If the Alert symbol still blinks when you try charging again after 60 minutes, the charger needs further troubleshooting or replacement. Contact your physician.

### Stimulator Battery cannot be Charged

The Alert symbol lights up amber and the See Patient Programmer symbol blinks. In addition, the charger emits the **alert signal** (a signal combination of high and low tones that is repeated 4 times). The symbols will stay lit for at least one minute, and they will continue to stay lit if the charger is plugged in.
When trying to charge the stimulator, the charger has detected that the stimulator is too discharged to be charged. Contact your physician.

### Charger Fully Charged

The Charger Battery Status symbol lights up green or blinks green.
The battery of the charger is charged.
You can use the charger to charge the stimulator. If the charger is connected to the charging cable, remove it before you start charging.

### Charger Sufficiently Charged

The Charger Battery Status symbol pulses amber or lights up amber.
The battery of the charger is sufficiently charged.
You can use the charger to charge the stimulator.

### Charger Battery too Low

The Charger Battery Status symbol blinks amber.

The battery of the charger is no longer sufficiently charged.

During the stimulator charging process or while starting the locating mode, the charger battery status may drop from low to very low. In this case, the charger emits the **alert signal** (a signal combination of high and low tones that is repeated 4 times).

Charge the charger at least until the Charger Battery Status symbol no longer blinks amber but pulses amber.
If possible, charge the charger until the Charger Battery Status symbol lights up green.

# 8 Using the Patient Programmer

## General Notes about the Device

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

**Note**

Unauthorized access to the patient programmer may result in insufficient or excessive stimulation.

- Protect your patient programmer against unauthorized access.
- Lock the patient programmer when you are not using it.
- To unlock the patient programmer, use a secure password that cannot be guessed. Refer to the smartphone manufacturer's information on how to create a secure password.
- When unlocking the patient programmer, ensure you are not in a location where someone could see your password.
- Keep the patient programmer in a secure place and do not disclose your password.
- If your patient programmer is lost or stolen, contact your physician.

The patient programmer comes with cellular network connectivity enabled. You should also connect the patient programmer to a wireless network (WiFi), such as those found in most homes. This can be done in the same way that you would connect your personal devices to your wireless network. This is recommended for ensuring app updates occur.

The patient programmer is designed for daily use.

If the battery capacity reduces over time and becomes unsuitable for daily use, please contact your physician to get a replacement.

### Note

Misuse of the patient programmer may result in insufficient or excessive stimulation.

- Only run applications on the patient programmer that are associated with the patient programmer app. Do not install or run any other app on the patient programmer.
- Do not manipulate the operating system of the patient programmer, in order to not compromise the built-in protection provided by the hardware or software manufacturer.
- If you suspect security issues, contact your physician.

## Notes on Daily Use

### Environment

The patient programmer is a standard smartphone and should only be used in places where the use of a smartphone is permitted. Before using the patient programmer, make sure that its use is not prohibited in your location.

## Communication with Stimulator

The patient programmer and the stimulator communicate wirelessly. For a reliable connection between the patient programmer and stimulator, please ensure the following:

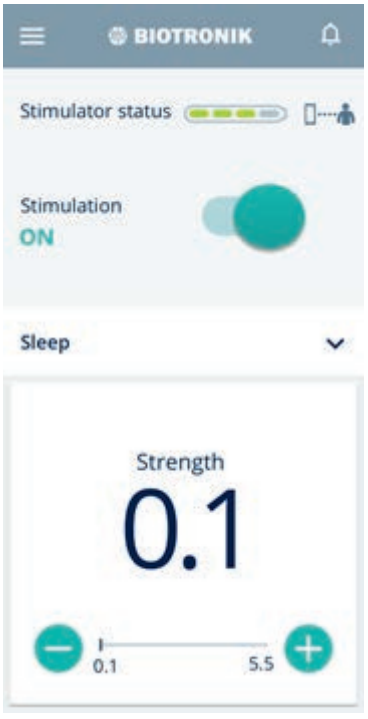
- Regularly charge the patient programmer.
- Charge the patient programmer nightly by your bedside or other location where you will be near the patient programmer on a daily basis.
- Regularly charge the stimulator.
- The distance to the stimulator should not exceed 5 ft (1.5 m) while in use.
- The Bluetooth function of the patient programmer should always be turned on.
- When the patient programmer is not in use, it is recommended that you leave it plugged in at your bedside or other location you are regularly near each day. This will allow your stimulator to transfer data to your patient programmer on a daily basis, even if you do not need to use your patient programmer for stimulation adjustments.
- Avoid restarting the patient programmer or the patient programmer app unless needed. In the event the patient programmer app is restarted, there will be some delay before communication with the stimulator is available again.

### Airplane Mode and other Settings

The patient programmer device can be put into airplane mode. In airplane mode, it can continue to be used for stimulation adjustments as long as the Bluetooth function is enabled.
It is recommended to disable the airplane mode when it is no longer needed.
To access settings associated with the smartphone, use the **[Additional Information]** menu outside of the patient programmer app, and refer to the smartphone manufacturer's information.

## Understanding the User Interface and Menu

Main screen



The following elements are available on the main screen:

| Element | Explanation |
|---|---|
| Menu  | Opens the menu. |
| Notifications  | Opens the **[Notifications]** screen. |
| Unread Notifications  | Indicates that unread notifications are present and opens the **[Notifications]** screen. The number indicates the number of notifications. |
| Connected  | Indicates that the stimulator is in communication with the patient programmer. |
| Disconnected  | Indication that the stimulator is not able to communicate with the patient programmer due to range or interference issues. |
| Battery Status  | Indicates the battery status of the stimulator. |
| Charging  | A lightning bolt symbol and blinking green battery status indicators show that the stimulator is being charged. |

| Element | Explanation |
|---|---|
| Stimulation on  | Indicates that the stimulation **is turned on** and turns the stimulation off when selected. |
| Stimulation off  | Indicates that the stimulation **is turned off** and turns the stimulation on when selected. |
| Therapy Programs  | Opens the list of programs that can be selected.<br>The currently selected program is displayed on the left. |
| [Strength] | Displays the current value of the program strength. |
| Adjusting the Program Strength  | Decreases or increases the program strength. |

## Selecting the Stimulation Program

### Note

The selected program or the settings may not be optimal for you and may not fully relieve your pain or may cause side effects.

1. Read the following instructions carefully.
2. Ensure that you understand the instructions and that you can operate the device properly.
3. If in doubt, ask your physician.

Depending on the therapy and your daily habits, your physician has configured various programs. You can select them on the patient programmer.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the button to open the list of programs that can be selected.
2. Select the desired program.

### Result

The desired program is selected, activated on the stimulator, and the stimulation starts.

## Turning the Stimulation on/off

Under certain circumstances it may be necessary to turn the stimulation on or off.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. **For turning on:** 
   When the stimulation is in this turned off state, select the switch to turn it on.

   **For turning off:** 
   When the stimulation is in this turned on state, select the switch to turn it off.

### Result

The stimulator starts or stops the stimulation.

## Setting Program Strength

The program strength can be increased or decreased, depending on your daily habits, using the patient programmer.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The stimulation is turned on.
- The patient programmer app is open and the main screen is displayed.

1. **Increase** the program strength:
   Select the + button.
   **Decrease** the program strength:
   Select the − button.

### Result

The stimulation continues with the adjusted program strength.

For possible errors when changing the program strength, see Troubleshooting while Using the Patient Programmer [Page 81].

## Checking the Battery Status of the Stimulator

To estimate the next charging cycle, you can check the battery status of the stimulator using the patient programmer.

The following battery statuses are displayed:

| Symbol | Battery Status of the Stimulator |
|---|---|
| 4 green segments  | The stimulator is fully or nearly fully charged. |
| 3 green segments  | The stimulator is partially charged. The remaining operating time, before you have to charge the stimulator again, depends on your stimulation settings. |
| 2 green segments  | The stimulator is partially charged. The remaining operating time, before you have to charge the stimulator again, depends on your stimulation settings. |
| 1 yellow segment  | The stimulator has a low charge. Charge the stimulator soon. |

| Symbol | Battery Status of the Stimulator |
|---|---|
| 1 red segment  | The stimulator is nearly empty. Stimulation may stop at any moment. The stimulator mus be charged. |
| All grey segments  | The stimulator has used up all the charge. Stimulation has stopped. The wireless connection will remain active for several days after this indication appears. The stimulator must be urgently charged. |
| Lightning bolt symbol  | The stimulator is currently charged. A lightning bolt symbol and blinking green battery status indicators show that the stimulator is being charged. |

On rare ocasions, other batery statuses are possible, see Troubleshooting while Using the Patient Programmer [Page 81].

## Displaying Notifications

### Note

Notifications from the stimulator or from your physician will be displayed in the patient programmer app. Messages from other sources, like the operating system of the smartphone, are displayed in other locations on the screen.

In all cases, follow the instructions on the screen carefully. If in doubt, ask your physician.

To view the notifications in the patient programmer app, proceed as follows.

### Prerequisite

- The patient programmer is adequately charged and is connected to the cellular network or wireless network (WiFi).
- The patient programmer app is open and the main screen is displayed.

1. Select the  button.

### Result

All notifications are displayed.

## Saving Default Strength

If you have more than one stimulation program available, every time you select a different stimulation program, the program strength will begin at a specific default strength. If you have adjusted the strength of a stimulation program, you have the option to save a new default strength so the program will always start at this value in the future.

### Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the desired program.
2. Adjust the desired stimulation strength.
3. Select the button for the menu.
4. Select the **[Save default strength]** menu item.
5. Confirm the new default strength for the current program selecting the **[Update]** button.

### Result

The new default strength is saved and, whenever the program is selected, it starts with the new program strength.

## Turning the MRI Mode on/off

The components of the spinal cord stimulation system should not undergo an MRI scan without restrictions. All external components like the charger, the patient programmer and the charger belt must not be taken to the MRI room.
Before undergoing an MRI scan with the spinal cord stimulation system, inform the examining physician about your spinal cord stimulation system. Together with the physician or a BIOTRONIK representative you will have to enable the MRI mode via your patient programmer.

**Note**

The stimulation is turned off while the MRI mode is turned on.

In case the MRI mode has been turned on accidentally, follow the instructions on how to turn it off.

### Turning the MRI Mode off

#### Prerequisite

- The stimulator is adequately charged. At least one bar is displayed in the battery status of the stimulator.
- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the **[Disable]** button on the main screen.


2. Confirm that you want to turn off the MRI mode, by selecting the **[PROCEED]** button.
   - ▶ The MRI mode in the stimulator is turned off and the main screen is displayed.
   - ▶ The stimulation is **not** automatically turned on.
3. Select the switch to turn on stimulation.

## Updating the Patient Programmer App

BIOTRONIK periodically updates the software of the patient programmer app when the patient programmer device is not actively being used. The updates are executed automatically. An active WiFi connection is required for the update. Connect the patient programmer to the WiFi to ensure updates occur. Additionally, plug in the patient programmer device when it is not in use. Do not turn the patient programmer device off overnight, so that the updates can be installed.

### Note

Additionally, updates for the operating system of the patient programmer will be available periodically. Make sure you do not need to make stimulation adjustments for a few minutes before proceeding.

- Keep the operating system of the patient programmer device up-to-date to ensure that you can perform stimulation adjustments without interruption.
- You may see a notification on the patient programmer device that an operating system update is available. Select the notification and follow the prompts to install the update. For more information, refer to the smartphone manufacturer's information on how to update the operating system.
- Make sure you do not need to make stimulation adjustments for a few minutes before proceeding.

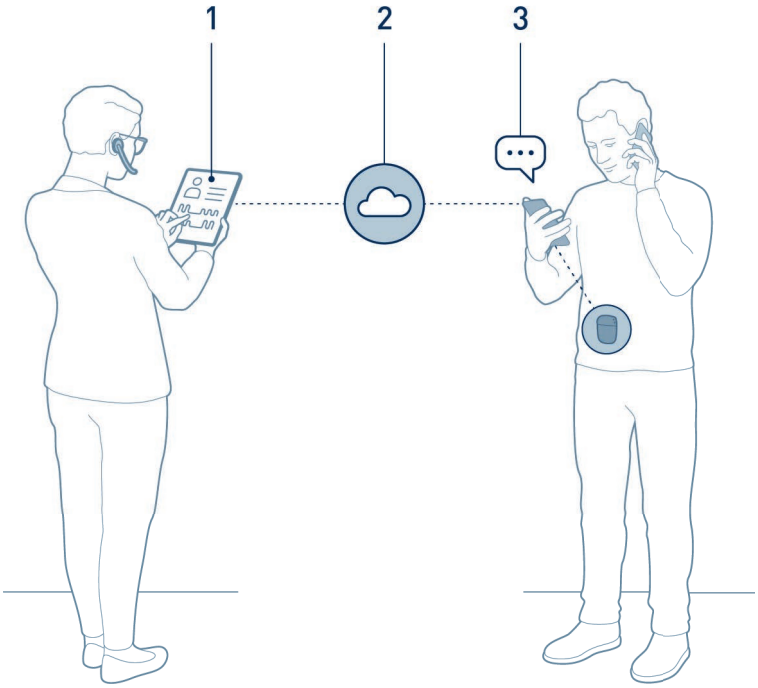
Please note the following information on data security for the patient programmer when using a network connection:

- Wireless communication between the clinician programmer, the stimulator, the patient programmer, and the BIOTRONIK server includes multiple levels of encryption to protect patient and clinician data.
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).

# 9 Remotely Receiving a New Program

## Overview

Receiving a new program remotely is a convenient way to receive a new stimulation program without having to visit your physician's office. You and your physician will decide during an in-office visit whether to turn this capability on in your stimulator.




| | |
|---|---|
| 1 | The physician will discuss and send the new program. |
| 2 | The transmission is sent in a secure and encrypted manner. |
| 3 | Program is sent to patient programmer where a confirmation box will be displayed. |

Receiving a new program happens in the following steps which are described in more detail in the following sections:

1. Your physician will call you to discuss your status and new program options.
2. The new program will be sent to your patient programmer remotely. To ensure your privacy and safety, the transmission is sent in a secure and encrypted manner.
3. Once received, a confirmation box will be displayed on the patient programmer for you to accept or reject the program.
4. If you accept the new program, it will be automatically installed on your stimulator.
5. The new program always starts with the minimum strength, 0.1. Increase the program strength as directed.

**Note**

You have to explicitly agree to participate in the remote service. No new program will be sent without your agreement.

## Preparing to Receive the Program

The following preparations must be made to receive a new program:

- You will need at least 15 minutes.
- Have a working phone on, so your physician can reach you.
- Go to a room where you will not be disturbed and where you can have a telephone conversation with your physician.
- Ensure the patient programmer is ready, adequately charged and the signal strength of the cellular or wireless network (WiFi) connection shows at least 2 bars. Shift your position or choose a different room if the signal strength is not sufficient.
- Ensure that the wireless communication between the patient programmer and the stimulator is working and the distance between them is less than 5 ft (1.5 m). The patient programmer main screen shows the active connection:

- Ensure that the battery status of the stimulator on the patient programmer shows at least 2 bars: 

## Installing the New Program

### Prerequisite

- The patient programmer app is active and the patient programmer is connected to the cellular network or the wireless network (WiFi). Your physician will establish a remote connection to your patient programmer and will check your spinal cord stimulation system status. The new program will then be sent to your patient programmer.

1. A confirmation box is displayed on the patient programmer indicating that the new program has been received. Accept the installation of the new program selecting the **[ACCEPT]** button.
   - ▶ Once the installation is successful, the **[Update successful]** confirmation box is displayed.
2. Select the **[CLOSE]** button to acknowledge this confirmation and return to the patient programmer **[Home]** screen.
   - ▶ The new program will be displayed as the currently selected program. The program strength will begin at 0.1.
3. Increase the stimulation selecting the + button.

### Result

The stimulation is started. The new program can be used like any other program on the patient programmer.

# 10 Everyday Life

## Risky Therapeutic and Diagnostic Procedures

The use of certain procedures during medical diagnosis and treatment poses a risk to you as a patient or may damage the spinal cord stimulation system. Therefore, certain procedures must be avoided. Other procedures may only be performed with special precautions.

Special precautions should be taken when using the following procedures:

- Diathermy
- HF ablation (tissue sclerotherapy)
- High frequency surgery
- Therapeutic ultrasound
- Hyperbaric oxygen therapy
- Magnetic resonance imaging

  An examination in the MRI scanner is possible. However, certain conditions must be met. For information on MRI mode, see Turning the MRI Mode on/off [Page 66].
- Transcutaneous electrical nerve stimulation (TENS)

**Attention**

**Undesirable Therapy Possible with TENS Use**

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver too much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

# Dos and Don'ts

## General Behavioral Information

Certain behaviour may pose a risk to your spinal cord stimulation system. Please pay attention to the following points:

⚠ **Attention**

**Impaired Charging due to Wrong Position of the Stimulator**

If the implanted stimulator is rotated or twisted in its pocket, the charger may not be able to establish a connection to the stimulator. As a result, the charging process may be prolonged or the stimulator may not be charged at all.

- **Do not rotate or twist the stimulator**.

## Interactions with Electromagnetic and other Environmental Influences

Certain factors such as electromagnetic or magnetic fields may pose a risk to you as a patient, or damage your spinal cord stimulation system, or damage other equipment. Please pay attention to the following points:

⚠ **Attention**

**Interference with the Stimulation Therapy due to Electromagnetic Interference**

Electromagnetic fields may affect the spinal cord stimulation system. The stimulation therapy may be disturbed temporarily.

- Turn the stimulation off temporarily.
- Avoid situations with especially risky electromagnetic impacts and choose alternatives if possible.
- Note that effects from electromagnetic interference may not be obvious but could lead to a malfunction of the system.
- Clear up any suspicion of a malfunction by contacting your physician to schedule a follow-up of the system.

**Attention**

**Undesired Therapies or Loss of Therapies due to Wrong Operating Conditions**

When you operate the implantable stimulator outside of the specified conditions it may be damaged.

- Only use the stimulator at altitudes below 9843 ft (3000m).
- Only use the stimulator at an atmospheric pressure of 700 hPa to 1060 hPa.

- Do not use non-BIOTRONIK wireless chargers in the vicinity of the implantable stimulator.
- Do not attempt to charge the implantable stimulator with a commercially available charger.
- Magnetic fields near the stimulator may deactivate the therapy function of the stimulator.
  Do not bring your stimulator close to strong magnetic fields.
- Do not pass through the metal detector at security checks. Use an alternate security check method. Turn off the charger and remove the charger from your body before a security check. Show your patient ID card to the security personnel.
- Avoid environmental influences that could potentially affect your spinal cord stimulation system.
- If you may be exposed to environmental influences that could potentially affect your spinal cord stimulation system, please contact your physician.
- Do not use the charger in an airplane.

## Physical Activities

Certain physical activities may pose a risk to your spinal cord stimulation system. Please pay attention to the following points:

### Note

As the leads are not firmly ingrown during the several weeks after the implantation, there is a risk that the leads may shift during physical activity, which could make the therapy less effective.

Your physician will provide you with instructions for limiting your physical activities for approximately the first 6 weeks after implantation. In general, this includes:

- Do not bend your upper body.
- Do not rotate your upper body.
- Do not stretch your upper body.
- Do not lift weights over 5 lbs (2 kg).
- Do not lift your arms overhead.

## Preparing for an In-Office Follow-Up

For an in-office follow-up the stimulator must be adequately charged.

- Ensure that the battery status of the stimulator on the patient programmer shows at least 2 bars.

For an in-office follow-up the patient programmer must be adequately charged.

## Care

**Attention**

**Product Damage due to Maintenance while the Charger is in Use**

If you perform any of the activities described in the chapter Care [Page 78] while the charger is in use, the charger may be damaged and the function impaired.

- Only perform the activities when the charger is not in use.

### Cleaning and Disinfecting the Charger

#### Conditions for Cleaning

- Disconnect the power plug from the wall outlet before cleaning.
- Do not allow the charger, wall adapter and the power cord to come in direct contact with water or solvents.

#### Cleaning the Charger

Use the following products for cleaning the charger and its components:

- A clean, soft lint-free cloth
- A mild soap solution

1. Clean the charger, the wall adapter and the power cord with a damp cloth and mild soap solution.
2. Dry the charger, the wall adapter and the power cord thoroughly.
3. After cleaning, check the charger, the wall adapter and all ports for dirt/contamination or visible damage.

### Disinfecting the Charger

Use the following products for disinfecting the charger:

- A clean, soft lint-free cloth
- An alcohol-based agent
- A quaternary ammonium agent wipe (e.g., PDI Sani-cloth)

1. Disinfect the charger using the alcohol-based agent or per disinfecting wipe manufacturer's instructions.
2. Allow the charger to dry thoroughly, until all residues of the disinfectant have completely evaporated.
3. After disinfecting, check the charger for visible damage.

### Cleaning the Charger Belt

Before cleaning the charger belt, make sure the charger is not in the pocket of the belt.

Clean the charger belt as needed.

Do not wash the charger belt in a washing machine and do not use a dryer to dry it.

Use the following products for cleaning the charger belt:

- Water
- A mild soap solution

1. Clean the charger belt using a mild soap solution.
2. Allow the charger belt to completely dry before you use it.

### Cleaning the Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

# 11 Troubleshooting

## Troubleshooting Stimulation

### Note

If an error occurs that is not described below, contact your physician.
If an error persists after you have tried the proposed solution, contact your physician.

**The stimulation turns off during use.**

- The stimulator battery is very low.
  Charge the stimulator with the charger.
- The stimulator came in contact with a strong magnet for longer than 1 minute.
  Use the patient programmer to confirm in notifications and then turn stimulation back on.
- A stimulator problem occurred.
  Use the patient programmer to check notifications for more information.

## Troubleshooting while Using the Charger

### Note

If an error occurs that is not described below, contact your physician.
If an error persists after you have tried the proposed solution, contact your physician.

**I don't understand the beeping and/or blinking signals of the charger.**

- See: Signals of the Charger [Page 46]

**The charger cannot connect with the stimulator while positioning it above the stimulator.**

- There is too much distance between the charger and the skin, for instance, due to thick clothing. Only wear a thin layer or no clothing between the charger belt and your skin.

**During the charging process, the stimulator or the charger emits excessive heat.**

- Interrupt the charging process if you feel uncomfortable heat near the charger or the stimulator.
- Ensure that the ambient temperature and the humidity are within the required limits, see General Characteristics for the Charger [Page 85].
- Make sure the charger is adequately ventilated. Only wear a thin layer or no clothing over the charger and do not cover the charger with blankets, pillows or other objects.
- Charge the stimulator in intervals of 30 minutes and interrupt charging process intermittently so that the temperature can be reduced.

**I have lost my charger.**

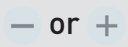
- If you have lost your charger, contact your physician to get a replacement.

## Troubleshooting while Using the Patient Programmer

**Note**

If an error occurs that is not described below, contact your physician.
If an error persists after you have tried the proposed solution, contact your physician.

**I don't understand the meaning of the symbols on the patient programmer.**

| Symbol | Meaning |
|---|---|
|  | The Disconnected symbol is displayed on the patient programmer.<br>**Cause:** The patient programmer is not connected to the stimulator.<br>**Proposed solution:**<br>• Regularly charge the stimulator.<br>• Ensure that the distance to the stimulator does not exceed 5 ft (1.5 m) during use.<br>• Ensure that the Bluetooth function of the patient programmer is always turned on.<br>• Remove any sources of interference such as power cables, microwave oven, fluorescent lights, or other wireless devices. |
|  | The button on the patient programmer is grayed out and the stimulation strength cannot be decreased or increased.<br>**Cause:** The minimum or maximum value for the program strength was reached.<br>**Proposed solution:** Contact your physician to change the strength limits of the existing program if a higher strength is desired. Alternatively, try changing to a different program. |
|  | The Battery Error symbol is displayed.<br>**Cause:** An error has occurred with the stimulator.<br>**Proposed solution:** Contact your physician. |

| Symbol | Meaning |
|---|---|
|  | The stimulator battery is empty.<br>**Cause:** The stimulator battery is completely empty. The stimulator cannot stimulate.<br>**Proposed solution:** Charge the stimulator. If you cannot turn on the stimulation after you have charged the stimulator, contact your physician. |

**The patient programmer cannot communicate with the stimulator.**

If it has been a long time since the stimulator was charged, this may be the reason the patient programmer cannot communicate. Try to charge your stimulator, see Charging the Stimulator [Page 37]. If the stimulator battery is very depleted, there will be a few seconds delay for the charger to recognize the location of the stimulator. When you position the charger, leave it in place for 4 seconds to wait for the confirmation signal before you try to reposition the charger.

**The patient programmer cannot identify the stimulator.**

If the patient programmer is not compatible with your stimulator hardware or software, no identification of the stimulator can take place during remote programming.
Contact your physician to arrange an update for your patient programmer.

# 12 Disposal

Dispose of the packaging in an environmentally sound manner in accordance to your applicable country-specific regulations.

If you no longer use the device, dispose of it and its associated wall adapter as electronic waste in accordance with the applicable country-specific regulations.

Dispose of the charger belt in the general trash.

You may also return the device and its accessories to your physician. Your physician will return all parts to BIOTRONIK. BIOTRONIK ensures disposal in accordance with the national versions of the European guideline 2012/19/EU on waste electrical and electronic equipment (WEEE 2).

# 13 Appendix

## Technical Data

### General Characteristics for the Charger

| Category | Design |
|---|---|
| Degree of protection | IP 22 |
| Operating mode | Continuous operation |
| Temperature range for operation | While the stimulator is being charged: +50 °F ... +95 °F (+10 °C ... +35 °C)<br>Otherwise: +50 °F ... +104 °F (+10 °C ... +40 °C) |
| Temperature range for storage | +14 °F ... +113 °F (-10 °C ... +45 °C) |
| Relative humidity | 15% ... 90%, non-condensing |
| Atmospheric pressure | 700 hPa ... 1060 hPa |
| Operation at altitudes | Up to 9,843 ft above sea level (3,000 m AMSL) |
| Power supply | Charging the charger with wall adapter: USB Type C<br>Internal power: Lithium-ion battery |
| Longevity | 3 years |
| Battery run time | > 2.5 h* |

*Determined through internal tests, with a new, fully charged battery.

## Wall Adapter of the Charger

| Category | Design |
|---|---|
| Model number | GlobTek, Inc GTM96180-1507-2.0 |
| Supply voltage | 100 V ... 240 V, ± 10%<br>50 Hz ... 60 Hz |
| Protection class | II |
| Degree of protection | IP 42 |
| Power Output | 15 W |
| Efficiency | According to efficiency level VI and efficiency standard CoC Tier 2 |

## Wireless Power Transfer (WPT)

| Category | Design |
|---|---|
| Frequency band | 125 kHz |
| Power of transmission | < 1.6 W |
| Maximum misalignment (deviation) between charger and stimulator | 0.6 inch (15 mm) radius from the center of the alignment markings on the underside of the charger to the center of the charging coil in implantable stimulator. |

## Patient Programmer

For phone-specific information about the patient programmer, please refer to the smartphone manufacturer's information.

## Data Security

Please note the following information on data security for the patient programmer:

- Security settings within the patient programmer are automatically set and remotely managed including user login settings, device lockdowns, device firewall, and anti-virus.
- Wireless communication between the clinician programmer, the stimulator, the patient programmer, and the BIOTRONIK server includes multiple levels of encryption to protect patient and clinician data.
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).
- Only accept remotely sent programs when directed by your physician.

## Note

Unauthorized access to the patient programmer may result in insufficient or excessive stimulation.

- Protect your patient programmer against unauthorized access.
- Lock the patient programmer when you are not using it.
- To unlock the patient programmer, use a secure password that cannot be guessed. Refer to the smartphone manufacturer's information on how to create a secure password.
- When unlocking the patient programmer, ensure you are not in a location where someone could see your password.
- Keep the patient programmer in a secure place and do not disclose your password.
- If your patient programmer is lost or stolen, contact your physician.

**Note**

Misuse of the patient programmer may result in insufficient or excessive stimulation.

- Only run applications on the patient programmer that are associated with the patient programmer app. Do not install or run any other app on the patient programmer.
- Do not manipulate the operating system of the patient programmer, in order to not compromise the built-in protection provided by the hardware or software manufacturer.
- If you suspect security issues, contact your physician.

**Note**

Notifications from the stimulator or from your physician will be displayed in the patient programmer app. Messages from other sources, like the operating system of the smartphone, are displayed in other locations on the screen.

In all cases, follow the instructions on the screen carefully. If in doubt, ask your physician.

## Quality of Service for Wireless Technology

2.4 GHz GFSK wireless technology is used for the communication between the stimulator and the clinician programmer or the patient programmer.

The quality of wireless communication will vary depending on the operating environment such as outdoors, home, operating room, or a recover room. The quality of service should be sufficient to transfer more than 8 kbps with latency depending on the type of transaction. Interrogation of 32 kB of data may take up to 20 s whereas 2 kB of data will require less than 5 s.

In the case of interference, the system will retry communication to ensure reliable data transfer resulting in longer durations for user transactions. In very high interference cases, you could lose the connection to the device.

To resolve communication issues, do the following:

1. Move the clinician programmer or the patient programmer closer to the stimulator.
2. Ensure there is a direct line of sight between the clinician programmer or the patient programmer and the stimulator.
3. Turn off or move away from other devices that may be operating in the 2.4 GHz band. Such devices include wireless home networks, mobile phones, wireless consumer devices, etc. For information on wireless security, see above, Data Security.

## Open Source and Commercial Software

A list of hardware and software components used is available upon request.

## Disclaimer, Warranty, and Warranty Conditions

https://www.biotronik.com/warranty-booklet-neuro/

# Country-Related Information

## International Radio Certification

### Telemetry Information for Australia

This device is in compliance with the Australian "Radiocommunications Act 1992" and, therefore, it is labeled according to the "Radiocommunications (Compliance labeling – Devices) Notice".

### Telemetry Information for the USA

The stimulator will be registered with the Federal Communications Commission under the following number:

- Implantable stimulator:
  FCC ID: QRI-SCSIPG

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The charger complies with Part 18 of the FCC Rules.
Operation is subject to the following two conditions:

- The charger may interfere with wireless charging systems (for example cell phone chargers).
- No maintenance of the charger is permitted (besides cleaning and disinfection).
- To avoid or correct interference, operate the charger away from metals and other wireless charging systems.

## Electromagnetic Compatibility

The charger is suitable for use in all home care and professional healthcare establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The charger device has no essential performance as defined by IEC 60601-1. Charging function may be temporarily disrupted during the presence of electromagnetic interference, but normal function resumes when the interference is removed. The devices are intended for use in the electromagnetic environment specified in the following tables. The user should ensure that they are used in such an environment.

The following tests were performed according to IEC 60601-1-2: 2014:

| Section | Test | Test Level |
|---|---|---|
| 7.1 | CISPR 11<br>RF Radiated emission | • Group 1<br>• Class B |
| 8.9 / 8.10 | IEC 61000-4-2<br>Electrostatic discharge (ESD) | • ± 8 kV contact discharge<br>• ± 2/4/8/15 kV air discharge |
| | IEC 61000-4-3<br>Radiated RF EM fields | • Modulation 1 kHz<br>• 10 V/m, 80 MHz ... 2.7 GHz<br>• Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9 V/m ... 28 V/m) |
| 8.9 | IEC 61000-4-6<br>Conducted disturbances induced by RF fields | • 3 Vrms<br>• 6 Vrms in ISM + Amateur Radio Bands<br>• 150 kHz ... 80 MHz |
| | IEC 61000-4-8<br>Power frequency magnetic fields | • 30 A/m<br>• 50/60 Hz |

⚠ **WARNING**

**Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment**

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 12 inches (30 cm) from this device, this can result in a reduction in its performance. This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennae), keep such devices at a distance of **at least 12 inches (30 cm) from the charger**.

⚠ **Attention**

**Risk of Electromagnetic Interference**

The use of the charger adjacent to or stacked with other devices should be avoided, as this may lead to the devices operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor the charger and the other device(s) being used with it in order to ensure that they are all working correctly.

**Attention**

**Risk of Electromagnetic Interference through the Use of Unauthorized Accessories**

The use of accessories, transducers or cables not listed by BIOTRONIK or of accessories other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- **Only use accessories authorized by BIOTRONIK**.

## Legend for the Label

The label icons symbolize the following:

| Symbol | Meaning |
|---|---|
| MD | Medical device |
|  | Manufacturing date |
| REF | BIOTRONIK order number |
| SN | Serial number |
| UDI | Unique device identifier |
|  | Temperature limit |
|  | Humidity limit |

| Symbol | Meaning |
|---|---|
|  | Acceptable atmospheric pressure range for storage |
|  | Consult the instructions for use! |
|  | Contents |
|  | Manufacturer |
|  | Distributor |
|  | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. |
|  | Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK. |
|  | Patient programmer |
|  | Charger |

| Symbol | Meaning |
|---|---|
|  | The transfer of energy from the charger to the stimulator takes place wirelessly |
|  | Implantable stimulator |
|  | Patient with stimulator |
|  | Charger belt |
|  | Wall adapter |
|  | Power plug adapter |

# Index

## T



## U



## W