BIOMONITOR III

ProMRI

Cardiac Monitor | premounted in the Fast Insert Tool OneStep | BIOTRONIK Home Monitoring

Technical Manual

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excellence for life

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1 Product Description

Intended Medical Use

Intended use

BIOMONITOR III is the product name of an implantable cardiac monitor for monitoring and automatically recording heart rhythms. The primary purpose is to provide early detection and diagnostics in the following clinical scenarios:

- Patients with clinical syndromes, which lead to an increased risk of cardiac rhythm disturbances
- Patients with temporary clinical symptoms, including dizziness, palpitations, syncope, or chest pain, which may be the result of a cardiac rhythm disturbance

Note: The cardiac monitor does not have any therapeutic function.

BIOMONITOR III is housed in the front part of the FIT OneStep insertion tool (Fast Insert Tool). The insertion tool is used for forming the device pocket and for subsequent positioning of the cardiac monitor in the subcutaneous left pectoral area. The use of this tool ensures an optimal anatomical implantation site, which is a requirement for recording meaningful subcutaneous ECGs.

Form of diagnosis

The heart rhythm is continuously and automatically recorded and monitored. The following are possible detection types:

- Atrial tachycardia
- High ventricular rate
- Asystole
- Bradycardia
- Sudden rate drop

Depending on the preset parameters, subcutaneous ECGs, and other data may be recorded.

The patient can also trigger the recording of subcutaneous ECGs using the Remote Assistant III accessory if subjectively symptomatic episodes occur.

The recordings can be transmitted to the BIOTRONIK Home Monitoring Service Center. This enables physicians to perform complete diagnosis management.

Guidelines of cardiological societies

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

Indications

Generally approved differential diagnostic methods, as well as the indications and recommendations for the medical use of implantable cardiac monitors apply to BIOMONITOR III.

The cardiac monitor BIOMONITOR III is an implantable monitoring system that records subcutaneous ECGs. Recording is activated both automatically and by the patient. Their use is indicated for the following cases:

- Clinical syndromes or increased risk of cardiac arrhythmias
- Temporary, unexplained symptoms that may indicate cardiac arrhythmia
- Evaluation of palpitations of unclear etiology
- Recurrent syncope of unclear etiology
- Confirmation or monitoring of atrial fibrillation
- Clarification of a cryptogenic cerebrovascular stroke

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 BIOMONITOR III

This device is not available in all countries.

Parts The system consists of the following parts:

- Device with flexible lead body; the device is inside the FIT OneStep insertion tool
- Incision tool
- Programmer and current software version for the device
- The Remote Assistant III accessory for triggering recordings by the patient (optional)

Incision tool

- The incision tool is used for making a surgical cut for the device pocket. The blade is 13 mm wide and due to its design it can cut a maximum of 10 mm deep.

Insertion tool (with premounted device)

- The FIT OneStep insertion tool is used for controlled insertion and positioning of the device. The device itself is sterile and located securely inside the tool, in the blue tunneling tip in front of the white gripping sleeve; the whole device is not visible from the outside, only the QR code of the device is visible through a small window.

Cardiac monitor The device itself is called BIOMONITOR III. It consists of a solid housing and a flexible lead body.

The device's housing is made of hermetically sealed biocompatible titanium coated in silicone. At the rounded end of the housing there is an opening in the coating, so that the metal housing forms the antipole to the lead tip.

The flexible lead body is made of silicone and it has a fractally coated electrode on its tip. The lead's conductor also serves as an antenna for Home Monitoring.

The device has an overall length of 7.75 cm, which is approximately identical to the sensing vector and correlates linearly with the sensing amplitude.

Programmer

Implantation and follow-up are performed with a portable BIOTRONIK programmer using the current PSW software version 1901.A or higher.

The standard program is activated in the device on initial programming via the programmer. The programmer is used to set parameter combinations, as well as for interrogation and saving of data from the device. Electrocardiogram, subcutaneous ECG, markers, and functions are displayed simultaneously on the color display.

Note: The programmer's ECG display must not be used for diagnostics, because it does not meet all the standard requirements for diagnostic ECG devices (IEC 60601-2-25).

Telemetry

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

BIOTRONIK Home Monitoring®

The BIOTRONIK cardiac monitors provide a complete diagnosis management system:

- With Home Monitoring, diagnostic information as well as device technical data are automatically and wirelessly sent to a stationary or mobile transmitter via an antenna in the lead body. The data is encrypted and sent from the transmitter to the protected internet platform BIOTRONIK Home Monitoring Service Center (HMSC) through a cellular phone network.
- The received data is deciphered and evaluated; the criteria for evaluation to be used for each patient can be set individually and the time of notification via e-mail or fax can be configured.
- A clear overview of the results of this evaluation is displayed on the HMSC.
- Data transmission from the device is performed at a preset time with a daily device message.
- Device messages that indicate special events in the heart or in the device are also forwarded at the preset time.
- A test message can be initiated at any time using the programmer to immediately check the Home Monitoring function.
- The recording of a subcutaneous ECG in the BIOMONITOR III device can be triggered by the patient using the external Remote Assistant III device.

BIOMONITOR III order number

This device is not available in all countries.

Device	Order number
BIOMONITOR III	436066

Package contents

The storage package includes the following:

- Sterile packaging with device premounted in the insertion tool and with incision tool
- Serial number label
- Patient ID card
- Quick reference guide for insertion of BIOMONITOR III

Note: The technical manual pertaining to the cardiac monitor is included in hard copy form in the storage package and/or is available in digital form on the internet.

Diagnostic Functions

General overview

- Automatic functions facilitate quick and simple setting and control of the BIOMONITOR III cardiac monitor.

Detection and data storage

- The sensing parameters are combined into one program (SensingConsult) and can be set individually for each patient:
  - Standard
  - Sense after large PVCs
  - Sense small PVCs
  - Sense short intervals
  - T-wave suppression
- The signals are automatically recorded and stored if a detection type is activated and detection occurs.
- Multiple detection types can be activated simultaneously.
- The device can store episodes with subcutaneous ECGs with a minimum overall length of 60 min.
- A total of 55 individual episodes with a length of at least 40 s each can be stored automatically. The maximum storage period for an individual episode is 60 s.

  A total of 4 recordings triggered by the patient with a duration of at least 7.5 min can be stored. The recording includes 7 min of pre-episode history and 0.5 min of post-episode history relative to the time of triggering.
- When performing in-office follow-ups using the programmer, the unfiltered subcutaneous ECG is indicated with markers. The filtered subcutaneous ECG can also be displayed if the corresponding settings have been made.

Diagnostics

The following functions are available:

- Longest AF episode
- AF burden
- AF details:
  - AF trend
  - AF time distribution
  - AF duration
  - Ventricular rate during AF
- Cardiac rhythm disturbances detections:
  - Atrial fibrillation
  - High ventricular rate
  - Bradycardia
  - Sudden rate drop
  - Asystole
  - Patient trigger
- Activity:
  - Heart rate variability
  - Patient activity
  - Heart rate
- Sensing
  - R-wave trend
  - Noise duration trend

Home Monitoring functions

Important medical information includes the following:

- Sustained atrial arrhythmias
- Sustained ventricular arrhythmias
- Current statistics
- Periodically recorded subcutaneous ECGs that are transmitted according to an individually adjustable timing interval in addition to the regular device message

  This is a necessary condition for performing Home Monitoring-supported follow-ups.

2 General Safety Instructions

General Information on Safe Handling of the Device

Follow notes and instructions

CAUTION
Risk to patient, risk to doctor, and interferences of device
The operation of electronic devices close to the heart is subject to special conditions. From transport to storage, concerns about sterility and technical complications, requirements for special care or risky therapies, as well as instructions regarding implantation and care for persons who have an implanted device must all be adhered to: The device is sensitive and must not be damaged, in order not to harm patients. • It is always necessary that all information in this, as well as related technical manuals, must be observed and followed.

Safety instructions and warnings in this technical manual

This technical manual provides safety-relevant information on several topics:

- On the one hand, there are general safety warnings, which are fundamentally valid. In this technical manual, the main topics are as below:
  - General information on the safe handling of the product
  - Operating conditions
  - Possible technical complications
  - Possible medical complications
- On the other hand, there are special and general warnings regarding the insertion of the device that provide education and instructions for safely working with and performing actions related to the device. In this technical manual, the main topics are as below:
  - Insertion Procedure
  - Precautionary measures while programming
  - Patient information
  - Disposal

• Warnings have been particularly indicated in this technical manual with a symbol and a signal word: Non-compliance with the instructions can cause injury to the patient.

Technical manuals

The following technical manuals provide information about usage of the device systems:

— Technical manual for the device

— Technical manual for the Home Monitoring Service Center (HMSC)

— Technical manuals for the programmer and the Remote Assistant III

— Technical manuals for the user interface

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

Note: Observe the quick reference guide included in the package contents.

Required expertise

In addition to having basic medical knowledge, the user must be thoroughly familiar with the operating conditions and functionality of an implantable cardiac monitor. Only qualified medical specialists with specialized knowledge are permitted to implant the BIOMONITOR III and make diagnoses.

Operating conditions

CAUTION

Risk to patient and interferences of device

The operation of electronic devices in the proximity of the heart is subject to special operating conditions. If these are not fulfilled, the functionality of the device may be impaired; if the functionality of the device is impaired, the patient may be at risk.

- Please observe the following operating conditions.

Care during shipping and storage

- Devices must not be stored or transported close to magnets or sources of electromagnetic interference.
- Note the effects of storage period and service time for the device. See Battery Data.

Temperature

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

- Permitted for shipping and storage:
  -10°C to +45°C (-40°F to 158°F)

Sterile delivery

The incision tool and the insertion tool as well as the device itself are delivered gas-sterilized (ethylene oxide). Sterility is guaranteed if the blister itself and the blister's sealing paper have not been damaged.

Device sterile packaging

Incision tool and insertion tool with premounted device are packaged inside a single sealed sterile blister pack.

Single use only

The incision tool and the insertion tool, as well as the device itself, are intended for single use only.

- Do not use the incision tool or the insertion tool with premounted device if the sterile packaging is damaged.
- Do not resterilize or reuse the incision tool or the insertion tool, or the device itself.

Possible Complications

CAUTION

Risk to patient and interferences of device

Electronic devices close to the heart may be subject to special complications. They must be considered, so that the functionality of the device is not impaired and as a result may put the patient at risk.

- Please take all the following safety information carefully into account.

General information on medical complications

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

- Known complications are foreign body rejection phenomena, local tissue reactions, migration of the device, accumulation of fluid in the device pocket, transdermal erosions, as well as hemorrhage, and/or infections. Primary sources of complication information include current scientific and technological knowledge.

Possible technical failures

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

- Component failure of the device or an accessory
- 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 and therapeutic 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

CAUTION

Risk to patient and interferences of device

Electronic devices close to the heart may be subject to special risks. They must be considered so that the functionality of the device is not impaired and, as a result, put the patient at risk.

- Please take all the following safety information carefully into account.

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:

- Hyperbaric oxygen therapy
- Applied pressure significantly higher than normal atmospheric pressure, maximum 1.5 bar

Risky therapeutic and diagnostic procedures

If electrical current from an external source is conducted through the body for diagnostic or therapeutic purposes, then the device can be subjected to interference, which can place the patient at risk.

Harmful effects may occur, for example, during electrocautery, HF ablation, HF surgery, shortwave therapy, or microwave therapy. For example, damaging pressure levels may arise during lithotripsy. Excessive warming of body tissue near the device may occur during therapeutic ultrasound. The effect on the device is not always immediately apparent.

If risky procedures cannot be avoided, the following should be observed at all times:

- Electrically insulate the patient.
- Do not localize energy near the device.
- Monitor the patient during and after every intervention.
- After every procedure, verify normal device function.

During lithotripsy, the following also applies:

- Keep the focus of the lithotripter beam at least 2.5 cm away from the device.

For HF ablation or HF surgery, the following also applies:

- Avoid direct contact between the ablation catheter and the device.
- Position the grounding pad so that the current path does not pass through or near the device; the current path must be at least 15 cm away from the device.

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.

- Position the adhesive electrode anterior-posterior or vertical to the direction of the device, with its sensing vector and at least 10 cm away from the device.

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 nevertheless to be used, prior risk/benefit analysis is absolutely necessary. The complexity of influencing factors such as different sources of radiation, a variety of devices and therapy conditions makes 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 risky therapeutic and diagnostic procedures.
- Shield device against radiation.
- After applying radiation, repeatedly check the device for proper functioning.

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

Magnetic resonance imaging

Magnetic resonance imaging (MRI) should only be performed under certain conditions. Damage or destruction of the device system by strong magnetic interaction or damage to the patient by excessive warming of the body tissue in the area surrounding the device system must be avoided.

BIOTRONIK devices with the "MR conditional" function display the identification ProMRI. Magnetic resonance imaging (MRI) should only be performed while following mandatory precautions to protect the device system and the patient.

- The ProMRI manual – MR conditional device systems – contains detailed information on safely conducting an MRI scan.
  - — Download the digital manual from the website: https:\\manuals.biotronik.com
  - — Order the printed manual from BIOTRONIK.
- Does approval as "MR conditional" apply in your country or region? Request current information from BIOTRONIK.

3 Handling

Insertion Procedure

CAUTION

Risk to patient, risk to physician, and interference with the device

Manufacturing, planning, and insertion procedures require special measures.

- Please follow all procedures carefully.

Having parts ready

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

- Insertion tool with premounted device from BIOTRONIK
- Incision tool
- BIOTRONIK programmer and BIOTRONIK approved cables, if necessary
- Have spares of all sterile components available

Unpack the parts

CAUTION

Inadequate function due to defective device

If a device still in packaging is dropped on a hard surface during handling, electronic parts could be damaged.

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

The incision tool and the insertion tool – including the premounted device – have been individually packaged in sterile blister packs.

- Check the use by date.
- Open blister at the marked position. The tools must not come into contact with persons who have not sterilized their hands or gloves or with non-sterile instruments!
- Remove the incision tool and the insertion tool from the package.

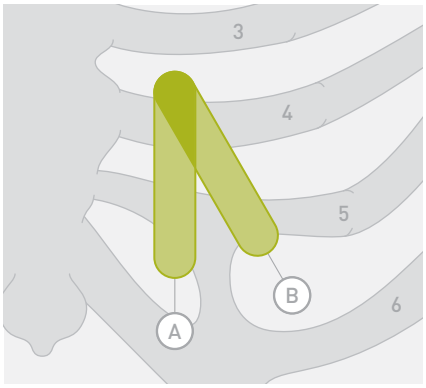
Note: The incision tool has a sharp blade; to avoid cuts, handle the tool with care.

Implantation site

The cardiac monitor is inserted subcutaneously on the left side of the patient.

Note: There are 2 primary positions for device placement, between the 3rd and 6th costal arch, with consideration to the patient's anatomy and the body tissue's texture.

For a high signal amplitude, it is important for the direction of the sensing vector to be parallel to the heart's electrical axis as much as possible.



Position A: device pocket in the left parasternal region

Position B: device pocket at an angle of about 45° to the sternum, parallel to the cardiac vector

Note: In exceptional cases, a position beneath the left breast can be selected.

- While selecting a position, also take into consideration future diagnostics, e.g., mammography.

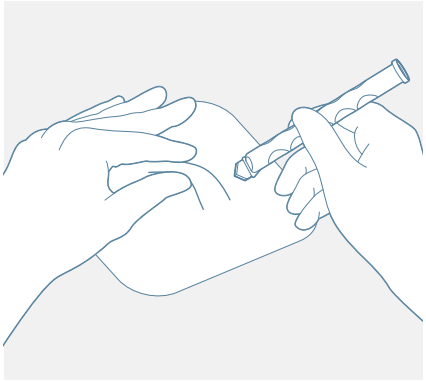
Note: The lead tip can be positioned upward or downward, considering patient-specific as well as cosmetic aspects: The subcutaneous electrocardiogram can also be displayed reversed by appropriate programming.

Sequence of the procedure

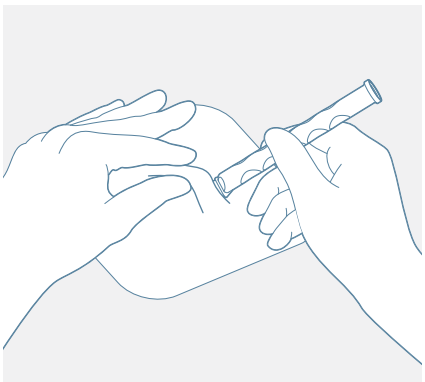
Follow these steps to insert the cardiac monitor:

Make a skin fold and an incision for the device pocket

- Make a skin fold across the direction of the incision and position the incision tool diagonally.

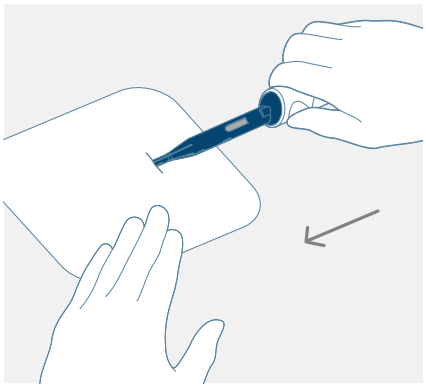


- Make an incision of the width and depth specified by the insertion tool tip; this incision will determine the placement of the device pocket.

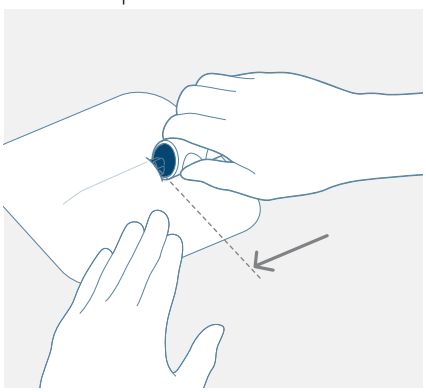


Position the insertion tool and tunnel

- Hold the insertion tool firmly by the white gripping sleeve, with the thumb on the front gripping tab and the other fingers in the gripping tab on the opposite side.
- Place the blue tunneling tip on the incision and push forward into the subcutaneous tissue layer to form the device pocket.

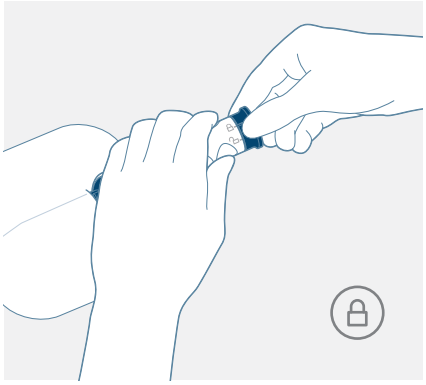


- Push the blue tunneling part subcutaneously, parallel to the surface of the chest, in to the incision up to the small, semi-cylindrical curvature just before the handle. The device pocket is now created, and the device is already in the correct position.

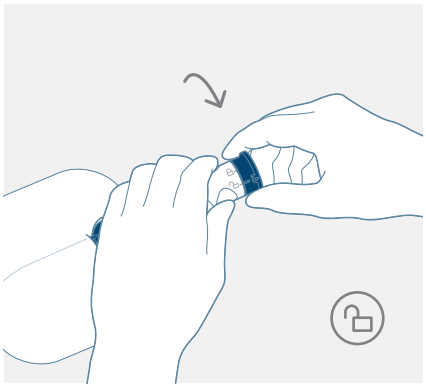


Release the insertion tool

- Hold the white gripping sleeve of the insertion tool firmly with one hand, and with the other hand turn the blue knob to release.

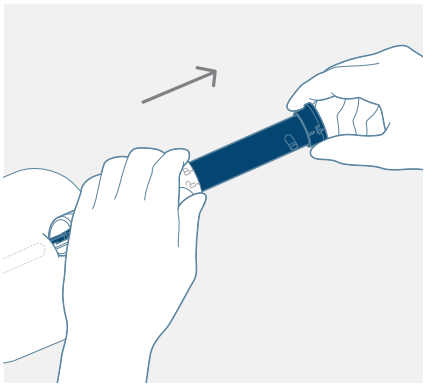


- The symbols on the gripping sleeve indicate in which direction to turn so that the premounted device inside can be released.

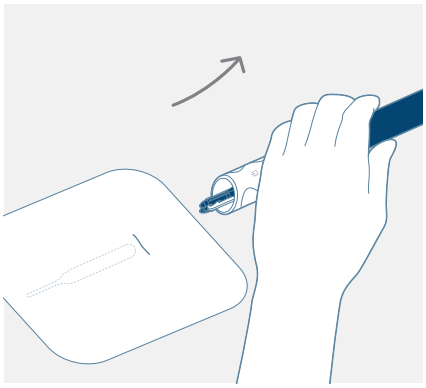


Pull back the insertion tool and lift to remove it

- While holding the white gripping sleeve in position, pull the blue rotary knob (in the released condition) outwards. The device is in the intended position when the blue inner part of the insertion tool is completely pulled back.



- Pull the tip of the tool remaining in the body out of the incision.



End the procedure

- If necessary, check the signals using the programmer.
- Close the device pocket.

Applying the programming head

Apply the programming head (PGH) and turn to align if necessary to ensure correct telemetry.

- Make sure the PGH is positioned correctly.

Establishing telemetry contact

- The device requires some time for interrogation once the programming head is applied.

Activate diagnostics

- Confirm the standard program is loaded on the programmer.

Precautionary measures while programming

CAUTION
Risk to patient
The programming of devices requires special precautionary measures.
• Please perform the following precautionary measures carefully.

Note when adjusting bigeminy rejection

For sensitive AF detection, **Bigeminy rejection** is preset to **Standard**.

If bigeminy rejection is set to **Aggressive**, the sensitivity of the AF detection may be slightly reduced, depending on the patient.

- Adjust the setting for this parameter based on the current patient data.

Follow-up

Follow-up intervals

Follow-ups can be performed at regular, agreed-upon intervals.

- Following the ingrowth phase, approximately 3 months after insertion, 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 is not intended to replace regular in-office appointments with the physician required for other medical reasons. Home Monitoring-supported follow-up 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 the 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, is sufficient. If not, an in-office follow-up must be performed.

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 (EOS). 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 if necessary.
2	Interrogate the device.
3	Check the sensing function.
4	Evaluate status and, if necessary, statistics and subcutaneous ECGs.
5	If necessary, customize the program functions and parameters and transmit the edited program to the device.
6	Print and document follow-up data (print report).
7	Finish the follow-up for this patient.

Patient information

Note: The education of patients requires special information. Please share all of the following information carefully.

Patient ID card

A patient ID card is included in package contents.

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

Prohibitive signs

Premises with prohibitive signs must be avoided.

- Educate the patient regarding 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.

- Educate the patient on sources of electromagnetic interference which include special household appliances, safety locks/anti-theft alarm systems, cell phones, and transmitters.
- Request patients to heed the following:
  - Use cell phones on the side of the body that is opposite of the device.
  - Keep the cell phone at least 15 cm away from the device both during use and during storage.

Recording via Remote Assistant

If needed, patients can also manually trigger the recording of a subcutaneous ECG in the BIOMONITOR III device using the Remote Assistant III accessory. Patient information includes:

- Making sure the patient understands how to handle the Remote Assistant III by means of the technical manual.
- When should the Remote Assistant III be used?

  In case of symptoms such as severe dizziness, indisposition, or palpitations, as well as after fainting.
- How is a recording triggered?

  The technical manual for the Remote Assistant III describes the handling of the small device and explains the meaning of the LED signals.
- What happens when a recording is triggered?

  The subcutaneous ECG of the last 7.5 min is stored. This includes 7 min of pre-episode history and 0.5 min of post-episode history relative to the time of triggering. Between 40 s and 60 s are transmitted at the daily transmission time via Home Monitoring.
- What has to happen after triggering a recording?

  The patient should contact the physician.

Replacement indications

Possible battery levels

- BOS: Beginning of Service
- ERI: Elective Replacement Indication
- EOS: End of Service

Elective replacement indication (ERI)

ERI is displayed on the programmer during the follow-up and transmitted via Home Monitoring.

Upon reaching ERI, recording of statistics and episodes is stopped.

Once ERI has been reached, the remaining life of the device is at least 2 months until EOS is reached.

Home Monitoring is still available for at least 2 weeks after reaching ERI. After this period, the device stops transmitting messages to the Home Monitoring Service Center.

EOS replacement indication

The end of service has been reached.

Explantation and Device Replacement

CAUTION

Risk to patient, environmental hazard

Explanations and device replacements require special measures.

- Please follow all procedures carefully.

Explantation

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

Device replacement

Basic principles:

- The device must not be resterilized or reused.

Cremation

Devices should not be cremated.

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

Disposal of the device

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.

Disposal of the tools

Incision tool and insertion tool:

- Used accessories must be disposed of as medical waste in an environmentally friendly and proper manner.

4 Parameters

Detection

Atrial fibrillation

The following can be set:

Parameter	Range of values	Standard
Atrial fibrillation (AF)	ON; OFF	ON
AF sensitivity	Low; Medium; High In case of change of the AF expert parameters: individual	Medium
RR variability limit	6; 9; 12; 15; 18 %	12 %
Confirmation time	1 ... (1) ... 6; 10; 20; 30 min	6 min
Bigeminy rejection	OFF; Standard; Aggressive	Standard

Additional AF expert parameters can be set individually:

Parameter	Range of values	Standard
Size of detection/termination window	8/16; 16/24; 24/32 cycles	8/16 cycles (medium)
Detection intervals	5 ... (2) ... 23 cycles	5 cycles (medium)
Number of detection windows	1 ... (1) ... 4	2 (medium)
Termination intervals	1 ... (2) ... 7 cycles	1 cycle (medium)
Number of termination windows	1 ... (1) ... 4	2 (medium)

The AF parameters are preset as follows:

Parameter	Low	Medium	High
RR variability limit	12 %	12 %	12 %
Size of detection/termination window	16/24 cycles	8/16 cycles	8/16 cycles
Detection intervals	11 cycles	5 cycles	5 cycles
Termination intervals	5 cycles	1 cycle	1 cycle
Number of detection windows	3	2	1
Number of termination windows	2	2	3

High ventricular rate (HVR)

The following can be set:

Parameter	Range of values	Standard
High ventricular rate	ON; OFF	ON
HVR limit	100 ... (10) ... 200 bpm	180 bpm
HVR counter	8 ... (4) ... 24; 32; 48 cycles	16 cycles

Bradycardia

The following can be set:

Parameter	Range of values	Standard
Bradycardia	ON; OFF	ON
Brady zone limit	30 ... (5) ... 80 bpm	40 bpm
Brady duration	5 ... (5) ... 30 s	10 s

Sudden rate drop

The following can be set:

Parameter	Range of values	Standard
Sudden rate drop (SRD)	ON; OFF	OFF
SRD rate decrease	20 ... (10) ... 70 %	50
SRD sensitivity	Low; Medium; High In case of change of the SRD expert parameters: individual	Medium

Additional SRD expert parameters can be set:

Parameter	Range of values	Standard
Baseline intervals	48; 64; 128; 256 cycles	64 cycles (medium)
Rate-drop intervals	8; 16; 32 cycles	16 cycles (medium)

The SRD expert parameters are preset as follows:

Parameter	Low	Medium	High
Baseline intervals	256 cycles	64 cycles	48 cycles
Rate-drop intervals	32 cycles	16 cycles	8 cycles

Asystole duration

The following can be set:

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

Patient trigger

The following can be set:

Parameter	Range of values	Standard
Patient trigger	ON; OFF	ON

Indication-dependent detection settings ProgramConsult

For each indication, there is a compilation of preset detection parameters (ProgramConsult):

Parameter	Range of values (standard)	Syncope	Palpitations	AF monitoring	Cryptogenic cerebrovascular stroke
Atrial fibrillation	**ON**; OFF	ON	ON	ON	ON
Sensitivity	Low; **Medium**; High	Low	Medium	Medium	High
RR variability	6; 8; **12**; 15; 18%	12 %	12 %	12 %	12 %
Confirmation time	1; 2; 3; 4; 5; **6**; 10; 20; 30 min	10 min	6 min	6 min	1 min
Bigeminy rejection	OFF; Standard; Aggressive	Aggressive	Aggressive	Standard	Standard
High ventricular rate	**ON**; OFF	ON	ON	ON	ON
Limit	100 ... (10) ... **180**; 190; 200 bpm	160 bpm	180 bpm	180 bpm	180 bpm
Counters	8; 12; **16**; 20; 24; 32; 48	16	32	48	48
Bradycardia	**ON**; OFF	ON	ON	ON	ON
Zone	30; 35; **40** ... (5) ... 80 bpm	35	30	30	30
Duration	5; **10** ... (5) ... 30 s	20	30	30	30

Parameter	Range of values (standard)	Syncope	Palpitations	AF monitoring	Cryptogenic cerebrovascular stroke
Asystole	**ON**; OFF	ON	ON	ON	ON
Duration	2; **3** ... (1) ... 10 s	3	5	5	5
Sudden rate drop	ON; **OFF**	ON	OFF	OFF	OFF
Rate decrease	20 ... (10) ... **50**; 60; 70%	50	—	—	—
Sensitivity	Low; **Medium**; High	Low	—	—	—

Resting rate period

All statistics-based settings are as follows:

Parameter	Range of values	Standard
Start resting period	00:00 ... (1:00 AM) ... 11:00 PM hh:mm	2:00 AM hh:mm
Duration of resting period	1 ... (1) ... 12 h	4 h

Sensing

The following can be set:

Parameter	Range of values	Standard
SensingConsult	Standard Sense after large PVCs Sense small PVCs Sense short intervals T-wave suppression	Standard
Sensing filter	4.5; 10; 18; 24	10 Hz
(SECG) Display	Normal; Inverted	Normal
(SECG) Signal filter	0.05; 0.5 Hz	0.5 Hz

Home Monitoring

General settings

The following settings apply to all detection types:

Parameter	Range of values	Standard
Home Monitoring	ON; OFF	ON
Time of transmission	STD; 00:00 ... (12:30 AM) ... 11:30 PM hh:mm	STD

Note: Selection and cycle length of periodic subcutaneous ECGs are set in the Home Monitoring Service Center (HMSC).

HM episode trigger

Episode triggers for Home Monitoring can be set for all automatic detection types:

Detection type	Range of values	Standard
Atrial fibrillation (AF)	ON; OFF; Detection only	ON
High ventricular rate (HVR)	ON; OFF	ON
Bradycardia	ON; OFF	ON
Sudden rate drop (SRD)	ON; OFF	OFF
Asystole	ON; OFF	ON
Patient trigger	ON; OFF	ON

Saving and Transmitting

When detection is set, it can also be decided, for all automatic detection types, as well as for the patient trigger, whether the subcutaneous ECG should be saved, and whether it should be transmitted to the Home Monitoring Service Center (HMSC).

Detection type	Detection	Saving	Sending to HMSC
Atrial fibrillation (AF)	ON; OFF	ON; OFF	ON; OFF; Detection only
High ventricular rate (HVR)	ON; OFF	ON; OFF	ON; OFF
Bradycardia	ON; OFF	ON; OFF	ON; OFF
Sudden rate drop (SRD)	ON; OFF	ON; OFF	ON; OFF
Asystole	ON; OFF	ON; OFF	ON; OFF
Patient trigger	ON; OFF	ON; OFF	ON; OFF

Note: When detection type AF, HVR, or Bradycardia is set, the oldest, the most recent, and the longest episodes are saved.
When detection type Asystole or SRD is set, the oldest and the two most recent episodes are saved.
When Patient trigger is set, the 4 most recent episodes are saved.

5 Technical Data

Mechanical Characteristics

Dimensions

	L x Diameter [mm]
Incision tool	130 x 13
Insertion tool	200 x 24

	L x H x D [mm]	Volume [cm^3]	Mass [g]
BIOMONITOR III device including antenna	77.5 x 8.6 x 4.6	1.9	4
Housing without antenna	47.5 x 8.3 x 4.3	1.7	—

X-ray identification

Materials in contact with body tissue

- Housing: titanium, electrode surface fractally coated with iridium
- Lead body: silicone
- Lead tip: titanium, fractally coated with iridium
- Insulation of the housing: silicone
- Additional components (adhesive): silicone
- Incision tool: plastic (POM) and stainless steel
- Insertion tool: plastic (POM)

Electrical Characteristics

Components and input values

Electrical characteristics determined at 37°C, 500 Ω

Circuit	Hybrid electronics with VLSI-CMOS chip
Input impedance	> 100 kΩ

Housing shape

The device housing has an elongated, flattened shape, connected to a narrow, flexible lead body.

Electrically conductive surfaces

There is an electrically conductive surface on the housing as well as on the lead body:

Area of the electrically conductive housing surface	Area of the electrically conductive lead tip
25 ± 5 mm^2	25 ± 5 mm^2

Telemetry

Telemetry data for Home Monitoring:

MICS frequencies	Maximum power of transmission
402 – 405 MHz	< 25 µW -16 dBm

International radio certification

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

- Telemetry information for Australia:

  This product is in compliance with the Australian "Radiocommunications Act 1992" and therefore it is labeled according to the "Radiocommunications (Compliance Labeling - Devices) Notice".

- 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-BM2610
  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:

  In accordance with Japanese law, this device has been assigned an identification number under the "Ordinance concerning certification of conformity with technical regulations etc. of specified radio equipment", Article 2-1-8.

- Telemetry information for the USA:

  This transmitter is authorized 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 to 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. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. 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: QRI-BM2610

Battery Data

Battery characteristics

The following data is provided by the manufacturers:

Manufacturer	**LITRONIK GmbH 01796 Pirna, Germany**
Battery type	LiS 2044 / LiS 2044k
System	Li-MDX / Li-CFx
Device type	BIOMONITOR III
Battery voltage at BOS	3.1 V / 3.0 V
Open-circuit voltage	3.2 V/ 3.1 V

Average service time

Based on the technical specifications of the battery manufacturer and the device-specific detection parameters, the average service time (until reaching ERI) of BIOMONITOR III is 48 months.

This calculation is based on:

- Sensing at 60 bpm
- 6-month storage period
- Daily device message via Home Monitoring, including recorded subcutaneous ECGs:

  1 automatic subcutaneous ECG per day
  plus up to 2 subcutaneous ECGs per month, triggered by the patient

Storage period

The storage period affects the battery service time.

- Devices should be implanted within 19 months between the manufacturing date and the use by date (indicated on the package).

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 3 months
- After 1.5 years by 6 months

Legend for the Label

Meaning of the symbols 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	LOT	Lot number
	Contents		Follow the instructions for use!
manuals.biotronik.com 		Follow the electronically available instructions for use!	

	Manufacturer	USA Distributor: Distributor in the USA
Rx only	Caution: Federal (U.S.A.) law restricts this device to sale by, or on the order of, a physician.	

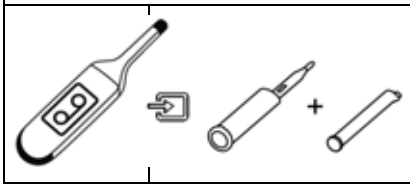
STERILE EO	Sterilized with ethylene oxide	1	Single sterile blister

	Do not resterilize		Single use only. Do not re-use!
	Do not use if packaging is damaged	NON STERILE	Non-sterile

	Transmitter with non-ionizing radiation at designated frequency

TP2	Compatibility with telemetry protocol version 2 of BIOTRONIK Home Monitoring

	Cardiac monitor, device		
	Incision tool		Risk of injury

	Insertion tool
	Device, premounted in the insertion tool, plus incision tool