CardioMessenger Smart

Transmitter for the BIOTRONIK Home Monitoring System

Technical Manual

404202

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BIOTRONIK

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Rx only

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Table of Contents

1 About this Technical Manual

Technical manuals are either included in hard copy form in the storage package or available in digital form on the internet: https://manuals.biotronik.com.

1. Consult the technical manual.
2. Keep the technical manual for future reference.

Conventions

Identification of Safety Warnings

The following symbol draws attention to potential safety risks:

Follow all safety warnings indicated by this symbol to avoid possible serious or fatal injury or damage to the system.

Safety warnings are also indicated by a signal word.

- **DANGER:** Non-compliance may immediately lead to severe injury or death.
- **WARNING:** Non-compliance leads to a potentially dangerous situation that can cause severe injuries or death.
- **Caution:** Non-compliance leads to a potentially dangerous situation that can cause moderate injuries.
- **Attention:** Non-compliance leads to a potentially dangerous situation that can cause minor injuries and/or material damage.

Typographical Conventions

The following typographical conventions are used in this technical manual:

Instructions

The individual steps of an instruction are numbered. Prerequisites, intermediate results, and results may be specified.

Prerequisite

- This is a prerequisite.

1. Step
2. Step
   ▶ Intermediate result
3. Step

Result

This is the result.

Cross references

Cross references are indicated using "see" or "see also".

Highlights

Text that needs to be highlighted is shown in **bold**.

Figures

Figures that show the product or the user interface are used for illustration. The details shown in the figure may differ from that of the delivered product or your software version.

Gender

If personal designations are used only in the male or female form for reasons of better readability, this expressly includes all other gender identities.

2 Product Description

Intended Purpose

The CardioMessenger Smart is a data transmitter. The use of the CardioMessenger Smart is necessary for a patient who carries a BIOTRONIK implantable device with Home Monitoring function to receive medical care via telemedicine.

The CardioMessenger Smart is a part of the telemetry chain of the BIOTRONIK Home Monitoring System. It relays data between the implanted device and the Home Monitoring Service Center. The CardioMessenger Smart receives data from the implant and transmits it to the BIOTRONIK Home Monitoring Service Center via the GSM network.

The CardioMessenger Smart is classified as an accessory of the implanted device and has no diagnostic or therapeutic function itself.

Indications

There are no indications for the CardioMessenger Smart as an isolated device. However, the use of a CardioMessenger Smart is required for proper functioning of the BIOTRONIK Home Monitoring System and is, therefore, indicated if a patient participates in Home Monitoring.

Any patient wearing a BIOTRONIK pacemaker, cardiac monitor, or cardiac defibrillator with the Home Monitoring function, and who has been equipped with a CardioMessenger Smart by their physician, can use Home Monitoring. As such, the use of the Home Monitoring Service is not tied to a specific disease. Instead, its use is indicated whenever remote monitoring for the diagnosis and monitoring of the patient's cardiac disease or the implanted device is deemed necessary or advantageous by the physician or suggested by the applicable guidelines.

The indications and contraindications for implantable cardiac pacemakers, implantable cardioverter-defibrillators (ICDs), implantable cardiac resynchronization therapy devices (CRTs), or implantable cardiac monitors remain the same, regardless of whether or not the Home Monitoring function is available.

Contraindications

There are no contraindications for the use of the CardioMessenger Smart, as the device has no diagnostic or therapeutic function.

However, there are situations in which the physician might decide not to monitor the patient in the Home Monitoring Service Center (see list below). Proper use of Home Monitoring requires the cooperation of the patient or their caregiver.

The CardioMessenger Smart is not recommended for use in the following situations:

- The patient or their caregiver is unable to correctly operate the CardioMessenger Smart due to their physical and/or mental condition.
- There is no cellular phone network available in the patient's vicinity whose operator is a roaming partner of T-Mobile.

Residual Risks

A thorough literature search of all scientific publications on remote monitoring systems, including BIOTRONIK Home Monitoring, has not identified any reported residual risks associated with the CardioMessenger Smart.

Residual risks have been reduced as far as possible by the manufacturer's risk management. The low residual risk is contingent upon the CardioMessenger Smart being used in accordance with its intended purpose by a qualified user, and on the user observing the safety instructions in this technical manual.

Intended Clinical Benefit

As a part of the BIOTRONIK Home Monitoring System, the CardioMessenger Smart serves as a data transmitter between the patient's BIOTRONIK implanted device and the Home Monitoring Service Center. In this function, the CardioMessenger Smart is essential for achieving the intended purpose of the BIOTRONIK Home Monitoring System. This purpose includes monitoring and supporting the diagnosis of cardiac arrhythmias by BIOTRONIK implanted cardiac devices, and monitoring the status of the active implanted device and its connected leads.

As an isolated device, the CardioMessenger Smart has no clinical benefit.

Patient Target Group

The CardioMessenger Smart is intended for patients wearing BIOTRONIK implantable devices that are equipped with the Home Monitoring function.

Part of the Body Applied or Interacted With

The CardioMessenger Smart is an external, non-sterile device. No invasive intervention is required in order to use it.

It is not necessary to touch the device for the CardioMessenger Smart to work. To operate it, the device can be picked up occasionally, e.g., to read the display, to clean it, or to put it in a pocket for mobile use.

Expected Longevity

The CardioMessenger Smart is designed to last for six years when continuously connected to power supply.

Mobile operation using a battery is designed for 500 charging cycles.

Product identification

Each product is identified by a so-called unique device identification (UDI), which contains product-specific information. In addition, a basic identifier called B-UDI-DI (basic – unique device identification – device identifier) is assigned to several products.

The B-UDI-DI is: 4035479BUDI00051Q3.

Using this B-UDI-DI, it will be possible to search the European Database on Medical Devices (EUDAMED) for additional information on the product.

Intended Conditions of Use

Place of use

The CardioMessenger Smart may be used anywhere within the specified temperature, pressure, and humidity ranges (see also the Precautionary Measures [Page 7] section). Excluded from this are places where the use of cellular phones is prohibited for safety reasons. This could be the case, for example, in airplanes or within certain areas of hospitals.

- The CardioMessenger Smart is typically placed on the patient's bedside table and connected to the electrical power supply (e.g., at home, while on vacation, in a care facility, or during a hospital stay).
- The patient can also carry the CardioMessenger Smart with them ("mobile operation") if the physician recommends it.
- To support clinical processes in the hospital, the CardioMessenger Smart is put into operation and operated by clinical staff outside the patient environment.

Intended User

The CardioMessenger Smart can be used by a person (i.e., a medical device operator according to IEC 60601-1) if the person:

- is able to read and comprehend a manual,
- has sufficient cognitive abilities to understand the explanations of the medical personnel (the training consists of how to install and use the CardioMessenger Smart),
- is able to connect and disconnect a power cord,
- is mentally capable of following instructions independently (in the case of remote interrogation via QuickCheck), and
- has normal vision (possibly corrected by visual aids).

To support clinical processes, the CardioMessenger Smart is used by trained personnel at the hospital.

BIOTRONIK provides target group-specific user training on request. Current information on training and education opportunities can be requested from BIOTRONIK: education.training@biotronik.com.

Time, Duration, and Frequency of Use

The CardioMessenger Smart enables data transmission between the implanted device and the BIOTRONIK Home Monitoring Service Center at any time, provided the patient is within the CardioMessenger Smart range.

The CardioMessenger Smart is used for as long as the patient participates in BIOTRONIK Home Monitoring.

Compatibility

The CardioMessenger Smart is compatible with all active implantable devices from BIOTRONIK, provided they have the Home Monitoring function. These include implantable pacemakers, implantable cardioverter defibrillators (ICDs), implantable devices for cardiac resynchronization therapy (CRT), and implantable cardiac monitors.

3 Precautionary Measures

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

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

⚠ WARNING

Please observe the following safety-relevant notes:

- The CardioMessenger Smart must not be placed next to a television set, microwave oven, or a similar source of electromagnetic interference; a distance of at least 30 cm (12 inches) must be maintained.
  If the CardioMessenger Smart is too close to a radio alarm or a television set, for example, you may hear noises typical of cellular phones.
- The CardioMessenger Smart must be protected from direct contact with water. In case of rain, it should be carried under a jacket or in a bag.
- The CardioMessenger Smart must not be carried inside the breast pocket of shirt or jacket as the distance from the implanted device could be less than 15 cm (6 inches).
- The CardioMessenger Smart must not be brought into the vicinity of fire.
- The CardioMessenger Smart must not be switched on if it has recently been in a cold environment. It must be allowed to warm up to room temperature for 30 minutes, otherwise the resulting condensation could damage the electronics.
- The CardioMessenger Smart must not be switched on if it has recently been in a hot environment. It must be allowed to cool to room temperature for 30 minutes.
- The CardioMessenger Smart must not be operated in areas where cellular phones are prohibited for safety reasons (for example, in certain areas of the hospital or on airplanes).
- The distance to the implanted device must be less than 2 m (6 feet) so that regular data transmission between the implanted device and the CardioMessenger Smart is ensured.

The CardioMessenger Smart and the power supply brick must be protected from:

- Liquids (water, solvents, acids, cleaning agents, and lyes)
- Violent shocks or other strong mechanical influences
- Intense light sources (direct sunlight, strong halogen spotlights)
- Extreme ambient conditions
  - Temperatures above 40°C (e.g., direct sunlight, strong halogen spotlights, fire)
  - Temperatures below -5°C (CardioMessenger Smart) and below 0°C (power supply brick)
  - Pressure below 700 hPa (corresponding to altitudes above 3000 m)
  - Pressure above 1060 hPa (corresponding to altitudes below sea level)
  - Relative humidity below 30% or above 75%

4 First Steps

Check the Package Contents

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

WARNING

Prior to usage, check the CardioMessenger Smart and its accessories for any visible damage and use only undamaged components. Return a damaged CardioMessenger Smart to your physician.

WARNING

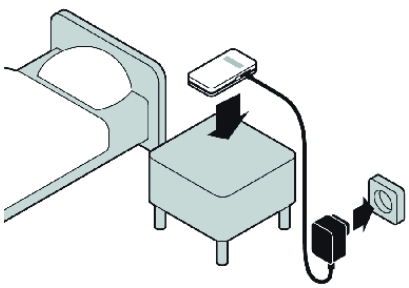
Use only the provided original power supply brick (see Technical Data).
Use of other equipment may impair proper functioning of the CardioMessenger Smart and increase the emitted electromagnetic interference or decrease the device's resistance to electromagnetic interference.

The product package includes the CardioMessenger Smart with power supply brick, the quick reference guide, and the technical manual.

WARNING

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

Where Do I Put the CardioMessenger Smart?



Attention

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

The best place for your CardioMessenger Smart is the bedside table, because there it rests on a solid base and cannot fall down, and you can clearly see the symbols on the display.

Attention

Make sure that the distance to the implanted device is less than 2 m (6 ft), so that regular data transmission between the implanted device and the CardioMessenger Smart is ensured.
Verify on a daily basis that it is ready for service.

However, if the **bedside table is made of metal**, you should not place the CardioMessenger directly on the table. For example, place it on a stack of books to establish a distance of approximately 5 cm (2 inches) between the two so that the metal does not interfere with the implanted device's data reception. If you want to use the CardioMessenger Smart 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 Smart?

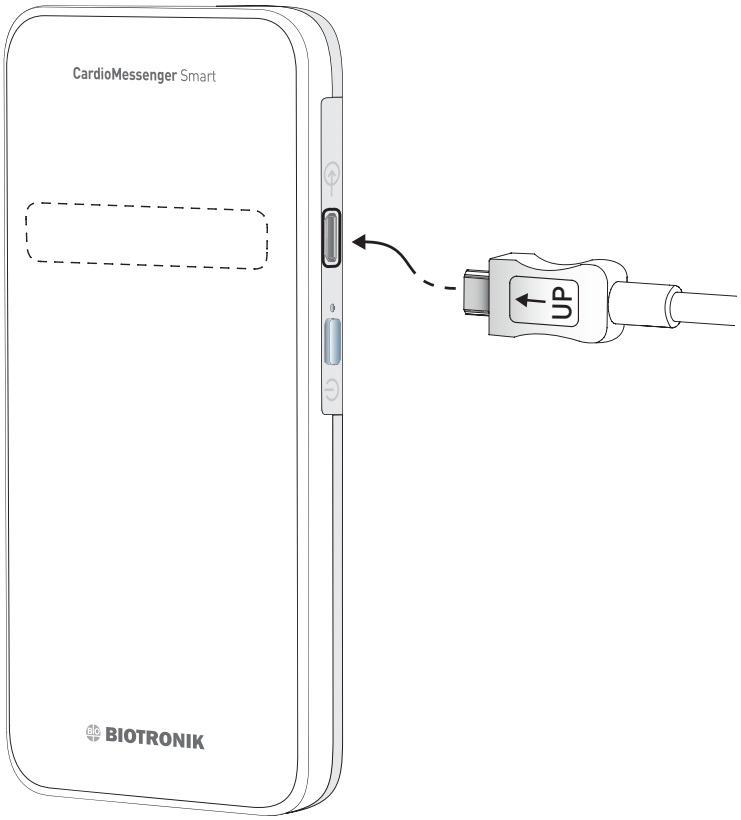
Your CardioMessenger Smart is already configured and is ready for use. You can operate it immediately by inserting the power plug into the outlet. For more information, consult the included quick reference guide.

⚠ Caution

Lay the power cord so that it is not a trip hazard or a risk of strangulation.

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

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

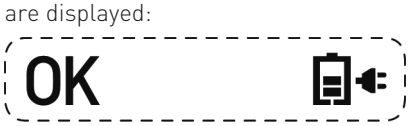


1. Insert the small connector (micro USB connector) on the right into the CardioMessenger Smart. The connector port is labeled with the following symbol:

2. Make sure that the marking on the connector is facing upward.
3. Insert the power plug into the wall outlet.

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

The CardioMessenger Smart 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 14].

How Do I Use the CardioMessenger Smart?

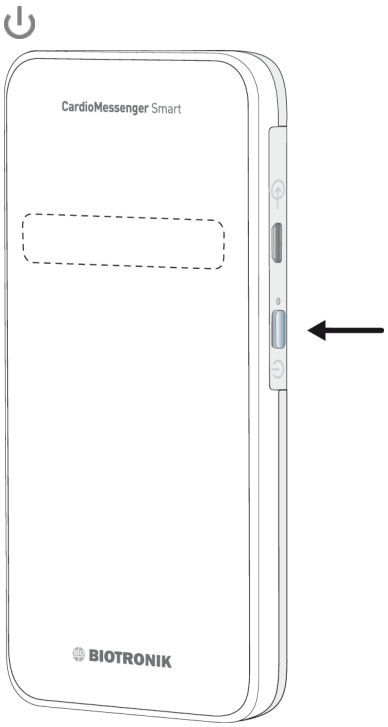
The CardioMessenger Smart automatically receives the information from your implanted device and transmits it to the BIOTRONIK Service Center.

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

This is indicated by the following icons:

How Do I Turn Off the CardioMessenger Smart?

Press and hold the blue key on the right side of the CardioMessenger Smart for approx. two seconds until the display turns off. The blue key is labeled with the following symbol:



Attention

If the CardioMessenger Smart is powered off for an extended period of time, data may be lost. After leaving the area where cellular phones are prohibited, power on the CardioMessenger Smart again.

Attention

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

In some locations, the use of cellular phones is prohibited to provide quiet zones (e.g., in a theater or cinema). As the CardioMessenger Smart is silent, it does not need to be powered off in such locations. The functions of your implanted device are not affected by the CardioMessenger Smart at any time. Your implanted device remains fully functional even if the CardioMessenger Smart is not ready for use.

5 The Display of the CardioMessenger Smart

The display of the CardioMessenger Smart has the following icons:	
OK	Operation icon
	Callback icon See Callback Function [Page 12]
	Information icon See Error Resolution [Page 14]
	The battery icon is always displayed with 1-3 bars according to the charging status.
	When the CardioMessenger Smart is connected to the power supply brick and is charging, a battery icon with a small power plug is displayed.

6 Functions

Self-Test

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

All icons on the CardioMessenger Smart are displayed.

The CardioMessenger Smart 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 Smart is now ready for use.

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

Additional information can be found under: Error Resolution [Page 14].

Callback Function

The callback function is an additional function that your physician can use in different ways. You will be informed by your physician if and how they plan to use this function.

For example, your physician can use the callback icon to ask you to contact them. 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 callback icon is flashing.

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

Turning off the callback icon

To turn off the callback icon, briefly power off the CardioMessenger Smart.

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

However, please do not forget to call your physician.

If the CardioMessenger Smart is connected to the power supply brick, it will start automatically; you neither have to wait nor power it on.

7 Error Resolution

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

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

According to the IEC 60601-1-2 standard, a distance of 0.3 m (12 inches) is recommended (for further details see: Electromagnetic Emitted Interference [Page 23] und Resistance to Electromagnetic Interference [Page 23]).

Malfunctions of the CardioMessenger Smart are indicated by 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, indicating that the CardioMessenger Smart is not ready for use.

Make sure that

- the micro USB connector is properly inserted into the CardioMessenger Smart,
- 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, indicating that the CardioMessenger Smart is not ready for use. Repeat the self-test as the CardioMessenger Smart was not able to complete it.

1. Disconnect the CardioMessenger Smart from the power supply brick if necessary.
2. Press the blue key on the right side of the CardioMessenger Smart for approx. two seconds.
3. Leave the CardioMessenger Smart powered off for about thirty seconds.
4. Power on the CardioMessenger Smart by connecting it to the power supply brick.

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

The connection test can take up to 15 minutes.

If all symbols continue to flash, the CardioMessenger Smart 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 Smart cannot connect to the BIOTRONIK Service Center.

1. Press the blue key on the right side of the CardioMessenger Smart for approx. two seconds.
2. Find a place with better cellular reception for the CardioMessenger Smart. Make sure that the distance to the implanted device is still less than 2 m (6 ft).
3. Press the blue key again for approx. two seconds.

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

The connection test can take up to 15 minutes.

Once the connection test is completed successfully, the operation and battery icon are displayed. Inadequate cellular phone network connection can occur in rooms with thick walls or when traveling.

⚠ Attention

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

8 Handling

The CardioMessenger Smart 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 Smart with 16 hours of power even after 500 complete charging cycles (which is at least two years).

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

To disconnect the CardioMessenger Smart from the alternating current supply, unplug the power supply brick from the wall outlet.

Charging

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

You should charge the CardioMessenger Smart once before the first mobile start-up. To do this, connect the CardioMessenger Smart to the electrical power supply. The charging process usually takes three hours.

WARNING

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

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

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

If the battery is defective, the CardioMessenger Smart can still be used with the power supply brick. Even if the battery is completely discharged, the CardioMessenger Smart can still operate using the power supply brick.

Attention

The CardioMessenger Smart must be charged at the latest when the battery icon flashes.

Cleaning

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

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

Protect the CardioMessenger Smart from direct contact with water.

WARNING

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

Maintenance

The CardioMessenger Smart is intended for continuous, automatic operation. When correctly in-use, ongoing maintenance is typically not required.

Reuse

The CardioMessenger Smart is intended for permanent use. After the end of use, it is not intended to reprocess and reuse the device.

Disposal

⚠ Attention

The CardioMessenger Smart and the associated power supply brick contain materials that must be correctly disposed of in accordance with environmental protection regulations.
If you no longer use the CardioMessenger Smart, you may dispose of it and its associated power supply brick as electronic waste in accordance with the applicable regulations or return it to your physician.

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

9 Appendix

Technical Data

General information on the CardioMessenger Smart and power supply bricks (configured as medical electrical system)

- Operating mode: continuous operation
- Longevity: 6 years
- IP 22
- Operating temperature: -5°C to +40°C
- Battery charging temperature: 0°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
- Information according to Section 33 of REACH, Regulation (EC) No. 1907/2006,
  see https://www.biotronik.com/material-compliance

CardioMessenger Smart

- Dimensions (L x W x H): approx. 130 x 65 x 17 mm
- Weight: approx. 127 g
- MICS frequencies: 402–405 MHz, FSK modulation
- MICS transmission power: 25 µW EIRP
- GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz
- GSM transmission power: 2 watts (850/900 MHz); 1 watt (1800/1900 MHz)
- LTE frequencies: 700 MHz, 800 MHz, 850 MHz, 900 MHz, 1700 MHz, 1800 MHz, 1900 MHz, 2100 MHz
- LTE transmission power: 0.25 W

Power supply bricks

FRIWO FW8000/05

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

Battery (integrated)

- Type: lithium-ions

Country-Related Information

Telemetry Data for Europe

Your implanted device transmits diagnostic data to the CardioMessenger Smart 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 implanted device and the CardioMessenger Smart. 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 Smart, like the implanted 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 Smart contains a radio modem that connects to the cellular network. 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 Canada

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

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 will be registered with Innovation, Science and Economic Development Canada under the following number:
IC: 4708A-CMSMART (CardioMessenger Smart 3G) and
IC: 4708A-CMSMART4GWW2 (CardioMessenger Smart 4G).

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-CMSMART4GWW2 (CardioMessenger Smart 4G)

Electromagnetic Compatibility

The CardioMessenger Smart is protected against interference from electromagnetic radiation, electrostatic discharges, and other sources of interference, including conducted interference. At the same time, electromagnetic interference emitted from the CardioMessenger Smart has been minimized.

⚠ Attention

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

Other devices such as mobile, radio transmitting devices can also cause interference to the CardioMessenger Smart. However, this potential electromagnetic interference does not affect the functionality of the implanted device.

The CardioMessenger Smart has been tested and meets applicable limits for radiofrequency (RF) exposure.

Specific absorption rate (SAR) refers to the rate at which the body absorbs RF energy. The SAR limit is 1.6 W/kg in countries that set the limit mean value over 1 g of body tissue, and 2.0 W/kg in countries that set the limit mean value over 10 g of body tissue.

To reduce exposure to RF energy, use wristbands or other similar accessories.

Housings with metal parts may change the RF performance of the device, including its compliance with RF exposure guidelines, in a manner that has not been tested or certified.
Although this device has been tested to meet SAR values in each band of operation, not all bands are available in all areas. Frequency bands are dependent on your service provider's wireless and roaming networks.

The highest SAR values are as follows:

- 1.553 [W/kg (1 g)]
- 1.477 [W/kg (10 g)]
- Distance from the body: 0 mm

Warranty

⚠ WARNING

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

- Do not modify the CardioMessenger Smart and the power supply brick under any circumstances and only use the original packaging for shipment.

Symbols

The symbols on the CardioMessenger Smart and the power supply brick have the following meaning:

Symbol	Meaning
	Comply with the technical manual (see Check the Package Contents [Page 8] and Cleaning [Page 16]).
UDI	Unique device identification
MD	Medical device
SN	Serial number
	Manufacturing date
	Manufacturer
IP22	Protection against contact with fingers, protection against foreign bodies with diameter greater than 12.5 mm Protection against water drops falling at an angle up to 15° from the vertical
	Store in a dry place
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
CE	CE mark
UK CA	UKCA mark
	Protection class II
	For interior use only

Legend for the Label

The label icons symbolize the following:

Symbol	Meaning
MD	Medical device
REF	BIOTRONIK order number
SN	Serial number
	Manufacturing date
	CardioMessenger Smart
TP2	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring
	Transceiver frequency
	Device
	Temperature limit
	Air pressure limit
	Humidity limit
	Contents
	Power supply brick
	Consult the instructions for use!

Symbol	Meaning
	Device contains materials that must be correctly disposed of in accordance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
CE	CE mark
UK CA	UKCA mark
UDI	Unique device identification

Electromagnetic Emitted Interference

Electromagnetic Emitted Interference according to IEC 60601-1-2		
7.1	EN 55011 (CISPR 11) Conducted interference emissions	100/240 V 50/60 Hz
	Radiated emission	
7.2.1	IEC 61000-3-2 Harmonic distortion (harmonic currents in the mains supply)	Not applicable See EN 61000-3-2 Section 7, power consumption < 75 W
7.2.2	IEC 61000-3-3 Voltage fluctuations and flicker in the mains supply	Not applicable See EN 61000-3-3 Section 6.1

Resistance to Electromagnetic Interference

Resistance to electromagnetic interference according to IEC 60601-1-2		
8.9	IEC 61000-4-2 Electrostatic discharge (ESD)	± (2, 4, 8) 15 kV air discharge
8.9/8.10	IEC 61000-4-3 Electromagnetic fields	10 V/m 80 Mhz- 2.7 Ghz 80% AM 1 kHz Other measurements see Table 9 (IEC 60601-1-2 8.10)
8.9	IEC 61000-4-4 Transient conducted surge voltages (EFT, bursts)	± 2 kV /100 KHz repetition frequency

Resistance to electromagnetic interference according to IEC 60601-1-2		
8.9	IEC 61000-4-5 Surge voltage waves on supply lines	± 0.5 kV ± 1 kV ± 2 kV
8.9	IEC 61000-4-6 Conducted radiofrequency interference	3 V/ 0.15 Mhz – 80 Mhz 6 V in ISM bands between 0.15 MHz and 80 MHz (according to Table 5) For modulation, see column 2, 80% AM 1 Khz
8.9	IEC 61000-4-8 AC frequency magnetic fields	30 A/m 50/60 Hz
8.9	IEC 61000-4-11 Voltage fluctuations and interruptions in supply voltage	100/240 V 50/60 Hz
8.11	IEC 61000-4-39 Magnetic fields in close proximity	8 A/m 30 kHz continuous wave 65 A/m 134.2 kHz pulse modulation 7.5 A/m 13.56 MHz pulse modulation