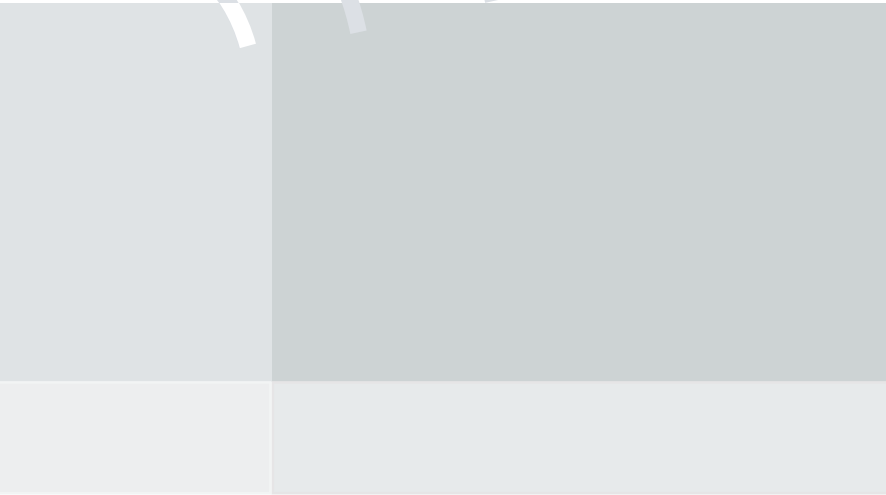


Brochure for patients using the
Home Monitoring
Patient Device



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Throughout this manual many references are made to “your doctor” for simplicity purposes. If you have a number of doctors, these references are for the specific doctor that follows your implanted device, pacemaker or defibrillator.

What is Home Monitoring?

Dear Patient,

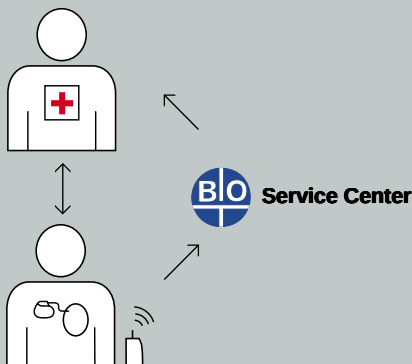
You are the recipient of an implanted pacemaker (PM) or Implantable Cardioverter Defibrillator (ICD). Your implant is a complex electronic device, which benefits your health and improves your quality of life.

BIOTRONIK has developed a new feature for your implant called,

the Home Monitoring function.

The Home Monitoring function permits implant-related monitoring by your doctor. Therefore, an optimal adaption of the implant to your personal and physical needs is possible. Your implanted device has a small wireless transmitter that sends out signals, which have been recorded by the device.

A patient device, provided to you for home use, receives these signals from the implant and transmits them to a BIOTRONIK Service Center. The implant data are compiled at the Service Center in a comprehensive report known as the Cardio Report.



The Cardio Report is sent to your doctor via FAX at certain predetermined periods decided upon by your doctor. Your doctor can then decide whether your implant settings should be optimized or if the therapy schedule should be changed. If necessary, he or she will contact you about an appointment for a follow-up examination to optimize your pacemaker or ICD.

Because of the restricted transmission range of your implant's wireless transmitter, the patient device is required for receiving and forwarding the implant data.

If your patient device is not operational or too far away from your implant, it does not affect the operation of your implanted device. In this case, your implant still “works” as usual. Only the Home Monitoring function is inactive. This means that messages can not be transmitted to the patient device and forwarded to the Service Center. The messages recorded by the implant can still be transmitted and evaluated during a regular follow-up examination. Your doctor will answer any further questions.

On the following pages you will learn interesting facts about the patient device and how to handle it.

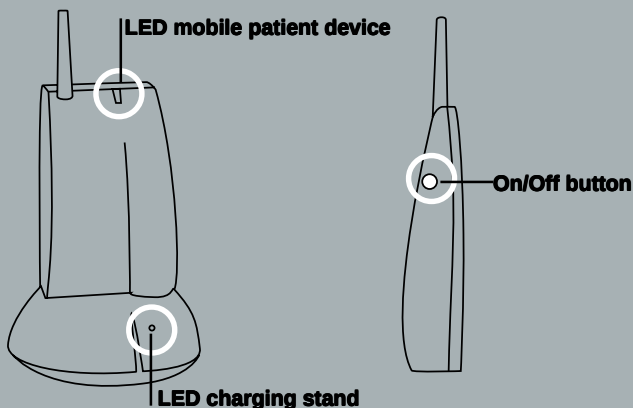


How does the patient device work?

BIOTRONIK has developed a mobile patient device which can always be taken with you to ensure that your personal freedom and mobility are restricted as little as possible. The patient unit consists of the following components:

- Mobile Patient device with internal batteries
- Charging stand with power supply set

The mobile patient device works similarly to a cellular telephone and transmits the messages received from the implant using the Short Message System (SMS). These digital messages are sent from the patient device to a BIOTRONIK Service Center. Once fully charged, the built-in batteries ensure approximately 15 hours of operating time. The mobile patient device remains operational while placed on the charging stand.



Safety precautions – What to look out for

The patient device and its components were developed, produced and tested according to the latest guidelines and standards. It meets the strict regulations for medical devices. So that your patient device functions without problems, the following safety measures must be carried out:

! Do not use the patient device in areas where a cellular phone is forbidden – hospitals, aircraft, etc.

Switch your patient device off before you enter areas where cellular phones are forbidden.



! Keep a minimum distance between the mobile patient device and your implant.

Your mobile patient device, similar to cellular telephones, can effect your implant if the distance between the mobile patient device and the implant is less than 15 cm (about 6 inches). To prevent disturbances, please keep the patient device at least this minimum distance from your implant. You can keep the mobile patient device in the supplied soft case, and transport it attached to your belt. Do not place the patient device directly over your implant. Do not carry the patient device inside the breast pocket of your shirt.

! Protect the patient device from external influences such as:

- Water immersion
- High humidity (e.g., in the bathroom)
- High temperatures >40°C (104°F)
- Low Temperatures <5°C (41°F)
- Extreme pressures
- Violent shocks or other strong mechanical influences
- Bending the charging contacts on the charging stand
- Placing conductive items in the charging stand (such as coins)
- Intensive light sources (direct sunlight, strong halogen bulbs)
- Detergents, solvents, acids and bases

! Do not use a damaged patient device.

Verify that none of the components are damaged before usage. Only use the following original parts from BIOTRONIK: The mobile patient device RUCM 200, the charging stand RUCL 1000 and the corresponding power supply (12Vdc @600mA, UL 2601-1 certified).

The patient device may only be opened and repaired by authorized qualified personnel.

If the device is damaged, please return it to your doctor. The batteries (type LG ICR 18650) installed by qualified personnel must also be replaced by these specialists.

! Handle the antenna with care.

Modifying or sticking other materials on the antenna interfere with the transmission qualities of the patient device.

! In the following cases, return the patient device to your doctor or to the clinic that issued the device:

- Your patient device does not function anymore.
- You do not need it anymore.

! Do not dispose of the device in household garbage.

Because of the rechargeable batteries (Lithium-ion batteries), the device must be disposed of separately.



How do I handle the patient device?

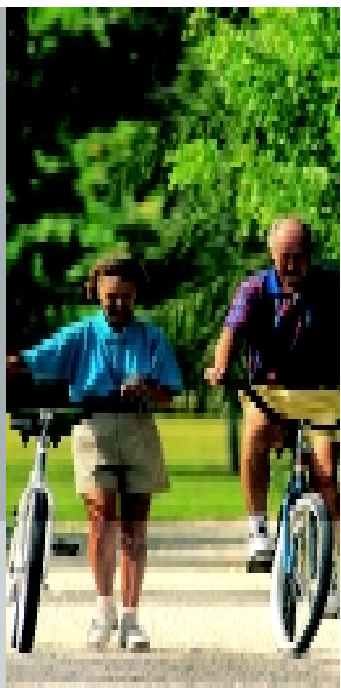
Below describes how to begin operating and how to use your patient device.

What must be done before starting to use the patient device?

Find a safe place for the device. That means:

- The device cannot be knocked to the floor or dropped.
- It is not too warm or too humid (not in a bathroom).
- The device is not in direct sun light.

Normally, a bedside table is a suitable place. When you sleep, the distance between your implant and the patient device should not be more than approximately two meters (about 6 feet). In this way, during the night your implant data can be successfully transmitted to the patient device.



How do you connect the device?

Check that the operating voltage of your power cord matches the outlet in your home (normally 120 Vac, 60Hz).

If both voltages correspond, insert the plug of the power cord into the wall-socket. The power supply cord has a small plug at the opposite end of the cable. Connect this plug to the socket that is located in the back of the charging stand.

1



Insert the plug of the power supply unit into the wall socket

2



Connect the small end of the power cord to the socket in the patient device's charging stand.

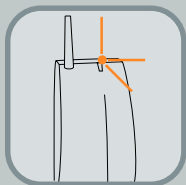
How do I turn the mobile patient device on?

1



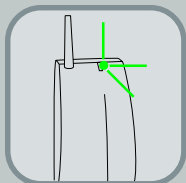
Push the button on the side of the mobile patient device until a short beep is heard.

2



The light on the top of the patient device will begin to flash orange for approximately 0.5 to 2 minutes.

3



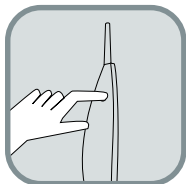
When the light begins flashing green, your patient device is ready for use.

If the light alternately flashes two times green and two times orange, your patient device is not able to log onto the local cellular phone system. In this instance, please place your device in another location which may receive a stronger signal from the cellular network. Once operational, the light will begin to flash green.

Note: When changing locations, turn the patient device off and then on again (i.e. switch off, find new location, switch on again).

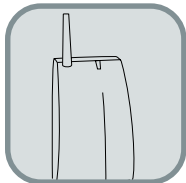
How do I turn the mobile patient device off?

1



Push and hold the power button on the side of the patient device until a short “beep” is heard and the light goes out.

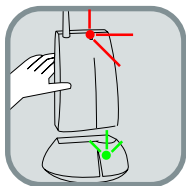
2



The unit is off, and no further data can be received or transmitted.

How do I recharge the batteries of the mobile patient device?

1



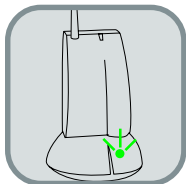
Place the mobile device onto the charging stand. Charging begins immediately. Charging will occur whether the mobile patient device is on or off.

2



During charging, the light on the charging stand is orange.

3



When the batteries are recharged, the light turns green again.

Note: The system is operational while charging if the mobile patient device has been left on. This is the preferable method. Usually, the charging operation takes no longer than 5 hours. It is acceptable to permanently keep the patient device in the charger stand.

How do I know if the batteries are low or discharged?

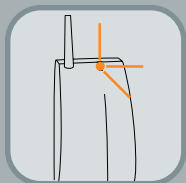
If the battery charge falls below 10% of the maximum charge, the light on the top of the mobile patient device flashes red. At the same time, 3 short beeps will be heard. When this occurs, recharge the mobile patient device in the charging stand.

How can I see if the patient device is transmitting messages?

When a message is being transmitted, the light on top of the patient device will flash orange for as long as two minutes. Transmission of data is conducted automatically at certain intervals as determined by your doctor. The message transmission by the implant is repeated several times in an interval of 8 to 9 minutes.

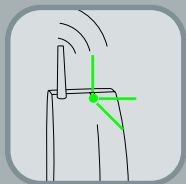
Transmission of message

1



During the entire message transmission, the light on the mobile patient device flashes orange.

2



After the transmission is finished, the light flashes green again.

What do I do if the mobile patient device does not function any more?

If the patient device does not function (i.e., the light is out and there is no beep), place the device in the charging stand to recharge it.

If the device does not function after recharging, first push the Reset button on the back of the mobile patient device with a pointed object. Then switch the device on, using the power on button on the side – as described on page 9. If the light does not flash green after 5 minutes, please inform your doctor.

Reset

1



Push the Reset button on the back of the patient device with a pointed object.

2



Push and hold the power on button on the side of the patient device until a short beep is heard.

When does my implant transmit messages?

Your doctor can adjust your implanted device so that it can transmit messages under certain circumstances. There are two possible ways to activate a message transmission:

1 Periodically after a predefined time interval. This interval is set by your doctor.

The doctor has adjusted your implant so that it transmits periodic messages at a certain time and at periodic intervals (for example: every night at 2:00 am).

2 Transmission activated by a special magnet (pacemaker patients only)

In certain cases, the transmission of data can be activated by placing a special magnet directly over the implant. Your doctor will explain to you if, how and when you should do this.

I Please use this function only if your doctor requests it and gives you a suitable magnet. Your doctor must program this function for your implant.

Note: Patients with implantable cardioverter defibrillators should not place a magnet over your chest, as this interferes with the proper functioning of your ICD.

How do I take care of the device?

In order to use the patient device over a long period of time, it is necessary to treat the device with care. The faultless operation of the device can only be ensured when the following conditions are observed:

- 1 Keep the device clean and away from dirty or dusty environments.
- 2 To clean, use a soft cloth. Moisten the cloth with water when necessary. Avoid direct contact of the device with water.
- 3 If the patient device does not work, return it to your doctor.



Frequently asked questions by patients

? What happens if I forget to recharge my mobile patient device?

The batteries generally supply power for about 15 hours. If the light on the mobile patient device turns red, place the device on the charging stand until the light turns green again (usually up to 5 hours). During the recharging process, the light on the charging stand is orange. If the mobile patient device is not recharged, the functions of the patient device are affected and no message can be received and transmitted to the Service Center.

There is no health risk if the patient device is not recharged because the regular functions of your implant are independent of the patient device.

? What happens if the patient device fails? Does that affect my implant?

No. Your implant “works” as usual. During a failure of the mobile patient device, only the Home Monitoring function is no longer available. This means that messages can not be transmitted via the patient device to your physician. The messages are still recorded by the implant and can be transmitted and evaluated during a regular follow-up examination with your doctor.

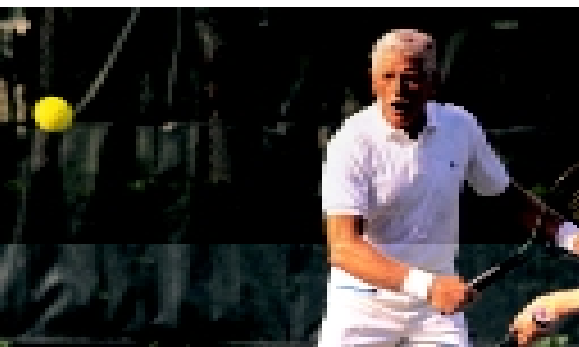
Try to turn it on again and to recharge the mobile patient device. If this does not work, inform your doctor and follow his instructions.

? Can I take my patient device with me everywhere—shopping, walking, sports?

Yes. You can always take your mobile patient device with you during your private and working activities, as long as your doctor recommends it and you are not within areas where cellular phones are not permitted. The mobile patient device can be comfortably transported attached to your belt in the supplied soft case. It is also possible to carry it in a normal bag or backpack. The distance between implant and patient device should not be more than approximately two meters (about 6 feet), but must be at least 15 cm (6 inches). The patient device is supplied with a big carrying case for convenient and secure transportation and travelling.

? What do I have to do when I go on vacation/travelling?

Consult your doctor beforehand and inform him/her of your travel plans. You can take the patient device with you everywhere and connect it where there is a suitable power outlet (120 Vac, 60Hz). A country-specific adapter may be necessary when travelling outside of the U.S. Your doctor will give you detailed information. When transporting the device on airlines, the regulations for cellular telephones must be followed (e.g., do not use the patient device during a flight).



Technical terms and abbreviations

SMS

Short Message Service – This is a digital communication system for mobile phones.

Cardio Report

Short report containing the current therapy status of the patient on the basis of data transmitted from the implant.

Home Monitoring

Technical feature of pacemakers and ICDs used to transmit messages over a certain frequency and make them available to your doctor.

Service Center

Location where implant data is received, analyzed and forwarded to your doctor.

Electronic Article Surveillance (EAS) Systems

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

Regulatory aspects

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

The transmitter is authorized by rule under the Medical Implant Communications service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this receiver will be free from interference.

The FCC ID number for this device is PG6BA0T

The patient device, as well as the implant itself, are tested by an independent regulatory authorities such as the FCC, to comply with the appropriate standards and regulations.

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

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with a Biotronik, Inc. accessory designated for this product, or when used with an accessory that contains no metal and that positions the device a minimum of 0.5 cm from the body.

Technical Data

	power supply	charging stand	mobile patient device
Model /type	120Vac, 600mA*	RUCL 1000	RUCM 200
Voltage/ power input	120 Vac±10%, 60 Hz	12 V dc, 600 mA	9 V DC, 500 mA
Voltage/ power output	12 Vdc DC/ 600 mA	9 V dc, 500 mA	—

* UL 2601-1 certified

Stock and Transportation Conditions

temperature	+5° C to +55° C
humidity	93% relative humidity
air pressure	50 mbar to 1250 mbar

Addresses

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