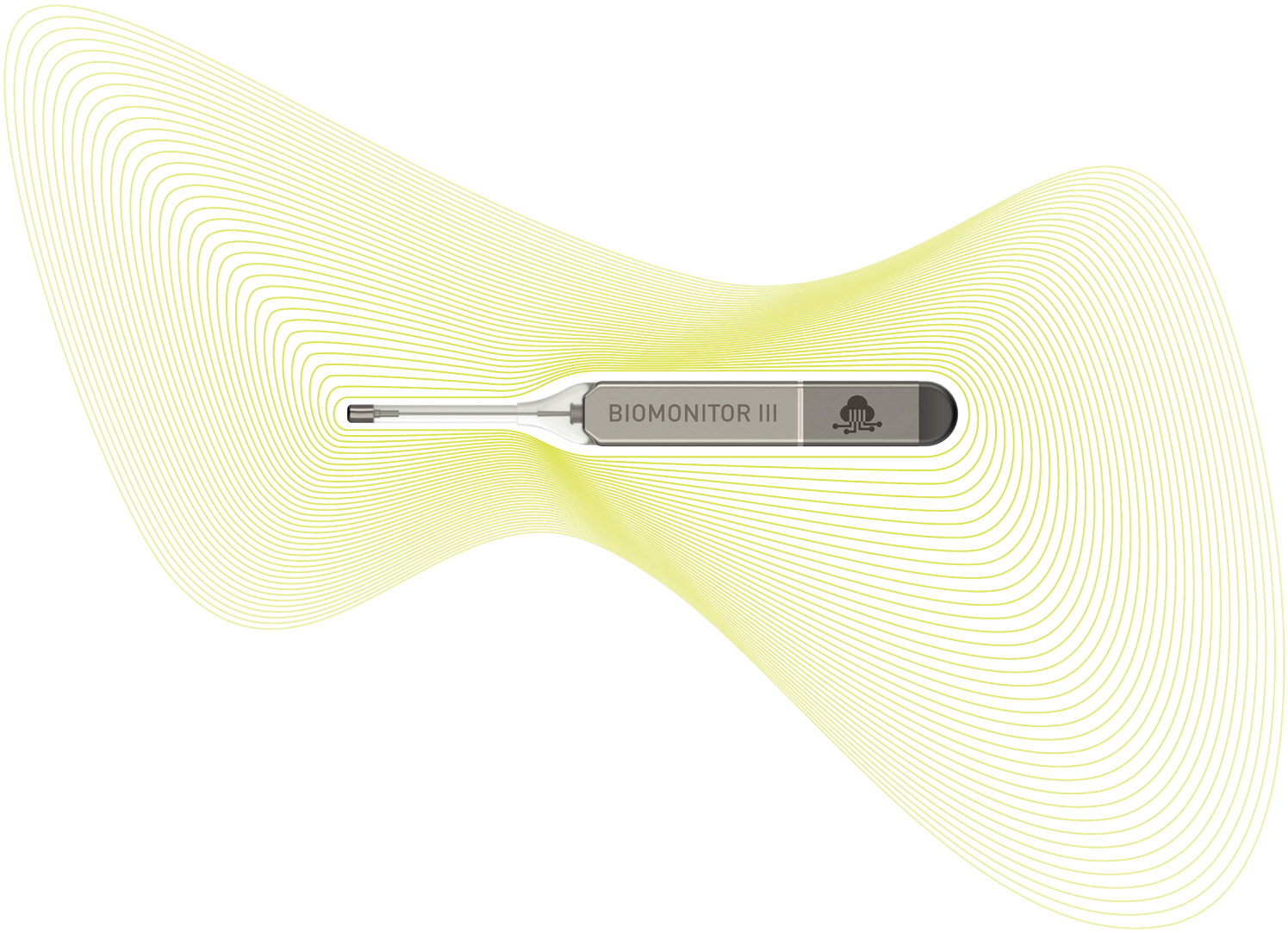


BIOMONITOR III

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

Function Manual

BIOTRONIK
excellence for life

Table of Contents

1 Characteristics of the Implantable Cardiac Monitor BIOMONITOR III

1.1 Product Description

Intended Medical Use

Intended use

BIOMONITOR III is the product name of an implantable cardiac rhythm monitoring system that records subcutaneous ECGs. Recording is activated both automatically and by the patient.

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.

Note

The cardiac monitor does not have any therapeutic function.

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 primary purpose is to provide early detection and diagnostics in the following clinical scenarios:

- Clinical syndromes, which lead to an increased risk of cardiac rhythm disturbances
- Temporary clinical symptoms, including dizziness, palpitations, syncope, or chest pain, which may be the result of a cardiac rhythm disturbances
- 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 permanently.

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 accommodated 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 designed to cut no deeper than 10 mm.

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 with 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 to interrogate and save 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 as it does not meet all the requirements of the standard 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 technical data of the device are automatically and wirelessly sent to a stationary or mobile transmitter via an antenna in the lead body of the device. 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 SMS 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

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 such 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 56 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. On selecting the corresponding setting, the filtered subcutaneous ECG can also be displayed.

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.

General overview

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

1.2 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. In order to not harm patients, it must not be damaged.

- It is always important to observe and follow all instructions in this and related technical manuals.

Safety instructions and warnings in this technical manual

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

- On the one hand, there are safety warnings, which are of a general nature. In this technical manual, the main general safety 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 which draw attention to the context of action and instruct safe working. In this technical manual, these are mainly the following topics:
  - Insertion procedure
  - Precautionary measures while programming
  - Patient information
  - Disposal
- ⚠ Warnings are particularly indicated with a symbol and a signal word in this technical manual: 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 for 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 with the 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

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 its sealing paper are undamaged.

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 with the 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 with the 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 – MR conditional device systems manual contains detailed information on safely conducting an MR 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.

1.3 Handling

Insertion Procedure

⚠ **Caution**

Risk to patient, risk to physician, and interferences of 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 the 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 the 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.

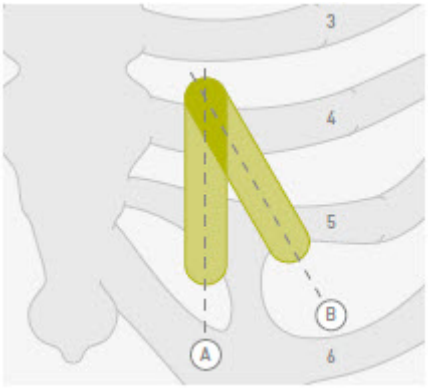
Implantation site

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

Note

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

A sensing vector as much parallel to the heart's electrical axis as possible is crucial for a high signal amplitude.



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 below the left breast can be selected.

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

Note

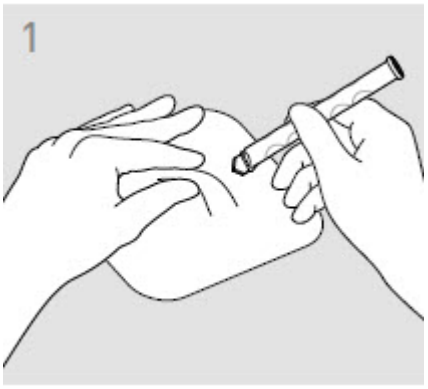
The lead tip can be positioned upward or downward, considering patient-specific as well as cosmetic aspects: The subcutaneous electrocardiogram can also be displayed reversed by appropriate programming.

Sequence of the procedure

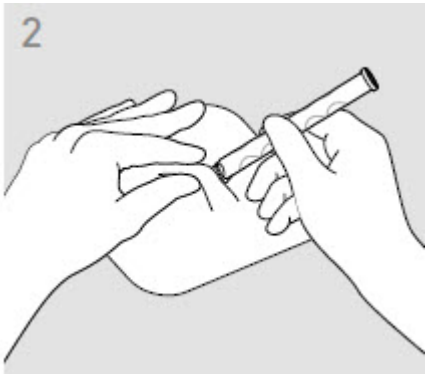
Follow these steps to insert the cardiac monitor:

Make a skin fold and an incision for the device pocket

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

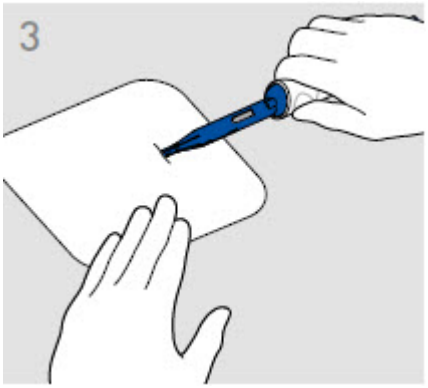


- Make an incision of the width and depth specified by the incision tool tip; this incision will determine the placement of the device pocket.

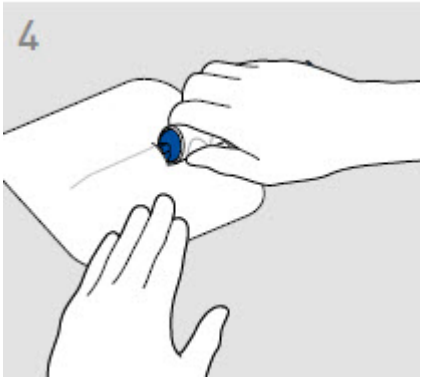


Position the insertion tool and tunnel

- 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.

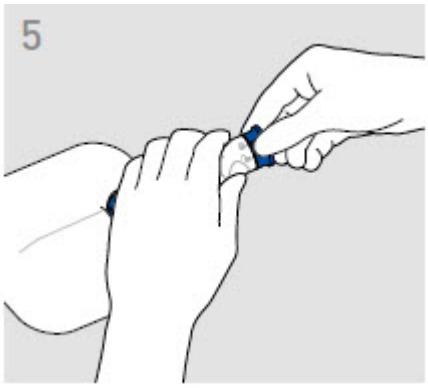


- Push the blue tunneling part subcutaneously, parallel to the surface of the chest, into the incision up to the small, semi-cylindrical curvature just before the handle. The device pocket is now created, and the device is already in the correct position.

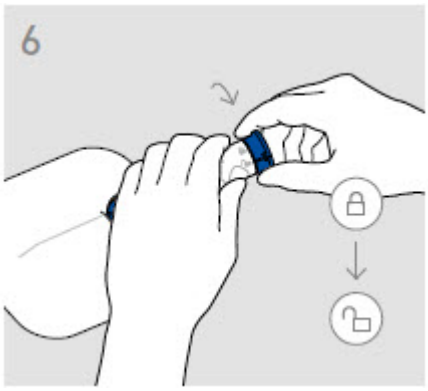


Release the insertion tool

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

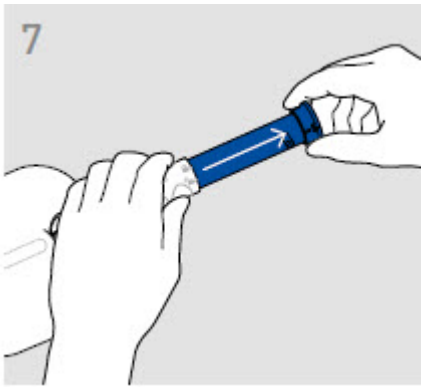


- The symbols on the gripping sleeve indicate in which direction to turn so that the premounted device inside can be released.

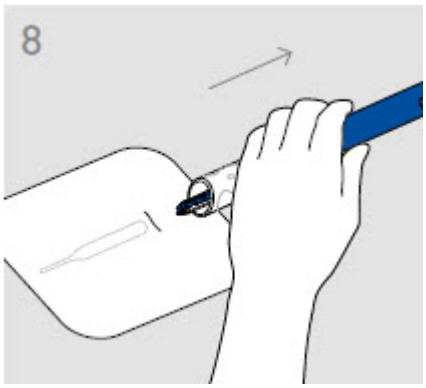


Pull back the insertion tool and lift to remove it

- 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 tool tip that is still 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 on the programmer that the standard program is loaded.

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-ups under the following conditions:

- The patient has been 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 indicate at an early stage 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 an in-office follow-up:

1	Record and evaluate the ECG if necessary.
2	Interrogate the device.
3	Check the sensing function.
4	Evaluate the 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 (print report) and document follow-up data.
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.

Note

Solderings within the housing contain lead > 0.1%. (Disclosure pursuant to § 33 REACH, EC Directive 1907/2006; SVHC candidate with CAS No. 7439-92-1)

- 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.

2 Functional Description and Handling

2.1 Safety Warnings

Note

Keep this technical manual for later use.

Note

One reason for false positive AF detections is the occurrence of extrasystoles. Bigeminy rejection detects periodic patterns of extrasystoles and prevents a consequent AF detection. For sensitive AF detection, bigeminy rejection is enabled with the parameter value `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 of this parameter individually for each patient.

2.2 Parameter

Diagnostics/Home Monitoring

Navigation: Parameters → Diagnostics/Home Monitoring

`Home Monitoring` **group box: see** Home Monitoring [**Page** 29]

`Trigger type` **group box**

`Atrial fibrillation (AF)`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

AF standard and expert parameters are described in the section Atrial fibrillation [Page 37].

`High ventricular rate`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

HVR standard parameters are described in the section High ventricular rate [Page 47].

`Bradycardia`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

Bradycardia standard parameters are described in the section Bradycardia [Page 48].

`Sudden rate drop`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

SRD standard and expert parameters are described in the section Sudden rate drop (SRD) [Page 50].

`Asystole`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

Asystole standard parameters are described in the section Asystole [Page 52].

`Patient trigger` **group box**

- `Patient trigger`: Activate the patient trigger so that a patient can initiate a recording in BIOMONITOR III manually using the Remote Assistant III.

`Resting rate period` **group box**

- `Start resting period`, `Resting period duration`: Allows you to set the start time and the duration of the resting period in order to record the patient's resting heart rate. This should normally be when the patient is asleep at night and should last for at least two hours.

Home Monitoring

Navigation: Parameters → Diagnostics/Home Monitoring

`Home Monitoring`

- `Home Monitoring`: Activate the function. This will set the Transmission function to ON for all activated trigger types. This setting leads to the transmission of the SECG (subcutaneous electrocardiogram) to the Home Monitoring Service Center. The transmitting function for atrial fibrillation transmits the detection and the termination SECG and offers an additional setting: `Detect. only`. With this setting, only the detection SECG will be transmitted.

  Transmission functions can be turned off individually.
- `Time of transmission`: This is the time when the device transmits its daily trend message. The patient should be in the immediate vicinity of the CardioMessenger at the time of transmission. Typically, this is a time at night when the patient is sleeping.

  When set to STD (= standard), the time of transmission is between 1 and 2 a.m.

`Send test message`

- `Send test message`: Pressing this key triggers the transmission of a test message by the device.
  The aim is to test the transmission of messages to the Home Monitoring Service Center.
  To do this, the following conditions must be met:
  - After pressing the key for 30 seconds, remove the programming head from the patient's chest.
  - A CardioMessenger has to be ready for use in the immediate vicinity of the patient.
  - A patient profile with the serial number of the implanted device must previously have been entered for the patient in the Home Monitoring Service Center.

    The test message is displayed in the Home Monitoring Service Center, in the patient's data, when the connection has been successful.
- `Last message type`: type of message last transmitted by the device
  - Trend message: Trend messages are transmitted once a day at the set time of transmission.
  - Event message: Event messages are transmitted when an episode has been detected. They usually contain an SECG.

    Event messages are transmitted only if transmission is activated for the corresponding episode type: **Parameters → Diagnostics/Home Monitoring →Transmission**
  - Test message: The message was triggered using the programmer and the `Send test message` function.
- `Message created on`: time of the last message

Update of the last message type display

Note

If you have sent a test message, the display status of the Last message type field is not automatically updated. Exit the application and reselect BIOMONITOR III from the implant list. Then scan for the device. The display status is updated.

What data is recorded for each arrhythmia event?

Type and duration of the recordings for `Atrial fibrillation`:

- AF detections trigger a recording of at least 40 seconds.
- At least three recordings are saved, in the following priority if overwriting is required: newest, oldest, longest.
- Number of AF detections
- AF episode duration (including the confirmation time)
- AF burden % (percentage of time under AF burden)
- Length of the longest AF episode

Histograms:

- Start of the AF (time of day)
- AF duration

Trends:

- AF duration per day
- AF episodes per day
- Mean heart rate during AF
- Maximum heart rate during AF

Type and duration of the recordings for high ventricular rate (HVR):

- HVR detections trigger a recording of at least 40 seconds.
- At least three recordings are saved, in the following priority if overwriting is required: newest, oldest, longest.
- Number of HVR detections
- Average rate for each episode

Type and duration of the recordings for bradycardia, sudden rate drop (SRD), asystole:

- Detections trigger a recording of at least 40 seconds.
- At least three recordings are saved, in the following priority if overwriting is required:
  - Asystole: 2 newest, oldest
  - Bradycardia: newest, oldest, longest
  - Sudden rate drop (SRD): 2 newest, oldest
- Mean rates of an SRD episode, including subcutaneous ECG
- Mean rates and length of a bradycardia episode, including subcutaneous ECG
- The number of detections is recorded for every arrhythmia event.

Transmission priority of various arrhythmia episodes

BIOMONITOR III is able to transmit up to six subcutaneous ECGs per day along with the trend message at the programmed transmission time.

If ...	Then ...
different types of arrhythmia episodes are registered within one day,	the most recent recordings of arrhythmia episodes are transmitted according to the following priorities: • Patient trigger • Asystole • High ventricular rate • Bradycardia • Sudden rate drop • Atrial fibrillation • Trend message

Example of order of transmission

The following events were recorded on one day:

1 patient triggering (1 Pt)
2 high ventricular rates (2 HVR)
1 sudden rate drop (1 SRD)
3 atrial fibrillations (3 AF)

The order of transmission to Home Monitoring if all episode triggers were activated [1]:

- Pt
  HVR1
  SRD
  AF1
  HVR2
  AF2

The order of transmission to Home Monitoring if only the HVR and AF episode triggers were activated [1]:

- HVR1
  AF1
  HVR2
  AF2
  AF3

The order of transmission to Home Monitoring if only the asystole episode trigger was activated:

- No episode transmission

1) Applies to programming the home monitoring transfer for AF episodes to: Detection only

Sensing Functions

Concept and settings: signal sensing

Sensing — Navigation: Parameters → Sensing

Group box: `SensingConsult`

- `SensingConsult`: Allows you to program the signal sensing parameters. You can choose between the following configurations:
- `Standard`: This is the standard setting that suppresses the sensing of P waves and T waves and brings the detection of R waves into focus.
- `Sense after large PVCs`: This setting is especially suitable for patients where extrasystoles occur with high amplitudes.
- `Sense small PVCs`: This setting is especially suitable for patients where extrasystoles occur with low amplitudes.
- `Sense short intervals`: This setting is especially suitable for patients where extrasystoles occur with short coupling intervals.
- `T-wave suppression`: This setting causes P waves and T waves to be excluded from the sensing particularly efficiently. It is therefore especially suitable for patients who have very large P waves and T waves that are being detected incorrectly as R waves.

Group box: `Sensing filter`

- `Sensing filter`: Allows you to set the rate of the sensing high pass filter used to filter the SECG signal for the sensing. The higher the rate set, the more P waves and T waves will be suppressed. However, this also reduces the amplitudes of the QRS complex slightly.

Group box: `SECG`

The abbreviation SECG stands for subcutaneous electrocardiogram.

`Display`

- `Normal`: Depending on the device orientation, signals are displayed without changes, saved, and sent to the Home Monitoring Service Center if the options are enabled.
- `Inverted`: Inverted signals are displayed, saved, and sent to the Home Monitoring Service Center if the options are enabled.

`Signal filter`

- The value 0.5 or 0.05 Hz can be set as the limit for the sensing high pass filter for the SECG.
  - The setting of 0.05 Hz provides the maximum details of the signal. Unwanted respiratory artifacts may however be visible.
- The setting of 0.5 Hz (standard) provides a detailed representation of the signal. Respiratory artifacts are typically hidden.

The settings under signal filter affect the display of the SECG on the programmer and the saved SECGs which are sent to the Home Monitoring Service Center if the options are enabled.

Concept: automatic sensitivity control and signal processing

Automatic signal processing

The device continuously analyzes the heart rate in order to start recording immediately if the set detection criteria are met. The cardiac monitor continuously registers the R amplitudes in the ventricle.

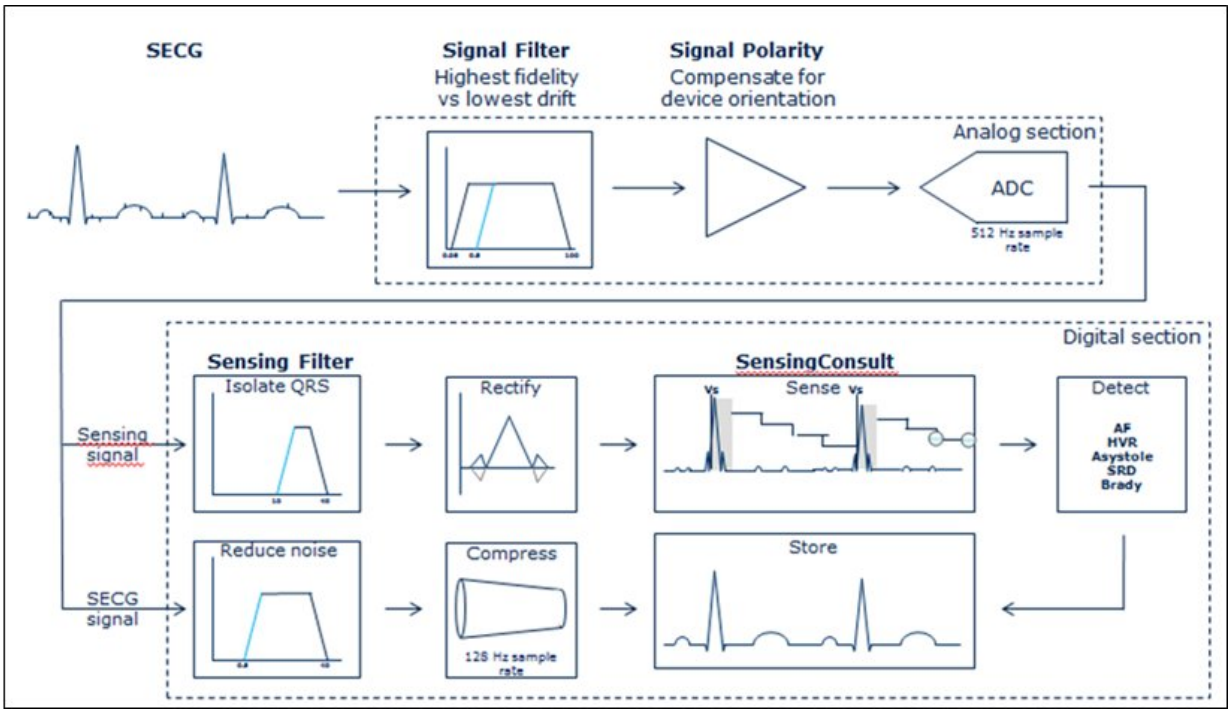


Fig. 1: Automatic signal processing

The resultant subcutaneous ECG can be displayed in two ways (as a sensing signal or a diagnostic signal), which are dependent on the mode of signal recording.

The automatic sensitivity control principle

Automatic sensitivity control is based on the principle of adaptive thresholds. Starting from a sensed R-wave peak, the upper sensing threshold is calculated at 62.5% or 100% (SensingConsult = T-wave suppression) of the R-wave peak, considering the programmed SensingConsult setting. The sensing threshold is decremented after a holding phase, until it reaches 25% of the maximum of the R-wave and remains there without changes until it is set to the lowest absolute value after a duration of 1 or 2 seconds (depending on the SensingConsult program).

The step duration and height of the threshold depends on the heart rate and the programmed SensingConsult setting. In beat-to-beat adjustment, each sensed amplitude is remeasured and the thresholds are reset accordingly.

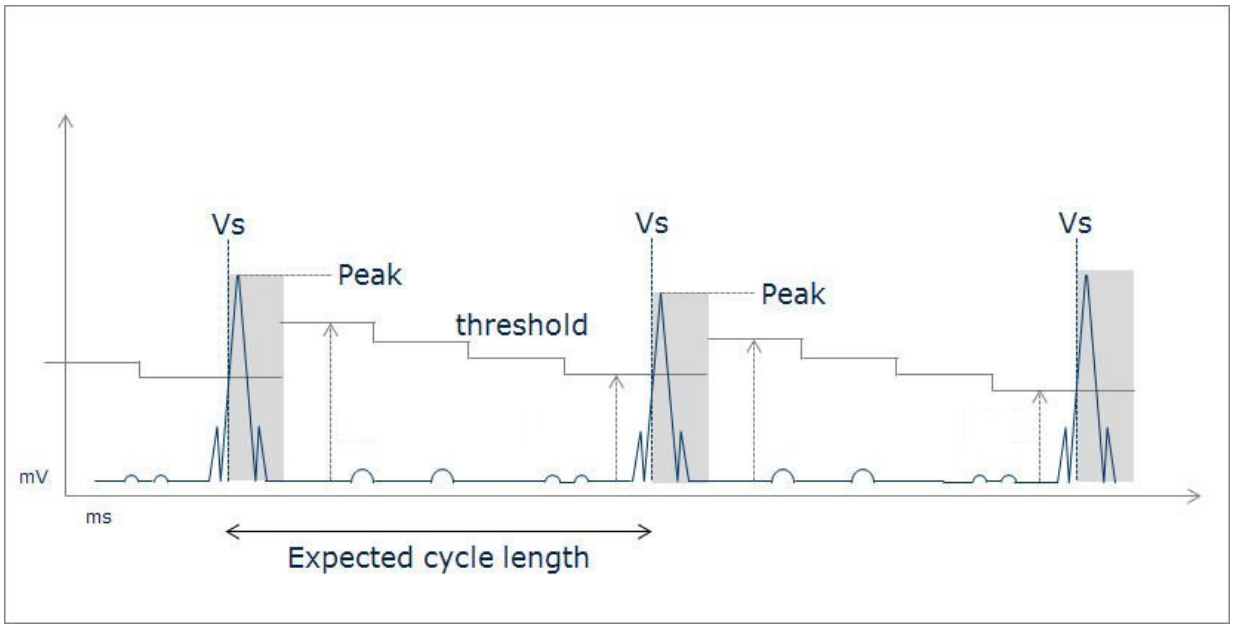


Fig. 2: Automatic sensitivity control

The rate decrease and step widths are based on the average heart rate of the patient at the specific time and the programmed SensingConsult setting. The X axis is in ms and the Y axis is in mV.

Treatment of artifacts: DHP and noise window

The detection hold-off period (DHP) and noise window functions increase the specificity of the rhythm evaluation and exclude interference signals from the rhythm evaluation.

The detection hold-off period (DHP) of 180 ms starts when the R amplitude exceeds the sensing threshold. All of the signals sensed during the DHP are ignored.

Due to the DHP being set to 180 ms, the maximum ventricular rate that can be sensed is 333 bpm.

The noise window starts at the same moment, and is retriggered every time an interference event is sensed. The interference interval has a value of 100 ms.

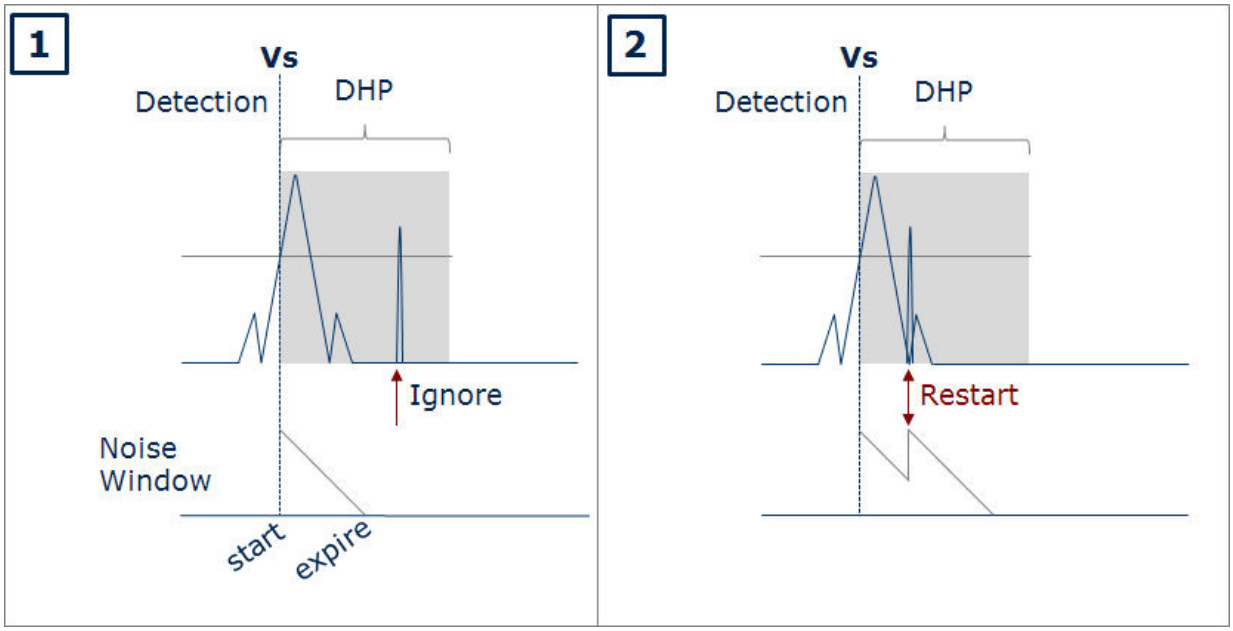


Fig. 3: Sensing during the detection hold-off period (DHP)

1. The noise window has ended; the event after that is ignored because the DHP still applies.	2. The noise window has not ended and is restarted when an interference is sensed because it is sensed within the 100 ms window.

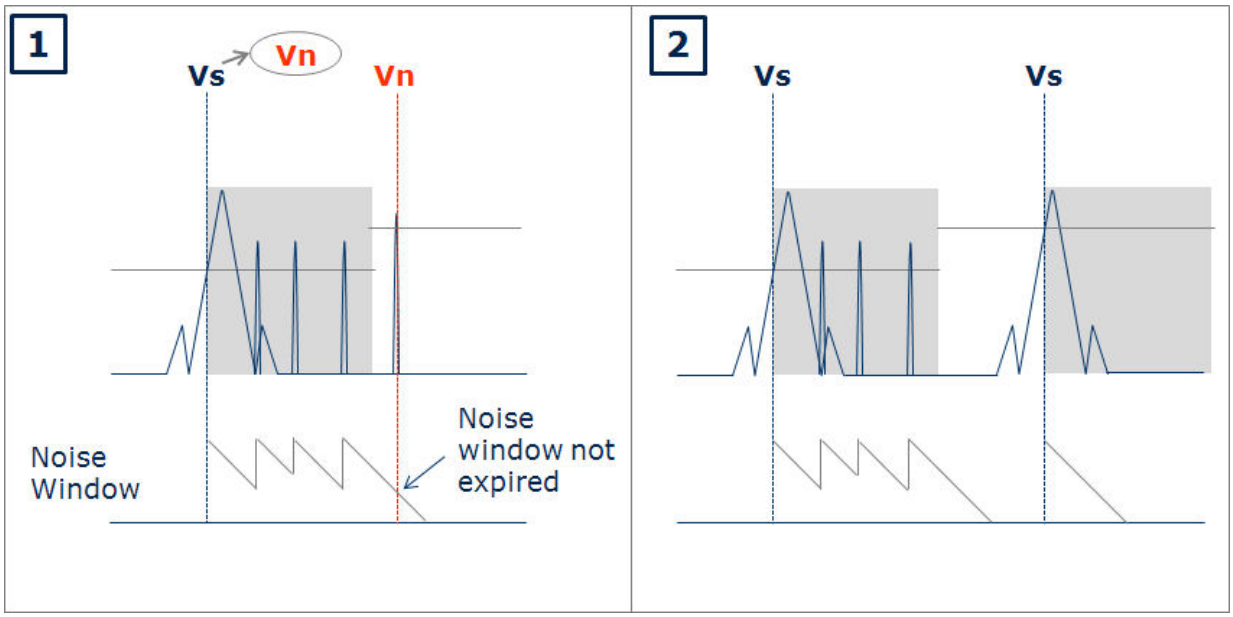


Fig. 4: Sensing after the detection hold-off period (DHP)

1. The noise window has not ended; the event is classified as interference (Vn). Vn is excluded from the rhythm evaluation. The previously detected Vs is also subsequently classified as Vn.	2. The noise window has ended and restarts sensing

Interference classification

Interference events are never included in the rhythm evaluation. They are excluded from arrhythmia detection.

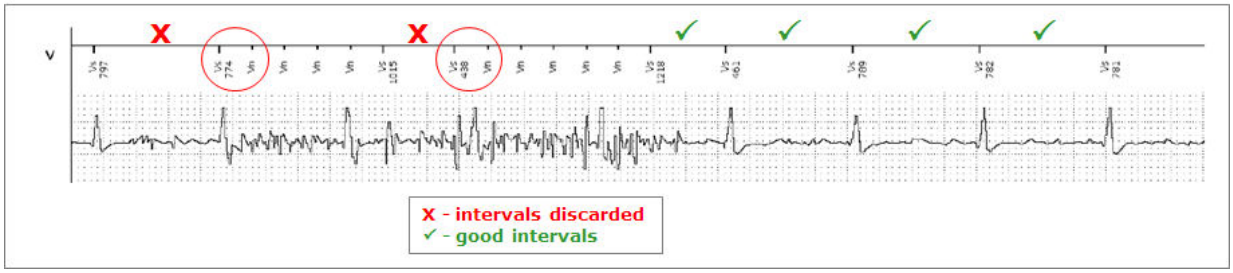


Fig. 5: Interference classification in the subcutaneous ECG

When a Vn sensed event follows a Vs, the preceding Vs-Vs interval will be excluded from the diagnostic evaluation in order to prevent interference causing a false positive detection of events.

Diagnostic Concept: Atrial Fibrillation (AF)

Atrial fibrillation

Navigation: Parameters → Diagnostics/Home Monitoring → Atrial fibrillation

Standard parameter: `Atrial fibrillation`

- `Atrial fibrillation`: Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.
  - `Transmission`: `ON`; detection and termination SECG will be transmitted
  - `Transmission`: `Detect. only`; detection SECG will be transmitted
- `AF sensitivity`: Allows you to program the sensitivity for sensing atrial fibrillation. You can choose between the following sensitivity levels: `Low`, `Medium`, and `High`. The settings directly affect the expert parameters; see the table below for `Atrial fibrillation` expert parameters.
- `RR variability limit`: Allows you to program the minimum percentage heart rate variability (fluctuation) at which an AF episode will be recorded, or in other words, the range of fluctuation in RR intervals at which an AF episode will be recorded.
- `Confirmation time`: Allows you to program the minimum number of minutes that an AF episode has to last before it is recorded.
- `Bigeminy rejection`: Allows you to program if and when (i.e., what sensitivity has to be applied) a bigeminy, trigeminy, quadrageminy rhythm should be detected, in order to reject AF detection.

  Observe the section: Safety Warnings [Page 26].

Expert parameters: `Atrial fibrillation`

The sensitivity levels of the parameter `AF sensitivity` have default settings:

Parameter	Low	Medium	High
Detection/termination window size	16/24	8/16	8/16
Detection intervals	11	5	5
Number of detection windows	3	2	1
Termination intervals	5	1	1
Number of termination windows	2	2	3

Note

Each value of the expert parameters can be changed individually. If you change a value of the expert parameters, the value `Individual` will be displayed in the `AF sensitivity` field.

- `Detection/termination window size`: The number of RR intervals to be examined for the detection (start) and termination (end) of an AF episode can be set here.

  For example, 8/16: 8 RR intervals are examined for detection of an AF episode and 16 RR intervals for termination.
- `Detection intervals`: The number of RR intervals whose RR variability has to be exceeded (minimum) by the programmed RR variability limit, so that the detection window is evaluated for AF detection (unstable) can be set here.
- `Number of detection windows`: The number of successive AF detection windows evaluated as unstable that are necessary to fulfill AF detection can be set here.
- `Termination intervals`: The number of RR intervals whose RR variability may exceed the maximum value of the programmed RR variability limit, so that the termination window is evaluated as stable for AF termination, can be set here.
- `Number of termination windows`: The number of successive AF termination windows evaluated as stable that are necessary to fulfill AF termination can be set here.

Algorithms for detecting atrial fibrillation

This section explains the algorithms for detection of atrial fibrillation and termination detection.

Diagnostic relevance

Nearly a third of all patients admitted with cardiac rhythm disturbances exhibit atrial arrhythmia such as atrial fibrillation (AF).

AF represents a high risk of secondary diseases such as congestive heart failure, cerebrovascular stroke, thromboembolic events with various manifestations and loss of atrial contraction.

It is therefore important to establish a confirmed diagnosis over a relatively long period of time in order to be able to initiate suitable therapeutic measures (antiarrrythmic agents, anticoagulation, ablation, etc.).

Characteristics of AF

Atrial fibrillation is defined by the following criteria:

- Irregular RR intervals (no periodicity)
- Absence of P waves (no coordinated contraction)
- Atrial rate > 300 bpm (re-entry tachycardia)

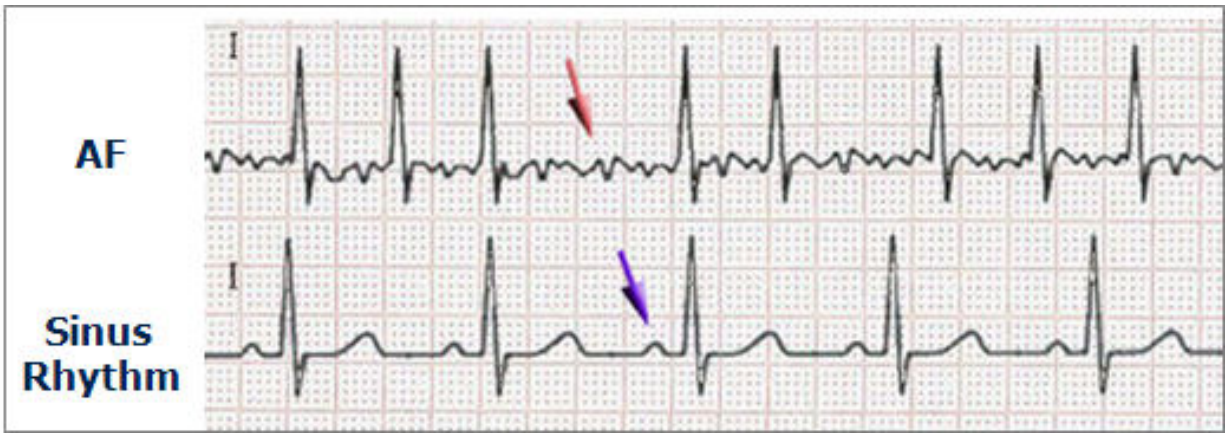


Fig. 6: Comparison of an ECG with atrial fibrillation with a sinus rhythm ECG

Algorithms for registering AF

AF detection is based on continuous checking of RR variability. RR intervals are analyzed without interruption and classified:

- RR intervals above a defined RR variability limit start the suspicious phase, during which the system will check whether AF is present. The RR variability limit is specified as a percentage and is applied to the average of the number of preceding RR intervals defined in the detection/termination window size parameter.
- The detection/termination window size parameter not only defines the number of RR intervals to be examined for detection of AF, but also the number of RR intervals to be examined which will lead to termination.
- The detection intervals parameter defines the minimum number of RR intervals which must be above the defined variability limit in order to initiate the AF suspicious phase. The number of detection intervals (X) is compared with the number of intervals (Y) defined in the detection/termination window size parameter.

  The detection windows parameter number defines the number of successive AF detection windows evaluated as unstable that are necessary to fulfill AF detection.

  Example: Detection interval = 5, detection/termination window size = 8/16. The X-of-Y criterion checks if at least 5 out of 8 RR intervals are above the variability limits and are confirmed in the successive series of windows that have been set with the detection windows parameter number. If the detection windows parameter number = 2 and two consecutive detection windows are evaluated as unstable, then the suspicious phase is opened.
- The termination intervals parameter is an X-of-Y criterion. The number of set intervals is compared with the set number of termination intervals in the detection/termination window size parameter.

  The termination windows parameter number defines the number of successive AF detection windows evaluated as stable that are necessary to fulfill AF termination.

  Example: Termination interval = 1, detection/termination window size = 8/16. The X-of-Y criterion checks if no more than 1 out of 16 RR intervals is above the variability limits and is confirmed in the successive series of windows that

have been set with the termination windows parameter number. If the terminating windows parameter number = 1 and 1 termination window is evaluated as stable, then the AF is terminated.

- The confirmation time parameter sets the duration of the suspicious phase for which an AF must last in order to confirm AF detection. If the suspicious phase is confirmed, then it is permanently stored to memory by the AF-SECG triggered by the detection. Otherwise the AF recording is discarded later.
- The bigeminy rejection parameter prevents bigeminy rhythms from being incorrectly detected as AF. A bigeminy is an ECG pattern in which every first, second, or third ventricular contraction is followed by a premature contraction.

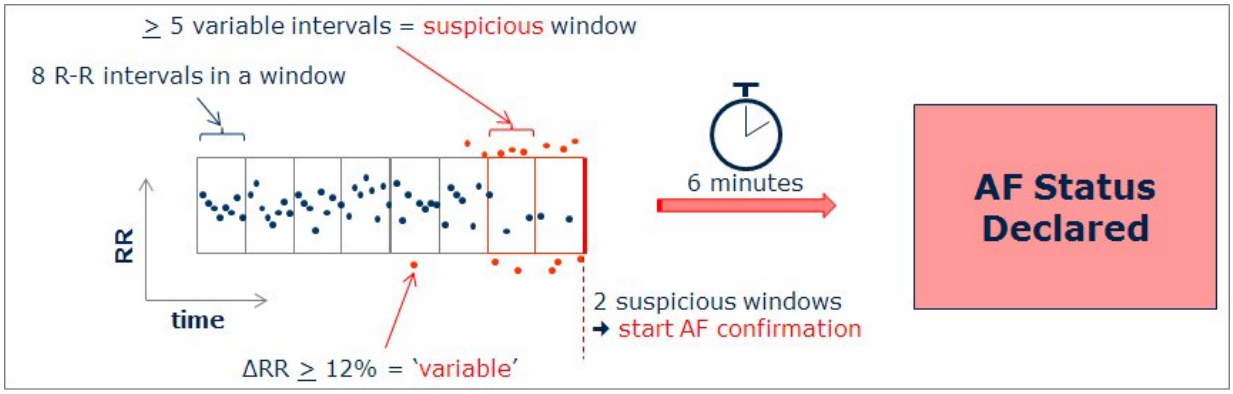


Fig. 7: Example: AF suspicious phase and confirmation

At least five intervals exceed the RR variability limit of 12% in two consecutive windows, thus beginning the suspicious phase, which is then confirmed after six minutes if no termination occurs during this period.

Effect of the RR variability limit parameter

The RR variability limit parameter has 5 adjustable values:

- Value range of RR variability limit [%]: 6; 9; 12; 15; 18

Examples of 3 value ranges are shown below:

Fig. 8: Example: RR variability limit settings

Effect of different settings of the RR variability limit parameter

Effect of the parameters for AF detection and AF termination

3 examples are shown below:

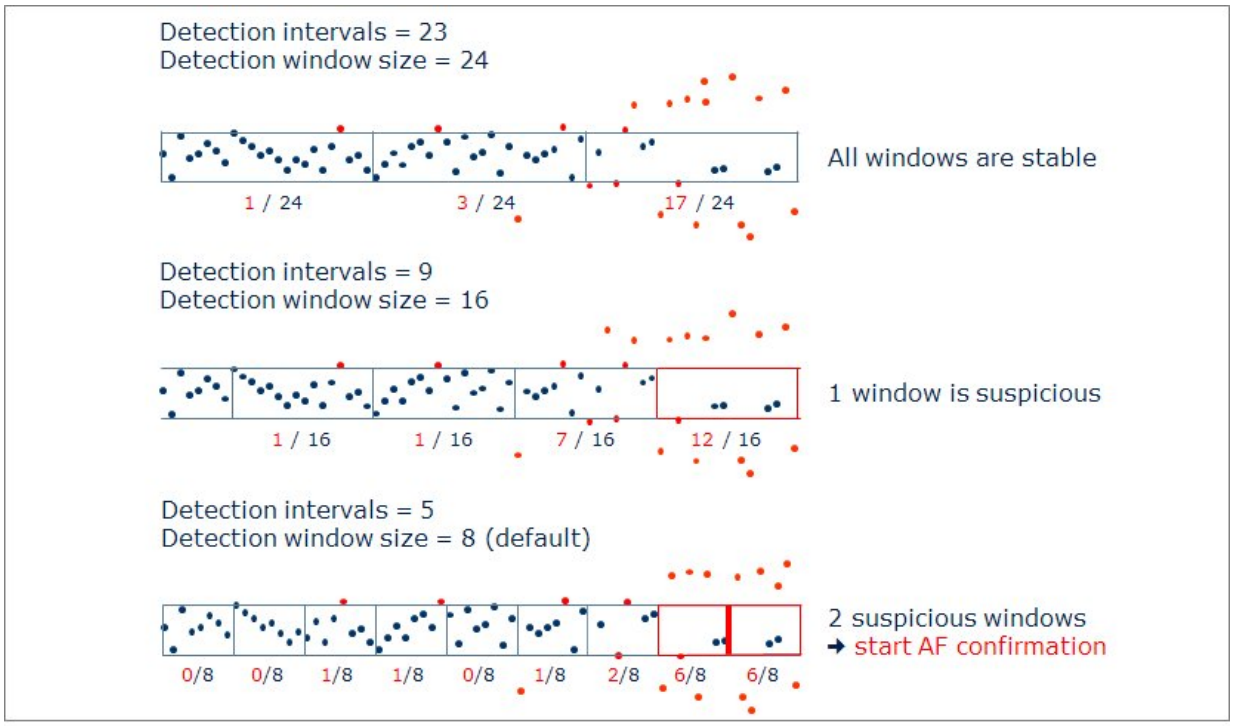


Fig. 9: Example: Settings for detection intervals and detection/termination window size

The detection/termination window size parameter can be adjusted to the values 8, 16, 24 RR intervals for the AF-detection. The settings of the detection interval parameter depend on the settings of the detection/termination window size parameter.

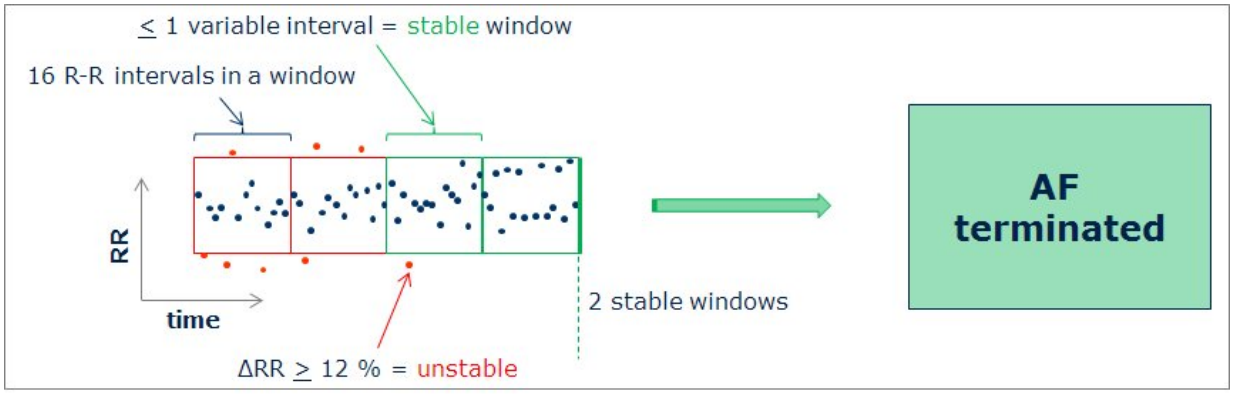


Fig. 10: Example: AF termination detection

AF termination detection is subject to the set variability limit. If the number of RR intervals set for the termination intervals parameter relative to the intervals set in the detection/termination window size (X-of-Y) is below the RR variability limit for two consecutive termination windows, then AF is declared to be ended. In the example, the terminating interval parameter = 1, number of termination windows = 2, and detection/termination window size = 8/16.

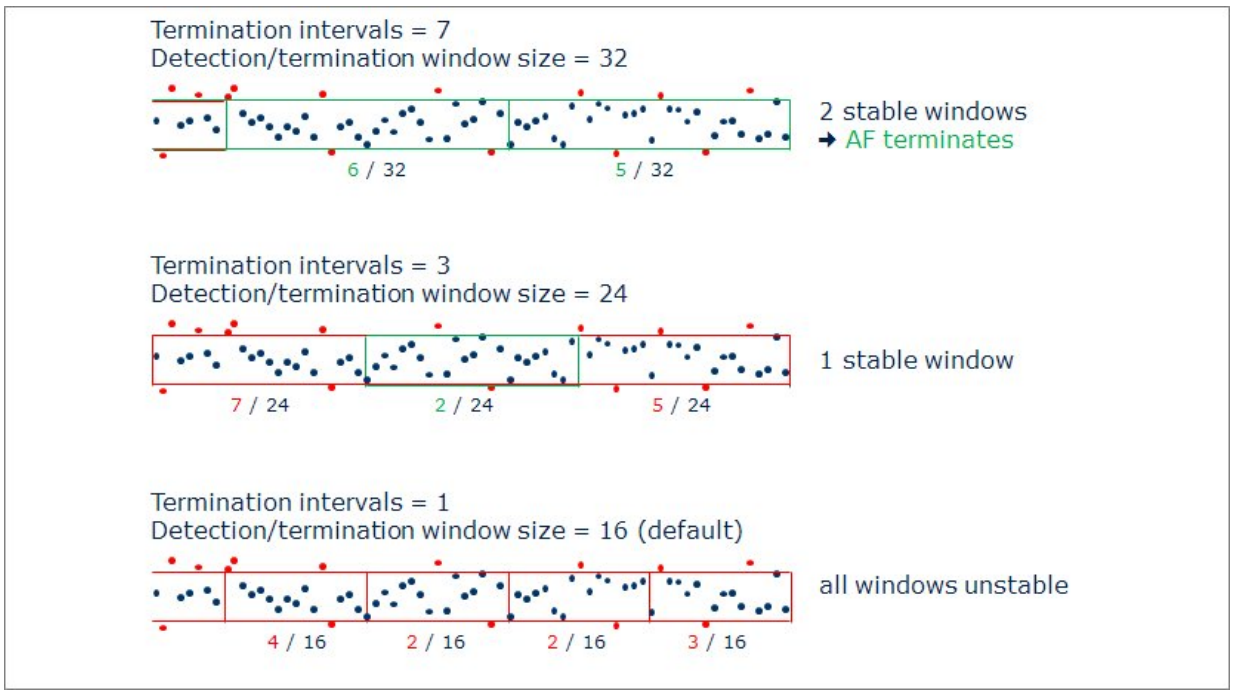


Fig. 11: Example: Settings for termination interval parameter and detection/termination window size

The detection/termination window size parameter can be adjusted to the values 16, 24, 32 RR intervals for the termination detection. The settings of the termination interval parameter depend on the settings of the detection/termination window size.

Note

If termination detection occurs during the AF confirmation time, the AF is considered to be unconfirmed.

AF sensing behavior in the event of interference

Interference events are never included in the rhythm evaluation. They are excluded from the rhythm evaluation by interference handling.

- There is an additional algorithm for interference assessment during AF detection and in the first 60 seconds of the confirmation phase:
  - An interference counter increments every interference event during sustained interference.
  - If the interference counter exceeds 25% of the number of events in the suspicious detection interval for two consecutive windows, the detection or confirmation of AF is canceled.

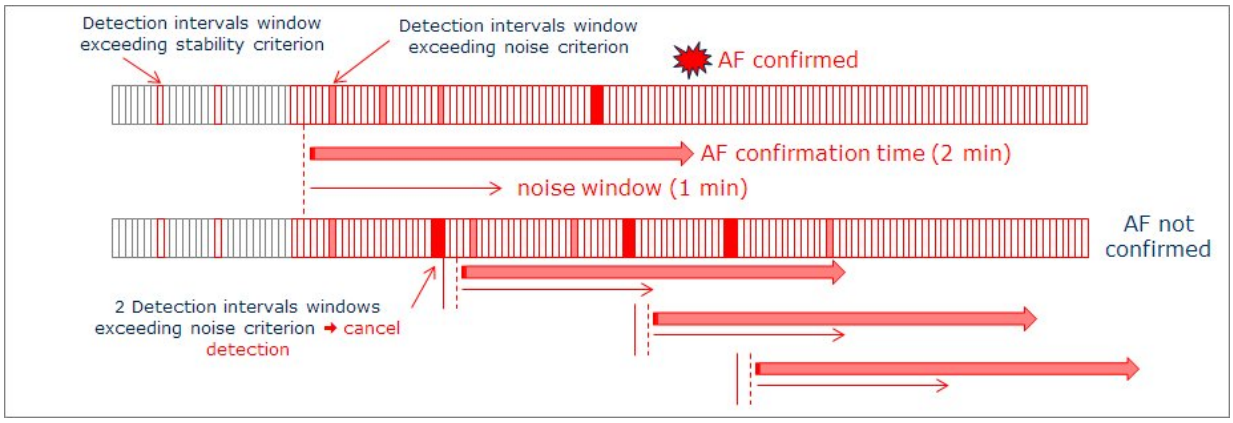


Fig. 12: Interference handling: example of two-minute confirmation phase

Bigeminy rejection

One reason for false positive AF detections is the occurrence of a series of extrasystoles with irregular coupling intervals. Bigeminy rejection detects patterns of periodically occurring extrasystoles and prevents AF detection from resulting.

The bigeminy rejection function is an algorithm to exclude the above-mentioned repetitive, pseudo-irregular interval patterns from the rhythm evaluation and detection of atrial fibrillation (AF).

Bigeminy is used as a general term referring to a succession of cardiac events which may occur in regular sequences of two beats, three beats, or four beats. These sequences are specifically named according to their periodicity, second order bigeminy, third order bigeminy and fourth order bigeminy.

Bigeminy displays the following characteristics:

- Atrial bigeminy: premature atrial contraction (PAC), narrow QRS complex
- Ventricular bigeminy: premature ventricular contraction (PVC), wide QRS complex

Periodicity of occurrence:

- Second order bigeminy: 1:1 alternation between sinus rhythm and ectopic events
- Third order bigeminy: 2:1 alternation between sinus rhythm and ectopic events
- Fourth order bigeminy: 3:1 alternation between sinus rhythm and ectopic events

Use of bigeminy rejection

False positive events are identified and eliminated by the use of the bigeminy rejection function, which classifies ectopic events that occur with a periodicity, during the first three minutes of confirmation for the detection as well as after the detection.

When the function is switched on, it starts with the start of AF detection in the suspicious phase.

The filter acts on periodic events that repeat every two, three or four beats. If bigeminy behavior is identified, AF detection is canceled.

Note

Bigeminy rejection is only active during the suspicious phase and the first three minutes of the confirmation phase.

If an AF detection is canceled due to bigeminy rejection, it is not documented in the recordings.

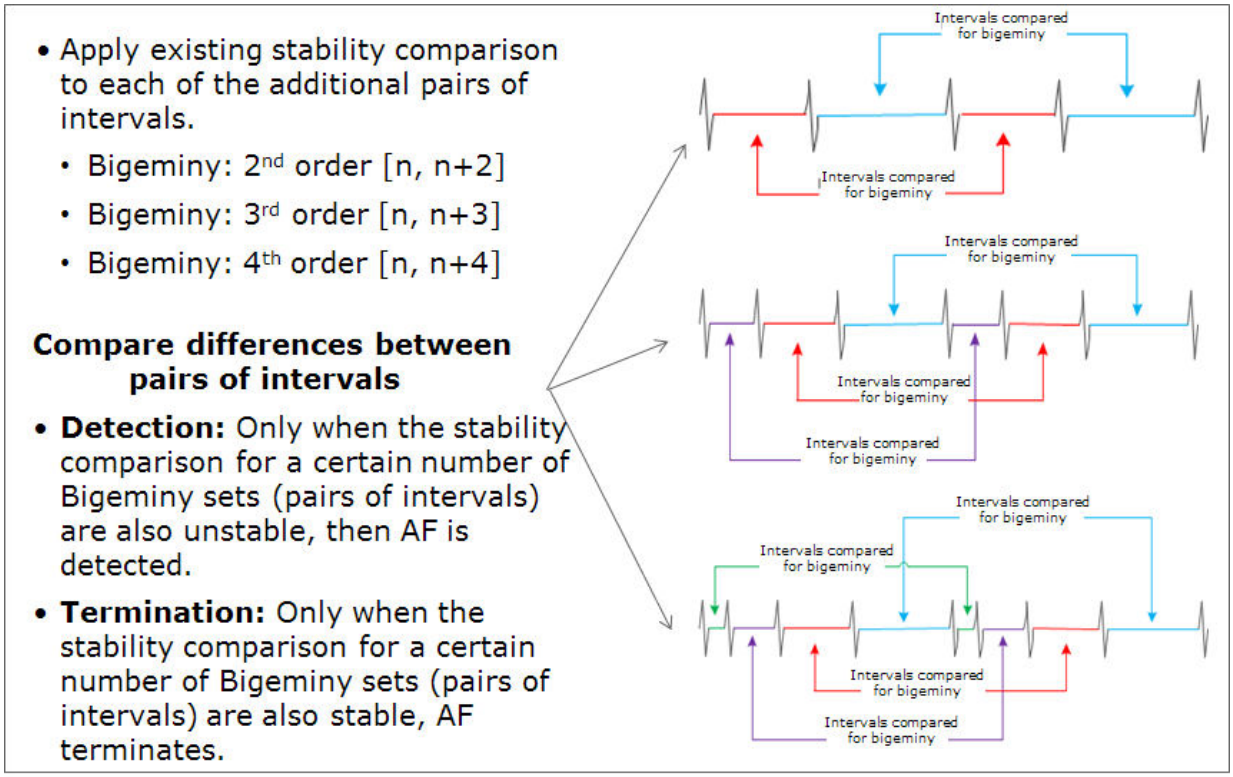


Fig. 13: Example: bigeminy rejection with the interval pattern short-long-short-long

The challenge of false positive AF detection

Regular, periodic ectopic events (PAC/PVC) display an instability pattern that is similar to genuine atrial fibrillation (AF).

This leads to a false positive detection of AF.

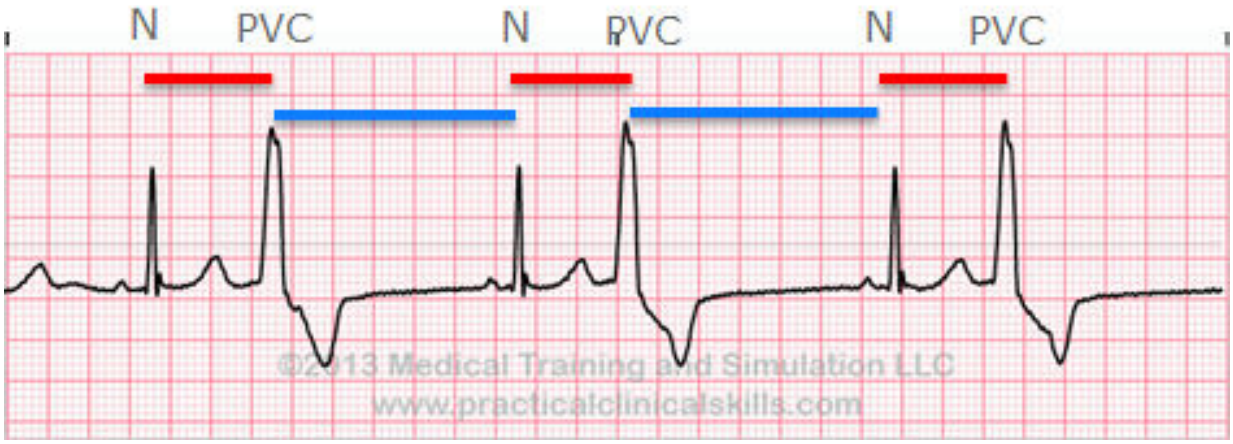


Fig. 14: Example: ventricular bigeminy with the interval pattern short-long-short-long

Bigeminy rejection settings

The following settings can be made:

- `OFF`: no bigeminy suppression
- `Standard`: setting for a reliable exclusion of periodic ectopic events in most cases. This setting registers and classifies most bigeminy events.

  AF detection with the bigeminy rejection setting `Standard` requires at least five unstable AF intervals and at least one second, third and fourth order unstable interval each.
- `Aggressive`: This setting requires more unstable intervals of the second, third and fourth order compared to the setting for `Standard`. The sensitivity of the AF detection can thus be reduced. This setting should be used for patients who have triggered a series of false positive recordings with the standard setting.

  AF detection with the bigeminy rejection setting `Aggressive` requires at least five unstable AF intervals, at least three unstable second and third order intervals each and at least two unstable fourth order intervals.

Concept and Settings: HVR, Bradycardia, SRD, and Asystole

Diagnostic concept: high ventricular rates (HVR)

High ventricular rate

Navigation: Parameters → Diagnostics/Home Monitoring → High ventricular rate

`High ventricular rate`

- `High ventricular rate (HVR)`: Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.
- `HVR limit`: Allows you to set the rate above which the RR intervals are classified as HVR.
- `HVR counter`: Allows you to set the number of RR intervals whose rate has to be above the HVR limit, so that these are detected as an episode and recorded.

  The counter of the counted RR intervals is decremented when a rate below the set limit is sensed.

An episode with high ventricular rate is considered terminated when 5 out of 5 RR intervals are below the set limit rate.

Possible causes of high ventricular rates

High ventricular rates can have various causes. Some examples include:

- Sinus tachycardia due to physical effort
- Atrial tachycardias with ventricular conduction
  - Atrial flutter
  - Atrial fibrillation (AF)
- Ventricular tachycardia (VT) – ectopic focus/foci in the ventricle cause(s) premature ventricular contractions (PVC)
  - 3 or more PVC = ventricular tachycardia (VT)
  - Duration < 30 seconds: non sustained VT
  - Duration > 30 seconds: sustained VT

Risks: low cardiac output => deficient circulation => ischemia => ventricular fibrillation

HVR detection and termination

The HVR detection function is controlled by two adjustable parameters. HVR limit defines the rate limit beyond which a ventricular interval (Vs) will be deemed to be tachycardic. HVR counter defines the number of intervals that must be above the HVR limit for the HVR to be verified. If the counter criterion is satisfied, an HVR is declared and recording is started.

- The HVR counter is a forward/backward counter:
  - Frequency ≥ HVR limit: counter incremented
  - Frequency < HVR limit: counter decremented
  - If interference is sensed, the counter is cleared

HVR termination:

- The HVR is terminated if 5 out of 5 consecutive intervals are detected below the HVR limit.
- Noise windows are not assessed and do not cause termination.

The set values are: HVR limit: 180 bpm (default); HVR counter: 4 (this value is only an example; lowest possible value = 8).

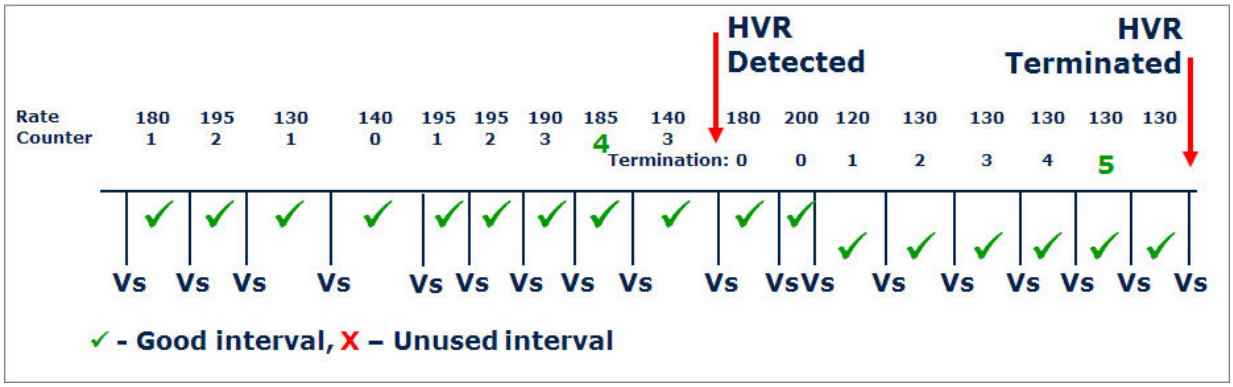


Fig. 15: Example: HVR detection without interference

During HVR detection, a Vs/Vn pair will be rated as interference. A noise window Vn clears the detection counter, but does not influence termination detection.

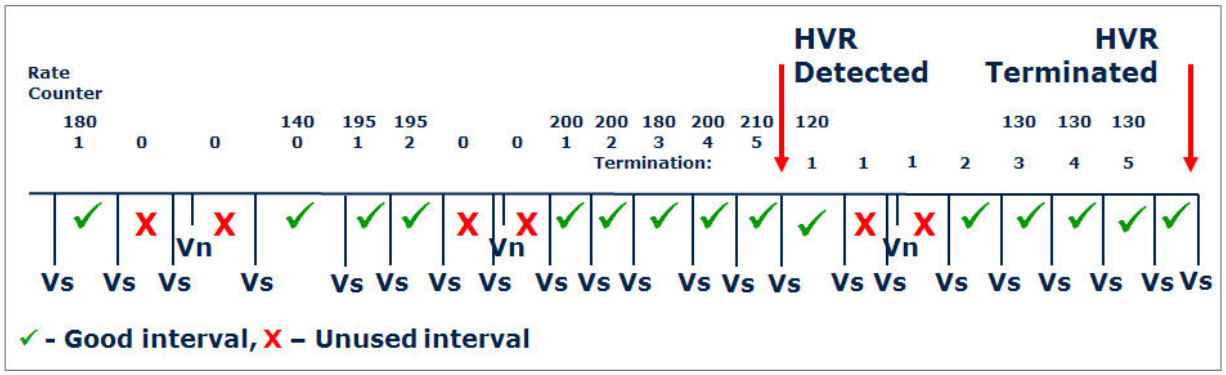


Fig. 16: Example: HVR detection with interference

Diagnostic concept: bradycardia, sudden rate drop, asystole

Bradycardia **Navigation: Parameters → Diagnostics/Home Monitoring →Bradycardia**

`Bradycardia`

Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.

- `Brady zone limit`: Define the rate for bradycardia here.
- `Brady duration`: Allows you to set the number of seconds for which the heart rate must be below the set rate (`Brady zone limit`) for it to be detected as a bradycardia episode.

A bradycardia episode is considered terminated when the rate for bradycardia has not fallen below limit for at least 10 RR intervals.

Diagnostics bradycardia

Bradycardia is diagnosed and recorded if the following conditions are met:

- Bradycardia detection starts if the heart rate falls below the set rate for the brady zone limit (default setting = 40 bpm).
- The bradycardia will only be confirmed if the rate is below the brady zone limit for longer than the set brady duration (default setting = 10 s).

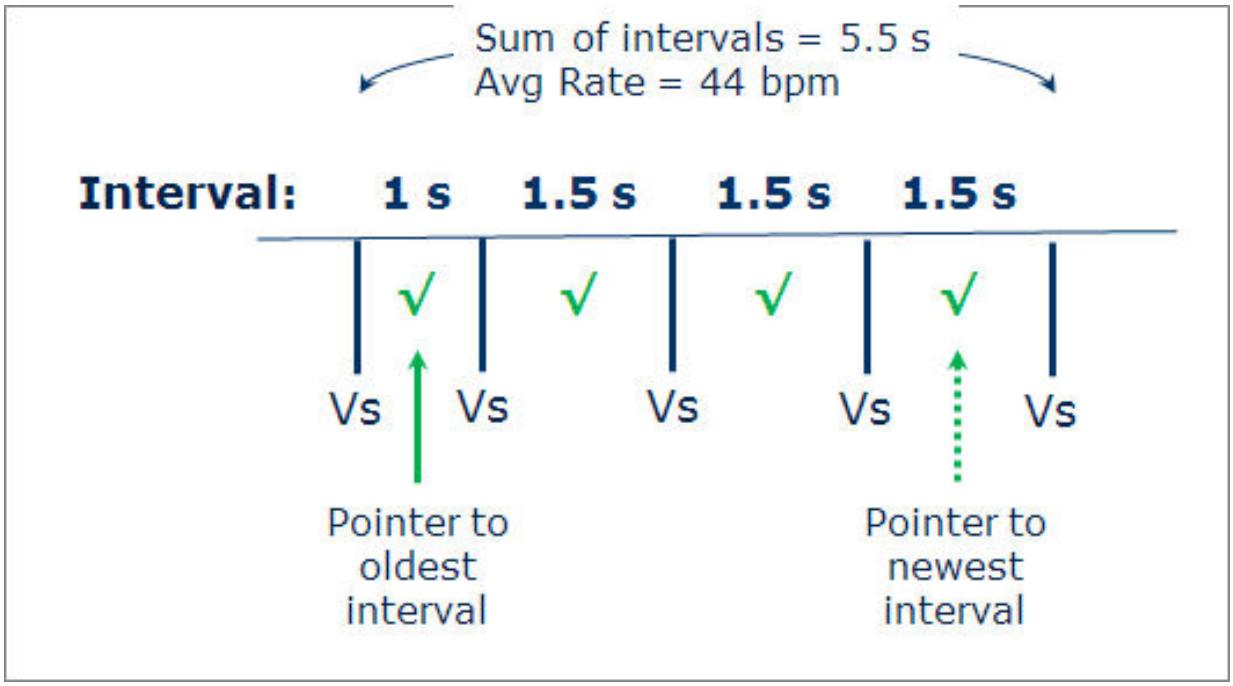


Fig. 17: Example: detection of bradycardia with a set brady zone limit of 50 bpm and a brady duration of 5 s

Diagnostics: bradycardia when exposed to interference

The bradycardia will not be confirmed if the required duration of 5 s is not reached due to a noise window. This involves an Vn interference event following a Vs-Vs classified interval with a set brady zone limit of 50 bpm and a brady duration of 5 s. The most recent interval will not be evaluated and the oldest interval will be discarded. If the interval total is less than or equal to the brady duration, bradycardia will not be confirmed.

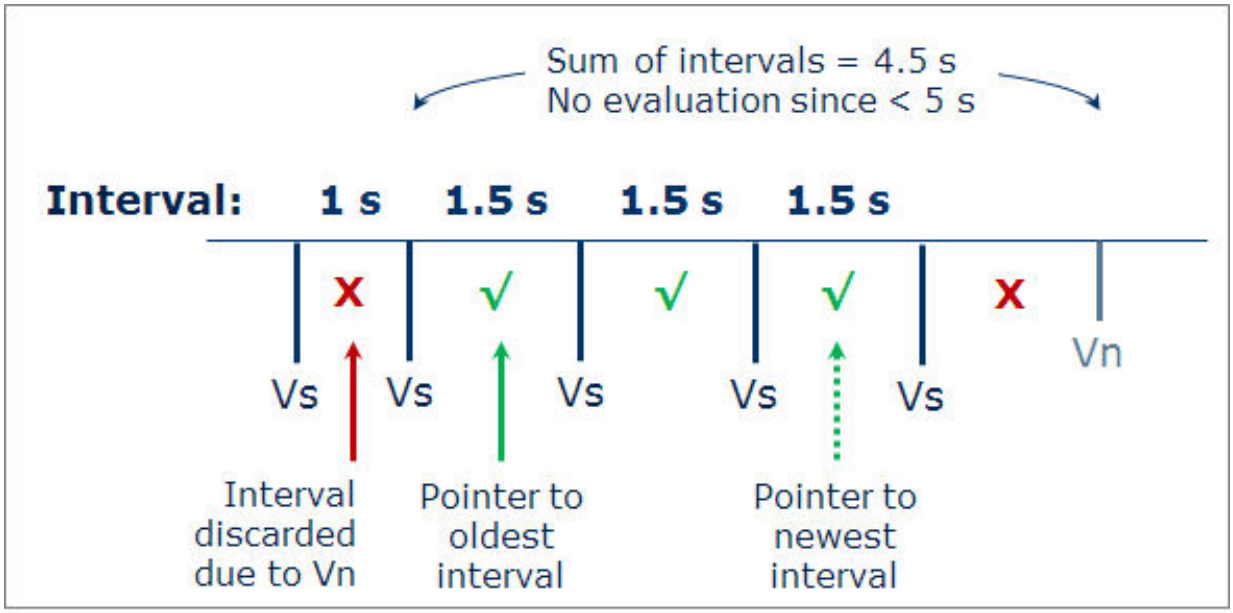


Fig. 18: Example 1: bradycardia detection discarded due to interference

The bradycardia will be confirmed if the required duration of 5 s is reached and exceeded despite a noise window. This involves an Vs interval following a Vs classified interval with a set brady zone limit of 50 bpm and a brady duration of 5 s. The most recent interval and the oldest interval will be evaluated. The interval total is greater than the brady duration, so bradycardia will be confirmed.

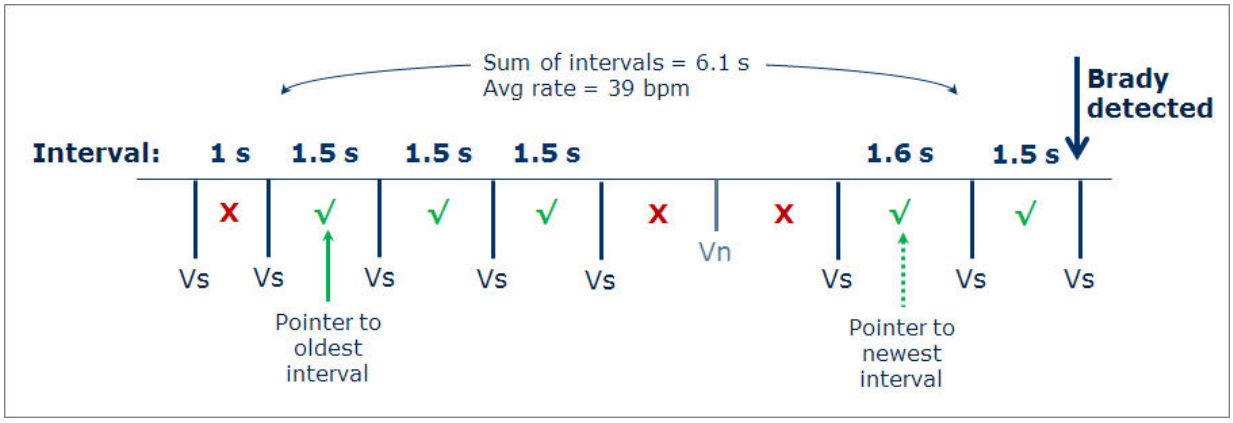


Fig. 19: Example 2: bradycardia detection confirmed despite interference

Bradycardia: termination detection

- Bradycardia detection is terminated by a termination counter.
  - If 10 intervals satisfy the criterion, bradycardia detection will be terminated.
- Detection of bradycardia causes the termination counter to be cleared.
- Every new Vs interval that is shorter than the rate limit interval increments the counter value.
- Every new Vs interval that is longer than the rate limit interval resets the counter to 0.
- A noise window Vn sets the counter back to 1.
  - Vn does not reset the counter to 0.
  - Vn never sets the counter to less than 0.

Sudden rate drop (SRD)

Navigation: Parameters → Diagnostics/Home Monitoring → Sudden rate drop

Standard parameter: `Sudden rate drop`

- `Sudden rate drop`: Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.
- `SRD rate decrease`: Allows you to set the percentage reduction in the heart rate at which an episode with sudden rate drop will be detected.
- `SRD sensitivity`: Allows you to set the sensitivity for sensing an episode with sudden rate drop. You can choose between the following sensitivity levels: `Low`, `Medium`, and `High`.

The sensitivity levels have default values, displayed under SRD expert parameters:

Expert parameters: `Sudden rate drop`

- `Baseline intervals`: Allows you to set the number of RR intervals which should be used to determine the mean heart rate before detection of a sudden rate drop.
- `Rate-drop intervals`: Allows you to set the number of RR intervals whose mean rate should be compared with the mean heart rate of the baseline intervals in order to detect a sudden rate drop.

  If the rate decrease for this number of RR intervals is above the set percentage (`SRD rate decrease`), it is confirmed as an episode with sudden rate drop.

Sensitivity levels with default values:

	Low	Medium	High	Individual
Baseline intervals	256	64	48	Range of values: 48; 64; 128; 256
Rate-drop intervals	32	16	8	Range of values: 8; 16; 32

Note

Each value of the expert parameters can be changed individually. If you change a value of the expert parameters, the value `Individual` will be displayed in the `SRD sensitivity` value field.

Termination algorithm is not defined for SRD episodes.

Diagnostics: sudden rate drop (SRD)

The detection algorithm compares a definable number of intervals (baseline intervals) before the rate decrease in reference to a definable number of intervals (rate-drop intervals) and calculates the percentage deviation. The percentage deviation is the adjustable `SRD rate decrease` detection criterion. If that percentage is exceeded, an SRD will be detected and recorded. The detection comes after the rate decrease.

- The oldest Vs marks the beginning of the baseline intervals phase.
- The most recent Vs marks the end of the rate-drop intervals phase.
- The longer the rate-drop intervals phase is set, the longer it will take to confirm an SRD.
- A noise window resets all the counters in both interval windows to 0.

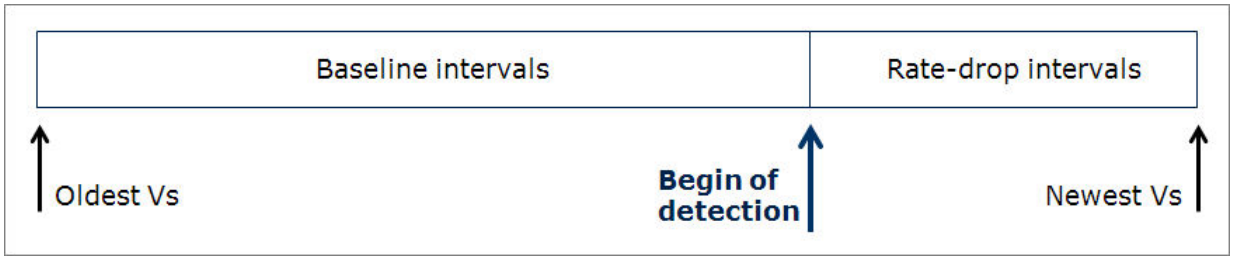


Fig. 20: SRD algorithm

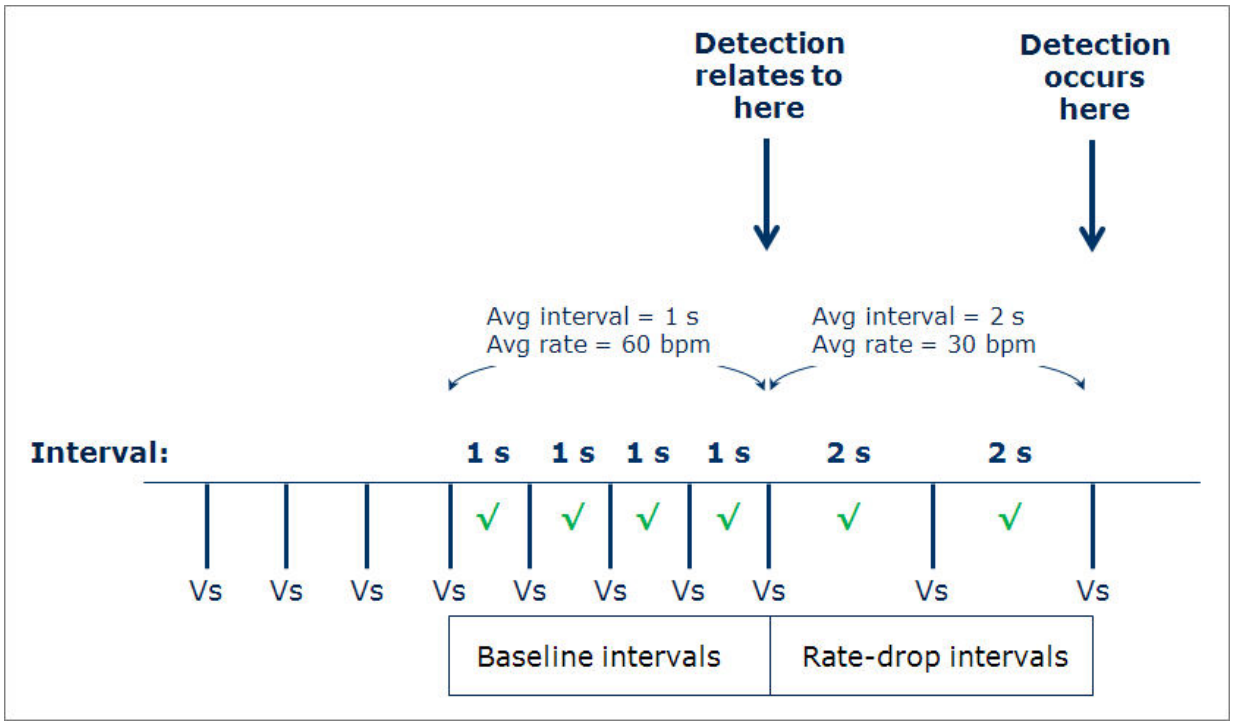


Fig. 21: Example of SRD detection: Baseline intervals: rate-drop intervals = 4:2

Asystole

`Asystole`

- `Asystole`: Activate or deactivate detection, recording, and data transfer of episodes to the Home Monitoring Service Center here.
- `Asystole duration`: Allows you to set the number of seconds after which an asystole episode will be recorded.

Termination algorithm is not defined for asystole episodes.

Diagnostics: Asystole

Asystole detection occurs if a Vs-Vs interval exceeds the set asystole time period. The asystole algorithm examines every Vs in relation to the preceding one. Noise windows are discarded. Only Vs-Vs intervals are utilized for assessment of an asystole.

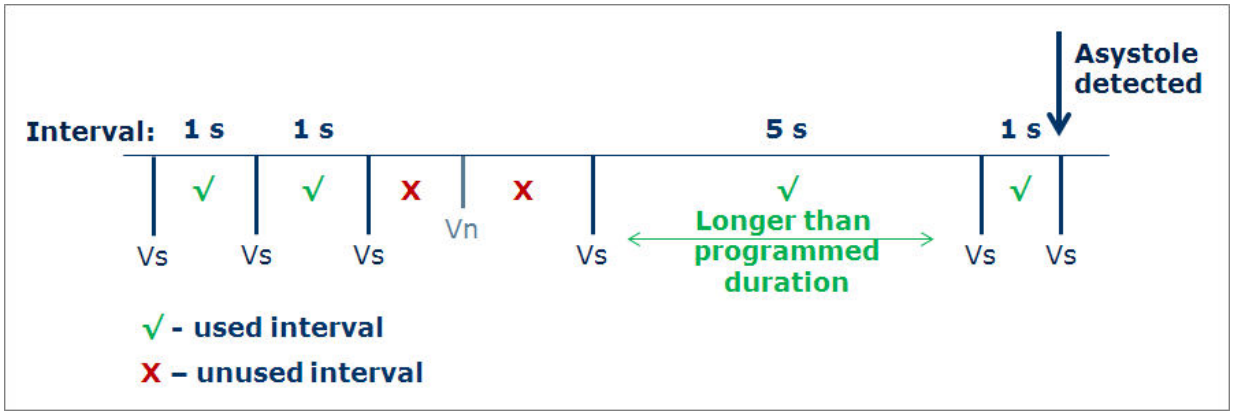


Fig. 22: Asystole detection

Diagnostics: asystole when exposed to interference

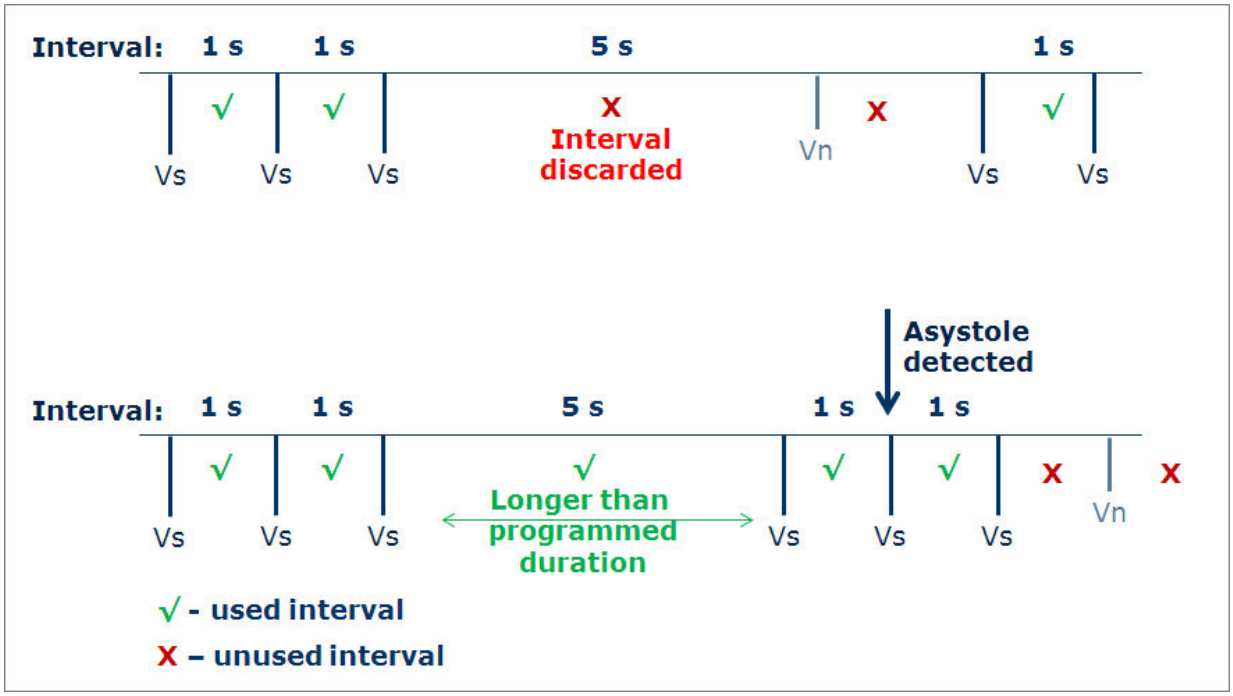


Fig. 23: Asystole detection when exposed to interference

Patient

Navigation: Parameters → Patient

The details on the Patient tab can be changed at any time and saved in the implanted device by clicking `Program`. They will be available again at the next interrogation.

You can enter details in the following input fields:

- `ID`
- `Last name`
- `First name`
- `Date of birth`
- `Gender`
- `Date of implant`
- `Hospital, City`
- `Physician`
- `Phone`
- `Remark`
- `Symptom`
- `Etiology`
- `NYHA`

2.3 Programs and ProgramConsult

Navigation: Parameters → Program sets

The following programs can be interrogated, set up, and stored in the Programs group box:

Displaying programs

- `Standard program`
- `First interrogated program`
- `Permanent program`

Store individual programs

- `Individual1`, `Individual2`, `Individual3` are memory locations for individually created programs that can be saved here under any name.

ProgramConsult

Tried and tested parameter combinations can be accessed and programmed using ProgramConsult. This applies to the following indications:

- `Syncope`
- `Palpitations`
- `AF monitoring`
- `Cryptogenic stroke`

Parameter settings for the individual indications:

Parameters Atrial fibrillation (AF)	**Range of values (standard)**	Syncope	Palpitations	AF monitoring	Cryptogenic stroke
Detection	**ON**/OFF	**ON**	**ON**	**ON**	**ON**
AF sensitivity	Low , (Medium), High	Low	Medium	Medium	High
RR variability limit	6, 9, **12**, 15, 18	12	12	12	12
Confirmation time	1, 2, 3, 4, 5, **6**, 10, 20, 30	10	6	6	1
Bigeminy rejection	OFF, **Standard**, Aggressive	Aggressive	Aggressive	Standard	Standard

Parameters High ventricular rate	**Range of values (standard)**	Syncope	Palpitations	AF monitoring	Cryptogenic stroke
Detection	**ON**/OFF	**ON**	**ON**	**ON**	**ON**
HVR limit	100 ... (10) ... **180**, 190, 200 bpm	160	180	180	180
HVR counter	8, 12, **16**, 20, 24, 32, 48	16	32	48	48

Parameters Bradycardia	**Range of values (standard)**	Syncope	Palpitations	AF monitoring	Cryptogenic stroke
Detection	**ON**/OFF	**ON**	**ON**	**ON**	**ON**
Brady zone limit	30, 35, **40** ... (5) ... 80 bpm	35	30	30	30
Brady duration	5, **10**, 15, 20, 25, 30 s	20	30	30	30

Parameters Sudden rate drop	**Range of values (standard)**	Syncope	Palpitations	AF monitoring	Cryptogenic stroke
Detection	**ON**/OFF	**ON**	**OFF**	**OFF**	**OFF**
SRD rate decrease	20, 30, 40, **50**, 60, 70 %	50	-	-	-
SRD sensitivity	Low , (Medium), High	Low	-	-	-

Parameters Asystole	**Range of values (standard)**	Syncope	Palpitations	AF monitoring	Cryptogenic stroke
Detection	**ON**/OFF	**ON**	**ON**	**ON**	**ON**
Asystole duration	2, **3** ... (1) ... 10 s	3	5	5	5

2.4 Follow-Up

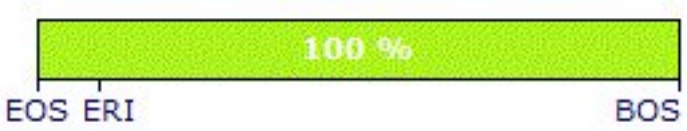
The Follow-up window shows how many episodes have been detected since the last follow-up and provides a link to the list of recorded episodes (see below). It also shows the battery and device status and the most important information about the patient.

Patient

- Name: You can change the name of the patient on the following tab: **Parameters → Patient**
- Last follow-up: This date was set automatically when the device was last interrogated.
- Date of implant: You can change the implant date on the following tab: **Parameters → Patient**

Device status

- Home Monitoring: You can switch the function on and off on the following tab: **Parameters → Diagnostics/Home Monitoring**
- Information on the battery status:
  - BOS: Beginning of Service – battery status at startup



- ERI: Elective Replacement Indication (i.e., RRT: Recommended Replacement Time) – indicates explantation

  Diagnostic data is no longer collected and recorded.

  The remaining time calculated for the battery is at least 2 months. Home Monitoring is deactivated 14 days after reaching ERI. Explant the device.
- EOS: End of Service

Diagnostics

In the Diagnostics group box, the date of the last Follow-up is always displayed.

- Atrial fibrillation (AF)
- High ventricular rate
- Bradycardia
- Sudden rate drop
- Asystole
- Patient trigger

The programmer displays if detection of the episode type is switched on and how many episodes have been detected since the last change in programming.

You can display the list of all recordings.

Select:

You can switch episode detection on and off on the following tab: **Parameters → Diagnostics/Home Monitoring**

`TrendView`

`TrendView` shows four recordings for the following parameters in the form of a diagram: see TrendView [Page 58].

`Longest AF episode [dd, hh:mm]`

`AF burden`: These recordings provide an overview of the atrial burden.

TrendView

`TrendView`

`TrendView` shows four long-term recordings in the form of a diagram:

- `Rate`
- `Heart rate variability`
- `Patient activity`
- `AF burden`

2.5 Recordings

List of Recordings

The device can record subcutaneous electrocardiograms (SECG) if detection and recording are enabled. You can switch episode detection and/or recordings on/off in the following tab: **Parameters** → **Diagnostics/Home Monitoring**

The recording duration of each detected episode is at least 40 s. Up to 56 recordings of automatically detected episodes can be saved in the memory.

The duration of recording triggered by the patient is always at least 7.5 minutes per recording. There are four memory locations for patient-triggered recordings.

Once all the space in the memory is used up, the device overwrites an existing recording with the next recording according to a defined hierarchy.

Displaying a recording

A previously viewed recording is not shown in bold on the list during the same follow-up.

Click on the symbol to view the recordings.

Deleting the recordings

The `Restart` function deletes all recordings of the device.

Display of the Recording

In the `Recordings` window, you have the following options:

- Move auxiliary line: multiple arrow keys for moving the two auxiliary lines: individually, simultaneously
  - Auxiliary line 1 shows the distance to auxiliary line 2 in ms
  - Auxiliary line 2 shows the distance to auxiliary line 1 in bpm
- Adjust resolution: plus/minus keys for adjusting the resolution
- Show/hide grid and marker text: select check box
- Select section: in the `Print/Store` submenu, select the section to be stored or printed

Special feature: The marker Vn indicates interference signals. The "n" designates "noise". RR intervals containing Vn markers are not evaluated by the arrhythmia detection algorithms.

2.6 Diagnostics

Diagnostic Functions: Home Monitoring

Tachogram and Lorenz plot

Diagnostic functions available in Home Monitoring

With BIOMONITOR III, the following diagnostic functions are exclusively available in the Home Monitoring Service Center:

Tachogram and Lorenz plot

What do the Lorenz plot and tachogram show?

The Lorenz plot (also called a Poincaré plot) is a scatter plot showing the change in RR interval length of the preceding change interval (dRR_{i-1}) in relation to the change of the current interval (dRR_i). This yields typical and relatively rate-independent patterns representing the underlying heart rhythm.

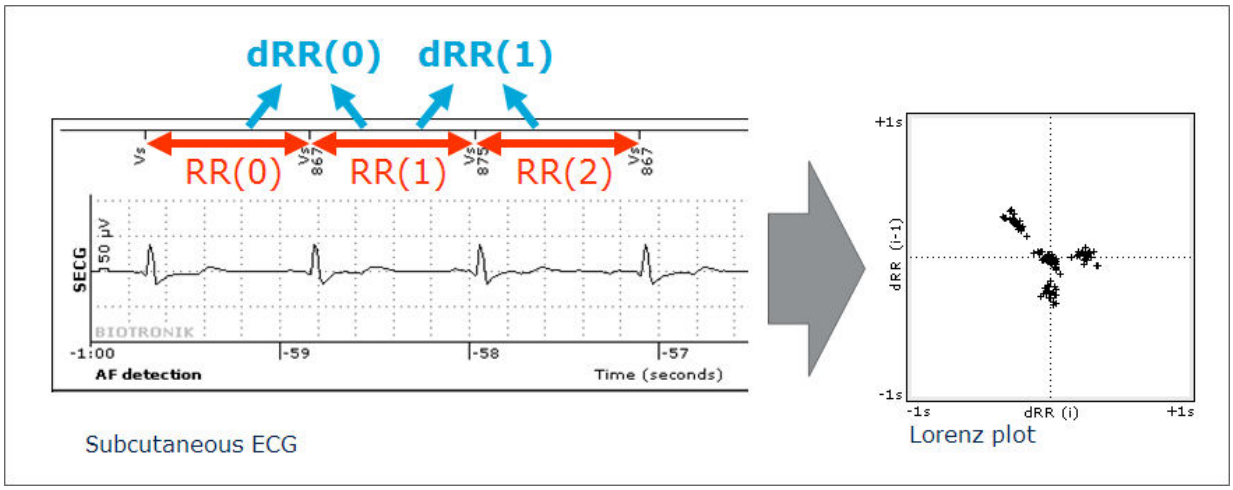


Fig. 24:

Note

Intervals classified as interference are shown in gray in the tachograms and the Lorenz plots.

In some cases it can be difficult to diagnose an arrhythmia with a subcutaneous ECG alone. The distribution of the rates in a tachogram and the size and shape of the Lorenz scatter plot help to clearly distinguish between, for example, atrial

fibrillation and non-atrial fibrillation and to clearly identify the occurrence of interference. The tachogram provides a quick overview of the rate distribution in an episode without any need to view all of the full subcutaneous ECG.

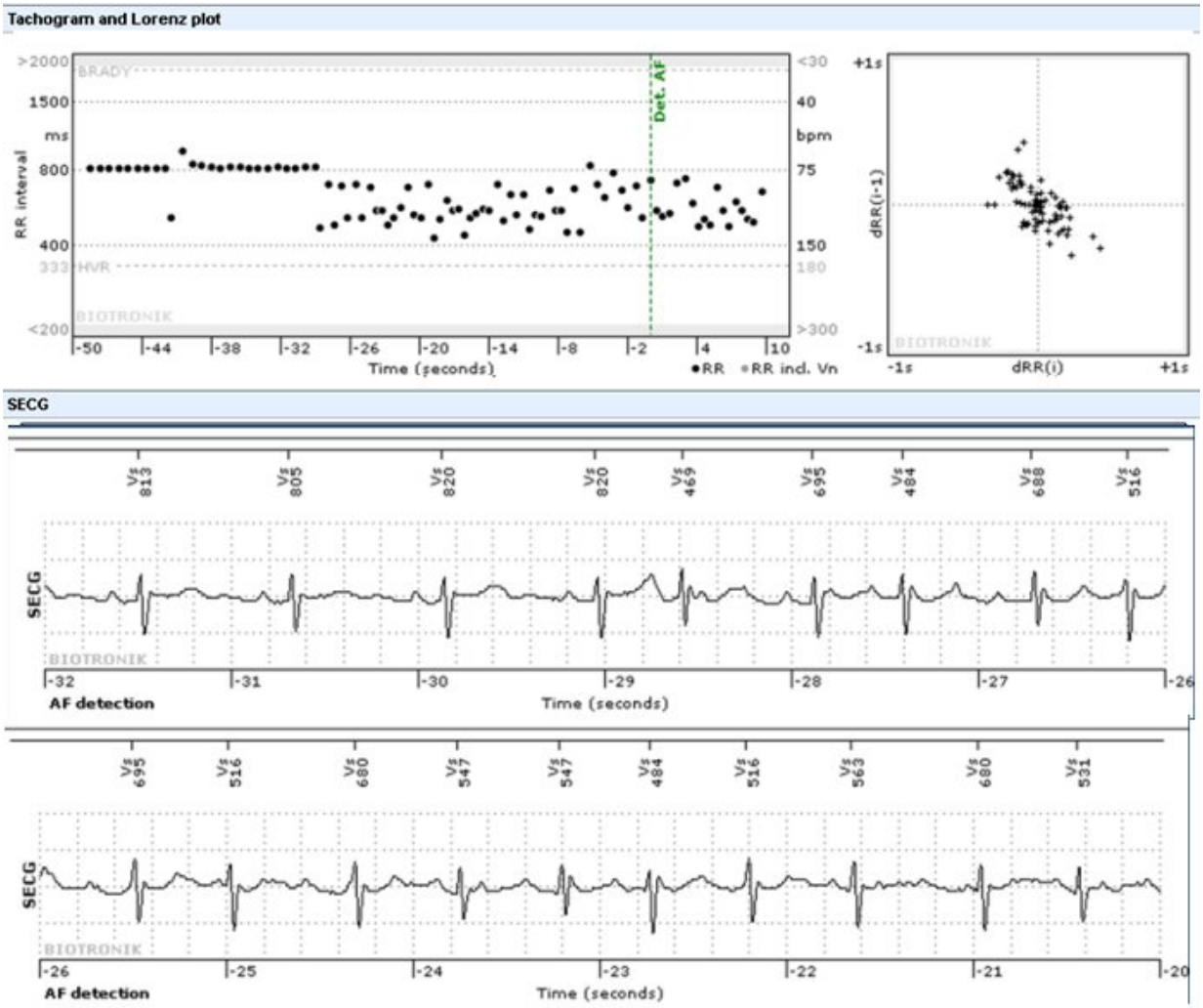


Fig. 25: Example: diagnosis AF

Examples of Lorenz plots

Lorenz plots can be assessed relatively easily as all heart rhythms correlate with certain patterns of the plot. Some typical examples are shown in the following figure. The distribution of the RR intervals allows a precise interpretation of the heart rhythm.

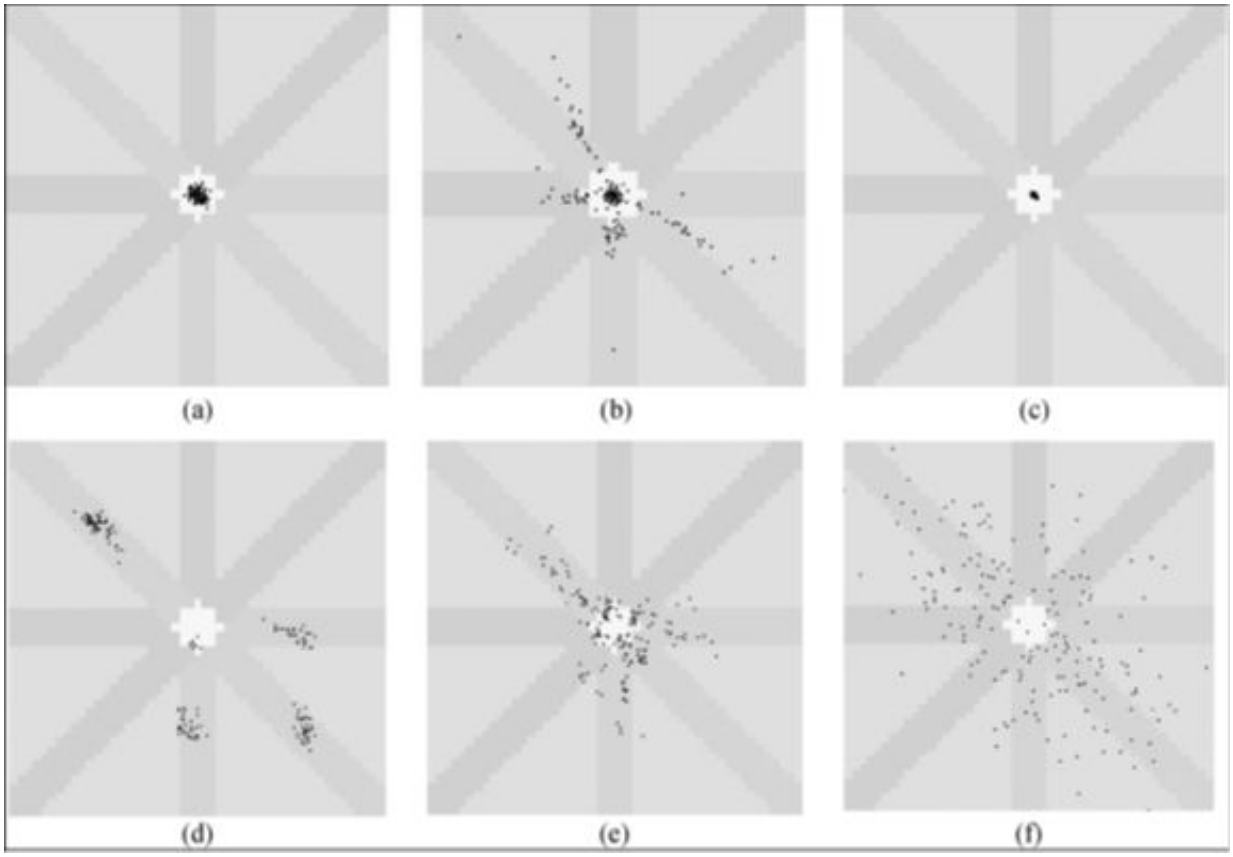


Fig. 26: Examples of Lorenz plots

- (a) Sinus rhythm
- (b) Supraventricular tachycardia (SVT)
- (c) Atrial flutter with 1:1 conduction
- (d) Atrial flutter with 3:1 and 4:1 conduction
- (e) Atrial flutter with irregular conduction
- (f) Atrial fibrillation

There is a typical Lorenz plot pattern for each heart rhythm. That makes it easy to distinguish quickly between different rhythms.

Example: high ventricular rate (HVR)

Typical characteristic:

- The tachogram shows a sudden change of interval lengths.
- The Lorenz plot shows a concentration of all the points around the center except for a few stray points.

The HVR algorithm requires a number of fast intervals to detect an HVR episode. The green mark in the tachogram shows that the detection criterion was met. The left-hand Y axis of the tachogram is notated in ms, whereas the rate in bpm is shown on the right.

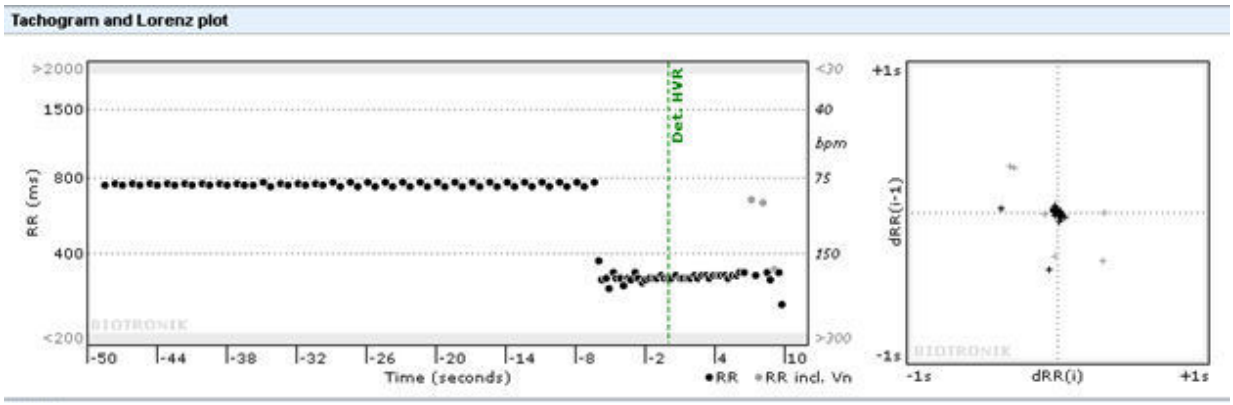


Fig. 27: Example: diagnosis HVR

Example: asystole

Characteristics:

- The tachogram shows a section without RR intervals.
- The Lorenz plot shows a typical sinus rhythm pattern with isolated points dispersed around the edge of the central plot.

An asystole is detected if the length of two ventricular sensing events (Vs) or one ventricular RR interval exceeds the programmed value (asystole duration in seconds).

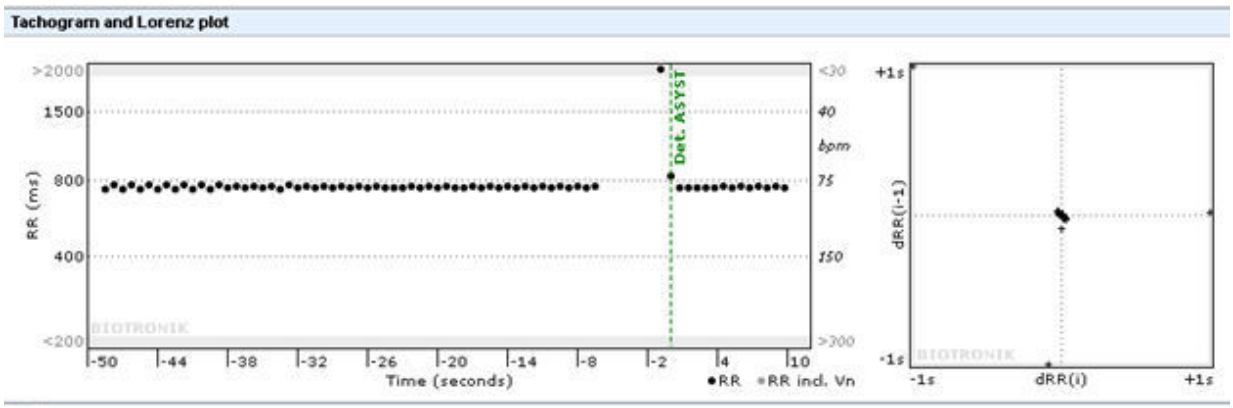


Fig. 28: Example: diagnosis Asystole

Example: sudden rate drop (SRD)

Characteristics:

- The tachogram shows a rate jump. This represents a sudden rate drop. Note the different y-axis scaling in ms and bpm.
- The Lorenz plot shows a typical sinus rhythm pattern with isolated points dispersed around the central plot at a short distance.

The detection algorithm compares a definable number of intervals (baseline intervals) before the rate decrease in reference to a definable number of intervals (rate-drop intervals) and calculates the percentage deviation. The percentage

deviation is the adjustable "SRD rate decrease" detection criterion. If that percentage is exceeded, an SRD will be detected and recorded. The detection comes after the rate decrease.

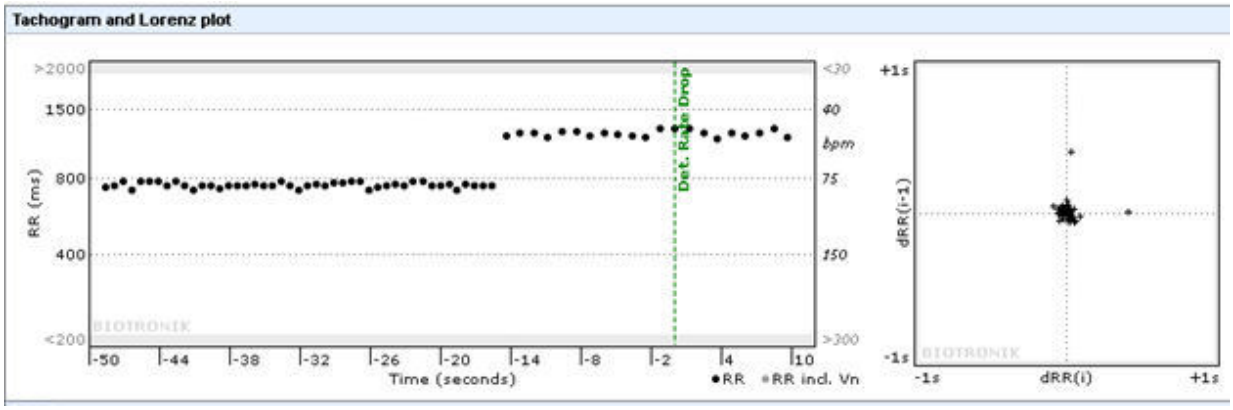


Fig. 29: Example: diagnosis SRD

Example: atrial fibrillation (AF)

Characteristics:

- The tachogram shows a highly irregular pattern of RR intervals distributed all over the tachogram.
- The Lorenz plot shows an irregular scattering of data points, distributed all over the plot. This is typical of a very irregularly conducted AF rhythm.

AF episodes will be detected and recorded if a programmed number X of detection intervals, expressed as a percentage of a programmed number Y of baseline intervals, reaches or exceeds the set RR variability limit.

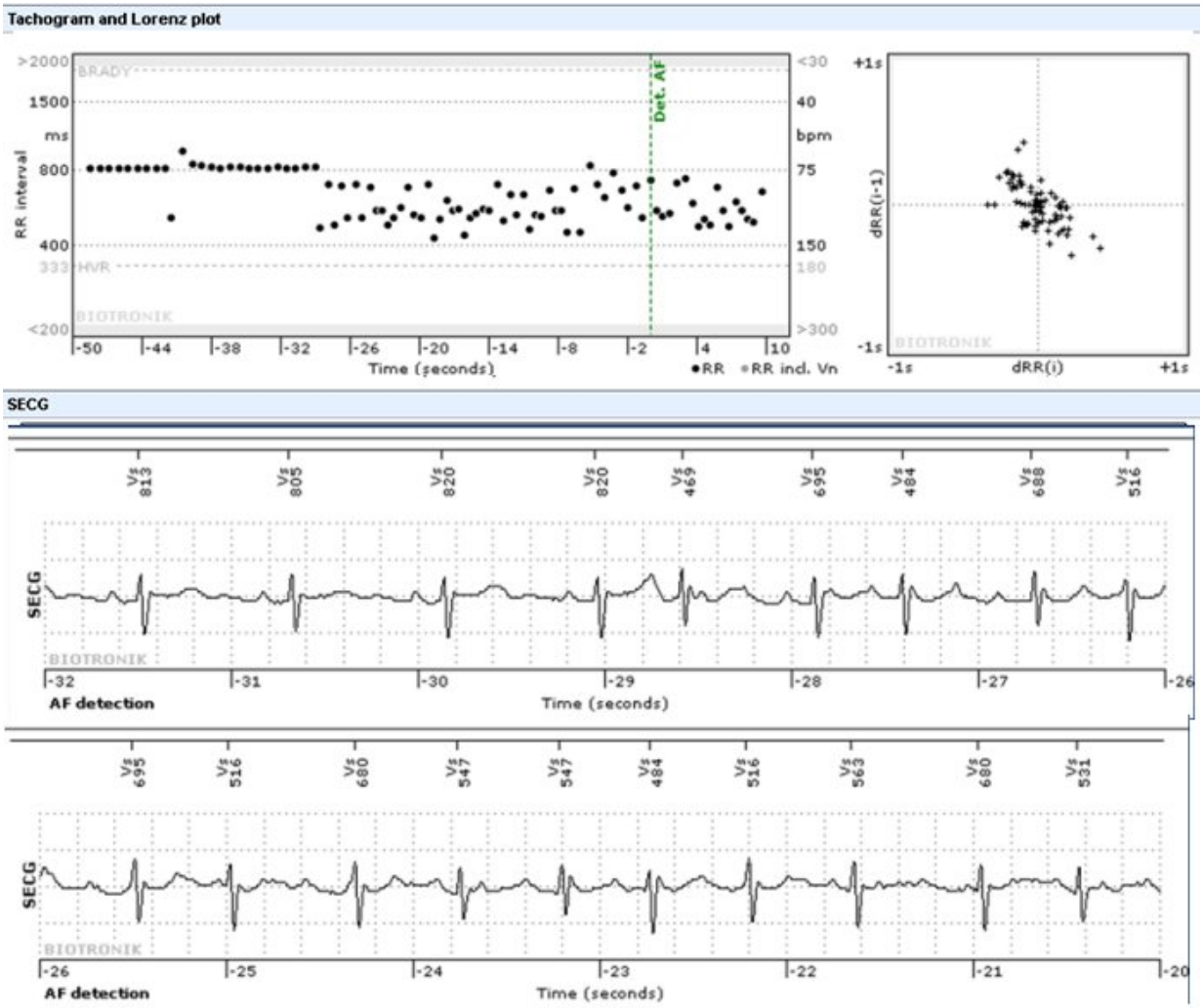


Fig. 30: Example: diagnosis AF

Example: periodic subcutaneous ECG with sinus rhythm

Characteristics:

- The tachogram shows a regular pattern of RR intervals with a certain bandwidth.
- The Lorenz plot shows a typical sinus rhythm pattern with a concentration of points near the center.

Typical periodic subcutaneous ECG with a rate of variation at 50 bpm. The degree of variation can be identified by the size of the scatter cloud in the Lorenz plot.

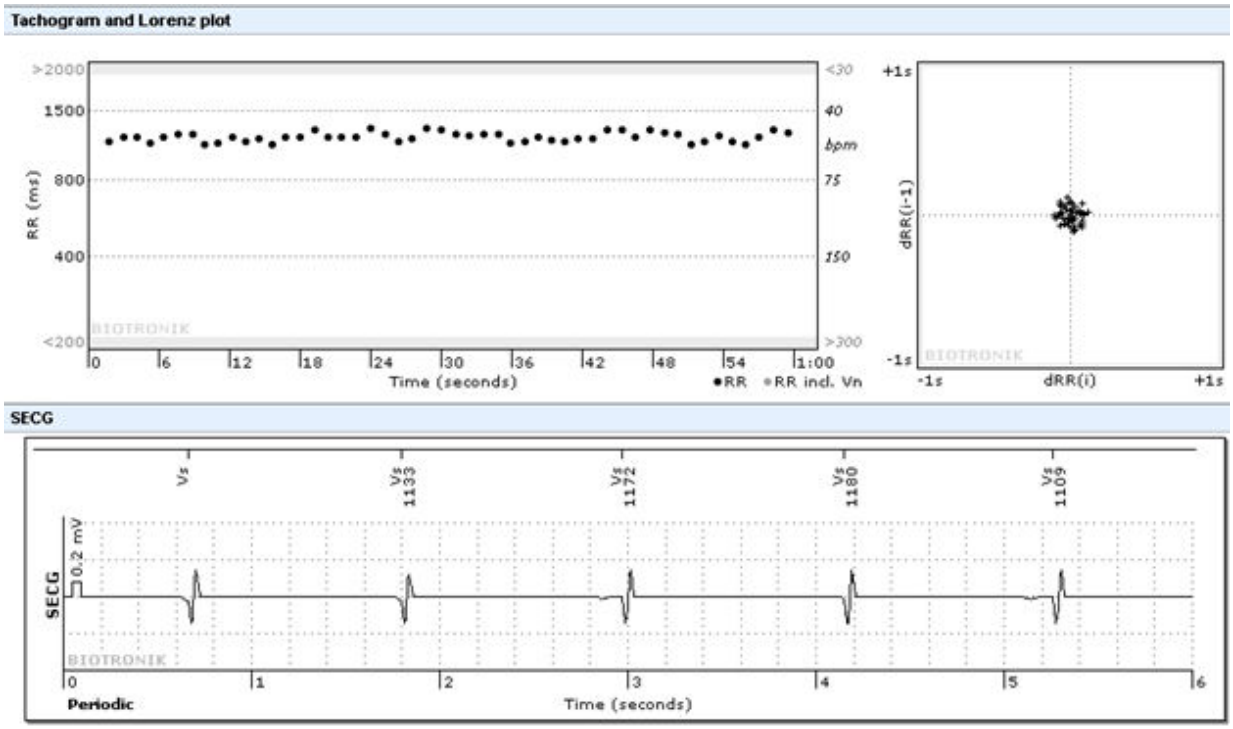


Fig. 31: Example: periodic subcutaneous ECG

Note

Intervals classified as interference are shown in gray in the tachograms and the Lorenz plots.

Diagnostics – AF Details

Navigation: Diagnostics → AF details

The tab displays the following four charts:

- `AF trends`: number of AF episodes per day and total duration of the AF episodes on each day
- `AF time of occurrence`: statistics of times at which AF episodes were detected
- `AF duration`: statistics for duration of AF episodes
- `Ventricular rate during AF`: maximum and mean ventricular heart rate during a day's AF episodes

Some of the charts have a vertical auxiliary line, which can be moved using the following buttons to display individual values:

At the upper and lower end of the line, the x and y values of the graph are displayed for the point of intersection with the vertical line.

Possible recording period: 240 days or unlimited for histograms.

`Start statistics` deletes all statistical data saved in the device. The statistical data will continue to be displayed on the programmer until the next interrogation.

Diagnostics – Activity

Navigation: Diagnostics → Activity

The `Activity` tab displays three charts:

- `Rate trends`: The rate trend is made up of the following data:
  - Mean heart rate (daily mean)
  - Mean heart rate during resting period

    You can adjust the resting period on the following tab: **Parameters → Diagnostics/Home Monitoring**
  - `Heart rate variability`: variability of the mean heart rate

    The recording period is 240 days. After that the oldest values are overwritten.
- `Rate histogram`: The recording period is unlimited.
- `Activity trend`: The motion sensor (accelerometer) of the device measures patient activity. The activity trend shows the percentage of the day that the patient was active.

  The recording period is 240 days. After that the oldest values are overwritten.

Each of the charts has a vertical auxiliary line, which can be moved using the following buttons to display individual values:

At the upper and lower end of the line, the x and y values of the graph are displayed for the point of intersection with the vertical line.

`Start statistics` deletes all statistical data saved in the device. The statistical data will continue to be displayed on the programmer until the next interrogation.

Diagnostics – Sensing

Navigation: Diagnostics → Sensing

The `Sensing` tab displays two charts:

- `R-wave trend`: displays the mean R wave amplitude per day.
- `Noise duration trend`: shows the time for which the device was in the interference status on a day (as a percentage). The noise duration is the time in which the device detects interfering noise signals. Noise signals inhibit automatic arrhythmia detection.

Each of the charts has a vertical auxiliary line, which can be moved using the following keys:

At the upper and lower end of the line, the x and y values of the graph are displayed for the point of intersection with the vertical line.

Possible recording period: 240 days or unlimited for histograms.

`Start statistics` deletes all statistical data saved in the device. The statistical data will continue to be displayed on the programmer until the next interrogation.

2.7 System Functions of the Device

BIOMONITOR III

Navigation: More → BIOMONITOR III

The functions and displays in the BIOMONITOR III window are used for analysis purposes and are required for technical support.

`Device Data`

- `Read out` starts the transmission of all device data to the programmer. You can then export the transmitted data, for instance, to a USB flash memory stick and forward it to BIOTRONIK. Only BIOTRONIK can evaluate the data.

`Parameters`

- The firmware and hardware ID are utilized under certain circumstances by BIOTRONIK staff when providing technical support.

3 ProMRI

3.1 MRI Scan

"ProMRI – MR Conditional Device Systems" Manual

Note

The following information exclusively applies to the PSW 1901.A (/x) software versions.

You can find the "ProMRI – MR Conditional Device Systems" manual with detailed information on how to safely conduct an MR scan on patients with a BIOTRONIK implanted MR conditional device system on the Internet by clicking the following link:

- manuals.biotronik.com

You can also use the following QR code:

4 Technical Data

4.1 Parameter

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
Detection/termination window size	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%
Detection/termination window size	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:

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 stroke
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
Asystole	**ON**; OFF	ON	ON	ON	ON
Duration	2; **3** ... (1) ... 10 s	3	5	5	5

Parameter	Range of values (standard)	Syncope	Palpi-tations	AF moni-toring	Crypto-genic stroke
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	12:00 AM ... (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; 12:00 AM ... (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:

Parameter	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.

4.2 Technical Data

Mechanical Characteristics

Dimensions

	Overall length x diameter of the handle [mm]
Incision tool	130 x 13
Insertion tool	201 x 24

	L x H x D [mm]	Volume [cm^3]	Mass [g]
BIOMONITOR III device with 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 complies with the Australian "Radiocommunications Act 1992" and is therefore labeled with the Regulatory Compliance Mark (RCM) in accordance with the requirements for radiocommunication devices.

- 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 for radio communication of medical devices 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 may only be used 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 the following:

- Sensing at 60 bpm
- Storage period of 6 months
- Daily device message via Home Monitoring including recorded subcutaneous ECGs:

  1 automatic subcutaneous ECG per day

  plus up to 2 patient-triggered subcutaneous ECGs per month

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:

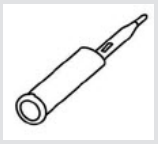
	Manufacturing date		Use by
	Storage temperature	REF	Order number
SN	Serial number	PID	Product identification number
CE	CE mark	LOT	Lot number
	Contents		Follow the instructions for use!
manuals.biotronik.com 	Follow the electronically available instructions for use!		

	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

	Transmitter with non-ionizing radiation at designated frequency
	MR conditional

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		

BIOMONITOR III

Function Manual

449223

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