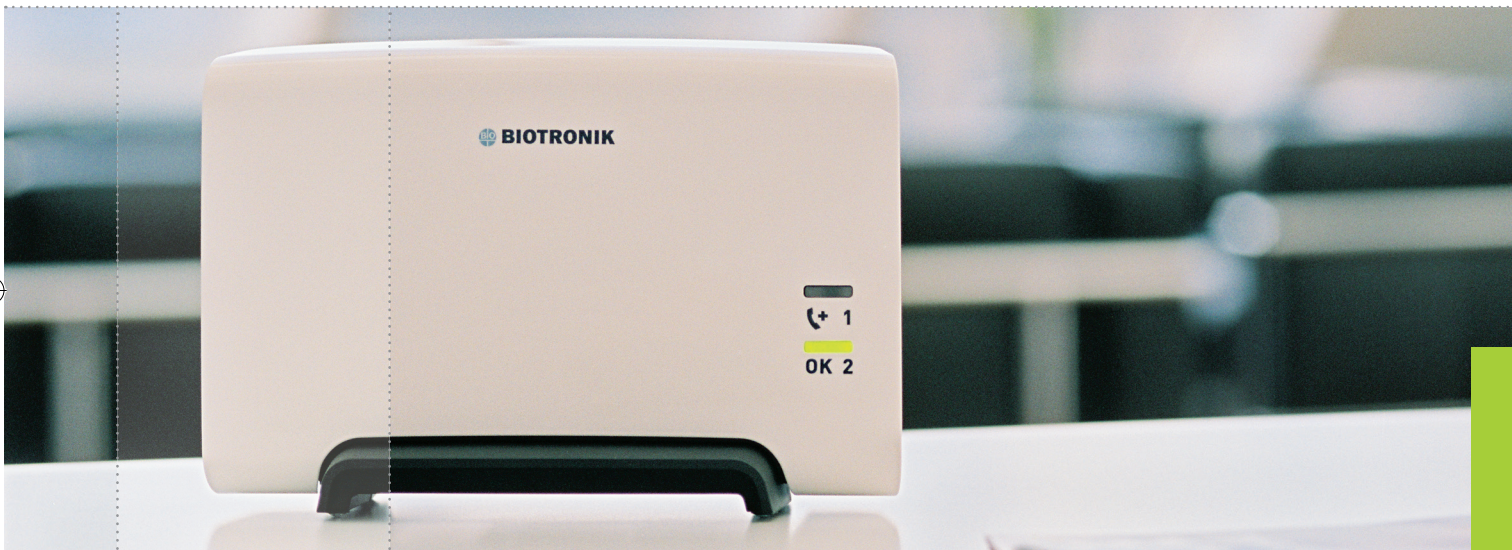




CardioMessenger®II-S TLine

Transmitter for BIOTRONIK Home Monitoring®

Technical Manual



 **BIOTRONIK**
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2008-D-05

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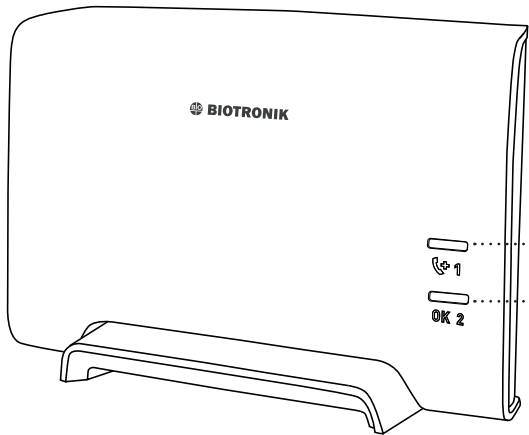
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www.biotronik.com

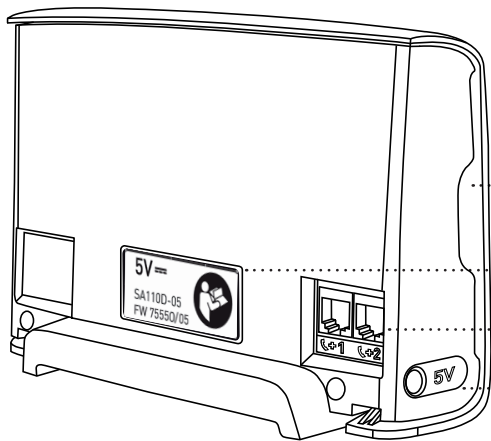
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Call back light (yellow, page 22)

Operating light (yellow/green, page 21)



Slot for the brief instructions guide (page 20)

Use only original power supply units (page 16)

Connections for the landline (page 9 - 14)

Connection for the power supply (page 16)





Content

Introduction 3

 How Home Monitoring works. 3

Check the completeness of the delivery ... 5

Setup 7

Connection 8

 Connection to the landline 8

 Connection to the power supply. 16

 Self-test 18

 Insert brief instructions guide 20

Operate 21

 Check lights 21

 Call back function 22

 Switching Off the System. 23

Debugging 24

Cleaning, maintenance, and disposal 28

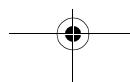
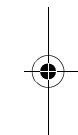
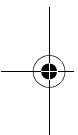
Precautionary measures 30

Guidelines 33

Technical data 37

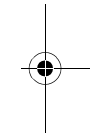
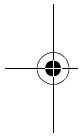
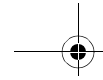
Appendix 39

Index 45

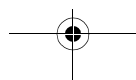




CM_II-S_TLinebook Page2 Tuesday, May 6, 2008 12:56 PM



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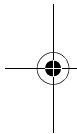




Introduction

Dear patient:

You have received a pacemaker or implantable cardioverter-defibrillator (ICD) with the additional Home Monitoring function by BIOTRONIK. With Home Monitoring, the state of your heart's health and your implant are surveyed on a daily basis while you are at home. Your physician can catch up at regular intervals on how your heart is doing.

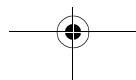
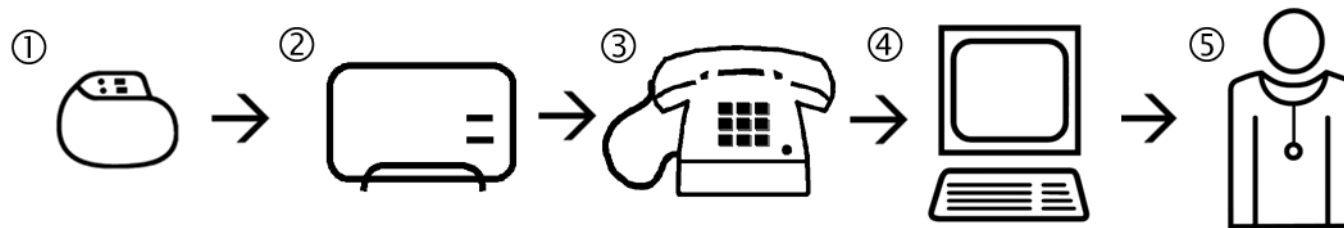
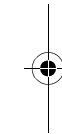


How Home Monitoring works

Your implant is equipped with a special transmitter (1). Usually at night, the transmitter sends daily information on your heart to the patient device, your CardioMessenger (2).

The transmission power from your implant 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 received from the implant and automatically transmits it to the

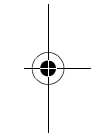
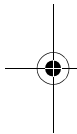




BIOTRONIK Service Center (4) as encoded messages via a landline connection (3).

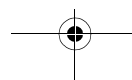
Here, the messages are decoded and made available for viewing by your physician (5) on a protected web site.

Based on the information received, your physician can decide if your implant is best configured, or if the therapy needs adjustments. In this way, Home Monitoring serves as a practical diagnostic aid to your physician.



4

Introduction





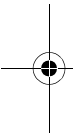
Check the completeness of the delivery

Check all components for visible damage before using them. Use only components which are undamaged.

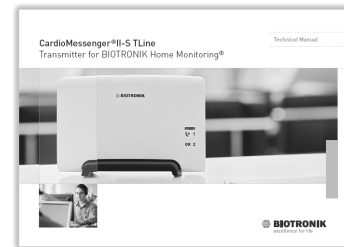
The delivery includes the following:



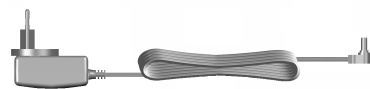
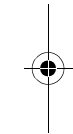
CardioMessenger II-S TLine



Telephone cable



Technical manual with brief instructions guide



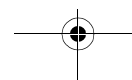
Power supply unit with electricity cable and DC plug

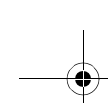
Warning!

Use the CardioMessenger only if it is undamaged. Return a damaged CardioMessenger to your physician.

CardioMessenger II-S TLine

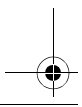
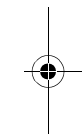
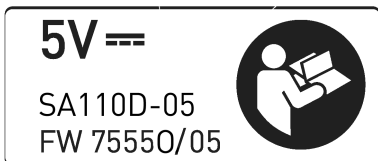
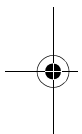
Check the completeness of the delivery





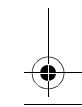
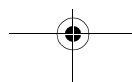
Warning!

Use only the original parts included (for details, see "Technical data", page 37). Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the device's susceptibility to interference. The label on the back side of the CardioMessenger indicates the approved power supply:



6

Check the completeness of the delivery

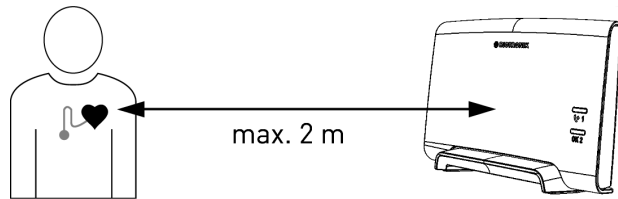
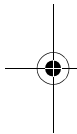




Setup

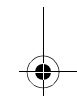
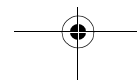
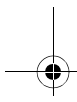
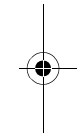
Place the CardioMessenger on your bedside table. The bedside table is suitable because it usually meets the following conditions:

- The CardioMessenger is placed on a solid base and cannot fall.
- The distance to the implant is less than 2 meters so that regular data transmission at night is assured.



Please take the following into consideration:

- Place the CardioMessenger in such a way that the lights can easily be viewed during the day. If the lights disturb you in your sleep, turn the CardioMessenger away from you. Do not place the CardioMessenger on the floor, next to, or under your bed.
- Do not place the CardioMessenger next to a television set, microwave oven, or a similar source of electromagnetic interference.
- Do not expose the CardioMessenger to temperatures exceeding 40 °C (104 °F). Do not put it on a place with direct sun light and do not place it directly under a halogen spotlight.
- Do not expose the CardioMessenger to temperatures lower than 10°C (50°F).
- Protect the CardioMessenger against water and high humidity. Do not place it in the bathroom.





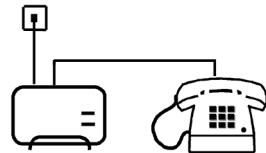
Connection

Connection to the landline

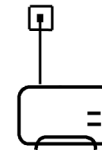
The CardioMessenger transmits the Home Monitoring data via landline.

There are two ways to connect the CardioMessenger to the landline:

- Method A
CardioMessenger and telephone are operated using the same telephone wall jack.



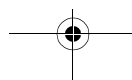
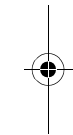
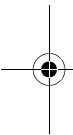
- Method B
The CardioMessenger is operated with a telephone wall jack to which no other device is connected.



In both cases, you can use your phone as usual.

Note

The CardioMessenger has been designed for use with an analog landline. Correct operation cannot be ensured if using a digital landline. If you are unsure what kind of landline you are using, please contact your telephone provider.





Method A

To operate both the CardioMessenger and the telephone using one telephone jack

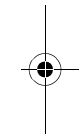
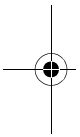
To operate CardioMessenger and telephone together in one telephone wall jack, proceed as follows:

1. On the back side of the CardioMessenger:
Remove the sealing plug from phone inlet 1.

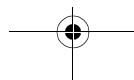
Phone inlet 1 is labeled with the following symbol:



2. Unplug the telephone cable from the telephone wall jack.



CardioMessenger II-S TLine



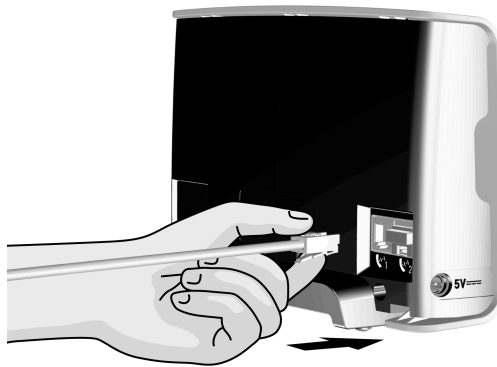
Connection

9

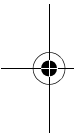




3. Connect the free end of the telephone cable to phone inlet 1 of the CardioMessenger.

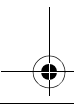
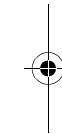
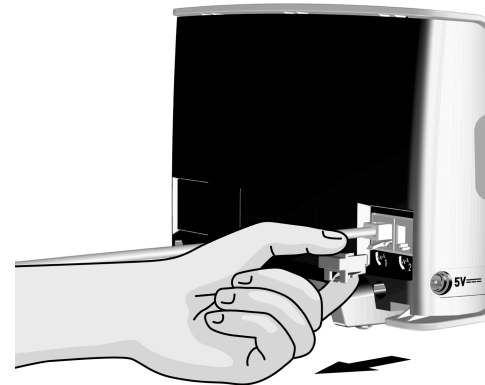


The telephone is now connected to the CardioMessenger.



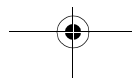
4. Remove the sealing plug from phone inlet 2.

Phone inlet 2 is labeled with the following symbol:



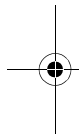
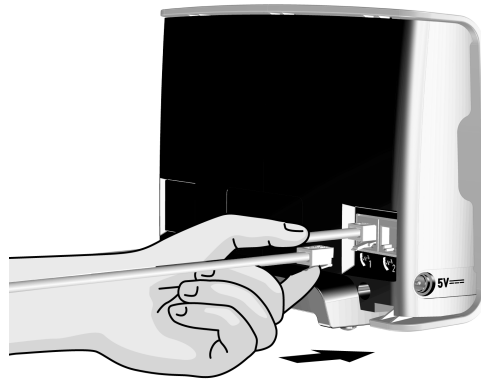
10

Connection

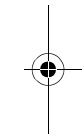
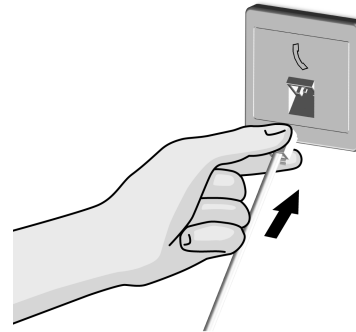




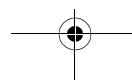
5. Take the supplied telephone cable and connect one end to phone inlet 2.



6. Connect the other end of the supplied telephone cable to the telephone wall jack.

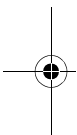
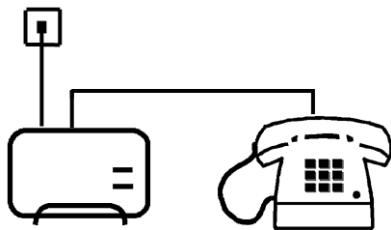


7. Check the telephone connection. Lift and listen to the receiver. The usual dialing tone should be audible.

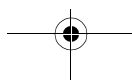
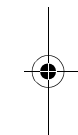




The telephone and CardioMessenger are now connected to the landline.



As a next step, connect the CardioMessenger to the power supply (see "Connection to the power supply", page 16).





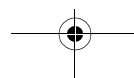
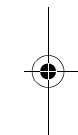
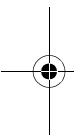
Method B

Operate the CardioMessenger using an available wall jack.

To operate the CardioMessenger in a telephone wall jack to which no other devices are connected, proceed as follows:

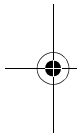
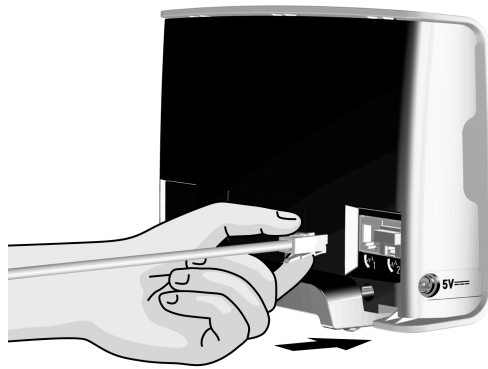
1. On the back side of the CardioMessenger:
Remove the sealing plug from phone inlet 1.

Phone inlet 1 is labeled with the following symbol:

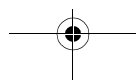
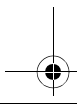
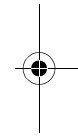
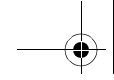
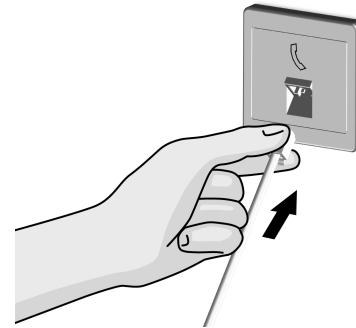


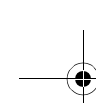


2. Take the supplied telephone cable and connect one end to phone inlet 1.

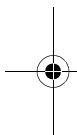
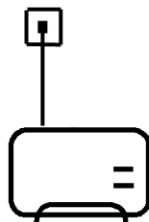


3. Connect the other end of the supplied telephone cable to the telephone wall jack.

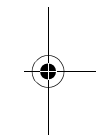




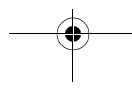
The CardioMessenger is now connected to the landline.



As a next step, connect the CardioMessenger to the power supply (see "Connection to the power supply", page 16).



CardioMessenger II-S TLine



Connection

15



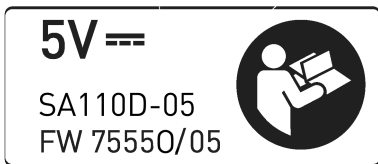


Connection to the power supply

Connect the CardioMessenger to the power supply. The outlet to be used has to be easily accessible. Use the supplied power supply unit with electricity cable and DC plug.

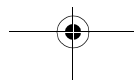
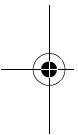
Warning!

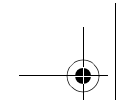
Use only the original parts included (for details, see "Technical data", page 37). Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the device's susceptibility to interference. The label on the back side of the CardioMessenger indicates the approved power supply:



1. Connect the DC plug at the end of the electricity cable to the port on the left side of the CardioMessenger.

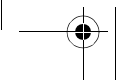
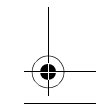
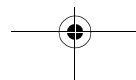
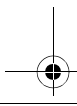
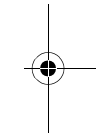
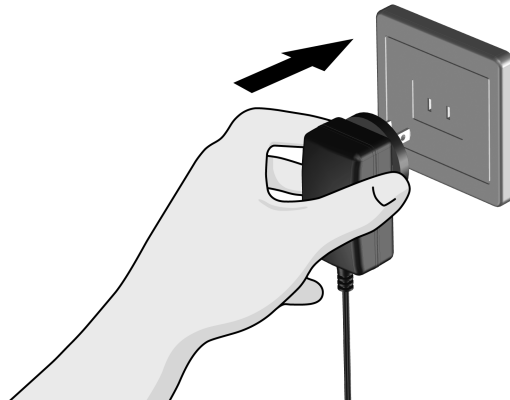
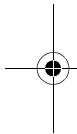
The connector port is labeled with the following symbol: **5V=**





2. Connect the power supply unit to the outlet.

See that the outlet is not controlled by a light switch. This will prevent you from turning off the CardioMessenger accidentally.

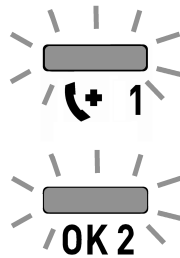




Self-test

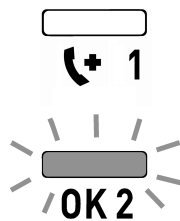
The CardioMessenger automatically conducts a self-test after being connected.

At first, both lamps on the front side of the CardioMessenger illuminate yellow for a short while.



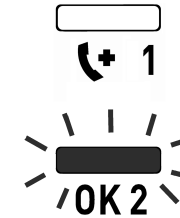
After about 10 seconds, the call back light will turn off.

Then the CardioMessenger checks the connection to the BIOTRONIK Service Center. Only the operating light illuminates yellow.



The connection check can take up to 15 minutes.

As soon as the connection has been checked successfully, the operating light illuminates green.

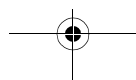
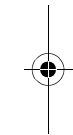
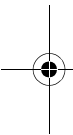


The CardioMessenger is now ready for use.

The CardioMessenger is intended for continuous operation. It should be connected at all times, especially at night.

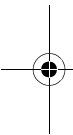
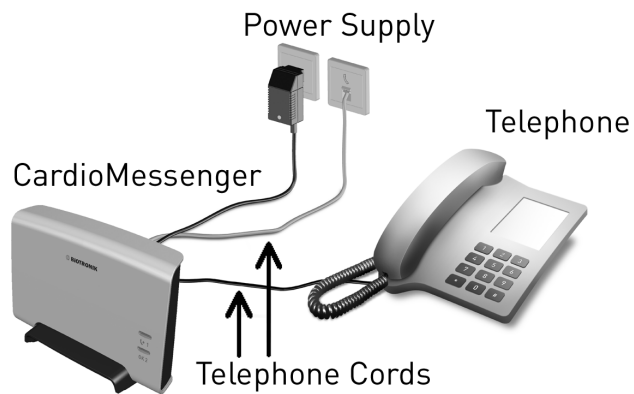
Note

It is a sign of malfunction if the operating light remains illuminated **yellow** for more than 15 minutes or if it does not light up at all. For details on the subject of "Debugging", see page 24.

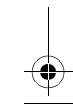
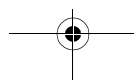
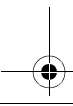
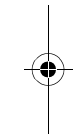
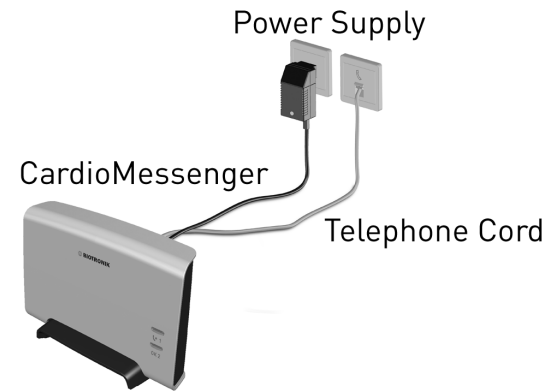




If you are operating CardioMessenger and telephone using one telephone wall jack (variant A), the readily connected CardioMessenger looks as follows:



If you are operating the CardioMessenger on a free telephone wall jack (variant B), the readily connected CardioMessenger looks as follows:



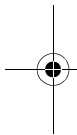


Insert brief instructions guide

Attached to the back cover of this technical manual is a removable instructions guide.

This guide helps to inform you quickly about the function and colors of the lights. Additionally, you can list your physician's phone number at the back cover of this guide.

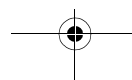
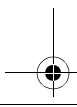
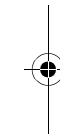
1. Remove the guide from this technical manual.
2. Write your physician's or the clinic's name and phone number on the back cover of this guide.



3. Insert the brief instructions guide into the slot on the left side into the housing of the CardioMessenger.



Now the brief instructions guide with your physician's phone number are ready at hand. Use it if the call back function of the CardioMessenger was activated by your physician. For details on the subject of "Call back function", see page 22.





Operate

The CardioMessenger does not have an on/off switch. After connecting it, it is ready for use as soon as the operating light illuminates green.



It is intended for continuous operation and should remain connected at all times, especially at night.

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

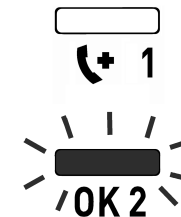
Note

It indicates a malfunction if the operating light illuminates **yellow** or does not light up at all. For details on the subject of "Debugging", see page 24.

Check lights

Check once a day whether either of the two lights is illuminated.

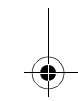
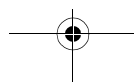
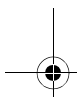
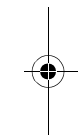
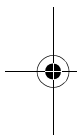
Usually the operating light illuminates green. The call back light is not illuminated.



Note

The functions of your implant are not affected at any time by the CardioMessenger, irrespective of the illumination or blinking of the lights.

See the next page for details on the subject "call back function".

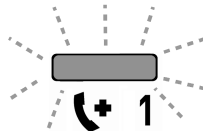




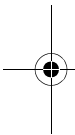
Call back function

With the aid of the call back light, your physician can ask you to call him. He can turn this light on via the landline. The light will then blink yellow for a maximum time of 3 days.

The call back light blinks if your physician expects your call.



Your physician will let you know whether he or she intends to use this function in general.

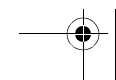
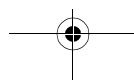
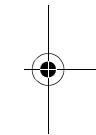
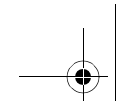
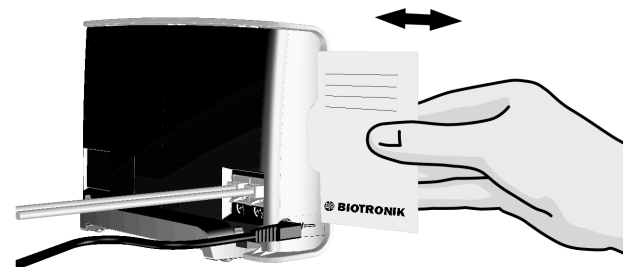


Perform call back

Call your physician as soon as you realize that the call back light is blinking.

Note

The brief instructions guide with your physician's phone number is located in the housing of the CardioMessenger (see "Insert brief instructions guide", page 20).





Turn off the call back light

To turn off the call back light, disconnect the CardioMessenger briefly from the main supply.

1. Pull the DC plug at the end of the electricity cable out of the port on the left side of the CardioMessenger.

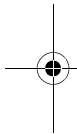
Both lights will turn off.

2. Connect the DC plug to the port again.

The CardioMessenger performs the self-test. Afterwards, the operating light will illuminate green and the call back light will no longer be blinking.

Note

For details on the subject of "Connection to the power supply", see page 16.

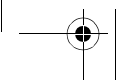
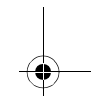
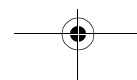
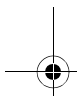
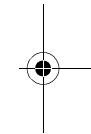
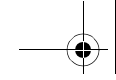


Switching Off the System

The CardioMessenger does not have an on/off switch. To turn off the CardioMessenger, disconnect it from the main supply.

1. Remove the power plug from the wall outlet.

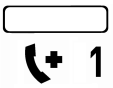
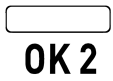
The operating control lamp will turn out. The CardioMessenger is switched off.

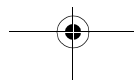
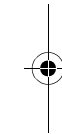
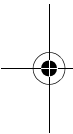




Debugging

You can identify issues with your CardioMessenger by use of the lights on the front side.

Light	Behavior	Operating status
Call back light 	Off	Normal operation; no malfunction
	Yellow blinking	Your attending physician is asking for a call (For details on the subject of "Call back function", see page 22.); no malfunction
	Yellow blinking	Error type B (both lights blink yellow): Repeat the self-test, see next page for further details
Operating light 	Off	Error type A: Check the power supply, see next page
	Green illumination	The CardioMessenger is ready for use; no malfunction
	Yellow blinking	Error type B (both lights blink yellow): Repeat the self-test, see next page for further details
	Yellow illumination	Error type C (only this light illuminates): Check the landline connection, see next page for further details





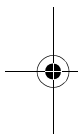
**Error type A:
Check the power supply**

The operating light is off. CardioMessenger is not ready for use.

Check the power supply:

- Make sure that the DC plug of the electrical cord is plugged in tightly into the port on the left side of the CardioMessenger.
- Make sure that the power supply unit is inserted properly into the wall outlet.
- Make sure that the outlet has current, for example by temporarily connecting the bedside lamp to the outlet and by turning the lamp on.

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

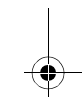
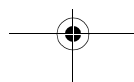
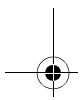
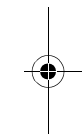


**Error type B
Repeat the self-test**

Both lights blink yellow. The CardioMessenger has not concluded the self-test. It is not yet ready for use.

1. Remove the power supply unit from the wall outlet.
2. Reconnect it.

The CardioMessenger restarts and performs the self-test. Both lights will illuminate yellow. The call back light will turn off once the self-test is complete. The operating light will remain illuminated yellow. Next, the CardioMessenger checks the connection to the BIOTRONIK Service Center. The operating light switches to green once the connection test is successful. The CardioMessenger is now ready for use.

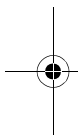




If both lights stay permanently illuminated yellow, the CardioMessenger is defective. Return it to your physician.

Note

The connection check can take up to 15 minutes.

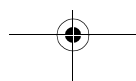
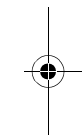
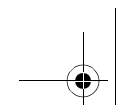


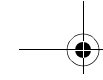
Error type C

Check the landline connection

The operating light illuminates yellow continuously (longer than 15 minutes). The call back light is off. CardioMessenger cannot connect to the BIOTRONIK Service Center.

1. Make sure that the one end of the telephone cable is properly inserted into the telephone wall jack.
2. Make sure that the other end of the telephone cable is properly inserted into phone inlet 1 on the back of the CardioMessenger.
3. Check whether the telephone line is available by lifting and listening to the receiver. You should be able to hear the normal dial tone.
4. Remove the power supply unit from the wall outlet.
5. Reconnect it.





The CardioMessenger restarts and performs the self-test. It checks the connection to the BIOTRONIK Service Center. The operating light switches to green once the connection test is successful. The CardioMessenger is now ready for use.

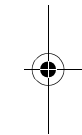
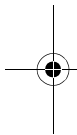
Note

The connection check can take up to 15 minutes.

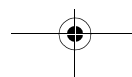
Note

The CardioMessenger has been designed for use with an analog landline. Correct operation cannot be ensured if using a digital landline. If you are unsure what kind of landline you are using, please contact your telephone provider.

If the operating light remains continuously illuminated yellow, contact your physician.

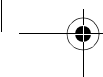


CardioMessenger II-S TLine



Debugging

27





Cleaning, maintenance, and disposal

Cleaning

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

Caution!

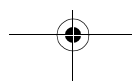
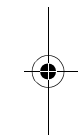
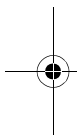
Disconnect the CardioMessenger from the main power supply before attempting to clean it with a moist cloth.

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

Maintenance

The CardioMessenger is intended for continuous, automatic operation. Once correctly installed, ongoing actions by you are typically not required (e.g., no maintenance is required).

In continuous operation, the longevity of the contained button cell corresponds to the longevity of the CardioMessenger.





Disposal

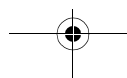
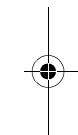
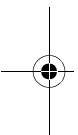
Do not dispose the CardioMessenger in the usual household trash.



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

If no longer required or if defective, please return the CardioMessenger and all other supplied parts to the physician. Your physician will return all parts to BIOTRONIK.

BIOTRONIK ensures the disposal in accordance with the national design of the European guideline 2002/96/EC on electric and electronic used devices (WEE).





Precautionary measures

The CardioMessenger is a medical device and therefore complies with strict requirements for their development, manufacture and testing.

Please take the following precautions:

Warning!

The device must be located outside the patient's vicinity if the intended user is to be introduced to the device in the hospital.

These legal requirements apply for electrical devices in hospitals and do not apply when the CardioMessenger is used at home.

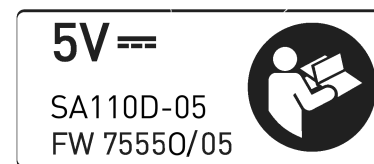
Warning!

Use the CardioMessenger only if it is undamaged. Return a damaged CardioMessenger to your physician.

Warning!

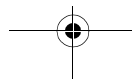
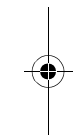
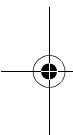
Use only the original parts included (for details, see "Technical data", page 37).

Other equipment may impair proper functioning of the CardioMessenger and increase the emitted interference and the device's susceptibility to interference. The label on the back side of the CardioMessenger indicates the approved power supply:



Caution!

Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician (or properly licensed practitioner).



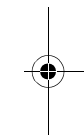
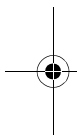


Caution!

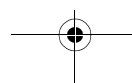
- Protect the CardioMessenger from:
- Water and high humidity
 - Temperatures above 40 °C (104 °F) (for example from direct sunlight and strong halogen spotlights)
 - Temperatures below 10 °C (50 °F)
 - Solvents, acids, detergents, and lyes

Caution!

The CardioMessenger may only be opened and repaired by authorized trained personnel.



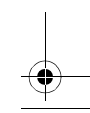
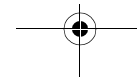
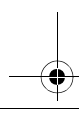
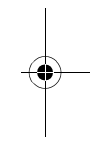
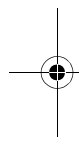
CardioMessenger II-S TLine



Precautionary measures

31







Guidelines

USA

FCC RF Exposure Requirements

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⁾.

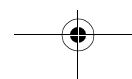
This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, 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.

1) Federal Communications Commission for Medical Implant Communications Service





The FCC ID number for the CardioMessenger is QRICM08V-1.

The ACTA ID number for the cable modem is AU7MMO1BMT5656SMI for the CardioMessenger II-S/1 and AU7MD04B2456 for the CardioMessenger II-S/2.

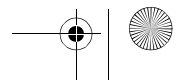
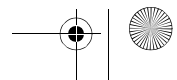
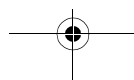
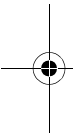
Statement according to FCC part 2.1091:
The internal/external antennas used for this mobile transmitter must provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Statement according to FCC part 15.105:
NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used

in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

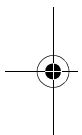
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by this company could void the user's authority to operate the equipment.





Address of responsible party:
BIOTRONIK, Inc.
6024 SW Jean rd. Bldg. B
Lake Oswego, OR 97035
Phone (800) 547-0394



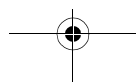
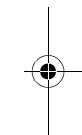
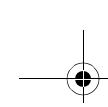
Canada

The CardioMessenger is registered at Industry Canada with the following number: IC: 4708A-CM08V1.

The cable modem is registered at Industry Canada with the following number: IC: 125A-0015 or 125A-0008.

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

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.





Electromagnetic compatibility

Note

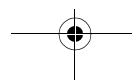
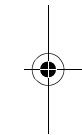
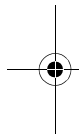
The CardioMessenger is protected from disturbances resulting from electromagnetic interference, electrostatic discharges, and other sources – including interference induced by cables. Interfering emissions from the CardioMessenger have been minimized. The CardioMessenger therefore meets the requirements 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

- Operating mode: Continuous operation

Permissible Environmental Conditions

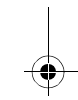
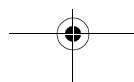
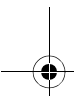
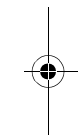
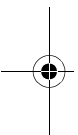
- Operating temperature: +10°C (50°F) to +40°C (104°F)
- Storage and transport temperature: -10°C (14°F) to +60°C (140°F)
- Relative humidity: 30% to 75% (non-condensing)
- Atmospheric pressure: 700 hPa to 1060 hPa

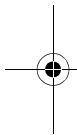
CardioMessenger

- Dimensions (WxHxD): approx. 203 x 136.5 x 80 mm
- MICS: Modulation FSK
- MICS frequencies: 402–405 MHz, 9 channels, 300 kHz frequency range
- MICS transmission power: 25 µW EIRP


Telephone cable

- Type: VK-117
- Length: approx. 2.5 m (8.2 ft)
- Outlet: Rj-11






Power supply unit

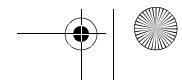
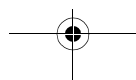
- Type: FRIWO MMP 15 FW75550/05
- Dimensions (WxHxD):
approx. 51.5 x 87.5 x 34 mm
- DC plug output:
Outer diameter 5.5 mm (mass),
Inner diameter 2.1 mm (plus)
- Input voltage:
100–240 V ~ 50–60 Hz 400 mA
- Output voltage:
5 V DC \pm 5 %, 2.4 A/12 W
- Safety class: II 

or:

- Type: Nordic Power (SAC) SA110D-05
- Dimensions (WxHxD): approx. 69 x 45 x 35 mm
- DC plug output:
Outer diameter 5.5 mm (mass),
Inner diameter 2.1 mm (plus)
- Input voltage:
100–240 V ~ 50–60 Hz 300 mA
- Output voltage:
5.1 V DC \pm 5 %, 2 A/10.2 W
- Safety class: II 

Technical manual

- Technical manual with brief instructions
guide CardioMessenger II-S TLine



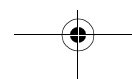
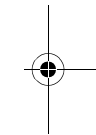
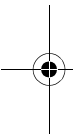


Appendix

Electromagnetic emitted interference according to IEC 60601-1-2

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 intended for residential purposes.
Interference of harmonics according to IEC 61000-3-2	Class A according to IEC 61000-3-2	
Voltage fluctuations/flicker emissions according to IEC 61000-3-3	Complies	

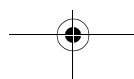
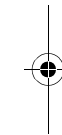
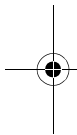


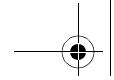


Electromagnetic emitted interference according to IEC 60601-1-2

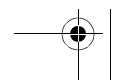
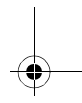
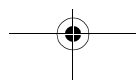
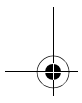
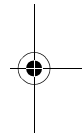
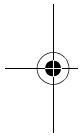
The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

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: 
<p>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.</p>			





- 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 re-orienting or relocating the CardioMessenger.
- b) Above the frequency range of 150KHz to 80MHz, ensure that field strengths are less than 3V/m.

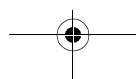
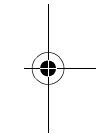
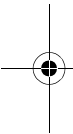




Electromagnetic emitted interference according to IEC 60601-1-2

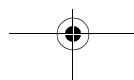
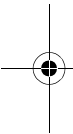
The CardioMessenger is suitable for operation in the indicated electromagnetic environment. The customer and/or operator of the CardioMessenger should make sure that it is used in an electromagnetic environment as described below.

Checking 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.





Checking immunity to noise	Test level according to IEC 60601-1-2	Conformance level	Guidelines for the electromagnetic environment
Voltage dips, brief interruptions and fluctuations in the supply voltage According to IEC 61000-4-11	<p>< 5% U_T for 1/2 cycle (> 95% drop)</p> <p>40% U_T for 5 periods (60% drop)</p> <p>70% U_T for 25 periods (30% drop)</p> <p>< 5% U_T for 5 s (> 95% drop)</p>	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	3A/m	Same as the test level	The magnetic field strength should correspond to the typical value in business and hospital environments.
Comment: U_T is the mains alternating voltage before applying the test levels.			



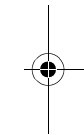
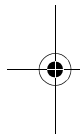


Recommended separation distances between portable and mobile RF communications equipment and the CardioMessenger

Transmission frequency	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Equation	$D = 1,17\sqrt{P}$	$D = 1,17\sqrt{P}$	$D = 2,34\sqrt{P}$
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.





Index

A

Ambient conditions	37
Appendix	39

B

Bedside table	7
BIOTRONIK Service Center	4, 21
Blinking	22, 24
Brief instructions guide	20, 22
Broken CardioMessenger	30

C

Call back function	22
Call back light	18, 22
Call your physician	22
Care	28
Check the landline connection ...	11, 18, 26
Check the telephone connection	11
Checking the power supply	25
Clean it	28
Cleaning	28

Connection to the landline	8, 19
Connection to the power supply	16, 19

D

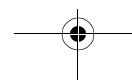
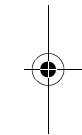
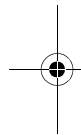
Damaged CardioMessenger	5, 30
DC plug	5, 23, 38
Debugging	24
Defective CardioMessenger	30
Disposal	29
Distance to the implant	7

E

Electricity cable	5, 16, 23
Electromagnetic Compatibility	36
Electromagnetic emitted interference ..	39

G

Green light	18, 21, 24
Guidelines Canada	35
Guidelines USA	33





H

Home Monitoring 3
 Hospital 30

I

Illumination 24
 Implant 3, 7

L

Landline connection 4
 Light 1 18, 21, 22, 24
 Light 2 18, 24

M

Maintenance 28

O

Operate 21
 Operating light 18, 21, 24
 Original parts 5, 37
 Outlet 17

P

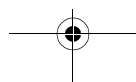
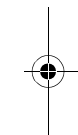
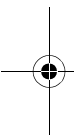
Package Contents 5
 Perform call back 22
 Phone inlet 1 9, 13
 Phone inlet 2 10
 Physician call back light 24
 Physician's phone number 20, 22
 Port for power connection 16
 Power connection port 16
 Power supply unit 5, 16, 38
 Precautionary measures 30

R

Ready-for-service status 21
 Recommended separation distances ... 44
 Repair 31

S

Safety instructions 30
 Sealing plug 9, 10, 13
 Self-test 18, 25
 Setup 7
 Suitable installation location 7

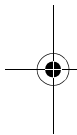




Switch off the system 23
 Switching on the system 21,23

T

Technical data 37
 Telephone cable 5,10,11,14,37
 Telephone wall jack 8,9,11,13,14
 Transmitter of the implant 3,7
 Turn off the call back light 23



U

Unsuitable installation location 7

W

Warranty 36

Y

Yellow light 18,22,24

