HomeStreamCP

Clinical Programming of Prospera SCS System Stimulators

Technical Manual

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BIOTRONIK

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Rx only

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1 About This Technical Manual

Objective

This technical manual provides information on programming the Prospera Spinal Cord Stimulation System, including the external and implantable stimulators, using the HomeStreamCP with software version MDP 2100.U or higher, in the following called clinician programmer.

Technical Manuals

Technical manuals are either included in hard copy form in the storage package or available in digital form on the internet: https://manuals.biotronik.com.

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:

- Tablet manufacturer's information on the HomeStreamCP
- Smartphone manufacturer's information on the patient programmer MyHomeStream
- Smartphone manufacturer's information on the patient programmer MyHomeStream TR
- Prospera Spinal Cord Stimulation System – Implantation Instructions for Physicians
- Prospera Spinal Cord Stimulation System – Patient Guide for the Implanted System
- Prospera Spinal Cord Stimulation System – Patient Guide for the Trial System
- Prospera Spinal Cord Stimulation System – MRI Guidelines

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

The following typographical conventions are used in this technical manual:

Elements	Description and Appearance
Instructions	The individual steps of an instruction 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.
Navigation paths	The elements of a navigation path are shown in bold and separated by ">". Example: **[Main menu]** > **[Sub-menu]** > **[Item]**
Cross references	Cross references are indicated using "see" or "see also".
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]**.
Emphasis	Text that needs to be emphasized is shown in **bold**.
Notes	Useful information is indicated using the word **Note**.

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
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
IP address	Internet Protocol address
ISO	International Standards Organization
IT	Information Technology
MAC address	Media Access Control address
MD	Medical Device
MR scan	Magnetic Resonance scan
MRI	Magnetic Resonance Imaging
NH-ISAC	National Health Information Sharing and Analysis Center
NIST	National Institute of Standards and Technology
SCS	Spinal Cord Stimulation
SID	Software Identification
SN	Serial Number
UDI	Unique Device Identifier
USB	Universal Serial Bus
WiFi	Wireless Fidelity
WPA2	WIFI 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 Product and System Description

Overview

The clinician programmer is part of the Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System, which contains the following main components:

- External stimulator: Prospera EPG
- Implantable leads for the trial system: Resilience 55TR, Resilience 75TR
- Patient programmer for the trial system: MyHomeStream TR
- Implantable stimulator: Prospera IPG
- Implantable leads for the permanent system: Resilience 55, Resilience 75
- Patient programmer for the permanent system: MyHomeStream
- Clinician programmer: HomeStreamCP
- Magnet: Neuro M50

Trial Phase

Before the implantation of the stimulator, the patient undergoes a trial phase in which an external stimulator is used to determine whether the Prospera SCS System is suitable for relieving the patient's pain.

- During the implantation of the leads for the trial phase, the external stimulator is paired with the clinician programmer to check the function and position of the leads.
- The clinician programmer is used to check the function and position of the leads, program the external stimulator, and specify the programs for the patient.
- At the end of the trial phase, the clinician programmer is used to reset the external stimulator.

Implantation of the Stimulator

If it is confirmed at the end of the trial phase that the Prospera SCS System is suitable for relieving the patient's pain, an implantable stimulator is implanted.

- During implantation, the implanted stimulator is paired with the clinician programmer.
- The clinician programmer is used to transfer the patient data to the implanted stimulator.
- The clinician programmer is used to check the function and position of the leads, program the implantable stimulator, and specify the programs for the patient.

Follow-Up

During follow-up, the clinician programmer is used to customize the programming of the stimulator.

- The clinician programmer is used to configure other programs and adjust the stimulation settings and stimulation parameters as required.
- The clinician programmer is used to transfer the programming adjustments remotely to the stimulator of the patient via the patient programmer.
- The patient data, the programmed parameters and the programs configured with the clinician programmer will be automatically stored to the BIOTRONIK server in the background to facilitate report generation.

Intended Use

Intended Medical Use – Prospera SCS System

The Prospera Spinal Cord Stimulation System is designed to manage chronic pain by delivering electrical impulses to nerve structures in and around the spinal cord. The implantable stimulator is intended to be used with compatible leads and associated accessories. The Prospera SCS System is intended to be implanted and managed by healthcare professionals familiar with the use of neurostimulation devices.

Intended Use – Clinician Programmer

The clinician programmer provides communication with Prospera SCS System stimulators during the implantation procedure or follow-up. The clinician programmer is intended to provide an interface for personnel who are trained in Prospera SCS System technical settings to set appropriate parameters for therapy and other options in a patient's stimulator. Therefore, the clinician programmer is used:

- For verification and optimization of the therapy delivered by the stimulator
- To support assessment of the Prospera SCS System through data collected by the stimulator

This is achieved by providing product characteristics that allow performing the following tasks:

- Identify the supported stimulators
- Create, retrieve, and display printable records of the Prospera SCS System programming settings and data
- Select appropriate settings for the supported stimulators
- Program the supported stimulators with the selected parameter values
- Perform test functions (such as impedance tests) to determine the internal status of the stimulator, the connected leads and the patient, and collect printable records of the test results
- Collect data (including real-time data) of the stimulator for analysis and reporting purposes that can be exported to a storage unit or a data processing system

Medical Indication and Contraindication

Indication – Prospera SCS System

The Prospera SCS System is indicated as an aid in the management of chronic, intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain, resulting from any of the following:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS surgery or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindicated Patient Conditions – Prospera SCS System

Implantation of a spinal cord stimulator may be contraindicated in patients with the following characteristics:

- Are unable to operate the Prospera SCS System
- Have failed to receive effective pain relief during SCS trial stimulation
- Are poor candidates for surgery

Note

The safety and effectiveness of spinal cord stimulation has not been established in pediatric patients or pregnant or nursing patients.

Medical Indication and Contraindication – Clinician Programmer

The clinician programmer is intended to support applications indicated for use with all supported Prospera SCS System stimulators during implantation, trial period, or follow-up of the Prospera SCS System. There are no indications or contraindications for the clinician programmer itself.

User Profile

The users of the clinician programmer are personnel who are trained in Prospera SCS System technical settings for therapy and other options in a patient's stimulator.

For all users of the clinician programmer the following is true:

- The user has the necessary knowledge regarding Neuromodulation therapy to perform clinician programmer actions during implantations, trial periods or follow-ups.
- The user received training on the HomeStreamCP.
- The user has access to all relevant manuals for the Prospera SCS System.
- The user has experience with touchscreen-operated graphical user interfaces of computers or tablet PCs running MS Windows, Android or similar mobile device operating systems.

3 Overview of the Application Screens

The following table gives you an overview of the screens of the clinician programmer app.

The menu items in the main menu depend on whether you are currently working in a programming session with or without a patient.

Main Menu

1	Main menu in a programming session	2	Main menu outside a programming session

Application Screen	Meaning or Available Setting	Description in Section
[Programming]	Configure programs	Editing Programs [Page 28]
[Leads and impedance]	Configure leads	Setting up, Testing, and Adjusting Leads [Page 23]
[Patient profile]	Edit patient profile	Creating and editing a patient profile
[Stimulator settings]	[MRI mode]	Turning MRI mode on and off [Page 40]
	[Sleep mode]	Setting and Resetting the Sleep Mode for Battery Preservation [Page 42]
	[Daily lead impedance measurement]	Enabling and Disabling Daily Lead Impedance Measurement [Page 42]
	[Clear lead failures in stimulator]	Clearing Lead Failures [Page 27]
[External stimulator settings]	[Reset trial stimulator]	Resetting the External Stimulator [Page 37]
	[Prepare for battery replacement]	Preparing for Battery Replacement [Page 42]
	[Daily lead impedance measurement]	Enabling and Disabling Daily Lead Impedance Measurement [Page 42]
	[Clear lead failures in stimulator]	Clearing Lead Failures [Page 27]
[Programmer settings]	[Resynchronize app content]	Resynchronizing the App Content [Page 43]
	[Patient programmer test mode]	Setting and Resetting Patient Programmer Test Mode [Page 43]
	[Release codes]	Entering Release Codes [Page 44]
	[About]	Troubleshooting [Page 48]
[Notifications]	Edit notifications	Checking Notifications [Page 44]
[Patients and devices]	Select patient or stimulator and start the programming session	Pairing and Assigning the Stimulator [Page 20]
[Remote patient management]	Start remote patient management for a patient	Remote Patient Management [Page 38]

Application Screen	Meaning or Available Setting	Description in Section
[Reports]	Display, export, and print follow-up reports	Viewing and Printing Reports [Page 47]

4 General Handling of the Clinician Programmer

Setting up the Clinician Programmer

Note

Unauthorized interference in data connection between clinician programmer, stimulator, patient programmer, and the BIOTRONIK server may lead to theft or loss of patient data or to unauthorized modification of the stimulator programming.

- If you use a network connection, use only a managed, trusted wireless network (WiFi).
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).
- Only run applications on the clinician programmer device that are associated with the BIOTRONIK apps for the clinician programmer.
- If you suspect security issues, end the programming session, if possible. Contact your IT security department or BIOTRONIK.

When setting up the clinician programmer device, pay attention and follow any notifications, including restarting to finish installation. Additionally, pay attention to any operating system update notifications which indicate an update is available or restart is necessary.

The first time you start the clinician programmer and connect it to the network, follow the prompts to perform initial set-up. Use the sign-in data provided to you.

During setup you define how to perform the two-factor authentication. Two-factor authentication is used to identify users by combining different components. Remote patient management uses two-factor authentication to increase security for the remote connection.

The first factor is always the password. For the second factor, you can choose from the following authentication mechanisms:

- Text message
- Phone call
- Microsoft Authenticator app

Depending on the authentication mechanisms, it may be necessary to enter a phone number.

If you already have a valid user ID, you will be signed-in directly. The latest clinician programmer software will then be downloaded.

An **active network connection** is required for initial registration, downloading, and to have the latest follow-ups for reporting. The clinician programmer is required to have a direct connection to the BIOTRONIK backend servers, without the use of an intercept proxy. Connect the clinician programmer to the network periodically to check for update notifications, see Updating the Clinician Programmer App [Page 47].

For the programming session, network connectivity is **not** required.

For assistance with first-time start-up, sign-in, and app installation, contact BIOTRONIK.

Launching the Clinician Programmer App

Note

Unauthorized access to the clinician programmer may result in theft or loss of patient data or unauthorized modification of the stimulator programming.

- Protect the clinician programmer against unauthorized access.
- Do not connect the clinician programmer to any unknown USB or Bluetooth device. Use only a USB device that includes pin and encryption.
- Lock the clinician programmer device when you interrupt the programming session. When you are not using the device, also lock it. In addition, ensure the device settings are set to automatically lock the screen after no more than 15 minutes of non-use. Refer to the tablet manufacturer's information on how to lock the screen and change the device settings.
- Keep the device in a secure place and do not disclose your password or pin.
- Use a secure, unique password that cannot be guessed. Follow the specific operating system rules for a secure password. Refer to the tablet manufacturer's information on how to create a secure password.
- When unlocking the clinician programmer, make sure that you are not being watched.
- At the end of the programming session, exit the session correctly and then close the app and sign out of the clinician programmer.
- If your clinician programmer is lost or stolen, contact your IT security department or BIOTRONIK.

Note

The clinician programmer is equipped with an internal rechargeable battery.

If the battery operating time between the charging cycles is greatly shortened, the battery of the clinician programmer will reach its end of service. In that case, contact BIOTRONIK to replace the clinician programmer.

Note

Keep the operating system of the clinician programmer device up-to-date to prevent the device from being forced to reboot during a programming session to perform the update:

- Operating system notifications will inform when an update is available. Refer to the tablet manufacturer's information on how to update the operating system.
- Connect the device to the network periodically and do not turn the device off so that the updates can be installed overnight.

Procedure for Launching the Clinician Programmer App

Prerequisite

- The clinician programmer is sufficiently charged.

1. Turn the clinician programmer on.
2. Unlock the clinician programmer.
3. Launch the BIOTRONIK app for programming stimulators. Select the **[HomeStreamCP]** app:

Result

The screen for selecting the stimulator is displayed, see Pairing and Assigning the Stimulator [Page 20].

Working with the User Interface

About the Clinician Programmer

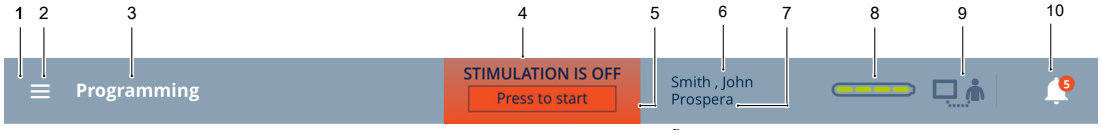
The following features make operation of the clinician programmer easier for you:

- The clinician programmer is equipped with a touch screen. You can perform the individual functions of the software by touching the operating elements with your finger to activate them.
- The keyboard for entering text or characters is displayed when you select a text entry field.
- The clinician programmer draws your attention to important information, such as notifications or successfully completed processes.
- Updates are performed automatically via the BIOTRONIK server as soon as you exit the app, see Updating the Clinician Programmer App [Page 47].

Note

Gloves may interfere with touch screen operation. In this case, a stylus pen recommended by the tablet manufacturer can be used to operate the touch screen.

Elements of the Status Bar



	Element	Meaning
1	Status bar	
2	Menu button	Use the Menu button to open the main menu. The menu items depend on whether you are currently working in or outside a programming session, see Overview of the Application Screens [Page 9].
3	Current screen	Name of the current screen.
4	Stimulation indicator	Shows whether the stimulation is turned on or off.
5	Stimulation ON/OFF button	Button for turning the stimulation on or off, see Turning Stimulation on and off [Page 35].
6	Current patient	Name of the current patient, whose stimulator is paired with the clinician programmer.
7	Current stimulator	Product name of the stimulator that is paired with the clinician programmer.
8	Stimulator battery status	Battery status of the stimulator that is paired with the clinician programmer, see Checking the Battery Status of the Stimulator [Page 46].
9	Pairing indication	Pairing indication for the stimulator, see Pairing and Assigning the Stimulator [Page 20]:  Indication that the stimulator is paired and in communication with the clinician programmer.  Indication that the stimulator is paired with the clinician programmer, but not able to communicate due to range or interference issues.
10	Notifications	Opens the **[Notifications]** screen, see Checking Notifications [Page 44]. The current number of notifications is displayed.

Basics for Editing

Topic	Action
Entries and changes to fields	To enter characters in a field or to change the contents of the field, select the field. The keyboard for input is displayed.
Deleting contents of a field	To delete the contents of a field, select the field. The **[X]** button is displayed to the right of the field. Select the **[X]** button.
Date selection	To select or change a date, use the date selection. When you select a date field, the date selection dialog box is displayed. Select the date. Apply the selected date using the **[Check mark]** button.
Selection lists	Selection lists can be recognized by the **[Down arrow]** button to the right of the field. Select the **[Down arrow]** button to open the list of options. Select one of the displayed selection options.
Moving a view	If not all items are visible in a menu or dialog box, you can move the view up or down by using the scroll bar or dragging in the center of the view.
Back	To return from a dialog box to the associated screen, select the **[Left arrow]** button in the status bar.

Ending Sessions and Signing out of the Clinician Programmer

Make sure at the end of a programming session you end the session correctly through the menu of the clinician programmer. When you have finished using the clinician programmer, close the app and lock the screen or sign out of the clinician programmer. This way you avoid unauthorized access to the clinician programmer and patient data, see Data Security [Page 52].

1. To sign out of a programming session, select the **[End session]** button in the main menu.
2. Close the app using the **[X]** button.
3. Sign out or lock the clinician programmer device.

5 During the Implantation and Follow-Up

Overview of the Use of the Clinician Programmer during Implantation

The clinician programmer assists you during the implantation of the leads and stimulator.

	Procedure	Step	Description in Section
1	Prepare the clinician programmer.		
		Find a suitable place for the clinician programmer outside the sterile environment.	Setting up the Workspace for the Clinician Programmer [Page 20]
		Turn the clinician programmer on and unlock it.	Launching the Clinician Programmer App [Page 13]
2	Check the battery status of the clinician programmer.		Refer to the tablet manufacturer's information on how to check the battery status and how to charge the clinician programmer device.
3	Pair the stimulator with the clinician programmer.		Pairing and Assigning the Stimulator [Page 20]
		Place the magnet on the stimulator.	Pairing the Clinician Programmer with the Stimulator [Page 20]
		Select the stimulator.	Patients and Devices [Page 21]
		Assign the stimulator to the patient.	Assigning a New Stimulator to a Patient [Page 22]
4	If no patient profile exists for the patient, create a patient profile.		Creating and Editing a Patient Profile [Page 23]
5	Check the battery status of the stimulator.		Checking the Battery Status of the Stimulator [Page 46]
6	Enter detailed information on the leads that are to be implanted. This detailed information includes, for example, product name, serial number, and implantation date.		Entering or Changing Detailed Information on the Leads and Their Extensions [Page 25]

	Procedure	Step	Description in Section
7	Supervise the implantation with the clinician programmer.		
		Configure the leads by specifying their relative positions.	Overview of the Screen for Configuring the Leads [Page 23] Configuring the Position of the Leads [Page 27]
		Conduct an impedance test to check the functionality of the leads.	Performing the Impedance Test [Page 24]
		If applicable, create at least one active program with at least one enabled subprogram to test the stimulation intraoperatively.	Editing Programs [Page 28]
		If applicable, carry out a test stimulation.	Turning Stimulation on and off [Page 35]
		If applicable, adjust the program for the test stimulation as appropriate for the individual patient.	Configuring the Subprogram [Page 32]
		If necessary, reposition the leads and test the stimulation again.	Configuring the Position of the Leads [Page 27]
8	Generate reports.		
		Generate the implantation documentation. Use the HomeStream Reports app to create the implantation documentation.	Viewing and Printing Reports [Page 47]
9	End the programming session.		
		End session and close the app, and sign out of the clinician programmer device.	Ending Sessions and Signing out of the Clinician Programmer [Page 16]

Overview of the Use of the Clinician Programmer during Follow-Up

The clinician programmer assists you during the follow-up of the stimulator.

	Procedure	Description in Section
1	Turn the clinician programmer on and unlock it.	Launching the Clinician Programmer App [Page 13]
2	Check the battery status of the clinician programmer.	Refer to the tablet manufacturer's information on how to check the battery status and how to charge the clinician programmer device.
3	Place the magnet on the stimulator and pair the stimulator with the clinician programmer.	Pairing the Clinician Programmer with the Stimulator [Page 20]
4	The programming screen is displayed. You can create new programs or edit, copy, rename, or delete existing programs.	Editing Programs [Page 28]
5	Check the notifications and carry out the necessary steps to resolve them.	Checking Notifications [Page 44]
6	If applicable, adjust the programs as appropriate for the individual patient.	Configuring the Subprogram [Page 32]
7	If applicable, test the stimulation based on the program changes.	Turning Stimulation on and off [Page 35]
8	Adjust the stimulator settings if necessary.	Enabling and Disabling Daily Lead Impedance Measurement [Page 42] Setting and Resetting the Sleep Mode for Battery Preservation [Page 42]
9	At the end of a trial period, reset the external stimulator before you remove it.	Resetting the External Stimulator [Page 37]
10	Generate the follow-up documentation. Use the HomeStream Reports app to create the follow-up documentation.	Viewing and Printing Reports [Page 47]
11	End the programming session. End session and close the app, and sign out of the clinician programmer device or lock the clinician programmer.	Ending Sessions and Signing out of the Clinician Programmer [Page 16]

Setting up the Workspace for the Clinician Programmer

Note

The clinician programmer must not be sterilized. Sterilization could damage the clinician programmer.

Find a suitable place for the clinician programmer outside the sterile environment:

1. Place the clinician programmer outside the sterile environment on a flat, dry surface.
2. For best results, place the clinician programmer within 5 ft (1.5 m) of the stimulator.
3. Turn the clinician programmer on and check the battery status of the clinician programmer. Refer to the tablet manufacturer's information on how to check the battery status and how to charge the clinician programmer.
4. On the clinician programmer turn the Bluetooth function on. Refer to the tablet manufacturer's information on how to turn on the Bluetooth function on the clinician programmer.

Pairing and Assigning the Stimulator

You must use the Neuro M50 magnet to pair the devices. When you place the magnet on the stimulator for at least 10 s, the stimulator enters a mode that enables pairing. While the magnet is placed on the stimulator, stimulation is temporarily turned off. The stimulation is turned on again as soon as you remove the magnet from the stimulator. If you place the magnet on the stimulator for longer than 60 s, the stimulation is suspended until it is reactivated with the programmer. In this case, the stimulation remains turned off even if you remove the magnet from the stimulator. A notification on the clinician programmer or the patient programmer will indicate that stimulation was turned off. To turn the stimulation on use the clinician programmer or the patient programmer.

Pairing the Clinician Programmer with the Stimulator

Note

The following factors may cause the stimulator not to pair with the clinician programmer or the connection between the stimulator and the clinician programmer may be impaired:

- If the distance between the stimulator and the clinician programmer is too great, the stimulator may not be able to pair with the clinician programmer.
- If the stimulator or the clinician programmer is not sufficiently charged, the stimulator cannot be paired with the clinician programmer.
- If the Bluetooth function on the clinician programmer is not enabled, the stimulator cannot be paired with the clinician programmer.
- The connection between the stimulator and the clinician programmer may be impaired by electromagnetic interference. Such interference can make it difficult or even impossible to interrogate or program the stimulator.

This can delay the implantation and lead to prolonged anesthesia or sedation.

1. For best results, place the clinician programmer within 5 ft (1.5 m) of the stimulator.
2. Ensure that the Bluetooth function is enabled in the clinician programmer device settings.
3. Before you start the implantation, pair the stimulator with the clinician programmer and verify that you can interrogate the stimulator without disturbances.
4. Check the battery status of the clinician programmer and ensure the stimulator has sufficient charge before each programming session.

Note

Leave the implantable stimulator in the sterile packaging while you are pairing the stimulator with the clinician programmer.

After the stimulator has been paired with the clinician programmer, the implantable stimulator can be brought into the sterile area. Ensure that the connection range between the clinician programmer and the stimulator is maintained.

Procedure for Pairing the Clinician Programmer with the Stimulator

Before you start the implantation, establish a stable connection between the stimulator and the clinician programmer:

Prerequisite

- The prerequisites for establishing a connection between the stimulator and the clinician programmer mentioned in the above notes have been met.
- The magnet is available for use.

1. Position the magnet horizontally to the connections in the device header.
2. Place it underneath the connections on the housing of the stimulator.
   Hold this position for at least 10 s and a maximum of 60 s.
   - ▶ For an external stimulator, the LED begins flashing when the stimulator is ready to be paired.
3. Remove the magnet.
4. On the **[Patients and devices]** screen, select the **[Search]** button to search for the stimulator.
   - ▶ The status of the search is displayed in the status bar in the pairing indication:
     First, it indicates that the clinician programmer is currently searching for an activated stimulator within connection range.
     Then it indicates that the connection to the stimulator is being established.
     Additional dialog boxes are possibly displayed in order to unpair from a previous stimulator or to pair with a new stimulator. Select the **[Yes]** button to confirm these dialog boxes.
     Finally, it indicates that the stimulator has been successfully paired with the clinician programmer.
   - ▶ After successful connection the stimulator and its serial number are displayed in the list; see also Patients and Devices [Page 21].
   - ▶ If the connection cannot be established, you will receive an error message; see Troubleshooting [Page 49].
5. Select the stimulator with which you want to start the programming session on the clinician programmer.
   - ▶ If you have selected a stimulator already being in use and assigned to a patient, the **[Programming]** screen is displayed, see Editing Programs [Page 28]
   - ▶ If you have selected a new stimulator, you first have to assign the stimulator to the patient. The **[Patient assignment]** screen is displayed, see Assigning a New Stimulator to a Patient [Page 22]

Patients and Devices

1. In the main menu, select the **[Patients and devices]** menu item or select the new device.

On the **[Patients and devices]** screen, the name of the patient, the associated stimulator, as well as its serial number are displayed for all the stimulators paired with the clinician programmer:

- **[Patient name]**: Indicates a stimulator with the associated patient, if the patient name is saved in the stimulator.
- **[New device]**: Indicates a newly paired stimulator, which has not yet been assigned a patient.
- **[No patient name specified]**: Indicates a stimulator, which has been assigned to a patient without a patient profile being created.

Assigning a New Stimulator to a Patient

Before implantation and before starting the programming session with a new stimulator, assign the stimulator to the patient.

Prerequisite

- The stimulator is sufficiently charged.
- The clinician programmer is sufficiently charged.
- The stimulator is paired with the clinician programmer.

1. In the main menu, select the **[Patients and devices]** menu item or select the new device.
   - ▶ In the **[Patients and devices]** list, the new stimulator is displayed with the entry **[New device]**.
2. Select the new stimulator.
   - ▶ The **[Patient assignment]** screen is displayed. You will see the list of all patients to whom you can assign the stimulator. The displayed patient information assists you to select the correct patient.
3. Select the patient for whom the stimulator is intended. You can scroll through the patient list or specifically search for a patient; see Searching for Patients [Page 22].
   - ▶ Detailed information is provided for the selected patient, which you can use to confirm the correct selection of the patient.
4. On the **[Patient assignment]** screen, based on the patient information displayed, check whether the correct patient has been selected.
5. Select the **[Transfer]** button to assign the new stimulator to the selected patient.
   - ▶ The **[Patient profile]** screen is displayed. The successful assignment of the implantable stimulator to the patient will be confirmed by a message.
6. In case no patient profile has as yet been created for the patient, select the **[Add new patient]** button to add a new patient and create a patient profile.
   - ▶ The **[Patient profile]** screen is displayed; see Creating and editing a patient profile .

Result

The patient data of the selected patient is transferred to the new stimulator.

Once the stimulator has been assigned to the patient, you can proceed to a therapy programming session.

Searching for Patients

On the **[Patient assignment]** screen, you can specifically search for an already created patient.

You have the following search options:

- Scroll through the list of displayed patients.
- In the **[Search]**  field, enter the name of the patient. You can enter the patient name, the clinic ID, or the previous external stimulator. Separate multiple entries with commas.
- To search for a patient by implantation date, select the date range selection  in the **[Search]** field.

Searching for a Patient using the Date Range Selection

1. In the date range selection, select a range for the implantation date or the date of the external stimulator, see also Basics for Editing [Page 16].
2. Select the **[SET]** button.
   - ▶ The selected date range is displayed in the **[Search]** field.
   - ▶ All patients whose implantation date lies within the specified range is displayed.
   - ▶ To remove the date range from the search, select the **[X]** button in front of the date range.

Creating and Editing a Patient Profile

On the **[Patient profile]** screen, you create the patient profile for a new patient or edit an already existing patient profile, see also Basics for Editing [Page 16].

Prerequisite

- The stimulator is paired with the clinician programmer.

1. In the main menu, select the **[Patient profile]** menu item.
   ▶ The **[Patient profile]** screen is displayed.
2. In the **[Patient details]** group box, select the data of the patient.
3. To enable remote services for this patient, select the **[Please check this box to enable remote services]** check box.
   Ensure the patient has provided appropriate consent before enabling remote services.
4. In the **[Stimulator details]** group box, the data of the associated stimulator is shown.
5. In the **[Clinician details]** group box, the names of the clinicians are shown. You can enter clinician notes (up to 500 characters) that are not visible on the patient programmer.
6. In the **[Clinic details]** group box, the name and address data of the clinic are shown.
7. Complete the input by saving the patient profile. Select the **[Save]** button.

Setting up, Testing, and Adjusting Leads

Overview of the Screen for Configuring the Leads

1. In the main menu, select the **[Leads and impedance]** menu item.

The **[Leads and impedance]** screen gives you an overview of the connected leads.

- In the **[Lead setup]** group box, the following information is displayed in a graphical representation:
  - Relative positions of the implanted leads
  - Impedances
    Representation of the impedance value in red draws your attention to an impedance value that is out of range. Yellow impedance values indicate impedances that are borderline.
  - Use the **[Edit]** button to configure the leads; see Configuring the Position of the Leads [Page 27].
- The **[Lead overview]** group box shows information about the leads and their extensions.
  - Use the **[View lead details]** button to switch to the detailed information; see Entering or Changing Detailed Information on the Leads and Their Extensions [Page 25].
- The **[Lead impedance]** group box shows the date and time and the result of the last impedance test.
  - Use the **[Run impedance test]** button to carry out the impedance test; see Performing the Impedance Test [Page 24].
  - The lead impedance measurement can be automatically performed daily, see Enabling and Disabling Daily Lead Impedance Measurement [Page 42].

Performing the Impedance Test

⚠ Attention

False Impedance Measurement Results due to Temperature Differences

Temperature differences between the stimulator and body or room temperature can lead to false results when measuring the lead impedance. If a false measurement is suspected, proceed as follows:

- Acclimate the temperature of the stimulator to room or body temperature before starting the implantation and the programming session.
- Pay attention to the conditions for operating the stimulator, see Prospera Spinal Cord Stimulation System – Implantation Instructions for Physicians.
- Perform the lead impedance measurement again.

Procedure for Performing the Impedance Test

The impedance test measures the impedances of the implanted leads.

- You can perform the impedance test manually to check the leads (for example, to detect a lead fracture) and assess the lead position.
- The lead impedance measurement can be automatically performed daily, see Enabling and Disabling Daily Lead Impedance Measurement [Page 42].

1. In the main menu, select the **[Leads and impedance]** menu item.
   ▶ The lead impedances are displayed in the **[Lead setup]** group box.
2. In the **[Lead impedance]** group box, select the **[Run impedance test]** button.

Result

The date and result of the impedance test are displayed in the **[Lead impedance]** group box.
A summary of the result of the impedance test is displayed on the **[Programming]** screen.

Results of the Impedance Test

- The impedance test was carried out **successfully**.
  - All lead impedances are **within** the tolerance range:
    The **[Lead impedance]** group box shows that all the measured impedances are within the tolerance range.
  - One or more lead impedances are **out of range**.
    The **[Out-of-range impedances detected]** group box shows the electrodes whose impedances are too high or too low.
    In the **[Lead setup]** group box, the impedance values that are out of range are displayed in red.
    Out-of-range impedance values indicate faulty electrodes which should not be used for therapy. In this case, use alternate electrodes or implant new leads; see also Troubleshooting [Page 48].
- The impedance test could **not** be carried out.
  The reason for this could be that the connection between the clinician programmer and the stimulator is disturbed; see also Troubleshooting [Page 48].

Entering or Changing Detailed Information on the Leads and Their Extensions

Before you configure the leads, enter detailed information on the implanted leads and their extension.

1. In the main menu, select the **[Leads and impedance]** menu item.
   ▶ The **[Lead overview]** group box shows information about the leads and extensions.
2. In the **[Lead overview]** group box, select the **[View lead details]** button.
   ▶ The **[Lead details]** dialog box displays the detailed information about the implanted leads and their extensions.
3. To enter and edit lead information, select the **[Edit]** button, see also Basics for Editing [Page 16].
4. In the **[Port A:]** group box, enter the information for the left lead, and in the **[Port B:]** group box, enter the information for the right lead.
5. Enter the product name and serial number in each case and select the manufacturer and implantation date.
6. In the selection list, select the location (Superior, Middle, Inferior) and the position of the lead tip on the spine (T1 to L5).
7. If it is a retrograde lead, enable the **[Retrograde lead]** check box. This will turn the orientation of the lead by 180°.
8. To enter information about the extensions for the respective lead, select the **[Add extension]** button.
   ▶ The fields for entering the information on the respective extensions are displayed.
9. Enter the product name, serial number, manufacturer, and implantation date of the extension.
10. Complete the input by saving the entries. Select the **[Save]** button.
11. Select the **[Left arrow]** button in the status bar to return to the **[Leads and impedance]** screen.

Deleting Information on the Leads or Extensions

You can delete detailed information for obsolete leads and their extensions.

1. In the main menu, select the **[Leads and impedance]** menu item.
2. In the **[Lead overview]** group box, select the **[View lead details]** button.
   - ▶ The **[Lead details]** dialog box displays the detailed information about the implanted leads and their extensions.
3. To delete, first select the **[Edit]** button.
4. To delete information about a lead select the **[Delete lead]** button for the respective lead.
5. To delete information about the extension, select the **[Delete extension]** button for the respective lead.
6. Confirm the notification. Please note that when the lead information is deleted, the extension information will also be deleted.
7. Save the change by selecting the **[Save]** button.

Result

After deletion of the lead information, the deleted lead will no longer be displayed in the screens for configuring the leads (**[Leads and impedance]** screen) and configuring the programs (**[Programming]** screen).

Configuring the Position of the Leads

After the implantation of the leads, configure their position and their connection to the stimulator. Indicate the relative position of the implanted leads based on the X-ray image. The relative position of the implanted leads is graphically displayed on the clinician programmer and facilitates the programming.

Note

If the stimulator is not paired with the clinician programmer at the beginning of implantation, the implantation may be delayed and result in prolonged anesthesia or sedation.

1. Before you start the implantation, pair the stimulator with the clinician programmer.
2. Check whether you are able to interrogate the stimulator without disturbances.

Prerequisite

- The leads are implanted and connected to the stimulator.
- The stimulator is paired with the clinician programmer.

1. In the main menu, select the **[Leads and impedance]** menu item.
   - ▶ In the **[Lead setup]** group box, the relative positions of the implanted leads as well as the impedances are graphically displayed.
   - ▶ Representation of the impedance value in red draws your attention to an impedance value that is out of range for this lead. In such a case, check the lead connection with the stimulator, and assess the lead for physical issues.
2. In the **[Lead setup]** group box, select the **[Edit]** button.
   - ▶ You can now configure the position of the lead tip.
3. Select the **[Pencil]** button to edit the position of the respective lead tip.
   - ▶ A dialog box for selecting the location and position of the lead tip on the spine is displayed.
4. In the selection list, select the location (Superior, Middle, Inferior) and the position of the lead tip on the spine (T1 to L5).
   If you setup a retrograde lead, it needs to be set in the **[Lead details]** dialog box, see Entering or Changing Detailed Information on the Leads and Their Extensions [Page 25].
5. To save, select the **[Save]** button.
6. If the connections of the right and the left lead to the ports of the stimulator are interchanged, you can use the **[Left and right]** button to also change the lead connections in the configuration.
7. Use the **[Up and down]** buttons to adjust the vertical position of the right lead tip relative to the position of the left lead tip.
   To do this, move the lead tips up or down until the electrodes of the right and left leads are in the desired positions.
8. Complete the configuration by saving the entries. Select the **[Save]** button.
   - ▶ If you exit without saving the changes, a message will inform you of the unsaved changes.

Clearing Lead Failures

For a better overview, you can clear the list of lead failures before you reposition or replace the lead.

1. In the main menu, select the **[Stimulator settings]** menu item.
2. In the **[Clear lead failures in stimulator]** setting, select the **[CLEAR]** button.

Editing Programs

Overview of the Screen for Configuring the Programs

1. In the main menu, select the **[Programming]** menu item.

On the **[Programming]** screen, the configured programs and their subprograms are displayed:

- In the **[Program List]** group box you can see all of the configured programs. You can create further programs for different activities, for example, sleeping, sitting, or walking.
- To the left of the program list, the currently active program is indicated with a green check mark, see also Activating or Deactivating the Program [Page 33]. In addition, invalid programs are indicated with a yellow exclamation mark, see Program List Indicators [Page 29]
- To the right of each program you can use the **[Context menu]** ⋮ button to open the context menu for the respective program. The context menu contains options to copy, rename, or delete the program.
- Use the **[Add program]** button to add a new program; see Creating a New Program [Page 30]. You can create a maximum of 12 programs.
- In the **[Program parameters]** group box you will see the parameters of the selected program. In a program, you can define the stimulation pulses delivered as part of the stimulation therapy. Define the stimulation mode, strength, maximum strength, and frequency, see Configuring the Program [Page 31].
- In the **[Subprogram parameters]** group box you will see box 4 tabs for the associated subprograms. For each program, you can create subprograms for the stimulation of the spinal cord for the affected pain areas. By enabling several subprograms in parallel, the pulses are interleaving. This allows you to maximize the coverage of the affected pain areas.
  In the subprograms, define the stimulation current pathway as well as the amplitude and pulse width of the pulses to be delivered by the stimulator. Define the stimulation current pathway by specifying which electrodes are anodes and cathodes. The position of the anodes and cathodes on the leads are displayed graphically. You can create a maximum of 4 subprograms per program; see Configuring the Subprogram [Page 32].

During implantation of the stimulator, create at least one program with at least one subprogram for intraoperative testing. Test the stimulation based on this program. Adjust the stimulation parameters as appropriate for the individual patient.

The program values configured during the programming session are automatically transferred to the stimulator. The stimulator will work with the changed values as soon as you turn the stimulation on.

You can create new programs or edit, copy, rename, or delete existing programs, see Copying the Program [Page 34], Renaming the Program or Subprogram [Page 34], Deleting the Program [Page 34].

You can create new subprograms or edit, rename, or delete existing subprograms, see Configuring the Subprogram [Page 32], Renaming the Program or Subprogram [Page 34].

Program List Indicators

To the left of the program list, an indicator shows which program is active and whether a program is invalid.

Indicator	Meaning
	Program is active.
	Program is invalid. An invalid program means that it is not configured to be able to deliver stimulation, for example because the electrodes are not defined or all subprograms are disabled. An invalid program will not appear on the patient programmer.

Basics for Editing Programs and Subprograms

Topic	Action
Context menu	On the **[Programming]** screen, to the right of the programs and subprograms, you can use the **[Context menu]** ⋮ button to open the context menu for the respective program. The context menu contains options to copy, rename, or delete the program or subprogram.
Changing the parameter values	• Gradually increase or decrease the parameter values using the **[+]** and **[-]** buttons. • Alternatively, you can select a default value for a parameter from a list. Open the list of default values by selecting the displayed parameter value. A dialog box with a selection of default values is displayed. Select one of the displayed default values.
Selection lists	Selection lists can be recognized by the **[Down arrow]** button to the right of the field. Select the **[Down arrow]** button to open the list of options. Select one of the displayed selection options.

Creating a New Program

Prerequisite

- The leads are implanted and connected to the stimulator.
- The leads are configured; see Configuring the Position of the Leads [Page 27].
- The stimulator is paired with the clinician programmer.
- The serial number of the stimulator you wish to program is displayed.

1. In the main menu, select the **[Programming]** menu item.
   - ▶ The **[Programming]** screen is displayed.
2. In the **[Program List]** group box, select the **[Add program]** button.
3. Enter the name of the new program in the displayed dialog box and confirm your entry.
   - ▶ A new program with a subprogram is created.
   - ▶ The subprogram is populated with the standard values, see Configuring the Subprogram [Page 32].
   - ▶ If no program as yet exists, the new program will be activated.
   - ▶ If an active program already exists, it continues to remain active.
   - ▶ The new program is displayed in the program list and is selected for editing; see Configuring the Program [Page 31].

Configuring the Program

Prerequisite

- The leads are implanted and connected to the stimulator.
- The leads are configured; see Configuring the Position of the Leads [Page 27].
- The stimulator is paired with the clinician programmer.
- The serial number of the stimulator you wish to program is displayed.

1. In the main menu, select the **[Programming]** menu item.
   ▶ The **[Programming]** screen is displayed.
2. In the **[Program List]** group box, select the program which you want to edit.
3. In the **[Program parameters]** group box, select the stimulation mode in the **[Stimulation mode]** field:
   [Standard]: Pulses are exchanged between a maximum of 4 anodes and 4 cathodes.
   [Multiphase]: Pulses are exchanged between 3 or 4 anodes and cathodes in rotation.
   Define the positions of these anodes and cathodes on the leads in the associated subprograms.
4. The **[Default strength]** field shows the initial value at which the stimulation amplitude (subprogram amplitude) will start, when the program is turned on.
   Please note that a program transferred via Remote Programming always starts with a strength of 0.1 mA.
5. The **[Strength]** field shows the maximum value of the amplitude used in the associated subprograms.
   When you change the program strength, you also cause an **absolute** change in the amplitude of each associated subprogram by the changed value.
   ▶ The following example illustrates the change in the subprograms:
   Before the change: program strength: 1.8 mA, amplitude subprogram A: 1.8 mA, amplitude subprogram B: 0.7 mA.
   You increase the program strength by 0.2 mA.
   After the change: program strength: 2.0 mA, subprogram A: 2.0 mA, subprogram B: 0.9 mA.
6. Select the maximum strength in the **[Maximum strength]** field. This defines the maximum permissible value of the amplitude of each associated subprogram. With the maximum program strength you restrict the program strength that the patient can change using the patient programmer.
   ▶ If, for instance, the maximum program strength is 2.0 mA, you can also increase the amplitude in the associated subprograms to a maximum 2.0 mA. If the amplitude in the subprogram is already 2.0 mA, you cannot increase the amplitude further and the **[+]** button will no longer be available. The same applies to the patient programmer.
7. Select the number of pulses per second in the **[Frequency]** field. The frequency is identical for all subprograms.
8. Configure at least one subprogram to define the position and the polarity of the electrodes (anodes and cathodes) as well as the amplitude and the pulse width of the pulse to be delivered by the stimulator; see Configuring the Subprogram [Page 32].

Parameter Values

The parameter ranges are dependent on the stimulation mode selected, the number of subprograms and the energy output based on the lead configuration for the stimulation therapy, see also Functional parameters and limit values.

For basics for editing the parameters, see Basics for Editing Programs and Subprograms [Page 29].

Configuring the Subprogram

When you create a new program, a subprogram with a default name is automatically created. You can rename the subprogram.

In the subprograms, you can configure the stimulation of the spinal cord for the affected pain areas. You can select which electrodes are anodes and cathodes, which will determine the stimulation current pathway. Additionally define the strength and the duration of the pulses to be delivered by the stimulator.

1. In the main menu, select the **[Programming]** menu item.
   - ▶ The **[Programming]** screen is displayed.
   - ▶ In the **[Subprogram parameters]** group box, you will see 4 tabs with the configured subprograms.
     For each subprogram that is configured, a summary of parameters and whether the subprogram is disabled is shown on the subprogram tab.
     If less than 4 subprograms are configured, **[Add subprogram]** is displayed on the subprogram tabs of the unconfigured subprograms.
2. To edit a subprogram, select its tab.
3. To rename or delete a subprogram, open the associated context menu. On the respective tab, select the **[Context menu]** ⋮ button to the right of the subprogram name.

Adding a New Subprogram

If fewer than 4 subprograms are created, you can add a new subprogram.

1. Select the **[Add subprogram]** tab.
   - ▶ A new subprogram with a default name is created.
2. To rename the subprogram, select the **[Context menu]** ⋮ button on the tab of the subprogram.
3. Select the **[Rename]** option.
4. Enter a new name in the displayed dialog box. Save the name and close the dialog box using the **[UPDATE]** button.

Result

The new subprogram can be edited.

Defining Polarities

The positions of the electrodes on the leads are graphically displayed in the selected subprogram.

Define the stimulation current pathway by assigning the electrodes negative (-) and positive (+) polarities. This defines the positions of the anodes and cathodes on the leads. The number and definition of anodes and cathodes depends on the selected stimulation mode.

1. In the graphical display of the leads, select an electrode to open the **[Lead edit]** dialog box for editing the polarity of the electrodes.
2. Select the electrode for which you want to define the polarity. Continue selecting the electrode until the required polarity (anode (+), cathode (-), or no polarity) is displayed.
   - ▶ The changed electrodes will be marked in color.
3. After you have defined the polarities of the electrodes, you can move the combination of the defined anode and cathode positions on the leads up or down. To do this, select the **[Electrode shift]** buttons.
4. Select the **[SAVE]** button to save the defined polarities.

Defining Parameters for the Subprogram

1. Select the program strength for the subprogram in the **[Amplitude]** field.
2. Select the duration of the stimulation pulses in the **[Pulse width]** field.

Parameter Values

The parameter ranges are dependent on the stimulation mode selected, the number of subprograms and the energy output based on the lead configuration for the stimulation therapy, see also Functional parameters and limit values.

For basics for editing the parameters, see Basics for Editing Programs and Subprograms [Page 29].

Enabling the Subprogram

1. To enable the subprogram, select the toggle switch .

Result

If the subprogram is valid, it will be enabled. If the associated program is active, this subprogram will have a direct effect on the stimulation.
If the stimulator cannot deliver the combination of the set parameter values and the polarities, the subprogram is invalid. A message is displayed. In this case, change the polarities or the parameters of the subprogram or the program.

Deleting the Subprogram

1. To delete the subprogram, select the **[Context menu]** button on the tab of the subprogram.
2. Select the **[Delete]** option.
   ▶ A dialog box is displayed, in which you can confirm or cancel the deletion of the subprogram.

Result

The selected subprogram is deleted. On the title of the tab, **[Add subprogram]** is displayed.

Activating or Deactivating the Program

After you have configured the program and at least one associated subprogram, you can activate the program. This program will be used for the stimulation of the stimulator. Only one program can be active at a time. To the left of the program list, an activated program is indicated with a green check mark, see Program List Indicators [Page 29].

Prerequisite

- The program must not be invalid, see Troubleshooting [Page 48].
- At least one associated subprogram has to be enabled, see Configuring the Subprogram [Page 32].

1. In the main menu, select the **[Programming]** menu item.
   ▶ The **[Programming]** screen is displayed.
2. In the **[Program List]** group box, select the program.
3. In the **[Program parameters]** group box, select the toggle switch to activate the program.
   ▶ The color of the toggle switch changes to green and indicates that the program is active.
4. Select the toggle switch to deactivate the program.
   ▶ The color of the toggle switch changes to black/white and indicates that the program is deactivated.

To use the activated program for stimulator stimulation, the stimulation must also be turned on; see Turning Stimulation on and off [Page 35].

Copying the Program

You can copy all settings and subprograms of a program into another program.

Prerequisite

- At least one program is configured, see Configuring the Program [Page 31].

1. In the main menu, select the **[Programming]** menu item.
   ▶ The **[Programming]** screen is displayed.
2. In the **[Program List]** group box, select the **[Context menu]** ⋮ button of the program to be copied.
3. Select the **[Copy]** option.
4. Enter a new name in the displayed dialog box.
5. Save the name and close the dialog box using the **[UPDATE]** button.

Deleting the Program

1. In the main menu, select the **[Programming]** menu item.
   ▶ The **[Programming]** screen is displayed.
2. In the **[Program List]** group box, select the **[Context menu]** ⋮ button of the program you want to delete.
3. Select the **[Delete]** option.
4. Confirm the confirmation prompt.

Renaming the Program or Subprogram

When you create a new program, a subprogram with a default name is automatically created. You can then rename the subprogram.

1. In the main menu, select the **[Programming]** menu item.
   ▶ The **[Programming]** screen is displayed.
2. Select the **[Context menu]** ⋮ button of the program or the subprogram to be renamed.
3. Select the **[Rename]** option.
4. Enter a new name in the displayed dialog box.
5. Save the name and close the dialog box using the **[UPDATE]** button.

Turning Stimulation on and off

With the Clinician Programmer

In the status bar you can see whether the stimulation is turned on or off.

1. To turn the stimulation **off**, select the **[Press to stop]** button in the status bar.
   ▶ Stimulation off is indicated in the status bar.

When the stimulation is off, you can only turn **on** the stimulation on the Programming screen:

1. To turn the stimulation **on**, select the **[Programming]** menu item in the main menu.
   ▶ The **[Programming]** screen is displayed.
2. Review the stimulation program before turning the stimulation on.
3. Select the **[Press to start]** button in the status bar.
   ▶ Stimulation on is indicated in the status bar.

Note

For remote programming and for MRI mode, these buttons change; see Turning MRI mode on and off [Page 40] and Remote Patient Management [Page 38].

With the magnet

While the magnet is placed on the stimulator, stimulation is temporarily turned off. The stimulation is turned on again as soon as you remove the magnet from the stimulator. If you place the magnet on the stimulator for longer than 60 s, the stimulation is turned off completely. In this case, the stimulation remains turned off even if you remove the magnet from the stimulator. To turn the stimulation on use the clinician programmer or the patient programmer.

To turn the stimulation **temporarily** off:

1. Place the magnet for at least 10 s and a maximum of 60 s on the housing of the stimulator.
2. To turn the stimulation on: Remove the magnet.

To turn the stimulation **permanently** off:

1. Place the magnet for more than 60 s on the housing of the stimulator.
2. To turn the stimulation on: Turn the stimulation on by using the clinician programmer as described above or the patient programmer.

Pairing the Patient Progammer with the Stimulator

You must use the Neuro M50 magnet to pair the devices. When you place the magnet on the stimulator for at least 10 s, the stimulator enters a mode that enables pairing. While the magnet is placed on the stimulator, stimulation is temporarily turned off. The stimulation is turned on again as soon as you remove the magnet from the stimulator. If you place the magnet on the stimulator for longer than 60 s, the stimulation is suspended until it is reactivated with the programmer. In this case, the stimulation remains turned off even if you remove the magnet from the stimulator. A notification on the clinician programmer or the patient programmer will indicate that stimulation was turned off. To turn the stimulation on use the clinician programmer or the patient programmer.

Prerequisite

- The patient programmer is adequately charged and the Bluetooth function is turned on.
- For best results, the distance to the stimulator is less than 1.5 m.
- The connection between the stimulator and the patient programmer is not impaired by electromagnetic interference.
- The stimulator must have been assigned to a patient using the clinician programmer.
- The magnet is available for use.

1. Open the patient programmer app and wait for the app to load.
2. Position the magnet directly over the stimulator for at least 10 s and not more than 60 s.
   - ▶ For an external stimulator, the LED begins flashing when the stimulator is ready to be paired.
3. If the patient programmer detects more than one stimulator, then select the applicable stimulator.
4. Remove the magnet.
5. Select the **[Pair]** button.
   - ▶ The patient programmer is paired with the stimulator.
   - ▶ If the pairing was successful, this is indicated by a message on the patient programmer.
6. If the pairing was not successful, re-apply the magnet and try again. Select the **[Retry]** button.

Result

The current settings of the stimulator are displayed on the patient programmer.

Resetting the External Stimulator

After completion of the trial phase, disconnect the external stimulator from the patient. Then reset the external stimulator. This will delete all data on the external stimulator and return it to its original state.

Note

Before resetting the external stimulator, document the data stored on the stimulator.

If you replace the external stimulator with an implantable stimulator after successful completion of the trial phase, you can transfer the patient data stored on the BIOTRONIK server to the implantable stimulator.

Prerequisite

- Stimulation is turned off.

1. In the main menu, select the **[Stimulator settings]** menu item.
2. In the **[Reset trial stimulator]** setting, select the **[RESET]** button.
3. Confirm the reset of the external stimulator by selecting the **[RESET]** button in the displayed confirmation box.

Result

All data on the external stimulator is deleted.

Note

The batteries must be replaced in the external stimulator to restore normal functionality. The external stimulator can then be prepared for use with the next patient.

Resetting the Patient Programmer

At the end of the trial phase, collect the patient programmer. To prepare the patient programmer for the next use, do the following at the end of the trial phase:

- Ensure the external stimulator has been reset via the clinician programmer. This will clear all patient information from the external stimulator.
- Reset the patient programmer so it is no longer paired with the external stimualtor.

Prerequisite

- The patient programmer is paired with the external stimulator.
- For best results, the distance to the stimulator is less than 1.5 m.

1. On the patient programmer, open the patient programmer app.
2. In the main menu, select the **[Settings]** > **[Advanced settings]** menu item.
3. Select the **[Release code entry]** setting.
4. Enter the release code "Factory" and select the **[Submit]** button.
   ▶ A confirmation message indicates that the release code is accepted.

Result

The patient programmer app will close automatically. Upon re-launching the application, it will no longer be paired with the external stimulator.

6 Remote Patient Management

Overview of Remote Patient Management

You can also make changes to the programming of the stimulator remotely and transfer these changes to the stimulator of the patient via the patient programmer.

1. Call the patient on the phone and jointly discuss the settings for a new program or the program to be changed.
2. Start a remote patient management connection with the patient programmer, see Starting Remote Programming [Page 38].
3. Program a new program or change an existing program and send the changes to the patient programmer, see Working in the Remote Programming Mode [Page 39].
4. If the patient confirms the changes to their patient programmer, the changes will be saved to the stimulator.
5. The patient starts the program. The program starts with a program strength of 0.1 mA.

Starting Remote Programming

Prerequisite

- The **[Please check this box to enable remote services]** check box on the **[Patient profile]** screen is selected.
  Ensure the patient has provided appropriate consent before enabling remote services.
- The clinician programmer has a good connection to cellular or wireless network (WiFi).
- The patient programmer is turned on, has a good connection to cellular or wireless network (WiFi), and is connected to the patient's stimulator.
- Two-factor authentication is set up. The authentication mechanism is defined during setup of the clinician programmer, see Setting up the Clinician Programmer [Page 12].

1. In the main menu, select the **[Remote patient management]** menu item.
   ▶ On the **[Remote programming]** screen, you will see a list of all available patients.
2. Select the patient for the remote programming.
3. To set up the remote patient management session, two-factor authentication is required. Enter your password.
   ▶ Depending on the authentication mechanism, the verification code for the two-factor authentication will be provided.
4. Enter the verification code.
5. Wait until the connection to the patient programmer for the displayed patient is set up.

Connection Was Successfully Established

If the connection to the patient programmer was successfully established, the **[Remote programming]** screen is displayed.

Connection Could Not Be Established

If the connection to the patient programmer could not be established, a message is displayed. In such case ensure that the patient programmer has a good connection to cellular or wireless network (WiFi).

1. Try again to reestablish the connection.
   ▶ If the connection could not be established again, a message is displayed. Terminate the process and contact BIOTRONIK.

Working in the Remote Programming Mode

After you have established a remote patient management connection, you can make changes to the programming of the stimulator and transmit these changes to the patient programmer. To apply the changes, the patient must confirm the changes on the patient programmer. In that case, the changes will be transmitted to the stimulator. The stimulator then uses the updated programs for the stimulation.

Prerequisite

- A remote patient management connection to the patient programmer exists.

1. On the **[Remote programming]** screen, you can make changes to one program at a time; see Configuring the Program [Page 31].
   The stimulation is turned off in the status bar as well as the displayed program is deactivated. Please note that the program is always started with a program strength of 0.1 mA.
   - ▶ On the **[Remote programming]** screen, the program strength of 0.1 mA is displayed.
2. After you have made all the changes, you can transmit the changes to the patient programmer. Select the **[Transmit]** button.
   - ▶ The program changes are highlighted until transmitted.
   - ▶ A dialog box is displayed showing the transmission in progress.
   - ▶ On the patient programmer it is indicated that an update of the programming is available. The patient can now decide whether they want to confirm or reject the update.
   - ▶ If the patient confirms the update on the patient programmer, the patient programmer will display that the update is being carried out. If the update was carried out successfully, a message is displayed on the patient programmer and the clinician programmer.
   - ▶ If the patient rejects the update on the patient programmer, a message is displayed on the patient programmer and the clinician programmer.

Result

After successful transmission of the program change, the patient can increase the program strength of the selected program on the patient programmer. Any program changes the patient makes, such as strength adjustment, will be visible on the clinician programmer.

Terminating the Remote Patient Management Connection

Terminate the remote patient management connection by ending the remote programming session with this patient.

1. In the main menu, select the **[End session]** button.

7 Routine Tasks

Adjusting Stimulator Settings

Overview of the Stimulator Settings

The following table gives you an overview of the stimulator settings.

Stimulator Settings	Setting	Description in Section
[Stimulator settings]	[MRI mode]	Turning MRI mode on and off [Page 40]
	[Sleep mode]	Setting and Resetting the Sleep Mode for Battery Preservation [Page 42]
	[Daily lead impedance measurement]	Enabling and Disabling Daily Lead Impedance Measurement [Page 42]
	[Clear lead failures in stimulator]	Clearing Lead Failures [Page 27]
[External stimulator settings]	[Reset trial stimulator]	Resetting the External Stimulator [Page 37]
	[Prepare for battery replacement]	Preparing for Battery Replacement [Page 42]
	[Daily lead impedance measurement]	Enabling and Disabling Daily Lead Impedance Measurement [Page 42]
	[Clear lead failures in stimulator]	Clearing Lead Failures [Page 27]

Turning MRI mode on and off

Note

Refer to Prospera Spinal Cord Stimulation System – MRI Guidelines for instructions, prerequisites, warnings, and precautions related to performing MRI scans on patients with an implanted Prospera SCS System.

Preparing the MRI Scan

Before an MRI scan, prepare the stimulator of the patient for the MRI scan. The stimulation is turned off in the MRI mode.

Note

Inform the patient about the effects of the MRI mode:

- Stimulation is turned off.
- While stimulation is off, the pain symptoms may return.
- After the MRI scan, stimulation can be turned on when the patient is outside the magnetic area.
- The stimulation can be turned on or off using the clinician programmer or the patient programmer.
- If the clinician programmer is not available on the day of the MRI appointment, the patient should bring the patient programmer to be able to turn the stimulation on or off for the MRI scan.

Turning the MRI Mode on

The MRI mode can be turned on in the following ways:

- On the clinician programmer, via the status bar or on the **[Stimulator settings]** screen.
- On the patient programmer. For more information, refer to Prospera Spinal Cord Stimulation System – MRI Guidelines.

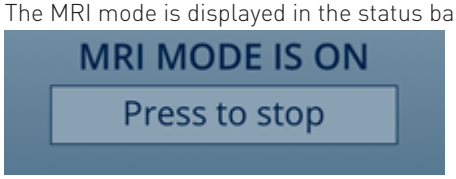
Turning the MRI Mode on Using the Clinician Programmer

1. In the main menu, select the **[Stimulator settings]** menu item.
   ▶ In the **[MRI mode]** setting it is displayed whether the stimulator is ready for the MRI scan.
2. Select the toggle switch to turn the MRI mode on.
   ▶ The displayed confirmation box refers you to Prospera Spinal Cord Stimulation System – MRI Guidelines. This manual contains information on prerequisites and specific cautionary notes and precautionary measure for performing an MRI scan.
3. Confirm the MRI mode by selecting the **[PROCEED]** button.

Result

The stimulator is in the MRI mode. Stimulation is turned off.

The MRI mode is displayed in the status bar.



Alternatively, the patient can use the patient programmer to turn the MRI mode on.

If the MRI mode cannot be enabled, you will see an error message, see Troubleshooting [Page 48].

Turning the MRI Mode off

After the MRI scan has ended and the patient has left the magnetic area, the MRI mode can be turned off in the following ways:

- On the clinician programmer, via the status bar or on the **[Stimulator settings]** screen.
- On the patient programmer. For more information, refer to Prospera Spinal Cord Stimulation System – MRI Guidelines.

Turning the MRI Mode off Using the Clinician Programmer

Prerequisite

- On the clinician programmer, the MRI mode is displayed in the status bar.

1. Select the **[Press to stop]** button.
2. Confirm turning off the MRI mode by selecting the **[PROCEED]** button.

Result

The stimulator is no longer in MRI mode. Stimulation continues to be turned off.

After turning the MRI mode off, turn the stimulation on; see Turning Stimulation on and off [Page 35].

Note

After the MRI scan and after turning the stimulation on, check that the stimulation is working as intended and that the desired stimulation program is running properly.

Setting and Resetting the Sleep Mode for Battery Preservation

Use the sleep mode to pause the therapies for patients who need a therapy pause due to surgery or pregnancy. The sleep mode disables the therapies and puts the stimulator into a power saving mode.

1. In the main menu, select the **[Stimulator settings]** menu item.
2. In the **[Sleep mode]** setting, select the **[SET MODE]** button.
3. Confirm turning on the sleep mode by selecting the **[PROCEED]** button.

If you charge the stimulator, the normal function is resumed.

Enabling and Disabling Daily Lead Impedance Measurement

Enable the daily lead impedance measurement so that the leads are automatically measured daily.

1. In the main menu, select the **[Stimulator settings]** menu item.
2. In the **[Daily lead impedance measurement]** setting, select the toggle switch.

To disable the automatic daily measurement, select the toggle switch again.

Preparing for Battery Replacement

If you need to replace the batteries of the external stimulator because they are weak or dead during the trial phase, prepare the external stimulator for replacement.

Prerequisite

- The external stimulator is connected to the clinician programmer.
- Stimulation is turned off.

1. In the main menu, select the **[Stimulator settings]** menu item.
2. In the **[Prepare for battery replacement]** setting, select the **[PROCEED]** button.

Result

Low power mode is activated.

Replace the batteries to resume normal function.

Adjusting Programmer Settings

Overview of the Programmer Settings

The following table gives you an overview of the programmer settings.

Programmer Setting	Description in Section
[Resynchronize app content]	Resynchronizing the App Content [Page 43]
[Patient programmer test mode]	Setting and Resetting Patient Programmer Test Mode [Page 43]
[Release codes]	Entering Release Codes [Page 44]
[About]	Troubleshooting [Page 48]

Resynchronizing the App Content

The content of the clinician programmer app is regularly synchronized with the BIOTRONIK server. If there are connection problems, you can also synchronize the content manually.

1. In the main menu, select the **[Programmer settings]** menu item.
2. Select the **[Resynchronize app content]** setting.

Setting and Resetting Patient Programmer Test Mode

In an in-person session using the Bluetooth function to connect to the stimulator directly, it is not possible to have simultaneous connections with the clinician programmer and the patient programmer. The patient programmer test mode allows for suspending the clinician programmer connection to use the patient programmer. Thus, it is not necessary to end the clinician programmer session and re-interrogate the stimulator in order to use the patient programmer.

Setting Patient Programmer Test Mode

1. In the main menu, select the **[Programmer settings]** menu item.
2. In the **[Patient programmer test mode]** setting, select the toggle switch.

Resetting Patient Programmer Test Mode

To exit the patient programmer test mode, select the toggle switch again.

Additionally, interrupt the connection with the patient programmer to allow the connection with the clinician programmer to resume.

1. On the **patient programmer**, select the menu button.
2. Select the **[Settings]** > **[Advanced settings]** menu item.
3. Select the **[Follow-up mode]** setting.
4. In the **[Enable follow-up mode]** dialog box, select the **[PROCEED]** button to interrupt the connection with the patient programmer.

Entering Release Codes

You can enter special BIOTRONIK release codes to enable advanced app functions. These advanced functions are intended for BIOTRONIK employees who have expert knowledge of the app.

1. In the main menu, select the **[Programmer settings]** menu item.
2. Select the **[Release codes]** setting.
3. Enter the release code.
4. Select the **[Submit]** button to transmit the release code.

Result

The release code is being verified.

On successful verification, a message that the release code has been accepted is displayed. You now have access to the advanced functions of the app.

Checking Notifications

Note

Notifications from the clinician programmer app are displayed on the **[Notifications]** screen. Notifications and messages from other sources, like the operating system of the clinician programmer device, are displayed in other locations on the screen. In all cases, follow these instructions carefully. If in doubt, contact BIOTRONIK.

For the clinician programmer app, you can see the number of existing notifications via the **[Notifications]** button in the status bar. 

The notifications display the current status of the stimulator. Notifications from the last session are not shown unless they are still present.

Regularly check the clinician programmer notifications:

Prerequisite

- The stimulator is paired with the clinician programmer.

1. In the status bar, select the **[Notifications]** button.
   Alternatively, you can also open the **[Notifications]** screen from the main menu.
   ▶ All the notifications for the current stimulator are displayed on the **[Notifications]** screen.
2. Carry out the necessary steps to resolve the notification.

Deleting Notifications

After you have edited a notification and followed the steps to resolve it, you can delete the notification.

For better organization and clarity, it is recommended to delete notifications that are resolved.

You can see the number of existing notifications via the **[Notifications]** button in the status bar. 

Notifications are deleted from view in the clinician programmer, but not in the stimulator itself.
A deleted notification will appear again in subsequent sessions in the event the notification state is still present in the stimulator.

Prerequisite

- The stimulator is paired with the clinician programmer.

1. In the status bar, select the **[Notifications]** button.
   - ▶ All the notifications for the current stimulator are displayed on the **[Notifications]** screen.
2. To delete **one** notification, select the trash can icon.
   - ▶ The notification will be deleted and removed from the list of displayed notifications.
3. To delete **all** notifications, select the **[Delete all]** button.
   - ▶ All notifications will be deleted.

Checking the Battery Status of the Stimulator

In the status bar of the app you can see the battery status of the stimulator paired with the clinician programmer.

At the beginning of each programming session, check the battery status of the paired stimulator. Only if the stimulator is sufficiently charged, the connection between the stimulator and the clinician programmer can be maintained throughout the entire programming session.

Symbol	Battery Status of the Stimulator
4 green segments 	The stimulator is fully or nearly fully charged.
3 green segments 	The stimulator is sufficiently charged.
2 green segments 	The stimulator is partially charged.
1 yellow segment 	The stimulator is near the end of its usable charge. The stimulator should be charged before starting the programming session.
1 red segment 	The stimulator has used all of the stimulation charge and it is nearing the point where therapy delivery will no longer be possible. You must charge the implantable stimulator or replace batteries in the external stimulator before proceeding with the programming session.
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. You must charge the implantable stimulator or replace batteries in the external stimulator before proceeding with the programming session.
Lightning bolt symbol 	The stimulator is currently being charged. A lightning bolt symbol and blinking green battery status indicators show that the stimulator is being charged.

Updating the Clinician Programmer App

BIOTRONIK periodically updates the software of the clinician programmer app. The updates to the clinician programmer app are executed automatically during inactive hours. An active network connection is required for the update. Connect the clinician programmer to the network periodically. Do not turn the clinician programmer device off and ensure good network connection so that the updates can be installed overnight.

Note

Unauthorized interference in data connection between clinician programmer, stimulator, patient programmer, and the BIOTRONIK server may lead to theft or loss of patient data or to unauthorized modification of the stimulator programming.

- If you use a network connection, use only a managed, trusted wireless network (WiFi).
- Use only wireless access points (WiFi) that are secure and require a password join (at least WPA2 security standard).
- Only run applications on the clinician programmer device that are associated with the BIOTRONIK apps for the clinician programmer.
- If you suspect security issues, end the programming session, if possible. Contact your IT security department or BIOTRONIK.

Viewing and Printing Reports

With the HomeStream Reports app you can easily view, export and print follow-up reports.

Note

The clinician programmer app does not provide data protection for data that is exported and stored in another location. Unauthorized access to patient data may result in theft or loss of the patient data.

- Follow data security practices for any data which is exported or printed from the HomeStream Reports app.
- Do not save any patient data locally.
- Save patient data only to secure locations, according to your organization's security policies for handling and storing data.
- Also, handle PDF reports securely by only saving and printing them in secure locations to which you have access, according to your organization's security policies for handling and storing data.
- Make sure that you are confident with the security of the printer so that you do not accidentally print to a device somewhere in the clinic that you do not know or to which you do not have access.
- Keep the printed documents in a safe, locked place.
- If you suspect a security issue, contact your IT security department or BIOTRONIK.

Prerequisite

- Ensure a network connection is present to make sure the latest reports are available.

1. In the main menu, when outside of a programming session, select the **[Reports]** menu item.
2. Alternatively, select the HomeStream Reports app from the tablet application menu.
3. Use the built-in operating system navigation to switch between the reports app and the clinician programmer app as needed.

8 Troubleshooting

Information about the App

If errors or malfunctions occur in the app or if you need support from BIOTRONIK employees, it is helpful to provide information about the app.

The **[About]** dialog box shows you all the information about the app, such as the software version or the IP address of the clinician programmer.

1. In the main menu, select the **[Programmer settings]** > **[About]** dialog box.
   ▶ The information about the app is displayed.
2. You can move the view up or down.

Possible Errors

Possible Errors when Pairing the Clinician Programmer or the Patient Programmer with the Stimulator	
[Attempting to reconnect] [Unable to find patients or devices] [Unable to establish connection] [Pairing failure] [Pairing incomplete] On the patient programmer: [Stimulator not found]	**Cause:** The clinical programmer or the patient programmer is more than 5 ft (1.5 m) from the stimulator. **Rectification:** For best results, ensure that the distance between the clinician programmer or the patient programmer and the stimulator is less than 5 ft (1.5 m).
	Cause: The Bluetooth function of the clinician programmer or the patient programmer is turned off. **Rectification:** Ensure that the Bluetooth function of the clinician programmer or the patient programmer is turned on.
	Cause: The connection of the stimulator is deactivated. **Rectification:** Contact BIOTRONIK.
	Cause: The clinician programmer, the patient programmer or the stimulator is not sufficiently charged. **Rectification:** Charge the clinician programmer, the patient programmer or the stimulator and then pair the stimulator with the programmer again.
	Cause: Electromagnetic interferences affect the connection between the clinician programmer and the stimulator. **Rectification:** Find another place for the clinician programmer within the connection range so that no electromagnetic interferences affect the connection.
	Cause: When attempting to pair the stimulator with the clinician programmer, the stimulator is not in pairing mode. **Rectification:** Re-position and re-apply the magnet over the stimulator.
	Cause: The stimulator has not been yet assigned to a patient via the clinician programmer. **Rectification:** Assign the stimulator to a patient using the clinician programmer.

Possible Errors while Performing the Impedance Test	
[Impedance test failed]	**Cause:** The connection between the clinician programmer and the stimulator is interrupted. **Rectification:** • Ensure that the Bluetooth function on the clinician programmer is turned on. • For best results, ensure that the distance between the clinician programmer and the stimulator is less than 5 ft (1.5 m). • Ensure that the clinician programmer is sufficiently charged. • Ensure that the stimulator is sufficiently charged.
Impedance values are displayed in red [Out-of-range impedances detected]	**Cause:** The impedance value of the electrodes marked in red is out of range. **Rectification:** • Using an external stimulator, examine the connection between the leads and the stimulator and repeat the measurement. For more information on connecting the leads to the external stimulator, see Prospera Spinal Cord Stimulation System – Implantation Instructions for Physicians. • Out-of-range impedance values can also indicate faulty electrodes which should not be used for therapy. In this case, use alternate electrodes or implant new leads.
Incorrect or implausible impedance results	**Cause:** There is a temperature difference between the stimulator and body or room temperature. **Rectification:** • Acclimate the temperature of the stimulator to room or body temperature. • Repeat the impedance measurement.

Possible Errors while Configuring Subprograms	
Subprogram is invalid and cannot be enabled	**Cause:** The stimulator cannot deliver the combination of the set parameter values and electrode polarities. This makes the subprogram invalid. **Rectification:** Change the polarities or the parameters of the subprogram or the program. Note that the number and specification of the anodes and cathodes depend on the stimulation mode.

Possible Errors while Configuring Leads	
[No leads in use. Add leads in "Lead details" page.]	**Cause:** There is no detailed information available on the implanted leads and their extension. **Rectification:** Enter detailed information on the implanted leads and their extension before configuring the leads; see Entering or Changing Detailed Information on the Leads and Their Extensions [Page 25].

Possible Errors while Turning the MRI Mode on	
[MRI mode cannot be enabled]	**Cause:** The stimulator battery is very low. The battery gauge must show at least one bar. **Rectification:** Charge the stimulator.
	Cause: The automatic daily lead impedance values are out of range or currently not available. **Rectification:** Check if the automatic daily lead impedance measurement has been disabled and perform an impedance test before proceeding. While the system check to enter MRI mode relies on the automatic daily lead impedance measurement, it is possible to satisfy the MR Conditional lead impedance requirements via a manual impedance test in the event the automatic daily measurement is outdated or unavailable.
Note: The clinician programmer will provide the option to OVERRIDE AND ENABLE MRI MODE, which should only be performed under a physician's direction and in full compliance with the MR Conditional prerequisites. For more information, refer to Prospera Spinal Cord Stimulation System – MRI Guidelines.	

Possible Errors in the System	
System error	**Cause:** A system error has occurred or the system no longer responds. **Rectification:** Contact BIOTRONIK.

9 Appendix

Technical Data

Functional Parameters and Limit Values

Category	Value
Electrode configuration (traditional therapy)	Maximum 4 cathodes, 4 anodes electrodes
Electrode configuration (interleaved pulses)	Maximum of 4 electrodes
Number of programs	Up to 12 programs (additionally, up to 4 sub-programs for traditional therapy)
Amplitude range	0.1 mA ... 20.0 mA
Pulse width range	30 µs ... 1000 µs
Frequency (rate) range	2 Hz ... 1400 Hz
Frequency (rate) range Traditional therapy	2 Hz ... 1400 Hz
Frequency (rate) range Interleaved pulses therapy	2 Hz ... 1400 Hz
Cycling	Continuous

Data Security

The following data security measurements have been implemented:

- Data is protected by application-level encryption and encryption provided by the clinician programmer device.
- The clinician programmer app does not provide data protection for data that is exported and stored in another location. Follow your organization's security policies for handling and storing data.
- Wirelessly sent critical data is encrypted by the clinician programmer before it is sent.
- 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.
- Security settings within the clinician programmer are automatically set and remotely managed including user login settings, device lockdowns, device firewall, and anti-virus.
- If you have any questions or concerns regarding the security of the device, contact your IT security department or BIOTRONIK.

Additional Cybersecurity Information

- BIOTRONIK follows its internal policies and procedures to address privacy and threat elimination and minimization as part of cybersecurity.
- BIOTRONIK follows framework, standards and processes for its approach to cybersecurity that are agreed upon within the medical and technology industries to be state-of-the-art best practices. Specifically, BIOTRONIK follows the NIST cybersecurity framework and operates its database according to information security management system certified to ISO27001.
  BIOTRONIK is a member of NH-ISAC which shares and disseminates Cyber Security Threat information to health care companies.
  Data is protected by encryption in transit and at rest.
- BIOTRONIK's cybersecurity assessment and controls are documented in a Cyber Security Risk Assessment document, in which controls are then traced to requirements and testing.
- BIOTRONIK has been audited by an independent cybersecurity compliance company to ensure compliance to industry best practice data security protocols. Specifically, an independent cybersecurity company audited architecture-level cybersecurity to ensure HIPAA and HITECH compliance as well as industry-expected cybersecurity protocols through penetration testing.

Note

Ensure the patient's consent to electronic processing of patient data to be compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Note

Unauthorized access to the clinician programmer may result in theft or loss of patient data or unauthorized modification of the stimulator programming.

- Protect the clinician programmer against unauthorized access.
- Do not connect the clinician programmer to any unknown USB or Bluetooth device. Use only a USB device that includes pin and encryption.
- Lock the clinician programmer device when you interrupt the programming session. When you are not using the device, also lock it. In addition, ensure the device settings are set to automatically lock the screen after no more than 15 minutes of non-use. Refer to the tablet manufacturer's information on how to lock the screen and change the device settings.
- Keep the device in a secure place and do not disclose your password or pin.
- Use a secure, unique password that cannot be guessed. Follow the specific operating system rules for a secure password. Refer to the tablet manufacturer's information on how to create a secure password.
- When unlocking the clinician programmer, make sure that you are not being watched.
- At the end of the programming session, exit the session correctly and then close the app and sign out of the clinician programmer.
- If your clinician programmer is lost or stolen, contact your IT security department or BIOTRONIK.

Note

Unauthorized interference in data connection between clinician programmer, stimulator, patient programmer, and the BIOTRONIK server may lead to theft or loss of patient data or to unauthorized modification of the stimulator programming.

- If you use a network connection, use only a managed, trusted wireless network (WiFi).
- Use only wireless access points (WiFi) that are secure and require a password to join (at least WPA2 security standard).
- Only run applications on the clinician programmer device that are associated with the BIOTRONIK apps for the clinician programmer.
- If you suspect security issues, end the programming session, if possible. Contact your IT security department or BIOTRONIK.

Note

The clinician programmer app does not provide data protection for data that is exported and stored in another location. Unauthorized access to patient data may result in theft or loss of the patient data.

- Follow data security practices for any data which is exported or printed from the HomeStream Reports app.
- Do not save any patient data locally.
- Save patient data only to secure locations, according to your organization's security policies for handling and storing data.
- Also, handle PDF reports securely by only saving and printing them in secure locations to which you have access, according to your organization's security policies for handling and storing data.
- Make sure that you are confident with the security of the printer so that you do not accidentally print to a device somewhere in the clinic that you do not know or to which you do not have access.
- Keep the printed documents in a safe, locked place.
- If you suspect a security issue, contact your IT security department or BIOTRONIK.

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

The app may include components or modules that are open source software or commercially available software programs. Copyright or other notices and license information for such software programs that are part of the app can be found in the software.

This open source software, commercial software, and the app may form a single joint unit, which is regulated under applicable laws. Please note that the respective conditions for permitted use under the applicable laws are no longer met once unauthorized changes are made to the app.

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

Disclaimer, Warranty, and Warranty Conditions

For warranty questions or a copy of the warranty, contact BIOTRONIK.

Disposal

For disposal of the clinician programmer, please return it to the distributor, BIOTRONIK NRO, INC.

Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
	BIOTRONIK order number
	Serial number
	Manufacturer
	Distributor

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