CRM

Cardiac Rhythm Management

External Devices

Gebrauchsanweisung

Technical Manual

Manual técnico

Manuel technique

Manuale tecnico di istruzione

Renamic

Medizinisches Programmier- und Überwachungsgerät • Medical programmer and monitoring device

Dispositivo médico de programación y monitorización • Appareil médical de programmation et de surveillance

Dispositivo medico di programmazione e monitoraggio

BIOTRONIK
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Table of Contents

1 Introduction

About the Device

General description Renamic is a portable programmer and monitoring device.

According the customer specification the device is equipped with a GSM, UMTS or WIFI module. This enables the direct export of patient data from Renamic to hospital or practice networks.

It is used during the implantation procedure and follow-up of implantable pulse generators and ICDs (implantable cardioverter-defibrillators).

Primary functions The device has the following primary functions:

Function	Purpose
Programming and testing functions	Program BIOTRONIK pacemakers and ICDs during the implantation procedure or follow-ups
ECG recorder and ECG monitor	Display and printout of up to three leads of surface ECGs, as well as up to three intracardiac derivations (IEGMs) and the corresponding event markers, in real-time
Data management	Store parameter values and ECG/IEGM recordings for computer-aided archiving and evaluation
Documentation	Print out follow-up reports using the internal and/or external printer

About this Technical Manual

Objective

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

The following topics are covered in this manual:

- Device startup
- Interrogation, testing and programming of implantable pulse generators and cardioverter-defibrillators (ICD)

Target group

This technical manual is intended for physicians and trained medical personnel who are familiar with the following:

- The use of implantable pulse generators and ICDs
- The risks and possible complications associated of using these systems

Additional requirements include:

- Medical knowledge:
  — Basic medical knowledge of the therapy applied
  — Training in the handling and programming of implantable pulse generators and ICDs
- Technical knowledge:
  — Ability to work with a PC
  — Ability to use software-controlled medical devices

Other technical manuals

- Technical software manual for programming the intended implantable pulse generator / ICD
- Technical manual for the intended implantable pulse generator / ICD

2 Safety During Use

Intended Medical Use

Intended medical use

The Renamic programmer provides communication with the implantable pulse generator or ICD during the implantation procedure or follow-ups.

The Renamic programmer is intended to be used for the following tasks:

- Conduct sensing, pacing threshold and impedance tests
- Interrogate data of the implanted device such as program parameters, recorded statistical data and episodes, as well as real-time IEGMs
- Display, printout, save and export data of the implanted device for analysis and reporting purposes
- Transfer parameters to the implanted device

Required Expertise

Required expertise

The programmer is intended for use by physicians and trained medical staff. Along with their basic medical knowledge, a detailed knowledge of cardiac electrotherapy is also required. Only qualified medical specialists with knowledge of cardiac electrotherapy can properly operate the device.

German medical device ordinance

This ordinance only applies in the Federal Republic of Germany. However, we recommend that customers in other countries comply with this ordinance as well.

According to section 2, § 5, operation and use:

'The user may operate a (...) listed medical product only after the manufacturer or the authorized agent who acts on behalf of the manufacturer has performed the following requirements:

- 1. Checked the functionality of this medical product at the location where the device will be used.

- 2. Trained the staff appointed by the user to correctly handle, use and operate the medical product. This training must include handling, using and operating the product in conjunction with other medical products, implements and accessories in accordance with the technical manual, as well as any applicable safety-related information and maintenance instructions.

(...)

(3) Proof of a functional test have been performed as stated in Paragraph 1 Item 1, and the training record of the staff appointed by the user, discussed in Paragraph 1 Item 2, are to be documented.'

Residual Risk

Risk analysis

The risk analysis carried out by the manufacturer's Risk Management Team has determined that the residual risk is as low as reasonably possible.

It is a prerequisite that the programmer 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.

General Safety Instructions

Technical manual Only use the programmer in accordance with this technical manual.

Risks of improper handling Disregarding the safety instructions can endanger the patient, the staff and the equipment.

> **Note:** Failure to observe the safety precautions 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 effects

Changes not permitted Only the manufacturer or a party expressly authorized by BIOTRONIK may perform corrective maintenance, enhancements or modifications to the device.

Replacement parts and accessories To ensure safety compliance, use only original replacement parts and accessories authorized by BIOTRONIK. Using any other parts voids the manufacturer's liability for any consequences, guarantee and warranty.

Defects Do not use defective or damaged devices.

Physician supervision The device should only be used under the constant supervision of a physician. During operation of the device, it is necessary to monitor the patient's heart rate and ensure that for each stimulation, the display of events and their results (using an external ECG monitor) is plausible.

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 ensure that in the event of an emergency the following basic equipment is available:

- Defibrillator
- Intubation set
- Oxygen
- Emergency drugs

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

Life support system Do not use this device as a life support system.

Liquids
- Never use a damp or wet device.
- Protect the device from the accidental ingression of fluids (e.g. infusion fluids).

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

External ECG device

During the implantation procedure, the patient's heart rate should be additionally monitored using an ECG monitor or ECG recorder.

Defibrillation

- When connected with the authorized ECG cable, the device is protected against defibrillation energy. Following a defibrillation, check all functions of the programmer.
- During defibrillation, do not touch the patient, the programmer the patient is connected to or the attached accessories. Otherwise, there is a danger that you may suffer an electrical shock.

Operating Conditions

Storage and transportation

- If the packaging 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. • Contact BIOTRONIK for testing and, if necessary, repair of the equipment.

Installation site

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

- No danger of explosion
- Suitable for medical purposes
- Class I power outlet with protection cable connection

Place the device on a flat, dry surface. It should be placed so that it can not slip even with the cable connected and so that the patient can only come into contact with the applied parts, namely the programming head and ECG cable.

Power supply

The device is operated via the 230 V / 50 Hz or 115 V / 60 Hz AC current of a room used for medical purposes. The electrical port must fulfill the following conditions:

- The network installation fulfills at least the requirements of IEC 60364-7-710:2002 group 1.
- The device cable feeds directly into a permanently installed socket. No portable power strips are connected in between.
- When used in combination with other devices, no portable multiple socket outlets should be used.
- Only those power connection cables can be used which are suitable for medical devices, e.g. BIOTRONIK power cords (see Accessories, p. 49) or power cords of equal value labeled H05VV 3 x 0.75 mm, H05VV 3 x 1 mm or SJT AWG18.

Cable and plug connections

- Replace any cable that shows even slight damage.
- Lay all cables between the patient and the device, as well as within the measuring apparatus, 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.
- As a general rule, cables should only be connected or disconnected when the device is switched off, unless expressly permitted in the corresponding section of this technical manual.
- 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 and when disconnecting the plugs, do not pull on the cable to release the lock.
- All lead connections are swap-safe and encoded at the lead connectors.

Patient environment

This device may be used in the patient environment.

Place the device on a flat, dry surface so that the patient can only come into contact with the applied parts, namely the programming head and ECG cable.

The physician must not touch any connections such as USB ports or interfaces for modules or the programming head and the patient at the same time.

Use with other devices

The device may not be used on the patient in conjunction with high frequency surgical equipment.

Start parameters and default settings

Once switched on, the device functions according to BIOTRONIK's default settings or the user-defined start parameters.

Note: In addition to BIOTRONIK's default start parameters, the user-defined start parameters can also be saved and recalled.

Electromagnetic Interference

Possible electromagnetic interference

The programmer is protected from disturbances resulting from electromagnetic interference, electrostatic discharges and other sources, including interference from cables. Simultaneously, the emitted interference has been reduced to a minimum. Thus the programmer conforms to the requirements of EN 60601-1-2 (in its valid form at the time of delivery).

However, 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 programmer in certain cases.

This kind of device malfunction should be considered if the following is observed:

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

Correct operation of the device can be restored with the following:

- Switch off the malfunctioning electronic device.
- Remove the source of interference from the device.
- Switch the programmer on and off or break the electrical connection between the device and the source of the interference as much as possible without causing any danger.

If the interference continues, contact BIOTRONIK immediately.

> **Note:** If accessories other than those specified by BIOTRONIK are used, increased interference or lower resistance to interference can be expected.

> **Note:** If accessories specified by BIOTRONIK are used on other devices, increased interference or lower resistance to interference can be expected.

> **Note:** Portable radio communication devices can interfere with the programmer functioning.

EMI test

The telemetry between the programming head and the implanted device can be impaired by electromagnetic interference (EMI). This can be observed when it becomes difficult or even impossible to interrogate or program the implanted device. Using the EMI test (refer to device software help), the source of the electromagnetic interference can be located and then turned off.

Maintenance, Care and Disposal

The following regulations are valid for the device.

WARNING
Exposure to fluids may result in fatal injury
Before cleaning and disinfecting device surfaces: Pull the power plug!

CAUTION
Danger of explosion if exposed to cleaning and disinfecting agents
Let cleaning and disinfection agents evaporate before operating the device.

CAUTION
May be damaged by cleaning agents
Strong and abrasive cleaning agents and other organic solvents, such as ether or benzine, corrode the surface of the device and must not be used.

Cleaning and disinfecting
- Use lint-free, soft cloths.
- Clean the housing with a damp cloth and mild soap solution or 70% isopro-panol.

  Disinfect with alcohol or aldehyde-based agents such as Aerodesin 2000, Fugaten spray, Lysoformin 2000 or Aldasan 2000.
- 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.
- To disinfect the patient cable and patient adapter, use a mixture of 70% isopropanol and 30% water oder Lysoformin 3000: Allow it to take effect for 15 minutes at 2% concentration.

Sterilization
- The device cannot be sterilized.

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 functional tests:
  — Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
  — Inspect cables and connection areas to ensure proper insulation, no breaks, etc.
  — Inspect that the stylus is in place
  — Inspect the labeling for legibility
  — Inspect the displays (e.g. time and date)
  — Simple electrical function test: switch the device on; an internal function test will be conducted automatically
  — If no error message appears, then no errors were found and the device can be used

Inspection The inspection consists of the regular safety inspection according to medical device standards. This ensures the safety of the device.

- The inspection must be performed
  - After using in conjunction with high-frequency surgical instruments or defibrillators
  - If malfunctions are suspected
  - Once a year
- This inspection can be performed by BIOTRONIK.
- The inspection should conform with the manufacturer specifications. These are available upon request. The specifications list all necessary test steps and the necessary equipment.

Changing a fuse The fuses are located above the power cord port in a fuse holder.

CAUTION
Mains voltage - risk of death from electric shock
Before changing the fuses, switch off the device and disconnect the power cord.

CAUTION
Risk of death from electric shock
Defective fuses may indicate a technical defect in the device. Conduct an inspection after changing fuses and before resuming operation of the device (see Inspection, p. 16).

Step	Action
1	To unlock the fuse holder, push the latches on the right and left inwards together.
2	Pull the fuse holder out.
3	Replace the old fuses with new ones of the same type (see Power cord port, p. 46).
4	Re-insert the fuse holder and ensure that it locks securely in place.

Disposal
- This device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE) applies.
- The symbol on the label – a crossed out garbage can – indicates that the device must be disposed of in accordance with the WEEE directive. The black bar indicates that the device was sold after the national implementation of the WEEE directive was enforced in your country.
- Return devices that are no longer used to BIOTRONIK.

Disposal of cables

Note: Cables to be disposed of due to contact with blood must be disposed of as medical waste, in accordance with environmental regulations.

Non-contaminated cables must be disposed of in accordance with the European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE).

3 Startup

Device Overview

Device in operating position

Bild 1: Device operating element in working position, viewed from the front right

Explanation of items Explanation of the individual items:

Item	Designation / description
1	Screen (touchscreen)
2	Device body
3	USB ports
4	ECG port
5	Slot for expansion module
6	Screen release button (right)
7	Fixation for carrying strap (right)
8	Pen holder

Item	Designation / description
9	PGH compartment lid release button
10	Printer buttons
11	Stylus in pen holder
12	Safe program button
13	Emergency shock button

Device in transport position

Bild 2:   Device operating element in transport position, viewed from the front left

Explanation of items   Explanation of the individual items:

Item	Designation / description
14	Carrying handle
15	Fixation for carrying strap (left)
16	Screen release button (left)
18	Paper tray for internal printer
19	On/off button
20	Power cord port and device fuse

PGH compartment
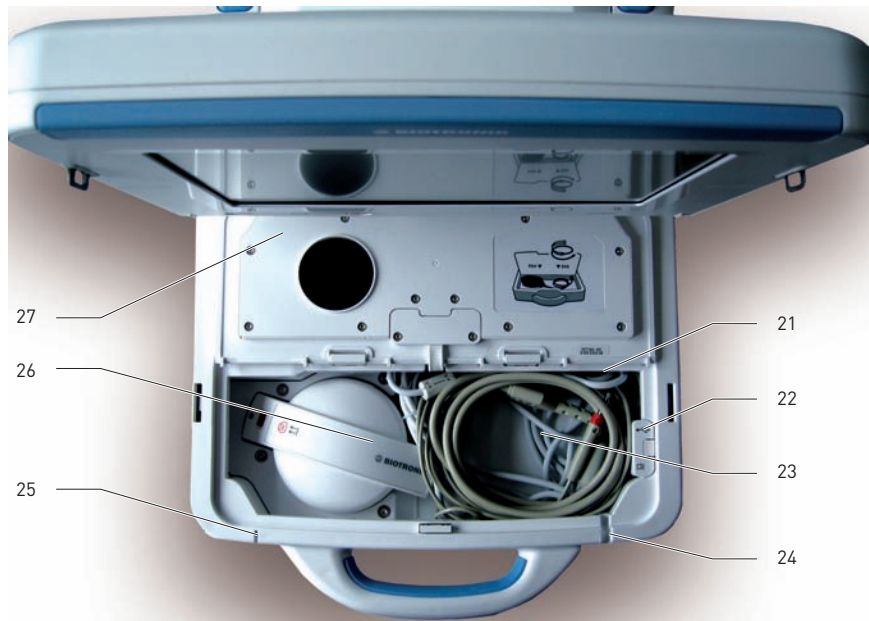
Bild 3:   Device operating elements, PGH compartment with lid open, viewed from above/in front

Explanation of items   Explanation of the individual items:

Item	Designation / description
21	PGH port
22	USB slot for Bluetooth USB adapter
23	PGH cable and ECG cable
24	Cable feedthrough for PGH cable
25	On/off LED
26	Programming head (PGH)
27	PGH compartment lid

Power cord storage compartment

Bild 4: Device operating elements, power cord storage compartment with lid open, viewed from above/behind

Explanation of items Explanation of the individual items:

Item	Designation / description
28	Anti-slip stand
29	Gripping tab
30	Power cord in power cord storage compartment
31	Power cord compartment lid

Transportation and Setup

Transporting the device
- Renamic has an integrated ergonomic handle in the front and a gripping tab in the back, which can be used to safely transport the device in any position.
- A carrying strap can also be attached to the device.
- The specially designed anti-slip pads allow for horizontal or vertical positioning of the device.
- When the device is slightly lifted (using the handle), the slick corners of the base allow for easy positioning on smooth surfaces (tables, shelves).
- After setting the device down, the anti-slip pads keep the device securely in place.

WARNING
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.

Setting up the device

WARNING
Danger to the patient
The device is not sterile and cannot be sterilized.
• Do not set up the device in a sterile area and do not position the device so that the fan blows air into a sterile area.

Note: The device can be operated in the patient's environment.

- Place the device on a flat dry surface. Make sure that it cannot shift even with the cable connected and that the patient can only come into contact with the applied parts, namely the programming head and ECG cable. The physician must not touch any connections such as USB ports or interfaces for modules or the programming head and the patient at the same time.

Tilting the screen up
- In transport position (screen closed), unlock the screen by pressing both release buttons at the same time. You can hear and feel the device unlock.
- Hold the sides of the screen with both hands and tilt it up to the position you would like to use it in (1).
- Pivot the screen around the upper end of the screen arm (2.). The operating position can be smoothly adjusted as needed.

  The screen will remain in any position due to its self-retaining bearings.

The two hinges of the screen arm allow for a wide range of working positions.
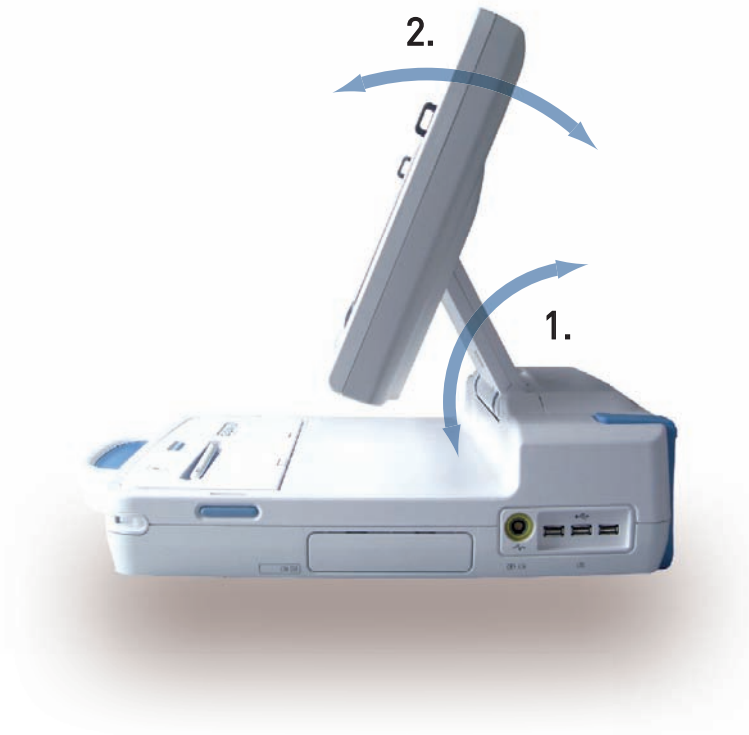

Bild 5:   Tilt radius of the screen and screen arm

Connections and Cables

Basic notes for cables and connections

> **Note:** Do not force the plugs into the ports. When disconnecting plugs, do not pull on the cable.

> **Note:** Only connect external devices that conform to DIN EN 60601 or DIN EN 60950 standards. Only then is the faultless functioning of the device guaranteed.

CAUTION

Allergic reactions and inflammations

Prevent the cable and programming head from coming into contact with the patient's wounds or skin.

Connect programming head

The PGH port is located at the top right of the device inside the PGH compartment. Refer to figure PGH compartment, p. 19, item #21.

- Pull the short end of the cable out of the PGH compartment and connect the PGH cable to the device PGH port.
- Feed the PGH cable through the PGH compartment cable feedthrough. Refer to figure PGH compartment, p. 19, item #24.

> **Note:** Since the device remains ready for operation in the transport position (screen flipped down and locked), the programming head can remain connected while the device is in this position.

Connect ECG cable

WARNING

Danger to patient by damaged cables

Damaged cables are limited in functionality and pose a danger to patients.

- Do not use damaged cables.

WARNING

Danger to the patient

Electrostatic potential differences can cause currents that are dangerous to the patient.

- Balance possible differences in electrostatic potential with the patient by touching the patient with your hand at a point a safe distance from the leads.

WARNING
Danger to the patient or user from electrical currents in surface ECG leads
Electrical energy that flows into surface ECG leads can cause injuries to the skin or cause an arrhythmia.
• The plugs of the ECG cables must not touch any conductive or grounded components, nor should they be inserted in electrical outlets or other connectors.
• Attach all PK-222 plugs on the patient end securely to the patient.
• Attach all unused plugs (e.g. if not all of the surface ECG connections are used) securely to the patient.

WARNING
Danger to patient from allergic reactions
If the cable comes into contact with open wounds, it can cause allergic reactions.
• Prevent the cable from coming into contact with open wounds.

WARNING
Danger from loss of function
Damp cables have limited functionality and pose a danger to patients.
• Do not use damp cables.

WARNING
Danger from electrical currents
Unused cable contacts can conduct electrical currents to patients.
• Adhere unused cable contacts close to the patient.

Note: The ECG port can be disconnected and reconnected while the device is still active.

Renamic can be used with the PK-222 ECG cable:
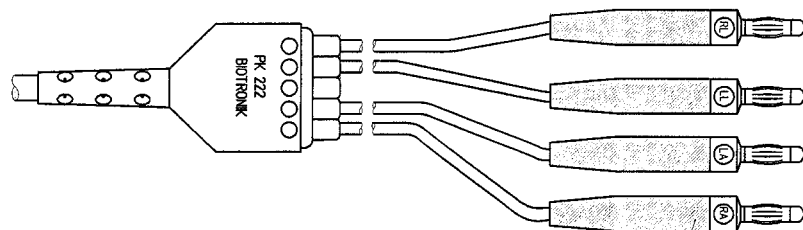
Bild 6:   ECG cable PK-222 with banana plugs for extremity leads (Einthoven)

The ECG cable PK-222 has

• Device: Redel plug, P series, 14-pole, 40°coded
• Patient: 4 color-coded banana plugs

Note: The PK-222 ECG cable is provided unsterile and cannot be sterilized. Follow the instructions on cleaning and disinfecting in section Maintenance, Care and Disposal, p. 15.

The ECG port is located on the back right of the device.

Bild 7:   Position of the ECG port

• Connect the ECG cable to the ECG port.

> **Note:** Cables to be disposed of due to contact with blood must be disposed of as medical waste in accordance with environmental regulations.

> **Note:** Information regarding approved adhesive and clamp leads for surface ECG electrodes can be found in section Optional accessories (compatibility with third party suppliers), p. 50.

Connection of USB devices   The device's USB ports are intended for connection to various compatible devices, e.g. a USB flash memory stick, an adapter for an external monitor or an adapter for a serial interface.

> **Note:** The USB flash drive used for data transfers must meet the Microsoft Bluetooth Stack standard.

> **Note:** The USB port can be disconnected and reconnected while the device is still active.

WARNING
Danger to the user when connecting non-conforming USB accessories.
Leakage currents can cause injuries to the skin or cause an arrhythmia.
• When using in combination with other devices, do not use portable multiple socket outlets, but connect all devices to fixed outlets in the same electrical circuit used for medical purposes.

CAUTION
Risk of exceeding the 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 applicable ISO, EN or IEC standards such as IEC 60601-1 or IEC 60950.
- Place devices that do not adhere to the IEC 60601-1 standard at least 1.5 m away from the patient.
- Before initial commissioning, check and document all device combinations according to IEC 60601-1 paragraph 16.6 for observance of leakage currents.

  You do not have to perform this inspection if the USB device is supplied via bus, which means it does not have its own power supply and has no electrically conductive connection to other devices or if it is connected to Renamic's USB port via an isolating separator (IEC 60601-1 paragraph 16.5) with a dialectric strength of at least 1.5 kV (e.g. isolating USB hub model UISOHUB4 made by B&B electronics).
- Perform this inspection at least once per year according to the legal requirements.
- Ensure that the leakage currents do not exceed the following maximum values when operating the device within the patient environment:
- Housing leakage current

  Normal condition: 0.1 mA
  Single fault condition: 1.5 mA
- Ground leakage current

  Normal condition: 0.5 mA
  Single fault condition: 1.0 mA
- Patient leakage current

  Normal condition: 0.01 mA= / 0.1 mA ˜
  Single fault condition: 0.05 mA= / 0.5 mA ˜
- Patient auxiliary current

  Normal condition: 0.01 mA= / 0.1 mA ˜
  Single fault condition: 0.05 mA= / 0.5 mA ˜

There are three USB ports located on the back right of the device and one in the PGH compartment (recommended USB port for the Bluetooth adapter).

Bild 8:   Position of the USB ports

- Connect the USB device or USB cable to the USB port.

Equipping the device with a Bluetooth adapter

If you equip the device with a Bluetooth adapter, various Bluetooth compatible devices can communicate wirelessly with the programmer.

BIOTRONIK supplies a compatible Bluetooth adapter with the programmer.

- Before using the Bluetooth adapter, ensure that it is authorized for Bluetooth radio communication in your respective country / region.

The recommended port for this Bluetooth adapter is located in the PGH compartment on the right hand side of the device underneath the protective cap. Refer to figure PGH compartment, p. 19, item #22.

We recommend connecting the Bluetooth adapter while the device is turned off.

- Open the PGH compartment and remove the protective cap from the port for the Bluetooth adapter.
- Connect the Bluetooth adapter to the USB port.
- Replace the protective cap over the Bluetooth adapter.

Power Supply

Power supply

The device is operated via the AC voltage of a room used for medical purposes:

- 100 – 115 V ±10% / 60 Hz / 1.2 A / AC
- 220 – 230 V ±10% / 50 Hz / 0.6 A / AC

Connecting the power cord to the device

The connection for the power supply is located on the back of the device on the left.
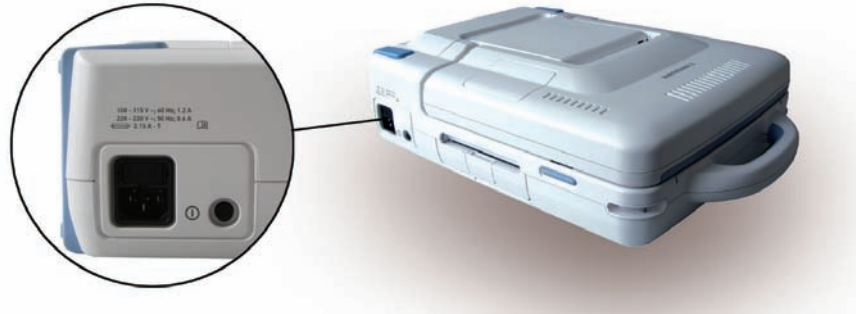
Bild 9:   Position of the power cord port

- Connect the provided power cord to the device's power cord port and then to a suitable power outlet.

Switching On and Off

Switching the device on The on/off button is located on the back left of the device.
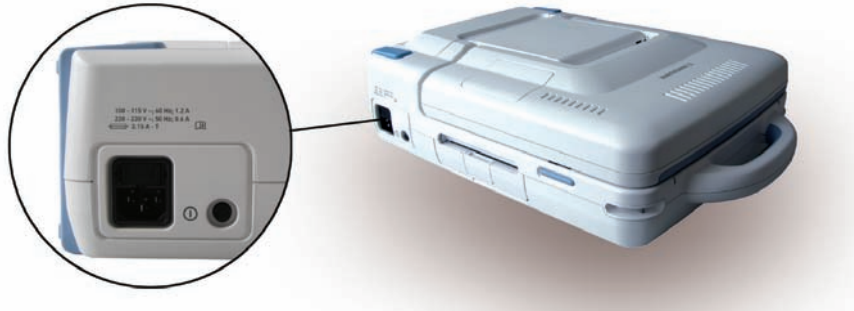
Bild 10:   The on/off button is positioned next to the power cord port.

- To switch the device on, press the on/off button once on the pressure point.
- The on/off LED on the front left of the device lights up.

  For the position of the on/off LED: refer toPGH compartment, p. 19, item #25.

> **Note:** The device can be switched on in both the working position (screen open) and in the transport positions (closed).
> The on/off LED is visible in both positions.

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 will also load.

Ready-for-service status, start screen 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 programming head is connected, the device has telemetry contact to an active implanted device and/or which other ports are occupied, then the start screen may display additional details.

Bild 11:   Start screen after successful booting of the operating system

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

Switching the device off
- To switch the device off, press the on/off button once on the pressure point or shut the device down using the software user interface.

CAUTION
Danger to data integrity
Sudden disconnection from the power source can lead to the corruption of data
• Only use the on/off button of the software user interface menu to switch the device off.

Note: The device does not switch off if you close the screen. Therefore, the device can be left in operating mode and put aside temporarily to save space. Pay attention to the connected cables. By reopening the screen, the programmer is immediately functional again.

4   Using Renamic

Keys, Displays and Signals

Keys on the device   The device has several keys to which fixed functions are assigned.

Overview of the device keys:

	Designation	Description
1	Emergency keys	• Safe program key to switch on the safe program of the implanted device (emergency pacing). The safe program comes into effect immediately (see: Emergency Programs, p. 33) • Emergency shock key to trigger emergency shock via the ICD. The emergency shock is delivered in 2 controlled steps (see: Emergency Programs, p. 33)
2	Printer keys	Keys for controlling the internal printer (see: Using the Internal Printer, p. 39)
3	On/off key	Key for switching the device on and off (see: Switching On and Off, p. 29)

• With the exception of the function for delivering an emergency shock, the respective function is activated by pressing the key once on the pressure point.

Position of the keys   The emergency keys are located on the front of the screen on the lower left.

Bild 1:   Location of the emergency keys

The printer keys are located on the left side of the PGH compartment lid.

Bild 2:   Location of the printer keys

On/off light indicator

The on/off light indicator shows whether the device is switched on (lit) or off (not lit).

It is located on the front left edge of the device. Refer to figure PGH compartment, p. 19, item #25.

Screen

The device screen is a touch screen that is operated using a stylus or finger.

The following is displayed on the screen:

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

Buttons on the screen

The individual functions can be selected using the software interface buttons on the screen. These buttons respond to touch or light pressure from the stylus or finger similarly to keys.

Signal beep

The device issues a sound when you press a key or button.

You can use the software program to switch off key and button sounds.

Emergency Programs

SAFE PROGRAM (EMERGENCY PACING):

Step	Action
1	Position the PGH above the implanted device so that telemetry contact is created.
2	Press the safe program button:

DELIVER EMERGENCY SHOCK:

Step	Action
1	Position the PGH above the ICD so that telemetry contact is created.
2	Press the emergency shock button:
3	In the dialog window, select **[EMERGENCY SHOCK]**.

Purpose of the emergency buttons

The emergency buttons are used for the following:

- They implement the parameters of the safe program (emergency pacing) by pressing a single button.
- They start emergency pacing or emergency shock.

WARNING
Danger to the patient from high electrical energies
High levels of electrical energy are conducted to the patient through the emergency programs.
• Only activate the safe program or emergency shock under the supervision of a physician.

Condition

The programming head creates telemetry contact between Renamic and the active implanted device.

Sequence

When the emergency buttons are activated, the following will occur:

- The current active programming in the implanted device will be deactivated.
- The corresponding emergency parameter values will be activated and the selected emergency program will start.

Location of the emergency buttons

Bild 3:   Location of the emergency buttons on the device

Start emergency pacing   Proceed as follows:

Step	Action
1	Position the PGH above the implanted device so that telemetry contact is created.
2	Press the safe program button:

Stop emergency pacing   Proceed as follows:

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

Trigger emergency shock   Proceed as follows:

Step	Action	Result
1	Position the PGH above the ICD so that telemetry contact is created.	Telemetry contact is created between the ICD and the Renamic programmer.
2	Press the emergency shock button:	• The emergency shock parameters are activated. • As a safety precaution, a dialog window will give you the option to cancel this action.
3	In the dialog window, select **[EMERGENCY SHOCK]**.	• The ICD shock capacitors are charged. • Renamic triggers a 30 or 36 J emergency shock via the ICD.

Parameter values   Tabelle 1:   Safe program default parameter values

Parameter	Value
Mode	VVI
Basic rate	70 ppm
Pulse amplitude	7.5 V
Pulse width	1.5 ms

Tabelle 2:   Emergency shock default parameter values

Parameter	Value
Shock waveform	Biphasic
Type	DF (defibrillation shock)
Energy	• 30 J • Implanted device with high engergy: 36 J

Programming Head

Bild 4:   Programming head (PGH) with connection cable

Prerequisites
- Connect the programming head to the Renamic programmer before you turn on the device (see: Connect programming head, p. 23).
- If you are using the programming head under sterile conditions, cover the programming head with a sterile cover (see: Scope of Delivery and Accessories, p. 49).

CAUTION
Risk to magnetically sensitive objects
The programming head contains a strong magnet.
• Do not place the programming head close to magnetically sensitive objects such as magnetic data media, credit cards or wristwatches.

Telemetry: Principle
Communication between the programmer and the implanted device takes place through telemetry via the programming head (PGH). The output data from the implanted device (digital and analog) are converted into digitally coded pulses and transmitted over an inductive coupling between the coils of the programming head and those of the implanted device.

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. Before the programming head and the implanted device can exchange data, the reed switch in the implanted device is closed.

When the reed switch is open, telemetry is blocked. This protects the implanted device from unintentional reprogramming. With some implanted devices, closing the reed switch also switches the device over to an asynchronous pacing program (see the technical manual of the respective implanted device).

Establishing telemetry Each programming head features arrows to assist in positioning the head. Silicone tines on the underside prevent the head from slipping.

Bild 5:   Position indicator for the programming head

- Place the programming head on the patient above the active implanted device so that the arrows are pointing toward the patient's head.

Tabelle 3:   Status display for telemetry contact

The LED at the front of the programming head indicates the telemetry contact to the implanted device:

LED status (flashing)	Telemetry status
Green	Telemetry contact optimal
Orange	Telemetry contact in limit range
Red	Telemetry contact disturbed
Off	No telemetry contact

Using the safe program The programming head is equipped with its own safe program button.

Bild 6:   Key for the safe program on the programming head

This function can be started immediately from any application if the programming head is positioned above the implanted device.

WARNING
Danger to the patient from high electrical energies
High levels of electrical energy are conducted to the patient by the emergency program.
• Only activate the safe program or emergency shock under the supervision of a physician.

Communication with Active Implanted Devices

Software

The interaction/communication between the Renamic programmer and active implanted devices is controlled using software specific to each implanted device.

- The software is installed on the Renamic device drive by BIOTRONIK employees.
- Software can only be updated on site by BIOTRONIK employees or by those authorized by BIOTRONIK.

Interrogating and program-ming the implanted device

BIOTRONIK implanted devices can communicate with Renamic in both directions via the programming head. As soon as the programming head is correctly posi-tioned over the implanted device, the program data and all data stored in the implanted device can be transmitted to the Renamic programmer.

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 Renamic programmer can detect obvious programming errors and requires that these errors be corrected before the program is trans-ferred to the implanted device.

The following programs can be transmitted:

- Permanent program
- Temporary program
- Safe program

A temporary program is a program that the pacemaker uses to provide temporary pacing as long as the programming head is in position.

A permanent program is a program that is programmed in the pacemaker using the programming head and which performs pacing permanently without telemetry contact to the programming head.

A safe program is a device-specific program used for safety pacing with high energy in either VVI or SSI mode.

> **Note:** 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:
> - Removing the programming head
>
> Or:
> - Switching off the programmer.

Data transfer

The follow-up data can be saved, sorted and/or exported as follows:

- Connect an external PC system for data processing (e.g., CDM 3000)
- Connect an external printer for printing out all data, with the exception of real-time ECGs
- Connect a USB flash drive

Reports

Internal printer for printing out the complete documentation:

- All follow-up reports such as program and test data as well as saved data
- All real-time ECGs, ECGs, IEGMs, event markers

Using the Internal Printer

The Renamic programmer has a high definition thermal printer that is capable of printing graphics. The device prints on thermal folding paper. See: Scope of Delivery, p. 49
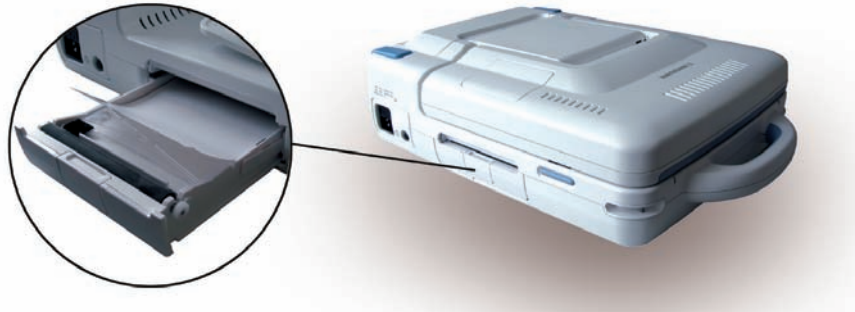
Bild 7:   Paper tray: position on the device

Note: The thermal paper printouts are moisture-sensitive and fade when exposed to strong sunlight. Make copies for permanent documentation.

Inserting paper   Proceed as follows:

CAUTION
Printouts that cannot be used or cause damage to the printer
The use of paper not intended for this device can lower the quality of the printout or cause damage to the device.
• Use paper specified by BIOTRONIK at all times. See: Scope of Delivery, p. 49.

Step	Action
1	To open the paper tray: • Open the lid by lightly pushing it up. • Pull the tray out until it stops. • In order to remove the tray from the device, press the lever down on the right side.

Step	Action
2	To insert paper: • Press back the separating flap. • Pull back the first page of the paper block. • Place the block of paper in the tray from above so that the wide marking of the paper block is on the left side. • Place the separating flap under the first sheet of paper. • Pull the first page over the separating flap and rubber roller.
3	To close the paper tray: • Push the tray back into the device until it stops. If there is too much paper in the tray and it is difficult to push it back into the device, then tear off enough paper and repeat the steps. • The cover locks automatically.

Note: The printer is ready for operation only when the paper tray has been inserted and closed.

Print   The printer buttons are located on the left front side.

Bild 8:   Printer buttons

Key assignment from left to right:

- You can use the numbered keys to switch on the printer with the respective printing speed in mm/s.
- Use the stop key to quit printing.
- The feed button is used to move the paper to the beginning of the next page. The feed mechanism automatically advances the paper to the next tear-off edge.

Using an External Printer

Prerequisites   You can connect an external printer to Renamic under the following electrical safety conditions:

- With the exception of the wireless connection, after the system has been installed in the hospital, compliance with the leakage current limit values according to IEC 60601-1, paragraph 16.6 must be demonstrated.

- The printer must be set up outside the patient environment (at least 1.5 meters away from the patient). You can use any printer that supports the PCL5 printer language and is compatible with a generic HP driver.

Configurations   In order to ensure electrical safety, it is only permissible to connect an external printer if one of the following conditions is met for the connection between the printer and Renamic:

- The printer is Bluetooth-compatible. The connection to Renamic is established using the accessory Bluetooth adapter (See Equipping the device with a Bluetooth adapter, p. 27).

- The printer is powered via the mains supply and is connected to the USB port of Renamic via an isolating separator (IEC 60601-1, Paragraph 16.5) with a dielectric strength of at least 1.5 kV (e.g. an isolating USB hub model UISOHUB4 by B&B electronics).

- The printer is supplied directly from the mains by a medical device power supply. Connect it to the USB port of Renamic.

ECG and IEGM Functions

Connecting the ECG cable

See section: Connect ECG cable, p. 23

ECG recorder and ECG monitor

All ECGs can be displayed in real time in the recorder or trigger mode and printed on the internal printer.

ECG leads

Tabelle 4:   Accessories for ECG leads

See also: Accessories, p. 49

Lead	Patient	Device
Up to 3 leads (Einthoven)	Permitted adhesive and clamp leads	PK-222

> **Note:** Follow the instructions for connecting the ECG cable PK-222 in section Connect ECG cable, p. 23.

> **Note:** It is not permitted to use the device's ECG display for diagnostic purposes because it does not meet all requirements for diagnostic ECG devices (IEC 60601-2-25).

Recording ECGs and IEGMs

The intracardiac electrograms received from the implanted device and the surface ECG can be displayed and printed simultaneously. The recording of the surface ECG is independent of other functions, so that the implanted device can be interrogated and programmed during the ongoing ECG display. The recorded electrograms can be saved and measured using electronic calipers.

Overmodulated ECG input

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

Step	Description
1	Test the lead contacts.
2	Remove other devices from the patient.
3	Turn off the sources of interference.

5 Appendix

Technical Data

Physical characteristics

Category	Design
Dimensions (W x D x H)	345 x 476 x 125 mm
Weight with cables and programming head	10,5 kg ± 10%
Housing material	PC/ABS

General classification

Category	Design
Classification	AIMD according to directive 90/385/EEC
Safety class	I
Protection rating	IP 30
Operating mode	Continuous operation

Longevity

Category	Design
Longevity	6 years

Ambient conditions

Category	Design
Temperature range for operation	+10°C ... +40°C
Temperature range for storage	0°C ... +50°C
Relative humidity	30% ... 75%, no condensation
Atmospheric pressure	700 ... 1060 hPa
Operation at altitudes	Up to 3000 m

Touch screen

Category	Design
Size	12.1'
Tilt	35 – 80 °
Resolution	800 x 600 SVGA
Contrast Ratio (CR)	200:1
Brightness	At least 150 cd/m

ECG module

Category	Design
Applied part classification	BF, defribrillation-proof with PK-222
Leads	3 (Einthoven)
A/D converter	12 bits
Scan rate	500 ... 1000 Hz
Interface	Redel plug, 14-pole

Programming head

Category	Design
Applied part classification	BF
Dimensions (W x D x H)	145 x 42 x 97 mm
Weight	0.3 kg
PGH cable	2.9 m
Protection rating	IP 30
Magnetic flux density	Max. 3 mT
Interface	Redel plug, 14-pole

Power cord port

Category		Design
Supply voltage		100 – 115 V, ±10% / 60 Hz / 1.2 A / AC
		220 – 230 V, ±10% / 50 Hz / 0.6 A / AC
Safety class		I
Fuse type		3.15 A; T; 250 V (G fuse IEC 60127 5 x 20 mm)
Max. power input	Duration	100 W
	Peak	150 W
Efficiency		> 75% (at 230 V/50 Hz)
On/off LED		Green LED, lit continuously

Mass storage

Category	Design
Type	Hard disk
Shock resistance	Min. 175 G (operating)
	Min. 700 G (non-operating)
Storage capacity	Min. 40 GB
Magnetic field resistance	50 mT

Internal printer

Category	Design
Type	Thermal printer
Printing width	4'
Resolution	8 Dots/mm
Paper	Z-fold
Paper format (B x L)	112 x 125 mm
Paper supply	200 + 10 sheets

MICS

Category	Design
Rate band	9 channels 402 – 405 Mhz
Range	300 kHz
Standard channel	403.65 MHz
Modulation	FSK
Encoding	Manchester
Data rate	32768, 16384, 8192, 4096, 2048 bit/s (unencoded)

GSM module

Category	Design
Model	GSM/GPRS quadband Motorola
Type	G24L bzw. G24
GSM rate	850 MHz, 900 MHz, 1800 MHz, 1900 MHz
Transmission power	2 W: 850/900 MHz 1 W: 1800/1900 MHz
GPRS	Multislot class 10 (4 Down, 2 Up)

UMTS module

Category	Design
Model	Motorola, 4 band GSM + 3 band UMTS
Type	H24
UMTS rate	850 MHz, 1900 MHz, 2100 MHz
GSM rate	850 MHz, 900 MHz, 1800 MHz, 1900 MHz
UMTS transmission power	0,25 W
GSM transmission power	2 W: 850/900 MHz 1 W: 1800/1900 MHz
UMTS	Max. Range: Uplink: 5.76 Mbps Downlink: 7.2 Mbps
	UE CAT [1-8], 11, 12 supported
	Compressed mode (3GPP TS25.212)
GSM	Multi-slot class 12 (4 down, 4 up, 4 total) Coding scheme: CS1–CS4

WLAN module

Category	Design
Transmitter rate	Europe: 2,412 GHz bis 2,472 GHz USA: 2,412 GHz bis 2,462 GHz
Max. transmission power	100 mW
Protocols	WEP, WPA, WPA2, HTTPS
Standards	IEEE 802.11b IEEE 802.11g
Channels	Europe: 13 channels USA: 11 channels

Scope of Delivery and Accessories

Scope of Delivery   Renamic (Order no.: 371960)

Item designation		Amount	Order no.
Renamic (single device)	WLAN module*	Customer-specific	379173
	GSM module*	Customer-specific	379174
	UMTS module*	Customer-specific	379366
	Without module	Customer-specific	365533
Programming head		1	371588
Power cord		1	Country-specific
PK-222-EU / 2.8 m or PK-222-US / 2.8 m		1	Country-specific
Bluetooth USB adapter		1	367929
Stylus		1	371586
Thermal printer paper		2	348728
PK Electrode Clip		1	340293
Multilingual technical manual (de, en, es, fr, it)		1	377213
Technical manual ZH (printed)		Country-specific	370975
Quick reference guide DE (printed)		Country-specific	370976
Quick reference guide EN (printed)		Country-specific	370977
Quick reference guide ES (printed)		Country-specific	370978
Quick reference guide FR (printed)		Country-specific	370979
Quick reference guide IT (printed)		Country-specific	370980
Quick reference guide ZH (printed)		Country-specific	370981
*Not available in all countries			

Accessories

Item designation	Description	Order no.
PK-222-EU / 2.8 m	ECG cable with banana plug for extremity leads according to Einthoven	335284
PK-222-US / 2.8 m	Same as the PK-222-EU with country-specific color coding of the banana plugs	335281
PGH ICD	Programming head without magnet with straight cable (2.9 m)	371589
NK-3	Power cord EU	107526
NK-11 (3 m)	Power cord US	128865
NK-16-GB (2 m)	Power cord for the United Kingdom	330705
NK-19-CN (2.5 m)	Power cord for Canada	339034
NK-21-AU,UY (2.5 m)	Power cord for Australia and Uruguay	339035
NK-22-AR (2.5 m)	Power cord for Argentina	339039
NK-26-CL, IT (2.5 m)	Power cord for Chile and Italy	339043
NK-28-DK (2.5 m)	Power cord for Denmark	339059
NK-25-CH (2.5 m)	Power cord for Switzerland	339042

Item designation	Description	Order no.
NK-27-IL (2.5 m)	Power cord for Israel	339044
NK-33-BR (2.5 m)	Power cord for Brazil	378933
Memory stick (compatible with Renamic)	USB flash memory stick for connection to the USB interface of the programmer; e.g. for data export	350017
USB adapter for serial interface	Virtual serial interface via USB	376437
USB adapter for VGA port	Virtual VGA interface via USB	377292
Sterile cover 1	Sterile cover for single use on programming head (cannot be re-sterilized)	118022
M 50	Permanent magnet; magnetic flux density: 12.5 min. in mT; dimensions (W x H x D): 60 x 17 x 26; weight: 0.185 kg (0.408 lb)	112149
Shoulder strap	Carrying strap that can be fixed to the Renamic hangers.	371962
Protective cover	Protective cover for Renamic	376999

Optional accessories (compatibility with third party suppliers)

Item designation	Manufacturer	Description
H34 SG	Kendall ARBO	Adhesive electrodes
T 60	SKINTACT	Adhesive electrodes
Type 454	Dahlhausen	Adhesive electrodes
Type 460	Dahlhausen	Adhesive electrodes
G 502	GOLMED	Clamp lead
Cruzer Micro	SanDisk	USB flash memory stick
USB 2.0 to DVI - VGA - HDMI adapter (61644)	DeLOCK	Visual VGA interface via USB
USB 2.0 to Serial (61425)	DeLOCK	Virtual serial interface via USB
G84-4400LUBDE-0	Cherry	Keyboard via USB
Mouse	Dell	Maus via USB
Passport II; 2.5'; 5400 RPM, 320 GB (WDXMS3200TE)	Western Digital	External hard drive via USB

Electromagnetic Compatibility in Compliance with EN 60601-1-2:2007

- As the user, you must ensure that the device is operated in a suitable electro-magnetic environment.

- The following guidelines may not be applicable in all cases. The propagation of electromagnetic values is, for example, affected by the absorption and reflection of structures, objects and people. This data is for your personal information.

	Devices with the warning sign "Beware of non-ionizing radiation" must not be operated in the environment of the device due to potential interferences.

Electromagnetic Emissions (Table 1)

Measuring the emitted interference	Compliance	Guidelines for the electromagnetic environment
RF interference according to CISPR 11	Group 1	The device uses RF energy exclusively for its own function. Therefore, the RF interference emitted is very low and not likely to cause any interference in nearby electronic equipment.
RF interference according to CISPR 11	Class B	The device is suitable for use in all establishments. This includes residences and facilities directly connected to the public power supply network that supplies buildings used for domestic purposes.
Interference of harmonic oscillations according to IEC 61000-3-2	Class A	
Emitted interference of voltage fluctuations according to IEC 61000-3-3	Complies	

Recommended safety distances (Table 6)

- Safety distances help prevent interference if you maintain a minimum distance between transmitters such as mobile RF telecommunication devices and the Renamic programmer. The necessary distance depends on the respective power output of the transmitter.

Note: At 80 MHz and at 800 MHz, the higher frequency range applies.

Transmission frequency	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Maximum output power of the transmitter [W]	Safety distance [m]		
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.70	3.70	7.40
100	11.7	11.7	23.4

- For transmitters whose maximum output power is not indicated in the table, the recommended safety distance [d] can be calculated in meters using an equation that is suitable for the respective transmission frequency range. P is the

maximum output power of the transmitter in watts [W] according to the specification of the transmitter's manufacturer.

Transmission frequency	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.34\sqrt{P}$

Resistance to electromagnetic interference (tables 2 and 4)

- When the measured field strength exceeds the specified compliance level at the operating location of the Renamic device, observe the device in order to determine whether it is functioning properly.
- If abnormal performance is observed, change the orientation or the location of the device. In the frequency range of 150 kHz to 80 MHz, ensure that field strengths are lower than 3 V/m.

Note: U_T is the mains alternating voltage before applying the test levels.

Test of resistance to interference	Test level according to IEC 60601-1-2	Compliance	Guidelines for the electromagnetic environment
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	Same as test level	• Operate the devices on floors made of wood, concrete, or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electric interferences (bursts) according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input and output lines	Same as test level	• Ensure that the power supply quality is that of a typical commercial and/or hospital environment.
Surges according to IEC 61000-4-5	±1kV push-pull voltage ±2 kV for common-mode voltage		
Voltage drops, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-1	<5% U_T for 1/2 cycle >95% drop 40% U_T for 5 cycles 60% drop 70% U_T for 25 cycles 30% drop <5% U_T for 5 s >95% drop	Same as test level	• Ensure that the power supply quality is that of a typical commercial and/or hospital environment. • If you require continued operation during power supply interruptions, connect the device to an uninterruptible power supply or use a battery for operation.
Magnetic field at the supply frequencies (50/60 Hz) according to IEC 61000-4-8	3 A/m	Same as test level	• Ensure that the magnetic field strengths are at levels characteristic of a location in a typical commercial and/or hospital environment.

Note: At 80 MHz and at 800 MHz, the higher frequency range applies.

Test of resistance to interference	Test level according to IEC 60601-1-2	Compliance	Guidelines for the electromagnetic environment
Conducted RF interferences according to IEC 61000-4-6	3 V_{eff}	3 V	• Maintain safety distance of mobile radio equipment to the Renamic programmer; see table 6.
Radiated RF interferences according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	• The field strength of stationary transmitting devices must be measured on site and must be lower than the compliance level at all frequencies: consider conducting a study of the site.
			• The field strength must be lower than 3 V/m over the frequency range of 150 kHz to 80 MHz.

Country-Related Information

UL certification	Renamic (Order no.: 371960) has been certified by Underwriters Laboratories Inc. in accordance with UL 2601-1 and CAN/CSAC22.2 No. 601.1-M90.

UL-certified devices are identified as follows:
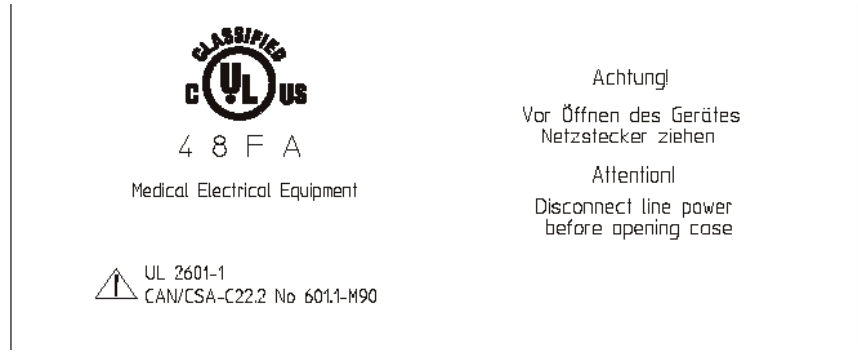
Distribution in the US and Canada	In the US and Canada, the device must be connected to a center-tapped power outlet if the voltage network carries 230 V at 60 Hz.

Identifications

Industry Canada:

- Renamic: 4708A-RENAMIC
- Programming head: 4708A-ICSPGH

    The code IC in front of the approval/registration number indicates that the technical requirements for Industry Canada are met.

Federal Communication Commission of the USA:

- Renamic: QRIRENAMIC
- Programming head: QRIICSPGH

Modifications which are not expressly approved by this company may void the rights to operate the devices.

FCC RF exposure requirements

Your device is equipped with a radio frequency (RF) transceiver for wireless communications. These communication are transmitted via an RF assigned by the Federal Communications Commission's (FCC) for Medical Implant Communications Service (MICS).

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 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.

Symbols on the Components

Symbols on the right side of the device

The symbols mean the following:

	ECG port with applied part classification BF, defibrillation-proof
	USB ports
	Binary interface (slot for expansion module)
	Follow the instructions in the technical manual!

Symbols on the left side of the device

The symbols mean the following:

	On/off button
	Fuse
	Follow the instructions in the technical manual!

Symbols on the monitor

The symbols mean the following:

	Caution!
	Emergency shock button
	Safe program button

Symbols on the PGH compartment

The symbols mean the following:

	Key for setting printer speed to 10 mm/s

	Key for setting printer speed to 25 mm/s
	Key for setting printer speed to 50 mm/s
	Key used to stop printing
	Feed button to feed the paper to the beginning of the next page

Symbols in the PGH compartment

The symbols mean the following:

	Programming head connection with applied part classification BF
	USB port
	Position and connection of the programming head and position of the ECG cable
	Follow the instructions in the technical manual!
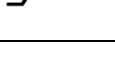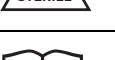
Symbols on the programming head

The symbols mean the following:
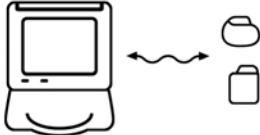
	Symbol for the safe program key
	Position indicator for the programming head

Legend for the Label

The label icons symbolize the following:

[icon: date box]	Manufacturing date
REF	BIOTRONIK order number
SN	Serial number
[icon: thermometer]	Acceptable temperature ranges for storage
[icon: pressure]	Acceptable atmospheric pressure range for storage
[icon: humidity %]	Acceptable relative humidity range for storage
NON STERILE	Non-sterile
[icon: manual i]	Follow the instructions in the technical manual!
[icon: open box]	Contents
[icon: damaged package]	Do not use if package is damaged!
CE	European approval mark
(!)	Country-specific restrictions concerning the circulation and implementation of the device
Rx only	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. European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE) applies. Return devices that are no longer used to BIOTRONIK.
	Programmer (Renamic) for electrotherapy implanted devices
	Cable and adapter
	Programming head
	Warning: Magnetic field

6 Directories

List of Keywords

P

R

S

T

U