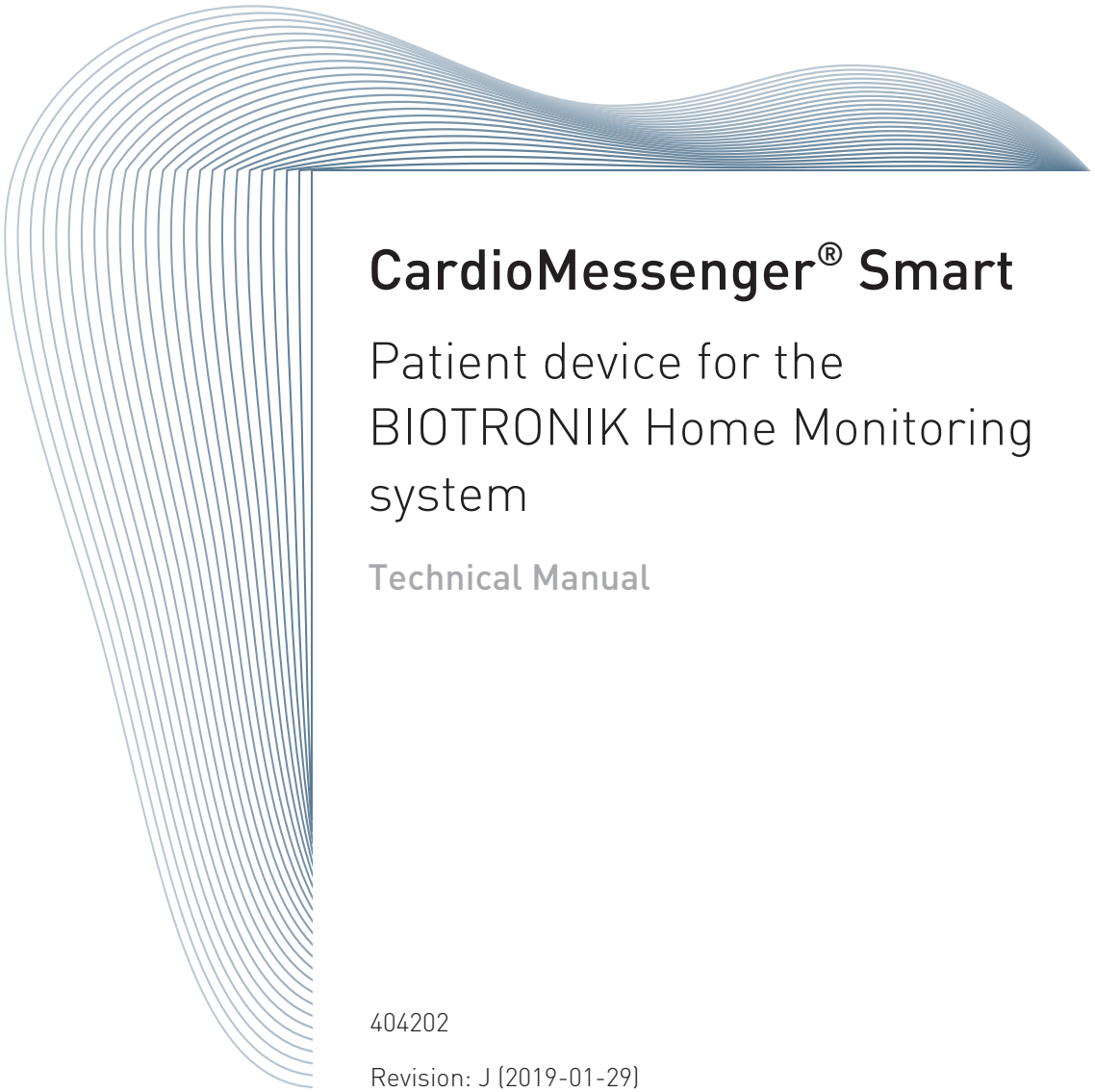

# CardioMessenger® Smart

## Patient device for the BIOTRONIK Home Monitoring system

Technical Manual

404202

Revision: J (2019-01-29)

BIOTRONIK
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CE 0123 2015

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# 1 Introduction

Dear Patient:

You have received a device with the additional Home Monitoring function by BIOTRONIK.

### How Home Monitoring works

Your device (1) is equipped with a special transmitter which sends cardiac information to your CardioMessenger (2). This usually happens at night.

The transmission power from your device 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 and transmits it to the BIOTRONIK Service Center (4) as encoded messages via a mobile connection (3).

Here, the messages are decoded and can be viewed by your physician (5) on a protected web site.


Usage of this additional data is specific to the patient and the implanted device. Your physician will explain to you how he or she will use the Home Monitoring function.

**⚠ Attention**

Home Monitoring is not an emergency system. If you are not feeling well, contact a physician.

# 2 First Steps

## Check the Package Contents

Your CardioMessenger is supplied ready for use, and you can operate it immediately by inserting the power plug into the wall outlet.

However, prior to usage, check the CardioMessenger and its accessories for any visible damage and use only undamaged components.

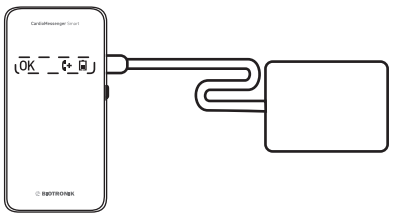
Return a damaged CardioMessenger to your physician.

Use only the provided original power supply brick (see the technical data).

Other equipment may impair proper functioning of the CardioMessenger and increase the emitted electromagnetic interference or decrease the CardioMessenger's resistance to electromagnetic interference.

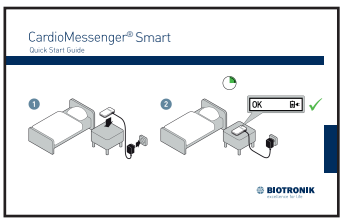
The product package includes the CardioMessenger (1) with power supply brick (2), the quick reference guide (3) and the technical manual (4).

(1)

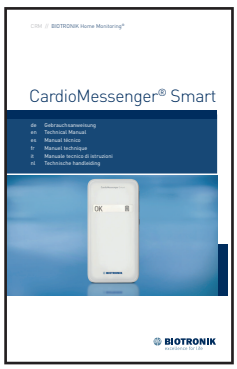


(2)

(3)



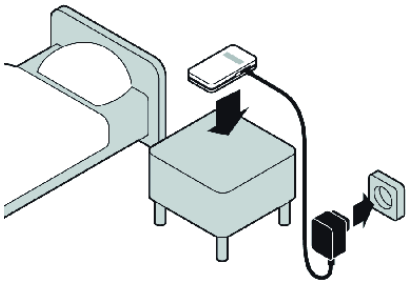

(4)




**WARNING**

The CardioMessenger package may contain ingestible small parts, therefore keep the package away from children under three years.

## Where Do I Put the CardioMessenger?



At night, the CardioMessenger should be placed close to your bed to ensure the nightly data transfer from the implanted device.

The bedside table is therefore the best location for your CardioMessenger, as it usually meets the following conditions:

- The CardioMessenger is placed on a solid base and cannot fall.
- The distance to the implanted device is less than 2 m (6 feet).
- Positioned on the bedside table, you can clearly see the symbols on the CardioMessenger's display.

**⚠ Attention**

Make sure that the distance to the device is less than 2 m (6 feet), so that regular data transmission from the implanted device to the CardioMessenger at night is assured. Verify on a daily basis that it is ready for use.

However, if the **bedside table is made of metal**, you should not place the CardioMessenger directly on the table. For example, place a stack of books to establish a distance of approx. 5 cm between the two so that the metal does not interfere with the device's data reception.

If you want to use the CardioMessenger in mobile operation, we recommend that you make a habit of charging it every night on the bedside table.

## How Do I Connect the CardioMessenger?

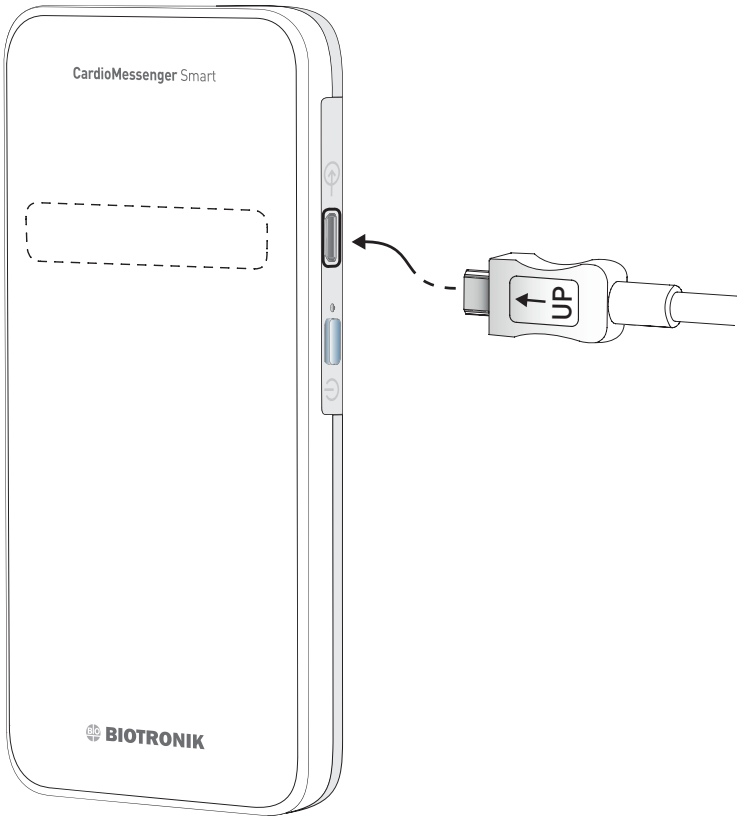
Your CardioMessenger is already configured and is ready for use. You can operate it immediately by inserting the power plug into the wall outlet. Also consult the included quick reference guide.

**⚠ WARNING**

- Lay the power cord so that there is no risk of strangulation and nobody may stumble.

The outlet must be easily accessible and not be connected to a light switch in order to prevent the CardioMessenger from accidentally being turned off.

Proceed as follows if the plug has been disconnected during removal from the package or during shipping:




1. Connect the small plug (micro USB plug) on the right to the CardioMessenger.
   The connector port is labeled with the following symbol:
   
2. Make sure that the marking is on the upper side of the plug.
3. Insert the power plug into the wall outlet.

The CardioMessenger now turns on automatically and performs a self-test.

The CardioMessenger is ready for use once the self-test is completed and the following icons are displayed:


If this is not the case, please refer to: Error Resolution [Page 12].

## How Do I Use the CardioMessenger?

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

**⚠ Attention**

Check once a day whether your CardioMessenger is switched on and ready for use.

This is indicated by the following icons:

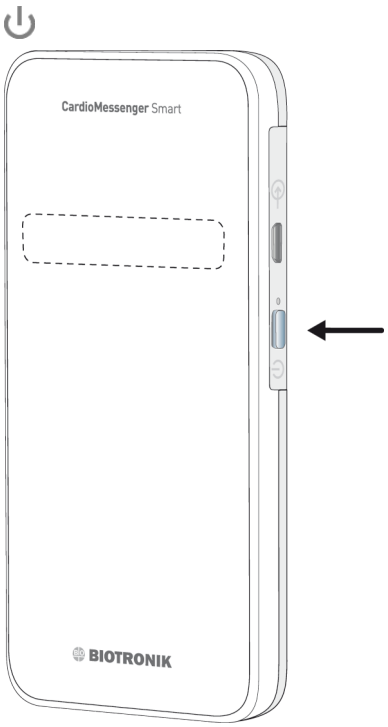
## How Do I Turn Off the CardioMessenger?

Since the CardioMessenger contains a mobile ("cellular") module, you may need to switch off the CardioMessenger for safety reasons in areas where the use of mobile phones is prohibited (e.g., in an airplane).

Such areas can be identified by the following or similar signs:

Press and hold the blue key on the right of the CardioMessenger for two seconds until the display turns off.

The blue key is labeled with the following symbol:




**⚠ WARNING**

If the CardioMessenger is turned off for a longer period of time, data may get lost.

- Turn on the CardioMessenger once you are leaving the area where the use of mobile phones is prohibited.

In some locations, the use of cellular phones is prohibited to provide quiet zones (e.g., in a theater or cinema). As the CardioMessenger is silent, it does not need to be turned off in such locations

The functions of your implanted device are not affected by the CardioMessenger at any time.

Your implanted device remains fully functional even if the CardioMessenger is not ready for use.

# 3 The CardioMessenger Icons

| The CardioMessenger has the following icons: | |
|---|---|
| OK | Operation icon |
|  | Call back icon<br>See Call Back Function [Page 11] |
|  | Information icon<br>See Error Resolution [Page 12] |
|  | The battery icon is always displayed with 1-3 bars according to the charging status. |
|  | When the CardioMessenger is connected to the power supply brick and charging, a battery icon with a small power plug is displayed. |

# 4 Functions

## Self-Test

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

All icons on the CardioMessenger are displayed.


The CardioMessenger then checks the connection to the cellular phone network.

The operation icon flashes and the battery icon is displayed.


The connection test can take up to 15 minutes.

Once the connection is established, the operation and battery icons remain permanently activated.


The CardioMessenger is now ready for use.

If the connection **was not** established, the information icon flashes.

Additional information can be found under: Error Resolution [Page 12].

## Call Back Function

The call back function is an additional function that your physician can use in different ways. You will be informed by your physician if and how he or she will use this function.

For example, your physician can use the call back icon to ask you for a call. Your physician can turn on the icon via the cellular phone network. It will then flash for a maximum of three days.

Contact your physician during office hours as soon as you notice that the call back icon is flashing.


**⚠ Attention**

Check once a day whether your CardioMessenger is switched on and ready for use.

### Turning off the call back icon

To turn off the call back icon, briefly turn off the CardioMessenger.

1. Press the blue key on the right side of the CardioMessenger for about two seconds.
2. All symbols disappear.
3. Wait approximately thirty seconds.
4. Press the blue key again for approximately two seconds.
5. The CardioMessenger performs a self-test.
6. The operation and battery icon is then displayed, and the call back icon stops flashing.


However, please do not forget to call your physician.

If the CardioMessenger is connected to the power supply brick, it starts automatically. You neither have to wait nor switch it on.

# 5 Error Resolution

If your physician contacts you because device messages are not being received but your CardioMessenger was ready for use during the period in question, you should remove possible sources of electromagnetic disturbance from the immediate vicinity of the CardioMessenger.

Possible sources of electromagnetic disturbance can be communication devices such as wireless home network equipment, cellular phones, cordless phones, and their base stations.

According to the standard IEC 60601-1-2: 2014 a distance of 0.3 m is recommended (for further details see: Appendix [Page 25]).

Malfunctions on the CardioMessenger are indicated by the icons.

| Symbol | Behavior | Operational status |
|---|---|---|
| | Off | Error type A: No power supply |
|  | Flashing | Error type B: Self-test failed |
|  | Flashing | Error type C: No mobile connection |

## Error Type A - No Power Supply

The operation icon is not displayed, that is, the CardioMessenger is not ready for use.

Make sure that

- the micro USB plug is properly inserted into the CardioMessenger,
- the power plug is properly inserted into the wall outlet,
- the outlet provides an electrical current, for example by temporarily connecting the bedside lamp to the outlet and turning the lamp on.

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

## Error Type B - Self-Test Failed

All symbols are flashing, thast is the CardioMessenger is not ready for use.

Repeat the self-test as the CardioMessenger did not finish it.

1. Disconnect the CardioMessenger from the power supply brick if relevant.
2. Press the blue key on the right side of the CardioMessenger for about two seconds.
3. Leave the CardioMessenger turned off for about thirty seconds.
4. Turn on the CardioMessenger by connecting it to the power supply.

The CardioMessenger starts and automatically repeats the self-test. When the self-test is completed, the CardioMessenger is ready for use.

The connection test can take up to 15 minutes.

If all symbols continue to flash, the CardioMessenger is defective. Return it to your physician.

## Error Type C - No Mobile Connection

The information icon flashes and the battery icon is displayed.

Check the mobile connection since the CardioMessenger cannot connect to the BIOTRONIK Service Center.

1. Press the blue key on the right side of the CardioMessenger for about two seconds.
2. Put the CardioMessenger in a place with better mobile reception. Make sure that the distance to the device is still less than 2 m (6 feet).
3. Press the blue key again for approximately two seconds.

The CardioMessenger restarts and performs the self-test. It checks the connection to the cellular phone network.

The connection test can take up to 15 minutes.

The operation and battery icon is displayed once the connection test is completed successfully. The CardioMessenger is now ready for use.

If the CardioMessenger is generally unable to connect to the cellular phone network from near your bed, contact your physician.

Missing cellular phone network connection can occur in rooms with thick walls or when travelling.

# 6 Handling

The CardioMessenger is intended primarily for continuous operation at home because it receives information from your implanted device once daily, usually at night, and forwards it to the BIOTRONIK Service Center.

If handled properly, the installed battery should supply the CardioMessenger with 16 hours of power even after 500 complete charging cycles (which is at least two years).

The CardioMessenger contains a mobile ("cellular") module. In order to prevent any interference with your implanted device, the prescribed minimum distance between the device and a cellular phone must also be maintained with the CardioMessenger.

**⚠ Attention**

The distance between the CardioMessenger and the implanted device must be at least 15 cm (6 inches) so that the CardioMessenger does not interfere with the device.

To disconnect the CardioMessenger from the alternating current supply, pull the power supply brick plug out of the socket.

## Charging

If you want to use the CardioMessenger in mobile operation, we recommend that you make a habit of charging it every night on the bedside table.

You should charge the CardioMessenger once before the first mobile commissioning. To do this, connect the CardioMessenger to the mains supply. The charging process usually takes three hours.

**⚠ WARNING**

Do not charge the CardioMessenger with the power supply brick in the outdoors.

**⚠ WARNING**

At the very latest, the CardioMessenger must be charged when the battery icon flashes.

During charging, the individual segments of the battery icon flash alternatingly and a small power plug is displayed.

The three bars on the battery icon flash successively until the CardioMessenger is fully charged. Once it is fully charged, all three bars are completely filled.

**Note**

The CardioMessenger can be used with the power supply brick if the battery is defective.

Even if the battery is completely discharged, the CardioMessenger can still operate using the power supply brick.

## Cleaning

Keep the CardioMessenger clean and away from dirty or dusty environments.

Use a soft, lint-free cloth for cleaning.

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

Protect the CardioMessenger from direct contact with water.

Unplug the CardioMessenger from the power supply brick before cleaning it with a damp cloth.

## Maintenance

The CardioMessenger is intended for continuous, automatic operation. Once correctly installed, ongoing maintenance typically is not required.

## Disposal

Do not dispose of the CardioMessenger with your household trash.

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

You may dispose of the CardioMessenger and its associated power supply brick as electronic waste in accordance with the applicable regulations if you no longer use it.

The CardioMessenger and all the parts from the package can be returned to your physician. Your physician will return all parts to BIOTRONIK.

BIOTRONIK ensures disposal in accordance with the national versions of the European guideline 2012/19/EC on waste electrical and electronic equipment (WEEE 2).

# 7 Precautionary Measures

The CardioMessenger is a medical product and therefore complies with the strict requirements for the development, manufacturing, and testing of medical devices.

Statutory regulations for electrical devices in hospitals require that the CardioMessenger and its accessories not be used in areas defined as patient environment (e.g., in the operating room).

Please observe the following safety-relevant notes:

- Do not place the CardioMessenger next to a television set, microwave oven, or a similar source of electromagnetic disturbance.

  You may hear noises typical of cellular phones if you place the CardioMessenger too close to a radio alarm or a television set, for example.
- Protect the CardioMessenger from direct contact with water. For example, wear it under your coat or keep it in a bag when it rains.
- Do not carry the CardioMessenger inside the breast pocket of your shirt or jacket as the distance from here to the implanted device could be less than 15 cm.
- Do not bring the CardioMessenger into the vicinity of fire.
- Do not turn on the CardioMessenger if it has recently been in a cold environment. Let it warm up slowly to room temperature, since the resulting condensed water may harm the electronic circuitry.
- Do not operate the CardioMessenger in areas where cellular phones are prohibited for safety reasons (for example, in certain areas of the hospital or in airplanes).
- Make sure that the distance to the device is less than 2 m (6 feet), so that regular data transmission from the implanted device to the CardioMessenger at night is assured.

Protect the CardioMessenger and the power supply brick from:

- Water and high humidity
- Temperatures above 40°C (104°F) (e.g., direct sunlight, strong halogen spotlights, fire)
- Temperatures below negative 5°C (23°F; CardioMessenger) and below 0°C (32°F; power supply brick)
- Solvents, acids, detergents, and lyes
- Pressure below 700 hPa (corresponding to altitudes above 3000 m, approx. 10,000 feet)
- Pressure above 1060 hPa (corresponding to altitudes below sea level)
- Violent shocks or other strong mechanical influences
- Intense light sources (direct sunlight, strong halogen spotlights)

# 8 Guidelines

## Telemetry Data for Europe

Your device transmits diagnostic data to the CardioMessenger via a radio frequency (RF) assigned by the European Conference of Postal and Telecommunications Administration for the operation of Ultra Low Power Active Medical Implants (CEPT/ERC REC 70-03).

BIOTRONIK is legally obligated to inform you that the radio service does not have exclusive use of the assigned frequencies and that the transmission of device data is not permitted to interfere with other radio services. The frequency and technical parameters of the built-in transmitter have been carefully selected to ensure that electromagnetic interference between other services and the data transmission of the device is unlikely.

Furthermore, BIOTRONIK is obligated to inform you that the regulatory agency can withdraw the frequency allocation and prohibit the radio service between the device and CardioMessenger. Since this service is currently established throughout Europe and North America, withdrawal of the frequency allocation is not expected in the foreseeable future.

The CardioMessenger, like the implantable device itself, has been evaluated by an independent testing authority for its compliance with statutory regulations. The CardioMessenger carries the following approval mark: CE 0123

In addition, the CardioMessenger contains a radio modem that connects to the cellular network at the frequencies of 850/900/1800/1900/1900 MHz. BIOTRONIK uses the radio modem in accordance with the manufacturer's specifications and in compliance with the approval requirements.

The radio modem has been evaluated by an independent authority for its compliance with the statutory regulations. As an indication of this, it carries the following approval mark: CE

## Telemetry Data for the USA

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in Part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 to 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.

This transmitter may only be used in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This device is registered with the Federal Communications Commission under the following number:

FCC ID: QRICMSMART (CardioMessenger Smart 3G) and

FCC ID: QRI-CMSMART4GNA (CardioMessenger Smart 4G).

## Telemetry Data for Canada

This device must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation.

This device meets the RSS standards of Industry Canada.

The operation is subject to the following two conditions: (1) The device must not cause interference and (2) the device must handle any interference received, including interference that may cause undesired operation.

The CardioMessenger is registered at Industry Canada under the following identification:

IC 4708A-CMSMART (CardioMessenger Smart 3G)

## Electromagnetic Compatibility

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

Other equipment, for example portable and mobile RF radiocommunications equipment, may also interfere with the CardioMessenger, even if this equipment complies with CISPR emission requirements. However, this possible electromagnetic interference does not affect the functionality of the device.

## Warranty

**⚠ WARNING**

The CardioMessenger and all original components by BIOTRONIK are not subject to warranty when modified, used other than intended, stored improperly, or transported incorrectly.

- Never alter the CardioMessenger and the power supply brick and only use the original packaging for shipment.

# 9 Appendix

## Technical Data

### General information on the CardioMessenger Smart and power supply bricks

- Operating mode: continuous operation
- Longevity: 6 years
- IP 22
- Operating temperature: -5°C to +40°C
- Storage and transport temperature: -20°C to +60°C
- Store in a dry place:
  Relative humidity: 30% to 75% (non-condensing)
- Atmospheric pressure: from sea level to approx. 3000 m
- Distance to the body: > 5 mm

### CardioMessenger Smart

- Dimensions (L x W x H): approx. 130 x 65 x 17 mm (5.1 x 2.6 x 0.7 inches)
- Weight: approx. 127 g
- MICS frequencies: 402–405 MHz, FSK modulation
- MICS transmission power: 25 µW EIRP

#### CardioMessenger Smart 2G

- GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz
  GSM transmission power: 2 watts (850/900 MHz); 1 watt (1800/1900 MHz)

#### CardioMessenger Smart 3G

- GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz
  GSM transmission power: 2 watts (850/900 MHz); 1 watt (1800/1900 MHz)
  UMTS frequencies: WCDMA band 850 MHz, 900 MHz, 1700 MHz, 1900 MHz, 2100 MHz
  UMTS transmission power: 0.25 W

#### CardioMessenger Smart 4G

- LTE frequencies: 700 MHz, 1700 MHz, 1900 MHz
  LTE transmission power: 0.25 W

### Power supply bricks

#### FRIWO FW7520/05

- Input voltage: 100–240 V AC at 50–60 Hz
- Output voltage: 5 V DC; 3 A
- Power cord type: micro USB-B

#### FRIWO FW8000/05

- Input voltage: 100–240 V AC at 50–60 Hz
- Output voltage: 5 V DC; 2 A
- Power cord type: micro USB-B

**GlobTek GTM96180-1107-2.0**

- Input voltage: 100–240 V AC at 50–60 Hz
- Output voltage: 5 V DC; 2,2 A
- Power cord type: micro USB-B

**Battery (integrated)**

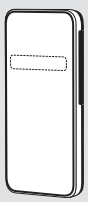
- Type: Lithium-ions

## Symbols on the Device

The label icons on the CardioMessenger symbolize the following:

| | |
|---|---|
|  | Observe the technical manual<br>(see Check the Package Contents [Page 4]) |
| IP 22 | Degree of protection against the ingress of solid objects and water |
|  | Store in a dry place |
|  | On and off key (standby) |
|  | Port for micro USB connector |

## Legend for the Label

| | |
|---|---|
| REF | BIOTRONIK order number |
| SN | Serial number |
|  | Manufacturing date |
|  | Follow the instructions for use |
|  | Storage temperature |
|  | Air pressure limit |
|  | Humidity limit |
| TP2 | Compabiltiy with telemetry protocol version 2 of BIOTRONIK Home Monitoring |
|  | Transceiver frequency |
|  | This device contains material that requires special waste disposal according to the environmental protection guidelines.<br>The European Directive 2012/19/EC on waste electrical and electronic equipment (WEEE 2) must be observed.<br>Return devices that are no longer used to BIOTRONIK. |
| CE | CE mark |
|  | Device |
|  | Contents |
|  | CardioMessenger Smart |

| | |
|---|---|
|  | Power supply brick |
| Rx only | Caution: US laws restrict this device to sale by or on the order of a medical practitioner. |

## Electromagnetic Emitted Interference

| Electromagnetic Emitted Interference according to IEC 60601-1-2 | | |
|---|---|---|
| 7.1 | EN 55011 (CISPR 11)<br>Conducted interference emissions | Group 1<br>Class B |
| | Radiated emission | |
| 7.2.1 | IEC 61000-3-2<br>Harmonic distortion (harmonic currents in the mains supply) | Not applicable<br>See EN 61000-3-2 Section 7, power consumption < 75 W |
| 7.2.2 | IEC 61000-3-3<br>Voltage fluctuations and flicker in the mains supply | Not applicable<br>See EN 61000-3-3 Section 6.1 |

## Resistance to Electromagnetic Interference

| Electromagnetic Resistance to Interference according to IEC 60601-1-2 | | |
|---|---|---|
| 8.9 | IEC 61000-4-2<br>Electrostatic discharge (ESD) | ± (2, 4, 8) 15 kV air discharge |
| 8.9/8.10 | IEC 61000-4-3<br>Electromagnetic fields | 10 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz<br>Other measurements see table 9 (IEC 60601-1-2 8.10) |
| 8.9 | IEC 61000-4-4<br>Transient conducted surge voltages (EFT, bursts) | ± 2 kV/100 KHz repetition frequency |
| 8.9 | IEC 61000-4-5<br>Surge voltage waves on supply lines | ± 0.5 kV<br>± 1 kV<br>± 2 kV |
| 8.9 | IEC 61000-4-6<br>Conducted radiofrequency interference | 3 V/0.15 MHz – 80 MHz<br>6 V in ISM bands between 0.15 MHz and 80 MHz (according to table 5)<br>For modulation see column 2, 80% AM 1 KHz |
| 8.9 | IEC 61000-4-8<br>AC frequency magnetic fields | 30 A/m<br>50/60 Hz |
| 8.9 | IEC 61000-4-11<br>Voltage fluctuations and interruptions in supply voltage | 100 to 240 V<br>50/60 Hz |