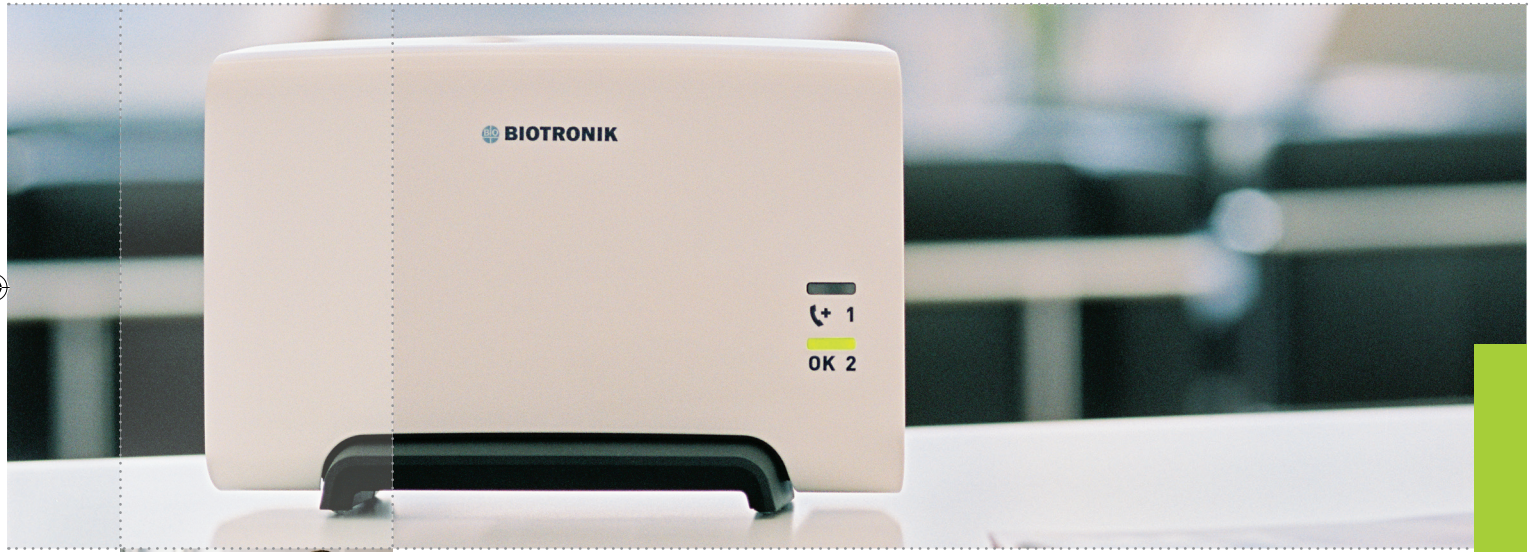
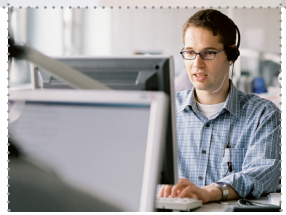
Technical Manual

CardioMessenger®II-S

Transmitter for BIOTRONIK Home Monitoring®





BIOTRONIK
excellence for life

2008-D-05

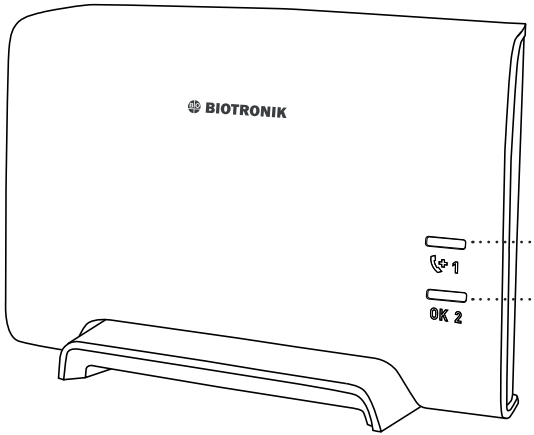
362454--D

BIOTRONIK GmbH & Co. KG
Woermannkehre 1
12359 Berlin · Germany
Tel +49 (0)30 68905-0
Fax +49 (0)30 6852804

BIOTRONIK, Inc.
6024 SW Jean rd. Bldg. B
Lake Oswego, OR 97035
Phone (800) 547-0394 (24-hr)
Fax (503) 635-9936

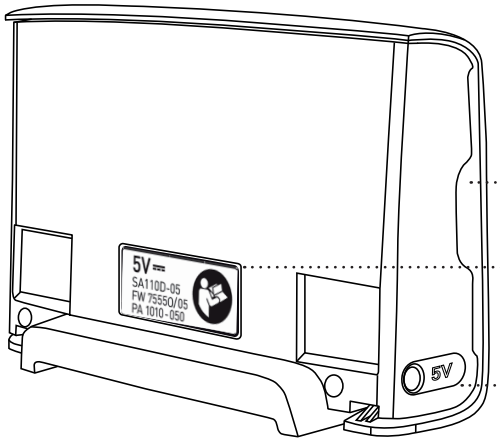
sales@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life



Call back light (yellow, page 14)

Operating light (yellow/green, page 13)



Slot for the brief instructions guide (page 12)

Use only original power supply units (page 9)

Connection for the power supply (page 9)

Contents

Introduction 3

How Home Monitoring works 3

Check the completeness of the delivery . . 5

Setup 7

Connection 9

Self-test 10

Insert brief instructions guide 12

Operate 13

Check lights 13

Call back function 14

Switch off the system 15

Debugging 16

Cleaning, maintenance, and disposal . . . 19

Precautionary measures 21

Guidelines 23

Technical data 27

Appendix 31

Index 37

Introduction

Dear patient:

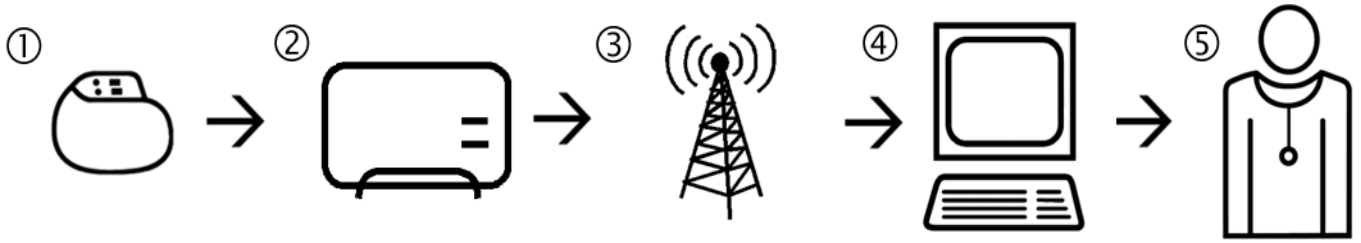
You have received a pacemaker or implantable cardioverter-defibrillator (ICD) with the additional Home Monitoring function by BIOTRONIK. With Home Monitoring, the state of your heart's health and your implant are surveyed on a daily basis while you are at home. Your physician can catch up at regular intervals on how your heart is doing.

How Home Monitoring works

Your implant is equipped with a special transmitter (1). Usually at night, the transmitter sends daily information on your heart to the patient device, your CardioMessenger (2).

The transmission power from your implant is low and does not impair your health in any way. Its limited transmission range, however, requires the use of the CardioMessenger.

The CardioMessenger collects the information received from the implant and automatically



transmits it to the BIOTRONIK Service Center (4) as encoded messages via a mobile connection (3).

Here, the messages are decoded and made available for viewing by your physician (5) on a protected web site.

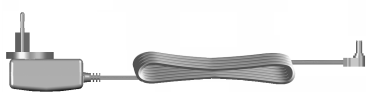
Based on the information received, your physician can decide if your implant is best configured, or if the therapy needs adjustments. In this way, Home Monitoring serves as a practical diagnostic aid to your physician.

Check the completeness of the delivery

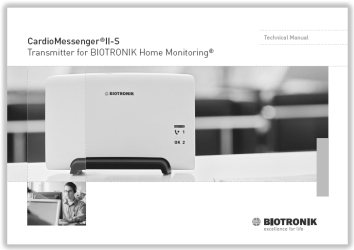
Check all components for visible damage before using them. Use only components which are undamaged.

The delivery includes the following:

CardioMessenger II-S



Power supply unit with electricity cable and DC plug



Technical manual with brief instructions guide

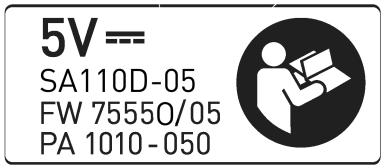
Warning!

Use the CardioMessenger only if it is undamaged. Return a damaged CardioMessenger to your physician.

Warning!

Use only the original parts included (for details, see "Technical data", page 27). Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the

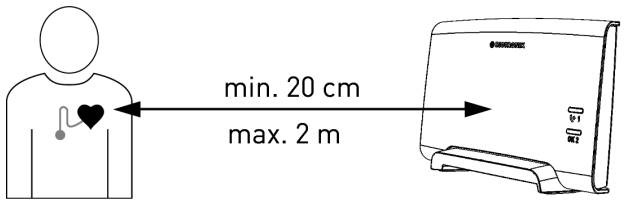
device's susceptibility to interference.
The label on the back side of the CardioMessenger indicates the approved power supply units:



Setup

Place the CardioMessenger on your bedside table. The bedside table is suitable because it usually meets the following conditions:

- The CardioMessenger is placed on a solid base and cannot fall.
- The distance to the implant is less than 2 meters so that regular data transmission at night is assured.
  At the same time is the distance to the implant more than 20 centimeters and the CardioMessenger has no influence on your implant.



Warning!

The distance between CardioMessenger and implant has to be at least 20 centimeters.

The CardioMessenger contains a mobile module ("Mobile"). In order to prevent any interferences of the implant, you have to keep the prescribed minimum distance between implant and cellular phone also to the CardioMessenger.

Please take the following also into consideration:

- Place the CardioMessenger in such a way that the lights can easily be viewed during the day. If the lights disturb you in your sleep, turn the CardioMessenger away from you. Do not place the CardioMessenger on the floor, next to, or under your bed.
- Do not place the CardioMessenger next to a television set, microwave oven, or a similar source of electromagnetic interference.

Note

If the CardioMessenger is too close to a loudspeaker (or a radio alarm or TV), you may hear interference noises typical for cellular phones.

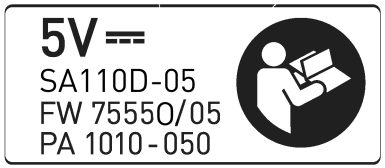
- Do not expose the CardioMessenger to temperatures exceeding 40 °C. Do not put it on a place with direct sun light and do not place it directly under a halogen spotlight.
- Do not expose the CardioMessenger to temperatures lower than 10 °C.
- Protect the CardioMessenger against water and high humidity. Do not place it in the bathroom.

Connection

Connect the CardioMessenger to the power supply. The outlet to be used has to be easily accessible. Use the supplied power supply unit with electricity cable and DC plug.

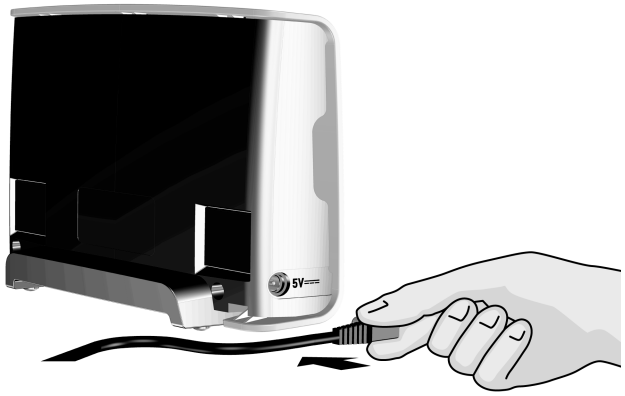
Warning!

Use only the original parts included (for details, see "Technical data", page 27). Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the device's susceptibility to interference.
The label on the back side of the CardioMessenger indicates the approved power supply units:



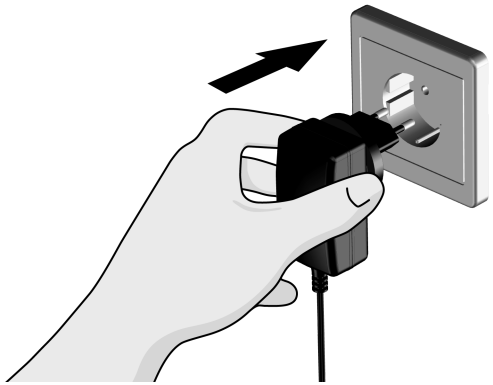
1. Connect the DC plug at the end of the electricity cable to the port on the left side of the CardioMessenger.

   The connector port is labeled with the following symbol: 5V ⎓



2. Connect the power supply unit to the outlet.

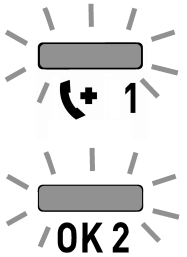
   See that the outlet is not controlled by a light switch. This will prevent you from turning off the CardioMessenger accidentally.



Self-test

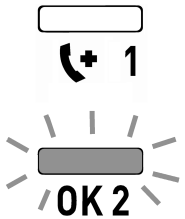
The CardioMessenger automatically conducts a self-test after being connected.

At first, both lamps on the front side of the CardioMessenger light up yellow for a short while.



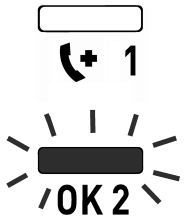
After about 10 seconds, the call back light will turn off.

Then the CardioMessenger checks the connection to the BIOTRONIK Service Center. Only the operating light illuminates yellow.



The connection check can take up to 15 minutes.

As soon as the connection has been checked successfully, the operating light illuminates green.



The CardioMessenger is now ready for use.

The CardioMessenger is intended for continuous operation. It should be connected at all times, especially at night.

Note

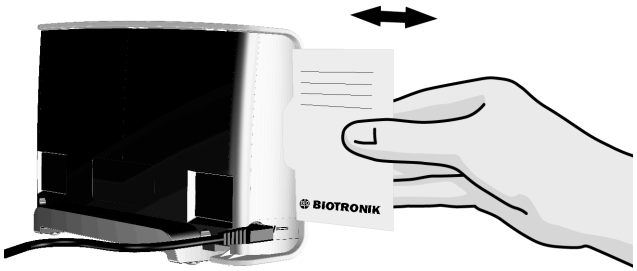
It is a sign of malfunction if the operating light remains illuminated **yellow** for more than 15 minutes or if it does not light up at all. Details on "Debugging" can be found on page 16.

Insert brief instructions guide

Attached to the back cover of this technical manual is a removable instructions guide.

This guide helps to inform you quickly about the function and colors of the lights. Additionally, you can list your physician's phone number at the back cover of this guide.

1. Remove the guide from this technical manual.
2. Write your physician's or the clinic's name and phone number on the back cover of this guide.
3. Insert the brief instructions guide into the slot on the left side into the housing of the CardioMessenger.



Now the brief instructions guide with your physician's phone number are ready at hand. Use it if the call back function of the CardioMessenger was activated by your physician. Details on "Call back function" can be found on page 14.

Operate

The CardioMessenger does not have an on/off switch. After connecting it, it is ready for use as soon as the operating light illuminates green.

It is intended for continuous operation and should remain connected at all times, especially at night.

The CardioMessenger automatically receives the information from your implant and transmits it to the BIOTRONIK Service Center.

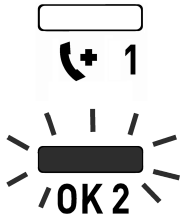
Note

It indicates a malfunction if the operating light illuminates **yellow** or does not light up at all. Details on "Debugging" can be found on page 16.

Check lights

Check once a day whether either of the two lights is illuminated.

Usually the operating light illuminates green. The call back light is not illuminated.



Note

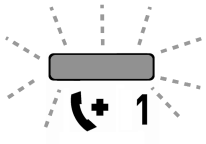
The functions of your implant are not affected at any time by the CardioMessenger, irrespective of the illumination or blinking of the lights.

See the next page for details on the subject "Call back function".

Call back function

With the aid of the call back light, your physician can ask you to call him. Via mobile network, he can turn the light on. The light will then blink yellow for a maximum time of 3 days.

The call back light blinks if your physician expects your call.



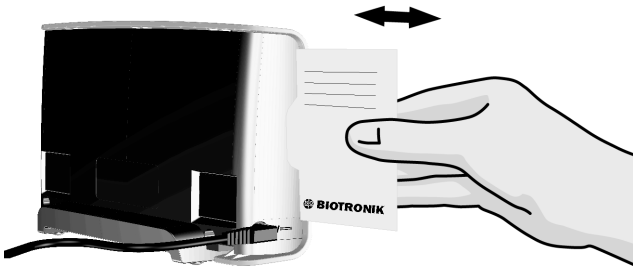
Your physician will let you know whether he or she intends to use this function in general.

Perform call back

Call your physician as soon as you realize that the call back light is blinking.

Note

The brief instructions guide with your physician's phone number is located in the housing of the CardioMessenger (see "Insert brief instructions guide", page 12).



Turn off the call back light

To turn off the call back light, disconnect the CardioMessenger briefly from the main supply.

1. Pull the DC plug at the end of the electricity cable out of the port on the left side of the CardioMessenger.

Both lights will turn off.

2. Connect the DC plug to the port again.

The CardioMessenger performs the self-test. Afterwards, the operating light will illuminate green and the call back light will no longer be blinking.

Note

Details on "Connection" can be found on page 9.

Switch off the system

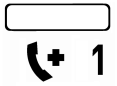
The CardioMessenger does not have an on/off switch. To turn off the CardioMessenger, disconnect it from the main supply.

1. Remove the power plug from the wall outlet.

The operating control lamp will turn out. The CardioMessenger is switched off.

Debugging

You can identify issues with your CardioMessenger by use of the lights on the front side.

Light	Behavior	Operating status
Call back light 	Off	Normal operation; **no malfunction**
	Yellow blinking	Your attending physician is asking for a call (Details on "Call back function" can be found on page 14.); **no malfunction**
	Yellow blinking	Error type B (both lights blink yellow): Repeat the self-test, see next page for further details
Operating light 	Off	Error type A: Check the power supply, see next page
	Green illumination	The CardioMessenger is now ready for use; **no malfunction**
	Yellow blinking	Error type B (both lights blink yellow): Repeat the self-test, see next page for further details
	Yellow illumination	Error type C (only this light illuminates): Check the mobile connection, see next page

Error type A
Check the power supply

The operating light is off. CardioMessenger is not ready for use.

Check the power supply:

- Make sure that the DC plug of the electrical cord is plugged in tightly into the port on the left side of the CardioMessenger.
- Make sure that the power supply unit is inserted properly into the wall outlet.
- Make sure that the outlet has current, for example by temporarily connecting the bedside lamp to the outlet and by turning the lamp on.

If you do not find any errors, contact your physician.

Error type B
Repeat the self-test

Both lights blink yellow. The CardioMessenger has not concluded the self-test. It is not yet ready for use.

1. Remove the power supply unit from the wall outlet.
2. Reconnect it.

The CardioMessenger restarts and performs the self-test. Both lights will illuminate yellow. The call back light will turn off once the self-test is complete. The operating light will remain illuminated yellow. Next, the CardioMessenger checks the connection to the BIOTRONIK Service Center. The operating light switches to green once the connection test is sucessful. The CardioMessenger is now ready for use.

If both lights stay permanently illuminated yellow, the CardioMessenger is defective. Return it to your physician.

Note

The connection check can take up to 15 minutes.

Error type C
Check the mobile connection

The operating light illuminates yellow continuously (longer than 15 minutes). The call back light is off. CardioMessenger cannot connect to the BIOTRONIK Service Center.

1. Remove the power supply unit from the wall outlet.
2. Put the CardioMessenger on a place with better mobile reception.

   Make sure that the distance to the implant is still less than two meters.
3. Reconnect the CardioMessenger.

The CardioMessenger restarts and performs the self-test. It checks the connection to the BIOTRONIK Service Center. The operating light switches to green once the connection test is sucessful. The CardioMessenger is now ready for use.

Note

The connection check can take up to 15 minutes.

If near your bed is a place where the CardioMessenger cannot get a connection to the BIOTRONIK Service Center in general, talk to your physician.

Cleaning, maintenance, and disposal

Cleaning

- Keep the CardioMessenger clean and away from dirty or dusty environments.
- Use a soft, lint-free cloth for cleaning.

Caution!
Disconnect the CardioMessenger from the main power supply before attempting to clean it with a moist cloth.

- Use a cloth wetted with water for cleaning. However, avoid bringing the CardioMessenger into direct contact with water or solvents.

Maintenance

The CardioMessenger is intended for continuous, automatic operation. Once correctly installed, ongoing actions by you are typically not required (e.g. no maintenance is required).

In continuous operation, the longevity of the contained button cell corresponds to the longevity of the CardioMessenger.

Disposal

Do not dispose the CardioMessenger in the usual household trash.

CardioMessenger and the power supply unit contain materials that must be correctly disposed of in accordance with environmental protection regulations.

If no longer required or if defective, please return the CardioMessenger and all other supplied parts to the physician. Your physician will return all parts to BIOTRONIK.

BIOTRONIK ensures the disposal in accordance with the national design of the European guideline 2002/96/EC on electric and electronic used devices (WEE).

Precautionary measures

The CardioMessenger is a medical device and therefore complies with strict requirements for their development, manufacture and testing.

Please take the following precautions:

Warning!

Do not operate the CardioMessenger in sections where cellular phones **are not permitted for safety reasons** (for example in certain hospital sections).

Warning!

The distance between CardioMessenger and implant has to be at least 20 centimeters.

This regulatory recommendation applies for cellular phones as well as for the CardioMessenger. The minimum distance assures that the CardioMessenger does not influence your implant.

Warning!

The device must be located outside the patient's vicinity if the intended user is to be introduced to the device in the hospital.

These legal requirements apply for electrical devices in hospitals and do not apply when the CardioMessenger is used at home.

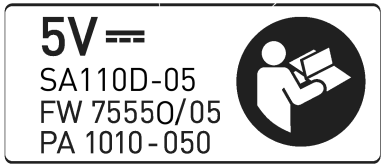
Warning!

Use the CardioMessenger only if it is undamaged. Return a damaged CardioMessenger to your physician.

Warning!

Use only the original parts included (for details, see "Technical data", page 27). Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the device's susceptibility to interference.

The label on the back side of the CardioMessenger indicates the approved power supply units:



Caution!

Protect the CardioMessenger from:

- Water and high humidity
- Temperatures above 40 °C (for example from direct sunlight and strong halogen spotlights)
- Temperatures below 10 °C
- Solvents, acids, detergents, and lyes

Caution!

The CardioMessenger may only be opened and repaired by authorized trained personnel.

Guidelines

USA

FCC RF exposure requirements

Your implant is equipped with a radio frequency (RF) transceiver for wireless communications to the CardioMessenger. These messages are transmitted via an RF assigned by the Federal Communications Commission's (FCC) Medical Implant Communications Service (MICS)[1)].

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.

This transceiver shall be used only in accordance with the FCC rules governing the Medical Implant Communications Service.

Analog and digital voice communications are prohibited. Although this transceiver has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transceiver will be free from interference.

1) Federal Communications Commission for Medical Implant Communications Service

The FCC ID number for the CardioMessenger is QRICM08V-1.

The FCC ID number for the GSM modem is IHDT56HQ1 for the CardioMessenger II-S/3 and IHDT56FV1 for the CardioMessenger II-S/4.

The integrated GSM module comply with the Grantees instructions for antenna configuration without having obtained a separate FCC equipment authorization for the module. New antenna configuration for that device will be considered unauthorized equipment.

Statement according to FCC part 2.1091:
The internal/external antennas used for this mobile transmitter must provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Statement according to FCC part 15.105:
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

— Reorient or relocate the receiving antenna.
— Increase the separation between the equipment and receiver.

— Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
— Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by this company could void the user's authority to operate the equipment.

Adress of responsible party:
BIOTRONIK, Inc.
6024 SW Jean rd. Bldg. B
Lake Oswego, OR 97035
Phone (800) 547-0394

Canada

The CardioMessenger is registered at Industry Canada with the following number: IC: 4708A-CM08V1.

The GSM modem is registered at Industry Canada with the following number: IC: 1090-FV1 or 1090-HQ1.

The term "IC:" before the certification/registration number only signifies that the Industry Canada technical specifications were met.

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.

Electromagnetic compatibility

Note

The CardioMessenger is protected from disturbances resulting from electromagnetic interference, electrostatic discharges, and other sources – including interference induced by cables. Interfering emissions from the CardioMessenger have been minimized. The CardioMessenger therefore meets the requirements of EN 60601-1-2 in every respect.

Warning!

Other equipment, including portable and mobile RF radiocommunications equipment may interfere with the CardioMessenger, even if this equipment complies with CISPR emission requirements. However, this possible interference does not affect the implant functionality.

Warranty

The CardioMessenger and all original components by BIOTRONIK are not subject to warranty when used improperly or stored and transported incorrectly. Use only the original packaging when shipping the device.

Technical data

General

- Operating mode: Continuous operation

Permissible Environmental Conditions

- Operating temperature: +10 °C to +40 °C
- Storage and transport temperature: -10 °C to + 60 °C
- Relative humidity: 30 % to 75 % (non-condensing)
- Atmospheric pressure: 700 hPa to 1060 hPa

CardioMessenger

- Type: CardioMessenger II-S
- Dimensions (WxHxD): approx. 203 x 136.5 x 80 mm
- MICS: Modulation FSK
- MICS frequencies: 402–405 MHz, 9 channels, 300 kHz frequency range
- MICS transmission power: 25 µW EIRP
- GSM: Modulation GMSK
- GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz, frequency range 9.6 kHz
- GSM transmission power: 2 Watts (850/900 MHz); 1 Watt(1800/1900 MHz)

Power supply unit

- Type: PowerBox PA 1010-050
- Dimensions (WxHxD): approx. 70 x 39 x 25 mm
- DC plug output:
  Outer diameter 5.5 mm (mass),
  Inner diameter 2.1 mm (plus)
- Input voltage:
  100–240 V ~ 50–60 Hz 400 mA
- Output voltage: 5 V DC ± 5 %, 2 A/10 W
- Safety class: II ⧈

or:

- Type: FRIWO MMP 15 FW7555O/05
- Dimensions (WxHxD): approx.
  51.5 x 87.5 x 34 mm
- DC plug output:
  Outer diameter 5.5 mm (mass),
  Inner diameter 2.1 mm (plus)
- Input voltage:
  100–240 V ~ 50–60 Hz 400 mA
- Output voltage:
  5 V DC ± 5 %, 2.4 A/12 W
- Safety class: II ⧈

or:

- Type: Nordic Power (SAC) SA110D-05
- Dimensions (WxHxD): approx. 69 x 45 x 35 mm
- DC plug output:
  Outer diameter 5.5 mm (mass),
  Inner diameter 2.1 mm (plus)
- Input voltage:
  100–240 V ~ 50–60 Hz 300 mA
- Output voltage:
  5.1 V DC ± 5 %, 2 A/10.2 W
- Safety class: II ⧈

Technical Manual

- Technical manual with brief instructions guide CardioMessenger II-S

Appendix

Electromagnetic emitted interference according to IEC 60601-1-2

The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

Measuring the emitted interference	**Compliance**	**Guidelines for the electromagnetic environment**
High-frequency interference according to CISPR 11	Group 1	The CardioMessenger uses RF energy only for its internal function. Therefore, the HF interference is very low and not likely to cause any interference in nearby electronic equipment.
High-frequency interference according to CISPR 11	Class B	The CardioMessenger is suitable for use in all areas, including living space and those areas that are directly connected to a public power supply system that also supplies buildings intended for residential purposes.
Interference of harmonics according to IEC 61000-3-2	Class A according to IEC 61000-3-2	
Voltage fluctuations/ flicker emissions according to IEC 61000-3-3	Complies	

Electromagnetic emitted interference according to IEC 60601-1-2

The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

Checking the interference resistance	**Test level according to IEC 60601-1-2**	**Compliance level**	**Guidelines for the electromagnetic environment**
Conducted RF interference according to IEC 61000-4-6	$3V_{eff}$ 150 kHz to 80 MHz	Same as test level	The minimum distance of the CardioMessenger from portable and mobile radio devices, including the cables, should correspond to the recommended safe distance that is calculated according to the equation for the suitable transmission frequency. Recommended safe distance: $D= 1.17\sqrt{P}$
Radiated conducted RF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Same as test level	$D = 1.17\sqrt{P}$ for 80 to 800 MHz $D = 2.34\sqrt{P}$ for 800 MHz to 2.5 GHz with P as the nominal output of the transmitter in Watts (W) according to the information from the transmitter manufacturer, and d as the recommended safe distance in meters (m). The field strength of stationary transmitting devices should be measured on site[a] and must be lower than the compliance level at all frequencies[b]. Interference can be generated when the CardioMessenger is close to devices that have the following warning sign: 
Note: The higher frequency range applies at 80 MHz and at 800 MHz. Note: These guidelines may not be applicable in all cases. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.			

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
   To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CardioMessenger is used exceeds the applicable RF compliance level above, the CardioMessenger should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CardioMessenger.
b) Above the frequency range of 150KHz to 80MHz, ensure that field strengths are less than 3V/m.

Electromagnetic emitted interference according to IEC 60601-1-2

The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

Checking the interference resistance	**Test level according to IEC 60601-1-2**	**Compliance level**	**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	Floors should be made of wood or cement, or have ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Rapid transient electrical disturbances/ bursts According to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	Same as the test level	The quality of the supply voltage should correspond to that in a typical business and/or hospital.
Surges voltages (Surges) According to IEC 61000-4-5	±1kV push-pull voltage ± 2 kV common mode voltage	Same as the test level	The quality of the supply voltage should correspond to that in a typical business and/or hospital.

Checking the interference resistance	Test level according to IEC 60601-1-2	Compliance level	Guidelines for the electromagnetic environment
Voltage drops, brief interruptions and fluctuations in the supply voltage According to IEC 61000-4-11	< 5 % U_T for 1/2 cycle (> 95 % drop) 40 % U_T for 5 periods (60 % drop) 70 % U_T for 25 periods (30 % drop) < 5 % U_T for 5 s (> 95 % drop)	Same as the test level	The quality of the supply voltage should correspond to that in a typical business and/or hospital. The CardioMessenger is powered by a battery. An interruption in the supply voltage to the power supply unit will not impair the functioning of the CardioMessenger.
Magnetic field at the supply frequencies (50/60 Hz) According to IEC 61000-4-8	3 A/m	Same as the test level	The magnetic field strength should correspond to the typical value in business and hospital environments.
Comment: U_T is the mains alternating voltage before applying the test levels.			

Recommended separation distances between portable and mobile RF communications equipment and the CardioMessenger

Transmission Frequency	**150 kHz to 80 MHz**	**80 MHz up to 800 MHz**	**800 MHz to 2.5 GHz**
Equation	$D = 1.17\sqrt{P}$	$D = 1.17\sqrt{P}$	$D = 2.34\sqrt{P}$
Rated power of transmitter (W)	**Safe distance (m)**	**Safe distance (m)**	**Safe 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	3,7	3,7	7,4
100	11,7	11,7	23,4

For transmitters whose maximum nominal output is not indicated in the above table, the distance can be calculated using the equation in the column, where P is the maximum nominal output of the transmitter in Watts (W) according to the transmitter's manufacturer.

Note: The higher frequency range applies at 80 MHz and at 800 MHz.
Note: These guidelines may not be applicable in all cases. The propagation of electromagnetic values is affected by absorption and reflection by structures, objects and people.

Index

A
Ambient conditions 27
Appendix 31

B
Bedside table 7
BIOTRONIK Service Center 4, 13
Blinking 14, 16
Brief instructions guide 12, 14
Broken CardioMessenger 21

C
Call back function 14
Call back light 10, 14
Call your physician 14
Care 19
Checking the mobile connection 10, 18
Checking the power supply 17
Clean it 19
Cleaning 19
Connection 9

D
Damaged CardioMessenger 5, 21
DC plug 5, 15, 28
Debugging 16
Defective CardioMessenger 21
Disposal 20
Distance to the implant 7

E
Electricity cable 5, 9, 15
Electromagnetic compatibility 26
Electromagnetic Emissions 31

G
Green light 10, 13, 16
Guidelines Canada 25
Guidelines USA 23

H
Home Monitoring 3
Hospital 21

I
Illumination 16
Implant 3,7

L
Light 1 10,13,14,16
Light 2 10,16

M
Maintenance 19
Mobile connection 4

O
Operate 13
Operating light 10,13,16
Original parts 5,27
Outlet 10

P
Package Contents 5
Perform call back 14
Physician call back light 16
Physician's phone number 12,14
Port for power connection 9
Power connection port 9
Power supply unit 5,9,28
Precautionary measures 21

R
Ready-for-service status 13
Recommended safe distance 36
Repair 22

S
Safety instructions 21
Self-test 10,17
Setup 7
Suitable installation location 7
Switch off the system 15
Switching on the system 13,15

T
Technical data 27
Transmitter of the implant 3,7
Turn off the call back light 15

U
Unsuitable installation location 7

W
Warranty 26

Y
Yellow light 10, 14, 16