Prospera Spinal Cord Stimulation System

ProMRI

Implantation Instructions for Physicians

Technical Manual

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Rx only

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1 About This Technical Manual

Objective

This technical manual contains information for physicians, trained users of the clinician programmer, and medical personnel regarding the implantation, setup, and follow-up of the Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System, for the trial phase and for permanent use.

- Implantation of percutaneous leads for trial and/or permanent use
- Connection of the leads for trial use to an external stimulator
- Implantation of an implantable stimulator
- Connection of the leads to an implantable stimulator
- Performance of intraoperative tests
- Explantation of leads and stimulators

All activities performed with the clinician programmer are carried out by a trained user of the clinician programmer. A detailed description for trained users of the clinician programmer on the handling of the clinician programmer can be found in HomeStreamCP – Clinical Programming of BIOTRONIK External and Implantable Spinal Cord Stimulators.

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:

- Prospera Spinal Cord Stimulation System – MRI Guidelines
- Prospera Spinal Cord Stimulation System – Patient Guide for the Implanted System
- Prospera Spinal Cord Stimulation System – Patient Guide for the Trial System
- Smartphone manufacturer's information on the patient programmer MyHomeStream
- Smartphone manufacturer's information on the patient programmer MyHomeStream TR
- HomeStreamCP – Clinical Programming of Prospera SCS System Stimulators
- Tablet manufacturer's information on the HomeStreamCP

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
ABS	Acrylnitril/Butadien/Styrol
CISPR	Comité International Spécial des Perturbations Radioélectriques
CRPS	Complex Regional Pain Syndrom
DDD	Degenerative Disk Disease
EIRP	Equivalent Isotropically Radiated Power
EM fields	Electromagnetic fields
ESD	Electrostatic Discharge
FBS	Failed Back Syndrom
FCC	Federal Communications Comission

Abbreviation	Meaning
GFSK	Gaussian Frequency Shift Keying
HIPAA	Health Insurance Portability and Accountability Act
ICD	Implantable Cardioverter-Defibrillator
Patient ID card	Patient Identification card
IEC	International Electrotechnical Commission
ISM band	Industrial, Scientific and Medical band
IT	Information Technology
LED	Light-Emitting Diode
MRI	Magnetic Resonance Imaging
OOK	On-Off Keying
OOS form	Out Of Service form
RF ablation	Radio Frequency ablation
RSD	Reflex Sympathetic Dystrophy
SCS	Spinal Cord Stimulation
TENS	Transcutaneous Electrical Nerve Stimulation
UDI	Unique Device Identifier
USB	Universal Serial Bus
WEEE 2	European guideline 2012/19/EU on waste electrical and electronic equipment
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 Safety

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

Warnings

Please follow the listed safety messages when handling the external stimulator:

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

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

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

Precautions

Safety Messages for Handling the Trial System

Please follow the listed safety messages when handling any of the system components:

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached pouch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected Correctly

The improper cleaning and disinfecting of an external stimulator may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after use by each patient.

Safety Messages for Handling the Implantable Stimulator

Please follow the listed safety messages when handling the implantable stimulator:

Product Damage and Risk of Injuries due to Modification of the Medical Device

Unauthorized modification to the medical device is prohibited. System integrity could be compromised and patient harm or injury may occur if the medical devices are modified without authorization.

- Do not modify the medical device.

Risk of Infection if an Explanted Stimulator Is Not Properly Disposed of

An explanted stimulator must not be reused due to the risk of infection, and it must be properly disposed of.

- Dispose of the explanted stimulator as medical waste in an environmentally sound and proper manner.
- Do not cremate the stimulator. Explant the stimulator to cremation of a deceased patient.
- Return the explanted stimulator to BIOTRONIK for an environmentally sound disposal.

Skin Erosion, Overheating, or Charging Difficulties due to an Improper Pocket Depth and Location

An improperly placed device pocket may lead to skin erosions if placed too close to the surface. It may lead to charging difficulties or to excessive heat development during the charging of the stimulator, if placed too deep.

- Please follow the instructions for the creation of a device pocket.
- If necessary, use the pocket template to shape the device pocket properly.
- Implant the stimulator no more than 2 cm (0.78 inch) below the skin surface with the labeled side facing the skin, so that the charging coil is close to the patient surface.
- Lay sutures through the eyelets at the stimulator header to prevent the stimulator from inverting or migrating.

Injury due to Heat Development during Charging when Using Metallic Clamps

When charging the implanted stimulator, surgical staples made of metal that are situated in the vicinity of the implanted stimulator may heat up and damage the patient's tissue in this area.

- Do not use surgical staples made of metal in the vicinity of the implanted stimulator.

Risk of Infection in case of Resterilization and Reuse

The implanted Prospera SCS System is designed for single use only. Resterilization and reuse of previously used implantable stimulators, leads or accessories can result in infections, embolisms, and damage to the components.

- Resterilization and reuse are prohibited.
- Please note the single-use label on the components.

Safety Messages for Handling the Implant Accessories

Please follow the listed safety messages when handling the implantation accessories:

Skin Injury if Tunneling Is too Shallow

If the tunneling of the implanted leads is too shallow, skin erosion and exposure of the implanted leads may occur.

- Please tunnel the leads deep enough to prevent skin erosion and exposure of the implanted leads.
- If very long tunneling is required, it is recommended to lead the lead out of the skin and create a second tunnel.

Spinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when accessing the epidural space. Furthermore, steep insertion angles may inhibit ability to subsequently insert the lead and/or may result in undesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the insertion needle into the epidural space.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

Risky Therapeutic and Diagnostic Procedures

Safety Messages for Handling the Trial System

Please follow the listed safety messages when handling the trial system:

WARNING

Adverse Interactions and Damage of the Trial System due to Medical Procedures

The following medical procedures may lead to adverse interactions and to damage to the external stimulator and implanted trial leads:
lithotripsy, RF ablation, hyperbaric oxygen therapy, electrocautery, diathermy, high-power ultrasound, radiation therapy, MRI scan.

- Do not apply the above-listed procedures while the patient is undergoing an SCS trial phase.
- Turn off the external stimulator and remove the external stimulator and implanted trial leads before using one of the above-listed procedures for this patient.

WARNING

Interference with the Operation of Implanted Pacemakers or ICDs

The Prospera SCS System may interfere with the operation of implanted pacemakers or ICDs. The effects of an implanted Prospera SCS System on other neurostimulators are unknown.

WARNING

Therapy Failure and Harm to the Patient due to External Defibrillation

External defibrillation may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage in the area of the implanted leads may occur due to excessive heat development at the lead tip.

- Turn the stimulation off temporarily.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the defibrillation.

Attention

Disruption of the Therapy of the External Stimulator by External Defibrillation

External defibrillation may lead to damage and function loss of the external stimulator.

- Replace an external stimulator that was worn during an external defibrillation of a patient with a new external stimulator.
- Return the external stimulator that was worn during an external defibrillation of a patient to BIOTRONIK.

Attention

Undesirable Therapy Possible with TENS Use

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

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

Safety Messages for Handling the Permanent System

Please follow the listed safety messages when handling the permanent system:

⚠ WARNING

Therapy Failure and Harm to the Patient due to Electrocautery

Electrocautery may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and serious patient injuries may occur in the area of the implanted stimulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Use bipolar electrocautery.
- Do not apply unipolar electrocautery.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electrocautery.

⚠ WARNING

Therapy Failure and Harm to the Patient due to External Defibrillation

External defibrillation may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage in the area of the implanted leads may occur due to excessive heat development at the lead tip.

- Turn the stimulation off temporarily.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the defibrillation.

⚠ WARNING

Interference with the Operation of Implanted Pacemakers or ICDs

The Prospera SCS System may interfere with the operation of implanted pacemakers or ICDs. The effects of an implanted Prospera SCS System on other neurostimulators are unknown.

⚠ WARNING

Therapy Failure and Harm to the Patient due to Diathermy Therapy, including Shortwave, Microwave, and Therapeutic Ultrasound Therapies

Diathermy therapy, including shortwave, microwave, and therapeutic ultrasound therapy, may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and serious patient injuries may occur in the area of the implanted stimulator or the leads.

- Avoid diathermy therapy if possible. If diathermy therapy is necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Do not apply the diathermy therapy in the immediate vicinity of the implanted stimulator or the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the diathermy therapy.

⚠ WARNING

Therapy Failure and Harm to the Patient due to the Use of Magnetic Resonance Imaging (MRI)

The use of magnetic resonance imaging outside of the specified conditions may damage the Prospera SCS System due to strong magnetic interactions. In addition, the patient may come to harm due to excessive heating of the body tissue in the area of the implanted system.

- Please inform yourself on the safe performance of an MRI scan. Refer to Prospera Spinal Cord Stimulation System – MRI Guidelines.
- You can download the MRI Guidelines on the internet: https://manuals.biotronik.com.
- A printed copy can be ordered from BIOTRONIK.

⚠ WARNING

Therapy Failure and Harm to the Patient due to Therapeutic or High-Power Ultrasound Treatment

Therapeutic and high-power ultrasound treatment exposes the Prospera SCS System to high doses of energy, which may lead to damage and function loss of the system and to therapy failure. Excessive heating may lead to tissue damage and patient injuries in the area of the implanted stimulator or the leads.

- Avoid therapeutic or high-power ultrasound treatments if possible. If these treatments are necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Do not apply the ultrasound treatment in the immediate vicinity of the implanted stimulator or the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electrical therapy.

⚠ Caution

Therapy Failure and Damage to the Prospera SCS System due to Lithotripsy

Lithotripsy may lead to damage and function loss of the system and to therapy failure.

- Turn the stimulation off temporarily.
- Keep the focal point of the lithotripsy at least 2.5 cm from the implanted Prospera SCS System.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the lithotripsy.

⚠ Caution

Therapy Failure and Damage to the Prospera SCS System due to RF Ablation

RF ablation may lead to damage and function loss of the system and to therapy failure.

- Turn the stimulation off temporarily.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the grounding plate in such a way that the current path does not run through or in the vicinity of the implanted stimulator and the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the RF ablation.

⚠ Caution

Therapy Failure Caused by Hyperbaric Ambient Conditions

Therapy environments with increased ambient pressure can lead to insufficient or excessive stimulation and the associated adverse stimulation side effects.

- Turn the stimulation off temporarily.
- Apply hyperbaric oxygen therapy only under ambient conditions listed as permissible in this technical manual (e.g., maximum pressure).
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the hyperbaric oxygen therapy.

⚠ Caution

Therapy Failure and Damage to the Stimulator due to Radiation Therapy

Radiation therapy may lead to damage and function loss of the stimulator and to therapy failure.

- Turn the stimulation off temporarily.
- Place a lead shield above the area of the stimulator.
- Note that damage might not be obvious and may lead to a malfunction of the stimulator.
- Perform a complete system follow-up after finishing the radiation therapy.

⚠ Attention

Undesirable Therapy Possible with TENS Use

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

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

Transport and Storage

⚠ Attention

Damage to the System due to Noncompliance with the Conditions for Transport and Storage

If the conditions for transport and storage stated in this technical manual are not met, the system may be damaged. The system function may be permanently compromised by this.

- Please follow the conditions for transport and storage listed in this technical manual.
- Do not use system components that were not transported or stored correctly.

Sterility

⚠ Sterile Delivered Products

⚠ Caution

Risk of Infection in case of Resterilization and Reuse

The implanted Prospera SCS System is designed for single use only. Resterilization and reuse of previously used implantable stimulators, leads or accessories can result in infections, embolisms, and damage to the components.

- Resterilization and reuse are prohibited.
- Please note the single-use label on the components.

The following components are sealed in 2 blisters, one within the other, and sterilized with ethylene oxide. As a result, the inner blister is also sterile on the outside.

- Implantable stimulator, torque wrench and pocket template
- Leads and accessories
- Active anchors
- Suture anchors
- Port plugs

The following components are sealed in a blister and sterilized with ethylene oxide.

- Intraoperative test cable
- Spare accessories
- Tunneling tool
- Insertion needle

⚠ Non-Sterile Delivered Products

The following products are delivered non-sterile:

- External stimulator
- Trial Kit
- Magnet
- Charger

Temperature during Transport and Storage

Store the following components at an ambient temperature of -4 °F to +140 °F (-20 °C to +60 °C):

- Magnet

Store the following components at an ambient temperature of +14 °F to +113 °F (-10 °C to +45 °C):

- External stimulator
- Charger
- Intraoperative test cable
- Trial kit

Store the following components at an ambient temperature of +14 °F to +131 °F (-10 °C to +55 °C):

- Implantable stimulator
- Leads
- Active anchor
- Suture anchor
- Port plugs
- Spare accessories
- Tunneling tool
- Long insertion needle

Storage Period

Store the following components for a storage period of 12 months:

- Implantable stimulator
- Leads
- Active anchor
- Suture anchor
- Tunneling tool
- Spare accessories
- Long insertion needle
- Port plugs

3 System Description

Overview of the System Components

The Prospera SCS System consists of various components: the implantable stimulator, one or two percutaneous leads, the clinician programmer, the external stimulator, the patient programmer, and the charger. There are also additional accessories that are implanted or used during or after the implantation.

First, trial leads are implanted and connected to an external stimulator. This system can be used to check the effectiveness of the therapy during a trial phase.

If the trial phase was successful, the patient is implanted with permanent leads and an implantable stimulator. The implantable stimulator is charged by the patient with a charger.

Both the external and the implantable stimulator are in wireless communication with the clinician programmer and the patient programmer.

Main Components

The Prospera SCS System consists of the following main components:

Implantable Stimulator

The implantable stimulator is a device for the electrical stimulation of nerves in the spinal cord.

The stimulator is made up of the housing and the header. The housing contains a rechargeable battery that can be charged transcutaneously. The header contains the connections for up to two leads that are attached with set screws and the charging coil for recharging the battery.

The implantable stimulator communicates wirelessly with other system components, such as the patient programmer, the clinician programmer, and the charger. With the help of the patient programmer and the clinician programmer, the therapy delivered by the implantable stimulator can be adapted to the needs of the patient. The implantable stimulator can also store data that can be read with the help of the clinician programmer.

External Stimulator

The external stimulator is a device that is able to deliver the same therapies as the implantable stimulator.

The external stimulator is made up of a housing and a header. The housing contains the batteries. In addition, the housing has a connection point where the header or the intraoperative test cable can be attached. The header has lead connections, to which the proximal ends of the trial leads are connected. The leads are held in place with a cover at the contacts of the lead connections.
The external stimulator is used during implantation to perform intraoperative tests. To this end, the implanted leads are connected to the external stimulator via the intraoperative test cable.

At the start of the trial phase, the external stimulator is connected to the trial leads and attached to the patient's body with an affixation pouch. The effectiveness of the delivered therapies can be assessed during the trial phase.

The external stimulator can communicate wirelessly with the patient programmer and the clinician programmer.

Leads

The leads have the purpose to deliver stimulation to the spinal cord. The leads are implanted in the epidural space.

The lead connector has 8 contacts that are connected to the header of the external stimulator, the implantable stimulator, or the intraoperative test cable. At the distal end of the lead, there are 8 ring electrodes, through which therapy is delivered.

The system comprises both trial and permanent leads. The trial leads are used during the trial phase and are connected to the intraoperative test cable or to the external stimulator. The permanent leads are used during the permanent implantation of an Prospera SCS System and are connected to the intraoperative test cable or to the implantable stimulator.

Clinician Programmer

The clinician programmer is a tablet able to communicate wirelessly with the implantable and the external stimulator. With the clinician programmer, a trained user of the clinician programmer can perform the following tasks:

- Pairing
- Intraoperative tests
- Programming parameter adjustments
- Preparing the external stimulator for battery replacement and removal
- Preparing the implantable stimulator for removal

Patient Programmer

The patient programmer is a phone which acts as the interface for communication with the external and the implantable stimulator. With the patient programmer, the patient can turn the stimulation on and off, adjust the intensity of the therapy, and receive and use programs transmitted by the physician.

Accessories

The Prospera SCS System also contains the following accessories that are implanted or used during or after the implantation:

Port Plug

The port plug is an implantable accessory. The port plug is used to close off an unused lead connection at the header of the implantable stimulator if only one lead is implanted.

Active Anchor

The active anchor is an implantable accessory. The lead is attached at the lead epidural exit site with the anchor.
The active anchor is pushed onto the lead and secured to the lead with a screw mechanism.
The anchor has eyelets for suturing it to the tissue.

Suture Anchor

The suture anchor is an implantable accessory. The lead is attached at the lead epidural exit site with the suture anchor in the same manner as the active anchor.
The suture anchor is secured to the lead by tying a suture around a ligature groove.

Insertion Needle

The insertion needle is used to provide access to the epidural space for lead insertion.

Clearing Wire

The clearing wire can be used during the implantation to predefine the insertion path of the lead into the epidural space.

Stylet

With the help of the stylet, the lead can be positioned at the desired implantation site during the implantation. Stylets are available in two configurations: straight and curved.

Tunneling Tool

The tunneling tool is used to tunnel subcutaneously from the lead implantation site to the device pocket during the implantation, to guide the lead from the implantation site to the device pocket.

Torque Wrench

The torque wrench is used during the implantation of the implantable stimulator to secure the leads to the header of the device with the set screws. In addition, the torque wrench is used to secure the active anchor to the lead via a set screw.

The torque wrench is available in two lengths, which can be selected depending on the anatomy of the patient.

Pocket Template

The pocket template is used before or during the implantation as template to shape the device pocket. The pocket template has the same shape and size as the implantable stimulator.

Intraoperative Test Cable

The intraoperative test cable connects the leads to the external stimulator during implantation for intraoperative testing.

The intraoperative test cable consists of the lead connection and the header, which are connected to a cable. The lead connection contains the lead contacts, to which the leads are attached. The header can be connected to the external stimulator that is used to perform the intraoperative tests.

Charger

The charger is used for transcutaneous charging of the implanted stimulator by the patient. The charger contains a rechargeable battery that is charged before charging the implantable stimulator. To charge the stimulator, the charger is placed over the header of the implantable stimulator.

Magnet

The magnet is used to pair the stimulators with the clinician programmer or the patient programmer. When the magnet is placed on the stimulator, the stimulator enters a mode that enables the communication. When the magnet is placed on the stimulator for longer than 60 s, the stimulation therapy is suspended.

Intended Medical Use

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.

Indications

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

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.

Adverse Effects

Below is a list of the potential adverse effects (e.g., complications) associated with the use of SCS systems. The Prospera SCS System is similar to other legally marketed SCS systems in intended use, target patient population, technology, device design, and output characteristics. Therefore, as there is no published data on the use of the Prospera SCS System, the following list of potential adverse effects have been identified from peer-reviewed published literature of studies and device labeling of other legally marketed fully implantable SCS systems similar to the Prospera SCS System.[1,2,3,4,5] The adverse effects include, in order of increasing specificity: (1) those associated with any surgical procedure, (2) those associated with the SCS system placement procedures, and (3) those associated with having an implanted SCS system to treat pain, including the Prospera SCS System. In addition to the risks listed below, there is the risk that the SCS therapy may not be effective in relieving symptoms or may cause worsening of symptoms. Additional intervention may be required to correct some of the adverse effects.

- Risks associated with any surgical procedure: abscess; cellulitis; excessive fibrotic tissue; wound dehiscence; wound, local or systemic infection; wound necrosis; edema; inflammation; foreign body reaction; hematoma; seroma; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; hypertension; pulmonary complications; organ, nerve or muscular damage; gastrointestinal or genitourinary compromise; seizure, convulsion, or changes to mental status; complications of pregnancy including miscarriage and fetal birth defects; inability to resume activities of daily living; and death.
- Risks associated with SCS system placement procedures: temporary pain at the implant site, infection, cerebrospinal fluid (CSF) leakage, CSF fistula, epidural hemorrhage, bacterial meningitis, seroma, hematoma, and paralysis. Patient use of anticoagulation therapies may increase the risk of procedure-related complications such as hematomas, which could produce paralysis.
- Risks associated with the use of an SCS system: lead migration; stimulator migration; allergic response or tissue reaction to the implanted system material; hematoma or seroma at the implant site; skin erosion at the implant site; persistent pain at the stimulator, extension, or lead site; radicular chest wall stimulation; disturbed urination; dysesthesia; decubitus; premature battery depletion; loss of assistance in managing pain over time; and uncomfortable stimulation or ineffective pain management caused by random failure of the system components or battery, changes in lead position, loose electrical connections, lead or extension insulation breaches or fractures.

Summaries of specific adverse events and device-related complications identified in a systematic review and meta-analysis of published clinical studies used to evaluate the safety of the Prospera SCS System, are provided in the section: Summary of Clinical Evaluation [Page 66]

[1]Algostim, LLC. Summary of Safety and Effectiveness Data: Algovita™ Spinal Cord Stimulation (SCS) System. 2015. P130028.
[2]Advanced Bionics Corporation. Summary of Safety and Effectiveness Data: PRECISION™ Spinal Cord Stimulator (SCS) System. 2004. P030017.
[3]Advanced Neuromodulation Systems (ANS), Inc. Summary of Safety and Effectiveness Data: Genesis Neurostimulation (IPG) System. 2001. P010032.
[4]Boston Scientific Neuromodulation Corporation. Summary of Safety and Effectiveness Data: Precision™ and Spectra WaveWriter™ Spinal Cord Stimulation (SCS) Systems. 2017. P030017/S275.
[5]Nevro Corp. Summary of Safety and Effectiveness Data: Senza Spinal Cord Stimulation (SCS) System. 2017. P130022.

Intended Users

Medical and Technical Users

The primary users of the Prospera SCS System for surgical and follow-up roles are physicians familiar with neurostimulator implantation, follow-up care, and risks associated with neurostimulation systems. Qualified BIOTRONIK representatives and other hospital staff will provide support for the needs of these primary users.

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

Patient User

The primary user of the Prospera SCS System for the role of operation of the patient programmer and the charger is the patient who receives the stimulator.

4 Overview of the Implantation Procedure and Process

Implantation Procedure

The implantation is divided into two phases. First, a trial system is implanted, and the effectiveness of the therapy is tested. If the effectiveness has been confirmed, the permanent system is implanted.

During the implantation of the trial system, up to two leads are temporarily implanted in the patient, the proximal ends exit the patient's body and are connected to an external stimulator with a header. The external stimulator is attached to the patient with an affixation pouch. After testing the effectiveness, the trial leads are removed.

If it was shown that the use of a stimulator is suitable, the permanent system with up to two leads and the implantable stimulator is implanted.

Procedures Overview

The steps performed with the clinician programmer are carried out by a trained user of the clinician programmer. This includes pairing, intraoperative testing, programming, preparing the external stimulator for battery replacement, preparing the external stimulator for removal, resetting the patient programmer at the end of the trial phase, and deactivating a stimulator prior to explant.

Steps for Implanting and Removing the Trial System

	Procedure	Step
1	Prepare the implantation	
		Instructions before the Implantation [Page 28]
		Replacing the Batteries of the External Stimulator before each Implantation [Page 28]
2	Implant the trial lead	
		Inserting the Lead [Page 29]
		Performing Intraoperative Tests [Page 30]
		Connecting the Lead [Page 31]
3	Attach and program the external stimulator	
		Attaching the External Stimulator to the Patient [Page 32]
		Programming the Stimulator [Page 32]
		Pairing the Patient Programmer with the External Stimulator [Page 32]
4	Remove the trial system	
		Removing the External Stimulator from the Patient [Page 33]
		Removing the Trial Leads [Page 35]
		Cleaning, Disinfecting, and Storing the External Stimulator [Page 36]

Steps for Implanting the Permanent System

	Procedure	Step
1	Prepare the implantation	
		Instructions before the Implantation [Page 38]
2	Implant the permanent lead	
		Inserting the Lead [Page 38]
		Performing Intraoperative Tests [Page 40]
		Anchoring the Lead [Page 41]
		Shaping the Pocket for the Stimulator and Tunnel the Lead [Page 42]
3	Implant the implantable stimulator	
		Implanting the Stimulator and Connecting the Lead [Page 44]
4	Program the stimulator	
		Programming the Stimulator [Page 45]
		Pairing the Patient Programmer with the Stimulator [Page 45]

Steps for Exchanging or Explanting the Permanent System

	Procedure	Step
1	Exchange the implantable stimulator	
		Exchanging the Stimulator [Page 46]
2	Explant the permanent system	
		Explanting the Permanent System [Page 46]

5 First Steps

Package Contents

Prospera IPG

The storage package includes the following:

- Sterile packaging with device and accessories
- Medical device registration form
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Implantable stimulator
- Torque wrench
- Pocket template

Resilience 55TR

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (55 cm)
- Straight stylet (55 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Resilience 75TR

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (75 cm)
- Straight stylet (75 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Prospera EPG

The storage package includes the following:

- External stimulator
- External stimulator cap

Prospera Trial Acc

The storage package includes the following:

- Header of the external stimulator
- External stimulator cap
- 2 patient affixation pouches
- 3 batteries, type AAA
- Prospera Spinal Cord Stimulation – Patient Guide for the Trial System

Resilience 55

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (55 cm)
- Straight stylet (55 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Resilience 75

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead Resilience 75 with inserted curved stylet (75 cm)
- Straight stylet (75 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

HomeStreamCP

The storage package includes the following:

- Tablet
- Tablet manufacturer's information on the clinician programmer
- Charging cable and power plug adapter

MyHomeStream TR

The storage packaging includes the following:

- Smartphone with installed application
- Smartphone manufacturer's information on the patient programmer
- Charging cable
- Power plug adapter

MyHomeStream

The storage packaging includes the following:

- Smartphone with installed application
- Smartphone manufacturer's information on the patient programmer
- Charging cable
- Power plug adapter

SCS PP

The storage package includes the following:

- Sterile packaging with port plugs
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- 2 port plugs

SCS Anchor

The storage package includes the following:

- Sterile packaging with active anchors
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- 2 active anchors

SCS NDL L

The storage package includes the following:

- Sterile packaging with insertion needle

The sterile packaging includes the following:

- Long insertion needle

Tunneler

The storage package includes the following:

- Sterile packaging with tunneling tool and accessories

The sterile packaging includes the following:

- Tunneling tool
- Tunneling shaft (premounted)
- Sharp tip
- Blunt tip

Prospera IOC

The storage package includes the following:

- Sterile packaging with intraoperative test cable

The sterile packaging includes the following:

- Intraoperative test cable (2.0 m)

SCS Resilience Acc

The storage package includes the following:

- Sterile packaging with spare parts

The sterile packaging includes the following:

- Curved stylet
  - 55 cm
  - 75 cm
- Straight stylet
  - 55 cm
  - 75 cm
- Straight insertion needle
- Long torque wrench (43 mm)

Prospera CHG

The storage packaging includes the following:

- Charger
- 2 charger belts of different lengths
- Wall adapter with USB connector and power plug adapters
- Prospera Spinal Cord Stimulation – Patient Guide for the Implanted System

Neuro M50

The storage package includes the following:

- Magnet

Unpacking

⚠ Attention

Functional Impairment due to External Damage

Mechanical impact, for example, dropping a component on hard surfaces – unpackaged already from a dropping height of just 5 cm – can permanently impair the function.

- Do not use the component.
- Return the component to BIOTRONIK.
- Exchange the dropped component against a new one.

Sterile Packaging

Please proceed as follows when unpacking the components from the sterile packaging.

Unpacking

1. Check whether the packaging is damaged.
   ▶ Do not use parts from damaged packaging.
   ▶ Have spares of sterile parts available.
2. Peel off the sealing paper of the outer blister in the direction indicated by the arrow.
   ▶ The inner blister must not come into contact with persons who have not sterilized their hands or gloves, or with non-sterile instruments!
3. Hold the inner blister at the gripping tab and lift it out of the outer blister.
4. Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

Checking Parts

1. Check that all parts are contained in the package contents.
2. Check whether parts are damaged.
   Exchange damaged parts.

Non-Sterile Packaging

Please proceed as follows when unpacking parts from non-sterile packaging.

Unpacking

1. Check whether the packaging is damaged.
   ▶ Do not use parts from damaged packaging.
2. Unpack all parts from the package contents.

Checking Parts

1. Check that all parts are contained in the package contents.
2. Check whether parts are damaged.
   Exchange damaged parts.

6 Implanting the Trial System

Preparing the Implantation

Instructions before the Implantation

1. Please follow the unpacking instructions and make sure that the sterility is ensured, see Unpacking [Page 27].
2. Check all needed components for damage and only use undamaged components.
3. Check the required components for, e.g., length and type and make sure that all required components match and are suited for the implantation and the patient.
4. Make sure that the intended location for the pouch that attaches the external stimulator to the patient is adequately prepared, for example by shaving.
5. Make sure that an already used external stimulator has been thoroughly cleaned and disinfected, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
6. Make sure that new batteries are always used for each patient, see Replacing the Batteries of the External Stimulator before each Implantation [Page 28]. If the batteries are not sufficiently charged, the intraoperative testing of the leads cannot be performed and delays in the implantation procedure will occur.
7. Pair the clinician programmer with the stimulator.
8. Make sure that no therapy program is programmed and active on the stimulator. For this, you can use the clinician programmer or the patient programmer.

Replacing the Batteries of the External Stimulator before each Implantation

Attention

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

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

- Do not modify the external stimulator.

Prerequisite

- Stimulation is turned off, and it is not connected to the leads.

1. Open the cover of the battery compartment.
2. Replace the batteries with the provided batteries, see External Stimulator [Page 51]. Ensure proper polarity alignment.
   ▶ If the batteries are inserted correctly, the LED lights up for 5 s and then turns off.
3. Close the cover of the battery compartment. Ensure the cover is secure and properly snapped into place.
4. Check the battery status with the patient programmer or the clinician programmer.

Inserting the Lead

⚠ Caution

Spinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when accessing the epidural space. Furthermore, steep insertion angles may inhibit ability to subsequently insert the lead and/or may result in undesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the insertion needle into the epidural space.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

Improper or careless handling of the system may damage the system and permanently impair the function.

- Handle the Prospera SCS System with care.
- Follow the instructions in this technical manual.
- Exchange damaged components.

Note

If the lead is handled excessively, it can be damaged.

- Handle the lead carefully.
- Avoid excessive bending, stretching, kinking etc. of the lead.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary precautionary measures.
3. If preoperative antibiotic prophylaxis had been judged to be necessary, make sure that it has been performed.
4. Inject a local anesthetic at the suitable insertion site for the insertion needle.
5. Check that the stylet is inserted in the insertion needle.
6. Carefully insert the insertion needle under fluoroscopy monitoring into the posterior ligament complex of the suited section of the spine. Make sure that the insertion angle is not too steep.
7. Remove the stylet from the insertion needle.
8. Check the position of the insertion needle by fluoroscopy monitoring.
9. Check the entry into the epidural space with a standard method, e.g., loss of resistance or using the provided clearing wire.
   If you use the clearing wire provided, handle it carefully and push it carefully through the insertion needle to prevent injury to spinal tissues.
10. Select an appropriate length lead to accommodate patient anatomy and strain relief loops.
11. Make sure the suitable stylet has been completely inserted into the lead and is extended to the tip of the lead.
12. Make sure that the insertion needle is not occluded.
13. Slowly push the lead with the stylet through the insertion needle into the epidural space.
14. Use the stylet to steer the lead under fluoroscopy monitoring to the respective section of the spine.
15. Proceed in the same manner when inserting a second lead. Make sure to insert the second insertion needle in such a way that the first lead is not damaged. Do not remove the needle of the first lead until both leads are implanted. The first needle protects the lead from the second needle.

Performing Intraoperative Tests

⚠ Attention

False 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 Implantable Stimulator [Page 49].
- Perform the lead impedance measurement again.

Once the lead position has been verified under fluoroscopy monitoring, perform an intraoperative test to check correct placement.

Throughout the intraoperative tests, be sure to handle the leads carefully.

1. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
2. Make sure during all handling steps that the position of the leads is not changed.
3. Slightly retract the stylet, ensuring that it remains in the lead but is not in the tip of the lead.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Make sure that the lead connection of the intraoperative test cable is only used in a sterile area, and the header for the external stimulator at the intraoperative test cable only in a non-sterile area.
6. In the sterile area, open the cover of the lead connection of the intraoperative test cable.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the lead connection cover of the intraoperative test cable.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. In the non-sterile area, plug the header of the intraoperative test cable into the external stimulator. While doing so, align the guide tabs of the header with the notches of the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.
13. Turn on the external stimulator and use the clinician programmer to perform all necessary intraoperative tests to verify the lead position.
14. When you have performed all necessary intraoperative tests, turn off the external stimulator.
15. Unlock the header tab and detach it from the external stimulator.
16. Open the lead connection cover and carefully detach the leads from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

Connecting the Lead

⚠ Attention

Incorrect Measurement Results, and Insufficient Therapy May Occur due to Improper Connection of the Leads

If the leads are not properly connected at the header, the connection between the leads and the stimulator may be poor or even non-existent. This can lead to incorrect results of the impedance measurement. The stimulation therapy can then not be optimally configured and performed.
In additional, if the leads are not properly inserted at the header, the lead can damaged by the screw.

- Follow the instructions for connecting the leads to the header in this technical manual.
- Make sure that the lead connector is completely inserted into the connector port.
- Before tighten the screw of the connector port, perform an impedance test and check the measurement values for plausibility.
- If the impedances are out of range, check the connection of the leads.

Note

The external stimulator cannot be sterilized. To prevent infection, do not connect any leads to the external stimulator that will be fully implanted in the body. By connecting them to the external stimulator, the leads of the trial system become non-sterile in the connection area and must be removed before implanting the permanent system.

- Connect only trial leads that will not be fully implanted in the body to the external stimulator.

1. Hold on to the lead while removing the stylet and insertion needle carefully and with minimal force. If the stylet is stuck and cannot be pulled out, remove the lead. Insert a new lead and perform the necessary intraoperative tests as described above.
2. Apply a suitable sterile bandage at the site at which the lead exits the body.
3. Form a strain relief loop.
4. Fixate the part of the lead that exits the body with suitable adhesive tape to the patient's skin.
5. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
6. Open the cover of the header for the external stimulator.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the header cover.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. Plug the header into the external stimulator. While doing so, align the guide tabs at the header along the notches at the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.

Attaching the External Stimulator to the Patient

⚠ Caution

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached pouch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

1. Thoroughly clean the skin in the planned area of the patient affixation pouch.
2. Put the external stimulator into a patient affixation pouch.
3. Remove the adhesive film on the closure of the patient affixation pouch.
4. Close the closure of the patient affixation pouch. Align the arrow markings on the pouch then press down. Ensure all edges and corners are properly sealed and there are no visible gaps.
5. Pull off the protective film at the backside of the patient affixation pouch to expose the adhesive surface.
6. Firmly press the patient affixation pouch against the patient's skin. Take care that the leads are not under tensile stress.
7. To additionally secure the patient affixation pouch, use bandaging material or medical adhesive tape as needed.

Programming the Stimulator

Use the clinician programmer to program the stimulator.

Pairing the Patient Programmer with the External Stimulator

Pairing the patient programmer with the stimulator is done by a trained user of the clinician programmer.

7 Replacing the Batteries of the External Stimulator during the Trial Phase

If the batteries become weak or die during the trial phase, you need to replace the batteries of the external stimulator. The battery status is shown on the clinician programmer and the patient programmer.

Removing the External Stimulator from the Patient

1. If the stimulation is turned on, turn it off with the clinician programmer or the patient programmer.
2. Carefully cut open the patient affixation pouch and remove the external stimulator. Take care not to damage the connected leads in the process.
3. Open the header latch.
4. Remove the header from the external stimulator and remove the stimulator from the patient.
5. Carefully detach the patient affixation pouch from the patient's skin.
6. Thoroughly clean the skin in the planned area of the patient affixation pouch.
7. Dispose of all used components that are not intended for reuse in an environmentally sound manner and according to the applicable country-specific directives.

Replacing the Batteries of the External Stimulator

Prerequisite

- The stimulation is turned off.
- The leads are not connected to the external stimulator.
- The external stimulator is not attached to the patient.

1. Connect the external stimulator to the clinician programmer and use the clinician programmer to prepare the battery swap for the external stimulator.
2. Wait 30 s and then open the cover of the battery compartment.
3. Replace the batteries. Pay attention to the correct polarity of the batteries.
   ► If the batteries are inserted correctly, the LED lights up for 10 s and then turns off.
4. Close the cover of the battery compartment.
5. On the patient programmer select **[Connect]**. Ensure the external stimulator is still connected to the patient programmer.
   Note that it takes a while for the external stimulator to connect to the patient programmer after battery replacement.

Attaching the Header at the External Stimulator

Prerequisite

- The stimulation is turned off.

1. Plug the header into the external stimulator. While doing so, align the guide tabs at the header along the notches at the external stimulator.
2. Close the latch on the header to lock it to the external stimulator.

Testing the Stimulation

Prerequisite

- The leads are connected at the header of the external stimulator.
- The external stimulator is connected to the patient programmer or the clinician programmer.

1. Turn on the stimulation with the clinician programmer or the patient programmer.
2. Select a suitable stimulation program.
3. With the assistance of the patient, check whether the stimulation is appropriate.

Attaching the External Stimulator to the Patient

⚠ Caution

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached pouch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

1. Thoroughly clean the skin in the planned area of the patient affixation pouch.
2. Put the external stimulator into a patient affixation pouch.
3. Remove the adhesive film on the closure of the patient affixation pouch.
4. Close the closure of the patient affixation pouch. Align the arrow markings on the pouch then press down. Ensure all edges and corners are properly sealed and there are no visible gaps.
5. Pull off the protective film at the backside of the patient affixation pouch to expose the adhesive surface.
6. Firmly press the patient affixation pouch against the patient's skin. Take care that the leads are not under tensile stress.
7. To additionally secure the patient affixation pouch, use bandaging material or medical adhesive tape as needed.

8 Removing the Trial System

Removing the External Stimulator from the Patient

1. If the stimulation is turned on, turn it off with the clinician programmer or the patient programmer.
2. Carefully cut open the patient affixation pouch and remove the external stimulator. Take care not to damage the connected leads in the process.
3. Open the header latch.
4. Remove the header from the external stimulator and remove the stimulator from the patient.
5. Carefully detach the patient affixation pouch from the patient's skin.
6. Thoroughly clean the skin in the area of the patient affixation pouch.
7. Thoroughly clean and disinfect the external stimulator, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
8. Use the clinician programmer to reset the external stimulator and delete all patient data to be able to use it for the next patient.
9. Store the external stimulator for the next patient, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
10. Dispose of all used components that are not intended for reuse in an environmentally sound manner and according to the applicable country-specific directives.

Removing the Trial Leads

1. Remove the sterile bandage at the site at which the lead exits the body.
2. Carefully pull the lead out of the patient.
3. Proceed in the same manner when removing a second lead.
4. If no further implantation steps are planned, close all wounds and provide them with bandage material in the usual surgical manner.
5. Dispose of all used components in an environmentally sound manner and according to the applicable country-specific directives.

Collecting the Patient Programmer at the End of the Trial Phase

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.

Cleaning, Disinfecting, and Storing the External Stimulator

⚠ Caution

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected Correctly

The improper cleaning and disinfecting of an external stimulator may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after use by each patient.

⚠ Attention

Damage to the System due to Noncompliance with the Conditions for Transport and Storage

If the conditions for transport and storage stated in this technical manual are not met, the system may be damaged. The system function may be permanently compromised by this.

- Please follow the conditions for transport and storage listed in this technical manual.
- Do not use system components that were not transported or stored correctly.

The external stimulator is intended for reuse. After you have removed the trial system, you must thoroughly clean the external stimulator, disinfect it sufficiently, and store it for the next patient.

Note

Avoid bringing the external stimulator into direct contact with water or solvents.

Prerequisites for Cleaning, Disinfection, and Storage

- The external stimulator is not attached to the patient, is not connected to the leads, and the stimulation is turned off.

Cleaning the External Stimulator

Use the following products for cleaning the external stimulator:

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

1. Place cap over the connector pins.
2. Clean the external stimulator with a damp cloth and mild soap solution.
3. Thoroughly dry the external stimulator.
4. Check the external stimulator for dirt or visible damage after the cleaning.

Disinfecting the External Stimulator

Use the following products for disinfecting the external stimulator:

- A quaternary ammonium agent (e.g. PDI Sani-cloth)

1. Place cap over connector pins.
2. Disinfect the external stimulator per disinfecting wipe manufacturer's instructions.
3. Allow the external stimulator to dry thoroughly, until all the residues of the disinfectant have completely evaporated.
4. Check the external stimulator for visible damage after the disinfection.

Storing the External Stimulator

⚠ Caution

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected Correctly

The improper cleaning and disinfecting of an external stimulator may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after use by each patient.

When the external stimulator has been cleaned and disinfected properly and shows no damage, store the external stimulator for the next patient.

1. Carefully put the external stimulator cap on the contact surface of the external stimulator to protect it. Take care not to damage the contact surfaces in the process.
2. Use the clinician programmer to connect the external stimulator to the clinician programmer and reset the external stimulator to delete its settings.
3. Store the external stimulator at a suitable and protected location. Pay attention to the storage temperatures, see External Stimulator [Page 51].

9 Implanting the Permanent System

Preparing the Implantation

Instructions before the Implantation

1. Please follow the unpacking instructions and make sure that the sterility is ensured, see Unpacking [Page 27].
2. Check all needed components for damage and only use undamaged components.
3. Check the required components for, e.g., length and type and make sure that all required components match and are suited for the implantation and the patient.
4. Acclimate the temperature of the stimulator to room temperature in the blister or package.
   The stimulator will not charge if the temperature is lower than +64.4 °F (+18 °C). Avoid charging in cold environments such as operating rooms.
5. Check the charging status of the stimulator and make sure it is sufficient for complete planned communication and testing. If necessary, charge the stimulator. For this, proceed as described in Prospera Spinal Cord Stimulation – Patient Guide for the Implanted System.
6. Pair the clinician programmer with the stimulator.
7. Make sure that no therapy program is programmed and active on the stimulator. For this, you can use the clinician programmer or the patient programmer.

Inserting the Lead

⚠ Caution

Spinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when accessing the epidural space. Furthermore, steep insertion angles may inhibit ability to subsequently insert the lead and/or may result in undesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the insertion needle into the epidural space.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

Improper or careless handling of the system may damage the system and permanently impair the function.

- Handle the Prospera SCS System with care.
- Follow the instructions in this technical manual.
- Exchange damaged components.

Note

If the lead is handled excessively, it can be damaged.

- Handle the lead carefully.
- Avoid excessive bending, stretching, kinking etc. of the lead.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary precautionary measures.
3. If preoperative antibiotic prophylaxis had been judged to be necessary, make sure that it has been performed.
4. Inject a local anesthetic at the suitable insertion site for the insertion needle.
5. Check that the stylet is inserted in the insertion needle.
6. Carefully insert the insertion needle under fluoroscopy monitoring into the posterior ligament complex of the suited section of the spine. Make sure that the insertion angle is not too steep.
7. Remove the stylet from the insertion needle.
8. Check the position of the insertion needle by fluoroscopy monitoring.
9. Check the entry into the epidural space with a standard method, e.g., loss of resistance or using the provided clearing wire.
   If you use the clearing wire provided, handle it carefully and push it carefully through the insertion needle to prevent injury to spinal tissues.
10. Select an appropriate length lead to accommodate patient anatomy and strain relief loops.
11. Make sure the suitable stylet has been completely inserted into the lead and is extended to the tip of the lead.
12. Make sure that the insertion needle is not occluded.
13. Slowly push the lead with the stylet through the insertion needle into the epidural space.
14. Use the stylet to steer the lead under fluoroscopy monitoring to the respective section of the spine.
15. Proceed in the same manner when inserting a second lead. Make sure to insert the second insertion needle in such a way that the first lead is not damaged. Do not remove the needle of the first lead until both leads are implanted. The first needle protects the lead from the second needle.

Performing Intraoperative Tests

⚠ Attention

False 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 Implantable Stimulator [Page 49].
- Perform the lead impedance measurement again.

Once the lead position has been verified under fluoroscopy monitoring, perform an intraoperative test to check correct placement.

Throughout the intraoperative tests, be sure to handle the leads carefully.

1. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
2. Make sure during all handling steps that the position of the leads is not changed.
3. Slightly retract the stylet, ensuring that it remains in the lead but is not in the tip of the lead.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Make sure that the lead connection of the intraoperative test cable is only used in a sterile area, and the header for the external stimulator at the intraoperative test cable only in a non-sterile area.
6. In the sterile area, open the cover of the lead connection of the intraoperative test cable.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the lead connection cover of the intraoperative test cable.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. In the non-sterile area, plug the header of the intraoperative test cable into the external stimulator. While doing so, align the guide tabs of the header with the notches of the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.
13. Turn on the external stimulator and use the clinician programmer to perform all necessary intraoperative tests to verify the lead position.
14. When you have performed all necessary intraoperative tests, turn off the external stimulator.
15. Unlock the header tab and detach it from the external stimulator.
16. Open the lead connection cover and carefully detach the leads from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

Anchoring the Lead

⚠ Caution

Product Damage and Risk of Injuries due to Modification of the Medical Device

Unauthorized modification to the medical device is prohibited. System integrity could be compromised and patient harm or injury may occur if the medical devices are modified without authorization.

- Do not modify the medical device.

⚠ Attention

Insufficient or Missing Therapy due to Improper Fixation of the Implanted Leads

If the anchors supplied as part of the shipment are not used during the implantation of the leads, the fixation of the leads at the supraspinous ligament might not be stable and the leads may shift from their intended position. Furthermore lead damage can occur from needle puncture or excessively tight sutures. In addition, an inappropriate angle of the anchor can cause lead conductor breakage. All this can lead to insufficient therapy or to a complete loss of therapy.

- Use only the anchor supplied as part of the shipment to fixate the leads safely and stably at the supraspinous ligament.
- If you use the active anchor, tighten the anchor set screw with the supplied torque wrench only to ensure lead is properly anchored.
- Handle the needle to attach the anchor to the lead with care and attentiveness.
- Anchor lead in neutral angle, do not excessively twist, tug, or bend lead when anchoring to reduce risk lead conductor breakage.

1. Make an incision around the insertion needle.
2. Gain access to the supraspinous ligament by sharp and blunt dissection.
3. Hold on to the lead while removing the stylet and insertion needle carefully and with minimal force. If the stylet is stuck and cannot be pulled out, remove the lead. Insert a new lead and perform the necessary intraoperative tests as described above.
4. Check the correct position of the lead by fluoroscopy monitoring and make sure the lead has not shifted when the insertion needle and the stylet were pulled out.
5. Continue as described below, depending on the chosen anchor.

Suture Anchor

1. Slide the anchor over the lead to the supraspinous ligament.
2. Secure the anchor to the lead with at least two suture loops. To prevent slippage and lead migration, use the ligature grooves to place two suture loops and tie the thread around the anchor, securing it to the lead body.
   Use non-resorbable suture material.
3. Use the eyelets or grooves of the anchor to suture the anchor to the supraspinous ligament or deep connective tissue.
   Use non-resorbable suture material.
4. Ensure that the suture seam is sufficiently tight.

Active Anchor

1. Slide the anchor over the lead to the supraspinous ligament.
2. Attach the anchor to the supraspinous ligament or deep in the connective tissue.
   Use non-resorbable suture material.
   Use the eyelets or grooves in the anchor to tie the suture to the anchor.
3. Ensure that the suture seam is sufficiently tight.
4. Tighten the set screw with the supplied torque wrench to attach the active anchor at the lead.
   To this end, turn the supplied torque wrench clockwise until you hear a click.

Shaping the Pocket for the Stimulator and Tunnel the Lead

⚠ Caution

Skin Injury if Tunneling Is too Shallow

If the tunneling of the implanted leads is too shallow, skin erosion and exposure of the implanted leads may occur.

- Please tunnel the leads deep enough to prevent skin erosion and exposure of the implanted leads.
- If very long tunneling is required, it is recommended to lead the lead out of the skin and create a second tunnel.

⚠ Caution

Skin Erosion, Overheating, or Charging Difficulties due to an Improper Pocket Depth and Location

An improperly placed device pocket may lead to skin erosions if placed too close to the surface. It may lead to charging difficulties or to excessive heat development during the charging of the stimulator, if placed too deep.

- Please follow the instructions for the creation of a device pocket.
- If necessary, use the pocket template to shape the device pocket properly.
- Implant the stimulator no more than 2 cm (0.78 inch) below the skin surface with the labeled side facing the skin, so that the charging coil is close to the patient surface.
- Lay sutures through the eyelets at the stimulator header to prevent the stimulator from inverting or migrating.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary sterile precautionary measures.
3. Identify a suitable implantation site. Take into account infection control and patient comfort. If the placement is too close to the surface, skin erosions may result, and if the placement is deeper than 2 cm (0.78 inch), excessive heat development may occur during the charging of the stimulator.
4. Anesthetize the implantation site for the pocket of the stimulator.
5. Mark the implantation site and make a sufficiently large incision that allows the insertion of the stimulator. Use the pocket template of the stimulator to correctly choose the size and position of the incision.
6. Form a subcutaneous pocket for the stimulator by blunt dissection. Keep in mind that the pocket may not be deeper than 2 cm (0.78 inch) below the skin and not be larger than the stimulator, to allow optimal charging of the stimulator.
7. Select a suitable tunneling tool tip.
8. Remove the protective cap and screw the tip onto the shaft of the tunneling tool.
9. Mark a suitable tunneling path.
10. Inject a local anesthetic along the tunneling path.
11. By careful bending, adjust the shaft of the tunneling tool to the patient's anatomy if necessary.
12. Tunnel a suitable tunnel between the pocket for the stimulator and the site of the lead anchor with the tunneling tool. Tunnel deep enough to prevent skin erosion and exposure of the implanted leads. Make sure to insert the tunneling tool far enough that the beginning of the tunneling sheath exits.
13. Have a sufficiently strong hold on the shaft and the tunneling tool tip.
14. Unscrew the tunneling tool tip and remove it. Make sure not to drop the tip.
15. Hold on to the tunneling sheath and carefully pull out the shaft of the tunneling tool. Make sure that the tunneling sheath does not change its position in the process.
16. Hold on to the tunneling sheath and insert the proximal end of the lead through the tunneling sheath to the implantation site of the stimulator.
17. Carefully pull the desired length of lead out of the tunneling sheath for both leads. Take stress relief loop into account when determining the amount of lead to pull.
18. Hold on to the leads at the site of the anchor and carefully pull out the tunneling sheath. Make sure that the leads don't change position in the process.

Implanting the Stimulator and Connecting the Lead

⚠ WARNING

Therapy Failure and Harm to the Patient due to Electrocautery

Electrocautery may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and serious patient injuries may occur in the area of the implanted stimulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Use bipolar electrocautery.
- Do not apply unipolar electrocautery.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electrocautery.

⚠ Caution

Injury due to Heat Development during Charging when Using Metallic Clamps

When charging the implanted stimulator, surgical staples made of metal that are situated in the vicinity of the implanted stimulator may heat up and damage the patient's tissue in this area.

- Do not use surgical staples made of metal in the vicinity of the implanted stimulator.

⚠ Attention

Incorrect Measurement Results, and Insufficient Therapy May Occur due to Improper Connection of the Leads

If the leads are not properly connected at the header, the connection between the leads and the stimulator may be poor or even non-existent. This can lead to incorrect results of the impedance measurement. The stimulation therapy can then not be optimally configured and performed. In additional, if the leads are not properly inserted at the header, the lead can damaged by the screw.

- Follow the instructions for connecting the leads to the header in this technical manual.
- Make sure that the lead connector is completely inserted into the connector port.
- Before tighten the screw of the connector port, perform an impedance test and check the measurement values for plausibility.
- If the impedances are out of range, check the connection of the leads.

1. Make sure that no hemostasis is required.
2. Avoid electrocautery if possible. If electrocautery is necessary, temporarily turn off the stimulation and apply only bipolar electrocautery.
3. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Carefully connect the lead to the respective connector port of the stimulator. Make sure that the lead connector is completely inserted into the connector port.
   If the lead connector cannot be completely inserted, check whether the set screw at the stimulator is not blocking access to the port. To this end, use the supplied torque wrench to loosen the screw by turning the screw counterclockwise.
6. If applicable, connect the second lead to the respective connector port of the stimulator in the same manner.
7. Make sure that the information of which lead is connected to which connector port will be available at a later time.
8. If only one lead was placed and connected, close the unused connector port of the stimulator with a port plug. Make sure that the port plug is completely inserted into the connector port.
9. Perform all necessary intraoperative tests, see Performing Intraoperative Tests [Page 40].
10. If the intraoperative tests were successful, use the supplied torque wrench to tighten the screw for the leads or the port plug of the respective connector port to the appropriate torque by turning clockwise until it clicks.
11. Wrap excessive parts of the lead behind the implanted stimulator in loosely coiled loops.
12. Place the stimulator in the subcutaneous pocket and align the stimulator with the labeled side facing the skin during the implantation.
13. Lay sutures through the eyelets at the stimulator and use non-resorbable suture material to secure the stimulator to the pocket.
14. Check the communication between the stimulator and the patient programmer.
15. Close all wounds and provide them with bandage material in the usual surgical manner. Do not use surgical staples made of metal for this because they heat up when the implanted stimulator is charged and may damage the patient's tissue in this area.

Programming the Stimulator

Use the clinician programmer to program the stimulator.

Pairing the Patient Programmer with the Stimulator

Pairing the patient programmer with the stimulator is done by a trained user of the clinician programmer.

10 Exchanging or Explanting the Permanent System

Exchanging the Stimulator

1. Connect the stimulator to the clinician programmer and deactivate all programs. Check that the stimulator is not delivering stimulation.
2. Surgically open the pocket of the stimulator. Make sure not to damage the leads in the process.
3. Avoid electrocautery, if possible, before the stimulator has been removed from the patient, and the leads from the stimulator. If electrocautery is necessary, temporarily turn off the stimulation and apply only bipolar electrocautery.
4. Take out the stimulator. Make sure that the position of the lead does not change in the process.
5. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
6. Use the supplied torque wrench to loosen the set screws securing the leads by turning counterclockwise. Make sure that the set screw is not removed in the process.
7. Carefully remove the lead from the stimulator. Make sure that the position of the lead does not change in the process.
8. If a second lead had been implanted, proceed in the same manner and remove it from the stimulator.
9. Dispose of the explanted stimulator and all used components in an environmentally sound manner and according to the applicable country-specific directives.
10. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
11. Carefully connect the lead to the respective connector port of the stimulator. Make sure that the lead connector is completely inserted into the connector port.
    If the lead connector cannot be completely inserted, check whether the set screw at the stimulator is not blocking access to the port. To this end, use the supplied torque wrench to loosen the screw by turning the screw counterclockwise.
12. If applicable, connect the second lead to the respective connector port of the stimulator in the same manner.
13. Make sure that the information of which lead is connected to which connector port will be available at a later time.
14. If only one lead was placed and connected, close the unused connector port of the stimulator with a port plug. Make sure that the port plug is completely inserted into the connector port.
15. Perform all necessary intraoperative tests, see Performing Intraoperative Tests [Page 40].
16. If the intraoperative tests were successful, use the supplied torque wrench to tighten the screw for the leads or the port plug of the respective connector port to the appropriate torque by turning clockwise until it clicks.
17. Wrap excessive parts of the lead behind the implanted stimulator in loosely coiled loops.
18. Place the stimulator in the subcutaneous pocket and align the stimulator with the labeled side facing the skin during the implantation.
19. Lay sutures through the eyelets at the stimulator and use non-resorbable suture material to secure the stimulator to the pocket.
20. Check the communication between the stimulator and the patient programmer.
21. Close all wounds and provide them with bandage material in the usual surgical manner. Do not use surgical staples made of metal for this because they heat up when the implanted stimulator is charged and may damage the patient's tissue in this area.

Explanting the Permanent System

1. Connect the stimulator to the clinician programmer and deactivate all programs. Check that the stimulator is not delivering stimulation.
2. Surgically remove the implanted stimulator and the leads.

11 Patient Education

Patient Implant Card

The system is provided with a patient ID card.

1. Fill in the patient ID card.
2. Hand over the patient ID card to the patient after the implantation.

Risky Therapeutic and Diagnostic Procedures

The therapeutic and diagnostic procedures listed in the Safety section must not be used at all or only under the listed conditions. See Risky Therapeutic and Diagnostic Procedures [Page 9].

Make your patient aware of this.

12 Disposal

⚠ Caution

Risk of Infection if an Explanted Stimulator Is Not Properly Disposed of

An explanted stimulator must not be reused due to the risk of infection, and it must be properly disposed of.

- Dispose of the explanted stimulator as medical waste in an environmentally sound and proper manner.
- Do not cremate the stimulator. Explant the stimulator to cremation of a deceased patient.
- Return the explanted stimulator to BIOTRONIK for an environmentally sound disposal.

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

Dispose of implantation accessories and implantation tools and explanted leads as medical waste in an environmentally sound manner.

The batteries of the external stimulator must not enter the environment uncontrolled. They must be disposed of in an environmentally sound manner according to the applicable country-specific regulations; we recommend a suitable recycling method. Do not break or damage the batteries before disposal.

If the external stimulator is no longer used and can't be reused, return it to BIOTRONIK.

If the patient has returned the charger or the patient programmer or its associated wall adapter and if the item can't be reused, dispose of it as electronic waste in accordance with the applicable country-specific regulations, or else return it to BIOTRONIK. Dispose of the charger belt in the general trash.

BIOTRONIK ensures disposal in accordance with the national versions of the European guideline 2012/19/EU on waste electrical and electronic equipment (WEEE 2).

13 Appendix

Technical Data

Implantable Stimulator

General and Physical Characteristics

Category	Design
Dimensions (W x D x H)	59 mm x 11 mm x 44 mm
Radiopaque ID code	
Polarity	Multi-Cathode with Multi-Anode Return (Traditional Therapy) Interleaved Pulses
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide

Material in Contact with Human Tissue

Component	Material
Housing	Titanium
Header	Epoxy
Strain relief	Silicone
Silicone plugs	Silicone

Service Time

Category	Design
Service time	9 years

The service time has been calculated as follows:

- 3.0 mA, single electrode pair, 40 Hz, passive balance, 200 µs pulse width, 750 Ω lead impedance, on 100% of the time, 14-day charge interval, no over discharge
- 6.5 mA, single electrode pair, 70 Hz, passive balance, 230 µs pulse width, 750 Ω lead impedance, on 100% of the time, 7-day charge interval, no over discharge
- 1.7 mA, 3 electrodes delivering interleaved pulses at a frequency of 600 Hz each, active balance, 300 µs pulse width, 750 Ω lead impedance, on 100% of the time, 24 hr charge interval, no over discharge

Environmental Conditions

Category	Design
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)
Atmospheric pressure	700 hPa ... 1060 hPa
Operation at altitudes	Up to 3000 m (9843 ft)
Relative humidity	15% ... 90%, non-condensing

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
Soft Start/Stop duration	2 s ramp up, starting at 50% of final amplitude
Cycling	Continuous

RF Parameters for Communication with the Patient Programmer and the Clinician Programmer

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

RF Parameters for Communication with the BIOwand

Category	Design
Operating frequency	32 kHz ... 64 kHz
Operating distance	< 10 cm
Bandwidth	17 kHz
Modulation	OOK

External Stimulator

General Characteristics

Category	Design
Dimensions (W x D x H)	77 mm x 86 mm x 20 mm
Battery life	7 days (with 3 disposable LiFeS2 AAA batteries)
Polarity	Multi-Cathode with Multi-Anode Return (Traditional Therapy) Interleaved Pulses
Sterilization	Non-sterile

Service Life

Category	Design
Service life of the external stimulator	2 years
Service life of the affixation pouch	7 days

Material in Contact with Human Tissue

Category	Design
Housing	Polycarbonate ABS blend
Affixation pouch	Tyvek and 3M 4075 adhesive

Environmental Conditions

Category	Operation	Transport and Storage
Temperature	+59 °F ... +99 °F (+15 °C ... +37 °C)	+14 °F ... +113 °F (-10 °C ... +45 °C)
Atmospheric pressure	700 hPa ... 1060 hPa	
Relative humidity	15% ... 90%, non-condensing	
Operation at altitudes	Up to 3000 m (9843 ft)	

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
Soft Start/Stop duration	2 s ramp up, starting at 50% of final amplitude
Cycling	Continuous

RF Parameters for Communication with the Patient Programmer and the Clinician Programmer

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

RF Parameters for Communication with the BIOwand

Category	Design
Operating frequency	32 kHz ... 64 kHz
Operating distance	< 10 cm
Bandwidth	17 kHz
Modulation	OOK

Lead

General and Physical Characteristics

Category	Design
Overall diameter	1.33 mm
Polarity	8 electrodes
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Lead Length

Model	Length
Resilience 55	55 cm
Resilience 55TR	55 cm
Resilience 75	75 cm
Resilience 75TR	75 cm

Lead Connector

Component	Material
Connector ring	MP35N
Insulation	Polyurethane
Anchor ring	MP35N

Conductor

Category	Design
Construction	Multi-stranded cable with insulative coating
Conductor material	MP35N jacket with silver core
Coating material	Fluoropolymer
Resistance	Max. 20 Ω

Lead Body

Category	Design
Insulation	Polyurethane
Diameter	1.33 mm

Lead Tip

Category	Design
Material	Polyurethane
Metal stopper material	MP35N
Length beyond first electrode	2.5 mm

Electrode Ring

Category	Design
Material	Platinum/iridium alloy (90% / 10%)
Surface area	12.5 mm^2
Ring width	3 mm
Electrode spacing	4 mm
Insulation material between electrodes	Polyurethane

Service Time

Category	Design
Service time	10 years

The service time can be influenced by several factors which are not attributable to the lead design such as but not limited to:

- Abnormal or special anatomy
- Implantation approach
- Experience of the implanting physician
- Excessive degree of physical activity
- Device location
- Number of implanted leads
- Lead fixation (active, passive)
- Location of the lead fixation
- Path of leads
- Lead slack
- Number of windings in the device pocket

Active Anchor

General and Physical Characteristics

Category	Design
Overall length	37.2 mm
Overall diameter	4.4 mm
Height	5 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

Component	Material
Body	Silicone
	TiO_2
Screw block	Titanium
Screw	Titanium
Mesh	Nitinol

Suture Anchor

General and Physical Characteristics

Category	Design
Overall length	30 mm
Overall diameter	4 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material in Contact with Human Tissue

Component	Material
Body	Silicone
	TiO_2

Port Plug

General and Physical Characteristics

Category	Design
Overall length	16.6 mm
Overall diameter	5.7 mm
Pin length	12.2 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

Component	Material
Handle	Silicone
Pin	Titanium

Magnet

Dimensions

Category	Design
Dimensions (W x D x H)	61 mm x 17 mm x 28.2 mm (2.4'' x 0.67'' x 1.1'')
Weight	0.192 kg (0.42 lbs)
Magnetic flux density minimum at a distance of 20 mm longitudinal	≥ 12.5 mT
Sterilization	Non-sterile
Longevity	8 years

Ambient Conditions

Category	Operation	Storage and Shipping
Temperature	+23 °F ... +104 °F (-5 °C ... +40 °C)	-4 °F ... +140 °F (-20 °C ... +60 °C)
Relative humidity	20% ... 75%, non-condensing	
Atmospheric pressure	700 hPa ... 1060 hPa	

Data Security

Please note the following information on data security for the stimulator:

- 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.
- Only authorized BIOTRONIK devices, such as the clinician programmer and the patient programmer, are able to pair and communicate with the stimulator.
- Only attempt to pair the stimulator with authorized BIOTRONIK devices, such as the clinician programmer and the patient programmer.
- Use only wireless access points (WiFi) that are secure and require a password to join (at least WPA2 security standard).
- The stimulator is capable of inductive communication with the BIOwand which is connected to the clinician programmer.
- Patient information and stimulator data are protected by the close proximity which is required for inductive communication.
- Only allow authorized BIOTRONIK representatives to attempt to communicate with the stimulator over the inductive link.
- Keep the external stimulator safe and protect it from unauthorized access. Only allow authorized personnel to touch or manipulate the external stimulator.
- If you have any questions or concerns regarding the security of the stimulator, contact your IT security department or BIOTRONIK.

Note

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

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.

Near-field coil telemetry is used for communication between the stimulator and BIOwand as a technical support tool used only by trained personnel. The quality of service will depend on the operating environment and how close the wand is in proximity to the stimulator.

The quality of service should be 90% with regard to successful interrogation and download of software to the stimulator. In the case of interference, ensure a minimum distance of 30 cm from potential interference sources and ensure the stimulator and BIOwand are in close proximity. For information on wireless security, see above, Data Security.

Open Source and Commercial Software

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

Order Numbers

Component	Order Number
Prospera IPG	457849
Resilience 55TR	457850
Resilience 75TR	457851
Resilience 55	457852
Resilience 75	457853
SCS PP	457854
Tunneler	457855
SCS NDL L	457857
SCS Anchor	457858
SCS Resilience Acc	457860
Prospera Trial Acc	457865
HomeStreamCP	459231
MyHomeStream	459232
MyHomeStream TR	459233
Prospera EPG	457861
Prospera CHG	457862
Neuro M50	457863
Prospera IOC	457866

Disclaimer, Warranty, and Warranty Conditions

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

Electromagnetic Compatibility

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

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

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

WARNING

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

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

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

Attention

Risk of Electromagnetic Interference

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

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

⚠ Attention

Risk of Electromagnetic Interference through the Use of Unauthorized Accessories

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

- Only use accessories authorized by BIOTRONIK.

Country-Related Information

International Radio Certification

Telemetry Information for Australia

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

Telemetry Information for the USA

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

- External stimulator:

  FCC ID: QRI-SCSTS
- Implantable stimulator:

  FCC ID: QRI-SCSIPG

This device complies with part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

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

Symbols on the Implantable Stimulator

Symbol	Meaning
	Identification of port A and port B placement

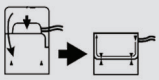
Symbols on the External Stimulator

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

Symbols on the Intraoperative Test Cable

Symbol	Meaning
	BIOTRONIK order number
	Do not reuse
	Lot number

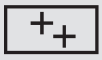
Symbols on the Patient Affixation Pouch

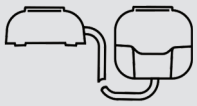
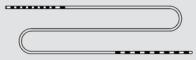
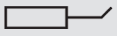
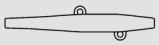
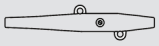
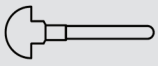
Symbol	Meaning
REF	BIOTRONIK order number
	Do not reuse
IP22	• Protection against the ingress of solid foreign bodies with a ≥ 12 mm diameter • Protection against dripping water falling at an angle up to 15°
	Storage instructions for the external stimulator

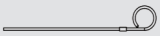
Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
MD	Medical device
	Manufacturing date
REF	BIOTRONIK order number
SN	Serial number
LOT	Lot number
	Use by
UDI	Unique device identification
PID	Product identification number
	Temperature limit
	Humidity limit
	Acceptable atmospheric pressure range for storage

Symbol	Meaning
manuals.biotronik.com 	Consult the technical manual
	Contents
	Do not use if packaging is damaged and consult the technical manual
	Manufacturer
	Distributor
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
	Quantity (in the package)
	MR Conditional
	Non-sterile
	Sterilized with ethylene oxide
	Do not resterilize
	Single use only. Do not reuse!
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
	Outer diameter

Symbol	Meaning
	Internal diameter
	Total length
	Implantable stimulator
	Pocket template of the implantable stimulator
	Identification of port A and port B placement
	External stimulator without external stimulator cap
	External stimulator cap
	Header for the external stimulator
	Intraoperative test cable
	Battery
	Affixation pouch
	Lead
	Stylet
	Straight Stylet Handle (gray)
	Curved Stylet Handle (white)
	Insertion needle
	Clearing wire
	Suture anchor
	Active anchor
	Port plug

Symbol	Meaning
	Tunneling tool
	Tunneling sheath (premounted)
	Blunt tip for tunneling tool
	Sharp tip for tunneling tool
	Torque wrench
	Magnet Neuro M50
	Magnetic field
	Patient with stimulator
	Compatible with BIOTRONIK products only.

Summary of Clinical Evaluation

The safety and effectiveness of the Prospera SCS System were based on a systematic review and meta-analysis (for safety outcomes) of published clinical studies that evaluated the safety and/or effectiveness of similar commercially available, fully implantable SCS systems in treating chronic intractable pain of the trunk and/or limbs, which may include unilateral or bilateral pain. The Prospera SCS System is similar in design, technology, performance, intended use, and patient population to the SCS systems evaluated in these studies. Therefore, the clinical data obtained from the published literature described below represents evidence supporting the safety and effectiveness of the Prospera SCS System for the treatment of chronic intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain. The literature review strategy was conducted according to the guidelines outlined in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement.[6]

A total of 19 studies (23 articles) were identified for inclusion in the systematic review (see references). A total of 13 studies (16 articles) representing a total of 626 patients were identified for inclusion in the safety analysis. A total of 18 studies (22 articles) representing a total of 864 patients were identified for inclusion in the effectiveness analysis.

The Prospera SCS System is similar to the SCS systems reported in the published literature in intended use, target patient population, device design and output characteristics. Based on these similarities the primary objective of the literature search was to provide clinical evidence of the safety and effectiveness of the Prospera device, for the relief of chronic, intractable pain in the trunk and/or limbs (unilateral or bilateral pain) resulting from any of the following:

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

[6]Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71.

Objectives of Systematic Review and Meta-Analysis

Effectiveness was demonstrated by the following:

- A reduction of pain as demonstrated by a clinically significant reduction in a validated patient-reported assessment of pain (e.g., visual analog scale [VAS], numeric rating scale [NRS], patient-reported pain relief [PRP])
- A 50% reduction in pain using a validated patient-reported assessment of pain (e.g., VAS, NRS, PRP) in at least 30% of patients included in the study
- A clinically significant difference in pain reduction as measured by a validated patient-reported assessment of pain (e.g., VAS, NRS, PRP) when compared to a control group

Safety of the Prospera SCS System was established using literature articles by examining the incidence of complications of the SCS systems used in each study. The articles report data for patient populations implanted with SCS systems to treat chronic, intractable pain in the trunk and/or limbs (unilateral or bilateral pain) resulting from any of the indications listed above.

Summary of Literature Search Strategy

The literature search was conducted on October 25, 2021 utilizing two databases:

- PubMed, which is the online version of Index Medicus produced by the US National Library of Medicine (NLM). It provides (among other resources) free access to MEDLINE, NLM's database of citations and abstracts in the fields of biomedicine and life sciences.
- To ensure the literature search was thorough and extensive, a second well-established database was searched: EMBASE, a comprehensive biomedical research database

The PubMed and EMBASE searches were designed to identify publications providing evidence of the safety and effectiveness of SCS systems that are similar to the Prospera SCS System.

Terms were searched as keywords within all fields (not only titles) and explored where possible in both PubMed and EMBASE. The PubMed database was searched first, and subsequently the EMBASE database search was carried out, including a secondary step to eliminate potential duplication of records obtained from the PubMed search.

The initial search of the two databases resulted in a total of 1713 records (Embase: 607, PubMed: 1106). After removal of duplicate records (N=23), 1690 records remained. Following the execution of the initial database searches and removal of duplicates, detailed screening of the 1690 articles against the protocol eligibility criteria was carried out in the following steps:

- Screening of the article information from the 1690 records yielded by the PubMed and EMBASE searches (e.g., information present in titles, abstracts, etc.) against the eligibility criteria was carried out independently by the two reviewing authors. Results from the independent classification were reviewed, and any differences between reviewers was resolved through discussion. Full publications were sought for all articles that appeared to meet the eligibility criteria or where there was any uncertainty, and one of these reports could not be obtained (N=207/1690 records selected).
- Clinical review for inclusion of the remaining publications was carried out independently by the two reviewing authors for the full text reports to further assess whether the article satisfied all pre-defined protocol eligibility criteria. The results of this independent classification were reviewed, and any differences were resolved through discussion.
- Final appraisal and selection of eligible articles by the two independent clinical reviewers and a statistical reviewer (N= 23/207 reports selected).
- Determination of studies meeting all protocol eligibility criteria including reporting of safety data/endpoints appropriate to evaluate the safety of the Prospera SCS System (N= 16 reports)
- Determination of studies meeting all eligibility criteria including reporting of effectiveness outcomes data/endpoints appropriate to evaluate the effectiveness of the Prospera SCS System (N= 22 reports).

Safety Results

The evaluation of safety is based on the incidence of adverse events (AE)s, device-related complications and/or surgical interventions reported from a total of 13 study populations representing a total of 626 patients implanted with SCS systems of similar design to the Prospera SCS System. The median sample size was 42 (range, 15 to 97) patients, and 386 (61.7%) of the patients were female. The median average age was 52 (range, 39.0 to 56.3) years. The median follow-up time was 12.1 (range, 3.0 to 60.0) months. The studies were published between 1999 and 2020, and 4/13 (30.8%) studies were conducted in the United States, representing 225 (35.9%) of the patients in the safety analysis. The primary treated pain diagnoses were FBSS: N=427 (68.2%), CRPS: N=153 (24.4%), radiculopathy/radicular pain syndrome: N=69 (11.0%) and DDD: N=49 (7.8%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated.

The safety profile was based on adverse events (AEs) device-related complications, and surgical interventions reported for patient populations with characteristics that are consistent with the Prospera SCS System indications, following treatment with a totally implantable SCS system of similar design to the Prospera SCS System.

Adverse Events, Device-related Complications, and Surgical Interventions

Standard summary statistics are provided for each adverse event type and surgical intervention. In cases where data for a particular event was reported in at least 4 studies, a random-effects model was used to estimate a pooled rate. Two models stratified by follow-up time post-implant (≥3 and < 12 months, ≥12 months) were conducted for adverse event and complications reported in at least 4 studies for their respective time periods. If the number of events was reported in the article rather than the number of participants experiencing an event, it was assumed that each event was experienced by a unique participant.

Ten adverse event/complication types/surgical interventions reported in at least four studies were formally meta-analyzed: pain at the implant site (e.g., stimulator, lead), infection, hematoma, cerebrospinal fluid leak, ineffective pain control (permanent implant), device malfunction (e.g., mechanical or technical failure of stimulator, lead, etc.), uncomfortable stimulation (target or non-target area), lead migration, lead fracture/failure, and surgical intervention (e.g., revision, explant, replacement).

Table 1 provides a summary of all meta-analyzed adverse events, device-related complications and surgical interventions.Table 1: Summary of Meta-analyzed Events: Adverse Events, Device-related Complications, Surgical Interventions

Event Type	N Studies (N Patients)*	Median (Range) Follow-up (months)	Pooled Rate (95% CI)	Median Rate (IQR) [Range]
Adverse Events				
Pain at the implant site (e.g. stimulator, lead)	8 (479)	11.5 (3.0 to 32.0)	3.9% (1.7-6.2)	3.7% (2.7 to 7.8) [2.2 to 16.7]
Infection	9 (469)	12.1 (3.0 to 32.0)	2.7% (0.8-4.7)	4.8% (2.2 to 6.7) [1.0 to 10.0]
Hematoma	4 (261)	9.8 (3.0 to 32.0)	2.3% (0-5.2) †	2.1% (2.1 to 5.4) [2.1 to 8.7]
Cerebrospinal Fluid (CSF) Leak	5 (345)	10.9 (3.0 to 12.1)	1.7 % (0.1-3.4) †	2.4% (2.1 to 4.2) [1.1 to 4.6]
Device-related complications				
Ineffective pain control (permanent implant)	6 (320)	13.3 (8.6 to 32.0)	12.6% (0-27.5)	7.4% (3.2 to 22.0) [0.2 to 53.3]
Device malfunction (e.g. mechanical or technical failure of stimulator, lead, etc.)	7 (322)	12.1 (3.0 to 32.0)	8.2 % (3.1-13.3)	8.7% (4.8 to 14.6) [1.1 to 16.7]
Uncomfortable stimulation, target or non-target area	5 (339)	10.9 (3.0 to 24.0)	7.9% (0.6-15.3)	9.2% (8.3 to 11.3) [1.1 to 14.6]
Lead Migration	9 (510)	12.0 (8.6 to 32.0	7.4% (4.7-10.0) †	7.1% (6.4 to 13.0) [5.2 to 16.7]
Lead Fracture/Failure	4 (130)	22.7 (12.1 to 32.0)	3.5% (0-8.6)	4.2% (3.2 to 5.5) [2.4 to 6.7]
Surgical intervention				
Surgical intervention (e.g. revision, explant, replacement)	12 (578)	12.1 (8.6 to 60.0)	31.4% (16.6-46.2)	27.1% (13.1 to 44.7) [5.3 to 75.0]

Tab. 1: Summary of Meta-analyzed Events: Adverse Events, Device-related Complications, Surgical Interventions

*Refers to the number of study populations and patients for which each outcome measure was assessed.
†To permit estimation, the variance matrix was forced to allow negative values in the restricted maximum likelihood (REML).

All other adverse event and device-related complications were reported in fewer than 4 studies and were not meta-analyzed. Table 2 provides an overall summary of non-meta-analyzed events, including summary statistics.

Event Type	N studies (N patients)	Median (Range) Follow-up (months)	Median Rate (Range)
Adverse Events			
Inflammation at implant site	2 (90)	7.6 (3.0-12.1)	11.2% (10.4 to 11.9)
Spinal tap	1 (36)	24.0	8.3%
Death (non-device related)	2 (126)	23.3 (11.0-35.6)	7.4% (1.0 to 13.8)
Recurrent rejection ascribed to SCS system	1 (24)	60.0	4.2%
Seroma	2 (107)	21.6 (12.1-31.0)	3.9% (3.1 to 4.8)
herpes zoster	1 (29)	12.0	3.5%
Ulcerative colitis	2 (60)	42 (24.0-60.0)	3.5% (2.8 to 4.2)
Implant site irritation (e.g. dermatitis, rash, pruritus)	3 (210)	7.0 (3.0-11.0)	3.1% (1.5 to 8.3)
Pain	3 (210)	10.9 (3.0-11.0)	3.1% (1.0 to 16.7)
Other postoperative pain	2 (139)	11.5 (11.0-12.1)	2.9% (1.0 to 4.8)
Cellulitis	1 (48)	3.0	2.1%
Hypoesthesia	1 (48)	3.0	2.1%
Muscle spasms	2 (97)	7.0 (3.0-11.0)	2.1% (2.1 to 2.1)
Nausea	1 (65)	11.0	1.5%
Abstinence syndrome	1 (65)	10.9	1.5%
Headache	3 (198)	11.0 (10.9-24)	1.5% (1.0 to 2.8)
Seizure	1 (65)	10.9	1.5%
Skin erosion	1 (93)	8.6	1.1%
Micturition urgency	1 (97)	11.0	1.0%
Anxiety	1 (97)	11.0	1.0%
Arrhythmia	1 (97)	11.0	1.0%
Cardiac arrest	1 (97)	11.0	1.0%

Event Type	N studies (N patients)	Median (Range) Follow-up (months)	Median Rate (Range)
Extradural abscess	1 (97)	11.0	1.0%
Implant site effusion	1 (97)	11.0	1.0%
Stitch abscess	1 (97)	11.0	1.0%
Tinnitus	1 (97)	11.0	1.0%
Urinary retention	1 (97)	11.0	1.0%
Dehiscence	1 (97)	11.0	0.0%
Impaired healing at implant site	1 (97)	11.0	0.0%
Motor dysfunction	1 (97)	11.0	0.0%
Other wound complication at implant site	1 (97)	11.0	0.0%
Paresis	1 (97)	11.0	0.0%
Suture removal	1 (97)	11.0	0.0%
Device-related complications			
SCS system explant (cessation of treatment)	1 (36)	24.0	11.1%
Over/under-stimulation	3 (107)	24.0 (12.1-35.6)	9.5% (2.8 to 20.7)
Recharging issue	2 (90)	7.6 (3-12.1)	7.6% (4.8 to 10.4)
Stimulator/lead heating	1 (15)	31.0	6.7%
Device connection issue (e.g. lead, lead connection)	2 (65)	22.1 (12.1-32.0)	5.7% (4.4 to 7.1)
Inability to place lead	1 (42)	12.1	4.8%
Damage to device	2 (135)	10.4 (8.6-12.1)	3.3% (2.4 to 13.8)
Device use error	2 (90)	7.6 (3.0-12.1)	3.3% (2.4 to 4.2)
Other stimulation issue	3 (181)	11.0 (3.0-24.0)	2.8% (1.0 to 4.2)
Technical procedure problems during the implantation	1 (36)	24.0	2.8%
Premature generator battery depletion	3 (219)	11.0 (8.6-35.6)	1.6% (1.0 to 2.2)
Stimulation-related neurologic deficit	2 (126)	11.5 (11.0-12.0)	0.0%

Tab. 2: Summary of Non-meta-analyzed Events: Adverse Events, Device-related Complications

Manufacturer and User Facility Device Experience (MAUDE) Database Search Results for SCS Systems used in Publications Selected to Evaluate the Safety and Effectiveness of the Prospera SCS System

To supplement the evaluation of safety in the systematic review, an analysis of MAUDE database event information was carried out for the similar commercial SCS systems implanted in the patient populations for all 19 selected studies. The MAUDE search included the overall time period from 1988 (date of approval of the earliest similar device PMA) through June 30, 2021. Search criteria included the product code: LGW (Stimulator, Spinal-Cord, Totally Implanted For Pain Relief), and the stimulator and lead model information obtained from the selected studies. The search identified a total of 117888 MDRs reporting a total of 128950 patient problems and 190562 device problems. Table 3 and Table 4 provide summaries of the reported patient problems and device problems.

Patient Problems	N Events (% Total Events)
Inadequate Pain Relief	21545 (16.708%)
Pain	19931 (15.456%)
Therapeutic Effects, Unexpected	18501 (14.347%)
Therapeutic Response, Decreased	7647 (5.930%)
Discomfort	7299 (5.660%)
Electric Shock	5152 (3.995%)
Complaint, Ill-Defined	5077 (3.937%)
Undesired Nerve Stimulation	4492 (3.484%)
Burning Sensation	4066 (3.153%)
Unspecified Infection	3803 (2.949%)
Device Overstimulation of Tissue	2808 (2.178%)
Ambulation Difficulties	1516 (1.176%)
Swelling	1322 (1.025%)
Fall	1256 (0.974%)
Bacterial Infection	926 (0.718%)
Post Operative Wound Infection	837 (0.649%)
Numbness	824 (0.639%)
Tingling	767 (0.595%)
Scar Tissue	661 (0.513%)
Muscle Spasm(s)	633 (0.491%)
Fluid Discharge	628 (0.487%)
Headache	626 (0.485%)

Patient Problems	N Events (% Total Events)
Erythema	597 (0.463%)
Wound Dehiscence	590 (0.458%)
Staphylococcus Aureus	572 (0.444%)
Weight Changes	521 (0.404%)
Sleep Dysfunction	518 (0.402%)
Erosion	513 (0.398%)
Fever	480 (0.372%)
Irritation	424 (0.329%)
Impaired Healing	401 (0.311%)
Cerebrospinal Fluid Leakage	388 (0.301%)
Burn(s)	328 (0.254%)
Purulent Discharge	307 (0.238%)
Nausea	306 (0.237%)
Inflammation	305 (0.237%)
Pocket Erosion	297 (0.230%)
Bruise/Contusion	287 (0.223%)
Seroma	287 (0.223%)
Muscle Weakness	285 (0.221%)
Hematoma	279 (0.216%)
Discharge	278 (0.216%)
Alteration In Body Temperature	257 (0.199%)
Hypersensitivity/Allergic reaction	252 (0.195%)
Malaise	245 (0.190%)
Weakness	245 (0.190%)
Skin Erosion	237 (0.184%)
Seizures	231 (0.179%)
Paralysis	212 (0.164%)
Cramp(s)	201 (0.156%)
Itching Sensation	199 (0.154%)
Device Embedded In Tissue or Plaque	197 (0.153%)

Patient Problems	N Events (% Total Events)
Shaking/Tremors	197 (0.153%)
Death	194 (0.150%)
Anxiety	185 (0.143%)
Muscular Rigidity	181 (0.140%)
Distress	174 (0.135%)
Neuropathy	174 (0.135%)
Shock	171 (0.133%)
Neck Pain	165 (0.128%)
Abdominal Pain	160 (0.124%)
Cognitive Changes	156 (0.121%)
Vomiting	155 (0.120%)
Neurological Deficit/Dysfunction	153 (0.119%)
Skin Irritation	149 (0.116%)
Rash	145 (0.112%)
Failure of Implant	144 (0.112%)
Incontinence	138 (0.107%)
Nerve Damage	135 (0.105%)
Foreign Body Reaction	134 (0.104%)
Other events (313 event types with individual incidence <0.1%)	5484 (4.253%)
Total	**128950 (100.0%)**

Tab. 3: MAUDE Database: Reported Patient Problems

Device Problem	N Events (% Total Events)
Device Operates Differently Than Expected	14742 (7.736%)
High impedance	11695 (6.137%)
Charging Problem	11514 (6.042%)
Failure to Deliver Energy	9417 (4.942%)
Battery Problem	8185 (4.295%)
Charging issue	6740 (3.537%)
Migration	5782 (3.034%)
Improper or Incorrect Procedure or Method	5261 (2.761%)
Unintended Collision	4893 (2.568%)
Therapeutic or Diagnostic Output Failure	4802 (2.520%)
Inappropriate Shock	4718 (2.476%)
Communication or transmission issue	4563 (2.394%)
Failure to Interrogate	4423 (2.321%)
Communication or Transmission Problem	4375 (2.296%)
Migration of device or device component	4133 (2.169%)
Migration or Expulsion of Device	3964 (2.080%)
Energy Output Problem	3714 (1.949%)
Intermittent Continuity	3513 (1.843%)
Device displays error message	3472 (1.822%)
Unexpected Therapeutic Results	3401 (1.785%)
Low Battery	3372 (1.770%)
Delayed Charge Time	3202 (1.680%)
Battery issue	3189 (1.673%)
Therapy Delivered to Incorrect Body Area	2892 (1.518%)
No Device Output	2531 (1.328%)
Use of Device Problem	2197 (1.153%)
Malposition of Device	1991 (1.045%)
Inappropriate/Inadequate Shock/Stimulation	1987 (1.043%)
Premature Discharge of Battery	1832 (0.961%)
Fracture	1829 (0.960%)

Device Problem	N Events (% Total Events)
Device Displays Incorrect Message	1824 (0.957%)
Patient Device Interaction Problem	1803 (0.946%)
Overheating of Device	1687 (0.885%)
Break	1664 (0.873%)
Impedance Problem	1640 (0.861%)
Use of Device Issue	1515 (0.795%)
Failure to Charge	1430 (0.750%)
Positioning Issue	1351 (0.709%)
Wireless Communication Problem	1329 (0.697%)
Low impedance	1254 (0.658%)
Device Inoperable	1222 (0.641%)
Unstable	1108 (0.581%)
Impedance issue	1105 (0.580%)
Electromagnetic Compatibility Problem	1066 (0.559%)
Connection Problem	975 (0.512%)
Temperature issue	931 (0.489%)
Connection issue	840 (0.441%)
Overheating of device or device component	793 (0.416%)
Electromagnetic Interference	708 (0.372%)
Electro-magnetic interference (EMI)	691 (0.363%)
Positioning Problem	681 (0.357%)
Electromagnetic compatibility issue	677 (0.355%)
Replace	661 (0.347%)
Explanted	630 (0.331%)
Material Integrity Problem	615 (0.323%)
Material integrity issue	597 (0.313%)
Display or Visual Feedback Problem	542 (0.284%)
Device remains implanted	510 (0.268%)

Device Problem	N Events (% Total Events)
Energy Output To Patient Tissue Incorrect	495 (0.260%)
Data Problem	473 (0.248%)
Implant, reprogramming of	450 (0.236%)
Disconnection	446 (0.234%)
Defective Device	398 (0.209%)
Pocket Stimulation	396 (0.208%)
Unknown (for use when the device problem is not known)	376 (0.197%)
Device Or Device Fragments Location Unknown	361 (0.189%)
Device Stops Intermittently	325 (0.171%)
Improper Device Output	303 (0.159%)
Patient-Device Incompatibility	285 (0.150%)
Electronic property issue	248 (0.130%)
Unintended Movement	248 (0.130%)
Device Remains Activated	219 (0.115%)
Material Deformation	212 (0.111%)
Loss of Data	209 (0.110%)
Incorrect display	194 (0.102%)
Other events (323 event types with individual incidence <0.1%)	6746 (3.540%)
Total	**190562 (100.0%)**

Tab. 4: MAUDE Database: Reported Device Problems

Effectiveness Results

The evaluation of effectiveness is based on data reported from a total of 18 studies (22 articles) representing a total of 864 patients implanted with SCS systems of similar design to the Prospera SCS System. The median sample size was 37 (range, 8 to 117) patients, and 600 (69.4%) of the patients were female. The median average age was 53.3 (range, 40.0 to 63.5) years. The median follow-up time was 12.0 (range, 3.0 to 60.0) months. The studies were published between 2000 and 2021, and 6/18 (33.3%) studies were conducted in the United States, representing 338 (39.1%) of the patients in the effectiveness analysis. The primary treated pain diagnoses were FBSS: N=638 (73.8%), CRPS: N=222 (25.7%), radiculopathy/radicular pain syndrome: N=137 (15.9%) and DDD: N=63 (7.3%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated.

A summary of effectiveness results in the selected studies is provided in Error! Reference source not found.. The number of patients with demographic data and pain diagnoses/etiologies reported in the publications is provided, as well as the total number of patients included in the effectiveness analysis. Reasons for differences between the total number of patients analyzed for effectiveness outcomes and the total number of patients with demographic/pain diagnoses include:

- For some articles, not all patients reported in the demographic summaries were assessed for the effectiveness outcomes at the respective time intervals (e.g., demographic data was reported for all enrolled patients, and not all enrolled patients were implanted and/or completed the respective follow-up).
- For some articles where sufficient outcomes data was reported separately for different SCS system types, treatments, pain etiologies, etc., the sub-set of patients meeting all systematic review protocol eligibility criteria were sub-selected for analysis (e.g., excluding patients not meeting all systematic review eligibility criteria)

Success percentages (e.g., responder rates) were determined by dividing the number of patients meeting one or more definitions of effectiveness listed above by the total number of patients that were evaluated for each respective time interval. The specific success criterion and time point for which the criteria was assessed are provided. If outcomes were reported for specific pain locations (e.g., overall, back, leg) and/or pain etiologies (e.g., FBSS, CRPS, etc.), outcomes results are provided for the respective pain areas and etiologies. For articles where a clinically significant change in the pain outcome measure was reported, summary statistics for the outcome measure at the assessed time points, along with the number of participants assessed and results of any statistical tests are provided.

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
Villavicencio et al. 2000	Retrospective, non-randomized, single-center study	27 (implanted): 44.4% female Cylindrical percutaneous leads (used for analysis): 15/27, mean age (range): 53 (24-74) years	FBSS: 60%, N=9 Causalgia I and II: 13%, N=2 Neuropathic pain: 7%, N=1 Other: 20%, N=3	Follow-up duration (percutaneous): mean: 10.3 months Follow-up time points: all patients followed at least 6 months	Responder rate % (Criterion: PRP ≥ 50%): Mean follow-up: 10.3 months: 80% (12/15)
Forouzanfar et al. 2004	Prospective, non-randomized, single-center study	36 (implanted): mean age (± SD): 40 (± 10.1) years, range: 26-59 years; 66.7% female	CRPS I: 100%, N=36	Follow-up duration: Median (range): 24 months (12 to 24 months) Follow-up time points (n patients completing): baseline (36/36), 6 months (36/36), 12 months (36/36), 24 months (31/36) post implantation	Responder rate % (Criterion: ≥ 50% reduction in VAS): 6 months: 63.9% (23/36) 12 months: 61.1% (22/36) 24 months: 45.2% (14/31)
Harke et al. 2005	Prospective, non-randomized, single-center study	29 (implanted): mean age (± SD): 49.8 (± 14.5) years, range: 27-86 years; 55.2% female	CRPS I: 100%, N=29	Follow-up duration: mean: 35.6 ± 21 months. Follow-up time points: all patients followed at least 12 months	Responder rate % (Criterion: ≥ 50% reduction in VAS): 12 months: Deep pain: 96.6% (28/29) Allodynia: 100.0% (22/22) Last follow-up: 35.6 ± 21 months Deep pain: 100.0% (29/29) Allodynia: 100.0% (22/22)

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
Oakley et al. 2007 Supplemental articles: Krames et al. 2008	Prospective, non-randomized, multicenter study	65 (trialed): mean age (range): 52.0 (28-84) years; 40.0% female	FBSS: 61.5%, N=40 CRPS: 13.9%, N=9 Radiculopathy/ neuropathy: 6.2%, N=4 Other: 4.6%, N=3 Unknown: 13.9%, N=9	Follow-up duration: mean: 10.9 months Follow-up time points: baseline, 2 weeks, 3 months, 6 months, and every six months thereafter until study closure	Responder rate % (Criterion: ≥ 50% VAS reduction, stim ON vs. Off): 3 months: 63% (24/38) 6 months: 55% (18/33)
Kemler et al. 2008 Supplemental articles: Kemler et al. 2000, 2004	Prospective, single-center, RCT (2:1)	36 (trialed): mean age (± SD): 40 (± 12) years; 61.1% female	CRPS I: 100%, N=24	Follow-up duration: Median: 60 months Follow-up time points (n patients completing): baseline, 3, 6, 12, 24 (24/24), 36, 48, 60 months (20/24)	Criterion: significant reduction in mean VAS 24 months: mean reduction in VAS (SCS+PT group): 3.0 cm (N=24) mean reduction in VAS (PT alone): 0.0 cm (N=16) p=0.001 60 months: mean reduction in VAS (SCS+PT group): 2.5 cm (N=20) mean reduction in VAS (PT alone): 1.0 cm (N=13) p=0.06
Van Buyten et al. 2008	Prospective, non-randomized, multicenter study	45 (trialed): mean age: 51.3 years, range: 31.1 to 69.4 years; 66.7% female	Post-operative back or leg pain: 55%, N=25 Radicular pain: 27%, N=12 CRPS I: 7%, N=3 CRPS II: 7%, N=3 Other: 4%, N=2	Follow-up duration: mean (range) 12 months (8 to 13 months) Follow-up time points: baseline, 6, 12 months post-implant	Responder rate % (Criterion: PRP ≥ 50%): 12 Months: 80.5% (33/41)

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
Moriyama et al. 2012	Prospective, non-randomized, multi-center study	34 (implanted): mean age (± SD): 53.5 (± 16.9) years; 52.9% female	FBSS: 50.0%, N=17 CRPS: 41.2%, N=14 Other: 8.8%, N=3	Follow-up duration: median: 6 months Follow-up time points (n patients completing): baseline, 1, 6 months (29/34)	Responder rate % (Criterion: ⩾ 50% reduction in VAS): 6 Months: Total Population: 65.5% (19/29), CRPS: 83.3% (10/12), FBSS: 46.7% (7/15), Other: 100% (2/2)
Kinfe et al. 2014	Prospective, non-randomized, single-center study	100 (trialed): mean age (range): 56.3 (27-89) years; 57.0% female Cylindrical percutaneous leads (used for analysis): N=50	FBSS: 100%, N=100	Follow-up duration: mean 1.2 ± 0.3 years (range: 0.4-2.0 years): Follow-up time points: all patients followed at least 4 months	Responder rate % (Criterion: ⩾ 50% reduction in VAS): 1.2 ± 0.3 years (range: 0.4-2.0 years): 70% (35/50) (cylindrical percutaneous leads) Percentage pain relief (SD): 69.6% (11.2%)(cylindrical percutaneous leads)
Kapural et al. 2016 (primary source for effectiveness analysis) Supplemental articles: Kapural et al. 2015 (primary source for safety analysis)	Prospective, multi-center RCT	87 (per protocol population): mean age (± SD): 55.2 (± 13.4) years, range: 19.2 to 82.3 years; 58.6% female	FBSS: 74.7%, N=65 Radiculopathy: 60.9%, N=53 Degenerative disc disease: 57.5%, N=49 Spondylosis: 36.8%, N=32 Mild/moderate spinal stenosis: 19.5%, N=17 Sacroiliac dysfunction: 16.1%, N=14 Lumbar facet-mediated pain: 16.1%, N=14 Spondylolisthesis: 2.3%, N=2 Other chronic pain: 20.7%,	Follow-up duration: median: 24 months Follow-up time points (n patients completing): baseline, 3, 6, 12 (80/81), 18, and 24 (71/81) months	Responder rate % (Criterion: ⩾ 50% reduction in VAS): Leg pain 12 months: 50.0% (40/80) 24 months: 49.3% (35/71) Back pain 12 months: 51.3% (41/80) 24 months: 49.3% (35/71)

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
			N=18 Other neuropathic pain: 12.6%, N=11		
Denisova et al. 2016	Prospective, non-randomized, single-center study	75 (implanted): median age (range): 51.6 (26 to 83) years; 62.7% female	FBSS: 70.7%, N=53 CRPS II: 12.0%, N=9 Other: 17.3%, N=13	Follow-up duration: Range: 6-18 months Follow-up timepoints: baseline, 3, 6, 12 months	Criterion: significant reduction in mean VAS N=75 Baseline (mean (range) VAS): 6.5 (5-10) cm 3 months (mean VAS): 3.1 cm, Difference in means: -3.4 cm 6 months (mean VAS): 3.1 cm, Difference in means: -3.4 cm 12 months (mean VAS): 3.6 cm, Difference in means: -2.9 cm
De Andres et al. 2017	Prospective, randomized, single-blinded (evaluators collecting pain ratings), single-center study	29 (implanted): mean age: 53.8 years; 62.1% female	FBSS: 100%, N=29	Follow-up duration: 12 months (all implanted participants) Follow-up time points (n patients completing): baseline (29/29), 3 (29/29), 6 (29/29), 12 months (29/29) post-implant	Criterion: significant reduction in mean NRS Conventional frequency group (excluding HF10) (N=29): 6 months: mean of the difference (SD): -1.67 (2.69), P.000 12 months: mean of the difference (SD) -1.44 (2.28), P.000
Deer et al. 2017	Prospective, multi-center, RCT	76 (trialed): mean age (± SD): 52.5 (± 11.5) years; 51.3% female	CRPS: 56.6%, N=43 Causalgia: 43.4%, N=33	Follow-up duration: median (implanted): 12 months (range: 3-12 months)	Responder rate % (Criterion: ≥ 50% reduction in VAS in the primary area of pain with no incidence of stimulation-

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
				Follow-up time points (n patients completing): baseline, 3 (54/54), 6 (52/54), 12 months (50/54)	induced neurological deficits): SCS arm: 3 months: 55.7% (39/70)* 6 months: 60.3% (41/68)* 12 months: 53.0% (35/66)* *Randomized subjects who did not proceed to permanent implant were considered treatment failures for this endpoint at each study visit.
Gatzinsky et al. 2017	Prospective, non-randomized, multi-center study	93 (trialed): mean age (± SD): 52 (± 12) years; 52.7% female	FBSS: 100.0%, N=93	Follow-up duration: median: 12 months Follow-up time points (n patients completing): baseline, 6 (68/81), 12 months (65/81) post implant	Responder rate % (Criterion: ⩾ 50% reduction in VAS): 6 months: Leg pain: 63.3% (38/60) Back pain: 34.0% (22/65) 12 months: Leg pain: 63.1% (41/65) Back pain: 40.3% (25/62)
Tanei et al. 2018	Retrospective, non-randomized, single-center study	8 (implanted): mean age (± SD): 63.5 (± 15.1) years, range: 40-78 years; 44.4% female	FBSS: 62.5%, N=5 Peripheral neuropathy: 25.0%, N=2 CRPS I: 12.5%, N=1	Follow-up duration: mean (± SD): 29.5 (± 16.8) months, range: 12-63 months Follow-up time points: baseline, 1, 6, 12 months, last follow-up	Responder rate % (Criterion: ⩾ 50% reduction in VAS): 6 Months: Total population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2) 12 Months: Total

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
					population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2) Last Follow-up (mean: 29.5 months): Total population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2)
Benyamin et al. 2020	Prospective, non-randomized, multi-center study	32 (implanted): mean age (± SD): 56.0 (± 11.9) years; 59.4% female	FBSS: 100.0%, N=32	Follow-up duration: median: 3 months Follow-up time points (n patients completing): baseline, 1, 2, and 3 months (29/32) post-implant	Responder rate % (Criterion: ≥ 3 point reduction in NRS) Overall pain 3 months: 69.0% (22/32), mean reduction of 3.7 points from baseline (P < 0.01)
Graziano et al. 2020	Prospective, non-randomized, single-center	23 (implanted): mean age (± SD): 61.6 (± 11.5) years, range: 38-79 years; 47.8% female	FBSS: 100.0%, N=23	Follow-up duration: mean (±SD): 12.9 (± 8.2) months, range: 1-25 months Follow-up time points: all patients followed at least 1 month.	Responder rate % (Criterion: VAS ≤ 3): 12.9 months (range: 1 to 25 months)*: 87.0% (20/23) *Patients meeting success criteria in the publication but with < 3 months follow-up are excluded from the analysis. Patients not meeting success criteria are included independent of follow-up time and counted as failures.
Hatheway et al. 2021	Prospective, non-randomized, single-arm, multi-center study	103 (implanted): mean age (range) 60.8 (29-93) years; 54.4% female	FBSS: 44.7%, N=46 Radicular pain syndrome: 27.2%, N=28	Follow-up duration: median: 12 months Follow-up time	Responder rate % (95% CI) (Criterion: ≥ 50% reduction in VAS): Overall pain, Low back pain, Leg

Publication	Study Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: Success % (N of Patients) or clinically significant change in primary outcome measure
			Degenerative disc disease: 13.6%, N=14 CRPS I: 1.0%, N=1 Other: 13.6%, N=14	points (n patients completing): baseline, 3 months (98/103), 6 months (96/103), 12 months (91/103) post-activation	pain 3 months (N=103): 68.3% (59.0–77.5%) 59.8% (49.9–69.7%) 77.4% (69.1–85.7%) 6 months (N=103): 66.2% (56.9–75.5%) 58.4% (48.8–68.1%) 72.2% (63.1–81.3%) 12 months (N=103): 59.1% (49.0–69.2%) 57.1% (47.1–67.1%) 67.9% (58.5–77.2%)
Kallewaard et al. 2021	Retrospective, multi-center observational cohort study	188 (implanted): mean age (± SD): 60.0 (± 12.3) years; 53.7% female	FBSS: 64%, N=120 Lumbosacral radiculopathy: 21%, N=40 Compressive myelopathy from spinal stenosis: 9%, N=17 Other: 6%, N=11	Follow-up duration: mean (± SD): 9.73 (±6.81) months Follow-up time points: baseline, 3 months, 12 months.	Responder rate % (Criterion: ⩾ 50% reduction in NRS for overall pain): 3 mo: 68.4% (80/117) 12 mo: 70.0% (63/90)

Conclusions

The clinical evidence provided to support the safety of the Prospera SCS System includes:

- A systematic literature review, safety summary results and meta-analysis of study populations implanted with SCS systems of similar design to the Prospera SCS System.
- Analysis of Manufacturer and User Facility Device Experience (MAUDE) Database search results for the SCS systems utilized in the studies selected in the systematic review.

Summary information for the adverse events, device-related complications and surgical interventions reported in the 13 study populations:

- A total of 135 AEs were reported in the safety population of 626 patients. Pain at the implant site was the most frequently occurring individual AE reported (30 events [5.9%]), followed by infection (19 events [3.2%]), pain (12 events [5.7%]) and inflammation at implant site (10 events [5.3%]).
- A total of 211 device-related complications were reported in the safety population of 626 patients. Lead migration was the most frequently occurring device-related complication (49 events [9.6%]), followed by ineffective pain control (31 events [9.7%], uncomfortable stimulation (30 events [8.8%), device malfunction (28 events [8.7%), premature generator battery depletion (19 events [8.7%] and over/under-stimulation (17 events [15.9%]).
- A total of 205 surgical interventions (e.g., stimulator/lead revision, explant, replacement) were reported in the safety population of 626 patients, resulting in an overall rate of 32.7%.

Summary information for the meta-analyzed events reported in at least 4 studies, including estimated pooled rates of occurrence:

- Four adverse event types: pain at the implant site (3.9%) infection (2.7%), hematoma (2.3%) and CSF leak (1.7%)
- Five device-related complication event types: ineffective pain control (permanent implant) (12.6%), device malfunction (8.2%), uncomfortable stimulation (7.9%), lead migration (7.4%), and lead fracture/failure (3.5%)
- Surgical intervention: any device-related intervention (e.g., stimulator/lead revision, explant, replacement) (31.4%)

The reported event rates including the estimated pooled rates of occurrence of these events that were appropriate for meta-analysis are consistent with trends reported in the literature and in other similarly designed evaluations of SCS system safety based on large-scale systematic reviews.[1,2,3,4,5] Additionally, the results reported for non-meta-analyzed event types, and the results of the MAUDE Database analysis of patient and device problems are consistent with the results above, and indicate relatively stable reporting of well-known, previously identified risks associated with SCS.

The results of the systematic literature review support the safety of SCS therapy (delivered by legally marketed, fully implantable SCS systems with similar designs to the Prospera SCS System) in treating patients who suffer from chronic, intractable pain in the trunk and/or limbs which may include unilateral or bilateral pain.

The evaluation of effectiveness is based on data reported from a total of 18 studies (22 articles) representing a total of 864 patients implanted with SCS systems of similar design to the Prospera SCS System. The median sample size was 37 (range, 8 to 117) patients, and 600 (69.4%) of the patients were female. The median average age was 53.3 (range, 40.0 to 63.5) years. The median follow-up time was 12.0 (range, 3.0 to 60.0) months. The studies were published between 2000 and 2021, and 6/18 (33.3%) studies were conducted in the United States, representing 338 (39.1%) of the patients in the effectiveness analysis. The primary treated pain diagnoses were FBSS: N=638 (73.8%), CRPS: N=222 (25.7%), radiculopathy/radicular pain syndrome: N=137 (15.9%) and DDD: N=63 (7.3%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated. SCS treatment with SCS systems of similar design to theProspera SCS System was demonstrated to be effective in all 18 patient populations described in the articles.

The improvement in pain across all conditions/etiologies/pain locations for the 15/18 studies with response rates reported ranged from:

- 34% to 100%, with 10/15 studies reporting success rates ≥ 50%, and 7/15 studies reporting success rates ≥ 68% (all follow-up durations)
- 40% to 100%, with 8/11 studies reporting success rates ≥ 50%, and 5/11 studies reporting success rates ≥ 70% (follow-up ≥ 12 months)

The results of the systematic literature review support the effectiveness of SCS therapy (delivered by legally marketed, fully implantable SCS systems of similar design to the Prospera SCS System) in treating patients who suffer from chronic, intractable pain in the trunk and/or limbs which may include unilateral or bilateral pain.

The results of the systematic review provide clinical evidence to support the safety and effectiveness of the Prospera SCS System, when used in accordance with the proposed indications for use, including support for its long-term performance. The clinical evidence supporting the safety and effectiveness of the Prospera SCS System is based on a foundation of 22 years of clinical research and experience as reported in the published studies of patient populations (with characteristics that are consistent with the Prospera SCS System indications) implanted with SCS systems of similar design to the Prospera SCS System. The presented analysis of clinical evidence also supports a favorable benefit-risk determination.

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Note on Limitations of the Data

The data used to support the effectiveness of the Prospera device was based on literature studies. Some studies were open label, in that patients knew they were receiving stimulation. Open label studies may cause an overestimation of the treatment effect in investigator and subject ratings. Also, open label studies do not assess the magnitude of the placebo response, regression to the mean, the effect of changes in medications or other treatments to alleviate pain or changes in the underlying severity of the pain disorder.

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HomeStreamCP

Clinical Programming of Prospera SCS System Stimulators

Technical Manual

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BIOTRONIK

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Table of Contents

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

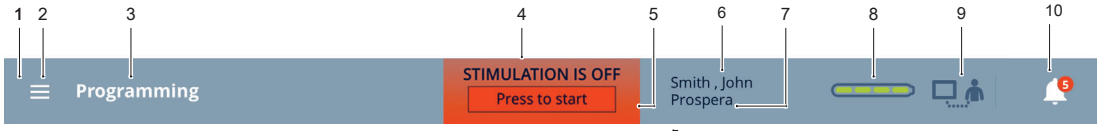
The following features make operation of the clinician programmer easier for you:

- 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.

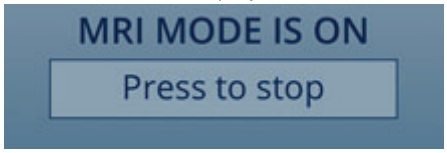
Turning the MRI Mode on Using the Clinician Programmer

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]	**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).
[Pairing failure] [Pairing incomplete] On the patient programmer: [Stimulator not found]	**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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BIOTRONIK
excellence for life

Rx only

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Table of Contents

1 About this Technical Manual

Objective

This technical manual provides information on safely conducting an MRI exam on patients with an implanted MR Conditional SCS system from BIOTRONIK.

In particular, it describes the restrictions and general conditions and safety measures to follow before, during and after an MRI exam of a patient with a Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System.

Correct and safe use of the Prospera SCS System is described in the technical manuals provided with the products and is not a subject of this technical manual.

Likewise, correct and safe use of an MRI system is not described in this technical manual.

Technical Manuals

Technical manuals are available in digital form at the following url: 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:

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

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
FBS	Full Body Scan
MRI	Magnetic Resonance Imaging
SAR	Specific Absorption Rate
SCS	Spinal Cord Stimulation

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 MR Conditional and Intended Use Information

Patients with an MR Conditional Prospera SCS System can undergo an MRI exam under certain conditions.

- The Prospera SCS System consists of an implantable stimulator with associated leads and, optionally, a port plug and/or anchors. Each device must be individually identified as MR Conditional and identified as MR Conditional system.

Fig. 1: MR Conditional

Patients with a Prospera SCS System having implanted devices labeled with this symbol on the packaging and patient ID cards can be examined using an MRI exam under precisely defined conditions. Failure to follow these conditions may result in patient injury or device damage.

General Considerations

Implantable stimulators and leads are sold independently of each other. You should consult the following tables to determine which combinations of stimulator and lead(s) are considered MR Conditional systems.

The conditions and requirements that must be observed for the respective combination are also indicated.

Lead	Implantable stimulator
	Prospera IPG (457849)
Resilience 55 (457852)	1.5 T FBS 3.0 T FBS
Resilience 75 (457853)	
SCS Anchor (457858)	
SCS PP (Port Plug) (457854)	

3 Interactions

Potential Interactions

Significant mechanisms which can lead to problematic interactions with implantable devices are described in this manual. Restrictions and special conditions for an MRI exam reduce the probability of adverse effects. The effects on the device and patient explained below are therefore minimized and limited to a tolerable level, though a residual risk cannot be excluded.

Fields in the MRI System

There are 3 types of fields generated in an MRI exam:

Static Magnetic Field

- A consistently strong, uniform magnetic field which is constantly present in the MRI system and its immediate surroundings, even if no scan is being performed.

Gradient Magnetic Fields

- A low-frequency pulsed magnetic field with a relatively low amplitude. During the MRI exam, the patient is exposed to 3 gradient magnetic fields that are perpendicular to each other.

RF Field (Radio-Frequency Field)

- This is a high-frequency electromagnetic field which excites the protons at their resonant frequency. It is switched on several times for short periods during the MRI exam. The RF field is created by so-called transmitting RF coils.

⚠ WARNING

The following affect the MRI exam and imaging:

Forces of the Static Magnetic Fields and the Gradient Magnetic Fields

- Implanted ferromagnetic materials are subject to the force of static magnetic fields and of gradient magnetic fields. Implanted devices can transmit tensile force, torque, or vibrations to the surrounding tissue. During the MRI exam, patients may feel a slight pulling sensation or vibration at the implantation site.

Interactions Resulting from Induced Voltages

- Gradient magnetic fields and radio-frequency fields can induce electrical currents in metallic devices that can negatively affect the implanted device.

Thermal Interactions

- MRI exams can cause warming of the device housing and the contact surfaces of the leads. MRI Conditionality has been evaluated with patients with a typical body temperature of 37°C. Tissue heating due to the MRI exam in conjunction with elevated body temperature may increase the risk of temporary or permanent tissue damage.

Image Interference and Artifacts

- The implantable device may have undesirable effects on MR imaging. Artifacts and distortion are possible if an implantable device is within or near the field of view of an MRI system. Image interference is less likely if an implantable device is outside the field of view.

4 MRI Conditions for Use

An MRI exam can be performed safely on patients with an MR Conditional Prospera SCS System from BIOTRONIK only if very specific requirements and basic conditions are met.

Do not perform an MRI exam for systems which have not been identified as MR Conditional by BIOTRONIK and have not been approved for MRI applications by a responsible authority.

Do not perform an MRI exam on patients with an MR Conditional system when any of the listed conditions is not adhered to.

If the patient exhibits signs of discomfort (i. e., warming is noted), discontinue the exam and remove the patient from the MRI System.

Failure to follow these conditions may result in patient injury or device damage.

Parameter	Condition
Device Configuration	• Stimulator with associated leads, and, optionally, a port plug and/or anchors • MRI Mode is ON, see Turning the MRI Mode on/off [Page 8].
Device Implantation Restrictions	• Leads between C2 and T12 • IPG implanted in upper buttock, back, or flank • Other active or passive devices are permitted if they are identified as MR conditional by the respective manufacturer and, if made of metal longer than 5 cm, not implanted within 4 cm of a BIOTRONIK lead • There are no other active or abandoned devices (e.g. lead extensions, lead adapters, or abandoned leads) in the patient's body that are not MR conditional
Device Condition	• Battery level at least 20% (1 bar as reported in programmer) • Implantable stimulator and leads intact and operating normally* *In order to ensure the implantable stimulator and leads are intact, the implantable stimulator does a self-check, which includes an impedance check, as part of enabling MRI mode. If a manual impedance check is needed, contact BIOTRONIK.

Parameter	Condition
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MRI System Type	Cylindrical, closed bore
Maximum Static Field Spatial Gradient	30 T/m (3000 gauss/cm)
Maximum Slew Rate	200 T/m/s per axis
RF Excitation	• Circularly Polarized (CP) • MC-2 (Multi-Channel TX, 2-Channel)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
RF Receive Coil Type	No Restrictions
MRI System Operating Mode	Normal Operating Mode
RF Conditions	• Whole Body Averaged SAR ⩽ 2 W/kg • Head Averaged SAR ⩽ 3.2 W/kg
Scan Duration	**1.5T Only**: Active scan time of up to 60 minutes within a 90-minute period
	3T Only: Active scan time of up to 30 minutes within a 60-minute period
Scan Regions	No Restrictions
Patient Scan Positions	

5 MRI Examination

Checking the suitability of the patient and the Prospera SCS System.

- Check and ensure that all requirements pertaining to the patient and the Prospera SCS System described are met. See General Considerations [Page 4] and MRI Conditions for Use [Page 6].
- Make sure the technical and clinical basic conditions for the MRI exam can be met and that the necessary preparations have been made. See MRI Conditions for Use [Page 6].

Turning the MRI Mode on/off

All external components, like the charger, the patient programmer, the trial stimulator, or the charger belt, are MR Unsafe and must not be taken into the MRI room.
The following instructions describe how to enable the MRI mode using the patient programmer. For additional options on enabling MRI mode, contact BIOTRONIK.

Turning MRI Mode On Using the Patient Programmer

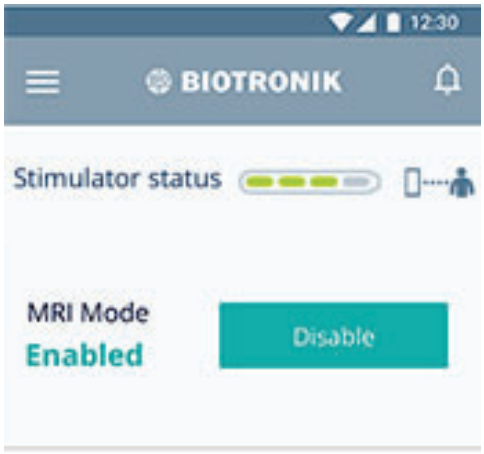
Prerequisite

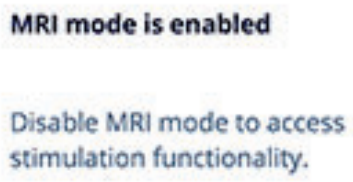
- The stimulator is adequately charged. At least one bar is displayed in the battery status of the stimulator.
- The patient programmer is adequately charged and the Bluetooth function is turned on.
- The patient programmer app is open and the main screen is displayed.

1. Select the button for the  menu.
2. Select the **[Settings]** menu item.
3. Select the **[MRI mode]** item.
4. Confirm that you want to turn on the MRI mode selecting the **[PROCEED]** button.
5. Verify on the patient programmer that the MRI mode is turned on before starting the MRI exam.

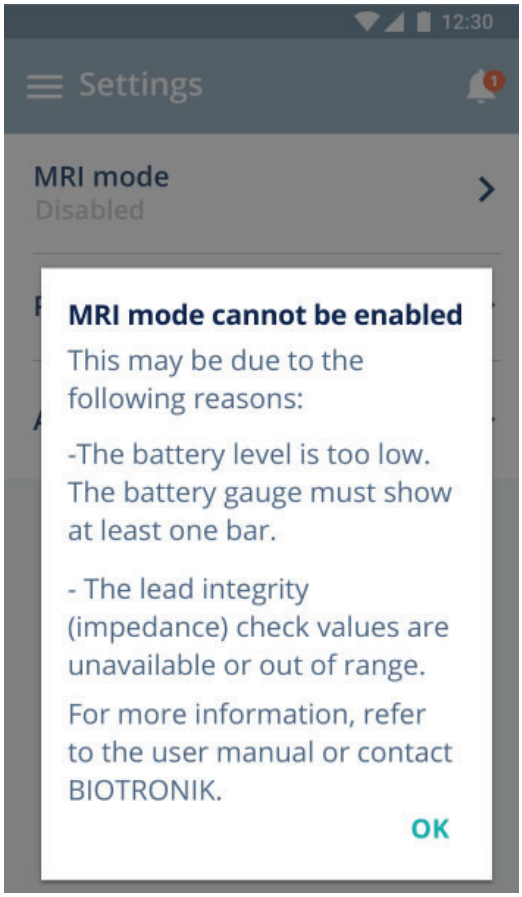
Result

The MRI mode in the stimulator is turned on and the stimulation is turned off.





If the stimulator fails the MRI self-check, the MRI mode cannot be turned on.



If the MRI mode cannot be turned on, do the following before attempting to turn on MRI mode again:

- Ensure that the stimulator is adequately charged. At least one bar is displayed in the battery status of the stimulator.
- Ensure that the stimulator and leads are intact. Contact BIOTRONIK for help with this step.

Turning the MRI Mode off

Prerequisite

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

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

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

BIOwand

Device for Wireless Communication with the Prospera Spinal Cord Stimulation System

Technical Manual

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BIOTRONIK
excellence for life

Rx only

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Table of Contents

1 Introduction

About the Device

General Description

BIOwand is used for service support of external and implantable Prospera SCS System stimulators. It enables wireless communication between the stimulator and the BIOwand app. The BIOwand app is operated on a device with a Bluetooth interface, which is used for communication with the BIOwand. The communication with the stimulator takes place via the coil telemetry of the programming head.

Intended Use and Contraindications

The BIOwand is a medical accessory to the Prospera Spinal Cord Stimulation System. It will be used in conjunction with off-the shelf hardware (commercial tablet or laptop) on which application tool for supporting stimulator software updates runs. The intended use of the BIOwand is to enable following points:

- Updating the software of the implantable or external stimulator.
- As a back-up communication means for recovering software of the implantable or external stimulator in the rare case that the stimulator state prevents Bluetooth communication.

The device is an accessory to the Prospera SCS System to enable the intended use of the Prospera SCS System. Medical indication and contraindication are identical to those of the Prospera SCS System.

Required Expertise

The use of the device and this technical manual are intended for field representatives of BIOTRONIK who are familiar with the following topics:

- The user has the necessary medical knowledge regarding the stimulation of the spinal cord.
- The user was trained in using the device, the BIOwand app, and the clinician programmer for Prospera SCS System stimulators.
- The user has access to the technical manuals of the device, the stimulators, and the clinician programmer for the Prospera SCS System stimulators.
- The user has experience in handling PCs or tablets that are controlled with a touchscreen.

Only BIOTRONIK field representatives who have the above-mentioned expertise required for the intended use of the device are permitted to use it.

Patient Group

The device is an accessory to the Prospera SCS System and enables their intended use. The patient group is therefore identical to that of the Prospera SCS System.

Residual Risk

The risk analysis carried out by the manufacturer's Risk Management Team has determined that the residual risk is as low as possible. Prerequisites for this are the intended use of a device that has been serviced and inspected according to the manufacturer's specifications by BIOTRONIK field representatives and the compliance with the safety-relevant instructions in this technical manual.

2 Safety during Use

Warnings

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

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

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

Risk of Electromagnetic Interference through the Use of Unauthorized Accessories

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

- Only use accessories authorized by BIOTRONIK.

Precautions

Risk of electromagnetic interference

The use of this device close to or in direct contact with other devices should be avoided, as this may lead to the device operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor this device and all additional devices in order to check that they are all working correctly.

General Safety Instructions

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:

- HomeStreamCP – Clinical Programming of Prospera SCS System Stimulators
- Tablet manufacturer's information on the HomeStreamCP
- Smartphone manufacturer's information on the patient programmer MyHomeStream
- Prospera Spinal Cord Stimulation System – Patient Guide for the Trial System
- Prospera Spinal Cord Stimulation System – Patient Guide for the Implanted System

Risks of Improper Handling

Disregarding the safety warnings can endanger the patient, the staff, and the equipment. Failure to observe the safety warnings voids all damage claims and manufacturer liability. The following dangers may arise in the event of improper use:

- Risk to the patient of receiving ineffective spinal cord stimulator therapy
- Personal endangerment due to electrical impact

Changes Not Permitted

Only the manufacturer BIOTRONIK or a party expressly authorized by the manufacturer may perform corrective maintenance, enhancements, or modifications to the device or its components.

Authorized Components

Only use components authorized by BIOTRONIK for your own safety. The use of any other parts voids the warranty and eliminates the manufacturer's liability for any consequences.

Use the components authorized by BIOTRONIK for the intended purpose as described in this technical manual.

Defects

Do not use defective or damaged devices and components.

Liquids

Never connect a damp or wet device to the mains supply and never use damp or wet components. Protect the device and its components from the accidental ingress of liquids and condensation.

Operating Conditions

Shipping and Storage

If the package is damaged, please contact BIOTRONIK immediately. Do not put the device into operation.

⚠ Attention

Functional Impairment due to Condensation

When the device undergoes significant changes in temperature (for example, when transporting the device or its components from a cold environment to a warm one) condensation can occur on or in the device or its components and permanently damage the electronics.

- Allow the device to acclimate to the new ambient conditions. Before powering on the device, wait at least 1 hour to allow condensation to evaporate.

Setup Location

⚠ Caution

Risk of Electromagnetic Interference

The use of this device close to or in direct contact with other devices should be avoided, as this may lead to the device operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor this device and all additional devices in order to check that they are all working correctly.

⚠ WARNING

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

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

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

Only operate the device in rooms that fulfill the following conditions:

- No danger of explosion
- Suitable for medical purposes
- Class I power outlet

Place the device and its components on a flat, dry surface. It should be placed so that it cannot slip, even while the cables are connected. Also ensure that it is protected from liquids and moisture, and that the patient only comes into contact with the programming head. In addition to this, ensure that the power plug of the power adapter is easily accessible and can be pulled out of the outlet at all times. Do not touch any plug connections such as Redel connectors and the patient at the same time.

Power Supply

The device is operated via the provided power adapter. The electrical outlet must fulfill the following conditions:

- The mains installation at least fulfills the requirements of IEC 60364-7-710:2002 group 1.
- The power plug of the power adapter goes directly into a permanently installed mains supply outlet. No portable multiple socket outlets or extension cables should be used.
- The power plug of the power adapter must be easily accessible at all times in order to be able to immediately disconnect the device from the mains supply.
- When used in combination with other devices, no portable multiple socket outlets may be used.
- Only power supply adapter authorized by BIOTRONIK may be used.

To disconnect the device from the mains supply, pull its power plug out from the outlet.

Cable and Plug Connections

- Replace the device or its components immediately if there is any visible, even minor damage to the cables.
- Lay all cables in such a way that they pose no danger of tripping over them and that any tensile forces that may occur can be safely buffered.
- Ensure that the contacts of all connections and plugs are clean. Dirty contacts can lead to signal distortions.
- Ensure that there is no condensation on the plugs or in the connector ports. If condensation is present, dry it before use.
- Do not force plugs into the connector ports and do not pull on the cable to release the lock when disconnecting the plugs.

Electromagnetic Interferences

Possible Electromagnetic Interference

This device is protected from electromagnetic interference and electrostatic discharges in a medical practice. At the same time, the emitted interference is reduced to a minimum. The device thus meets all requirements of IEC 60601-1-2.

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

Section	Test	Test Level
7.1	EN 55011 (CISPR 11) Conducted interference emissions	• Group 1 • Class B
	EN 55011 (CISPR 11) Radiated emission	
7.2.1	IEC 61000-3-2 Harmonic distortion (harmonic currents in the mains supply)	• Class A
7.2.2	IEC 61000-3-3 Voltage fluctuations and flicker in the mains supply	
8.9	IEC 61000-4-2 Electrostatic discharge (ESD)	• ± 8 kV contact discharge • ±15 kV air discharge
8.9/8.10	IEC 61000-4-3 Electromagnetic fields	• Modulation: 1 kHz • 3 V/m, 80 MHz – 2.7 GHz • Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9 – 28 V/m)

Section	Test	Test Level
8.9	IEC 61000-4-4 Transient conducted surge voltages (EFT, bursts)	• ± 2 kV mains supply • ± 1 kV signal line
	IEC 61000-4-5 Surge voltage waves on supply lines	• ± 0.5 kV, ± 1 kV line to line
	IEC 61000-4-6 Conducted radiofrequency interference	• 3 V • 6 V in ISM bands
	IEC 61000-4-8 AC frequency magnetic fields	• 30 A/m • 50 Hz
	IEC 61000-4-11 Voltage fluctuations and interruptions in supply voltage	• 0% U_T; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° • 0% U_T; 1 cycle At 0° • 70% U_T; 25 cycles, 30 cycles At 0° • 0% U_T; 250 cycles, 300 cycles

Strong electromagnetic interferences that occur in the close vicinity of electrical motors, power cables, PCs, monitors or other – possibly defective – electrical devices may compromise the function of the device in certain cases.

This kind of device malfunction should be considered as a possible cause if the following is observed:

- The device switches on by itself.
- The device displays other inexplicable behaviors.

Correct operation of the device can be restored by the following methods:

- Switch off the interfering electrical device.
- Remove the source of interference from this device.
- Switch this device off and on.

If the interference continues, contact BIOTRONIK immediately.

WARNING

Risk of Electromagnetic Interference through the Use of Unauthorized Accessories

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

- Only use accessories authorized by BIOTRONIK.

⚠ Caution

Risk of Electromagnetic Interference

The use of this device close to or in direct contact with other devices should be avoided, as this may lead to the device operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor this device and all additional devices in order to check that they are all working correctly.

⚠ WARNING

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

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

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

Care and Disposal

Cleaning and Disinfecting

The following regulations are applicable to the device and its components:

- Disconnect the power plug from the outlet before cleaning and/or disinfecting.
- Use lint-free, soft cloths.
- Clean the housing with a damp cloth and mild soap solution.
- Disinfect with agents based on alcohol (e.g., AHD 2000), on hydrogen peroxide (e.g., Diosol), or on quaternary ammonium compounds (e.g., C.F. 40).
- Visually inspect the connections: Make sure that the contacts for all connections and cables are clean and free of any type of dirt.

Sterilization

The device, the programming head, and the power adapter cannot be sterilized.

Disposal

The symbol on the type plate, a crossed out garbage can, indicates that the device must be disposed of in accordance with the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2). Disposal of this device and its components in an environmentally unfriendly manner will result in environmental pollution, as this device and its components contain materials that must be disposed of in accordance with environmental protection regulations (e.g., WEEE, RoHS, REACH). Return the following devices to BIOTRONIK:

- Defective devices
- Devices that are no longer used
- Devices whose longevity has been exceeded

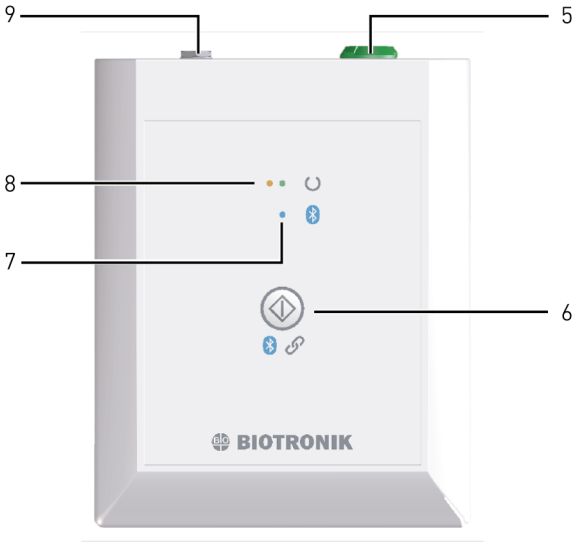
3 Getting Started

Device Overview

Power Adapter and Programming Head

1	Redel plug of the programming head
2	Programming head (BIOwand PGH)
3	Power adapter (FW8000M/12) with on/off light indicator and power plug
4	Plug for connecting the power adapter to the device

BIOwand Device



5	Programming head connection (BIOwand PGH)
6	Pair/disconnect key for establishing and disconnecting a Bluetooth connection
7	Bluetooth status indicator (LED)
8	BIOwand status indicator (LED)
9	Power supply connection

Symbols on the Device

Device Symbols

	BIOwand status indicator
	Bluetooth status indicator
	Pair/Disconnect button for establishing and disconnecting the Bluetooth connection
	Power supply connection
	Programming head connection
	Type BF applied part
	Observe the technical manual
	Position for the guide cam of the Redel plug
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
	Follow the instructions for use!
	CE mark
	Serial number
	Manufacturing date
GTIN	Global Trade Item Number
	Regulatory compliance mark (RCM)

Additional Symbols of the Power Adapter

	Approved for indoor use only
	Protection class II

BIOwand Status Indicator (LED)

The BIOwand status indicator shows the following device statuses:

LED Behavior and Color	Device Status
LED does not indicate any behavior	No power received (disabled)
LED flashes green	Device performing self-test
LED lights up green continuously	Ready for use
LED lights up orange continuously	Device is not ready for use (an error has occurred, see Error Resolution [Page 14])

Power Adapter On/Off Light Indicator (LED)

The on/off light indicator of the power adapter shows the following statuses:

LED Behavior and Color	Device Status
LED does not indicate any behavior	Disabled
LED lights up green continuously	Ready for use

Bluetooth Status Indicator (LED)

The status indicator for pairing/disconnecting the Bluetooth connection shows the following device statuses:

LED Behavior and Color	Device Status
LED does not indicate any behavior	There is no Bluetooth connection
LED flashes blue	A Bluetooth connection to the device is being established (pairing)
LED lights up blue continuously	There is a Bluetooth connection

Telemetry Status Indicator on the Programming Head

The indicator for the telemetry status is a ring LED directly on the programming head. The ring LED indicates the following status of the telemetry contact:

Ring LED behavior	Telemetry status
Ring LED does not indicate any behavior	There is no telemetry contact between the programming head and a stimulator.
Flashing green	There is telemetry contact between the programming head and a stimulator.
Flashing red	The connection to the stimulator is disturbed due to electromagnetic interferences.

Setting up the Device

To set up the BIOwand, proceed as follows:

1. Place the device and its components on a flat, dry surface.
2. Make sure that the device and its components are protected against liquids and moisture.
3. Make sure that the device cannot shift, even with the cable connected, and that the patient can only come into contact with the programming head. Do not touch any plug connections such as Redel connectors and the patient at the same time.

Connecting the Programming Head (BIOwand PGH)

The port for the programming head is located on the right rear side of the device. To connect the BIOwand PGH, proceed as follows:

1. Insert the Redel plug of the programming head cable into the programming head connector on the device. Pay attention to the correct position of the guide cam of the Redel plug. It clicks into place.

Connect the programming head so that the cable is resting with some slack in the cable and there is no danger of tripping.

Connecting the Power Adapter and Switching on the Device

The device switches on automatically as soon as the provided power adapter (FW8000M/12) is connected. The package contents include various country-specific adapters for the power plug. The port for the power adapter is located on the left rear side of the device.

To **connect the power adapter** (FW8000M/12) and to **switch on** the device, proceed as follows:

1. Select the appropriate power plug adapter for your region for the enclosed power adapter.
2. Insert the required power plug adapter into the power adapter. It clicks into place.
3. Connect the power adapter to the outlet.
4. Insert the plug of the power adapter cable into the power supply port of the device.
   - ▶ The device performs a self-test and the BIOwand status indicator (LED) flashes green. After successful self-test, the BIOwand status indicator (LED) lights up green continuously. If the self-test is not successful, the BIOwand status indicator (LED) lights up orange continuously, see Error Resolution [Page 14].

Connect the power adapter so that the cable is laid without tensile stress and there is no danger of tripping. Ensure that the power plug is freely accessible at all times.

To **switch off** the device, proceed as follows:

1. Disconnect the power plug of the power adapter from the wall outlet.
   - ▶ The BIOwand status indicator (LED) of the device turns off.

Establishing a Connection to the BIOwand App

Note

The display name of the respective BIOwand is printed on its type plate on the underside of the device. It consists of the product name "BIOwand" and the last three digits of the serial number (e.g., BIOwand678).

The Bluetooth connection must be established manually the first time the BIOwand is used. After the Bluetooth connection has been established, BIOwand automatically connects to the device on which the BIOwand app is installed as soon as BIOwand is ready for use.

To establish a Bluetooth connection to the BIOwand app for the first time, proceed as follows:

1. Switch on the device with the Bluetooth interface on which the BIOwand app is installed.
2. Ensure that BIOwand is ready for use.
3. On the device on which the BIOwand app is installed, open the menu to establish a Bluetooth connection.
4. View all available Bluetooth devices.
5. Select the desired BIOwand.
   The display name of the respective BIOwand is printed on its type plate.
6. In the menu, select the Connect menu item.
   ▶ The Bluetooth status indicator (LED) on the BIOwand starts flashing blue.
7. Within a max. 30 s, press the Pair/Disconnect key of the BIOwand to establish the Bluetooth connection.
   ▶ The Bluetooth status indicator (LED) lights up blue continuously.

Disconnecting the BIOwand Bluetooth Connection

To disconnect the Bluetooth connection, proceed as follows:

1. Press the Pair/Disconnect key of the BIOwand to disconnect the Bluetooth connection.
   ▶ The Bluetooth status indicator (LED), which lights up blue continuously, turns off.

Establishing a Connection to a Stimulator

To ensure that the connection between BIOwand and the stimulator is not interrupted, the stimulation must be turned off. To turn the stimulation off, use the clinician programmer, the patient programmer or the magnet.

To establish a connection to a stimulator, proceed as follows:

Prerequisite

- The stimulation is turned off.

1. Ensure that there is a Bluetooth connection to the device on which the BIOwand app is installed.
2. Ensure that the BIOwand app is installed and running.
3. Place the programming head on the patient, at the point where the stimulator is implanted or the external stimulator is attached.
4. Ensure the connection quality between the programming head and the stimulator using the telemetry status indicator (ring LED) on the PGH, see Telemetry Status Indicator on the Programming Head [Page 11].
5. Follow all further instructions and proceed as described in the documentation for the BIOwand app.
6. If the BIOwand session is finished, disconnect BIOwand and the stimulator and then turn the stimulation back on.

Error Resolution

When the provided power adapter is connected, the device performs a self-test. If the self-test is not successful, the BIOwand status indicator (LED) lights up orange continuously. The following errors can lead to an unsuccessful self-test:

Error	Error Resolution
No programming head (BIOwand PGH) is connected.	1. Check whether the programming head (BIOwand PGH) has been correctly connected. 2. Connect a programming head (BIOwand PGH).
An internal error has occurred.	1. To switch off the device, pull the plug of the power adapter out of the device. 2. To switch on the device, reinsert the plug of the power adapter into the device. The device performs a self-test again. If this self-test is once more unsuccessful and the BIOwand status indicator (LED) lights up orange continuously, return the device to BIOTRONIK.

4 Appendix

Technical Data

General Characteristics for the Device and the Power Adapter (Configured as an Medical Electrical System)

Category	Design
Operating mode	Continuous operation
Temperature range for operation	+10°C ... +33°C / 50°F ... 91°F
Temperature range for storage	0°C ... +50°C / 32°F ... 122°F
Relative humidity	20% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa
Operation at altitudes	Up to 3,000 m
Power supply to the device	Operation with power adapter (FW8000M/12)

Physical Properties

Category	Design
Dimensions (W x D x H)	120 x 150 x 42.8 mm
Weight with programming head	230 g
Disclosure pursuant to Section 33 REACH, Regulation (EC) No. 1907/2006	See: https://www.biotronik.com/material-compliance

Longevity

Category	Design
Longevity	2 years

Programming Head (BIOwand PGH)

Category	Design
Applied part classification	BF
Dimensions (W x D x H)	102 x 132 x 37 mm
PGH cable	2.8 m
Frequency band	9–315 kHz
Operating frequency	32–64 kHz

Category	Design
Maximum transmitter field strength	< -36 dBµA/m Max. peak @ 10 m
Modulation	OOK
Data rate	Up to 64 kbit/s

Power Adapter (FW8000M/12)

Category	Design
Supply voltage	100–240 V, ± 10% / 50–60 Hz, 0.3–0.15 A / AC
Protection class	II
Maximum power input	12 W
Level of efficiency	≥ 82.95% (at 115 V/60 Hz and 230 V/50 Hz)
On/off light indicator	Green LED, lighted continuously

Bluetooth

Category	Design
Frequency band	2.4 GHz ISM Band
Operating frequency	2400–2483.5 MHz
Number of channels	40
Frequency range	2 MHz per channel
Maximum power of transmission (EIRP)	Class 2: 4 dBm (2.5 mW)
Modulation	GFSK, DQPSK, 8DPSK
Standard	BLE 5.0

Accessories

BIOwand is only available as a complete system (device, power adapter, and programming head).

Country-related Information

International Radio Certification

Telemetry Information for Australia

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

Telemetry Information for the USA

This device complies with part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

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

Note

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 95 of the FCC Rules.
This device may not interfere with stations operating in the 400.150 – 406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.

This device will be registered with the Federal Communications Commission under the following number:

- FCC ID: QRI-BIOWAND

Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
BW	BIOwand
	Programming head (BIOwand PGH)
	Signal transmission
SCS	Prospera Spinal Cord Stimulation System
MD	Medical device
	Manufacturing date

Symbol	Meaning
REF	BIOTRONIK order number
SN	Serial number
	Temperature limit
	Humidity limit
	Acceptable atmospheric pressure range for storage
manuals.biotronik.com	Follow the electronically available instructions for use!
	Contents
	Do not use if packaging is damaged and consult the technical manual
	Manufacturer
	Distributor
Rx only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.