Renamic Neo

Medical Programmer and Monitoring Device

Technical Manual

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BIOTRONIK

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BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin / Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

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Table of Contents

1 Introduction

About the Device

General description

Renamic Neo is a portable programmer and monitoring device with an integrated pacing system analyzer (PSA), which is used in the implantation and follow-up of BIOTRONIK implantable pacemakers, ICDs (implantable cardioverter-defibrillator), or implantable cardiac monitors. In daily operation, it can be operated with a power supply brick or, alternatively, with a battery. It can be custom-equipped with a mobile internet stick authorized by BIOTRONIK.

Intended Medical Use

The device provides communication with implantable pacemakers, ICDs, or implantable BIOTRONIK cardiac monitors (ICMs) during the implantation or a follow-up. It is intended to enable normal use of the implantable products by providing a user interface for the functions of the device.

The device is used for the following applications:

- For verification and optimization of the therapy which is delivered by the device
- For support of the diagnosis of the patient status through data that is sent by the device

This is achieved by providing product properties that enable the execution of the following tasks:

- Identify supported implantable devices and retrieve, display, and print current parameter settings
- Retrieve, display, and print the recorded statistical data and episodes from the memory of the device
- Retrieve real-time IEGM data from the device
- Retrieve real-time ECG data from the ECG leads affixed to the patient
- Select the appropriate settings for the supported implantable devices by the user
- Program the supported devices with the selected parameter values
- Execute test functions (e.g., sensing, pacing threshold, and impedance test) in order to determine the internal status of the device, the connected leads, and the patient
- Initiate special programs and shocks for therapeutic purposes
- Support the implantation of leads through intraoperative measurements of the electrophysiological parameters, such as the detection of intrinsic cardiac signals, pacing threshold, lead impedance, and timing features (timing cycles) as well as to provide temporary functions of an external pacemaker
- Export data (including recordings of real-time data) of the implanted device for analysis and reporting purposes, as an automatic and user-initiated function, to a data storage unit or to a data processing system

Contraindications

The device is intended for use with all supported BIOTRONIK pacemakers, ICDs, and implantable cardiac monitors (ICMs) during an implantation or follow-up of an implanted device. There are no contraindications for the device itself. The following applications are contraindicated for use of the integrated pacing system analyzer (PSA):

- With AV conduction disorders:
  - Atrial single-chamber pacing
- With competing intrinsic rhythms:
  - Modes that have no sensing and inhibition function in the corresponding chamber

- With chronic atrial tachycardia as well as chronic atrial fibrillation or flutter:
  - Atrial-controlled modes (DDD, VDD)
- With poor tolerance of high ventricular rates (e.g., angina pectoris):
  - High upper rate
  - Under certain conditions: atrial-controlled modes
- With retrograde conduction after ventricular pacing:
  - Programming a short AV delay
  - Under certain conditions: DDI, DVI, or VVI mode
- Use as an external pacemaker outside of the implantation procedure

Possible complications

Depending on the patient's condition and depending on the scope and type of pacing program, the following possible complications associated with the use of pacing system analyzers are reported in medical references: life-threatening atrial and ventricular arrhythmia, bradycardia, tachycardia, and asystole.

Required expertise

The use of the device and this technical manual are intended for trained and experienced physicians, hospital technicians and nursing staff, general practitioners, as well as sales representatives of BIOTRONIK, who are familiar with the following topics:

- The use of implantable pacemakers, ICDs, and implantable cardiac monitors (ICMs)
- Risks and possible contraindications accompanying the use of these systems

Additional requirements include:

- Medical knowledge:
  - Basic medical knowledge of the therapy applied
  - Training in the handling and programming of implantable pacemakers, ICDs, and implantable cardiac monitors (ICMs)
- Technical knowledge:
  - Ability to work with a PC
  - Ability to use software-controlled medical devices

Only trained personnel having the above-mentioned expertise required for the proper use of the device are permitted to use it.

Patient group

The device is intended for use with patients who have a BIOTRONIK implanted device, regardless of their age or state of health. Patients may be anesthetized, partially sedated, or conscious.

Residual risk

The risk analysis carried out by the manufacturer's Risk Management Team has determined that the residual risk is at the lowest possible level. It is a requirement that the device has been serviced and inspected according to the manufacturer's specifications by qualified medical staff and in compliance with the safety-relevant instructions in this technical manual.

About this Technical Manual

Objective

This technical manual provides the user with the safety information required to use the programmer.

The following topics are covered in this manual:

- Device startup
- Interrogation, testing and programming of BIOTRONIK implantable pacemakers, implantable cardioverter-defibrillators (ICDs) or implantable cardiac monitors (ICMs)

Explanation of the essential features and basic functions of the programmer's software is provided in a separate technical manual on the internet at the following address: manuals.biotronik.com.

Keep this technical manual for later use.

Other technical manuals

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

- Technical manual for the basic functions of the programmer's software
- Technical manual for programming the intended implantable pacemaker, ICD, or implantable cardiac monitor
- Technical manual for the leads and the intended implantable pacemaker, ICD, or cardiac monitor
- Technical manual for the accessories required for implantation
- Technical manuals for the cable and the electrodes for the surface ECG
- Technical manuals for other devices, such as adapters, external monitors, USB or Bluetooth devices

2 Safety during Use

General Safety Warnings

Technical manual

Only use the programmer in accordance with this technical manual. Also observe the technical manuals for devices that are connected to the programmer (see Other technical manuals [Page 4]).

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:

- Failure of important device functions
- 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, the battery and other accessories and spare parts.

Replacement parts and accessories

For your own safety, only use accessories and replacement parts authorized by BIOTRONIK. The use of any other parts voids the warranty and eliminates the manufacturer's liability for any consequences.

In addition, the accessories and spare parts authorized by BIOTRONIK must only be used for the purpose they are intended and as described in this technical manual.

Defects

Do not use defective or damaged devices.

Physician supervision

The device should only be used under the supervision of a physician. During operation of the device, monitor the patient's heart rate using an external surface ECG with rate control and ensure that for each pacing, the display of events and their results is plausible (using an external ECG monitor).

Patient observation

Ensure that patients are individually observed over a suitable period of time in order to monitor the compatibility and effectiveness of parameter combinations.

Emergency equipment

Always keep basic equipment ready for emergencies in order to be able to take immediate life support action. This includes, for example:

- External defibrillator
- Intubation set
- Oxygen
- Emergency drugs

For pacemaker-dependent patients, an additional external pacemaker must also be available.

Life support system

The device may not be used as a life support system. During implantation, the device is suitable for temporary external pacing, but the patient must be monitored constantly by medical personnel.

Liquids

Never use a damp or wet device. Protect the device from accidental ingress of fluids (e.g., infusion fluids). Protect the device from condensation.

Electrostatic potentials

Ensure that electrostatic potentials between medical staff and patients are balanced. Before handling the device, the electrostatic potential between the physician or medical staff and the patient must be balanced by touching the patient at a point as far away from the electrodes as possible.

Defibrillation

The device is only defibrillation protected if connected with the authorized ECG cable. During defibrillation, do not touch the patient, the programmer that the patient is connected to, or the attached accessories. Otherwise, there is a danger that you may suffer an electrical shock. The device's recovery time after defibrillation is 5 seconds. Following a defibrillation, check all functions of the device.

Using in combination with radio frequency devices

The device is protected against damage when using it in conjunction with high-frequency surgical instruments. Even though this protection was tested, its effectiveness depends on the strength, wave shape, and transmission path of the induced current. When used in conjunction with high-frequency surgical instruments, this device does not provide protection against burns for the patient. Dangerous currents can be induced in the patient which can enter the patient's heart.

- Disconnect the patient cables from the device when using with high-frequency surgical instruments.
- Perform an inspection after use with high-frequency surgical instruments.

Battery charging status

A battery may be included in the package contents of the device upon customer request. Due to aviation regulations, the charging status at the time of delivery is a max. 30%. Only ship devices with a battery, or the battery itself, with a max. charging status of 30%.

Before using the device on the patient for the first time, the battery should be fully charged; this is reached after approximately 3 hours. The battery is charged by inserting it into the device and connecting the device to the mains supply using the power supply brick. Only use the device to charge the battery, as this is the only way to ensure its proper functionality. Charge the battery for a few hours before using it on the patient in order to ensure an adequate charging status.

Ensure that the storage conditions are met and pay attention to their effect on the charging status of the battery (see Shipping and storage [Page 9]).

IT network

When the device is integrated into an IT network, the following hazardous situations may occur:

- The follow-up may be disturbed by an active data connection.
- The device may go to an undefined state due to an impaired connection.

In addition to this, integrating the device into an IT network that includes other devices may present previously unknown risks to patients, users, or third parties. You, as the organization responsible for integrating the device into an IT network, must identify, analyze, assess, and control the risks.

The following changes to the IT network can lead to new risks and therefore require additional analyses and actions, where required:

- Changes to the configuration of the IT network
- Connecting additional elements to the IT network
- Removing elements from the IT network
- Update to devices that are connected to the IT network
- Upgrade of devices that are connected to the IT network

Storage of follow-up data

The device is not designed for long-term archiving of follow-up data. Ensure archiving of the follow-up data in an external management system by, for example, printing or exporting the data.

Data protection

As a user of the device and the ReportShare® service, you are solely responsible for complying with the applicable confidentiality and data protection laws of the country in which you use the programmer and the ReportShare® service.

BIOTRONIK is an external service provider that does not evaluate or interpret medical data. BIOTRONIK also does not make any recommendations on treatment of patients nor does it intervene in them. BIOTRONIK is only liable to pay damages, regardless of their legal basis, in cases of intent or gross negligence. In cases of simple negligence, BIOTRONIK is only liable for damage resulting from injury to life, limb, or health. In the case of damage arising from a failure to fulfill a material contractual obligation (breach of contract), liability is limited to foreseeable, typically occurring damage.

Obtain the prior, written consent from the patient for the collection, processing, and recording of patient data as part of using the device and ReportShare®. The sole responsibility for the diagnosis and treatment of the patient rests with the user of the device and ReportShare®.

Handling patient data in the event of a change of ownership

For reasons of confidentiality and data protection, you must delete patient data stored on the device before the ownership of the programmer changes.

Handling patient data for BIOTRONIK servicing of device

Back up and delete the patient data stored on the device before sending it to BIOTRONIK for service. BIOTRONIK does not guarantee that data and passwords will still be available after the service.

General Safety Warning on Pacing System Analyzer (PSA)

Patient cable

If the patient cable is connected to the leads and the device connector of the patient cable is not yet connected to the device, this can result in undesired electrical current induction. First connect the patient cable to the device and then connect the patient cable to the leads.

Threshold test

Examine the patient's health before performing a threshold test. A loss of capture, asystole and pacing during the vulnerable periods can occur.

Stopping the pacing

Do not stop the pacing abruptly as this can result in sustained asystoles in some patients. Gradually decrease the pacing rate until the patient's intrinsic rhythm is detected.

Mode selection

While selecting the mode, make sure that the leads required for it are used with the appropriate patient cables. Loss of pacing could pose a risk to the patient.

Wenckebach test

Since atrial single-chamber pacing is contraindicated for use in patients with no AV conduction, the Wenckebach test must not be performed on these patients.

Burst pacing

Burst pacing can induce or accelerate dangerous arrhythmias. Always have emergency resuscitation equipment immediately available when using this feature.

Sensitivity

Selecting a lower sensitivity value could lead to greater interference from electromagnetic fields due to increased sensitivity of the device. Low sensitivity values should only be set if absolutely necessary for medical reasons.

Operating Conditions

Shipping and storage

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

⚠ Caution

Functional impairment due to external damage

Mechanical impact, for example dropping the unit – even from a height of over 5 cm if unpackaged – can permanently impair the function of the system.

- Do not use the device if it shows visible damage.
- Carry out an inspection or contact BIOTRONIK for the testing and, if necessary, for repair of the device

⚠ Attention

Functional impairment due to condensation

Due to significant changes in temperature, for example when transporting the device from a cold environment to a warm environment, condensation can occur on or in the device and permanently damage the electronics.

- Allow the device to acclimate to the new ambient conditions. Before powering on the device, wait at least 2 hours to allow condensation to evaporate.

Store and transport the battery in a way that protects it from damage and dirt at all times. Pay attention to the following while storing the battery:

- Minimize the risk of short-circuit by using the original packaging, a plastic bag or covering the contacts with masking tape.
- Store the battery in a way that protects it from exposure to heat. Do not leave the battery in the car at high temperatures. Do not put it in the microwave.
- Store the battery in a way that protects it from water, chemicals, and foodstuffs.
- Do not store the battery in pressurized containers.
- Store the battery out of the reach of children, and never leave children unsupervised with the device if the battery is inserted.

Only use undamaged batteries. If you notice any change (color, smell, etc.) in the battery while storing, inserting, handling, charging, or during normal use of the battery, remove it immediately or do not use it.

Comply with the following ambient conditions for storing the battery:

Temperature range for storage	0 °C ... +50 °C
Recommended storage temperature	23 °C

If the battery has been damaged due to high temperatures, rinse the leaking fluid with sufficiently clean water. If the leaking fluid comes into contact with the eyes, rinse them with sufficiently clean water and consult an appropriate physician.

Depending on the storage temperature, the charging status and the actual battery capacity may be reduced to the extent that the battery becomes completely discharged and can no longer be used. Therefore, depending on the storage temperature, the battery must be charged at regular intervals.

Storage temperature of the battery	Time to charge the battery
⩽ 35 °C	After 6 months
⩽ 45 °C	After 3 months
⩽ 50 °C	After 1 month

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 the other device(s) being used with it in order to ensure that they are all working correctly.

⚠ WARNING

Risk of electromagnetic interference through the use of portable RF communication equipment

Use of portable RF communication devices (including peripheral devices such as antenna cables and external antennas) within 30 cm (12 inches) from this device can result in a reduction of its performance. This applies even when using the associated cables.

- When operating portable RF communication devices (including peripheral devices such as antenna cables and external antennas), keep these 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 with protective conductor connection

Place the device on a flat, dry surface. It should be placed in a manner that does not allow it to slip, even while the cable is connected, and so that it is protected from fluids and moisture. Also, ensure that the patient only comes into contact with the applied parts, namely the programming head, ECG cable and patient cable for the PSA. In addition to this, ensure that the power plug of the power supply brick is easily accessible and can be pulled out of the outlet at all times. The physician must not touch any touchable plug connections such as USB ports, nor any device contacts for the battery in the battery compartment, simultaneously with the patient.

To prevent overheating of the device and the programming head, take the following measures:

- Place the programming head outside the PGH and ECG power cord compartment.
- Ensure that the ventilation slots are free so that the exhaust air can freely circulate.
- Do not place the device on hot surfaces.
- Open the screen into working position.
- Comply with the operating temperatures and regulate the ambient temperature appropriately.

If these measures do not suffice and the device exceeds a certain temperature limit, the device will automatically switch off in order to prevent overheating.

Power supply

The device can be operated in mains power supply mode and in battery power mode. In the mains power supply mode, the device is operated through the power supply brick and power cable provided with the device. The electrical port must fulfill the following conditions:

- The electrical installation at least fulfills the requirements of IEC 60364-7-710:2002 Group 1.
- The power plug of the power supply brick goes directly into a permanently installed electrical outlet of a mains supply with PE conductor. No portable multiple socket outlets or extension cables should be used.
- The power plug of the power supply brick must be easily accessible at all times in order to be able to disconnect the device at any time from the mains supply.
- When used in combination with other devices, no portable multiple socket outlets may be used.
- Only power connection cables (power cords) and power supply bricks authorized by BIOTRONIK may be used (see Accessories and Spare Parts [Page 57]).

To disconnect the device from the mains supply, pull its power plug out of the outlet. Ensure that the device does not switch off when the battery is inserted, but instead switches over to battery power mode.

If the device has been disconnected from the mains supply, and no battery is inserted, the device switches off completely. In the process, the follow-up data generated may be lost and the pacing of the PSA will be terminated. Use the device with the battery inserted when you use the PSA.

Cable and plug connections

- Replace cables of any type immediately whenever damage is detected, even if it is only minor.
- Lay all cables between the patient and the device, as well as within the measuring apparatus, in a way that poses no danger of tripping over them and that any tensile forces that may occur can be safely buffered.
- Do not establish any connection with an external device or a network during implantation or follow-up to avoid disruptions in the communication between the device and the implanted device.
- Ensure that the contacts of all connections and plugs are clean. Soiled contacts can lead to signal distortions, and thus to false diagnoses.
- 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. When disconnecting the plugs, do not pull on the cable to release the lock.
- All plug connections are non-interchangeable and encoded at the connecting points.

Patient environment

The device can be operated in the patient environment. Place the device on a flat, dry surface and orient the device so that the patient only comes into contact with the applied parts, namely the programming head, ECG cable and patient cable for the PSA. The physician must not touch any touchable plug connections such as USB ports, nor any device contacts for the battery in the battery compartment, simultaneously with the patient.

Use with other devices

The device may be used in the vicinity of high-frequency surgical instruments. Remove all patient cables if used in conjunction with high-frequency surgical instruments. If this is not possible, perform an inspection (see Inspection [Page 16]) following use in conjunction with high-frequency surgical instruments.

Current software version

The range of functions of the device depends on the correct software version.

- Make sure that the current software version is installed.

Software is available for download at: www.biotronik.com or by contacting BIOTRONIK.

Electromagnetic Interferences

Possible electromagnetic interference

This device is protected against electromagnetic interference and electrostatic discharges in the specialized environment in the vicinity of high-frequency surgical instruments. When used in a residential area, this device does not provide adequate protection for radio services. 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 conducted according to IEC 60601-1-2: 2014:

Section of IEC 60601-1-2: 2014	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	• Class A
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: 2 Hz • Modulation: 10 Hz • 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 of IEC 60601-1-2: 2014	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, ±2 kV common mode • ±0.5 kV, ±1 kV push-pull mode
	IEC 61000-4-6 Conducted radio frequency interference	• Modulation: 2 Hz • Modulation: 10 Hz • 3 V • 6 V in ISM bands
	IEC 61000-4-8 AC frequency magnetic fields	• 30 A/m • 50/60 Hz
	IEC 61000-4-11 Voltage fluctuations and interruptions in supply voltage	

However, strong electromagnetic interference (EMI) that occurs in the close vicinity of electrical motors, high-voltage power lines, PCs, monitors, or other, possibly defective, electrical devices may in certain cases interfere with the ECG/IEGM, interfere with transmission via wireless RF telemetry, and compromise the function of the device when using the PSA.

EMI should be considered as a possible cause if the following is observed:

- The device switches on by itself.
- The device senses false intrinsic events (artifacts) in the ECG, IEGM, or marker channel.
- The device displays other inexplicable behaviors.

If this kind of interference is present, only use telemetry via the programming head for communication between the device and the implanted device. Do not use wireless RF telemetry.

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

- Power off the interfering electrical device.
- Remove the source of interference from this device.
- Power on and power off the device or break the electrical connection between this device and the source of interference, if this can be done safely.

If the interference continues, contact BIOTRONIK immediately.

⚠ 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 the other device(s) being used with it in order to ensure that they are all working correctly.

⚠ WARNING

Risk of electromagnetic interference through the use of unauthorized accessories

The use of accessory parts, 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.

⚠ WARNING

Risk of electromagnetic interference through the use of portable RF communication equipment

Use of portable RF communication devices (including peripheral devices such as antenna cables and external antennas) within 30 cm (12 inches) from this device can result in a reduction of its performance. This applies even when using the associated cables.

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

In the case of disruptions exceeding the limit values as a result of electromagnetic interference (EMI), the PSA switches to asynchronous pacing, when the limit values are exceeded. The sensing amplifier is turned off for the duration of the presence of the noise in the channel in which the noise is detected. Pacing continues if it is switched on in this channel. These disruptions are visible on the IEGM channel, but no markers will be displayed.

Determining electromagnetic interference (EMI)

Wireless RF telemetry and telemetry between the programming head and the implanted device may be impaired by electromagnetic interference (EMI). This can be observed when transmission using wireless RF telemetry is disturbed or it becomes difficult, or even impossible, to interrogate or program the implanted device.

When using telemetry between the programming head and the implanted device, you can detect the sources of electromagnetic interference using EMI tests (refer to the device software help). If such an interference is present, you must locate the source of interference and turn off the source.

When using wireless RF telemetry, you can detect the sources of electromagnetic interference using the RF monitor (refer to the device software help). If this kind of interference is present, only use telemetry via the programming head for communication between this device and the implanted device. Do not use wireless RF telemetry.

Maintenance, Care, and Disposal

Cleaning and disinfecting

The following regulations are applicable to the device:

- Use lint-free, soft cloths.
- Clean the housing with a damp cloth and mild soap solution.
- For disinfecting, use alcohol-based agents (e.g., AHD 2000) for disinfection, hydrogen peroxide-based agents (e.g., Diosol) or quaternary ammonium-based agents (e.g., C.F.40).
- Vacuum the ventilation slots regularly.
- Visually inspect the connections: Make sure that the contacts for all connections and cables are clean and free of any type of dirt.
- Clean the contacts of the battery. Use a clean, lint-free, soft, dry cloth for this.

Sterilization

The device and the programming head (PGH) cannot be sterilized. Only use the PGH in the sterile area with the sterile cover for the PGH (see Accessories and Spare Parts [Page 57]).

Test before each use

A short test of the device and the approved accessories should be performed prior to each use. This test consists of the following visual inspections and a simple function test:

1. Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
2. Inspect the cables (for insulation, fractures, etc.) and cable connection areas.
3. Inspect the labeling for legibility.
4. Check the indicators and the screen (e.g., time and date).
5. Perform a simple electrical function test: Power on the device.

   An internal function test is performed automatically.

If no error message appears, no errors were found and the device can be used. If you find any damage or failures, please contact BIOTRONIK.

Inspection

The inspection consists of the regular technical safety check according to medical device standards. This ensures the safety of the device. Inspections must be performed in the following situations:

- After use in conjunction with high-frequency surgical instruments or cardiac defibrillators.
- If malfunctions are suspected.
- At the regular intervals prescribed by the national regulations and at least every two years.

This inspection can be performed by BIOTRONIK. The inspection should conform with the manufacturer's specifications, which are available upon request. The specifications list all necessary test steps and the necessary equipment.

Replacement of various components

The exchangeable replacement parts can be found in the following section: Accessories and Spare Parts [Page 57].

Programming head (PGH) and ECG power cord compartment cover

The cover for the PGH and ECG power cord compartment can be replaced by you or by BIOTRONIK. To replace the cover, proceed as follows:

1. Press the release key and open the PGH and ECG power cord compartment.
2. Take out the programming head and place it aside.
3. Press one of the two bearing caps from the bottom out of the housing until the pins on the cover are visible.
4. Simultaneously pull out the pins of the cover from the bearing position of the bearing cap. To do this, pull the cover at an angle toward the front.
5. Do the same with the second bearing cap and remove the cover.
6. Dispose of the cover to be replaced properly in accordance with the applicable directives.
7. Attach the new cover in the reverse sequence. The pins snap audibly into place.

USB ports cover

To replace the cover, proceed as follows:

1. The cover can be pushed down sideways. To do this, press on the cover and slide it sideways away from the device.
2. Dispose of the cover to be replaced properly in accordance with the applicable directives.
3. Slide the replacement cover for the USB port sideways completely up to the snap-in point on the device.

Battery compartment and battery cover

To replace the cover, proceed as follows:

1. Place the device on its back with the bottom facing up.
2. Press the lock of the battery compartment cover downwards and slide the cover off in the direction of the printed arrow.
3. Dispose of the cover to be replaced properly in accordance with the applicable directives.
4. Slide the replacement cover for the battery compartment completely up to the snap-in point on the device.

To replace the battery, proceed as follows:

Prerequisite
The device is switched off and the On/Off light indicator is not lit.

1. Place the device on its back with the bottom facing up.
2. Press the lock of the battery compartment cover downwards and slide the cover off in the direction of the printed arrow.
3. Remove the battery using the tag.
4. Insert a new battery. Ensure the correct position of the contacts and also that the battery is completely inserted in the battery compartment. While doing so, ensure a suitable position of the tag for easy removal of the battery.
5. Slide the battery compartment cover completely up to the snap-in point on the device.

Do not insert or remove any battery in the device while using the device on a patient in order to ensure provision of error-free and continuous care to the patient. Pay attention to the charging status of the battery before you use the device on the patient. Never use the device without the cover of the battery compartment in order to prevent conduction of leakage currents when the contacts are touched.

Disposal

The symbol on the type plate, a crossed out garbage can, indicates that the device must be disposed of in accordance with the European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2). If the device is not disposed of in an environmentally friendly manner, it will result in environmental pollution as this device contains materials which must be disposed of in accordance with environmental protection requirements (e.g., WEEE, RoHS, REACH). Return devices that are no longer in use to BIOTRONIK.

The battery must not enter the environment uncontrolled. It must be disposed of in an environmentally safe manner according to the applicable country-specific directives; Do not throw the battery in the sewage system or in any waters, and do not burn it. Do not break or damage the battery before disposal. The battery should be completely discharged before it is recycled.

3 Startup

Device Overview

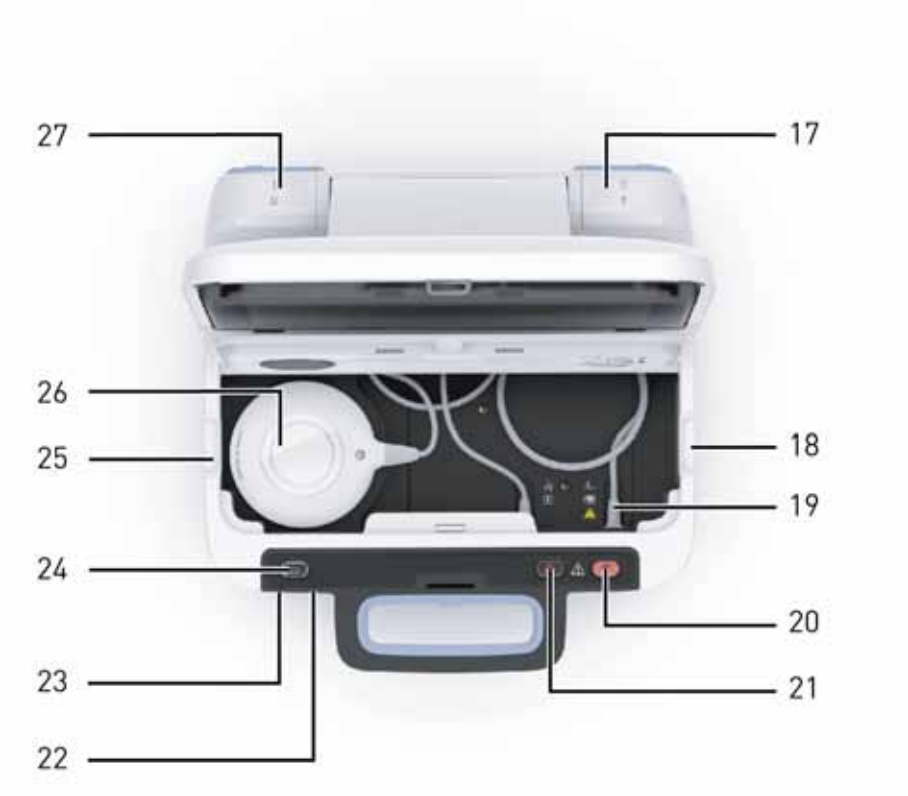
View from the top, right

1	Pacing system analyzer (PSA)
2	Cable feedthrough for ECG cable
3	Closed screen (touch screen)
4	Ventilation slots
5	Carrying handle
6	Screen release key

View from the top, left

7	Open screen (touch screen)
8	Programming head (PGH) and ECG power cord compartment
9	Stylus in pen holder
10	Release key for the PGH/ECG power cord compartment
11	USB port for connecting a printer or for exporting data to a USB flash memory stick
12	
13	Mini display port
14	Ethernet port
15	Power supply port
16	Ventilation slots

View from the top, PGH/ECG power cord compartment

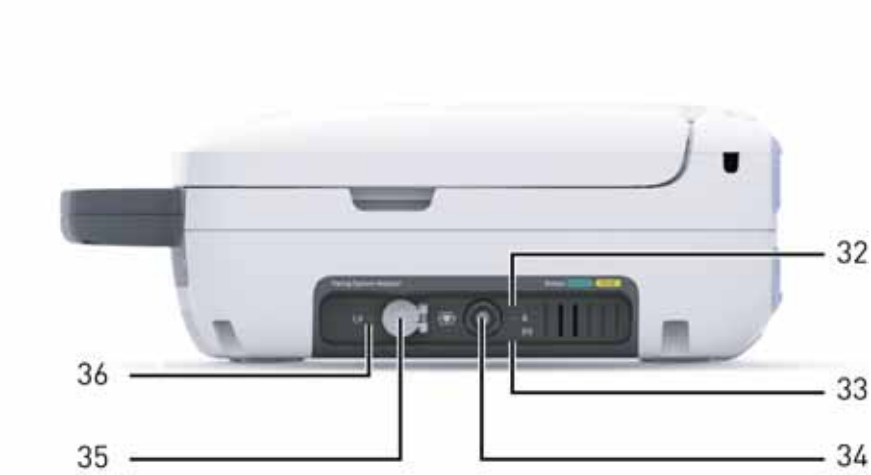


17	Cover of USB port for connecting a mouse, a keyboard or a barcode scanner
18	Cable feedthrough for ECG cable and the programming head cable
19	Connector for ECG cable PK-222 or PK-222-L
20	Emergency shock key
21	Safe program key
22	Charging status indicator (LED)
23	On/off light indicator (LED)
24	On/Off key
25	Cable feedthrough for ECG cable and the programming head cable
26	Programming Head (PGH)
27	Cover of USB port for connecting a mobile internet stick authorized by BIOTRONIK

View from the bottom

28	Type plates
29	Battery compartment cover
30	Release key of the battery compartment
31	Anti-slip pads

Pacing system analyzer (PSA)



32	Indicator for the atrial sensing/pacing (LED)
33	Indicator for the right ventricular sensing/pacing (LED)
34	RV/A: port for the atrial/right ventricular patient cable
35	LV: port with cover for the left ventricular patient cable
36	Indicator for the left ventricular sensing/pacing (LED)

Symbols on the Device

Symbols on the device

	On/Off light indicator
	Charging status indicator
	Caution!
	Emergency shock key
	Safe program key
	On/Off key
	USB ports
	Follow the instructions for use!
	Observe the technical manual
	Ethernet connection
	Mini display port
	Power supply port

Symbols in the PGH/ECG power cord compartment

	Location and storage instructions for the programming head and ECG cable
	ECG port
	Type CF applied part, defibrillation protected in connection with the approved cables
	PGH port
	Type BF applied part

Symbols on the pacing system analyzer (PSA)

	Type CF applied part, defibrillation protected in connection with the approved cables
A	Atrium
RV	Right ventricle
LV	Left ventricle
SENSE	Sensing
PACE	Pacing

Symbols on the type plate

	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU regarding waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
CE	CE mark
IP30	• Protection against the ingress of solid foreign bodies with a ⩾ 2.5 mm diameter • No protection against ingress of water

Transportation and Setup

Transporting the device

⚠ Caution

Danger to the user

Danger of tripping over connected cables during device transport.

- Prior to transporting the device, remove the attached cables and store them in the compartments intended for this purpose.

The device has an integrated ergonomic handle at the front, which can be used to safely transport the device in any position. A case can additionally be slid over the device in such a way that the handle is accessible from the opening provided for it in the case. The case has special compartments in which the power supply brick and the power cord can be stowed.

The specially designed anti-slip pads allow for horizontal or vertical positioning of the device. When the device is slightly lifted in the front (using the handle), the slick corners of the bottom part of the housing allow for easy positioning on smooth surfaces (tables, shelves). After the device is set down, the anti-slip pads keep the device securely in place.

Setting up the device

⚠ 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 the other device(s) being used with it in order to ensure that they are all working correctly.

⚠ WARNING

Risk of electromagnetic interference through the use of portable RF communication equipment

Use of portable RF communication devices (including peripheral devices such as antenna cables and external antennas) within 30 cm (12 inches) from this device can result in a reduction of its performance. This applies even when using the associated cables.

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

To set up the device, proceed as follows:

1. Place the device on a flat dry surface.
2. Never use the device without the cover of the battery compartment in order to prevent conduction of leakage currents when the contacts are touched.
3. Connect the power supply brick and the power cord in a way that the cables are laid without tensile stress and they do not pose a tripping hazard.
4. Do not place the power supply brick on the floor and ensure that the power plug is easily accessible at all times.
5. Ensure that the device is protected from fluids and moisture.
6. Ensure that the device does not slip, even while the cable is connected, and the patient only comes into contact with the applied parts, namely the programming head, ECG cable and patient cable for the PSA. The physician must not touch any touchable plug connections such as USB ports, nor any device contacts for the battery in the battery compartment, simultaneously with the patient.

To prevent overheating of the device and the programming head, take the following measures:

- Place the programming head outside the PGH and ECG power cord compartment.
- Ensure that the ventilation slots are free so that the exhaust air can freely circulate.
- Do not place the device on hot surfaces.
- Open the screen into working position.
- Comply with the operating temperatures and regulate the ambient temperature appropriately.

If these measures do not suffice and the device exceeds a certain temperature limit, the device will automatically switch off in order to prevent overheating.

Open the screen

The release key for the screen is located on the inner side of the handle.

To open the screen, proceed as follows:

1. Press the release key on the inner side of the handle. The device will unlock.
2. Tilt the screen upwards to the desired working position. The working position can be smoothly adjusted as needed. The screen will remain in any position due to its self-retaining bearings.

Power Supply

Connect the power supply brick

The device is powered via the provided power supply brick and power cord. The port for the power supply brick is located at the back, on the left side of the device.

⚠ WARNING

Electric shock

If the device is connected to a mains supply without a PE conductor, an electric shock may occur.

- Only connect the device to a mains supply with PE conductor.

To connect the power supply brick, proceed as follows:

- Connect the power supply brick with the provided power cord.
- Insert the plug of the power cord into the wall outlet.
- Insert the plug of the power supply brick cable into the power supply port of the device.

Insert battery

A battery may be included in the package contents of the device upon customer request. Using the battery, the device can be deployed as a mobile device. Due to aviation regulations, the charging status at the time of delivery is a max. 30%. Before using the device on the patient for the first time, the battery should be fully charged; this is reached after approximately 3 hours. The battery is charged, while the device is switched on and off, by inserting it into the device and connecting the device to the mains supply using the power supply brick. Only charge the battery while using the device, as this is the only way to ensure its proper functionality, and charge the battery for a few hours before using it on the patient to ensure an adequate charging status.

Information on charging status and charging state can be found in the Battery indicators [Page 39].

Note

- Use only batteries that are damage-free and approved by BIOTRONIK.
- Before inserting the battery, clean the dirt on the contacts if required. Use a lint-free, soft, clean, dry cloth for this.
- While handling the battery, ensure that it does not fall.
- If you notice any change (color, smell, etc.) in the battery while storing, inserting, handling, charging, or during normal use of the battery, remove it immediately or do not use it.
- Store the battery out of the reach of children and never leave children unsupervised with the device if the battery is inserted.

The battery compartment is located on the rear side of the housing and is provided with a cover.

To insert the battery, proceed as follows:

1. Place the device on its back with the bottom facing up.
2. Press the lock of the battery compartment cover downwards and slide the cover off in the direction of the printed arrow.
3. Insert the battery. Ensure the correct position of the contacts and also that the battery is completely inserted in the battery compartment. While doing so, ensure a suitable position of the tag for easy removal of the battery.
4. Slide the battery compartment cover completely up to the snap-in point on the device.

Do not insert or remove any battery in the device while using the device on a patient in order to ensure provision of error-free and continuous care to the patient. Pay attention to the charging status of the battery before you use the device on the patient. Never use the device without the cover of the battery compartment in order to prevent conduction of leakage currents when the contacts are touched.

Connections and Cables

Basic notes for cables and connections

⚠ Attention

Disruption in communication between the device and the implanted device

While connecting external devices and while connecting to a network, there may be disruptions in the communication between the device and the implanted device.

- Do not establish connection to an external device or a network during an implantation or follow-up.

⚠ Caution

Risk of exceeding leakage currents when connecting external devices with their own power supply or an electrically conductive connection to other devices

- Only connect devices that comply with the IEC 60601-1 standard or IEC 60950.
- Line-powered devices must comply with the IEC 60601-1 standard or must be connected to the USB port via an isolating separator (IEC 60601-1:2012, paragraph 16.5) with a dielectric strength of at least 1.5 kV. Should the isolating separator require an independent power supply, it must also comply with IEC 60950.
- Place devices that do not adhere to the IEC 60601-1 standard at least 1.5 m away from the patient.
- Before commissioning for the first time, check and document all device combinations according to IEC standard 60601-1.
- Carry out this check at regular intervals prescribed by national regulations.

Note

The ECG cable and the patient cable for the PSA can be connected and again disconnected when the device is switched on and during an implantation or follow-up. All other connections can be established and again disconnected while the device is switched on, however, avoid doing this during an implantation or follow-up to prevent disruptions in the communication.

Connect ECG cables

⚠ Attention

Wrong diagnosis due to incorrect ECG display

The ECG display of the device is used for a function test of the implanted device and is not suitable for diagnostic purposes. The device is not an ECG recorder according to the requirements of IEC 60601-2-25.

- Do not use the ECG display for diagnostics.
- Use a suitable and approved ECG device for diagnostics.

The device may only be used with the PK-222 or PK-222-L ECG cables. The PK-222 (2.8 m) and PK-222-L (4.0 m) patient cables differ from each other in length and in their patient-side connectors. The PK-222 has four color coded 4 mm lamella-basket plug (banana plug) on the patient-side and the PK-222-L has four color-coded and permanently mounted patient cable electrode clips. On the device side, both cables have a yellow, 14-pin Redel plug (P series, 40° coded) Please observe the technical manual for the patient cables.

The ECG port is located on the front right in the PGH/ECG power cord compartment.

To connect the ECG cable, proceed as follows:

1. Press the release key and open the PGH and ECG power cord compartment.

2. Connect the device-side, yellow, 14-pin Redel plug (P series, 40° coded) of the ECG cable to the ECG port.
3. Place a part of the patient cable in the PGH and ECG power cord compartment and guide the rest out of the device via the cable feedthrough.
4. Close the PGH/ECG power cord compartment. The cover snaps audibly.

The ECG can be displayed in real time in the recorder mode or the trigger mode. Furthermore, the ECG can be printed on an external printer. With the approved adhesive and clamp electrodes (see the PK-222 and PK-222-L technical manuals) you can obtain up to 3 derivations according to Einthoven. The ECG is not suitable for use on an open heart.

Overmodulated ECG input

When the ECG input is overmodulated, the signal is only displayed as a solid line on the upper edge of the ECG window or as a missing line. Proceed as follows to fix the overmodulation:

1. Check for correct contacting of the electrodes.
2. Remove other devices from the patient.
3. Switch off the sources of interference.

Connect a mobile internet stick

Depending on the country, the device may be equipped with a mobile Internet stick authorized by BIOTRONIK. (see Accessories and Spare Parts [Page 57]).

Note

The other three USB ports on the device are not intended for connecting a mobile internet stick.

- Only connect the mobile internet stick to the USB port under the cover on the top side, at the rear left end of the device.
- Only connect a mobile internet stick authorized by BIOTRONIK.

The USB port for the mobile internet stick is located under a cover on the top side, at the rear left of the device.

To connect the BIOTRONIK authorized mobile internet stick, proceed as follows:

1. The cover can be pushed down sideways. To do this, press your finger on the cover and slide it sideways away from the device.
2. Remove the cap of the mobile internet stick.
3. Hold the mobile internet stick at the sides and insert it into the USB port.
   While doing so, ensure that the contacts of the mobile internet stick point towards the rear side of the housing.
4. Slide the cover of the USB port sideways again, completely up to the snap-in point on the device.

Connect USB devices

The device has three USB ports to connect the following USB devices:

- External USB printer for printing patient data
- USB flash memory sticks for exporting patient data
- USB mouse
- USB keyboard
- USB barcode scanner

One of the two USB ports for connecting an external printer or USB stick is located on the left front of the device.

The second USB port for connecting an external printer or a USB stick is located on the left side of the device.

The USB port for connecting a USB mouse, a USB keyboard or a USB barcode scanner is located under a cover on the top side, at the rear right of the device. The cover of the USB port is provided with an opening. Route the cable of the mouse or keyboard through the opening in the cover.

To connect the respective USB device, proceed as follows:

1. The cover can be pushed down sideways. To do this, press on the cover and slide it sideways away from the device.
2. Insert the USB connector of the respective USB device into the USB port.
3. Route the cable of the connected USB device, if applicable, out of the device via the opening on the side.
4. Slide the cover of the USB port sideways again, completely up to the snap-in point on the device.

Connect an external monitor

Depending on your software version, an external monitor can be connected. The mini display port for connecting an external monitor is located on the left side of the device.

To connect an external monitor,

1. insert the plug of the mini display port cable into the mini display port.

Connect an ethernet cable

The ethernet port for connecting an ethernet cable is located on the left side of the device.

Depending on the approved software version, you can connect the device to a network using the ethernet port, for instance, to use a network printer or to export patient data to network directories. To connect an ethernet cable, proceed as follows:

1. Insert the plug of the ethernet cable into the ethernet port.

Set up Wireless and Network Connections

WLAN, Bluetooth, and network connection via an ethernet cable

To enable the export of data, the device is equipped with an internal WLAN and Bluetooth module as well as an ethernet port. The range of functions depends on the approved software version and the configuration of the WLAN, Bluetooth, and the network connection via an ethernet cable is based on the set-up of standard devices such as PCs. The exact description for setting up can be found in the "Handling Basics" section of the technical manual for the software. It is available in digital form on the programmer and on the internet: https://manuals.biotronik.com.

Switching On and Off

Switching the device on

The On/Off key is located on the left side, on the surface area in front of the power cord compartment. The On/Off key is only accessible when the screen is open.

To switch on the device, proceed as follows:

1. Press the release key of the screen and open the screen.
2. Press the On/Off key once up to the pressure point.
3. The On/Off light indicator on the front left of the device continuously lights up green.

For more information about the on/off light indicator, can be found in the chapter On/off light indicator [Page 39].

The device can be switched on with the screen swiveled up as well as with the screen closed.

Startup of the operating system

After switching the device on, the operating system will boot. During this time, the device cannot be operated. Meanwhile, the start screen loads gradually. After successful booting of the operating system, the screen displays the complete start screen, which indicates the device's ready-for-service status. Depending on whether a telemetry contact to an implanted device exists, and which other settings are enabled (e.g., password protection), the start screen may display additional details.

1. Check all displays and signals at all times for correct functionality. If a display does not function correctly, look for the cause. If necessary, switch the device off and then on again.

Switching the device off

To switch off the device, proceed as follows:

1. Press the On/Off key for more than 2 seconds up to the pressure point.

   A dialog window will appear on the user interface.
2. Select the desired action from the dialog window:

   [Shutdown]

   [Standby]

   [Cancel]

Result
The device shuts down in a controlled manner and the On/Off light indicator continues to remain lit for some time.

Functions of the On/Off key when shutting down

Using the On/Off key, you can execute three actions:

Action	Function
Pressing for ⩽ 2 s	**In the Start screen** Activating the Standby mode (in battery power mode, this is only possible when there is sufficient battery capacity: min. 40%)
	In the Follow-up window Closing the follow-up window and the indicators of the start screen
Pressing for 2-6 s	Switching off
Only in exceptional cases, if the device cannot be switched off properly:	
Pressing for ⩾ 6 s	Forced shutdown

⚠ Caution

Danger to data integrity

Without a battery inserted, sudden disconnection from the mains supply can lead to corruption of data.

- Only use the ON/OFF key to switch the device off.

Note

The device does not switch off when the screen is tilted down and locked into positon. Therefore, the device can be left in operating mode and put aside temporarily to save space. Pay attention to the connected cables. By tilting the screen up again, the programmer is immediately functional again.

The stand-by mode is suitable for mobile use, but the device should not be set in the stand-by mode continuously. Switch off the device if you are not using it for an extended period of time. During stand-by mode, the device behaves as follows:

- The fan is active.
- The start time when switching on is very short.
- When the power supply is connected and the battery is inserted, the battery will be charged.
- All clinical functions are inactive.
- The screen is switched off.

To disconnect the programmer from the mains supply, pull its power plug out from the outlet. Ensure that the device does not switch off when the battery is inserted, but instead switches over to battery power mode.

4 Using Renamic Neo

Screen

The device screen is a capacitive touch screen that is operated using the corresponding stylus or a finger. If using a stylus for operation, only use the special styluses for capacitive touch screens approved by BIOTRONIK (see Accessories and Spare Parts [Page 57]).

The following is displayed on the screen:

- Parameters and measured values
- ECG, IEGM, and marker channel
- Buttons

Indicators on the Device

On/off light indicator

The On/Off light indicator is located at the front left of the device and is labeled with an open circle.

The On/Off light indicator shows three device statuses:

Device status	LED behavior
Standby mode	LED flashes green
Ready for use	LED lights up green continuously
Disabled	LED does not indicate any behavior

Battery indicators

⚠ Attention

Danger to the patient because of termination of follow-up due to low battery capacity

The actual battery capacity may decrease in the life cycle of a battery. A battery charged up to 100% with a low actual battery capacity only has a small battery life and is not suitable for mobile use.

- Check the actual battery capacity regularly in order to be able to estimate the actual battery life and replace the battery if required.

Battery level indicator

The battery level indicator shows what percentage of the battery is charged. Due to aviation regulations, the charging status at the time of delivery is a maximum 30%. Before using the device on the patient for the first time, the battery should be fully charged; this is reached after approximately 3 hours. The battery is charged, while the device is switched on and off, by inserting it into the device and connecting the device to the mains supply using the power supply brick. Only charge the battery using the Renamic Neo, as this is the only way to ensure its proper functionality. Charge the battery for a few hours before using it on the patient in order to ensure an adequate charging status.

When a functioning battery approved by BIOTRONIK is inserted, a battery icon and the charging status are displayed on the user interface.

In addition to this, the battery itself has an indicator to show the charging status without the device being switched on. To find out the charging status without switching on the device, proceed as follows:

1. Place the device on its back with the bottom facing up.
2. Press the lock of the battery compartment cover downwards and slide the cover off in the direction of the printed arrow.
3. Press the red button on the right side of the battery, right below the charging status scale, including the LED indicator.
   You do not need to remove the battery from the device to do this.

The respective LED on the scale lights up to indicate the charging status.

4. Slide the battery compartment cover completely up to the snap-in point on the device. While doing so, ensure a suitable position of the tag for easy removal of the battery.

The charging status indication is divided into four levels:

Status bar	Charging status in percentage
100	75–100%
75	50–74%
50	25–49%
25	0–24%

When evaluating the charging status, the **actual battery capacity** must always be taken into consideration. The actual battery capacity may decrease in the life cycle of a battery. This means that a battery charged to 100% can only have a high battery life if the actual battery capacity is also high. A battery charged up to 100% with a low actual battery capacity only has a small battery life and is not suitable for mobile use. Regularly check the remaining life of the battery indicated on the user interface in combination with the charging status to decide whether the device can be used in battery power mode or you need to change over to mains power supply mode and whether you need to replace the battery.

The actual battery capacity is displayed on the user interface. The exact description can be found in the "Handling Basics" section of the technical manual for the software. Observe the following points so that the decrease in the actual battery capacity is not accelerated:

- Do not store the battery uncharged for an extended period of time.
- Remove the battery from the device, if you are operating the device in mains power supply mode and not in battery power mode.
- Charge the battery at least every six months.
- Avoid short charging cycles and regularly charge the battery fully.

Do not insert or remove any battery while using the device on a patient in order to ensure that error-free and continuous care is provided to the patient.

Charging status indicator

The charging status indicator is located at the front left of the device and is labeled with a battery symbol.

The charging status indicator shows the following:

LED behavior	Explanation
Flashing green	The device is powered via the power supply brick and the battery is being charged.
Continuously lighted up green	The device is powered via the power supply brick and the battery is fully charged.

If the LED does not indicate any behavior, i.e., off when the device is switched on, the following circumstances may be present:

- No battery is inserted in the device.
- The inserted battery is not charging (failure/error).
- The device is solely in battery operation.

Telemetry status indicator on the programming head (PGH)

The indicator for the telemetry status is a ring LED directly on the programming head (PGH).

The ring LED indicates the following status of the telemetry contact:

Ring LED behavior	Telemetry status
Flashing green	Telemetry contact between PGH and an implanted device has been established.
Flashing red	The connection with the device is disturbed due to electromagnetic interference.
Flashing orange	• The telemetry of the PGH is deactivated and RF telemetry is activated or • during the existing telemetry contact to an implanted device, the PGH was placed on another implanted device.

The description for indicators of the telemetry status on the user interface can be found in the "Handling Basics" section of the technical manual for the software. It is available in digital form on the programmer and on the internet: https://manuals.biotronik.com.

Indicator for the sensing/pacing of the PSA

The indicator (LED) for the sensing/pacing of the PSA is located directly next to the respective ports/ connectors on the right side of the device.

The device indicates for each channel whether sensing or pacing is being carried out in that channel:

LED	LED behavior	Status
A	Green	Atrial sensing
	Yellow	Atrial pacing
RV	Green	Right ventricular sensing
	Yellow	Right ventricular pacing
LV	Green	Left ventricular sensing
	Yellow	Left ventricular pacing

Programming Head (PGH)

⚠ Caution

Higher energy consumption by the implanted device

RF telemetry requires slightly more power. Consumption during implantation corresponds to approximately 7 days of service time, and consumption during a 20-minute follow-up corresponds to approximately 3 days. After 5 minutes without input, the telemetry switches to the economy mode.

- Do not establish any unnecessary RF telemetry.
- Check the device's battery capacity regularly.

⚠ Caution

Danger to the patient due to non-sterile PGH

The programming head (PGH) is not sterile and cannot be sterilized.

- Only use the PGH in the sterile area with the sterile cover for the PGH (see Accessories and Spare Parts [Page 57]).

The device is equipped with a permanently installed programming head (PGH) for communication with the BIOTRONIK implanted devices. The programming head contains a strong magnet. Therefore, do not place it close to magnetically sensitive objects such as magnetic data media, credit cards, or wristwatches. The programming head (PGH) is in the PGH/ECG power cord compartment at the time of delivery of the device.

The communication with the implanted device takes place telemetrically via the programming head or RF telemetry. RF telemetry involves the output data from the implanted device (digital as well as analog) being converted into digitally coded pulses and transmitted over an inductive coupling between the coils of the programming head and those of the implanted device.

Not every device supports RF telemetry (consult the technical manual of the respective implantable pacemaker/ICD/implantable cardiac monitor). RF telemetry establishes a telemetry connection, without the programming head, between the programmer and implanted devices that support RF telemetry. The programmer and these devices are equipped with a special transmitter and receiver, which enable high frequency radio transmission. The establishment of RF telemetry depends on the implanted device being used. To establish RF telemetry, proceed as described in the programmer's software help and the device's technical manual.

With some implanted devices, telemetry cannot be carried out until a reed switch in the implanted device has been closed. For this purpose, a strong permanent magnet has been integrated into the programming head. The reed switch in the implanted device will be closed by means of this permanent magnet, before the programming head and the implanted device exchange data. When the reed switch is open, telemetry is blocked. This protects the implanted device from unintentional reprogramming. In some implanted devices, closing the reed switch also switches the device over to asynchronous pacing (see the technical manual of the respective device).

Establishing telemetry contact

To establish **telemetry via the programming head**, proceed as follows:

1. Switch on the device.
2. Press the release key and open the PGH and ECG power cord compartment.

3. Take out the programming head and place it over the implanted device or cardiac monitor.

   The ring LED on the programming head shows the status of the telemetry contact with the implanted device.

To establish **RF telemetry**, proceed as follows:

1. The establishment of RF telemetry depends on the implanted device being used. To establish RF telemetry, proceed as described in the programmer's software help and the device's technical manual.

Information on telemetry status indication (ring LED) can be found in the Chapter: Telemetry status indicator on the programming head (PGH) [Page 41].

Communication with the Device and Cardiac Monitors

Software

The interaction/communication between the device and an implanted device or cardiac monitor is controlled using software provided by BIOTRONIK. The software can be installed in the following ways:

- It can be installed by a BIOTRONIK employee.
- Software can be downloaded from the internet on to a USB stick: www.biotronik.com.
- Software can be downloaded from the internet via WLAN*, an ethernet cable* or cellular phone network directly onto the device.

*The range of functions depends on the approved software version.

Interrogating and programming the implanted device

BIOTRONIK implanted devices can communicate bidirectionally with the device. As soon as the telemetry is established, diagnostic and therapeutic information as well as technical data are transferred to the device. Depending on the implanted device, a large number of adjustable parameter sets are available. These parameter sets are combined and saved in the program that is currently active. The software of the device detects obvious program errors and requires these to be corrected before the program is transferred to the implanted device.

The following programs can be transmitted:

- Permanent program
  A permanent program includes all settings with which the implanted device works continuously, without telemetry contact.
- A temporary program
  A temporary program includes settings with which the implanted device works temporarily, when there is telemetry contact and a test is being conducted.
- Safe program (emergency pacing)
  A safe program is a program for backup stimulation, which is triggered using the safe program key.

⚠ WARNING

Use of a temporary program can be stopped at any time and the permanent program of the implanted device can be automatically reactivated with the following:

- Telemetry via the programming head
  Lift the programming head or switch off the device.
- RF telemetry
  Switch off the device or move it out of the range of the implanted device.

Data transfer

The follow-up data can be saved, sorted, and exported. For exporting data, the following options are available:

- A network connection via an ethernet cable or via WLAN (the range of functions depends on the approved software version)
  Export of data to the network or via the ReportShare® service (the range of functions depends on the approved software version)
- A mobile connection:
  Export of data via the ReportShare® service (the range of functions depends on the approved software version)
- Bluetooth connection (the range of functions depends on the approved software version)
  Export of data to a directly connected terminal device (e.g., PC)
- USB ports:
  Export of data to a mass storage medium
- Connect an external printer for printing out all data on paper

The configuration of an external printer, WLAN, Bluetooth, and the network connection via an ethernet cable is based on the set-up of standard devices such as PCs. The exact description for setting up and exporting data can be found in the "Handling Basics" section of the technical manual for the software. It is available in digital form on the programmer and on the internet: https://manuals.biotronik.com.

Pacing System Analyzer (PSA)

The pacing system analyzer (PSA) is used for evaluating the position and integrity of leads as well as to determine the suitable pacing parameters for the implanted device. The PSA is located on the right side of the device.

Overview of the patient cables

The following patient cables and patient adapters can be used with the PSA:

Patient-side connection	Patient cable and adapter	Device-side connection
Alligator clips	PK-141	Redel plug
Alligator clips	PK-67-S/L with PK-155 (2x)	Redel plug
2-mm connector port	PK-67-S/L with PA-1-B	Redel plug
2-mm connector port	PK-67-S/L with PA-1-C	Redel plug
IS-1 connector port	PK-67-S/L with PA-2	Redel plug

Connect patient cables

Patient cables can be connected or disconnected while the device is switched on. Only connect the patient cable to the device when it is ready for use. Before connecting the patient cable to the device, check the current parameter settings. When connecting the patient cables, please observe their technical manuals.

⚠ **WARNING**

Danger to patient from electrical current induction

If the patient cable is connected to the leads and the device connector of the patient cable is not yet connected to the device, this can result in undesired electrical current induction.

- First connect the patient cable to the device and then connect the patient cable to the leads.

To connect the patient cable for the right side of the heart (**A/RV**), proceed as follows:

1. Insert the Redel plug of the patient cable into the A/RV connector. Ensure that the plug is securely positioned in the connection.
2. Connect the patient connections of the patient cable or adapter to the patient's A/RV leads.

To connect the patient cable for the left side of the heart (**LV**), proceed as follows:

1. Insert the Redel plug of the patient cable into the LV connector. Ensure that the plug is securely positioned in the connection.
2. Connect the patient connections of the patient cable or adapter to the patient's left ventricular leads.

Disconnect patient cables

1. Open the clamps and disconnect the lead from the patient cable or adapter.
2. Remove the Redel plug of the patient cable from the external device.

Emergency Programs

Purpose of the emergency keys

Using the two emergency keys start the emergency pacing (safe program) or the emergency shock. The two emergency keys are located on the front right of the device, on the surface area in front of the power cord compartment. The two emergency keys are only accessible when the screen is open.

Pressing the safe program key will cause the following to occur:

- The current active programming in the implanted device or the settings of the PSA are replaced by the emergency parameter values and the safe program is started.
- The safe program is active until you send a new permanent program to the implanted device.

Pressing the emergency shock key will cause the following to occur:

- The emergency shock parameters are activated. For safety reasons, a dialog also gives the option of canceling the action.
- After an emergency shock is triggered, the previously set programming of the implanted device becomes active again.

Prerequisite

- Safe program key:
  A safe program cannot be triggered in a cardiac monitor.
  - Telemetry contact must exist between the device and an implantable pacemaker or ICD.

    or
  - Implanted leads are connected to the pacing system analyzer (PSA) using patient cables.
- Emergency shock key:
  When a PSA is being used, an emergency shock cannot be triggered with an implantable cardiac pacemaker or with a cardiac monitor.
  - Telemetry contact must exist between the device and an ICD with ICD lead.

Start/End emergency pacing

To **start** emergency pacing, proceed as follows:

1. When the PSA application of the software is active: Ensure that the implanted leads are connected using patient cables.
   When the PSA application of the software is **not** active: Ensure that the telemetry contact to the implanted cardiac pacemaker or ICD exists.
2. Press the safe program key:
   

To **end** emergency pacing, proceed as follows:

1. Activate the desired parameters of the permanent program in the software and transfer them to the implanted device.

Trigger emergency shock

To trigger an emergency shock, proceed as follows:

1. Ensure telemetry contact with the ICD.
2. Press the emergency shock key:

   The emergency shock parameters are activated. For safety reasons, a dialog also gives the option of canceling the action.
3. In the dialog window, select **[EMERGENCY SHOCK]**.

   The capacitors of the ICDs are charged and the ICD delivers an emergency shock with its maximum shock energy.

Parameter values of the emergency programs

The following parameter values are preset for the safe program:

Parameter	Value
Pacing mode	VVI (RV)
Basic rate	70 bpm
Pulse amplitude	7.5 V
Pulse width	1.0 ms

The following parameter values are preset for the emergency shock:

Parameter	Value
Shock waveform	Biphasic
Type	DF (defibrillation shock)
Energy	Maximum shock energy of the respective ICD

5 Appendix

Technical Data

General characteristics for the device and the power supply brick (configured as medical electrical system)

Category	Design
Degree of protection	IP 30
Operating mode	Continuous operation
Temperature range for operation	+10 °C ... +33 °C
Temperature range for storage	0 °C ... +50 °C
Relative humidity:	20% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa
Operation at altitudes	Up to 3,000 m AMSL (AMSL - above mean sea level)
Power supply to the device	Operation using power supply brick
	Internal power supply: rechargeable battery

Physical properties

Category	Design
Dimensions (W x D x H)	340 x 346 x 120 mm
Weight with programming head, stylus, and battery	7.3 kg
Disclosure pursuant to Section 33 REACH, EC Directive 1907/2006	SVHC candidate with CAS No. 127-19-5 > 0.1%: N,N-Dimethylacetamide (DMAc)
	SVHC candidate with CAS No. 556-67-2 > 0.1%: Octamethylcyclotetrasiloxane
	SVHC candidate with CAS No. 7439-92-1 > 0.1%: Lead

Longevity

Category	Design
Longevity	8 years

Display

Category	Design
Size	12.1"
Resolution	1280*800 WXGA
Contrast ratio	750:1
Brightness	At least 300 cd/m^2

Pacing system analyzer (PSA)

Category	Design
Applied part classification	CF, defibrillation protected

Parameter values of the PSA

Parameter		Factory setting	Range of values	Step size
Basic rate		90 bpm	30 to 180 bpm (±10%)	1 bpm
Amplitude (atrium, ventricle)		5 V	0.1 to 10 V (±10% or ±0.1 V)	< 2.0 V: 0.1 V ⩾ 2.0 V: 0.2 V ⩾ 5.0 V: 0.5 V
Pulse width (atrium, right ventricle, left ventricle)		0.4 ms	0.1 to 2.0 ms (±10% or ±0.1 ms)	0.1 ms
Sensitivity	Atrium	1.0 mV	0.2 to 20 mV (±10% or ±0.2 mV)	0.1 mV
	Ventricle	2.5 mV	0.5 to 20 mV (±10% or ±0.2 mV)	
Refractory period	Atrium (TARP, PVARP)	425 ms (± 5 ms)	–	–
	Ventricle (RVRP, LVRP)	250 ms (± 5 ms)		
AV delay		120 ms	0 to 300 ms (±10% or ±5 ms)	5 ms
VV delay (RV > LV)		5 ms	-100 to 100 ms (±10% or ±5 ms)	5 ms

Parameter	Factory setting	Range of values	Step size
Upper rate	425 ms/141 bpm (±5 ms)	–	–
Burst rate	–	80 to 1,000 bpm (±10%)	10 bpm
High rate protection	–	200 bpm (±15 bpm)	–
Blanking (Atrium, right ventricle, left ventricle)	25 ms (± 5 ms)	–	–
Impedance	–	100 to 3000 Ω (±10%)	1 Ω

When two tolerance values are specified, the greater value applies.

ECG

Category	Design
Applied part classification	CF, defibrillation protected with PK-222 and PK-222-L
Derivations	3 (Einthoven)
A/D converter	24 bits
Scan rate	500 ... 1000 Hz

Programming head

Category	Design
Applied part classification	BF
Dimensions (W x D x H)	102 x 132 x 37 mm
PGH cable	2.8 m
Degree of protection	IP 30
Frequency band	9–315 kHz
Operating frequency	32–64 kHz
Maximum transmitter field strength	< -36 dBµA/m Max. peak @ 10 m
Modulation	OOK
Data rate	Up to 64 kbit/s

Power cord port (power supply brick)

Category	Design
Supply voltage	100-240 V, ±10%/50-60 Hz, 1.2-0.5 A/AC
Protection class	I
Maximum power input	90 W
Level of efficiency	⩾ 88% (at 115 V / 60 Hz and 230 V / 50 Hz)
On/Off light indicator	Green LED, lighted continuously

Rechargeable battery

Category	Design
Temperature range for storage	0 °C ... +50 °C
Recommended storage temperature for the battery	23 °C
Charging status at the time of delivery	Max. 30%
Duration of a charging cycle up to a charging status of 90% in fully discharged battery	< 3 h
Battery runtime[1)]	Min. 1.5 h
Battery charging process	IU charging process

1) Determined through internal tests, in which a general and typically expected application, incl. RF telemetry and export, was assumed and with a new, fully charged battery.

Depending on the storage temperature, the charging status and the actual battery capacity may be reduced to the extent that the battery becomes completely discharged and can no longer be used. Therefore, depending on the storage temperature, the battery must be charged at regular intervals.

Storage temperature of the battery	Time to charge the battery
⩽ 35 °C	After 6 months
⩽ 45 °C	After 3 months
⩽ 50 °C	After 1 month

Mass storage

Category	Design
Type	SSD
Storage capacity	⩾ 128 GB

MICS

Category	Design
Frequency band	MICS 402–405 Mhz
Operating frequency	402.45–402.85 Mhz
Frequency range	300 kHz
Maximum RF power	25 µW (EIRP)
Number of channels	9
Modulation	FSK
Data rates	32/64/164/197 kbit/s

WLAN

Category		Design			
Frequency band		2.4 GHz ISM Band	5 GHz Unlicensed National Information Infrastructure (U-NII) Band		
			Subband 1	Subband 2	Subband 3
Operating frequency [MHz]	Europe	2400–2483,5	5150–5350	5470–5725	–
	USA	2402–2472	5150–5350	5470–5730	5735–5835
	Japan	2400–2482	5170–5330	5490–5710	–
Maximum power of transmission (EIRP): Global for all regions		20 dBm (100 mW)	20 dBm (100 mW)	20 dBm (100 mW)	28 dBm (630 mW)
Modulation		DSSS, OFDM, DBPSK, DQPSK, CCK, 16-QAM, 64-QAM			
Standard		IEEE 802.11 a/b/g/n/ac			
Frequency range		20 MHz (a/b/g/n); 20, 40, 80 MHz (ac)			

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	4.2, BLE

Ethernet

Category	Design
Data rate	100 MBit/s

Accessories and Spare Parts

Accessories

Not all accessories are available in all countries.

Item designation	Description	Order no.
Battery (Renamic Neo)	Battery pack: Molicell ME202EK	445510
LTE Dongle x72h-517 America	LTE mobile internet stick for America	441429
LTE Dongle x72h-607 APAC	LTE mobile internet stick for Asia	441428
LTE Dongle x72h-153 EU	LTE mobile internet stick for Europe	441427
UMTS Dongle x31i-8 Global	UMTS mobile internet stick for worldwide deployment	429022
Power supply brick (Renamic Neo)	Power supply brick: Adaptertech ATM090T-P190	447108
Power cord NK-40	Power cord, 2.5 m; for European Union	449319
Power cord NK-41	Power cord, 2.5 m, for USA	449320
Power cord NK-42	Power cord 2.5 m for United Kingdom	449321
Power cord NK-43	Power cord, 2.5 m, for China	449322
Power cord NK-44	Power cord, 2.5 m, for Australia and Uruguay	449323
Power cord NK-45	Power cord, 2.5 m, for Argentina	449324
Power cord NK-46	Power cord, 2.5 m, for Switzerland	449325
Power cord NK-47	Power cord, 2.5 m, for Chile and Italy	449326
Power cord NK-48	Power cord, 2.5 m, for Israel	449327
Power cord NK-49	Power cord, 2.5 m, for Denmark	449328
Power cord NK-50	Power cord, 2.5 m, for Brazil	449329
PGH plastic cover (sterile)	Sterile cover for the PGH; for single use; cannot be re-sterilized; 10 pcs.	396985
Stylus	Stylus for operating the device	445511
Accessories case	Carrying case with special compartments for the power supply brick and the power cord	445749
PK-222-L ECG cable	ECG cable with permanently attached patient cable electrode clips for extremity derivations according to Einthoven, 4.0 m	429747
PK-222-L ECG cable US	Same as PK-222-L with country-specific color coding of the patient cable electrode clips, 4.0 m; for USA	429748

Item designation	Description	Order no.
PK-222 EU	ECG cable with lamella-basket plugs for extremity derivations according to Einthoven, 2.8 m	335284
PK-222 US	Same as PK-222 EU with country-specific color coding of the lamella-basket plugs, 2.8 m; for USA	335281
PK Electrode Clip	4 patient cable electrode clips for the patient cable PK-222	340293
PK-141	Patient cable with 4 alligator clips; 2.8 m; can be re-sterilized	353181
PK-67-S	Can be used with PK-155 and PK-155-B; 0.8 m; can be re-sterilized	128085
PK-67-L	Can be used with PA-1-B, PA-1-C, PA-2, PA-4, PK-155, and PK-155-B; 2.6 m; can be re-sterilized	123672
PK-155	Patient cable with 2 alligator clips; 2.0 m; for single use	337358
PK-155-B	Patient cable with 2 alligator clips; 2.0 m; for single use	404027
PA-1-B	Patient adapter for 4 touch-proof 2-mm plugs; can be re-sterilized	123751
PA-1-C	Patient adapter for 2 touch-proof 2-mm plugs; can be re-sterilized	349723
PA-2	Patient adapter for 2 IS-1 connectors; can be re-sterilized	123157

Spare parts

Item designation	Description	Order no.
USB compartment lid, left	Left USB port cover	445517
USB compartment lid, right	Right USB port cover	445518
Battery compartment lid	Battery compartment cover	445519
PGH/ECG power cord compartment flap	PGH/ECG power cord compartment cover	445520

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 Canada

This device must neither interfere with meteorological and earth resources technology satellites nor with meteorological stations working in the 400.150 to 406.000 MHZ band, and it must accept any interference received, including interference that may cause undesired operation.

This device will be registered with Industry Canada under the following number:
IC: 4708A-RENAMICNEO
The code IC in front of the certification/registration number only indicates that the technical requirements for Industry Canada are met.

Telemetry information for the USA

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in Part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 to 406.000 MHz band in Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This device will be registered with the Federal Communications Commission under the following number:
FCC ID: QRI-RENAMICNEO

Telemetry information for Japan

In accordance with Japanese law, this device has been assigned an identification number under the "Ordinance concerning certification of conformity with technical regulations, etc., of specified radio equipment", Article 2-1-8.

Legend for the Label

The label icons symbolize the following:

	Manufacturing date
	BIOTRONIK order number
	Serial number
	Temperature limit for storage
	Acceptable atmospheric pressure range for storage
	Acceptable relative humidity range for storage
	Follow the instructions for use!
	Contents
	Do not use if packaging is damaged
	CE mark
	Country-specific restrictions concerning distribution and commissioning
	Caution: Federal (U.S.A.) law 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 regarding waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
	Programmer
	Signal transmission
	BIOTRONIK device