

Your CardioMessenger has four lights and one light on the charging station.

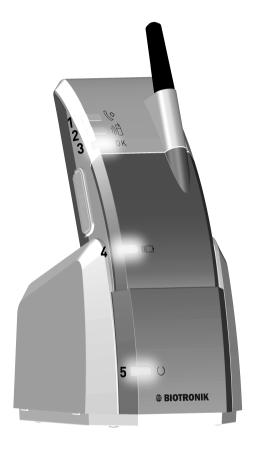
The lights numbered 1 - 3 represent the general functions of the CardioMessenger, light 4 is the battery monitor light, and light 5 shows the operational status of the charging station.

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

Light 1

Off - This is the normal status.

Yellow flashing – When this light flashes yellow, your physician wants you to call. This situation may never occur. You will be informed by your physician if s/he will use this feature.

















Note: After you have switched the CardioMessenger off and on, this light will not flash anymore. However, please do not forget to call your physician.

Light 2 »)

This light will only be used during a follow-up visit and can be triggered via the implant programmer ICS 3000. Your physician will find further information in the ICS 3000 manual.

Note: Light 2 is **not** illuminated when your implant transmits regular messages.

This light may be illuminated or flash yellow, or flash green.

Off - This is the normal status.

Yellow illumination – When the light is illuminated yellow, the CardioMessenger is receiving a message. Please wait until the

data transmission has finished (light flashing green) before you walk away from the CardioMessenger.

Green flashing – When the light flashes green several times, the transmission of the message has been completed.

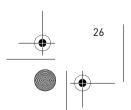
Yellow flashing – However, when the light flashes yellow several times, the transmission was not successful. Your physician will decide what to do next.

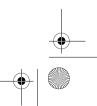
Light 3 [®] ⊠

This light informs you about the normal operation of the CardioMessenger.

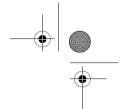
Green flashing 🌣 — — 🌣 –

When the light single-flashes green repeatedly, the CardioMessenger is operating properly. This is the normal status.











When the light double-flashes green repeatedly, the CardioMessenger is also operating properly. Additionally, there are messages stored that have to be transmitted to the Service Center.



When the light double-flashes yellow repeatedly, there is no connection to the GSM network or modem and additionally the CardioMessenger has messages stored to be transmitted to the Service Center. For further information, see the "How Do I Resolve Problems?" on page 32.

Yellow illumination – When the light is illuminated yellow, the CardioMessenger is performing a self-test.

This test should last no longer than 10 seconds after the CardioMessenger has been switched on.

Off – The CardioMessenger is switched off.

Light 4 III

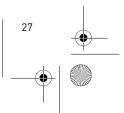
In the following, the four statuses of the battery monitor light are described as follows:

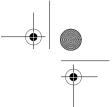
Green Illumination – When the light is illuminated green, the CardioMessenger is fully charged. You may now use it in mobile operation for at least 24 hours. But the CardioMessenger can certainly also be kept in the charging station.

Off – This is the normal status when the CardioMessenger is used in mobile operation.

When this light is off but the CardioMessenger is in the charging station, please refer to "How Do I Resolve Problems?" on page 32.







Red flashing – When the light flashes red, the CardioMessenger batteries are nearly depleted. Please place the CardioMessenger in the charging station.

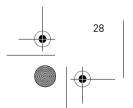
Yellow illumination – When the light is illuminated yellow, the CardioMessenger is charging.

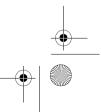
Light 5 ()

Green Illumination – This is the normal status when the charging station is connected to the power supply.

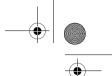
If this is not the case, there might be an error. Additional information can be found in "How Do I Resolve Problems?" on page 32.













As soon as you place the CardioMessenger in the charging station, it is automatically switched on.

You certainly may also switch on the CardioMessenger when it is not placed in the charging station; the On/Off button is located on the right side of the CardioMessenger.

Press the On/Off button (1) of the CardioMessenger until you can feel slight resistance. A brief tone will sound, the CardioMessenger will start its self-test, and light 3 will be illuminated yellow. You can now release the button.









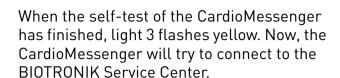












After a successful connection to the Service Center, light 3 flashes green. Your CardioMessenger is now operational.

In case light 3 does not flash green, please refer to "How Do I Resolve Problems?" on page 32.

Note: When the CardioMessenger has not been used for a long time or if it was stored below operational temperature, the battery can be completely depleted. In this case, the CardioMessenger switches itself on only after the battery has been charged for about 30 minutes.

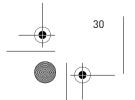
How Do I Turn Off the CardioMessenger?

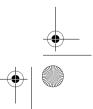
Press and hold the CardioMessenger On/Off button for at least two seconds. A brief tone will sound and light 3 will go out after a short period of time.

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

Note: A switched-off or improperly functioning CardioMessenger does not affect the operation of your implant.















How Do I Charge the CardioMessenger?

The CardioMessenger has to be charged when the battery monitor light (light 4) flashes red. If you wish to use the CardioMessenger in mobile operation, you should charge it every 24 hours.

It is recommended that you charge the CardioMessenger before you use it for the first time.

To do so, place the CardioMessenger in the charging station; the charging process will start immediately.

During the charging process, the battery monitor light (light 4) of the CardioMessenger will be illuminated yellow.

Once the CardioMessenger is charged, the battery monitor light is illuminated green. Charging usually takes no longer than three and a half hours.





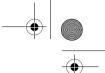














However, if the battery monitor light (light 4) is off even though the CardioMessenger is in the charging station, there might be a problem.

Please refer to "How Do I Resolve Problems?" on page 32 to find out how to resolve this problem.

Note: In case the CardioMessenger has been stored outside the operational temperature, i.e., below 0° (32° F) and above 40° Celsius (104° F), the batteries discharge themselves much more quickly. You should then first charge the CardioMessenger before attempting to use it.

How Do I Resolve Problems?

Problems with your CardioMessenger are easy to identify, and they are ususally easy to resolve.

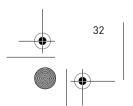
Light 3 0K

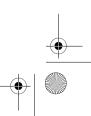
Yellow illumination – When this light is continuously illuminated yellow, the CardioMessenger was not able to end its self-test.

Solution – Reset the CardioMessenger and turn it on again. If light 3 is still illuminated yellow, inform your physician. You will find information on a reset in "How Do I Reset the CardioMessenger?" on page 34.

Yellow flashing – When this light continuously flashes yellow, the CardioMessenger cannot connect to the Service Center.

Solutions – Check if the charging station is connected to the power supply and if the cables from the charging station to the telephone wall outlet are loose.









Check that the standard telephone line is not dead, i.e., the CardioMessenger is not blocked by other devices.

Check if you are able to dial toll-free numbers with your telephone. If this is generally not possible, have this service set up for you by your telephone provider or inform your physician.

Light 4 III

Off – When this light is off even though the CardioMessenger is in the charging station, proceed as follows:

Solutions – Check if light 5 on the charging station is illuminated. Is this not the case, refer to the solutions described for light 5.

If light 5 is illuminated, check whether the connecting parts on the CardioMessenger or on the charging station are easily accessible and not dirty.

If light 4 is still off, inform your physician so that the device can be checked and the battery may be exchanged.

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

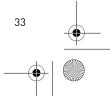
Light 5 ()

Off – If this light is off, proceed as follows:

Solutions – Check that the plugs of the power cables are connected both to the outlet in the wall and to the power supply.

Check that the green light of the power supply is illuminated. If this is not the case, either the power outlet is not being supplied with electricity or the power supply is defective. Return a non-functioning power supply to your physician.













How Do I Reset the CardioMessenger?

You should reset your CardioMessenger by restarting it when light 3 is lit continuously in yellow and if this error could not be eliminated by turning the CardioMessenger off and on.



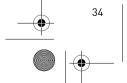
The reset button is located on the back of the CardioMessenger, on the left towards the lower end of the belt clip.

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





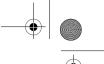














If the problem still exists, inform your physician.

Note: Only reset the CardioMessenger if you have eliminated other sources of error. When resetting the CardioMessenger, you abruptly cut off the current and data might be lost. Also, please note when you have done a reset; this could be useful for future troubleshooting.

How Do I Take Care of the CardioMessenger?

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:

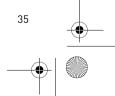
- Keep the CardioMessenger clean and away from dirty or dusty environments.
- Don't bend the antenna and don't hold the CardioMessenger by the antenna.

- Use a soft cloth for cleaning. If necessary, this can be moistened with water or ethyl alcohol. However, avoid bringing the device into direct contact with water or other solvents.
- Protect the CardioMessenger from direct contact with water. For example, wear it under your coat when it rains.
- Don't turn on the CardioMessenger if it has been recently stored in a cold environment. Let it warm up slowly to room temperature, since the resulting condensed water may harm the electronic circuit.

Return the CardioMessenger to your physician if it no longer works.

Maintenance at regular intervals is not necessary for the CardioMessenger.

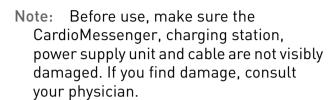








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If handled properly, the installed batteries should supply the CardioMessenger with 24 hours of power even after 500 charging cycles (which is at least two years).

If you feel the CardioMessenger is not lasting long enough during mobile operation, ensure that it has been charged in the charging station for at least three and a half hours before mobile use. Additional information can be found in "How Do I Charge the CardioMessenger?" on page 31.

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.

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

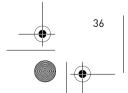
How Do I Carry the CardioMessenger?

You can wear your CardioMessenger in various ways:

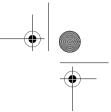
- With the clip of the CardioMessenger on your belt
- With the carrying strap

If you don't need the clip or if you wish to attach the carrying strap, proceed as follows:

Remove the clip by pressing the symbol with your thumb (see figure) and slide the clip downwards - away from the antenna.





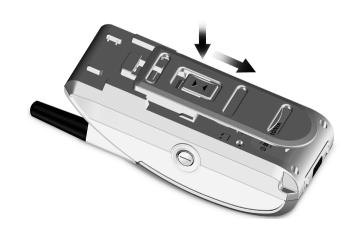


The carrying strap has a clip attached. Take the carrying strap and reattach the clip of the carrying strap.

To do so, slide the clip upwards toward the antenna until the clip snaps in.

Warning! When you use the clip with the carrying strap, make sure that the distance between the implant and CardioMessenger is greater than 20 centimeters (7 inches).

Warning! Do not carry the CardioMessenger inside the breast pocket of your shirt or jacket, and do not place it directly on your skin.



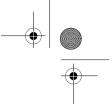












Safety Precautions - What Should I Watch Out For?

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

Please observe the following safety instructions, which are summarized below:

Warning! Turn off the CardioMessenger in locations where cell phones are prohibited for safety reasons (such as in hospitals or airplanes).

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



Warning! To avoid interference, maintain a minimum distance of 20 centimeters (7 inches) between the CardioMessenger and implant.

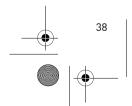
Like a cellular phone, the CardioMessenger device can temporarily interfere with your implant if it is too close to it.

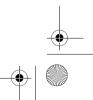
Warning! Do not carry the CardioMessenger inside the breast pocket of your shirt or jacket, and do not place it directly on your skin.

Warning! According to government regulations, the charging station of the CardioMessenger may not be operated within a distance of 1.5 m (5 feet) of a patient in a hospital environment. At home, this restriction does not apply.

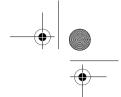
Caution! Protect the CardioMessenger and charging station from:

- Water and high humidity (e.g., in the bathroom)
- Temperatures above 40° C (104° F)
- Temperatures below -5° C (23° F)









(mobile operation for CardioMessenger)

- Barometric pressure below 700 and above 1060 hPa
- Violent shocks or other strong mechanical influences
- Intensive light sources (direct sunlight, strong halogen emitters)
- -Solvents, acids, detergents, and lyes

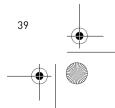
Caution! Never use the CardioMessenger if it has been damaged; return it to your physician.

Before use, make sure that none of the components are visibly damaged and that all necessary components have been delivered to you. Additional information can be found in "Included Equipment" on page 4.

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

Note: For proper operation, the CardioMessenger must be put into the charging station for at least three and a half hours each day.



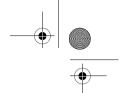














USA

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

The transmitter is authorized by rule of 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

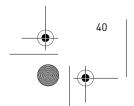
such aids, including interference that may cause undesired operation. This transceiver shall be used only in accordance with the FCC rules governing the Medical Implant Communications Service.

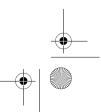
Analog and digital voice communications are prohibited. Although this transceiver has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transceiver will be free from interference

The FCC ID number for the CardioMessenger is QRICM06-1.

The FCC ID number for the cable modem in the charging station is AU7MD04B2456.

¹⁾ Federal Communications Commission for Medical Implant Communications Service















The CardioMessenger uses a GSM modem that connects to the mobile cellular telephone service at 850/1900 MHz. BIOTRONIK uses the modem according to the specifications of the manufacturer in compliance with FCC approval requirements.



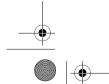
This device has been tested for operation when worn on the body and meets the FCC RF exposure guidelines when used with BIOTRONIK accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

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).

Canada

The CardioMessenger is registered at Industry Canada with the following number: IC: 4708A-CM06V1.

The cable modem in the charging station is registered at Industry Canada with the following number: IC: 125A-0008.









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

Note: 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.

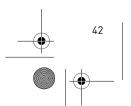
In addition, the CardioMessenger contains a GSM modem (Motorola g24) that establishes the connection to the cellular network at the frequencies of 900/1800 MHz. BIOTRONIK uses the modem in accordance with the manufacturer's specifications and in compliance with the approval requirements.

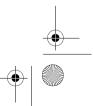
The GSM modem has been evaluated and approved by an independent authority for its compliance with the statutory regulations. As an indication of this, it carries the following approval mark [IMFI Number: 35726200-xxxxxx-x]:

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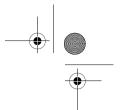
Electromagnetic Compatibility

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









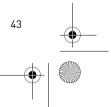
Warning! Other equipment, including portable and mobile RF radiocommunications equipment may interfere with the CardioMessenger, even if this equipment complies with CISPR emission requirements. However, this possible interference does not affect the implant functionality.

Warranty

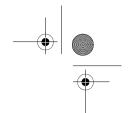
The CardioMessenger and all original components by BIOTRONIK are not subject to warranty when used improperly or stored and transported incorrectly. Use only the original packaging when shipping the device.











Technical Data

General

- Class of protection: II
- Operating mode: Continuous operation

Permissible Environmental Conditions

During Operation:

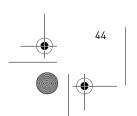
- Temperature: 5° C (23° F) to + 40° C (104° F) (remote unit)
 0° C (32° F) to + 40° C (104° F) (charging station)
- Relative humidity: 30% to 75% (non-condensing)
- Atmospheric pressure: 700 hPa to 1060 hPa

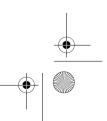
Shipping and Storage:

- Temperature:- 20°C (- 4° F) to + 60° C (140° F)
- Relative humidity: 30% to 75% (non-condensing)
- Atmospheric pressure: 700 hPa to 1060 hPa

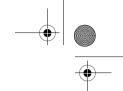
CardioMessenger Remote Unit

- Dimensions (WxHxD): 60 x 132 x 45 mm
- Charging voltage: 5,2 V DC / 0.8 A
- Max. charge time: 3.5 hours
- Interfaces: Serial infrared port and IrDA1.0 standard
- MICS: Modulation FSK









■ MICS frequencies: 402 - 405 MHz, 9 channels, 300 kHz band width

■ MICS transmission power: 25 µW EIRP

■ GSM: Modulation GMSK

■ GSM frequencies: 850 MHz, 900 MHz, 1800 MHz, 1900 MHz, 9,6 kHz band width

GSM transmission power:0.8 Watt (850 MHz); 2 Watt (900 MHz);1 Watt (1800/1900 MHz)

CardioMessenger Charging Station

■ Dimensions (WxHxD): 90 x 82 x 105 mm

■ Input voltage: 6 V DC / 1 A

■ Output voltage: 5.2 V DC / 1 A

Rechargeable Battery (integrated)

■ Type: Lithium ions (CGA 103460A)

■ Dimensions (WxHxD): approx. 36.5 x 64.5 x 12 mm

■ Operating voltage: 3.6 V (nominal)

■ Charging voltage: 4.1 V DC

■ Max. charging current: 2 A

■ Capacity: 1850 mAh or more

Power Supply

■ Type: FW 7555M/06

■ Dimensions: 51.5 x 87.5 x 34 mm

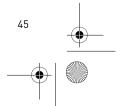
■ Power cable in m: 2.0

■ Connector type to the device: According to EN 60320/C8

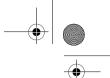
■ Input voltage: 100 - 240 V AC at 50 - 60 Hz, 400 mA

■ Output voltage: 6 V DC / 2.1 A











Appendix

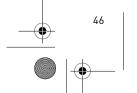
Electromagnetic emitted interference according to IEC 601-1-2

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.

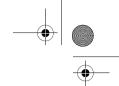
| Measuring the interference | Compliance | Guidelines for the Electromagnetic Environment | |
|--|------------------------------------|--|--|
| High-frequency interference according to CISPR 11 | Group 1 | The CardioMessenger uses RF energy only for its internal function. Therefore, the HF interference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













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.

| Testing resistance 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 | 3V _{eff} 150 kHz to 80 MHz | Same as test level | The minimum distance of the CardioMessenger from portable and mobile radio devices, including the cables, should correspond to the recommended safe distance that is calculated according to the equation for the suitable transmission frequency. Recommended safe distance: $D=1,17\sqrt{p}$ |
| Radiated RF interference according to IEC 61000-4-3 | 3V/m 80 MHz to 2.5 GHz | Same as test level | D= 1,17 \sqrt{p} for 80 to 800 MHz D= 2,34 \sqrt{p} for 800 MHz to 2.5 GHz with P as the nominal output of the transmitter in Watts (W) according to the information from the transmitter manufacturer, and d as the recommended safe distance in meters (m). The field strength of stationary transmitting devices should be measured on site ^a and must be lower than the compliance level at all frequencies ^b . Interference can be generated when the CardioMessenger is close to devices that have the following warning sign: |

Note: The higher frequency range applies at 80MHz and at 800MHz.

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

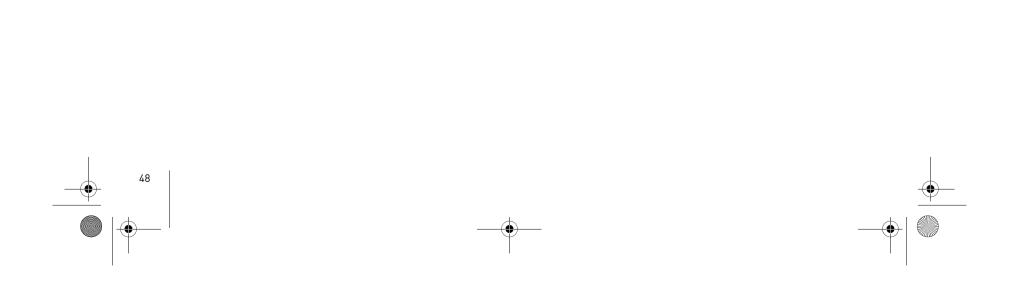








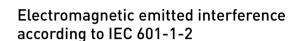
- a. Field strengths from fixed transmitters, such as base stations for radio (cellular(/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
 To assess the electromagnetic environment due to fixed RF transmitters,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









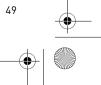


The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

| Checking immunity to noise | 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 supply lines ± 1 kV for input/output lines | Same as the test level | The quality of the supply voltage should correspond to that in a typical business and/or hospital. |
| Surge According to IEC 61000- 4-5 | ±1kV 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. |











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| | | level | |
|---|--|---------------------------|---|
| interruptions and fluctuations in the supply voltage According to IEC 61000-4-11 | < 5% U _T for 1/2 cycle (> 95% drop) 40% U _T for 5 periods (60% drop) 70% U _T for 25 periods (30% drop) < 5% U _T for 5 s (> 95% drop) | Same as the test level | The quality of the supply voltage should correspond to that in a typical business and/or hospital. The CardioMessenger is powered by a battery. An interruption in the supply voltage to the power supply unit will not impair the functioning of the CardioMessenger. |
| Magnetic field at the supply frequencies (50/60 Hz) According to IEC 61000-4-8 Comment: U _T is the mains a | 3A/m | Same as the test level | The magnetic field strength should correspond to the typical value in business and hospital environments. |



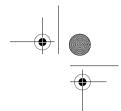


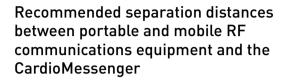












| Transmission frequency | 150 kHz to 80 MHz | 80 kHz to 800 MHz | 800 MHz to 2.5 GHz |
|--------------------------------|-------------------|-------------------|-----------------------------|
| Equation | D= 1,17√p : | D= 1,17√p : | D= 2,34 \(\subseteq p \) : |
| Rated power of transmitter (W) | Safe distance (m) | Safe distance (m) | Safe distance (m) |
| 0.01 | 0.12 | 0.12 | 0.24 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.34 |
| 10 | 3.7 | 3.7 | 7.4 |
| 100 | 11.7 | 11.7 | 23.4 |

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

Note: The higher frequency range applies at 80MHz and at 800MHz.

Note: These guidelines may not be applicable in all cases. The propagation of electromagnetic values is affected by absorption and reflection by structures, objects and people.





