

BioMonitor 2

Patient Information

ProMRI®



Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

BioMonitor 2



We Listen to Your Heart

Dear patient,

Your doctor has chosen the BioMonitor 2 insertable cardiac monitor for you. This device is designed to continually monitor your cardiac rhythm over an extended period of time and report any irregularities in your heartbeat to your doctor.

This pamphlet explains what BioMonitor 2 does and how it works.

BioMonitor 2 and Accessories



BioMonitor 2

for recording heart rate



Remote Assistant

for symptom recording
by the patient



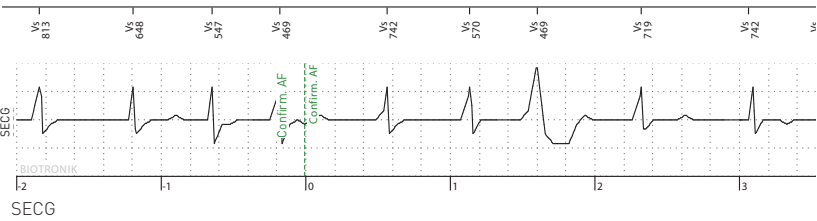
CardioMessenger Smart

for transmitting reports
to your doctor using
BIOTRONIK Home
Monitoring®

The Heart at a Glance

What Is a Cardiac Monitor?

A cardiac monitor such as BioMonitor 2 is a small ECG (electrocardiogram) device that continuously records your heart rhythm over an extended period of time and stores information about any irregularities in your heartbeat. With the help of these ECG recordings, your doctor is in a better position to make decisions 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

What Does BioMonitor 2 Do?

Some cardiac rhythm disturbances can occur spontaneously, and as a patient you may or may not experience symptoms (such as lightheadedness, dizziness, or fainting) associated with these events. That does not make the diagnosis easy for your doctor. BioMonitor 2 offers your physician the opportunity of closely monitoring your heart rhythm over weeks and months in order to make an informed diagnosis.

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

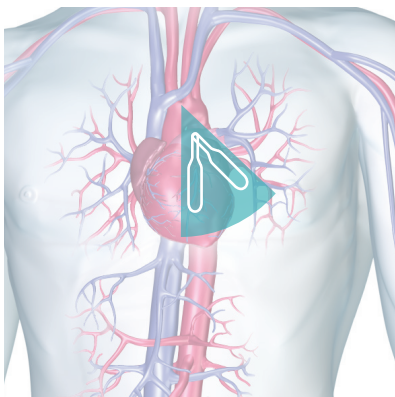
Your doctor will be the best person to explain to you in a personal consultation what the advantages of BioMonitor 2 are for you and how it can support your treatment.



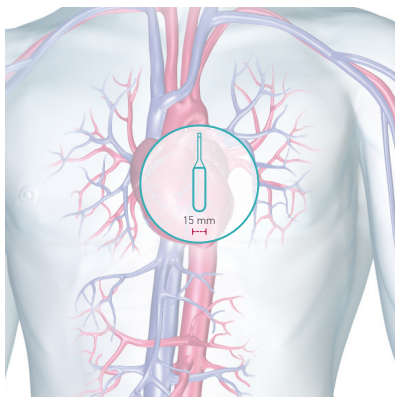
Easy Insertion

How Is BioMonitor 2 Inserted?

Insertion of BioMonitor 2 is a minor routine procedure that is performed under local anesthesia and only takes a few minutes. BioMonitor 2 is a small cardiac monitor that adapts itself to the natural shape of your body, above all through its flexible antenna. It is usually inserted subcutaneously (under the skin) on the left side of the chest above the heart in order to best measure heart signals.



Possible positions of BioMonitor 2



Small scar after the insertion of BioMonitor 2

For How Long Do I Need 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. However, the duration necessary for you to use the cardiac monitor will depend on your condition and the medical opinion of your doctor.

Reliable Sensing

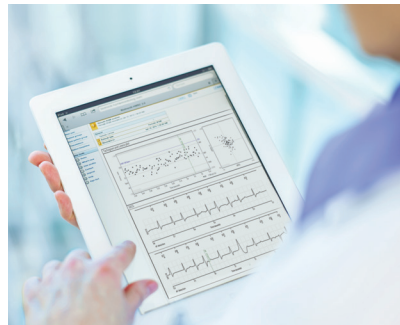
How Does BioMonitor 2 Work?

BioMonitor 2 measures heart signals using sensors that are located at both ends of the cardiac monitor. Unlike an external heart monitoring device, BioMonitor 2 operates without cables or attachments to the skin. As a result, you can maintain normal activities 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 through the BIOTRONIK Home Monitoring® Service Center.



CardioMessenger Smart and BioMonitor 2



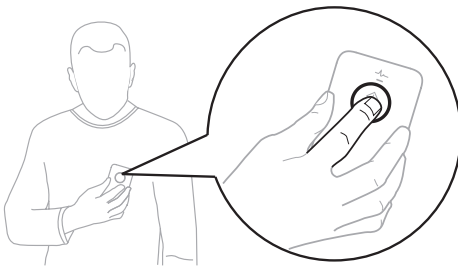
ECG analysis using BIOTRONIK Home Monitoring®

Capture the Precise Moment

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 or she 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 placing 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 as an ECG. Your doctor then has the opportunity of confirming, if necessary, any correlations between your symptoms and your heart rhythm. It is important to only use the Remote Assistant when you experience symptoms.



In order to save the ECG recording, 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

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 shielded from and protected against electromagnetic interference from other devices.

You can use the following household devices anytime 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, and printers.

Everyday Life

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, such as, 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 approved for MRI scans of the body.

Travel Freely

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

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

When passing 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

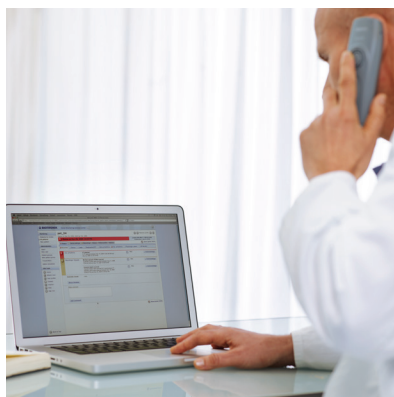
How Does BioMonitor 2 Detect Cardiac Rhythm Disturbances Promptly?

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

In this way, your 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 – no matter where you are.



Daily remote cardiac monitoring

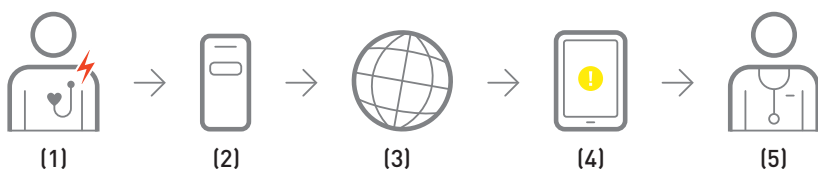


ECG transmission to the doctor

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 your cardiac rhythm on a daily basis **(5)**.

Data Transmission with BIOTRONIK Home Monitoring



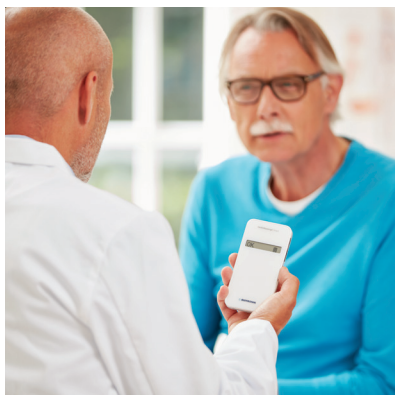
The CardioMessenger Smart transmits your heart data automatically once a day, anywhere in the world where there is cellular phone coverage.

Continuous Remote Assistance Anytime, Anywhere

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

To enable the remote transmission of BioMonitor 2 data using BIOTRONIK Home Monitoring®, you need a CardioMessenger device.

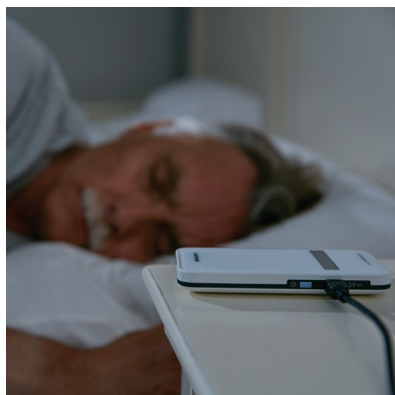
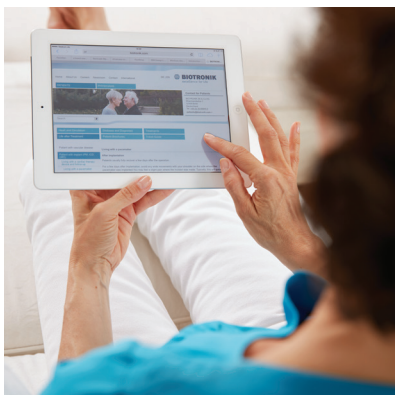
When the CardioMessenger is provided to you, allow your doctor or a trained member of the nursing staff to explain to you what the CardioMessenger does. If possible, find out how and when you can reach your practice or clinic if you need to.



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 CardioMessenger on your bedside table (less than six feet from where you sleep) before bedtime and charge it via the power cable. Avoid carrying 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



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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