

# BioMonitor 2

Patient Information

ProMRI®



# BioMonitor 2



# We Listen to Your Heart

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## Dear patient,

Your doctor has decided to implant a cardiac monitor – BioMonitor 2 – to continually monitor your cardiac rhythm over an extended period of time and be able to establish any irregularities in your heartbeat or the cause of any symptoms.

The following pages of the brochure will tell you what BioMonitor 2 does and how it works.

## BioMonitor 2 and Any Accessories



### BioMonitor 2

for recording heart rate



### Remote Assistant

for ECG recording  
by the patient



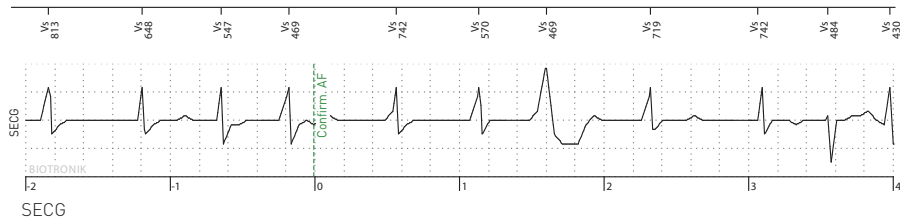
### CardioMessenger Smart

for telemedical  
care using  
BIOTRONIK Home  
Monitoring®

# The Heart at a Glance

## What Is a Cardiac Monitor?

A cardiac monitor such as BioMonitor 2 is a type of mini-ECG device that can continuously record your heart rhythm over an extended period of time and store any irregularities in your heartbeat with an ECG (electrocardiogram). With the help of these ECG recordings, your doctor is in a better position to make a decision about treatment and give you the best care.



Example of an ECG recording with BioMonitor 2



BioMonitor 2 with Remote Assistant



"CardioMessenger Smart" patient device

# Reliable Diagnostics

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## What Does BioMonitor 2 Do?

Some cardiac rhythm disturbances can occur spontaneously and be asymptomatic. That does not make the diagnosis easy for the doctor. BioMonitor 2 offers him the opportunity of closely monitoring your heart rhythm over weeks and months and making a firm diagnosis of an existing cardiac disease.

BioMonitor 2 is usually recommended to patients whose doctor suspects cardiac rhythm disturbances in the atria or chambers of the heart. Using BioMonitor 2, he can firmly diagnose each rhythm disturbance and from that initiate appropriate therapy. Atrial fibrillation, for example, can be reliably detected and complications such as strokes prevented. Furthermore, BioMonitor 2 can also provide important information on the cause of dizziness or fainting spells of unknown origin.

Your doctor will be the best person to explain to you in a personal consultation what the advantages of BioMonitor 2 are for you and how it can support your treatment.

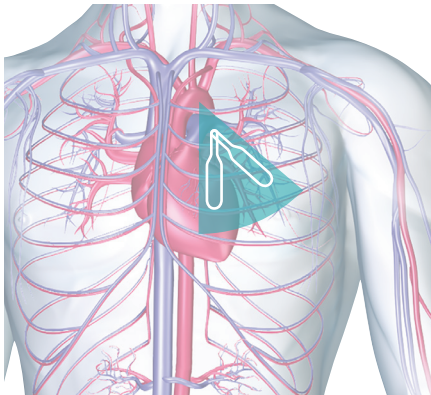


# Easy Insertion

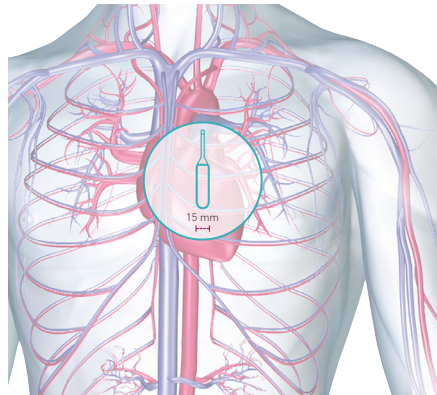
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## How Is BioMonitor 2 Inserted?

The insertion of BioMonitor 2 is a minor routine procedure that is performed under local anesthesia and only takes a few minutes<sup>1</sup>. BioMonitor 2 is a small cardiac monitor that adapts itself perfectly to the natural shape of your body, above all through its flexible antenna. It is usually inserted subcutaneously on the left side above the heart in order to measure the best heart signals.



Possible positions of BioMonitor 2



Unremarkable scar after the insertion of BioMonitor 2

## For How Long Do I Have to Have BioMonitor 2?

The battery capacity of BioMonitor 2 is enough to be able to monitor a patient's heart rhythm for up to four years around the clock and record rhythm disturbances at all times. However, for how long you actually have to have the cardiac monitor will depend on your condition and the medical opinion of your doctor.

<sup>1</sup> Interim Report 1, BioMonitor 2 Pilot Study, Version 1.0, 10 August 2015, BIOTRONIK SE & Co. KG

# Reliable Sensing

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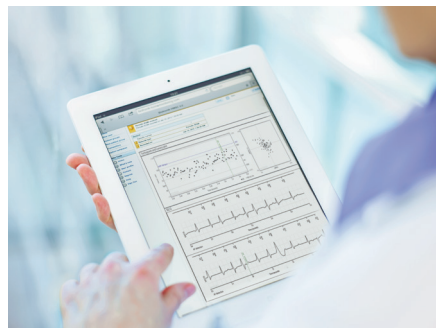
## How Does BioMonitor 2 Work?

BioMonitor 2 measures all heart signals using sensors that are located at both ends of the cardiac monitor. Unlike an external ECG device, BioMonitor 2 therefore manages to operate without an ECG cable. As a result, you can remain completely flexible in your everyday life.

The special design of BioMonitor 2 allows optimal signal quality – it can record irregularities in the heartbeat very precisely and then store them. All stored ECGs can be transmitted to the doctor by telemedicine using the BIOTRONIK Home Monitoring Service Center and assessed by him on a daily basis.



CardioMessenger Smart and BioMonitor 2



ECG analysis using BIOTRONIK Home Monitoring

# Capture the Precise Moment

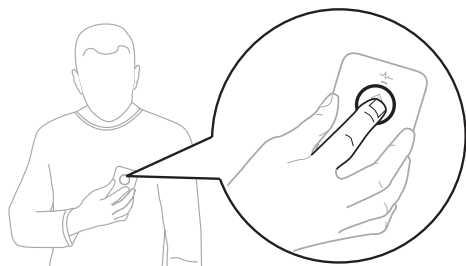
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## What Is the Remote Assistant and How Do I Use It?

Usually, BioMonitor 2 records each measured irregularity in your heart rhythm independently and automatically.

If your doctor thinks it necessary, he can give you the Remote Assistant to take home. You then have the opportunity of triggering additional ECG recordings – e. g. after loss of consciousness or if you experience symptoms such as dizziness or racing heart.

You can start the ECG recording by guiding the Remote Assistant onto the point on your chest where BioMonitor 2 has been inserted. Press the trigger key and hold the device in this position for at least three seconds. BioMonitor 2 then saves all heart rhythms from the last seven minutes retrospectively as an ECG. Your doctor then has the opportunity of establishing, if necessary, any correlations between your symptoms and your heart rhythm.



In order to save the ECG recording, you have to briefly press the trigger key on the Remote Assistant and hold it over BioMonitor 2 for at least three seconds.

Note: If you receive a Remote Assistant, always carry it with you if possible, but not in your breast pocket. Only use it after receiving detailed instructions from your doctor. If necessary, instruct your relatives or your partner in how to use the Remote Assistant. Please refer to the technical manual for further information.



# Everyday Life

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## What Impact Does BioMonitor 2 Have on My Everyday Life?

As the insertion of BioMonitor 2 only requires a minor procedure, most patients can return to their normal activities soon afterwards. The cardiac monitor does not restrict your lifestyle.

## Is BioMonitor 2 Affected by Electronic Equipment?

BioMonitor 2 is effectively shielded from and fully protected against electromagnetic interference from other devices.

You can therefore use the following household devices at all times without hesitation:

- TV/projector, radios, wireless headphones, stereo equipment and similar audiovisual devices
- Cordless phones/cellular phones
- Hair dryers, electric shavers and other electronic bathroom equipment
- Common household and kitchen appliances, such as washing machines, vacuum cleaners, dishwashers, hand-held blenders and microwaves with the exception of induction cooktops
- Blood pressure devices and heart rate monitors
- Computers/notebooks, WLAN, fax machines, copy machines, printers and the like

# Everyday Life

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## What Else Do I Need to Know?

As a patient with an inserted device, you should generally avoid equipment and devices that generate strong mechanical forces or electromagnetic fields. These can interfere with the proper functioning of your cardiac monitor and affect the data recording.

Use your cellular phone on the opposite side of your body away from the cardiac monitor and hold it at least 15 cm (6 inches) away from the inserted BioMonitor 2, both when using it and when storing it.

**You should use or access the following electronic devices or equipment with particular caution. Please also follow the special instructions of the device manufacturer.**

- Induction cooktops
- Body fat scales
- Power tools and machines that generate strong vibrations (electric drills, saws, firearms, etc.)
- Electric devices with strong electric fields or high-voltage cables
- Electric welders
- Large transmission facilities for radio, television and radar; electric, unshielded ignition systems

## Information on Medical Examinations

If you want to undergo a diagnostic test, e.g. in MRI scanners (magnetic resonance imaging) or are planning a medical procedure, please tell your doctor that you have a cardiac monitor.

BioMonitor 2 is generally approved for MRI scans of the body.

# Unimpeded Travel

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## What Do I Need to Know for Anti-Theft Devices or the Security Checks at the Airport?

Your BioMonitor 2 is fully protected against interference, e. g. from department store anti-theft devices and security systems at airports. However, strong magnetic fields can influence BioMonitor 2 and may trigger unwanted ECG recordings.

If you have to pass anti-theft devices in department stores, please do not stop within such facilities, but pass through them rapidly. You might want to point out that you have a cardiac monitor inserted and that you could trigger an alarm as a result. Remember that you can show your patient ID card if required. The same applies to security checks at airports or elsewhere.



MRI scan



Travel safely

# Continuous Remote Assistance Anytime, Anywhere

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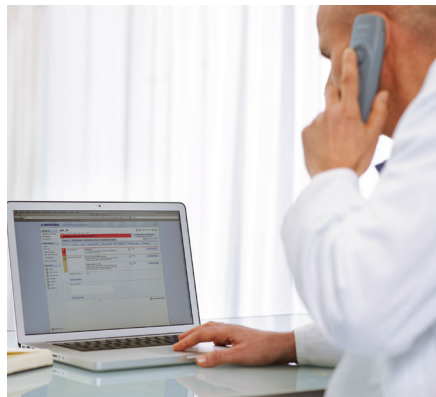
## How Does BioMonitor 2 Detect Cardiac Rhythm Disturbances Promptly?

BIOTRONIK has for many years been offering the opportunity of transmitting the saved device data by telemedicine to the doctor via BIOTRONIK Home Monitoring.

In this way, the doctor has the opportunity to remotely monitor your cardiac rhythm with the ECG data on a daily basis and easily diagnose any rhythm disturbances. Each recorded episode is automatically transmitted within 24 hours and sent to your doctor by e-mail or fax – no matter where you are.



Daily remote cardiac monitoring



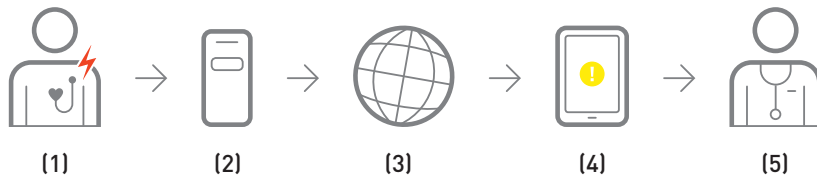
ECG transmission to the doctor

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## How Does BIOTRONIK Home Monitoring Process the Data?

Your BioMonitor 2 **(1)** records important heart and device information on a daily basis and automatically passes this on during the night to the CardioMessenger Smart **(2)**. The CardioMessenger Smart sends these data encrypted over the cellular phone network **(3)** to the Home Monitoring Service Center. There, all information is evaluated for each individual patient, filtered and summarized in what is known as a CardioReport **(4)**. Your doctor can then access all the values via a protected web page and follow any patient's cardiac rhythm on a daily basis **(5)**.

## Data Transmission with BIOTRONIK Home Monitoring



The CardioMessenger Smart transmits your heart data automatically once a day and anywhere in the world where there is a cellular phone signal.

# Continuous Remote Assistance Anytime, Anywhere

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## What Do I Need for Data Transmission with BIOTRONIK Home Monitoring?

To enable the telemedical transmission of BioMonitor 2 data using BIOTRONIK Home Monitoring, you need a cellular phone-enabled patient device, the CardioMessenger Smart.

When the CardioMessenger is being handed over, allow your doctor or a trained member of the nursing staff to explain to you what the CardioMessenger Smart does and at the same time satisfy yourself that the device is working properly. If possible, find out how and when you can reach your practice or clinic if you need to.



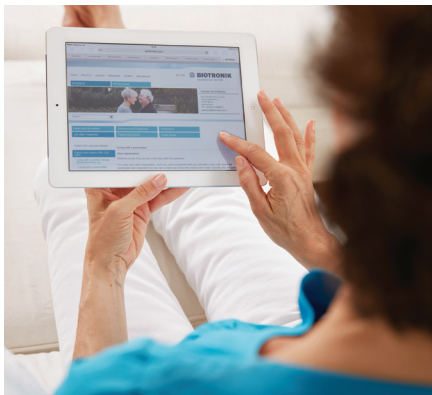
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## How Do I Operate the CardioMessenger Smart at Home?

To ensure that your device data can be reliably transmitted to your doctor every day, place your device on your bedside table before bedtime and charge it via the power cable. An LED-free on/off light indicator ensures undisturbed sleep. Make sure that you never carry the CardioMessenger Smart directly over the cardiac monitor, such as in your breast pocket. The same applies to cellular phones that you use on a daily basis. Please refer to the CardioMessenger Smart technical manual for further information.

Further information about treatment and follow-up care can be found online at the following website: [www.biotronik.com/patients](http://www.biotronik.com/patients)

Please do not hesitate to contact the BIOTRONIK service team by e-mail at [patients@biotronik.com](mailto:patients@biotronik.com) should you have any questions about your cardiac monitor or Home Monitoring care.



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# BioMonitor 2

## Patient Information

### 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.



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