

Preliminary Manual for CardioMessenger



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BIOTRONIK GmbH & Co.

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What is Home Monitoring?

Dear Patient.

You have received a BIOTRONIK pacemaker or implantable cardioverter-defibrillator (ICD) with a Home Monitoring function. The Home Monitoring feature provides your attending physician with messages recorded by your implant at regular intervals, giving him or her information about your heart's status.

Your implant has a small wireless transmitter. Your patient device, which we will call the Cardio-Messenger, receives the implant messages and transmits them to the BIOTRONIK Service Center. The data are processed there and can be viewed only by your physician via fax and on the Internet (when available) in the form of a comprehensive report called a Cardio report.

Your doctor can use these data to decide whether your implant settings need to be updated or if your therapy plan needs to be changed. If necessary, your physician will contact you about making an appointment for a follow-up examination.

For Home Monitoring to work, your implant must have the Home Monitoring function, and there must be cellular service in your area (GSM network).

The power of the transmission in your implant is low so as not to impair your health in any way. Since the transmission range is so short (less than 2 meters, or 6 feet), you need to use the CardioMessenger to send the information to the BIOTRONIK Service Center.

Note: If the CardioMessenger is not operational or is located too far from the implant to receive information (more than 6 feet), your implant still functions normally. Only the Home Monitoring function is inactive. Although the data recorded by the implant cannot be transmitted, they are saved so that your physician can evaluate them during your regularly scheduled follow-up examination. If you have any questions, please contact your physician.

About This Technical Manual

User group

The CardioMessenger is to be used by patients with a BIOTRONIK pacemaker or an implantable cardioverter-defibrillator (ICD) with the Home Monitoring function.

Conventions used in this technical manual

Note: Provides additional information on the features of the CardioMessenger and how to operate it.

Caution! If these instructions are not observed, minor injury or equipment damage may occur.

WARNING! If these instructions are not observed, death, serious physical injury, or major equipment damage may result.

The CardioMessenger Set and Its Components

The BIOTRONIK CardioMessenger will not restrict your routine activities. The set comes equipped with the following components:

- The CardioMessenger with rechargeable batteries
- A charging station with a power supply unit and cable

Accessories:

- Belt clip¹⁾
- Carrying strap²⁾
- Belt carrying case³⁾

The CardioMessenger works like a cell phone and transmits the information received from the implant as a short message (SMS) via a mobile telephone network to the BIOTRONIK Service Center. The built-in, rechargeable batteries provide at least 24 hours of wireless operation (away from the charging station). Naturally, the CardioMessenger can also be used when placed in the charging station.

1) Catalog number 343 265

2) Catalog number 343 227

3) Catalog number 343 228

Safety Precautions – What Should I Watch Out For?

The CardioMessenger and its components are medical devices and therefore comply with strict standards for their development, manufacture, and testing.

Please observe the following safety instructions:

WARNING! Turn off the CardioMessenger in locations where cell phones are **prohibited**, such as hospitals or airplanes. Such areas can be identified by the following or similar signs:



WARNING! Maintain a minimum distance between the patient device and your implant.

Like a cellular phone, the CardioMessenger device can temporarily interfere with your implant if it is too close to it. To avoid interference, maintain a minimum distance of 20 centimeters (7 inches) between the CardioMessenger and implant.

Never place the CardioMessenger on your chest directly over the implant.

Do not carry the CardioMessenger inside the breast pocket of your shirt or jacket, and not directly on your skin.

Caution! Protect the CardioMessenger and charging station from:

- Water and high humidity (e.g., in the bathroom)
- Temperatures above 40°C (104°F)
- Temperatures below 10°C (50°F) for the charging station

- Temperatures below -5°C (23°F) for the CardioMessenger
- Barometric pressure below 700 and above 1060 hPa
- Violent shocks or other strong mechanical influences
- Strong sources of light (direct sunlight, strong halogen lamps)
- Solvents, acids, detergents, and lyes
- Handle the antenna with care.

Caution! Never use the CardioMessenger if it has been damaged; return it to your physician.

Before use, make sure that none of the components are visibly damaged.

Only use the following original BIOTRONIK devices:



- The CardioMessenger
- The charging station with the appropriate power supply unit, type FW 7555 M/06

Other accessories can increase the interference emitted and the device's susceptibility to interference.

Caution! The CardioMessenger may only be opened and repaired by authorized trained personnel, and the rechargeable batteries (type LP 103463) may only be exchanged by professionals.

Note: Do not throw away the CardioMessenger with household trash. Dispose of it according to legal guidelines, like you would for other electronic components, such as computers.

In particular, rechargeable lithium ion batteries should be disposed of by the manufacturer according to legal guidelines.

Caution! The covered data ports are not intended for the user. Do not remove the cover.



Electronic Article Surveillance (EAS) Systems

Equipment such as retail theft prevention systems may interact with the implanted device. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.

How Do I Use the Cardio-Messenger?

The following section describes how to operate and use the CardioMessenger.

What must be done before using the CardioMessenger?

Find a suitable place to put the CardioMessenger and charging station.

The distance between your implant and the Cardio-Messenger should not be too close in order to prevent interference with implant operation. On the other hand, the distance should not be beyond the implant transmitter's range.

Note: Home Monitoring can only work when the distance between the implant and CardioMessenger is not less than 20 centimeters (7 inches) and not more than 2 meters (6 feet).

- Place the device on a solid base so that it cannot fall.
- Keep the CardioMessenger from being exposed to moisture; bathrooms, for example, are unsuitable locations for the CardioMessenger.
- Do not expose the device to heat; direct sunlight is also not recommended.
- Do not place the device next to a television, microwave oven, or a similar source of interference.

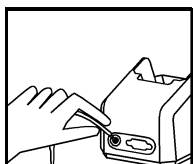
Where should I put the CardioMessenger?

A nightstand would be a good place for the Cardio-Messenger since the distance between you and the CardioMessenger would probably not be more than 2 meters (6 feet). In addition, your attending physician will probably select nighttime as the regular transmission time.

While resting at night, your implant data can be sent to the CardioMessenger and then transmitted to the BIOTRONIK Service Center.

How do I plug in the CardioMessenger?

Make sure that the local supply voltage lies within the permissible operating range of 100-240 Volts at 50-60 Hz.



If this is the case, insert the power supply cable plug into the socket.

The power supply has a long cable with a small plug at the end. Connect this plug to the charging station.



The corresponding port is located on the back of the charging station.



After connecting the charging station, the light will be illuminated, and the charging station will then be operational.

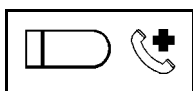
The CardioMessenger "traffic light" system

Your CardioMessenger has four lights. Three are arranged like a traffic light, and one is separate and monitors the battery. All lights can be lit continuously, flash quickly or slowly, or out.

Whether or not the lights flash or are lit continuously, the operation of your implant remains unaffected.

Lights

The following section discusses the three modes of the "traffic light" system.



Red: When the red light flashes, your attending physician wants you to call. This will rarely occur. You will be informed by your physician if it is necessary to use this feature.



Yellow: An illuminated or flashing yellow light indicates a temporary stage. This occurs, for example, when the CardioMessenger is looking for a connection to the GSM network.

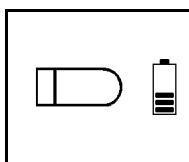
When the yellow light is continuously lit, there is a problem. For further information, see the "Troubleshooting" section on page 13.



Green: When the green light flashes, it means that the CardioMessenger is operating properly.

Battery monitor light

In the following, the three states of the battery monitor light are described as follows:

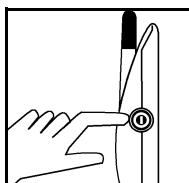


Red: When the light flashes red, the CardioMessenger batteries are nearly empty.

Yellow: When the light flashes yellow, there is a problem with charging the CardioMessenger. If the light is continuously yellow, the CardioMessenger is charging.

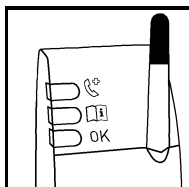
Green: When the light is green, the CardioMessenger is fully charged and can be used up to 24 hours away from the base.

Turning on the CardioMessenger



Press the on/off button of the CardioMessenger for approximately two seconds. A brief tone will sound, and the yellow light goes on.

After approximately ten seconds when the CardioMessenger self-test is over, the yellow and green lights will start to flash. The CardioMessenger is then trying to establish a connection with the mobile telephone network.

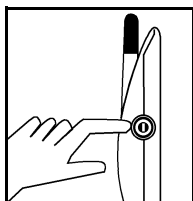


After five minutes at most, the yellow light will stop flashing, and the green light will start to flash slowly.

This means your CardioMessenger is now ready to work.

If this does not happen, please refer to the "Troubleshooting" section on page 13.

Turning off the CardioMessenger

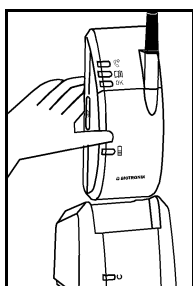


Press the CardioMessenger on/off button for approximately two seconds. You will hear a brief tone, and the yellow light will go out.

The CardioMessenger is now switched off; no data can be received or transmitted.

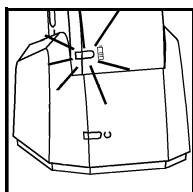
You can only turn the CardioMessenger back on after approximately five to six seconds.

Charging the CardioMessenger



When the battery monitoring light flashes red, the CardioMessenger needs to be recharged.

Place the CardioMessenger in the charging station. The charging process will start immediately.



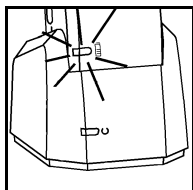
During the charging process, the battery monitor light of the CardioMessenger will be yellow.

If the battery monitor light flashes yellow, there is a problem. Please refer to the "Troubleshooting" section on page 13 to find out how to resolve this problem.

When the battery monitor light of the CardioMessenger is green, charging is complete. Charging usually takes no longer than six hours.

Note: When the CardioMessenger is being charged and used at the same time, the battery monitor light can be alternately illuminated green and yellow at the end of the charging process. This does not signify a problem; it simply means that the battery is almost completely charged.

How do I know when the batteries are running low?



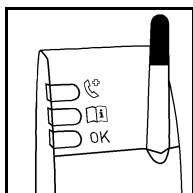
When the CardioMessenger batteries are nearly empty, the battery monitor light will flash red.

Place the CardioMessenger in the charging station. Charging will start immediately, which is indicated when the battery monitor light is illuminated yellow. When the batteries are completely charged, the battery monitor light will be green.

Note: If you take the CardioMessenger out of the charging station, the battery monitor light will go out to save energy.

How do I know that the CardioMessenger is receiving and transmitting implant data?

The data are received and transmitted automatically at specific intervals determined by your doctor so that you do not have to monitor data transmission.



When the CardioMessenger is receiving data from your implant, the green light will flash faster than normal for two to three seconds.

Since this usually occurs at night, you will rarely observe the rapidly flashing green light of the CardioMessenger.

After the CardioMessenger receives the implant data, they are sent to the BIOTRONIK Service Center.

The green light will flash again slowly until the information has been transmitted to the BIOTRONIK Service Center.

Troubleshooting

Problems with your CardioMessenger are easy to identify, and they are usually easy to deal with.

Note: When the red light in the “traffic light” flashes, it does **not** indicate a problem. It means you must call your physician. Your physician will inform you if this feature is used.

However, when the yellow light in the “traffic light” flashes or is continuously lit, there is a problem.

Continuous
flashing

First turn the CardioMessenger on and off. If you see the green and yellow light flashing for five minutes after turning the CardioMessenger back on, there is no connection to the GSM network.

If you place the CardioMessenger in a location with good reception, you will not necessarily need to turn it on or off.

Note: It can take up to 15 minutes before a connection is established to a GSM network.

If the CardioMessenger is close to your bed and generally cannot establish a connection to the GSM network, contact your physician.

Continuous
illumination

Turn the CardioMessenger on and off. If the yellow light continues to be illuminated, reset the CardioMessenger by restarting it.

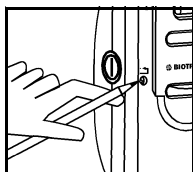
Note: Other transmitters can interfere with the receiver that the CardioMessenger uses for implant information. If this should occur, the physician will contact you.

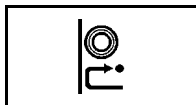
Note: A properly functioning CardioMessenger has no influence on the operation of your implant.

Resetting

If the yellow CardioMessenger light is flashing or continuously illuminated, you have already turned it on and off, and you have eliminated all possible sources of error, reset it by restarting the CardioMessenger.

Press the reset button (located on the back of the CardioMessenger) with a sharp object such as a ball-point pen or the end of a straightened paper clip.





Then turn the CardioMessenger on as usual. If only the yellow light is illuminated after five minutes, the CardioMessenger may be defective. Talk with your physician.

When Does My Implant Transmit Data?

There are three times when your implant sends information.

- Your implant is configured by your physician to periodically send messages at a specific time, usually while you are sleeping.
- Your physician can also set your implant to automatically send a message when certain events occur.
- Transmission can be activated by a special magnet (pacemaker patients only). This is done by placing the magnet directly over the implant. Your doctor will explain this to you if, how, and when it is necessary.

WARNING! Patients with implantable cardioverter-defibrillators should not place a magnet over their chest, as this interferes with the proper functioning of their ICD.

WARNING! Pacemakers sometimes use a special magnet to trigger a message. If you have a pacemaker, only apply the magnet if your physician explicitly requests it and gives you a suitable magnet.

How Do I Take Care of the Cardio-Messenger?

Handle the CardioMessenger with care, so that you will be able to use it for a long time and so that BIOTRONIK can guarantee its proper operation:

- Keep the device clean and away from dirty or dusty environments.
- Use a soft cloth for cleaning. If necessary, the cloth can be moistened with water. Do not immerse the device in water.
- Protect the device from direct contact with water. For example, wear the device under your coat when it rains, and use the provided belt carrying case.

Give the CardioMessenger back to your doctor when it no longer works.

The CardioMessenger does not need to be serviced at regular intervals by a technician.

Note: Before each use, inspect the CardioMessenger, charging station, power supply unit and cable, and make sure they are not damaged. If you find damage, consult your physician.

If handled properly, the installed batteries should supply the CardioMessenger with 24 hours of power even after 500 charging cycles (which is about two years).

If this is not the case, check whether the Cardio-Messenger was completely charged during the next charging cycle. Additional information can be found in the "Charging the CardioMessenger" section on page 12.

If you find that the battery is always running low too soon, contact your physician. The physician will have a new battery installed.

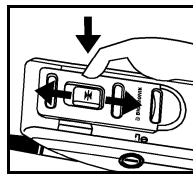
Note: When authorized personnel change the battery, they should also check the button cell.

Accessories

You can wear your CardioMessenger in various ways:

- With a clip on your belt (with or without the belt carrying case)
- With the clip and the carrying strap.

If you wear the CardioMessenger infrequently or do not need the clip to wear it, you can remove the clip.



Press the holder and slide it downwards (away from the antenna) and remove the clip.

To reattach the clip, slide the holder upwards toward the antenna.

Note:

When you use the clip with the carrying strap, make sure that the distance between the implant and the CardioMessenger is not less than 20 centimeters (7 inches).

Frequently Asked Questions

What happens if I forget to recharge my CardioMessenger?

If the CardioMessenger is not charged, it cannot receive any data from your implant and transmit them to the BIOTRONIK Service Center.

There is no danger to your health, since the implant operates independently from your CardioMessenger.

The data recorded by your implant will not get lost either; they will remain available to your physician during your next follow-up appointment.

Just recharge the CardioMessenger in the charging station. If this does not work, inform your doctor and follow his instructions.

What happens if the CardioMessenger device fails? Does this affect my implant?

No, your implant will continue to function as usual.

If the CardioMessenger stops working, it cannot receive any information from your implant and send it to the BIOTRONIK Service Center.

The messages are still recorded by the implant and can be transmitted and evaluated during a regular follow-up examination with your doctor.

Try to turn on the CardioMessenger. Additional information can be found in the "Troubleshooting" section on page 13. If this does not work, inform your physician.

Can I take my CardioMessenger with me everywhere – while I go shopping, walk, or participate in sports?

Yes. You can always take your CardioMessenger with you during work or leisure activities, as long as you are not in areas where the use of cellular phones is prohibited.

The CardioMessenger can be comfortably attached to your belt and transported with and without the provided belt carrying case. You can also use a carrying strap. Additional information can be found in the "Accessories" section on page 18.

You can also carry it in a normal bag or a backpack.

Please always remember that the distance between the implant and CardioMessenger should not be less than 20 centimeters (7 inches).

What should I do when I want to travel?

Consult your physician beforehand and inform him or her of your travel plans. You can take the CardioMessenger everywhere and plug it in wherever there is suitable supply voltage of 100 - 240 Volts at 50 - 60 Hz. You might need a country-specific adapter.

A suitable cellular network is required for the Home Monitoring function. Ask your travel agent about the cellular networks in the country where you'll be going.

While en route to your destination, you must follow the instructions of the carrier, i.e., you will need to turn off the CardioMessenger when on an airplane.

Technical Terms and Abbreviations

Cardio Report

A report informing a physician of his or her patient's current therapy status; the report is based on the data sent by the implant.

GSM

Global System for Mobile Communications – digital telephone network.

Home Monitoring

Pacemakers and ICDs with the Home Monitoring function are equipped with a transmitter that sends messages over a specific frequency to a mobile patient device.

These messages are then transmitted via a cellular network to the BIOTRONIK Service Center and can only be viewed by your physician via fax and the Internet (when available) in the form of a Cardio Report.

BIOTRONIK Service Center

This is where the implant data from the patient device are received, processed into graphs and tables, and sent to your physician.

SMS

Short Message Service – The transmission of text messages on the cellular network.

US Regulatory Requirements

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

The transmitter is authorized by rule under the Medical Implant Communications service (47 CFR Part 95) 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 aids, including interference that may cause undesired operation. This transmitter 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 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 receiver will be free from interference.

The FCC ID number for this device is QRICM02-1.

The patient device, as well as the implant itself, must conform with appropriate government standards and regulations.

The patient device uses a GSM-Modem that connects to the mobile cellular telephone service at (1900 MHz). BIOTRONIK uses the modem according to the specifications of the manufacturer in compliance with FCC approval requirements.

FCC RF Exposure Requirements

For body-worn operation, this phone has been tested and meets the FCC RF exposure guidelines when used with BIOTRONIK accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

This EUT (Equipment Under Test) has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and had been tested in accordance with the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. 1528-200X (Draft 6.5, January 2002).

Legal Considerations

Your implant transmits diagnostic data to the CardioMessenger via an 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 implant 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 interference with other services as well as with the data transmission of the implant 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 implant and CardioMessenger. Since this service is currently being established throughout Europe and North America, withdrawal of the frequency allocation is not expected in the foreseeable future.

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



In addition, the CardioMessenger contains a GSM modem (Motorola g18e) that establishes the connection to the cellular network at the frequencies of 900/1800 MHz and 1900 MHz. BIOTRONIK uses the modem in accordance with the manufacturer's specifications and in compliance with regulatory requirements.

The GSM modem has been evaluated and approved by an independent authority for its compliance with the statutory regulations. As an indication of this, it carries the following approval mark (IMEI Number: 350030-95-xxxxxx-x):



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 60601 in every respect.

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 information

Class of protection	II
Degree of protection	IP 30
Operating mode	Continuous operation

Permissible environmental conditions

During operation:

Temperature:	+ 10°C to + 40°C (50°F to 104°F) while charging - 5°C to + 40°C (23°F to 104°F) while discharging
Rel. humidity:	30% to 70% (non-condensing)
Atmospheric pressure:	700 hPa to 1060 hPa

Shipping and storage:

Storage temp.:	- 20°C to + 25°C (- 4°F to 77°F) for 2 years with battery - 20°C to + 70°C (- 4°F to 158°F) without battery
Shipping temp.:	- 20°C to + 50°C (- 4°F to 122°F) for 2 weeks with battery
Rel. humidity:	30% to 70% (non-condensing)
Atmospheric pressure:	700 hPa to 1060 hPa

CardioMessenger remote unit

Dimensions (WxHxD)	60 x 132 x 38 mm
Weight	Approx. 200 g (with battery)
Charging voltage	5.2 V DC / 0.8 A
Max. charge time	6 hours
Serial ports	Infrared and 15-pin connector
Receiving frequency	403.65 MHz

Bandwidth	300 kHz
Transmission frequencies	900/1800 MHz (not for US), 1900 MHz
Transmission power	Max. 1 Watt (1900 MHz); Max. 2 Watt (900/1800 MHz)

CardioMessenger charging station

Dimensions (WxHxD)	90 x 82 x 105 mm
Weight	Approx. 110 g
Input voltage	6 V DC / 1 A
Output voltage	5.2 V DC / 1 A

Rechargeable battery (integrated)

Model	Lithium ion (LP 103463 AR)
Dimensions (WxHxD)	Approx. 34 x 63 x 10.2 mm
Weight	Approx. 45 g
Operating voltage	3.7 V (nominal)
Charge voltage	4,2 V DC
Max. charging current	1.5 C (2700 mA)
Capacity	1800 mAh (typical)

Power supply

Model	FW 7555M/06
Dimensions	51.5 x 87.5 x 34 mm
Power cable length	2 meters
Connector type to the device	According to EN 60320/C7
Connector type to the power outlet	According to EN 50075 p.1
Input voltage	100 - 240 V AC at 50 - 60 Hz, 400 mA
Output voltage	6 V DC / 2.1 A

Appendix

Electromagnetic emitted interference according to IEC 601-1-2

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	Conformance	Guidelines for the electromagnetic environment
Radiofrequency emitted interference according to CISPR 11	Group 1	The CardioMessenger must transmit electromagnetic energy to fulfill the function for which it was intended. Nearby electronic devices can be affected.
Radiofrequency emitted interference according to CISPR 11	Class B	
Emitted interference of harmonics according to IEC 61000-3-2	Class D according to IEC 61000-3-2	
Emitted interference of voltage fluctuations/flicker according to IEC 61000-3-3	Conformance	

Susceptibility to electromagnetic interference according to IEC601-1-2

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.			
Testing susceptibility to interference	Test level according to IEC 60601-1-2	Conformance level	Guidelines for the electromagnetic environment
Conducted RF interference according to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	Same as the 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: $D = 1, 2 \sqrt{P}$
Radiated RF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	Same as the test level	$D = 1, 2 \sqrt{P}$ for 80 to 800 MHz $D = 2, 3 \sqrt{P}$ 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).

Note: These guidelines may not be applicable in all instances. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.

Note: Interference can be generated when the CardioMessenger is close to devices that have the following warning sign:



Susceptibility to electromagnetic interference according to IEC 601-1-2

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 susceptibility to interference	Test level according to IEC 60601-1-2	Conformance level	Guidelines for the electromagnetic environment
Discharge of static electricity (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. When the floor consists of a 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 cables	Same as the test level	The quality of the supply voltage should correspond to that in a typical business and/or hospital.
Power surges according to IEC 61000-4-5	± 1 kV normal mode 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.
Voltage dips, brief interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	$< 5\% U_T$ for 1/2 period ($> 95\%$ 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.
NOTE: U_T is the AC supply voltage before applying the test level			

Note: The user can experience environmental conditions in a home different from those cited in the guidelines concerning the electromagnetic environment without endangering himself or herself.

Susceptibility to electromagnetic interference for devices that are not life-sustaining.

Transmission frequency	150 kHz to 80 MHz	150 kHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$D = 1, 2\sqrt{P}$	$D = 1, 2\sqrt{P}$	$D = 2, 3\sqrt{P}$
Nominal output of the transmitter (W)	Safe distance (m)	Safe distance (m)	Safe distance (m)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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: These guidelines may not be applicable in all instances. The spread of electromagnetic waves is influenced by absorption and reflection from structures, objects, and humans.			

These guidelines may not be applicable in all instances. The spread of electromagnetic waves is influenced by absorption and reflection from structures, objects, and humans.