

CardioMessenger[®] Smart

Transmitter for BIOTRONIK Home Monitoring[®]

Technical Manual

Doc. Id.: tbd_A

Table of Contents

| | |
|--|-----------|
| Introduction | 4 |
| First Steps | 5 |
| Check the completeness of the delivery | 5 |
| Where Do I Put the CardioMessenger? | 6 |
| How Do I Connect the CardioMessenger? | 7 |
| How Do I Use the CardioMessenger? | 7 |
| How Do I Turn Off the CardioMessenger? | 8 |
| Icons on the CardioMessenger | 9 |
| Functions | 10 |
| Self-test | 10 |
| Call back function | 11 |
| Error Resolution | 12 |
| Error type A: | 12 |
| Error type B | 13 |
| Error type C | 13 |
| Handling | 14 |
| Charging | 15 |
| Cleaning | 15 |
| Maintenance | 16 |
| Disposal | 16 |
| Precautionary Measures | 17 |
| Guidelines | 18 |
| Technical Data | 19 |

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. It sends information on your heart to the transmitter, your CardioMessenger (2), usually 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.



Based on the information received, your physician can decide if your device is optimally programmed or if the therapy needs adjustments. In this way, Home Monitoring serves as a practical diagnostic aid for your physician.

2 First Steps

Check the completeness of the delivery

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

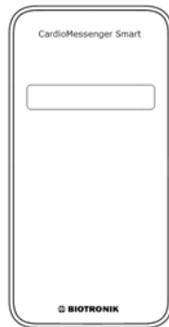
However, prior to usage, check the CardioMessenger for any visible damage and use only an undamaged CardioMessenger.

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 interference or decrease the CardioMessenger's resistance to interference.

The delivery includes the following:



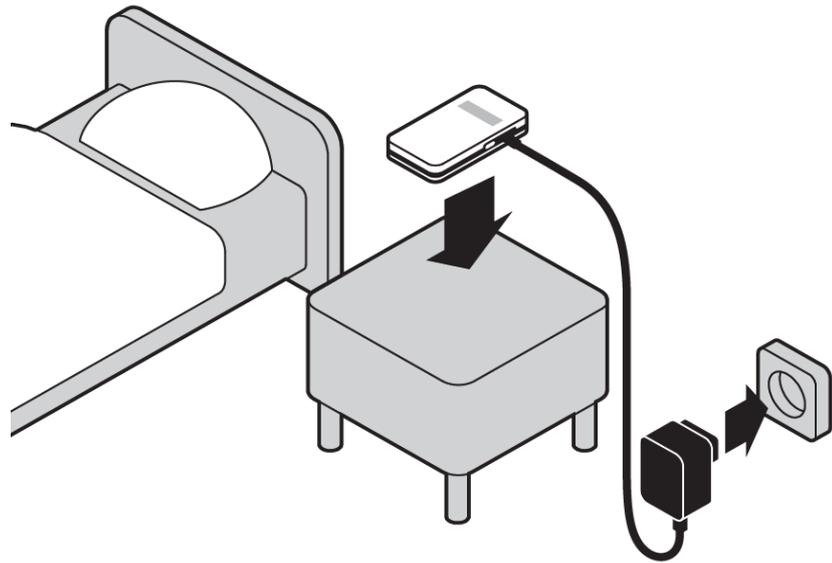
The CardioMessenger Smart



The power supply brick with power cord and power plug

Technical manual with quick reference guide

Where Do I Put the CardioMessenger?



Your CardioMessenger has a battery so you can take it along as needed during the day.

However, it should be placed close to your bed at night for the nightly data transfer from the device to the CardioMessenger.

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 device is less than 2 m (6 feet), so that regular data transmission from the device to the CardioMessenger at night is assured.
- On the bedside table, the icons on the CardioMessenger's display can be read well so you can 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 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.

Please take the following also into consideration:

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

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.

- Do not expose the CardioMessenger to temperatures exceeding 40°C (104°F). Do not put it in places where it is subjected to direct sunlight and do not put it directly under a halogen spotlight.
- Do not expose the CardioMessenger to temperatures below 0°C (32°F).
- Protect the CardioMessenger against water and high humidity.

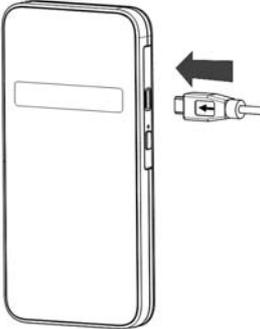
Do not place it in the bathroom.

How Do I Connect the CardioMessenger?

Your CardioMessenger is already pre-installed and supplied ready for use. You can operate it immediately by inserting the power plug into the wall outlet.

Also consult the included quick reference guide.

However, proceed as follows if the plug has disconnected during removal from the package or during shipping:

| | |
|---|--|
| 1 | <p>Connect the small plug (micro USB plug) on the right to the CardioMessenger. Make sure that the marking (white arrow) is on the upper side of the plug.</p>  <p>The connector port is labeled with the following symbol:</p> <p>5V </p> |
| 2 | <p>Insert the power plug into the wall outlet.</p> |

Make sure that the outlet is not connected to a light switch, in order to prevent the CardioMessenger from accidentally being turned off.

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

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



If this is not displayed, please refer to Error Resolution, p. 12

How Do I Use the CardioMessenger?

The CardioMessenger automatically receives the information from your device and transmits it to the BIOTRONIK Service Center. Therefore, there are only a few points that you need to consider.

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

This is indicated by the following icons:



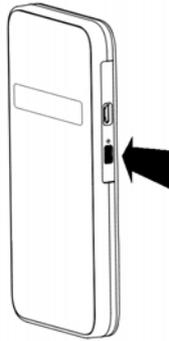
If you want to use the CardioMessenger in mobile operation, we recommend that you make a habit of charging it every night on the bedside table.

How Do I Turn Off the CardioMessenger?

Since the CardioMessenger contains a mobile ("cellular") module, you may need to switch off the CardioMessenger for safety reasons (e.g., in an airplane).

The use of cellular phones is prohibited in some locations to provide quiet zones (e.g., in a theater or cinema). The CardioMessenger does not need to be turned off in such places because it produces no noise.

Press the on/off key for approximately 5 seconds until the display turns off.



The CardioMessenger is switched off.

You can also switch off the CardioMessenger by disconnecting the plug of the power supply brick from the wall outlet. Pull on the power plug, not the cable.

Note: The functions of your device are not affected by the CardioMessenger at any time.
Your device remains fully functional even if the CardioMessenger is not ready for use.

3 Icons on the CardioMessenger

The CardioMessenger has the following icons:

| | | |
|---|---|--|
| 1 |  | Operation icon |
| 2 |  | Call back icon See Call back function, p. 11 |
| 3 |  | Information icon See Error Resolution, p. 12 |
| 4 |   | The battery icon is always displayed with 1-3 bars according to the charging status. When the CardioMessenger is 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.

| | |
|---|---|
| 1 | <p>All icons on the CardioMessenger are displayed.</p>  <p>The CardioMessenger then checks the connection to the cellular phone network.</p> |
| 2 | <p>The operation icon flashes and the battery icon is displayed.</p>  <p>The connection test can take up to 15 minutes.</p> |
| 3 | <p>Once the connection is established, the operation and battery icon remains permanently activated.</p>  <p>The CardioMessenger is now ready for use.</p> |

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

Additional information can be found under: Error Resolution, p. 12.

Call back function

With the call back icon, your physician can request you to call him/her. Your physician can turn on the icon via the cellular phone network. It will then flash for a maximum of 3 days.

The call back icon flashes if your physician wants you to call. Your physician will let you know in advance whether he or she intends to use this function in general.



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

Turning off the call back icon

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

| | |
|---|--|
| 1 | Press the on/off key on the right of the CardioMessenger for approximately five seconds. |
| 2 | The operation icon turns off. |
| 3 | Press the on/off key again for approximately five seconds. |

The CardioMessenger performs a self-test.

The operation and battery icon is then displayed and the call back icon stops flashing.



However, please do not forget to call your physician.

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 radio interference from the immediate vicinity of the CardioMessenger.

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

The standard IEC 60601-1-2: 2007 recommends a distance of 3.3 m.

Malfunctions on the CardioMessenger are indicated by the icons.

| Icon | Behavior | Operational status |
|---|---------------|------------------------------------|
|  | Off | Error type A: No power supply |
|  | Constantly on | 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. CardioMessenger is not ready for use.

- Make sure that the micro USB plug is properly inserted in the CardioMessenger.
- Make sure that the power plug is properly inserted into the wall outlet.
- Make sure that 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 The information icon is displayed.
Repeat the self-test because the CardioMessenger did not finish it.
The CardioMessenger is not ready for use.

| | |
|---|--|
| 1 | Press the on/off key on the right of the CardioMessenger for approximately five seconds. |
| 2 | Press the on/off key again for approximately five seconds. |

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

Note: The connection test can take up to 15 minutes.

If the information icon continues 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 because the CardioMessenger cannot connect to the BIOTRONIK Service Center.

| | |
|---|---|
| 1 | Press the on/off key on the right of the CardioMessenger for approximately five 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 on/off key again for approximately five seconds. |

The CardioMessenger restarts and performs the self-test. It checks the connection to the cellular phone network. The operation and battery icon is displayed once the connection test is completed successfully. The CardioMessenger is now ready for use.

Note: The connection test can take up to 15 minutes.

If the CardioMessenger generally cannot connect to the cellular phone network from positions near your bed, contact your physician.

6 Handling

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

Make a habit of charging the CardioMessenger at night so that it can be used in mobile operation during the day.

You can use the CardioMessenger while mobile for up to 48 hours, but note the following:

- Protect the CardioMessenger from direct contact with water. For example, wear it under your coat or in a pocket when it rains.
- Do not carry the CardioMessenger inside the breast pocket of your shirt or jacket, and do not place it directly on your skin.
- Do not bring the CardioMessenger into the vicinity of fire.
- Do not expose the CardioMessenger to temperatures below minus 5 C (23 F).

The battery longevity of the CardioMessenger may decrease at lower temperatures.

- Do not turn on the CardioMessenger if it was recently in a cold environment. Let it warm up slowly to room temperature, since the resulting condensed water may harm the electronic circuit.
- 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).

Note: The distance between the CardioMessenger and the device must be at least 15 cm so that the CardioMessenger does not interfere with the device.

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

Unplug the power supply brick of the CardioMessenger during thunderstorms or if you will not use the CardioMessenger for an extended period of time.

Charging

Note: You should charge the CardioMessenger once before using it for the first time.

It is also recommended that you operate the CardioMessenger with the power supply brick on the bedside table to fully charge the battery.

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



Proceed as follows:

| | |
|---|--|
| 1 | Connect the CardioMessenger to the mains supply. |
|---|--|

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 is fully charged. Once it is fully charged, all three bars are completely filled. Charging usually takes no longer than two hours.

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.

If handled properly, the installed battery should supply the CardioMessenger with 48 hours of power even after 500 charging cycles (which is at least two years).

Cleaning



WARNING

Turn off the CardioMessenger before cleaning it with a damp cloth.

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

Maintenance

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

Disposal

European Directive 2002/96/EC regarding waste electrical and electronic equipment (WEEE) applies to the CardioMessenger and associated power supply brick, because they contain materials that must be correctly disposed of for reasons of environmental protection.

If you no longer require the CardioMessenger or it is defective, please return it and all other supplied parts to your physician.

You can also dispose of the CardioMessenger as electronic scrap according to the applicable regulations.

BIOTRONIK ensures disposal in accordance with the national versions of the European guideline 2002/96/EC on waste electrical and electronic equipment (WEEE).

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.

Please take the following precautions:

Statutory regulations for electrical devices in hospitals require that the CardioMessenger not be used in areas where cellular phones are prohibited.

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



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 0°C (32 F)
- Solvents, acids, detergents, and lyes
- Pressure below 700 hPa (corresponding to altitudes above 3000 m)
- 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)

**WARNING**

Lay the power cord so that there is no risk of strangulation.

**WARNING**

Keep the CardioMessenger away from children under three years old due to ingestible small parts.

8 Guidelines

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 400.150-406.000 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 shall be used only 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

Electromagnetic compatibility

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

Note: Other equipment, for example 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 functionality of the device.

Warranty

The CardioMessenger and all original components by BIOTRONIK are not subject to warranty when used, stored, or transported incorrectly or modified. Only use the original packaging for shipment.

9 Technical Data

- | | |
|---------------------------------------|---|
| General | <ul style="list-style-type: none">• Operating mode: Continuous operation• Longevity: 6 years• IP 21: Protection against dripping water |
| Permissible ambient conditions | <ul style="list-style-type: none">• Operating temperature: -5°C to +40°C• Storage and transport temperature: -20°C to +60°C• Store in a dry place:<ul style="list-style-type: none">— Relative humidity: 30% to 75% (non-condensing)• Atmospheric pressure: 700 hPa to 1060 hPa |
| CardioMessenger | <ul style="list-style-type: none">• Type: CardioMessenger Smart• Dimensions (WxLxH): approx. 67 x 135 x 17 mm• Weight: approx. 110 g• MICS frequencies: 402–405 MHz, FSK modulation• MICS transmission power: 25 µW EIRP• GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz• UMTS frequencies: WCDMA band (I, II, IV, V, VI, VIII, and XIX)• GSM transmission power: 2 watts (850/900 MHz); 1 watt (1800/1900 MHz)• UMTS transmission power: 0.25 W |
| Power supply brick | <ul style="list-style-type: none">• Type: FRIWO FW7520/05• Dimensions (WxHxD): approx. 51.5 x 87.5 x 34 mm• Housing type: MMP 15• Housing material: PC / ABS V0 125• Input voltage: 100–240 V AC at 50–60 Hz• Output voltage: 5 V DC; 3 A• Power cord: approx. 1.83 m• Operating temperature: 0°C to +40°C• Storage and transport temperature: -40 °C to +70 °C• Store in a dry place:<ul style="list-style-type: none">— Relative humidity: 30% to 75% (non-condensing)• Atmospheric pressure: 700 hPa to 1060 hPa |
| Battery (integrated) | <ul style="list-style-type: none">• Type: Lithium-ion |

Legend for the Label

The label icons symbolize the following:

| | |
|---|---|
|  | BIOTRONIK order number |
|  | Serial number |
|  | Manufacturing date |
|  | Follow the instructions for use |
|  | Store in a dry place |
|  | Storage temperature |
|  | Air pressure limit |
|  | Humidity limit |
|  | Transmitter with non-ionizing radiation at designated frequency |
|  | Transceiver frequency |
|  | This device contains material that requires special waste disposal according to the environmental protection guidelines. The European Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) must be observed. Return devices that are no longer used to BIOTRONIK. |
|  | CE mark |
|  | Device |
|  | Contents |
|  | CardioMessenger Smart |
|  | Power supply brick |