

# BIOMONITOR

## Patient Information

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

 **BIOTRONIK**  
excellence for life

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# We Listen to Your Heart

Dear patient,

Your doctor has chosen the BIOMONITOR 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 your BIOMONITOR does and how it works.

## BIOMONITOR and Accessories



### BIOMONITOR

for recording  
heart rhythm



### Remote Assistant III

for recording heart  
rhythm during  
symptomatic events



### 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 the BIOMONITOR, 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.



# Reliable Diagnostics

## What Does the BIOMONITOR Do?

Some cardiac rhythm disturbances can occur spontaneously. As a patient, you may or may not experience symptoms (such as lightheadedness, dizziness, or fainting) associated with these events. This can make finding a clear diagnosis difficult for your doctor. The BIOMONITOR offers your physician the ability to closely monitor your heart rhythm over weeks or months in order to make an informed diagnosis.

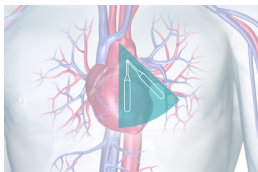
The BIOMONITOR is usually recommended to patients whose doctor suspects cardiac rhythm disturbances in the atria or other chambers of the heart. Using the BIOMONITOR, your doctor can firmly diagnose each rhythm disturbance and from that initiate appropriate therapy. Atrial fibrillation, for example,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

Your doctor will be the best person to consult regarding what advantages the BIOMONITOR will have for you and how it can support your treatment.

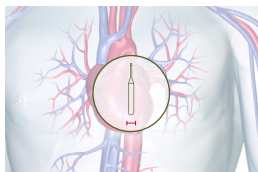
# Easy Insertion

## How Is the BIOMONITOR Inserted?

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



Possible positions of  
the BIOMONITOR



Small scar after the insertion  
of the BIOMONITOR

## How Long Do I Need the BIOMONITOR?

The battery capacity of the BIOMONITOR is enough to be able to monitor a patient's heart rhythm for approximately 5 years<sup>1</sup>. However, the duration necessary for you to use the cardiac monitor will depend on your condition and the medical opinion of your doctor.

1. 5 years is the expected longevity for BIOMONITOR IV. For previous devices please consult the appropriate device technical manual for longevity estimation. Please note differences in device usage or programming may influence the final longevity of the device.

# Reliable Sensing

## How Does the BIOMONITOR Work?

The BIOMONITOR measures heart signals using sensing electrodes that are located at both ends of the cardiac monitor. Unlike an external heart monitoring device, the BIOMONITOR operates without cables or attachments to the skin. As a result, you can maintain normal activities in your everyday life.

The special design of the BIOMONITOR allows for optimal signal quality and precision of recorded ECGs. These recordings depict irregularities in the heartbeat such as atrial fibrillation. The ECGs are then stored in the BIOMONITOR and transmitted to the doctor through the BIOTRONIK Home Monitoring® Service Center at the daily transmission time.

**Note:** If your implanted device is a BIOMONITOR IV, you may be asked by your physician or medical provider to remain close to your Cardio Messenger Smart during the day to get up to two additional transmissions.

During an in-person, in-office visit with your doctor, they may request support from a BIOTRONIK technical representative. The technical representative may be asked to re-program your device or offer your doctor recommendations regarding device settings. In all cases, your doctor will make the final decision on all device settings and other aspects of your care.



ECG analysis using  
BIOTRONIK Home Monitoring®



BIOMONITOR

# Capture the Precise Moment

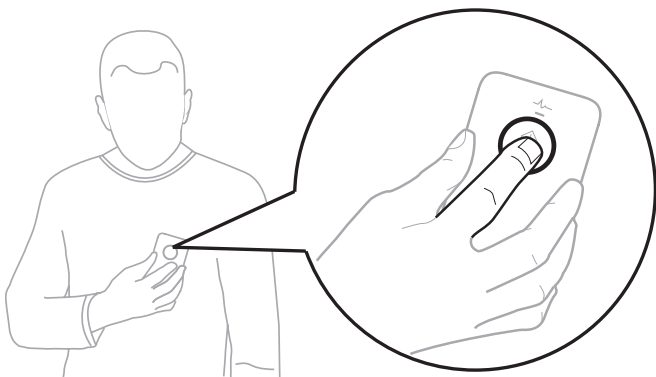
## What Is the Remote Assistant III and How Do I Use It?

Usually, the BIOMONITOR records each measured irregularity in your heart rhythm independently and automatically as programmed. If your doctor thinks it is necessary, they can provide you a Remote Assistant III to carry with you. With the BIOMONITOR and Remote Assistant III, you then have the opportunity to trigger additional ECG recordings as needed, such as after loss of consciousness or if you experience symptoms such as dizziness or a racing heart.

You can start the ECG recording by placing the Remote Assistant III on your chest where the BIOMONITOR has been inserted. Press the trigger key and hold the device in this position for at least three seconds. The BIOMONITOR saves all heart rhythms from the last seven and a half 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 III when you experience symptoms.







In order to save the ECG recording, place the Remote Assistant III over the implanted BIOMONITOR and briefly press the trigger key on the Remote Assistant III and hold it over the BIOMONITOR for at least three seconds.

**Note:** If you receive a Remote Assistant III, always carry it with you if possible. Only use it after receiving detailed instructions from your doctor. If necessary, instruct your relatives or your partner on how to use the Remote Assistant III. Please refer to the technical manual for further information.

# Everyday Life

## What Impact Does the BIOMONITOR Have on My Everyday Life?

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

## Is the BIOMONITOR Affected by Electronic Equipment?

The BIOMONITOR 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

# Everyday Life

- 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.

## 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 6 inches (15 cm) away from the inserted BIOMONITOR, both when using it and when storing it.

# Everyday Life

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 diagnostics test, such as an MRI (magnetic resonance imaging) scan, or are planning a medical procedure, please inform the healthcare professionals including your doctor that you have a cardiac monitor.

The BIOMONITOR is approved for MRI scans of the body when certain conditions are observed. Healthcare professionals can contact BIOTRONIK support to receive the conditions as needed.

# Travel Freely

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

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

We recommend that you carry your BIOTRONIK Patient Identification Card with you at all times. When passing through anti-theft devices (found in locations such as airports, department stores, and schools), please do not stop or linger within the field. It is best to pass directly through without stopping. It is possible that your BIOMONITOR could trigger the alarm when you walk through an anti-theft field. You may need to point this out to security personnel. Remember that you can show your Patient Identification Card if required.

Full-body scanners, such as millimeter wave scanners, are whole-body imaging devices that use a form of electromagnetic radiation. They are used at the majority of airports in the United States, and many other countries as well. Full-body scanner interference with the implanted device is considered unlikely.



Travel safely

# Continuous Remote Assistance Anytime, Anywhere

## How Does the BIOMONITOR Detect Cardiac Rhythm Disturbances Promptly?

BIOTRONIK has, for many years, been offering the opportunity of transmitting the saved device data in your BIOMONITOR via remote monitoring to your doctor via BIOTRONIK Home Monitoring®<sup>2</sup>.

In this way, your doctor has the opportunity to remotely monitor your cardiac rhythm with the ECG data on a daily basis to easily diagnose any rhythm disturbances. Each recorded episode is automatically transmitted within 24 hours and sent to your doctor – no matter where you are. Please see the following section for a detailed description of how this data transmission occurs.



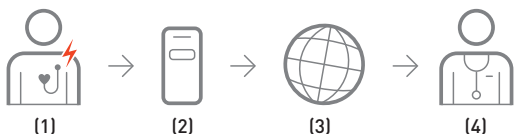
Daily remote cardiac monitoring



ECG transmission to the doctor

2. BIOTRONIK Home Monitoring requires enrollment by your physician.

## How Does BIOTRONIK Home Monitoring® Transmit the Data?



Your BIOMONITOR records and transmits data in the following manner:

1. Your BIOMONITOR records important heart and device information, storing it in internal memory each day.
2. This information is then automatically sent to your CardioMessenger Smart at the daily transmission time, which will typically be set by your physician to be each night when you are sleeping. If you have a BIOMONITOR IV, information can be sent at times other than the daily transmission time. Your physician will instruct you on how and when to use this feature.
3. The CardioMessenger Smart then sends the encrypted data over the cellular phone network to the Home Monitoring Service Center. This is possible from anywhere in the world where the CardioMessenger has cellular phone coverage.
4. Your data is then stored securely on the Home Monitoring Service Center where it can be reviewed by your physician. They can track your cardiac rhythm on a daily basis to evaluate your status and diagnose cardiac irregularities.

# Continuous Remote Assistance Anytime, Anywhere

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

To enable the remote transmission of your BIOMONITOR data using BIOTRONIK Home Monitoring®, you need a CardioMessenger Smart device.

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

Please note: If you have received a BIOMONITOR IV implant, and your doctor gave you a Remote Assistant III to trigger additional symptom related ECG recordings, your doctor may also advise you about the possibility of additional transmissions in addition to the daily transmission. If this is the case, please ensure you have your CardioMessenger Smart close to you for at least 3 hours after you use the Remote Assistant III.

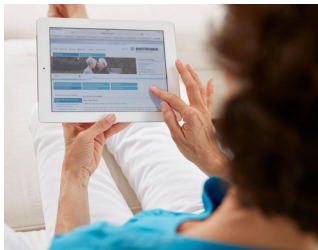


## How Do I Operate the CardioMessenger Smart at Home?

To ensure that your device data can be reliably transmitted to your doctor every day, place your CardioMessenger Smart 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.

Additional information about treatment and follow-up care can be found online at the following website:

<https://www.biotronik.com/en-us/patients>



# BIOTRONIK Patient App

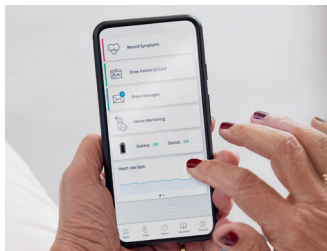
## What is the Patient App?

The BIOTRONIK Patient App is a software application with additional functions in relation to the injectable cardiac monitor and is dedicated to patients with a BIOMONITOR III (or later model)<sup>3</sup>.

## How Can the App Be Used?

The App can be used in three ways:

- Keep an eye on your own health. Use the Patient App to record your symptoms quickly and conveniently for discussion with your physician.
- Have visibility over the data transmission. Determine the status of the last data transmission from your injected device to BIOTRONIK Home Monitoring. The App helps you to resolve possible transmission errors.
- Simplify your everyday life with convenient app functions. Quickly access your patient ID card when needed, such as during an airport security check.



3. BIOTRONIK Patient App is a solution the physician must opt in to use.



## **BIOTRONIK, Inc.**

At BIOTRONIK, patient well-being is our top priority and has been for 60 years. BIOTRONIK is a leading global medical technology company with products and services that save and improve the lives of millions suffering from heart and blood vessel diseases. Driven by a purpose to perfectly match technology with the human body, we are dedicated innovators who develop trusted cardiovascular and endovascular solutions. BIOTRONIK is headquartered in Berlin, Germany, and is represented in over 100 countries.



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