BioMonitor 2

(ProMRI®)

Implantable cardiac monitor with Home Monitoring
Implantierbarer Herzmonitor mit Home Monitoring
Monitor cardiaco implantable con Home Monitoring
Moniteur cardiaque implantable avec Téléc@rdiologie

Technical manual • en
Gebrauchsanweisung • de
Manual técnico • es
Manuel technique • fr

BIOTRONIK
excellence for life

CE 0123
0681 2015

14-D-xx
Revision: 0 (2014-09-05)

406435

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin · Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life

BioMonitor 2

Implantable cardiac monitor with
Home Monitoring

Technical manual for the device

GA-HW_en_406435-0xx_BioMonitor 2_(ProMRI)

Table of Contents

1 Product Description

Intended Medical Use

Intended use

BioMonitor 2 is the name of an implantable cardiac monitor for the monitoring of heart rhythm.
Its primary purpose is to provide early detection and diagnostics of symptoms of arrhythmias, such as atrial fibrillation and the causes of syncope, which can be manifested clinically.

Note: BioMonitor 2 does not have a pacing function.

Form of diagnosis

The heart rhythm is continuously monitored; the possible detection types are atrial fibrillation, high ventricular rate, asystole, or bradycardia. Depending on the preset parameters, subcutaneous ECGs and other data are recorded.
The patient can also initiate a recording of a subcutaneous ECG.
BIOTRONIK Home Monitoring® enables physicians to perform a multi-year diagnosis management at any time.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operation of the implantable cardiac monitor and the specified conditions for its use. Only qualified medical specialists having the special knowledge are permitted to implant the BioMonitor 2 and make diagnoses.

Guidelines of cardiological societies

It is recommended that the indications published by the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung) and the ESC (European Society of Cardiology) are observed. This also applies to the guidelines published by the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and other national cardiology associations.

Indications

- Clinical symptoms or increased risk of cardiac arrhythmias
- Temporary symptoms that may indicate cardiac arrhythmia

Contraindications

There are no known contraindications.
However, the particular patient's state of health determines whether a subcutaneous device will be tolerated long-term.

System Overview

Device family

BioMonitor 2 is a cardiac monitor.The device family consists of BioMonitor 2-AF and BioMonitor 2-S. Not all device types are available in ecvery country.

Parts

The system consists of the following parts:

- Device with electrode integrated in the header and insertion tool
- Programmer
- Current software version for the implanted device
- Remote Assistant for the patient

Cardiac monitor

These devices have a retrospective loop memory, which continuously records the last

minutes of a patient's electrocardiograms. They include a patient-activation function, which allows the patient to activate ECG storage (with the help of a patient device) as a result of a symptomatic episode, and an auto-detection function that allows capture of events without relying on patient compliance or perception of symptoms
The device's housing is made of biocompatible titanium, welded from the outside and therefore hermetically sealed. It is coated in silicone or parylene. The shape facilitates ingrowth into the pectoral muscle area.
The cardiac monitor's sensing principle is based on one vector.
The device labeling provides information about the BioMonitor 2.

Programmer

Implantation and follow-up are performed with a portable BIOTRONIK programmer. During the implantation, the current device program is transferred to the device on initial interrogation via the programmer. In addition, the programmer is used to set parameter combinations, as well as for interrogation and device data storage. Subcutaneous ECG, markers, and functions are displayed simultaneously on the color display.

Note: It is not permitted to use the device's ECG display for diagnostic purposes because it does not meet all requirements of the standard (IEC 60601-2-25) concerning diagnostic ECG devices.

Telemetry

Telemetric communication between the device and the programmer can be carried out by applying a programming head (PGH).

BIOTRONIK Home Monitoring®

The BIOTRONIK cardiac monitor provides a complete diagnosis management system:

- With Home Monitoring, diagnostic information as well as technical data of the device are automatically and wirelessly sent to a stationary or mobile transmitter via an antenna in the device header. The data are encrypted and sent from the transmitter to the BIOTRONIK Service Center via the cellular phone network.
- The received data are deciphered and evaluated. Each physician can set the criteria for evaluation to be used for each patient and can configure the time of notification via E-mail, SMS or fax.
- A clear overview of the results of this analysis is displayed for the attending physicians on the protected Internet platform Home Monitoring Service Center (HMSC).
- Data transmission from the device is performed with a daily device message.
- Device messages which indicate special events in the heart or in the device are forwarded at the set time.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.

BioMonitor 2 order numbers

Not all device types are available in all countries:

Device	Coating	Order number
BioMonitor 2-S	Silicone	398494
BioMonitor 2-S	Parylene	403227
BioMonitor 2-AF	Silicone	398493
BioMonitor 2-AF	Parylene	403226

Package contents

The storage package includes the following:

- Sterile packaging with device
- Serial number label
- Patient ID card
- Technical manual for the device

The sterile packaging includes the following:

- Device

Diagnostic Functions

General overview

- Automatic functions simplify the expeditious implantation, configuration, and assessment of the BioMonitor 2.

Detection and data storage

- Parameters like Sensing high pass filter, Target sensing threshold or Interference interval are based on the sensing settings and may be customized.
- The sensing parameters are subsumed in one program (SensingConsult). In addition to a customized program, there are preconfigured programs for PVC detection, T wave suppression and Variable amplitude.
- The signals are recorded and stored once a detection type is set.
- Multiple detection types can be set simultaneously.
- Single episodes up to 40 s in length can be stored. Patient-triggered recordings are stored up to 7.5 min.
- The device can record a total of 35.8 min of episodes in subcutaneous ECGs.
- When performing follow-ups using the programmer, the subcutaneous ECG is indicated with markers after applying the programming head.

Home Monitoring functions

Important medical information includes but is not limited to the following:

- Ongoing atrial and ventricular arrhythmia
- Current statistics
- High definition subcutaneous ECGs and sending of these recordings with device messages

2 General Safety Instructions

Operating Conditions

Technical manuals

The following technical manuals provide information about usage of the device systems:
— Technical manual for the device
— Technical manual for the HMSC
— Technical manuals for the programmer and its accessories
— Technical manuals for the user interface
— Technical manuals for cables, adapters and accessories

- Technical manuals are either included in hard copy form in the product package or in digital form on the internet:
  https://manuals.biotronik.com/manuals/home
- Follow all relevant technical manuals.
- Preserve technical manuals for later use.

Care during shipping and storage

- Devices must not be stored or transported close to magnets or sources of electromagnetic interference.
- Observe the 'use by date (UBD)' (see the battery data).

Temperature

Extremely low and high temperatures affect the service time of the battery in the device.

- The following temperatures are permitted for transport, storage, and use:
  -10°C to 45°C

Sterile delivery

The device is delivered after gas sterilization. Sterility is guaranteed only if the blister and quality control seal have not been damaged.

Sterile packaging

The device is packaged in two separately sealed blisters. The inner blister is also sterile on the outside so that it can be transferred in a sterile state during implantation.

Single use only

The device is only intended for one-time use.

- Do not use the device if the package is damaged.
- The device must not be resterilized and reused.

Possible Complications

General information on medical complications

Complications for patients and device systems generally recognized among practitioners also apply to BIOTRONIK devices.

- Complications may include, for example, foreign body rejection phenomena, local tissue reactions, migration of the device, or infections. Primary sources of complication information include current scientific and technological knowledge.
- It is impossible to guarantee the efficacy of implantable cardiac monitors.

Possible technical failures

Technical failure of a device system cannot be entirely ruled out. Possible causes may include the following:

- Device component failures
- Battery depletion

Electromagnetic interference (EMI)

Any device can be sensitive to interference, for example, when external signals are sensed as intrinsic rhythm.

- BIOTRONIK devices have been designed so that their susceptibility to EMI is minimal.
- Under unfavorable conditions, especially during diagnostic procedures, sources of interference may induce such a high level of energy into the device that the data recording can be influenced or the device may be damaged.

Possible Risks

Procedures to avoid

The following procedures must be avoided as they may cause harm to the patient or damage the device and, as a result, put the system functionality at risk:

- Therapeutic ultrasound
- Transcutaneous electrical nerve stimulation
- Hyperbaric oxygen therapy
- Applied higher than normal pressures

Risky therapeutic and diagnostic procedures

If energy from an external source is introduced to the body for diagnostic or therapeutic purposes, then the device can be subjected to interference and its function can be impaired.
Harmful effects may occur, for example, during electrocautery, HF ablation, HF surgery, or lithotripsy. Influences on the device are not always immediately clear.
If risky procedures cannot be avoided, the following should be observed at all times:

- Electrically insulate the patient.
- Do not approximate energy nearby the device.
- Monitor the patient during and after every intervention.

External defibrillation

The device is protected against the energy that is normally induced by external defibrillation. Nevertheless, any implanted device may be damaged by external defibrillation. The sensing properties may change as a result.

- Place adhesive electrodes anterior-posterior or perpendicular to the axis formed from the device to the heart at least 10 cm away from the device and from implanted leads.

Radiation therapy

The use of radiation therapy must be avoided due to possible damage to the device and the resulting impaired functional safety. If this type of therapy is to be used anyway, prior risk/benefit analysis is absolutely necessary. The complexity of influencing factors such as different sources of radiation, a variety of devices and therapeutic conditions make it impossible to issue directives that guarantee radiation therapy without an impact on the device. The EN 45502 standard pertaining to active implantable medical devices requires the following information in combination with therapeutic ionizing radiation:

- Adhere to instructions for potentially risky therapeutic and diagnostic procedures.
- Shield device against radiation.
- After applying radiation, double-check the device system to make sure it is functioning properly.

Note: Please contact BIOTRONIK with questions on the risk/benefit analysis.

Magnetic resonance imaging

Magnetic resonance imaging must be avoided due to the associated high frequency fields and magnetic flux density: damage or destruction of the device by strong magnetic interaction and damage to the patient by excessive warming of the body tissue in the area surrounding the device.
Under certain conditions and while maintaining mandatory measures, magnetic resonance imaging can be performed to protect the patient and device.

- The ProMRI® manual – MR conditional device systems – contains detailed information on safely conducting an MR scan.
  - Download the digital manual from the internet: https://manuals.biotronik.com/manuals/home
  - Order the printed manual from BIOTRONIK.
- Does approval as "MR conditional" apply in your country or region? Ask for current information at BIOTRONIK.

3 Implantation

Implantation Procedure

Having parts ready

The following parts that correspond to the requirements of the EC Directive 90/385/EEC are required:

- BIOTRONIK device and insertion tool
- BIOTRONIK programmer and approved cables
- External multi-channel ECG device
- Keep spare parts for all sterile components.

Keeping an external defibrillator ready

In order to promptly respond to unforeseeable emergencies or possible technical failures of the device:

- Keep an external defibrillator and paddles or patch electrodes ready.

Unpacking the device

WARNING

Inadequate function due to defective device

If an unpacked device is dropped on a hard surface during handling, electronic parts could be damaged.

- Use a replacement device.
- Return the damaged device to BIOTRONIK.

- Peel the sealing paper off of the outer blister at the marked position in the direction indicated by the arrow. The inner blister must not come into contact with persons who have not sterilized their hands or gloves, nor with non-sterile instruments!
- Take hold of the inner blister by the gripping tab and take it out of the outer blister.
- Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

Implantation site

- Depending on the patient's anatomy, the BIOTRONIK cardiac monitor can be implanted subpectorally or subcutaneously on the left side.

Preventing leakage currents

Leakage currents between the tools and the device must be prevented during implantation.

- Electrically insulate the patient.

Implanting

1	Form the device pocket with help of the insertion tool.
2	Insert the device.
3	Position the device optimally.
4	Check the signals.
5	Close the device pocket.

Position the device optimally

While the device is being positioned, the signals are recorded by the programming head. It must therefore be placed in the surgical field in sterile condition.

- Use the programming head with a suitable sterile cover.

W CAUTION

Poor signal quality

Unreliable signals may impair sensing and even lead to misinterpreted sensing.

- Try different positions for the implanted device until the best signals are displayed on the programmer.

Applying the programming head

The programming head features a diagram of the device. This is used to assist in positioning the head to ensure proper telemetry.

- Make sure the PGH is positioned correctly.

Establishing telemetry contact

- When the programming head is applied, time remains for device interrogation. All detection parameters are disabled during this time.

Activate diagnostics

- Select the current software version with the standard program on the programmer.

Follow-up

Follow-up intervals

Follow-ups must be performed at regular, agreed intervals.

- Following the ingrowth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up).
- The next in-office follow-up should be carried out once a year and no later than 12 months after the last in-office follow-up.

Follow-up with BIOTRONIK Home Monitoring®

Monitoring using the Home Monitoring function does not serve to replace regular in-office appointments with the physician required for other medical reasons. Follow-up supported by Home Monitoring can be used to functionally replace in-office follow-up under the following conditions:

- The patient was informed that the physician must be contacted if symptoms worsen or if new symptoms arise despite use of the Home Monitoring function.
- Device messages are transmitted regularly.
- The physician decides whether the data transmitted via Home Monitoring with regard to the patient's clinical condition as well as the technical state of the device system are sufficient. If not, an in-office follow-up has to be carried out.

Possible early detection due to information gained via Home Monitoring may necessitate an additional in-office follow-up. For example, the data may provide early indication of a foreseeable end of service time (ERI). Furthermore, the data could provide indications of previously unrecognized arrhythmias.

Follow-up with the programmer

Use the following procedure for in-office follow-up:

1	Record and evaluate the ECG
2	Interrogate the device.
3	Check the sensing function.
4	Evaluate the status and automatically measured follow-up data.
5	Possibly evaluate statistics and subcutaneous ECGs.
6	If necessary, customize the program functions and parameters.
7	Transmit the program permanently to the device.
8	Print and document follow-up data (print report).
9	Finish the follow-up for this patient.

Patient Information

Patient ID card

A patient ID card is included in delivery.

- Provide the patient with the patient ID.
- Request that patients contact the physician in case of uncertainties.

Prohibitive signs

Places with prohibitive signs must be avoided.

- Draw the patient's attention to prohibitive signs.

Possible sources of interference

Electromagnetic interference should be avoided in daily activities. Sources of interference should not be brought into close proximity with the device.

- Draw the patient's attention to special household appliances, safety locks, anti-theft devices, strong electromagnetic fields, cell phones, and transmitters among other things.
- Request patients to do the following:
  - Use cell phones on the opposite side of their body from the device.
  - Keep the cell phone at least 15 cm away from the device both during use and when storing.

Replacement Indications

Possible battery levels

- BOS: Beginning of Service: > 70% charge
- ERI: Elective Replacement Indication
- EOS: End of Service

Elective Replacement Indication (ERI)

The device can no longer monitor the heart rhythm when in ERI charging status. ERI can be detected by Home Monitoring.

EOS replacement indication

The end of service has been reached.

Explantation and Device Replacement

Explantation

- Interrogate the device status.
- Remove the device using state-of-the-art technology.
- Explants are biologically contaminated and must be disposed of safely due to risk of infection.

Device replacement

Basic principles:

- The device must not be resterilized and reused.

Cremation

Devices should not be cremated.

- Explant the device before the cremation of a deceased patient.

Disposal

BIOTRONIK takes back used products for the purpose of environmentally safe disposal.

- Clean the explant with a solution of at least 1% sodium hypochlorite.
- Rinse off with water.
- Send the cleaned explant to BIOTRONIK.

4 Parameters

Note: All parameters are subject to change!

Arrhythmia Detection Parameters

SensingConsult

The programs with sensing expert parameters (SensingConsult) are preset as follows:

Parameter	Programs			
	Standard	T-wave suppression	Variable amplitude	PVC detection
Lower sensing threshold	50%	40%	35%	25%
Sensing high pass filter	10 Hz	18 Hz	10 Hz	10 Hz
Recordings and real-time ECG	Full morphology	Full morphology	Full morphology	Full morphology
Interference interval	100 ms	100 ms	100 ms	100 ms

Sensing settings

The sensing expert parameters included in the programs can be customized as follows:

Parameter	Range of values	Standard	Factory
Sensing settings (SensingConsult)	Standard; T-wave suppression; Variable amplitude; PVC detection	Standard	Standard
Lower sensing threshold	25; 35; 40; 50%	50%	50%
Sensing high pass filter	OFF 10; 18; 24 Hz	10 Hz	10 Hz
Recordings and real-time ECG	Sensing signal; full morphology	Full morphology	Full morphology
Interference interval	100; 140; 180 ms	100 ms	100 ms

Diagnostics: Atrial fibrillation

The following can be set:

Parameter	Range of values	Standard	Factory
Atrial fibrillation (AF)	ON; OFF	ON	OFF

The programs with AF expert parameters are preset as follows:

AF sensitivity	Low	Medium	High
RR variability limit	18.75%	12.5%	6.25%
Analysis window Onset/end	16/24	8/16	8/16
Onset intervals	9	5	5
Resolution intervals	3	1	1
Confirmation time	6 min	6 min	6 min

The AF expert parameters included in the programs can be customized as follows:

Parameter	Range of values	Standard	Factory
RR variability limit	6.25; 12.5; 18.75%	12.5%	—
Analysis window onset/end	8/16; 16/24; 24/32 detection/end	8/16	—
Onset intervals	5 ... (2) ... 23 minimum number of consecutive RR cycles with an RR interval outside of the variability limit	5	—
Resolution intervals	1 ... (2) ... 7 maximum number of consecutive RR cycles with an RR interval outside of the variability limit	3	—
Confirmation time	1 ... (1) ... 6; 10; 20; 30 min	6 min	—

Diagnostics: High ventricular rate

The following can be set:

Parameter	Range of values	Standard	Factory
High ventricular rate	ON; OFF	ON	OFF
HVR limit	150 ... (10) ... 200 bpm	180 bpm	—
HVR counter	4; 8; 12; 16; 32; 64	16	—

Diagnostics: Bradycardia

The following can be set:

Parameter	Range of values	Standard	Factory
Brady zone limit	OFF 30 ... (5) ... 80 bpm	40 bpm	OFF
Brady duration	5 ... (5) ... 30 s	10 s	—
Brady rate decrease	OFF 10 ... (10) ... 50%	50%	—
Brady sensitivity	Low; medium; high	Low	—

Additional bradycardia expert parameters can be set:

Parameter	Range of values	Standard	Factory
Baseline intervals	32; 48; 64	64	—
Rate-drop intervals	4; 8; 16	16	—

Diagnostics: Asystole duration

The following can be set:

Parameter	Range of values	Standard	Factory
Asystole duration	OFF 2 ... (1) ... 10 s	3 s	OFF

Diagnostics: Patient trigger

The following can be set:

Parameter	Range of values	Standard	Factory
Patient trigger	ON; OFF	ON	OFF

Global parameters

The following settings apply to all detection types:

Parameter	Range of values	Standard	Factory
Start resting period	00:00 ... (60) ... 23:00 hh:mm	2:00 hh:mm	—
Duration of resting period	00:30 ... (30) ... 12:00 hh:mm	4:00 hh:mm	—

Home Monitoring Parameter Settings

Home Monitoring: HM episode trigger

Home Monitoring can be set for all detection types:

Parameter	Range of values	Standard	Factory
Home Monitoring	ON; OFF	ON	OFF
HM episode trigger: AF; HVF; Bradycardia; Asystole; Patient trigger	ON; OFF	ON	OFF

Note: Depending on the set detection type, the oldest, newest, and the longest episode is stored. In the case of patient-triggered recordings, the oldest and the two newest episodes are stored.

Global parameters

The following settings apply to all detection types:

Parameter	Range of values	Standard	Factory
Time of transmission	STD; 00:00 ... (30) ... 23:30 hh:mm	STD	—
Periodic subcutaneous ECG	OFF; 1; 2; 30; 60; 90; 120; 180 days	30 days	—

5 Technical Data

Mechanical Characteristics

Measurements for the housing

Device	W x H x D [mm]	Volume [cm³]	Mass [g]
BioMonitor 2	85 x 15 x 6,5	4.5	10 g [± 2 g]

X-ray identification

BIO VP

Materials in contact with body tissue

- Housing: titanium
- Leads: titanium, fractally coated
- Housing sheath: silicone
- Silicone plug (screw cover): Silicone
- Header: epoxy resin

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω:

Circuit	Hybrid electronics with VLSI-CMOS chip
Input impedance	> 50 kΩ

Telemetry

Telemetry data for Home Monitoring:

Nominal carrier frequency	Maximum power of transmission
403.62 MHz	< 25 µW -16 dBm

Telemetry data

- Nominal carrier frequency: 403.62 MHz
- Maximum power of transmission: < 25 µW (–16 dBm)

International radio certification

Devices with BIOTRONIK Home Monitoring® are equipped with an antenna for wireless communication.

- Telemetry information for Canada:

  This device must neither interfere with meteorological and earth resources technology satellites nor with meteorological stations working in the 400,150 to 406,000 MHZ band, and it must accept any interference received, including interference that may cause undesired operation.
  This device will be registered with Industry Canada under the following number:

  IC: 4708A-BM2
  The code IC in front of the certification/registration number only indicates that the technical requirements for Industry Canada are met.
- Telemetry information for Japan:

  Japanese Radio Law and Japanese Telecommunications Business Law Compliance.
  This device is granted pursuant to the Japanese Radio Law **(電波法)**
  and the Japanese Telecommunications Business Law **(電気通信事業法)**
  This device should not be modified (otherwise the granted designation number will become invalid
  R: 202-SMC062
- Telemetry information for the USA:

  Telemetry data for the USA: This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) 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 stations, including interference that may cause undesired operation. 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 transmitter will be free from interference.
  This device will be registered with Federal Communications Commission under the following number:

  FCC ID: QRIBM2

Battery Data

Note: All battery data are subject to change!

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	**LITRONIK GmbH 01796 Pirna Germany**
Battery type	LiS 2460
System	$LiMn0_x$
Type of device	
Battery voltage at BOS	3.1 V
Open-circuit voltage	3.1 V
Nominal capacity	1.2 Ah
Remaining capacity at ERI	0.15 Ah

Power consumption

- Battery current: 9 µA
- Average additional battery current in transmission mode: 4 µA

Average service time

Average service times are precalculated using the battery manufacturer's technical specifications and the setting of different detection parameters.
For BioMonitor 2: 4 years

Shortening of the service time after long storage period

Depending on the storage period, the service time from the beginning of service BOS to the replacement time ERI decreases as follows:

- After 1 year: by n.N. months
- After 1.5 years: by n.N. months

Legend for the Label

The label icons symbolize the following:

	Manufacturing date		Use by
	Storage temperature	REF	Order number
SN	Serial number	PID	Product identification number
CE	CE mark		
	Contents		Follow the instructions for use

STERILE EO	Sterilized with ethylene oxide		
2 STERILIZE	Do not resterilize	2	Single use only. Do not reuse!
	Do not use if packaging is damaged	NON STERILE	Non-sterile

	Transmitter with non-ionizing radiation at designated frequency
MR	MR conditional: Patients can be examined using an MRI scan under defined conditions if the device system in their body consists of devices whose packaging is labeled with this symbol.

	Implantable cardiac monitor		Insertion tool