



**BIOTRONIK**  
**Home Monitoring**  
Information for Patients  
and Their Relatives

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## Make Life Easy

Each year, more than one million patients worldwide receive an insertable cardiac monitor, a pacemaker, a cardioverter-defibrillator (ICD) or a system for cardiac resynchronization therapy (CRT). These implantable devices now resemble tiny computers with enormous capacity, and they are becoming increasingly complex. They therefore need to be regularly checked and adjusted. Routine checks of the implanted devices and the heart by a cardiologist are thus unavoidable.

**The use of BIOTRONIK Home Monitoring® provides patients with implanted devices safety beyond routine testing.** Automatic data transmission allows cardiologists to detect diseases at an early stage. This provides them with information about the state of the patients' hearts and the implanted device on a daily basis, directly from the patients' domestic environment. Thus, doctors are enabled to respond to changes in

patients' state of health at all times, reducing the amount of examinations to a manageable number.

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Patients can flexibly structure their daily routines and remain under constant medical care, even when they are not visiting their doctors.

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On the following pages we explain how the BIOTRONIK Home Monitoring service functions. To have your personal questions answered, it is recommended that you speak to your doctor or the BIOTRONIK patient service before the device is implanted. We will also gladly answer any technical questions you may have. Further information in this regard is provided at the end of the brochure.



## The Secure Choice: BIOTRONIK Home Monitoring

**Observing Your Heart around the Clock**  
BIOTRONIK Home Monitoring implanted devices provide versatile options to improve the day-to-day treatment and safety of patients. The heart rhythm and the implanted device are automatically and continuously monitored. Daily updates of cardiac and device status allow the cardiologist to regularly evaluate the patient's condition and know if the implanted device functions properly. The patients are able to engage in their routine activities and remain in their familiar environment.

**Therapy as Individual as You**  
Every heart changes over time, for example as a result of medication or lifestyle. Home Monitoring allows your doctor to monitor the state of your health at a distance and to adapt your treatment to changes in your circumstances. For patients suffering from congestive heart failure, close monitoring of certain values is a prerequisite for maintaining a stable

heart function and improving their well-being in the long term. For patients with an ICD, Home Monitoring can provide significant relief, as unnecessary shock deliveries can be clearly reduced with the aid of reliable information.<sup>1</sup> Patients who are dependent on a pacemaker, on the other hand, increase their safety levels, as the success of their therapy can be checked at any time.

### **You're in Safe Hands with Reliable Early Detection**

Study data has shown that patients with congestive heart failure have clear survival advantages when under close Home Monitoring care.<sup>2,3,7</sup> Furthermore, Home Monitoring patients usually feel safer and benefit from a higher quality of life as clinical events can be more rapidly identified and treated.<sup>4,5</sup> This means that fewer hospital stays are required.<sup>1,5,6,2</sup>





# On the Cutting-Edge of Remote Monitoring

## Care Beyond the Implant thanks to Continuous Data Transmission

All BIOTRONIK Home Monitoring implanted devices have a tiny antenna and are thus suitable for remote monitoring. The device records all heart and implanted device activities around the clock. Any tiny deviation in the cardiac or system function is thus recorded and saved on the implanted device. Once a day – usually at night while you sleep – the Home Monitoring device transmits all this data to a patient device (your Cardio Messenger) by radio, without you having to do anything, or even noticing. Any data transmission gaps could delay the timely detection of critical changes.

Any faulty data transmissions are therefore automatically recorded by the system and reported to the doctor.

## Your Data – Encrypted and Highly Protected

Your implanted device (1) records important cardiac and device information each day and automatically transmits it to the CardioMessenger at night (2). The CardioMessenger transmits this data to the Home Monitoring Service Center (3) in encrypted form via the cellular phone network. All information is evaluated, filtered and summarized in a so-called CardioReport for each patient at the center (4). Your doctor can then access all values via a secure website and is thus provided with a day-to-day therapy progress report (5).





# On the Cutting-Edge of Remote Monitoring

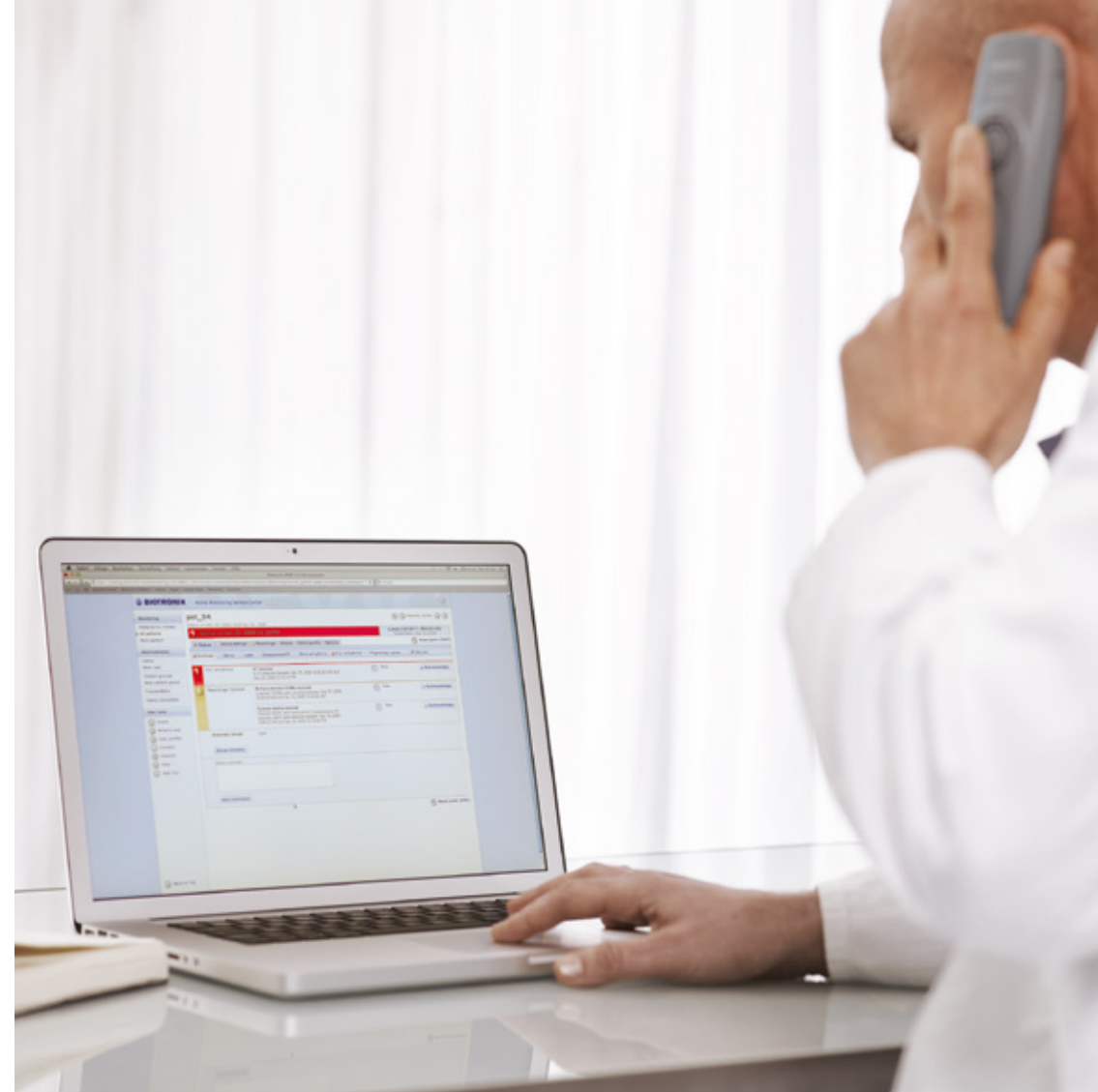
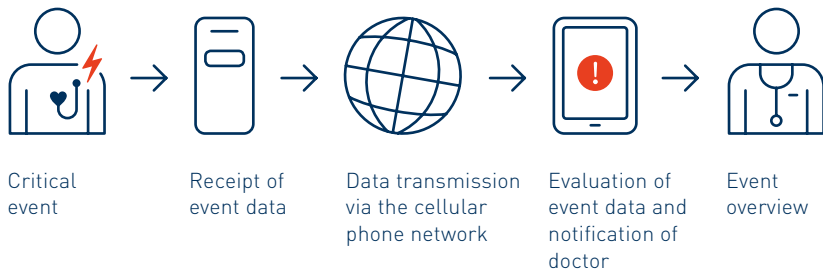
## Prioritization According to the "Traffic Light" Principle in order to Detect and Treat Problems at an Early Stage

By making use of a simple color scheme similar to a traffic light system, your cardiologist can determine which changes in your state of health should be classified as critical and trigger a notification. Depending on their urgency, your doctor can divide these into "yellow" (important) and "red" (critical) alarm messages. Your doctor will be automatically informed about any events marked as red or yellow within 24 hours by e-mail, fax or SMS. This means that any health and technical problems can be detected

long before the next routine examination. Your doctor can contact you rapidly and treat the problem at an early stage.

- Start and duration of a rhythm disturbance
- Intracardial ECG recording (IEGM Online)
- Device therapies such as electrical pulses and shock delivery
- Current battery status of your implanted device
- State and functionality of the leads
- Special measuring values to evaluate existing congestive heart failure

## Automatic Transmission of Event Reports Using BIOTRONIK Home Monitoring





# CardioMessenger – Fully Mobile

## CardioMessenger - Always Ready

Your doctor has given you an easy-to-operate transmitter for regular transmission of your cardiac device data to take home.

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This so-called CardioMessenger is ready for use and will transmit your data to your doctor in encrypted form via the cellular phone network on a daily basis.

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The device comes in two variants.

## Convenient as a Smartphone – the CardioMessenger Smart

The CardioMessenger Smart is a transmitter of the latest generation, weighing a mere 127 grams. It resembles a smartphone and has a rechargeable battery that allows it to be used as a mobile device for up to 48 hours. To ensure that your cardiac device data can be reliably transmitted to your doctor every day, simply place your device on your bedside table when

going to bed and charge it via the power cable. The on/off indicator has no LED and will thus not disturb your sleep. If you wish to go on holiday or will be traveling overnight, remember to take the power supply unit along. You should also ensure that you never wear the CardioMessenger Smart directly above the implanted device, such as in your breast pocket. The same applies to your cellular phones in day-to-day use. More detailed information is provided in your technical manual.

## Easy to Use – the Stationary CardioMessenger II-S

The stationary CardioMessenger II-S must be connected to the mains supply throughout in order to transmit the implanted device data. Plug the CardioMessenger into a socket near your bed and place it on your bedside table. Thus your implanted device data will be automatically transmitted via the cellular phone network to your doctor every night while you sleep. More detailed technical information, including on the LED lights, may be found in the technical manual.



# Better Quality of Life with BIOTRONIK Home Monitoring

## Flexible Follow-Up Care – Demand Driven and from Home

Although, in an emergency, remote monitoring cannot replace a call to your doctor or a stay in hospital, routine follow-up care can be reduced to a reasonable level as a result of Home Monitoring transmissions. Such care will no longer be required at rigid time intervals, but in accordance with your health requirements. As long as the state of your heart and implanted device allows it, your doctor will be able to provide some of your routine follow-up care in the form of remote monitoring. Thus, you and your relatives will not only save time, but also unnecessary traveling.

## Safety throughout the Day

Whether you are at home or traveling, your CardioMessenger will allow you to have regular contact with your doctor. Wireless data transmission via the cellular phone network ensures that you remain flexible, yet cared for – wherever you may be.

## Carefree Holidays

Similarly to a smartphone, you can easily take the CardioMessenger along while you are traveling. The worldwide cellular phone network is used to transmit implanted device data from over 160 countries to the practice or clinic. To avoid transmission gaps, please inform your center in advance if you will be traveling to countries with other time zones.

## We Are There for You.

You will find more detailed information about therapy and follow-up care online on the following website: **[www.biotronik.com/patients](http://www.biotronik.com/patients)** If you have any questions about your implanted device or about Home Monitoring care, the BIOTRONIK service team will be pleased to answer them, either by phone at **(030) 68905-0** or by e-mail at **[patients@biotronik.com](mailto:patients@biotronik.com)**.





# Frequently Asked Questions



## Questions About BIOTRONIK Home Monitoring

### **What Is so Special about the BIOTRONIK Home Monitoring System?**

BIOTRONIK Home Monitoring is the first and only monitoring system that ensures fully automated and highly reliable transmission of implanted device data on a daily basis.<sup>10</sup> It is the only system that has been specially approved for the early detection of medical and technical complications and can replace medical follow-ups of your implanted device with remote monitoring.<sup>6</sup>

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Study data has shown that the use of Home Monitoring allows for more rapid intervention, thus improving the survival chances of patients with implanted devices.<sup>2,3,7</sup>

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Automatic data transmission via the cellular phone-enabled CardioMessenger allows Home Monitoring to be used with ease anywhere in the world.

### **How Many People Are Using Home Monitoring?**

Every month some 3,500 patients decide to make use of the increased safety and mobility of BIOTRONIK Home Monitoring, the world's first cellular phone-based remote monitoring system that allows for automatic, reliable follow-up care for you and your implanted device. The Home Monitoring Service is now being used in over 60 countries and in more than 7,300 hospitals and practices. Over 800,000 patients worldwide currently have the option of being mobile, while still maintaining contact with their doctors.



# Frequently Asked Questions

## Can Any Patient with an Implanted Device Make Use of Home Monitoring?

In order to transmit remote medical data via the Home Monitoring service, your implanted device must incorporate a special antenna. Not all cardiac pacemakers, ICD and CRT devices are equipped with this – , but an increasing number are. Whether you, as a patient, will receive an implanted device capable of transmitting medical data will depend on your consent and on the medical evaluation of your doctor. You will need to jointly decide whether Home Monitoring constitutes a meaningful addition to your therapy. However, remote monitoring for patients with implanted devices is increasingly being recommended in treatment guidelines.<sup>8,9</sup> There are also medical funds that already routinely pay for the cost of the CardioMessenger and Home Monitoring system.

## Can Admission to Hospital Be Prevented with the Aid of Home Monitoring?

Close monitoring allows for rapid identification of malfunctioning implanted devices or leads, as well as any deterioration in your cardiac function. The early detection of atrial fibrillation, for example, can prevent strokes, while timely correction of therapy can result in a long-term improvement of the disease

progression.<sup>1,5,6</sup> Early adaptation to: your medication, settings of the implanted device, or to your lifestyle, can help avoid hospital admission and maintain the efficiency of the heart.<sup>3</sup> Vital pulses and shock deliveries by the implanted device can also be reduced to the essentials by close monitoring, thereby protecting your heart.<sup>1</sup>

## Can Home Monitoring Replace an Emergency Call or a Visit to the Emergency Ward?

Home Monitoring allows for safe and early detection and treatment of medical and technical problems and changes which you often do not perceive at all.<sup>5</sup> Based on this information, your doctor can respond at an early stage and invite you to report to the practice for treatment. Review of the patient's data usually takes place during normal clinic or practice hours.

**Home Monitoring** has not been designed to act as an emergency system. In this instance, visit the emergency ward or place an emergency call.








# Frequently Asked Questions

## Questions About the CardioMessenger

### How Do I Know that My CardioMessenger Is Working Correctly?

The LED will light up in green  (CardioMessenger II-S) or the **OK** symbol will appear on the LCD screen (CardioMessenger Smart).

### What Does the Telephone Symbol on the CardioMessenger II-S and Smart Signify?

If the yellow light next to the telephone symbol on your CardioMessenger II-S starts flashing  or if the telephone receiver symbol  appears on the display of your CardioMessenger Smart, please contact your practice or clinic. The light will be activated for a maximum of three days. If you have managed to contact your doctor and wish to switch off the light, simply disconnect the power plug for a short while.

### What Happens when I Go Away and Forget the CardioMessenger?

From a technical point of view, this is not a problem. Your CardioMessenger will continue to remain functional. As soon as you return home and are in the proximity of your CardioMessenger again, all information collected during

your absence will be transferred with the next transmission interval that is usually taking place at night. If you intentionally wish to leave your CardioMessenger at home, please briefly inform your practice or clinic in order to avoid error messages and needless worry to your cardiologist.

### What Do I Need to Take into Account if I Use the CardioMessenger Smart whilst Traveling or on the Road?

When traveling by plane, you can also take the CardioMessenger Smart along and switch it off for the duration of the flight. Once you switch on the device after landing, all events recorded in the interim will be automatically transmitted to your doctor via the cellular phone network.





# Frequently Asked Questions

## What if Smartphones Are Prohibited?

Prohibitions on the use of cellular phones on airplanes or in hospitals, designed to prevent potential interference, also apply to your Cardio Messenger Smart. Please switch off the device in this case. Prohibitions on the use of cellular phones to avoid noise, for example on a train, at the theater or in a cinema, will not apply to your CardioMessenger Smart. You can leave it switched on in these environments.

## How Much Power Does My CardioMessenger Consume?

The annual energy use of the Cardio Messenger is minimal. The power costs for operation amount to approximately EUR 2.50 per annum. Where do I place the CardioMessenger? To ensure data transmission, remember to place the CardioMessenger not less than 8 inches (20 cm) away from you and no more than 6 feet (2 meters) away from the place where you sleep.

## Questions About Data Transmission

### How Can I Be Sure that My Data Will Remain Secure?

BIOTRONIK takes the protection of your personal data very seriously. Remote monitoring of your implanted device

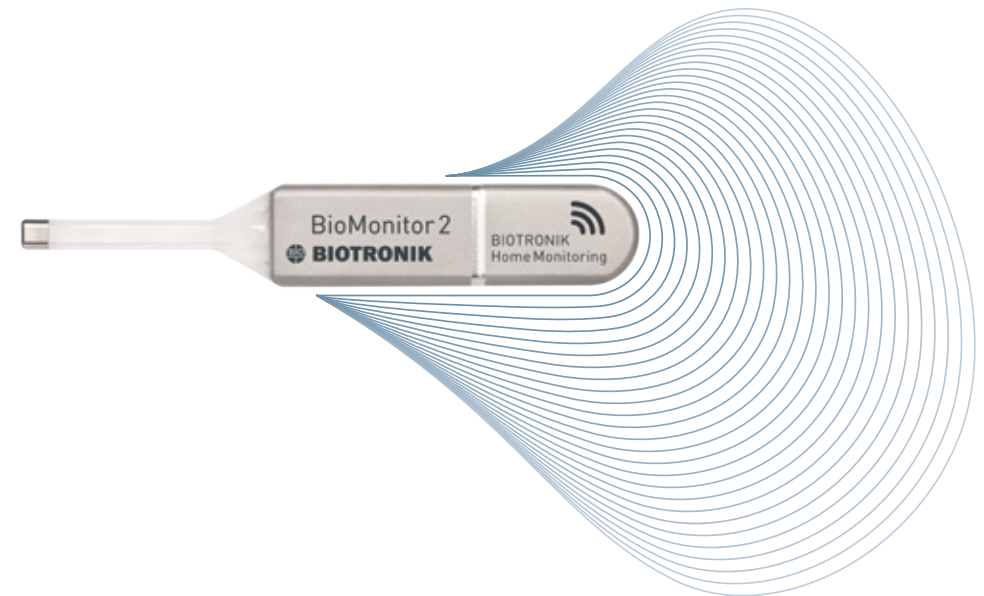
will only take place with your explicit consent. During data transmission, your medical data is encrypted, without any personal information, thus no conclusions can be drawn about your identity as a patient. Processing of the Home Monitoring data takes place only in Germany and is thus subject to German data protection regulations, which are among the strictest in the world.

### Are the Data Transmissions of the CardioMessenger Hazardous to My Health?

No, BIOTRONIK implanted devices and the CardioMessenger make use of a special transmission frequency (Medical Implant Communication Service band) only reserved for medical products and requiring a mere 25  $\mu$ W. This excludes any risk of a health hazard.

### Could My Cellular Phone Disrupt the Data Transmission of the CardioMessenger?

No, cellular telephones transmit on another frequency and will not interfere with the function of the CardioMessenger.





# Frequently Asked Questions

## Could Errors Occur during Data Transmission?

Data transmission with Home Monitoring is extremely reliable. If a lack of cellular phone coverage should result in transmission problems at any stage, your data will be temporarily stored in the CardioMessenger. If the problem persists, your hospital or practice will be informed. As soon as your CardioMessenger has its cellular phone transmission restored, the transmission process will be repeated and the data will be updated on a daily basis.

## Do Daily Data Transmissions Reduce the Service Life of My Implanted Device?

No. All Home Monitoring data outside the implanted device are analyzed and processed in a specially set-up and secured computer center (Home Monitoring Service Center). Therefore, the battery capacity is extended and the service life of your device will not be affected. Close monitoring with the aid of cellular phone and internet technology helps to improve your state of health and reduces the number of shock deliveries required. The early detection of technical defects and the reduction of unnecessary therapies contribute towards the optimal use of the battery service life by limiting all device activities to the essentials.<sup>1</sup>

## Key Aspects at a Glance

### What Should I Do when I Get Dizzy, My Heart Is Racing or I Experience Any Other Symptoms?

If you should experience any symptoms such as dizziness, nausea or a racing heart, please inform your doctor and make a note of the exact time of the event. This will allow your doctor to later determine whether the symptoms are being caused by the implanted device or by your heart.

### How Do I Behave after Shock Delivery by the ICD?

An ICD is designed to emit strong power pulses (shocks) in the event of life-threatening ventricular fibrillation. As soon as your ICD delivers a shock, your doctor will be informed the next time you are near your CardioMessenger. Although shock delivery constitutes an important part of the ICD therapy, it should always be followed by an examination in order to detect potential changes to your heart and the function of your implanted device. Therefore please contact your doctor after each shock delivery.



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# BIOTRONIK Home Monitoring

## Information for Patients and Their Relatives

### BIOTRONIK SE & Co. KG

As one of the world's leading cardiovascular medical device companies, with several million devices implanted, BIOTRONIK is represented in over 100 countries by its global workforce of more than 5600 employees. Quality, innovation and reliability define BIOTRONIK and its growing success – and deliver confidence and peace of mind to physicians and their patients worldwide.

### Do You Have Any Further Questions?

Our patient service will be pleased to assist you on the phone or in writing:

**(030) 68905-0 or [patients@biotronik.com](mailto:patients@biotronik.com)**

