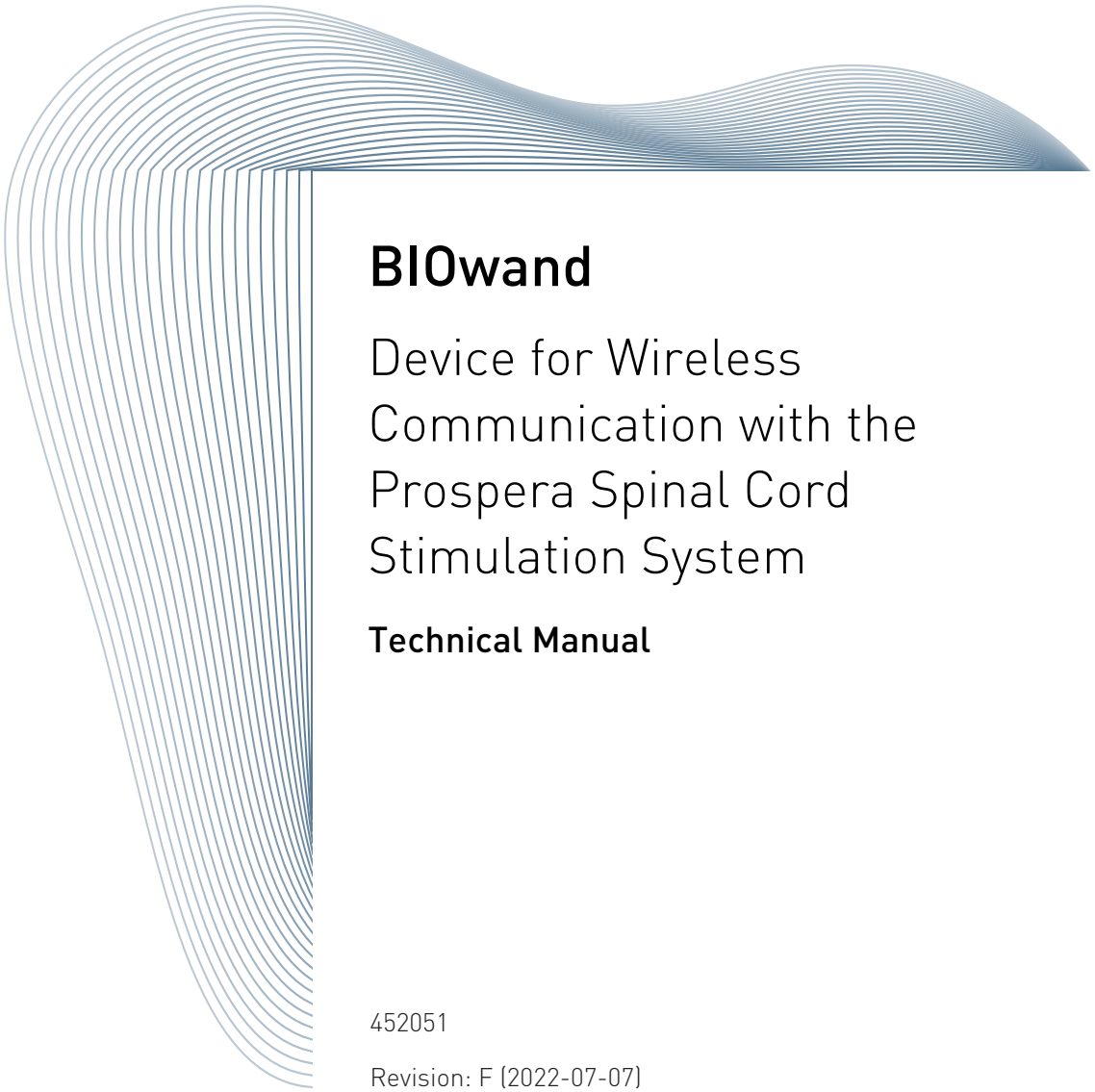

BIOwand

Device for Wireless Communication with the Prospera Spinal Cord Stimulation System

Technical Manual

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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

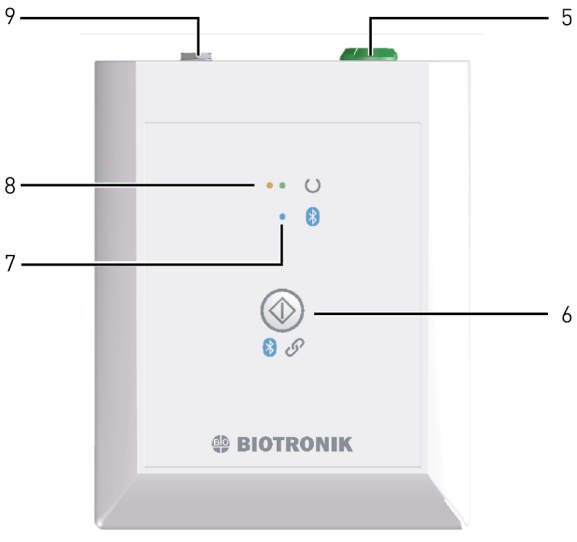
3 Getting Started

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
	BIOTRONIK order number
	Serial number
	Temperature limit
	Humidity limit
	Acceptable atmospheric pressure range for storage
	Follow the electronically available instructions for use!
	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.