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Revision: D (2011-04-26)
11-D-xx

380184

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BIOTRONIK
excellence for life

Cardiac Rhythm Management

External Devices

Gebrauchsanweisung

SafeSync Module

Erweiterungsmodul für Programmiergeräte zur drahtlosen Kommunikation

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Table of Contents

1 Introduction

What's in this chapter?

This chapter contains the following topics:

About the Device

General description

The SafeSync Module can be connected to the ICS 3000 and Renamic programmers and permits:

- A wandless telemetry connection (SafeSync RF telemetry) between the programmer and devices with the BIOTRONIK SafeSync function and
- Optional communication with networks via the cellular phone network or WLAN (depending on the software version of the programmer).

Devices with the BIOTRONIK SafeSync function are equipped with a special transmitter and receiver (1). This sends all the relevant information to the SafeSync Module (2), which then forwards the information to the programmer (3). The device also receives all information that the programmer forwards to the SafeSync Module for transmission.

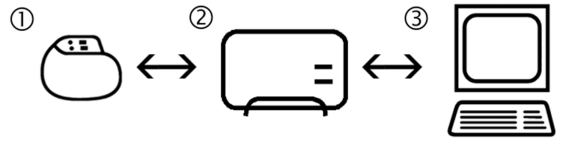

Fig. 1: SafeSync function principle

It is used during the implantation procedure and follow-up of implantable pacemakers and ICDs (implantable cardioverter-defibrillators) with the BIOTRONIK SafeSync function.

Primary function

The device extends the programming devices of BIOTRONIK to include the following functions:

Function	Purpose
BIOTRONIK SafeSync function	Wandless telemetry connection (SafeSync RF telemetry) for interrogating, testing and programming pacemakers and ICDs with the BIOTRONIK SafeSync function

Other functions (depending on the software version of the programmer)

The device extends the programming devices of BIOTRONIK to include the following functions:

Function	Purpose
Data transfer	Exporting the follow-up data in hospital or private practice networks
Update function	Downloading the latest, approved software version for the programmer from BIOTRONIK

About this Technical Manual

Objective

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

The following topics are covered in this manual:
- Device startup

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 with 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

To ensure the safe and correct use of the device, you must follow these additional instructions:
- The technical manual for the programmer
- Technical software manual for programming the intended implantable pulse generator / ICD
- Technical manual for the intended implantable pulse generator / ICD

2 Safety During Use

What's in this chapter?

This chapter contains the following topics:

Intended Medical Use

Intended medical use

During implantation or follow-up, the SafeSync Module establishes telemetry between a device with BIOTRONIK SafeSync function and the ICS 3000 or Renamic programmer.

Thus the programmer is able to perform the following without a programming head:

- 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
- Transferring parameters to the 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
- Danger to persons 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.

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.

Electromagnetic Interference

Possible electromagnetic interference

The programmer is protected from disturbances resulting from electromagnetic irradiation, electrostatic discharges and other sources. 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 unit passes on incorrect intrinsic events, which are displayed on the ECG, IEGM or marker channel (artifacts) of the programmer and monitoring device.
- 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 cut off the electrical connection between the device and the source of interference if this is 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

Telemetry between the SafeSync Module 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.

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

Place the unit on a flat, dry surface so that the patient cannot touch it. The unit should be placed so that it cannot slide – even with the cables connected.

Power supply

The unit is powered via the programmer's USB cable.

Cable and plug connections

- Replace any cable that shows even slight damage.
- Lay all cables 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 unit 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.
- Do not touch any connections such as USB ports or interfaces for modules and the patient at the same time.

- 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.

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 the device surface: Disconnect all USB cables!

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 soft, lint-free cloths.
- Clean the housing with a damp cloth and mild soap solution or 70% isopropanol.
- Disinfect with alcohol or aldehyde-based agents such as Aerodesin 2000, Fugaten spray, Lysoformin 2000 or Aldasan 2000.
- 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 or Lysoformin 3000: Allow it to take effect for 15 minutes at 2% concentration.
- Do not use the unit for about 1 hour after cleaning and disinfecting.

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 test:
  - Inspect the housing for mechanical damage, dents, loose parts, cracks, etc.
  - Inspect cables and connection areas to ensure proper insulation, no breaks, etc.
  - Inspect the labeling for legibility
  - Simple electrical function test: by connecting the unit, 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 use 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.

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

What's in this chapter?

This chapter contains the following topics:

Device Overview

Front view

Fig. 2: View of the unit from the front

Explanation of items

Explanation of the individual items:

Item	Designation / description
1	Status indicator for SafeSync RF telemetry
2	Status indicator for WLAN or mobile connection

Back view

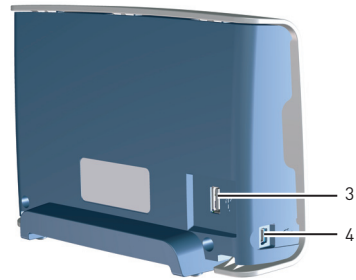

Fig. 3: View of the unit from the back

Explanation of items

Explanation of the individual items:

Item	Designation / description
3	Port for a USB printer or flash memory stick (functional only when using the ICS 3000)
4	Mini USB port to connect to the programmer.

Transportation and Setup

Transporting the device

- The unit can be transported in the included carrying case.

WARNING

Danger to the user

Danger of tripping over connected cables during device transport.

- Prior to transporting the unit, remove the attached cables and store them carefully.

Setting up the device

WARNING

Danger to the patient

The device is not sterile and cannot be sterilized.

- Do not set up the unit in a sterile area.

- Place the device on a flat dry surface. Make sure that the unit cannot slip even with the cables connected and cannot be touched by the patient. The physician must not touch any connections such as USB ports or interfaces for modules and the patient at the same time.
- Make sure that the distance between the SafeSync Module (2) and the patient (3) does not exceed 3 m and that the patient cannot touch the SafeSync Module (2).
- Make sure that the distance between the SafeSync Module (2) and the programmer (1) is at least 50 cm and does not exceed 3 m.

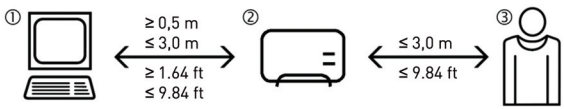

Fig. 4: Distance of the SafeSync Module from the programmer and from the patient

Connections and Cables

Basic notes for cables and connections

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 patient from allergic reactions

If the cable comes into contact with open wounds, it can cause allergic reactions.

- Prevent cables from coming into contact with open wounds and the patient's skin.

WARNING

Danger from loss of function

Damp cables have limited functionality and pose a danger to patients.

- Do not use damp cables.

Note:

- Cables to be disposed of due to contact with blood must be disposed of as medical waste in accordance with environmental regulations.
- Do not force the plugs into the ports. When disconnecting plugs, do not pull on the cable.

Connect

WARNING

Risk to the patient caused by interference with or termination of the ECG display.

Connecting or disconnecting the SafeSync Module from the programmer can result in interference with or termination of the ECG display.

- Do not connect the unit to a programmer during follow-up.
- Do not disconnect the unit from the programmer during follow-up.
- Do not remove the Operation Module from the ICS 3000 during follow-up.

Note: The SafeSync Module can be connected when the programmer is switched on.

The mini USB port for connecting to the programmer is located on the left side of the device.

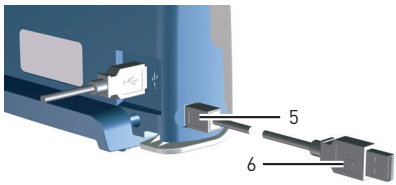

Fig. 5: Mini USB connector on the SafeSync Module

- Connect the mini USB connector (5) of the USB cable to the SafeSync Module and the USB connector (6) to the programmer.

If the programmer is switched on, the unit performs a self-test and the LEDs all light up yellow.

- After successful completion of the self-test, the LEDs all light up green.
- If the self-test is not successful, the LEDs flash yellow.

Note:

- You cannot connect more than 1 SafeSync Module to a single programmer.
- You cannot connect a SafeSync Module to another SafeSync Module.

Connection of USB devices

WARNING

Risk to the patient caused by interference with or termination of the ECG display.

Connecting or disconnecting USB devices to the SafeSync Module can result in interference with or termination of the ECG display

- Do not connect any USB devices to the SafeSync Module during follow-up.
- Do not disconnect any USB devices from the SafeSync Module during follow-up.

CAUTION

Damage to the USB port caused by connecting non-compatible USB devices.

Connecting non-compatible USB devices can damage the USB port.

- Only connect the USB devices listed below.

Only the following compatible devices can be connected to the unit's USB port:

- USB flash memory sticks with USB 2.0 and older USB standards
- Printers with USB 2.0 and older USB standard (battery-powered or mains-operated)

Note:

- Units that derive their power from the USB port may not require more than 100 mA.
- 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 IEC standard 60601-1:2005 or IEC 60950.
- Line-powered devices must comply with the standard IEC 60601-1:2005 or must be connected to the USB port via an isolating separator (IEC 60601-1:2005 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).
- Place devices that do not adhere to the IEC 60601-1:2005 standard at least 1.5 m away from the patient.
- Before initial commissioning, check and document all device combinations according to IEC 60601-1:2005 paragraph 16.6 for observance of leakage currents.
- Perform this inspection at least once per year according to the legal requirements.

An ECG port is located on the back left of the unit.

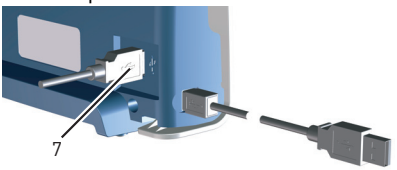

Fig. 6: Position of the USB port

- Connect the respective USB device (7) to the USB port.

Unit Handling

Indicators during operation

The LEDs provide information on the status of the SafeSync Module or the respective function.

LED behavior	Status
Both LEDs are constantly yellow	Self-test is being performed or the firmware of the SafeSync Module is being updated
The respective LED flashes yellow	Self-test not passed; function is not available
The respective LED is constantly green	The function is technically ready for use (but may be turned off in the programmer software)
The respective LED flashes green	The function is active and data is being exchanged with a device or network

Establishing SafeSync RF telemetry

The telemetry connection is controlled using the programmer software.

- The software is installed on the drive of the programmer by BIOTRONIK employees.

You can use the programmer's user interface to activate or disable the SafeSync function independent of the WLAN and cellular function. Both features can be activated, but you can not use both simultaneously. Using the user interface, you can either establish SafeSync RF telemetry with a device or set up communication with a network (depending on the software version of the programmer).

Establishment of the SafeSync RF telemetry depends on the respective device and the suitable location of the SafeSync Module.

- To establish SafeSync RF telemetry, proceed as described in the device's technical manual.
- Position the SafeSync Module using the user interface and the programmer's online help.

WARNING

Risk to the patient caused by termination of the ECG display.

Removing the Operation Module on the ICS 3000 causes termination of the ECG display, which may pose a risk to the patient.

- Do not remove the Operation Module from the ICS 3000 during follow-up.

WARNING

Risk to the patient due to higher power consumption in the device.

The SafeSync RF telemetry requires more energy and decreases the device's longevity.

- Only establish SafeSync RF telemetry if necessary.
- Check the device's battery capacity at regular intervals (refer to the online help for the programmer).

Interrogating and programming the device

The BIOTRONIK devices can communicate bidirectionally with the programmer. Once the telemetry connection has been established via the SafeSync Module, the program data and all data stored in the device can be transferred to the 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 programmer detects obvious program errors and requires these to be corrected before the program is transferred to the device.

The following programs can be transmitted:

- Permanent program
  A permanent program is a program that is programmed in the pacemaker and which performs pacing permanently without a telemetry connection.

- Temporary program
  A temporary program is a program that the pacemaker uses to provide temporary pacing as long as the telemetry connection exists.
- Safe program
  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:
- Disconnect the telemetry connection using the programmer's user interface.

Or:
- Switch the programmer off.

Establishing a WLAN or mobile connection (depending on the programmer's software version)

You can use the programmer's user interface to activate or disable the WLAN or cellular function independent of the SafeSync function. Both features can be activated, but you can not use both simultaneously. Using the user interface, you can either establish SafeSync RF telemetry with a device or set up communication with a network (depending on the software version of the programmer).

Establishing the WLAN or mobile connection depends on the respective network.

- To set up the WLAN or mobile connection, proceed as described in the programmer's online help.

4 Appendix

What's in this chapter?

This chapter contains the following topics:

Technical Data

Physical characteristics

Category	Design
Dimensions (W x D x H)	203 x 136.5 x 80 mm
Weight	approx. 450 g
Housing material	PC/ABS

General classification

Category	Design
Classification	AIMD according to directive 90/385/EEC
Safety class	IIb
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

MICS

Category	Design
Frequency band	9 channels 402 – 405 MHz
Bandwidth	300 kHz
Modulation	FSK

GSM module

Category	Design
Model	G24L or G24
Type	GSM/GPRS quadband Motorola
GSM frequency	850 MHz, 900 MHz, 1800 MHz, 1900 MHz
Max. power of transmission	2 W, 850/900 MHz
	1 W, 1800/1900 MHz
Max. bandwidth (Downlink)	GPRS (G24L/G24): 85.6 kbps
	EGPRS (G24): 270 kbps
GPRS	Multislot class 10

UMTS module

Category	Design
Model	H24
Type	Motorola, 4 band GSM + 3 band UMTS
UMTS frequencies	850 MHz, 1900 MHz, 2100 MHz
GSM frequencies	850 MHz, 900 MHz, 1800 MHz, 1900 MHz
Max. UMTS transmission power	0.25 W
Max. GSM power of transmission	2 W, 850/900 MHz1 W, 1800/1900 MHz

Category	Design
Max. bandwidth (Downlink)	UMTS: 7.2 Mbps UE CAT [1-8], 11, 12 supported Compressed mode (3GPP TS25.212)
	GPRS: 80 kbps
	EGPRS: 236 kbps
GPRS	Multislot class 12

WLAN module

Category	Design
Model	WiReach BK
Transmission frequencies	Europe: 2.412 GHz to 2.472 GHz
	USA: 2.412 GHz to 2.462 GHz
	Japan: 2.412 GHz to 2.484 GHz
Typ. transmission power	250 mA @ 16 dbm
	235 mA @ 12 dbm
Reports	WEP, WPA, WPA2, HTTPS
Standards	IEEE 802.11b, IEEE 802.11g
Channels	Europe: 13 channels
	USA: 11 channels
	Japan: 14 channels

Scope of Delivery

Scope of Delivery SafeSync Module (order no.: 37xxxx)

Item designation		**Amount**
SafeSync Module (single device)	WLAN module*	Customer-specific
	GSM module*	Customer-specific
	UMTS module*	Customer-specific
USB cable		1
Case		1
Protective cover		1
Multilingual technical manual (de, en, es, fr, it)		Country-specific
Multilingual technical manual (pl, tr)		Country-specific
Technical manual ZH (printed)		Country-specific
Quick reference guide DE (printed)		Country-specific
Quick reference guide EN (printed)		Country-specific
Quick reference guide ES (printed)		Country-specific
Quick reference guide FR (printed)		Country-specific
Quick reference guide IT (printed)		Country-specific
Quick reference guide PL (printed)		Country-specific
Quick reference guide TR (printed)		Country-specific
Quick reference guide ZH (printed)		Country-specific
*Not available in all countries		

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

- As the user, you must ensure that the device is operated in a suitable electromagnetic 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. There should be at least 20 cm distance between the device and the SafeSync Module to avoid interference with the device caused by the electromagnetic fields emitted by the SafeSync Module.

	Units with the warning sign “Transmitter with non-ionizing radiation at designated frequency” must not be operated in the environment of the device due to potential interference.

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.

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 M Hz**	**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%.

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

Testing 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. • 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.
Radiated RF interferences according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Legend for the Label

The label icons symbolize the following:

	Manufacturing date
	BIOTRONIK order number
	Serial number
	Temperature limit for storage
	Air pressure limit for storage
	Humidity limit for storage
	Non-sterile
	Consult the instructions for use
	Contents
	Do not use if packaging is damaged
	European approval mark
	Caution: Federal (U.S.A.) law restricts this product 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.
	SafeSync Module

Symbols on the Device

Symbols on the front side

The symbols mean the following:

	SafeSync RF telemetry
	WLAN or mobile connection

Symbols on the back

The symbols mean the following:

	USB port
	Consult the instructions for use

Symbols on the left side

The symbols mean the following:

	USB port

5 Directories

What's in this chapter?

This chapter contains the following topics:

List of Keywords

S

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