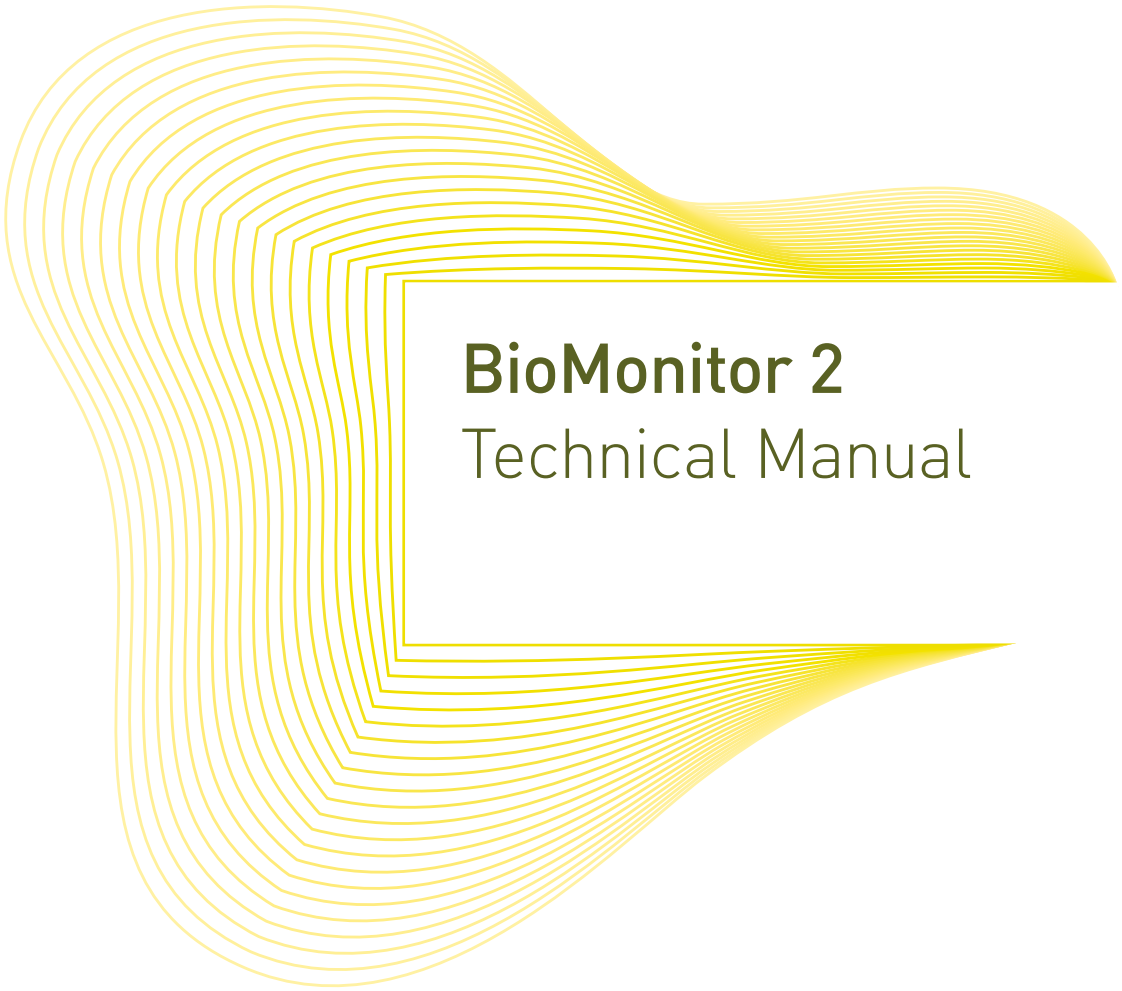


BioMonitor 2
Technical Manual

BIOTRONIK
excellence for life

BioMonitor 2

Insertable Monitor

BioMonitor 2
X-Ray identification

Radiopaque Identification

A radiopaque identification code is visible on standard X-ray, and identifies the insertable monitor:

BioMonitor 2	AO

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of, a physician (or properly licensed practitioner).

Contents

This page left intentionally blank

1. Device Description

BioMonitor 2 is a programmable, subcutaneous insertable monitor able to record subcutaneous ECGs (sECGs) and other physiological parameters.

The BioMonitor 2 is designed to automatically record the occurrence of arrhythmias in a patient. Arrhythmia may be classified as atrial fibrillation (AF), bradyarrhythmia, asystole, sudden rate drop, or high ventricular rate. In addition, the BioMonitor 2 can be activated by the patient to record cardiac rhythm during symptomatic episodes.

The BioMonitor 2 system consists of 3 main components:

- BIOTRONIK BioMonitor 2 insertable cardiac monitor - The BioMonitor 2 is a small, leadless device that is typically inserted under the skin, in the chest. The device uses two electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. The device memory can store up to 36 min of subcutaneous ECG (sECG) recordings from automatically detected arrhythmias and up to 30 min of sECG recordings from patient-triggered episodes. When a patient experiences symptoms, the sECG recordings can be manually triggered by placing the Remote Assistant over the BioMonitor 2.

Note - The BioMonitor 2 subcutaneous ECG may differ from a surface ECG due to differences in electrode separation and device placement in the body.

BioMonitor 2 detects a subcutaneous ECG from a pair of electrodes. These signals are filtered in two different ways. For detection of QRS complexes, the signals are filtered with a passband of 10-40 Hz in order to suppress T-waves, artifacts, and baseline drift at low frequencies, and myoptentials and EMI at high frequencies. The resulting signal is appropriate for QRS detection as other components of the signal have been suppressed. This signal naturally does not have a typical ECG morphology due to the bandpass. For waveform display to the physician (real-time streaming sECG with the physician's programmer and snapshots for review by the physician), a different passband is utilized to retain signal features that may have diagnostic value. This passband is 0.5Hz – 40Hz, which is designed to retain morphological features of a typical ECG while still rejecting large low frequency artifacts and baseline drift.

- BIOTRONIK Renamic / ICS 3000 Programmer – The programmer is used to set up the BioMonitor 2 to detect arrhythmias. It also allows you to view, save, or print the stored information.

- BIOTRONIK CardioMessenger® II and II-S Devices – The CardioMessenger® II/II-S are telemetry patient devices that forward the data from the BioMonitor 2 to BIOTRONIK's Home Monitoring Service Center.

BioMonitor 2 also employs BIOTRONIK Home Monitoring® technology, which is an automatic, wireless, remote monitoring system for management of patients with insertable cardiac monitors. With Home Monitoring, physicians can review data about the patient's cardiac status and insertable cardiac monitor's functionality between regular follow-up visits, allowing the physician to optimize the diagnostic process.

BIOTRONIK conducted the TRUST study to evaluate the safety and effectiveness of Home Monitoring. With the TRUST study, BIOTRONIK was able to show the following with regards to Home Monitoring:

- BIOTRONIK Home Monitoring information may be used as a replacement for device interrogation during in-office follow-up visits.
- A strategy of care using BIOTRONIK Home Monitoring with office visits when needed has been shown to extend the time between routine, scheduled in-office follow-ups of BIOTRONIK insertable devices in many patients. Home Monitoring data is helpful in determining the need for additional in-office follow-up.
- BIOTRONIK Home Monitoring-patients—who are followed remotely with office visits when needed—have been shown to have similar numbers of strokes, invasive procedures and deaths as patients followed with conventional in-office follow-ups.
- BIOTRONIK Home Monitoring provides early detection of arrhythmias.
- BIOTRONIK Home Monitoring provides early detection of silent, asymptomatic arrhythmias.

- Automatic early detection of arrhythmias and device system anomalies by BIOTRONIK Home Monitoring allows for earlier intervention than conventional in-office follow-ups.
- BIOTRONIK Home Monitoring allows for improved access to patient device data compared to conventional in-office follow-ups since device interrogation is automatically scheduled at regular intervals.

2. Indications

The BioMonitor 2 is indicated to detect the following cardiac arrhythmias:

- atrial fibrillation
- bradycardia,
- sudden rate drop,
- high ventricular rate (HVR),
- asystole.

The BioMonitor 2 is indicated for use in:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- The device has not been tested for and it is not intended for pediatric use

This page left intentionally blank

3. Contraindications

There are no known contraindications for the insertion of the BioMonitor 2. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

This page left intentionally blank

4. Warnings and Precautions

Certain therapeutic and diagnostic procedures may cause undetected damage to an insertable cardiac monitor (ICM), resulting in malfunction or failure at a later time. Please note the following warnings and precautions:

MR Conditional - The cardiac monitor is labeled and certified MR conditional.

4.1 MR SAFETY INFORMATION

4.1.1 Patient Pre-MRI Conditions

The following requirements must always be fulfilled in order to perform an MR scan using BIOTRONIK's BioMonitor 2:

- There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.
- Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.

  NOTE: An MR scan is permitted only if the product-specific conditions are met for all implants and if no metal insertable device longer than 5 cm is in the vicinity of the BIOTRONIK cardiac monitor within a distance of less than 4 cm.
- The device is located in the patient's chest area.

4.1.2 MR Scanner Limitations

The MR scanner has to meet the following conditions:

- Use of a clinical MR system with a cylindrical bore and a static magnetic field strength of:
  - 1.5 Tesla (for BioMonitor and BioMonitor 2) or
  - 3.0 Tesla quadrature transmit coils only (for BioMonitor 2).
- The slew rate of the MR scanner's gradient fields should not exceed 200 T/m/s per axis.
- For the head: May also use local transmit and/or receiver coils.
- For the extremities: May also use local transmit and/or receiver coils.
- Only local receiver coils may be used for the thorax (chest region).
- Maximum spatial gradient of the static magnetic field specification must be ⩽ 100T/m (10,000 gauss/cm).
- Under worst case conditions, the BioMonitor 2 is expected to produce a maximum temperature rise of <4.5° C after 30 minutes of continuous scanning.
- Image artifact and distortion can result from the presence of the BioMonitor 2 device within the field of view. Image artifact and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MR images.

4.1.3 Restrictions during the MR Scan

The following conditions must be met during the MR scan:

- The MR scan should be performed with the patient in supine position.
- The mean specific absorption rate (SAR) for the whole body as displayed by the MR scanner must not exceed 4.0W/kg.
- The head absorption rate displayed by the MR scanner must not exceed 3.2 W/kg.

4.2 Implanted Pacemakers and Defibrillators

The BioMonitor 2 is not intended for use in patients with an implanted pacemaker or defibrillator. If the patient has a co-implanted pacemaker or defibrillator, the automatic detection of arrhythmic episodes in the BioMonitor 2 may be affected by the paced heart rhythm.

4.3 Medical Therapy

Before applying one of the following procedures, a detailed analysis of the advantages and risks should be made. Cardiac activity during one of these procedures should be confirmed by continuous monitoring of peripheral pulse or blood pressure. Following the procedures, insertable cardiac monitor function must be checked.

Therapeutic Diathermy Equipment - Use of therapeutic diathermy equipment is to be avoided for insertable cardiac monitor patients due to possible heating effects of the insertable cardiac monitor and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the insertable cardiac monitor. The patient's peripheral pulse should be monitored continuously during the treatment.

Transcutaneous Electrical Nerve Stimulation (TENS) - Transcutaneous electrical nerve stimulation may interfere with insertable cardiac monitor function. If necessary, the following measures may reduce the possibility of interference:

- Place the TENS electrodes as close to each other as possible.
- Place the TENS electrodes as far from the insertable cardiac monitor as possible.
- Monitor cardiac activity during TENS use.

Defibrillation - The following precautions are recommended to minimize the inherent risk of insertable cardiac monitor operation being adversely affected by defibrillation:

- The paddles should be placed anterior-posterior or along a line perpendicular to the axis formed by the insertable cardiac monitor
- The energy setting should not be higher than required to achieve defibrillation.

Radiation - Insertable cardiac monitor electronics may be damaged by exposure to radiation during radiotherapy. To minimize this risk when using such therapy, the insertable cardiac monitor should be protected with local radiation shielding.

Lithotripsy - Lithotripsy treatment should be avoided for insertable cardiac monitor patients since electrical and/or mechanical interference with the insertable cardiac monitor is possible. If this procedure must be used, the greatest possible distance from the point of electrical and mechanical strain should be chosen in order to minimize a potential interference with the insertable cardiac monitor.

Electrocautery - Position the grounding pad so that the current path does not pass through or near the device. When possible, a bipolar electrocautery system should be used.

Transurethral resection of the prostate - It is recommended that the cautery ground plate be placed under the buttocks or around the thigh, but not in the thoracic area where the current pathway could pass through or near the cardiac monitor.

4.4 Storage and Sterilization

Storage (temperature) - Recommended storage temperature range is -10° to 45°C (14°-113°F). Exposure to temperatures outside this range may result in insertable cardiac monitor malfunction (see Section 8.1).

Handling - Do not drop. If an unpackaged insertable cardiac monitor is dropped onto a hard surface, return it to BIOTRONIK (see Section 8.1).

FOR SINGLE USE ONLY - Do not resterilize the insertable cardiac monitor, it is intended for one-time use.

Device Packaging - Do not use the device if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.

Storage - Store the device in a clean area, away from sources of disturbance to avoid damage to the device.

Temperature Stabilization - Allow the device to reach room temperature before programming or implanting the device. Temperature extremes may affect the initial device function.

Use Before Date - Do not implant the device after the USE BEFORE DATE because the device sterility and longevity may be compromised.

4.5 Home Monitoring

BIOTRONIK's Home Monitoring system is designed to notify clinicians in less than 24 hours of changes to the patient's condition or status of the inserted device. Updated data may not be available if:

- The patient's CardioMessenger is off or damaged and is not able to connect to the Home Monitoring Service Center.
- The CardioMessenger cannot establish a connection to the inserted device.
- The telephone and/or Internet connection do not operate properly
- The Home Monitoring Service Center is off-line (upgrades are typically completed in less than 24 hours)

Patient's Ability - Use of the Home Monitoring system requires the patient and/or caregiver to follow the system instructions and cooperate fully when transmitting data.

If the patient cannot understand or follow the instructions because of physical or mental challenges, another adult who can follow the instructions will be necessary for proper transmission.

Electromagnetic Interference (EMI) - Precautions for EMI interference with the BioMonitor 2 insertable cardiac monitors are provided in Section 4.6. Sources of EMI including cellular telephones, electronic article surveillance systems, and others are discussed therein.

Use in Cellular Phone Restricted Areas - The mobile patient device (transmitter/receiver) should not be utilized in areas where cellular phones are restricted or prohibited (i.e., commercial aircraft).

Elective Replacement Indicator (ERI) - When ERI mode is reached, this status is transmitted. Home Monitoring data transmissions will continue for another 2 weeks. After 2 weeks, data will no longer be transmitted to the Service Center.

Communication Loss - A system alert appears in the physician's queue on the Home Monitoring website if no data transmissions occur for a period of time programmed by the user. You may configure alerts so that an SMS, fax and/or e-mail message is sent to the physician regarding the communication loss. If no data transmissions have been received by HMSC after 90 days, the patient will be deactivated. In the event of sustained communication loss, an in-office follow-up visit is recommended.

4.6 Electromagnetic Interference (EMI)

The operation of any insertable cardiac monitor can be affected by certain environmental sources generating signals that resemble cardiac activity. In some cases the disturbance sources can couple sufficient energy to damage the insertable cardiac monitor.

BIOTRONIK insertable cardiac monitors have been designed to significantly reduce susceptibility to disturbance sources. However, due to the variety and complexity of sources creating interference, there is no absolute protection against disturbance sources. Generally, it is assumed that disturbance sources produce only minor effects, if any, in insertable cardiac monitor patients. If the patient presumably will be exposed to one of the following environmental conditions, then the patient should be given the appropriate warnings.

4.6.1 Home and Occupational Environments

The following equipment (and similar devices) may affect normal insertable cardiac monitor operation: electric arc welders, electric melting furnaces, radio/television and radar transmitters, power generating facilities, high voltage transmission lines, electrical ignition systems (also of gasoline powered devices) if protective hoods, shrouds, etc., are removed, electrical tools, anti-theft devices of shopping centers and electrical appliances, if not in proper condition or not correctly grounded and encased.

Patients should exercise reasonable caution in avoidance of devices which generate a strong electric or magnetic field. Some potential EMI sources include:

- **High Voltage Power Transmission Lines -** High voltage power transmission lines may generate enough EMI to interfere with insertable cardiac monitor operation if approached too closely.
- **Home Appliances -** Home appliances normally do not affect insertable cardiac monitor operation if the appliances are in proper condition and correctly grounded and encased. There are reports of insertable cardiac monitor disturbances caused by electrical tools and by electric razors that have touched the skin directly over the insertable cardiac monitor.
- **Communication Equipment -** Communication equipment such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with insertable cardiac monitor operation if approached too closely.
- **Commercial Electrical Equipment -** Commercial electrical equipment such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with insertable cardiac monitor operation if approached too closely.
- **Electrical Appliances -** Electric hand-tools and electric razors (used directly over the skin of the insertable cardiac monitor) have been reported to cause insertable cardiac monitor disturbances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with the insertable cardiac monitor operation.
- **Electronic Article Surveillance (EAS) -** Equipment such as retail theft prevention systems may interact with the insertable cardiac monitor devices. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.

4.6.2 Cellular Phones

Recent studies have indicated there may be a potential interaction between cellular phones and insertable cardiac monitor operation. Potential effects may be due to the radio frequency signal when the phone is within close proximity (within 6 inches [15 centimeters]) to the insertable cardiac monitor.

Based on testing to date, effects resulting from an interaction between cellular phones and the insertable cardiac monitors have been temporary. Simply moving the phone away from the inserted device will return it to its previous state of operation.

To minimize such interactions, patients having an inserted cardiac monitor who operate a cellular phone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular phone and the inserted device. Portable and mobile cellular phones generally transmit at higher power levels compared to hand held models. For phones transmitting above 3 watts, maintain a minimum separation of 12 inches (30 centimeters) between the antenna and the inserted device.
- Patients should hold the phone to the ear opposite the side of the inserted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the inserted device as some phones emit signals when they are turned ON but not in use (i.e., in the listen or standby mode). Store the phone in a location opposite the side of the cardiac monitor.

4.6.3 Hospital and Medical Environments

Ablation/Electrocautery - Position the grounding pad so that the current path does not pass through or near the device. When possible, a bipolar electrocautery system should be used. After ablation or electrocautery, evaluate the BioMonitor 2 for proper function.

Lithotripsy - Lithotripsy may damage the insertable cardiac monitor. If lithotripsy must be used, do not focus the beam near the insertable cardiac monitor.

External Defibrillation - External defibrillation may damage the insertable cardiac monitor. Attempt to minimize current flowing through the insertable cardiac monitor by following the precautions.

High Radiation Sources - High radiation sources such as cobalt 60 or gamma radiation should not be directed at the insertable cardiac monitor. If a patient requires radiation therapy in the vicinity of the insertable cardiac monitor, place lead shielding over the device to prevent radiation damage.

4.7 Insertable Cardiac Monitor Explant and Disposal

Device Incineration - Never incinerate an insertable cardiac monitor. Be sure the insertable cardiac monitor is explanted before a patient who has died is cremated (see Section 12).

Explanted Devices - Return all explanted devices to BIOTRONIK.

This page left intentionally blank

5. Programmable Parameters

For a complete list of programmable parameters and the available settings, see Section 12. Refer to the programmer manual for additional information.

5.1 Parameters

The Diagnostics page under Parameters, shown in Figure 1, allows set-up of the recording criteria of the device to include atrial fibrillation (AF), high ventricular rate (HVR), bradycardia, asystole and patient triggered events. Additionally, the resting rate period is also programmable (- AF device only). Each of these will be discussed in greater detail in this section.

Figure 1: Main Parameter screen

5.1.1 Atrial Fibrillation (AF)

NOTE: This section is only applicable to BioMonitor 2-AF, not BioMonitor 2-S.

The Atrial fibrillation menu (Figure 2) allows the user to program AF detection ON or OFF as well as set the detection criteria.

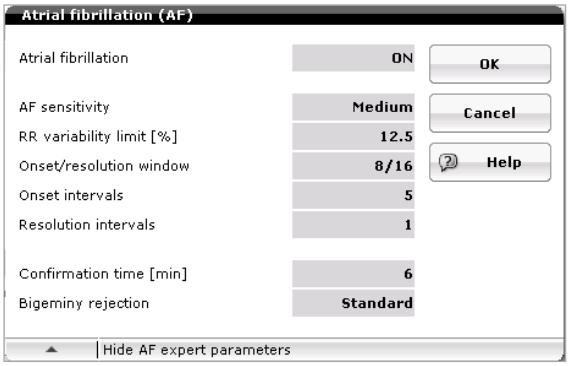


Figure 2: AF menu

This section allows the user to program the settings for AF detection. This section includes:

Atrial fibrillation

Programmable ON or OFF

AF sensitivity

Low, Medium, High

Allows the user to select preset criteria for AF determination. These are shown in the following table. The user can also select non-preset options to make an Individual program.

Low is the least sensitive setting. This setting requires greater RR variability and more intervals for the device to declare AF. Conversely, the High setting requires lesser RR variability and fewer events to declare AF.

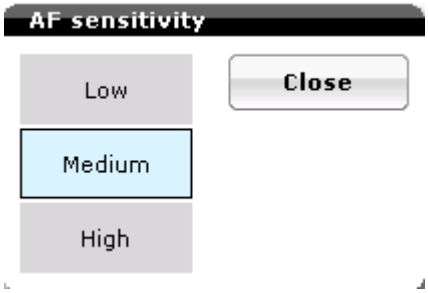


Figure 3: AF sensitivity

Parameter	Range	Low	Medium	High
RR Variability (%)	6.25, 12.5, 18.75	18.75%	12.5%	6.25%
Onset/Resolution	8/16, 16/24, 24/32	16/24	8/16	8/16
Onset intervals	5...(2)...23	9	5	5
Resolution intervals	1, 3, 5, 7	3	1	1
Confirmation time (minutes)	1, 2, 3, 4, 5, 6, 10, 20, 30	6	6	6

Table 1: Parameter summary for AF sensitivity

RR variability

This parameter represents the maximum percentage of variation between Vs-Vs cycle lengths to be considered stable by the device. The smaller the value, the greater the likelihood of AF being declared. Intervals greater than the RR variability value from the mean cycle length will be considered AF intervals and count towards the onset or resolution threshold.

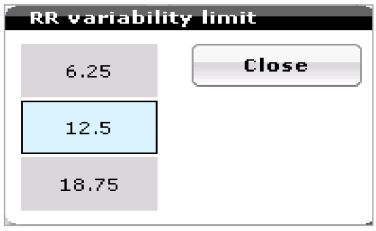


Figure 4: RR variability limit

Onset/Resolution window

The number of cycle lengths used to determine detection and termination of AF. Figure 5 shows the selectable values for Onset and Resolution. For example, an Onset value of 8 means the device monitors groups of 8 cycle lengths to determine the RR variability value and compares each of those 8 events to the variability limit value. If the number of events that are determined to be unstable exceed the programmed Onset interval value, AF suspicion criterion is met.

A Resolution criterion of 16 means the device is monitoring groups of 16 events. If the number of unstable events is greater than the programmed Resolution value, the rhythm will continue to be considered unstable (AF).

The Onset/Resolution window are not sliding windows, but consecutive windows.

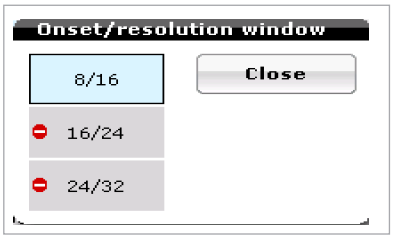


Figure 5: Onset/Resolution window

Onset intervals

Onset intervals is the number of intervals that must be unstable within the programmed onset window for the rhythm to be considered unstable.

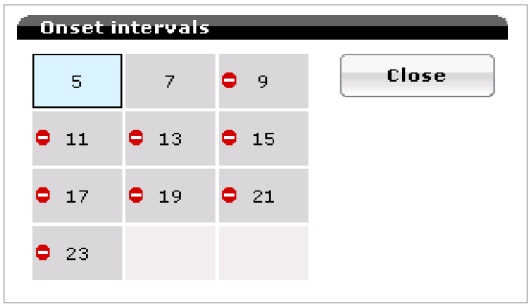


Figure 6: Onset intervals

Resolution intervals

The Resolution intervals represent the maximum number of unstable events within the programmed resolution window allowed to terminate an AF episode. If more than the programmed number of intervals are present, the device will continue to declare an AF event active.

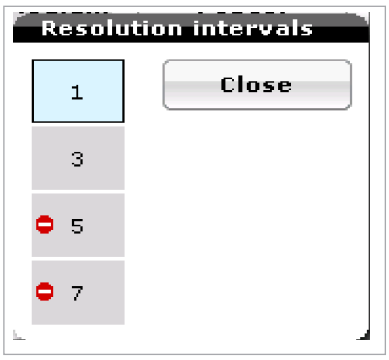


Figure 7: Resolution intervals

Confirmation time

The time before a recording of the AF event occurs. If the events are detected but do not reach the confirmation time period (suspicion phase), the event will not be counted.

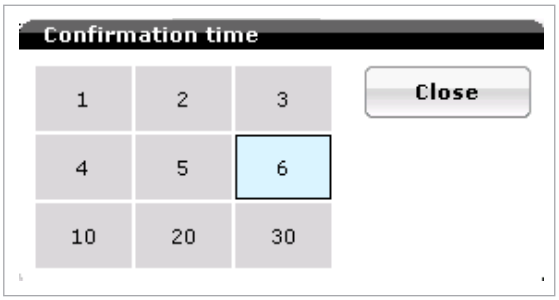


Figure 8: Confirmation time

Bigeminy Rejection

Short-long interval patterns indicative of bigeminy may be detected as AF. The bigeminy rejection parameter is designed to recognize these periodic interval patterns. When enabled to Standard, the bigeminy rhythms are recognized and prevented from triggering AF detections. The Aggressive setting is provided for more comprehensive filtering of complex bigeminy rhythms. The default setting for the bigeminy rejection parameter is Standard.

NOTE: If bigeminy rejection is set to the parameter Aggressive, the AF sensitivity may be reduced.

5.1.2 High ventricular rate (HVR)

BioMonitor 2 may be programmed to record high ventricular rate events using a rate limit and counter for criteria. Both the HVR limit and HVR counter criteria must be met for an event to be classified as a HVR episode. An event meeting the criteria would record a sECG and update the counters on the Diagnostics section of the device.

HVR limit

This parameter value represents the lowest rate limit required to be considered a HVR episode.

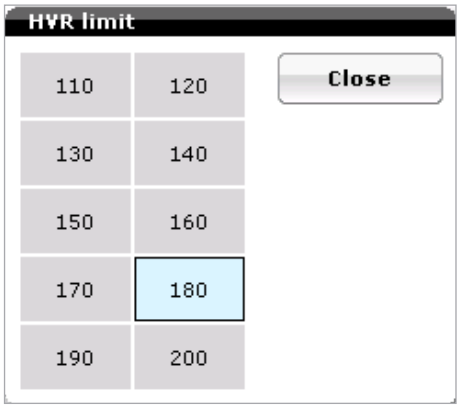


Figure 9: HVR limit

HVR counter

This parameter value represents the count limit for high ventricular rate classification. This is an up/down counter. Each event slower than the HVR limit decreases the count by 1, while each event faster than the HVR limit increments the counter by 1.

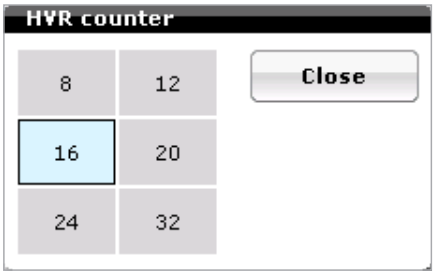


Figure 10: HVR counter

5.1.3 Bradycardia

Bradycardia zone limit

Rates determined to be below the programmed bradycardia zone limit will be classified as a bradycardia event. In addition to the rate limit, the rate must also meet the bradycardia duration limit. This prevents single slow events from being classified as a bradycardia episode.

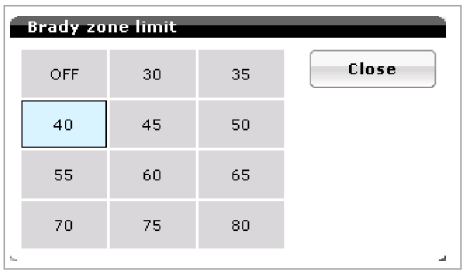


Figure 11: Bradycardia zone limit

Bradycardia duration

The brady duration is the time over which the average heart rate is calculated. When the average heart rate is below the programmed bradycardia zone limit for the device, bradycardia is confirmed.

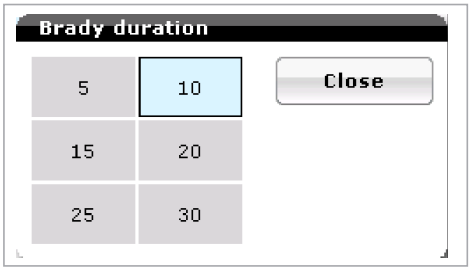


Figure 12: Brady duration

5.1.4 Sudden rate drop (SRD)

SRD rate decrease

This parameter value represents the percentage in rate decrease that triggers a sudden rate drop event count. The device compares the average rate of the most recent events (rate-drop intervals) and compares it to the average rate of the previous events (baseline intervals).

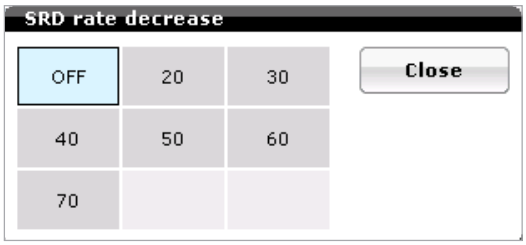


Figure 13: SRD rate decrease

SRD sensitivity

This parameter programs preset value setting for baseline intervals and rate-drop intervals.

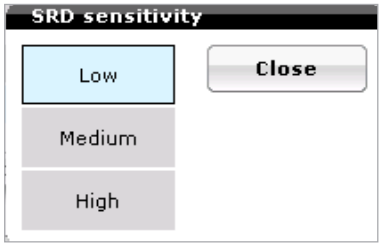


Figure 14: Brady sensitivity

Baseline intervals

This parameter value represents the number of averaged intervals to determine a baseline rate for sudden rate drop determination.

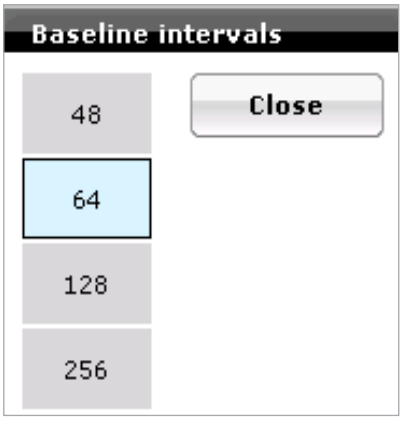


Figure 15: Baseline intervals

Rate-drop intervals

This parameter value represents the number of averaged intervals to determine a change in the heart rate. It uses the most recent events and determines the average rate of those events to determine the rate-drop rate value.

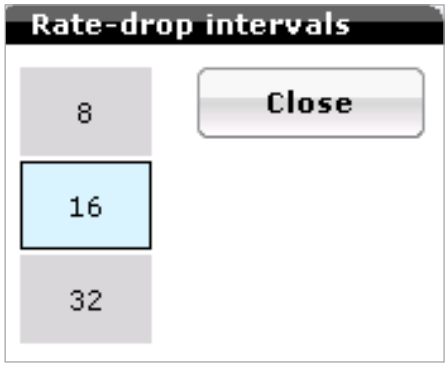


Figure 16: Rate-drop intervals

5.1.5 Asystole duration

Asystole duration

The minimum total duration in seconds between R waves for the device to declare an Asystolic event.

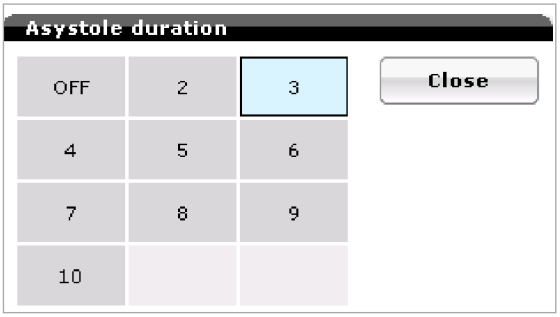


Figure 17: Asystole duration

5.1.6 Patient trigger

Patient trigger

This is an ON/OFF feature which allows a patient to record an sECG by placing the Remote Assistant over the device and pressing the button.

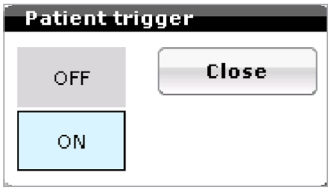


Figure 18: Patient trigger

5.1.7 Resting rate period

Start resting period

The Start resting period is the time the device starts collecting heart rate information for the Rate trend diagnostic. The default time is 2 A.M. for recording of data. This time was chosen to reduce the chance of patient activity interfering with data collection.

The Resting period duration parameter is the time duration the data is collected for the Resting Rate trend diagnostic. BioMonitor 2 collects resting heart rate values in 10-minute blocks of time. The lowest average collected over the recording period is used as the statistical point for that given day

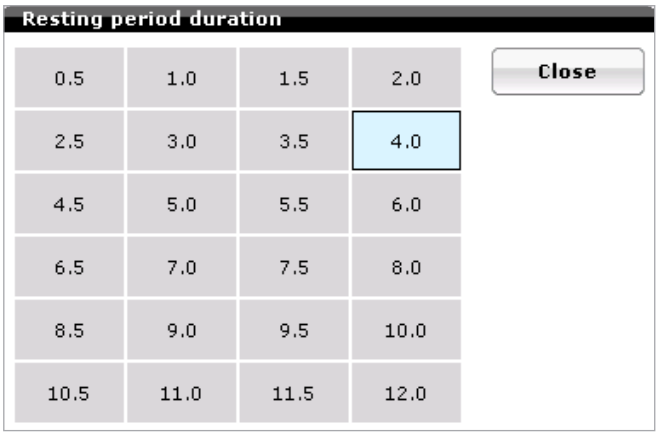


Figure 19: Resting period duration

5.2 Home Monitoring (HM)

The availability of parameters and parameter values is determined by the software used for programming/ interrogating the insertable monitor.

5.2.1 HM PID

The HM PID is the product Identification number. This is a unique ID number for each product and is used when registering a patient to the Home Monitoring Service Center (HSMC).

5.2.2 Home Monitoring

Programmable ON or OFF

5.2.3 Time of transmission

By default, the BioMonitor 2 will transmit all data and a daily trend report between 1:00 A.M. and 2:00 A.M. daily. Transmission time is also programmable by the user and is based on a 24-hour clock. It is important to keep in mind that the programmer updates the BioMonitor 2 time based on the programmer time. If the programmer time is different than the local time, the transmission time may be different than expected.

Figure 20: Time of transmission

5.2.4 Periodic subcutaneous electrocardiogram (sECG)

The BioMonitor 2 can send a 40-second sECG periodically based on user preference. This allows the user to assess sECGs routinely, even in the case of no events occurring. The timer begins when the Periodic sECG programming command is sent to the device. Programming options (in days) are shown in Figure 21.

When the option of Selection is made, the user can enter up to 5 specific dates on which to send a periodic sECG. Following the last programmed periodic sECG, the device will revert to sending sECGs every 30 days until new dates are entered

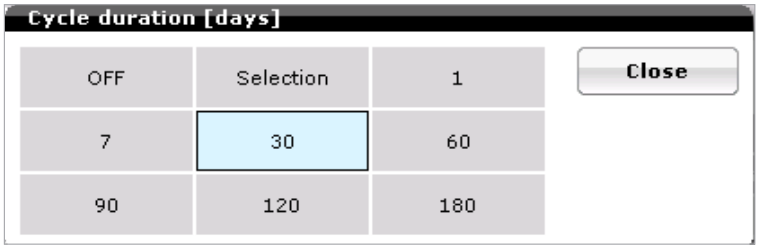


Figure 21: Periodic Subcutaneous ECG

5.2.5 Last message

Message Type

This box shows the last message type created by the device.

Message created on

This parameter shows the date and time the last message was created. The clock time is based on a 24-hour clock.

Send test message

When performing the "Send Test Message" function, a note will appear with the following message:

Please remove programmer head for 10 seconds to allow implant to send test message. Afterwards, please interrogate to update status.

Once the OK button is pressed, a "programming was successful" message will appear on the bottom-left corner of the screen.

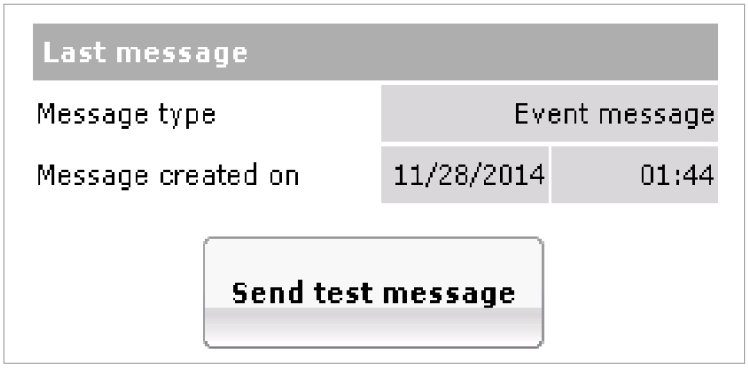


Figure 22: Last message

5.2.6 HM episode trigger

This section provides an overview of which triggers are currently programmed ON.

This will show which triggers are enabled, and thereby able to be selected for HM upload.

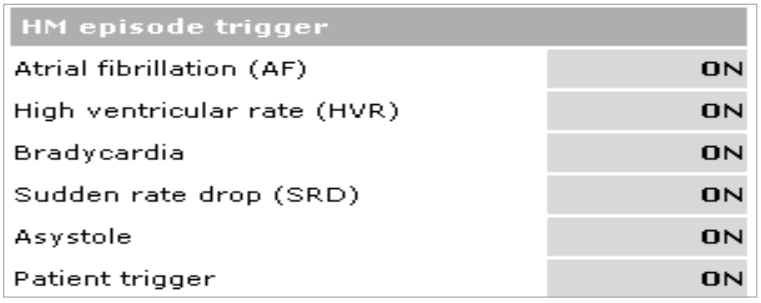


Figure 23: HM episode trigger

5.3 Patient data

This section allows the user to add patient, physician, hospital and other information. This information is stored in the device and can be accessed with any compatible programmer.

The data in this section can be modified at any time.

5.3.1 ID

This section allows the user to input up to a 12 (twelve) digit alphanumeric code to serve as a patient identifier. This may be a medical records number or a study number if the patient is enrolled in a study.

Figure 24: Patient ID

5.3.2 First / last name

These sections allows the user to input the patient's first and last name into the memory of the device. This is a free text box, allowing up to 20 characters for the first name, as well as for the last name. Enter the patient's name and select the enter key.

Figure 25: First name

Figure 26: Last name

5.3.3 Date of birth

This section allows the user to input the patient's birth date. The birth date is entered as MM/DD/YYYY, as shown in Figure 27. When initially accessed, the current day will be displayed. The date can be changed using the following methods:

- Selecting the keypad icon to the left of the OK button will bring up a number keypad allowing the user to manually input the date.
- The day can be selected simply by touching the appropriate day on the screen.
- Pressing the month will bring up a listing of the 12 months, and the user can select the appropriate month.
- Selecting the year will bring up a numeric keypad, allowing the user to enter a year.
- The double arrow will change the year by one value each time it is touched. The left double arrows decrease the value and the right double arrows increase the value.
- The single arrow will change the month by one. The left arrow decreases the value and the right arrow increases the value.

Once the date is entered, select the OK button

Figure 27: Date of birth

5.3.4 Gender

This section allows the user to select the patients gender.

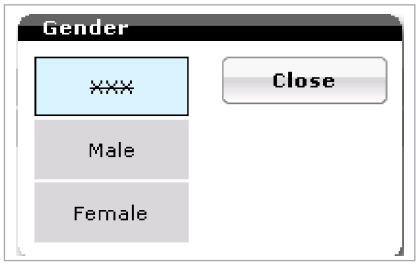


Figure 28: Gender

5.3.5 Date of implant

The implantation date is entered by the user.

Figure 29: Date of Implant

5.3.6 Hospital, City

The hospital name and city name can be added. As with entering the patient's name, up to 20 characters are available to add hospital and city information.

Figure 30: Hospital, City

5.3.7 Physician

The physician name can be added. As with the patient name, up to 20 characters are available to add physician information. It is a good idea to add the physician's first name also to help prevent confusion.

Figure 31: Physician

5.3.8 NYHA

This refers to the New York Heart Association classification. A value can be entered if it is known.

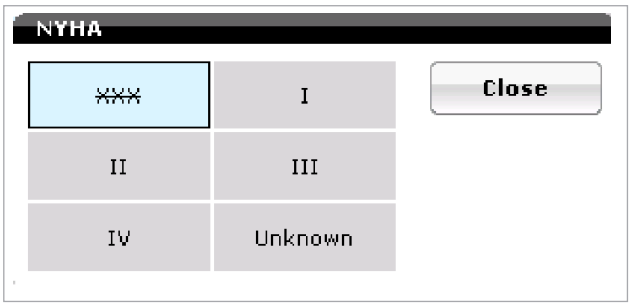


Figure 32: NYHA

5.3.9 Symptom

This section allows the user to select one or multiple symptoms related to the patient. Selecting a symptom will result in a check mark appearing in the box to the left. Once completed, press the OK button. The selection(s) will appear on the main patient page.

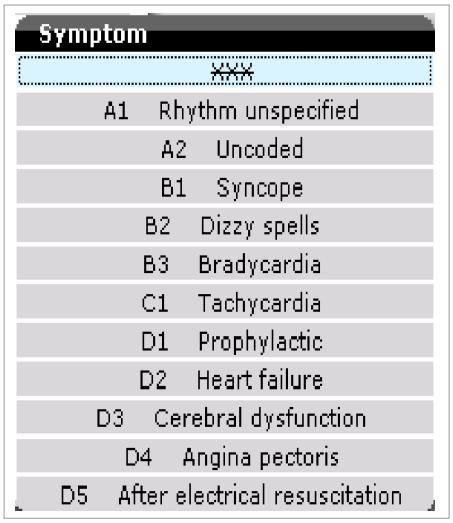


Figure 33: Symptom.

5.3.10 Etiology

This section allows the user to select an etiology related to the patient.

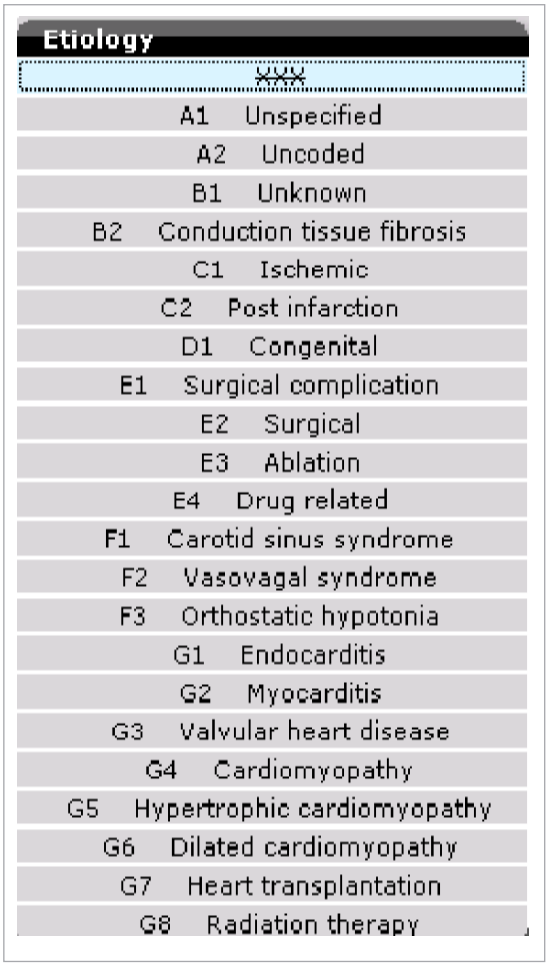


Figure 34: Etiology

5.4 Sensitivity settings

This section allows the user to change filter settings, sensing target, noise interval and sECG/real-time signal choices.

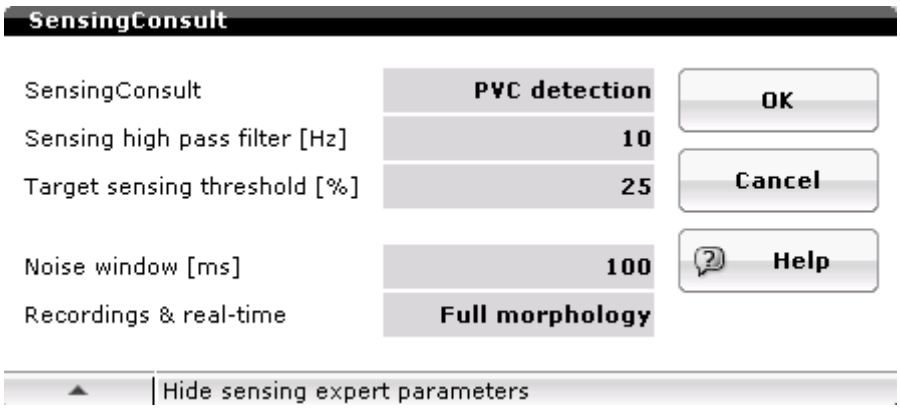


Figure 35: Sensitivity setting

5.4.1 SensingConsult

SensingConsult is a feature that allows the user to select options to match the patient condition. Selecting one of the four options results in the device automatically adjusting the filter and target threshold to optimize sensing for a particular patient.

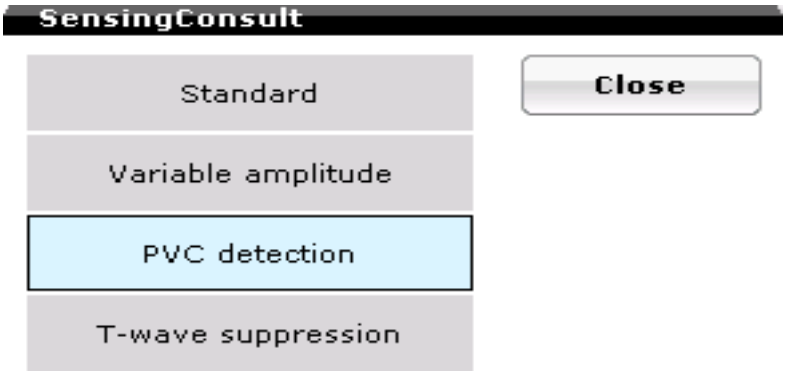


Figure 36: SensingConsult

Parameter	Filter setting (Hz)	Target sensing threshold (%)
Standard	10	50
PVC	10	25
Variable amplitude	10	35
T-wave suppression	18	40

Table 2: Parameter summary for R-wave sensing

5.4.2 High Pass Filter

This section allows the user to change the filter setting of the signal. The higher the value, the more of the baseline and T-wave signals are removed from the signal. This may be used if the baseline signal wanders or if oversensing from T wave occurs.

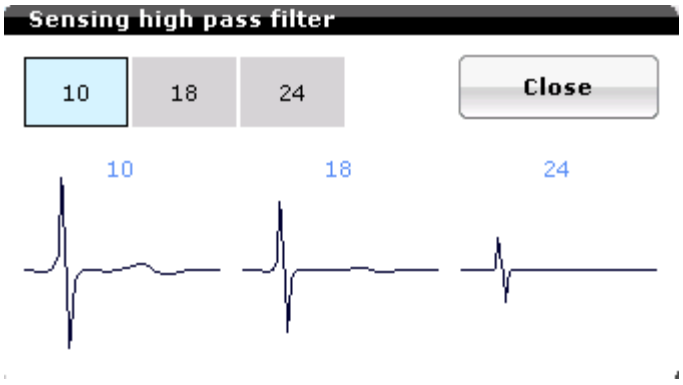


Figure 37: High pass band filters

5.4.3 Target sensing threshold

This section allows the user to change the sensitivity level at the time the next incoming signal is expected (assuming a stable rhythm).

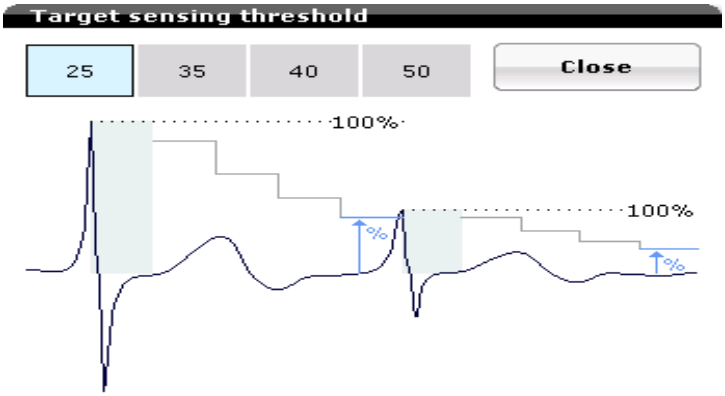


Figure 38: Target sensing threshold

5.4.4 Noise window

The user may extend the noise window to prevent sensing of non-physiologic events. Caution should be used when extending to higher values as it is possible to cause undersensing of intrinsic cardiac events.

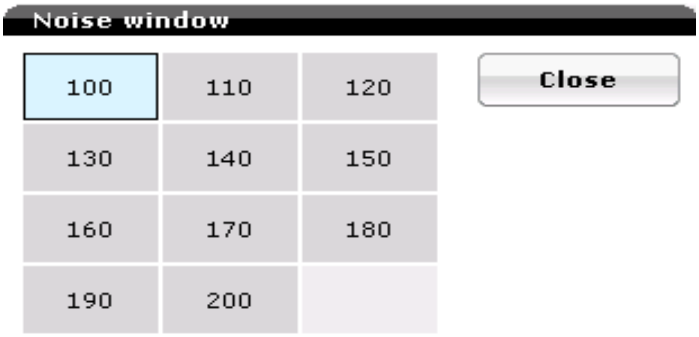


Figure 39: Noise window

5.4.5 Recording and real-time sECG

These selections determine which signal is used for display and stored sECGs. Full morphology is the unfiltered signal used for diagnostic interpretation, and the sensing signal is the processed signal used for R-wave sensing.

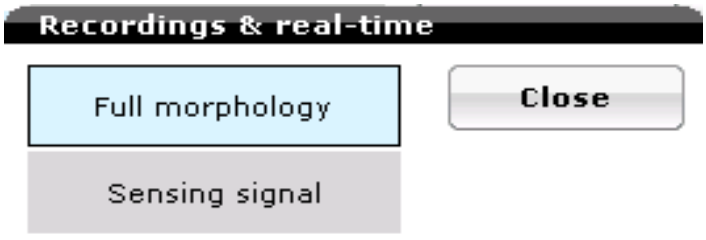


Figure 40: Recordings and real-time

This page left intentionally blank

6. Diagnostics

6.1 Diagnostics Overview

BioMonitor 2 can store a variety of statistical information. The various statistics consist of such features as rate histograms, rate trends, and activity trends, which are described in the following sections.

Activity

- Rate trends
- Rate histograms
- Activity trend

Number of Episodes

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

AF Details

- AF Trends
- AF Time of Occurrence
- AF Duration
- Ventricular rate during AF

Sensing

- R-wave trends
- Noise duration trend

6.1.1 General Statistical Information

The BioMonitor 2 statistics modes are always in operation and cannot be selected OFF.

The counters within the statistic features are reset each time the insertable monitor is permanently programmed.

The histogram information is a 240 day duration. Afterwards, the oldest data are overwritten.

Ongoing episodes are not counted.

6.2 Activity

The Activity diagnostic provides information related to heart rate, heart rate at rest, variability, rate histograms and activity.

Data is collected for the most recent 240 days. The user can look at information for a specific day by using the left/right arrows on the lower left screen or by simply touching on the screen. The date is listed at the bottom of the graph with the data results at the top of the graph.

6.2.1 Rate trends

Heart rate trends provide information related to heart rate, mean heart rate at rest and heart rate variability. Data is collected for the most recent 240 days. The user can look at information for a specific day by using the left/right arrows on the lower left screen or by simply touching on the screen. The date is listed at the bottom of the graph with the data results at the top of the graph.

Heart rate information is based on the daily average heart rate and is displayed as a single data point for the day.

BioMonitor 2 collects resting heart rate values in 10-minute blocks of time during the mean heart rate at rest recording time. The lowest average collected over the recording period is used as the statistical point for that given day.

Heart rate variability is calculated using SDANN. Data is collected in 5 minutes windows and calculated to a single daily data point.

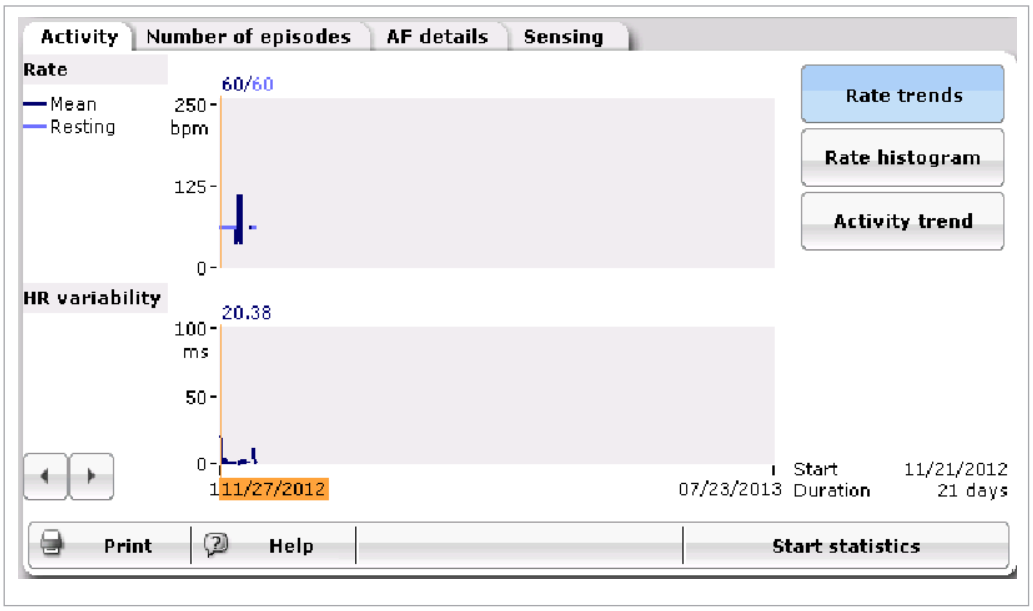


Figure 41: Rate trends

6.2.2 Rate Histogram

The Rate histogram shown in Figure 42, provides the percentage of activity in each rate bin for the BioMonitor 2. Rate bins are divided into 10 bpm increments.

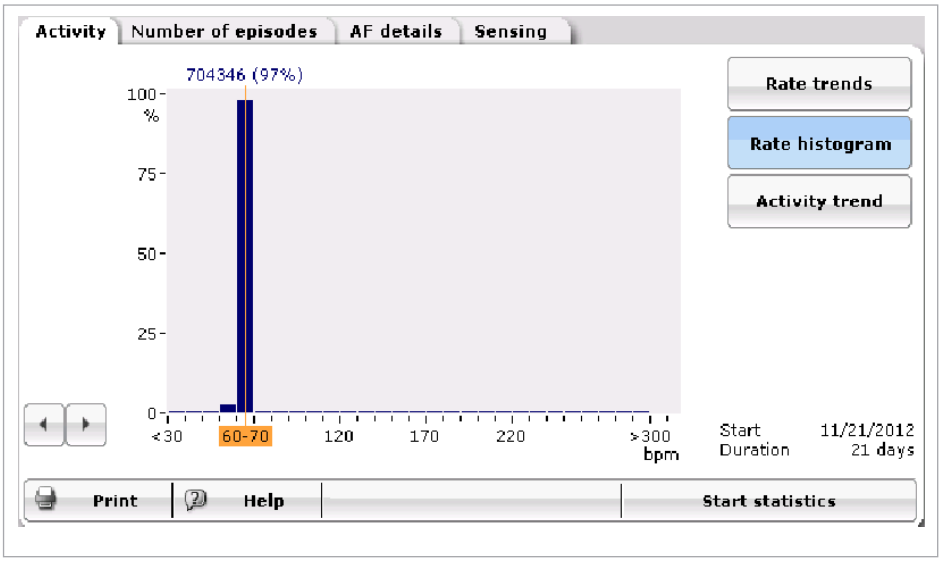


Figure 42: Rate histogram shows the percentage of activity in each rate bin

6.2.3 Activity trend

The Activity trend, shown in Figure 43, displays the daily percentage of activity as detected by the motion sensor of the device.

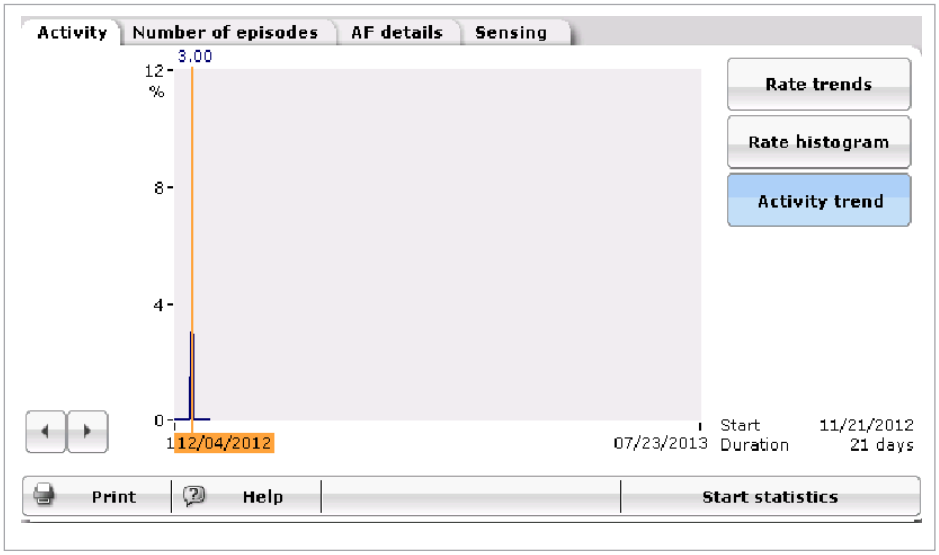


Figure 43: Activity trend

6.3 Number of episodes

The number of episodes, Figure 44, displays the total number of events that occurred since the previous follow-up.

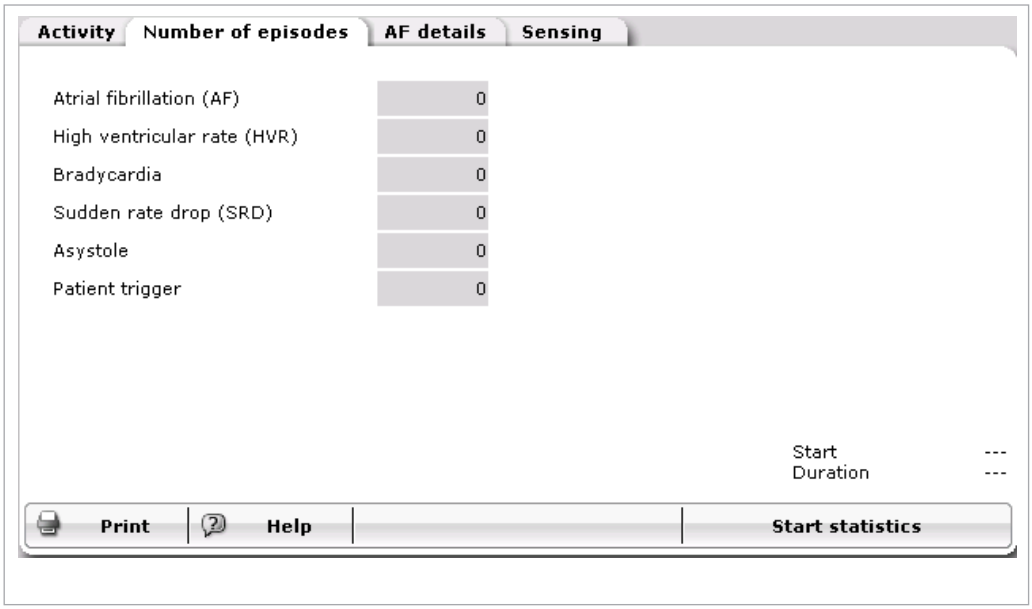


Figure 44: Number of episodes

6.4 AF details

6.4.1 AF trends

The AF trends diagnostic provides information related to the number and duration in hours of AF events on a daily basis.

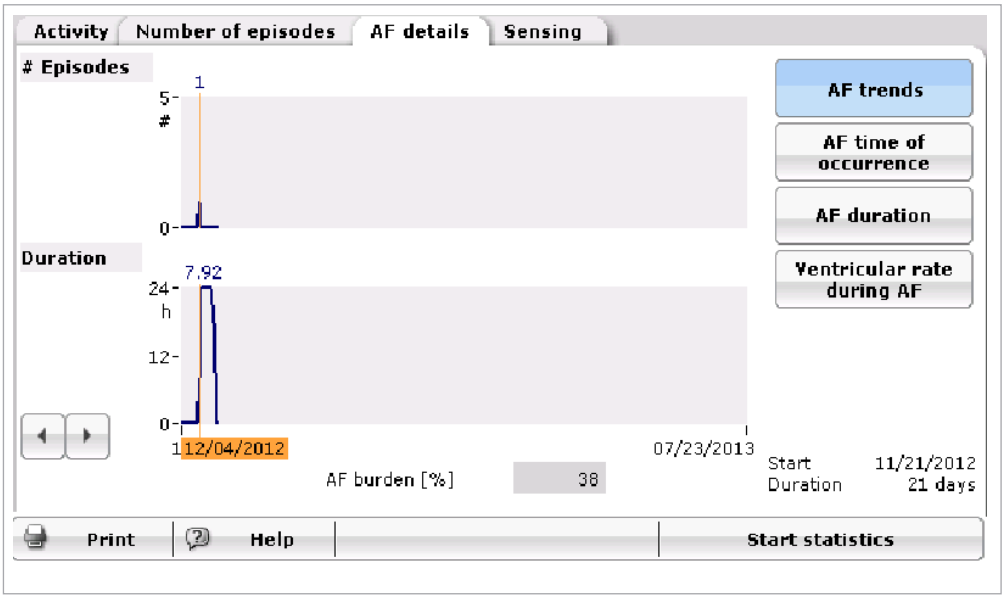


Figure 45: AF trends

6.4.2 AF time of occurrence

The time of occurrence, shown in Figure 46, summarizes the times of day that atrial tachyarrhythmia episodes began and is broken into three-hour time blocks. Knowing the time of day when atrial tachyarrhythmias begin may help determine whether a particular event will precipitate the tachyarrhythmia.

The total number of events is listed at the bottom of the graph.

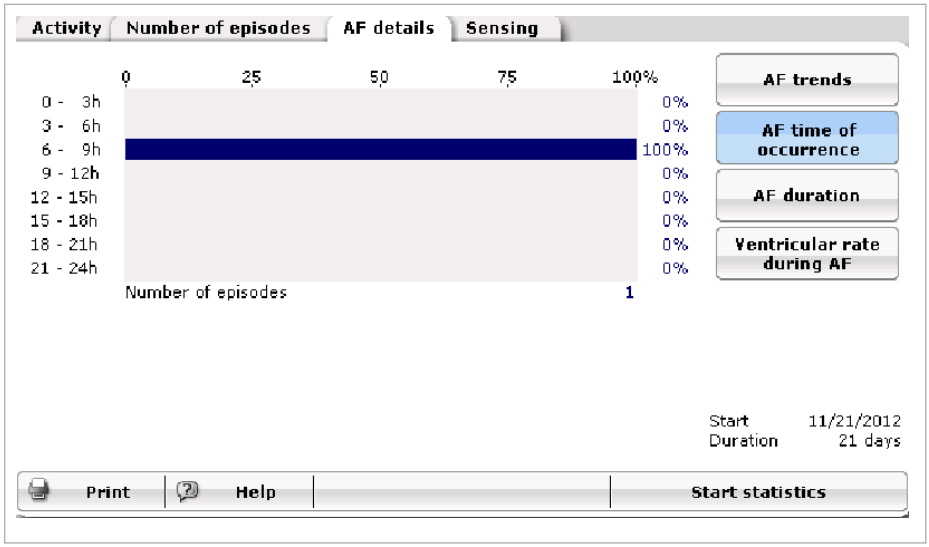


Figure 46: Time of Occurrence

6.4.3 AF duration

AF duration shows the length of each AF episode in time bins and provides a percentage of the episodes which occur in each time bin versus the total number of episodes. Ongoing episodes are not counted on the graph.

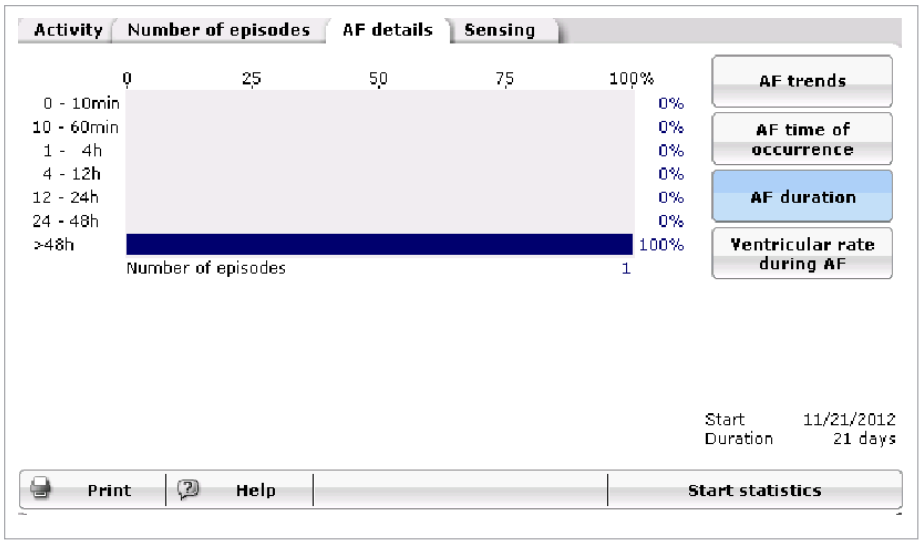


Figure 47: AF duration

6.4.4 Ventricular rate during AF

The ventricular rate during AF graph provides the mean and the maximum heart rate during AF. Large differences in the mean and maximum rates may indicate an irregular ventricular response during the AF while small differences may imply that ventricular rate is more stable during AF.

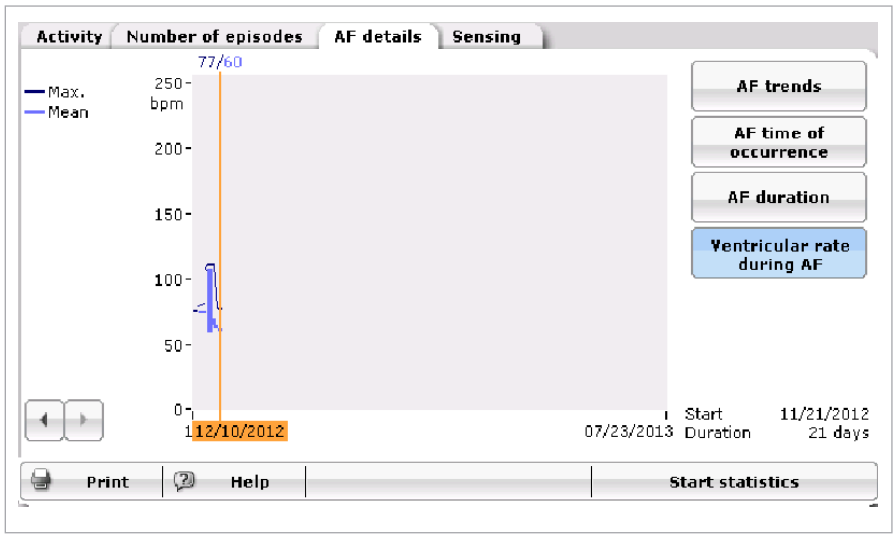


Figure 48: Ventricular rate during AF

6.5 Sensing

6.5.1 R-wave trend

The R-wave trend provides average daily R-wave measurement values for up to 240 days.

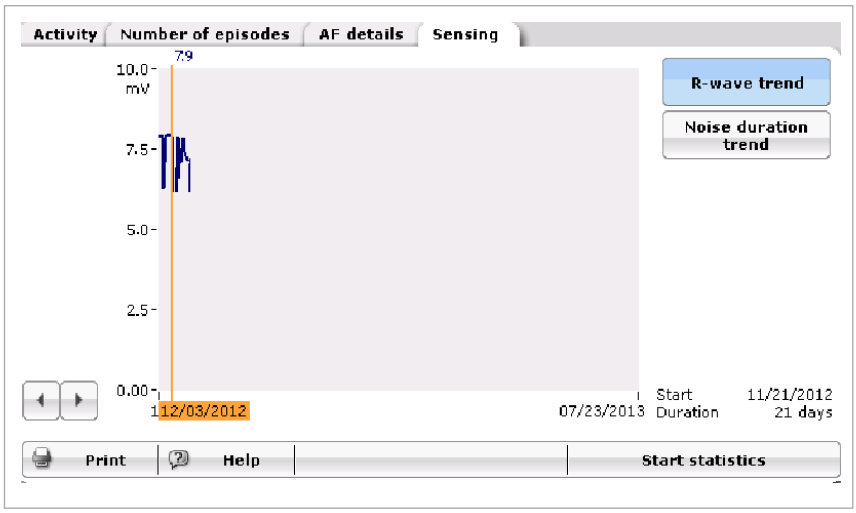


Figure 49: R-wave trend

6.5.2 Noise duration trend

The noise duration trend provides the amount of noise sensed daily by the device, expressed as a percentage of time per day by the BioMonitor 2. A high percentage of noise events could interfere with the BioMonitor 2's ability to detect arrhythmias.

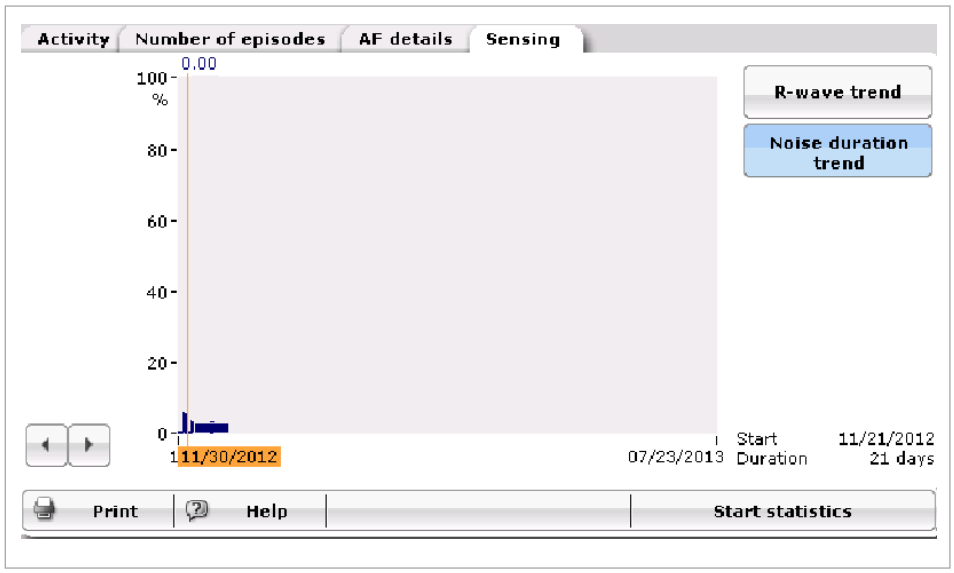


Figure 50: Noise duration trend

This page left intentionally blank

7. Other Functions/Features

BioMonitor 2 insertable monitors offer many additional functions and features to assist the physician in the care of the patient.

7.1 Home Monitoring

Home Monitoring enables the exchange of information about a patient's cardiac status from the cardiac monitor to the physician. Home Monitoring can be used to provide the physician with reports from the BioMonitor 2 and can process them into graphical and tabular format called a Cardio Report. This information helps the physician optimize the therapy process, as it allows the patient to be scheduled for additional clinical appointments between regular follow-up visits if necessary.

7.1.1 Transmission of Information

The cardiac monitor transmits information with a small transmitter, which has a range of about 6 feet (2 meters). The patient's cardiac monitor data are sent daily to the corresponding patient device and periodic sECGs are sent in configurable intervals when Home Monitoring is programmed ON.

The minimal distance between the cardiac monitor and the patient device must be 8 inches (20 cm).

7.1.2 Patient Data

The patient device is designed for use in or away from the home. Power is supplied by a standard wall plug. The patient device can be placed on the patient's nightstand or within 6 ft of where data transmission is to occur. Patient devices are either cell capable or plugged into a standard phone line.

For additional information about the patient device, please refer to its manual.

7.1.3 Transmitting Data

The cardiac monitor's information is digitally formatted by the BIOTRONIK Service Center and processed into a concise report called a Cardio Report. The Cardio Report, which is adjusted to the individual needs of the patient, contains current and previous cardiac monitor data. The Cardio Report is sent to the attending physician via fax or is available on the Internet, which is selected during registration of the patient. For more information on registering for Home Monitoring, contact your BIOTRONIK sales representative.

The password protected BIOTRONIK Home Monitoring website can be accessed at the following URL:

www.biotronik-homemonitoring.com

An online help menu is available in order to assist with the use of the Home Monitoring website.

Additionally, the attending physician may register to be informed of the occurrence of an Event Triggered Message through email or SMS (i.e., mobile phone) with a brief text message. If registered for Internet availability, the patient's detailed cardiac monitor data can then be viewed by logging onto the Home Monitoring website.

7.1.4 Types of Report Transmissions

When the Home Monitoring function is activated, the transmission of a report (Cardio Report) from the implant can be triggered as follows:

- Trend report—the time period (daily) initiates the report
- Event report—the BioMonitor 2 detects certain events, which initiate a report.

Trend Report

The time of the report transmission is programmable. For periodic messages, the time can be set anywhere between 00:00 and 23:30 hours. It is recommended to select a time between 0:00 and 4:00.

The length of the time interval (monitoring interval) is preset to "daily". For each monitoring interval, a data set is generated in the cardiac monitor and the transmission is initiated at the designated time.

Event Report

When certain cardiac and technical events are detected by the cardiac monitor, a report transmission is automatically triggered. This is described as an "event message" as part of the daily transmission.

The following clinical and technical events initiate a Home Monitoring message transmission:

- Event recording
- ERI detected

NOTE: The attending physician can go onto the Home Monitoring website to change or modify which of these events he/she wishes to be informed.

7.1.5 Description of Transmitted Data

The Monitoring Interval

The monitoring interval is considered the time period since the last periodic message was transmitted. In a periodic report, the monitoring interval since the previous periodic report would be 24 hours.

The following data are transmitted for the Cardio Report by the Home Monitoring system, when activated. In addition to the medical data, the serial number of the BioMonitor 2 is also transmitted.

Device Status & Home Monitoring Settings

Containing device and message identifying values that pertain to the cardiac monitor and Home Monitoring:

- Implantation Date
- Device Status
- Remaining capacity for ERI calculation (done by the Service Center)
- Last follow-up
- Device Serial Number
- Message Creation Date/Time
- Device settings

Physiologic data

- Heart rate
- Heart rate variability
- Patient activity
- Number of recordings and episode list

7.2 Patient Data Memory

Individual patient data can be stored in the insertable monitor's memory. The stored data is automatically displayed upon each interrogation. The patient data memory contains the following data categories:

- Patient ID (Code)
- Patient Name
- Date of Birth
- Gender
- Symptom
- Etiology
- Physician
- Implantation Date
- Lead Position
- NYHA Class
- Hospital
- City

Symptom and etiology are specified using the European PASSPORT code system. The PASSPORT code is an identification system of two character codes that represent specific conditions. A listing of the codes available with definitions is displayed on the screen of the programmer when patient data is selected. When the patient data screen is entered symptom or etiology may be entered, and can be accessed following interrogation to check code definition.

When the patient data screen is printed, the date of last follow-up is automatically given on the print-out.

7.3 Position Indicator

The position indicator facilitates positioning of the programmer head. The programmer optically and acoustically indicates whether the programmer head is in communication with the insertable monitor.

CAUTION

EMI – Computerized systems are subject to EMI or "noise". In the sources of such disturbance, telemetry communication may be interrupted and prevent programming.

This page left intentionally blank

8. Product Storage and Handling

8.1 Sterilization and Storage

The insertable monitor is shipped in a cardboard box, equipped with a quality control seal, and product information label. The label contains the model specifications, technical data, serial number, expiration date, and sterilization and storage information of the insertable monitor. The box contains a double container with the insertable monitor and product documentation.

The insertable monitor and its accessories have been sealed in a container and gas sterilized with ethylene oxide. To assure sterility, the container should be checked for integrity prior to opening. If a breach of sterility is suspected, return the insertable monitor to BIOTRONIK.

CAUTION

Storage (temperature) – Recommended storage temperature range is -10° to 45°C (14°-113°F). Exposure to temperatures outside this range may result in cardiac monitor malfunction.

Handling – Do not drop. If an unpackaged insertable monitor is dropped onto a hard surface, return it to BIOTRONIK.

CAUTION

FOR SINGLE USE ONLY – Do not resterilize the insertable monitor or accessories packaged with the cardiac monitor, they are intended for one-time use.

Device Packaging – Do not use the device if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to BIOTRONIK.

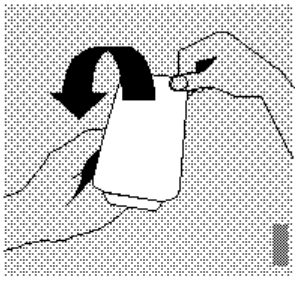
Storage – Store the device in a clean area, away from sources of electromagnetic interference (EMI) to avoid damage to the device.

Use Before Date – Do not implant the device after the USE BEFORE DATE because the device may have reduced longevity.

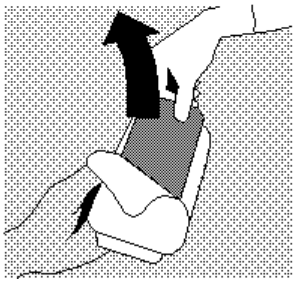
If a replacement insertable monitor is needed, contact your local BIOTRONIK representative.

8.2 Opening the Sterile Container

The insertable monitor is packaged in two plastic containers, one within the other. Each is individually sealed and then sterilized with ethylene oxide. Due to the double packing, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed on the sterile field.



Peel off the sealing paper of the outer container as indicated by the arrow.



Take out the inner sterile container by the gripping tab and open it by peeling the sealing paper as indicated by the arrow.

8.3 Insertable monitor orientation

Either side of the insertable monitor can face the skin.

9. Follow-up Procedures

9.1 General Considerations

The insertable monitor follow-up serves to monitor and provide information related to the patient's rhythm.

The follow-up intervals are, therefore, primarily determined by medical judgment.

The following notes are meant to stress certain product features, which are of importance for follow-up visits. For detailed information on follow-up procedures and medical aspects, please refer to the pertinent medical literature.

NOTE: In order to enable full device functionality, including statistics functions and ERI detection, transmit a permanent program after insertion by pressing the **[Transmit/Program]** button.

9.2 Real-time sECG Transmission

The insertable monitors provide real-time transmission of the subcutaneous electrogram (sECG) to the programmer. The sECG's may be transmitted to the programmer via the programming head positioned over the inserted monitor. They are then displayed together with surface ECG and markers on the programmer screen and printed on the ECG recorder.

9.3 Follow-up page

The follow-up page shown in Figure 51 provides information including the cardiac monitor and last follow-up date, the device status, number of the diagnostics recordings and Home Monitoring status.

Figure 51: Follow-up page

The ECG and sECG signal display may be adjusted to make viewing easier by pressing on the icon shown in Figure 51.

9.4 Recordings

The Recordings page provides a list of stored episodes since the last time it was cleared. Information includes the time and date of the event, the duration, the type of event, mean heart rate and a sECG link to the recording.

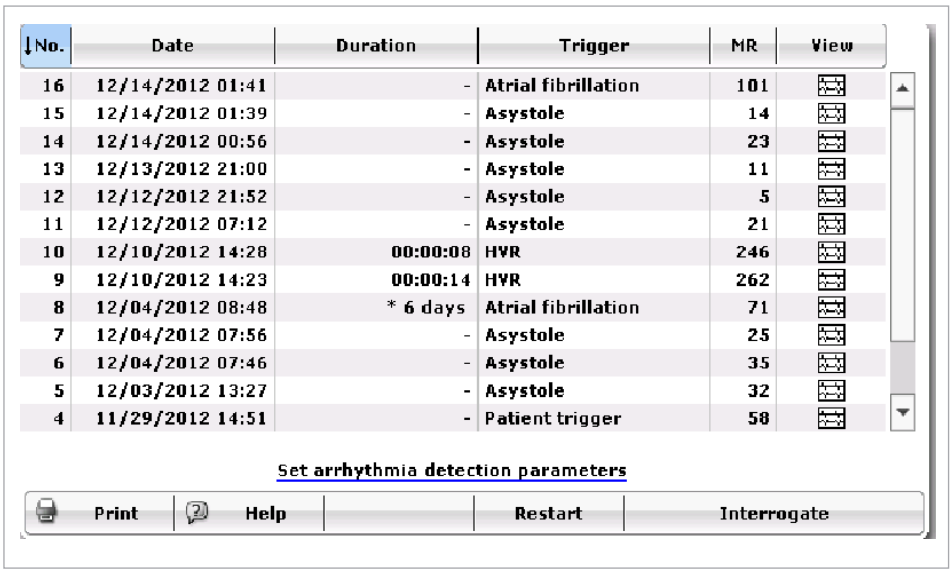


Figure 52: Recordings page

9.5 sECG

BioMonitor 2 can store 66 minutes of sECGs. The types of sECG recording include HVR, Bradycardia, SRD, AF, Asystole and Patient triggered events.

If sECG snapshots of all arrhythmia types are available, the minimum number of each type of snapshot in the device is the following:

Arrhythmia Type	Number of Snapshots	Episode recording scheme
AF	3	Oldest, newest, longest
High Ventricular Rate	3	Oldest, newest, longest
Bradycardia	3	Oldest, newest, longest
SRD	3	Two newest, oldest
Asystole	3	Two newest, oldest
Patient trigger	4	Three most recent, oldest

Examples of the different recordings are provided in the following sections. Figures 54-57 are for demonstration purposes only and are not clinically derived.

9.5.1 Atrial fibrillation

Figure 53 shows an example of an atrial fibrillation recording with the sECG and marker channels. The user can scroll through the example and print only a section or the entire recording may be printed.

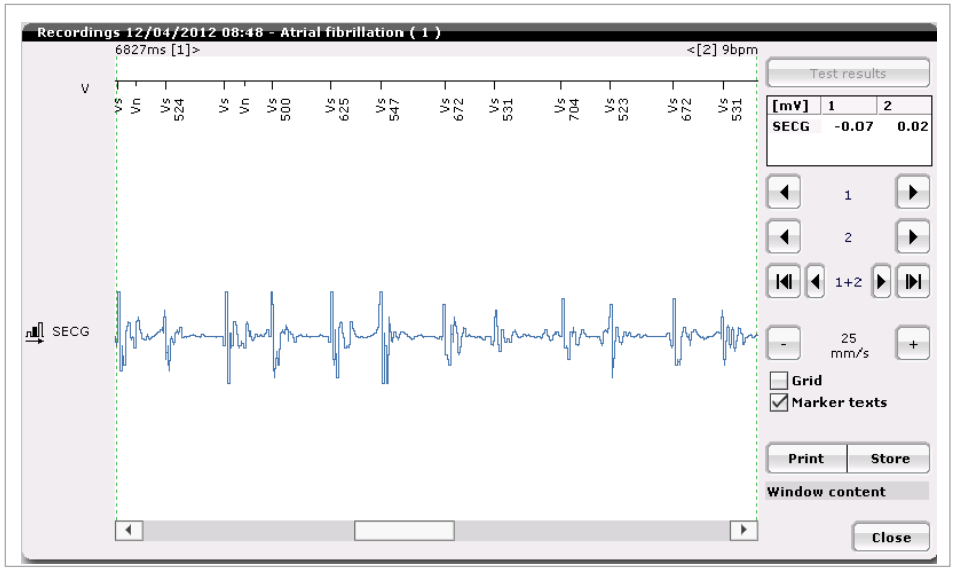


Figure 53: Atrial fibrillation sECG

9.5.2 High ventricular rate

Figure 54 shows an example of a high ventricular rate sECG. The black vertical bar indicates when the HVR criteria was met.

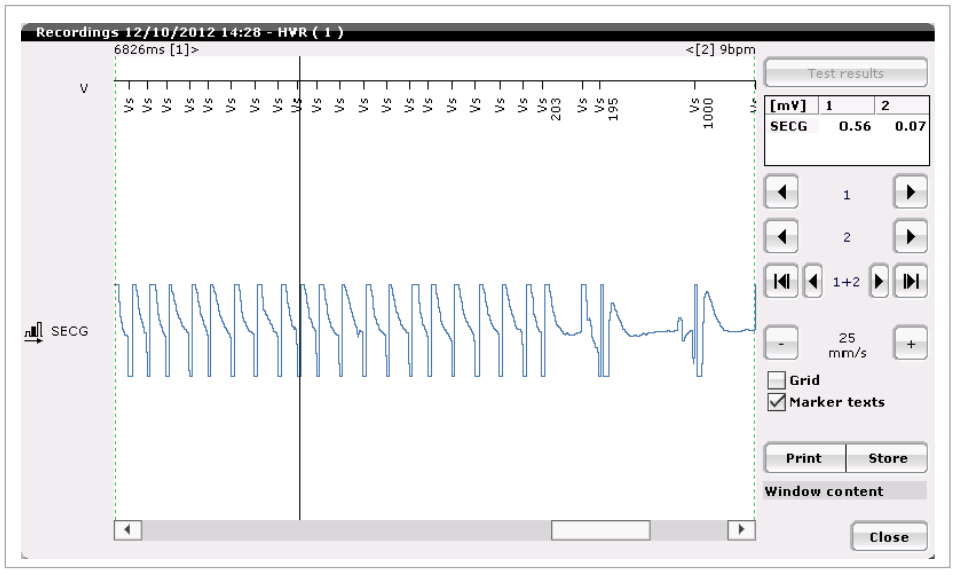


Figure 54: High ventricular rate sECG

9.5.3 Bradycardia

Figure 55 shows an example of a bradycardia recording.

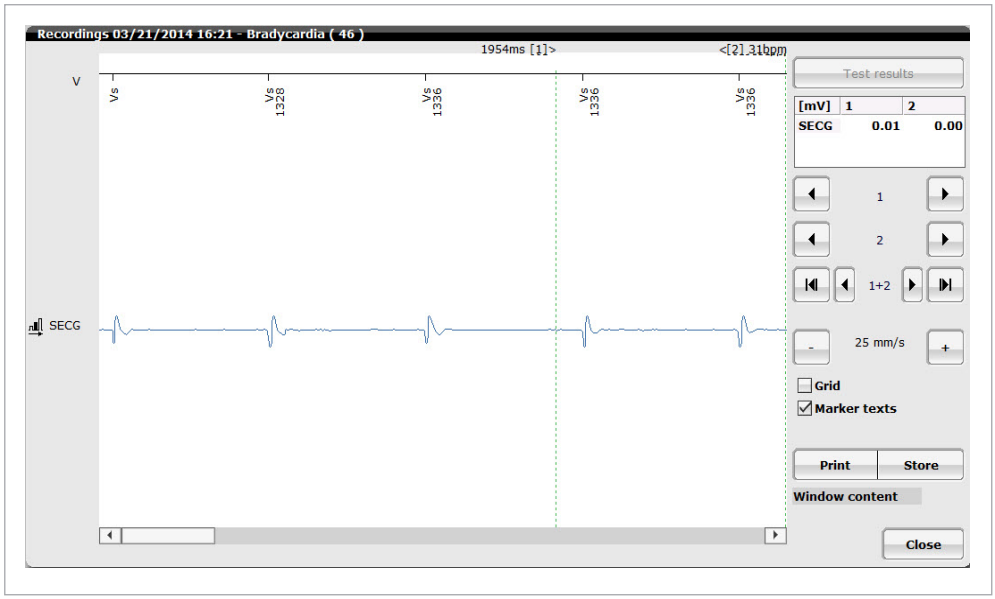


Figure 55: Bradycardia

9.5.4 Asystole

Figure 56 shows an Asystole recording.

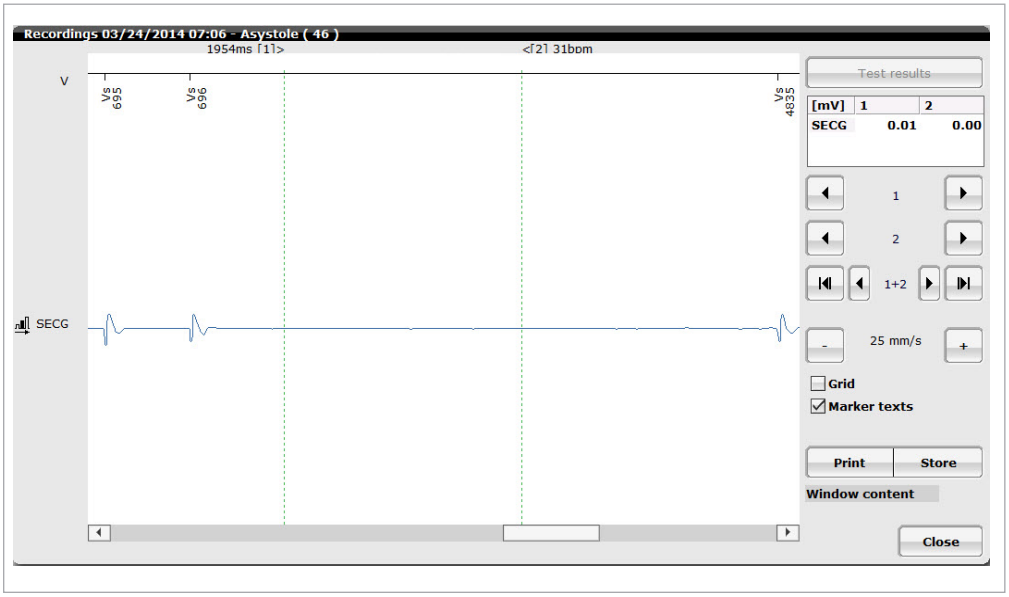


Figure 56: Asystole

9.5.5 Patient trigger

Figure 57 shows a sECG recording from a patient trigger event.

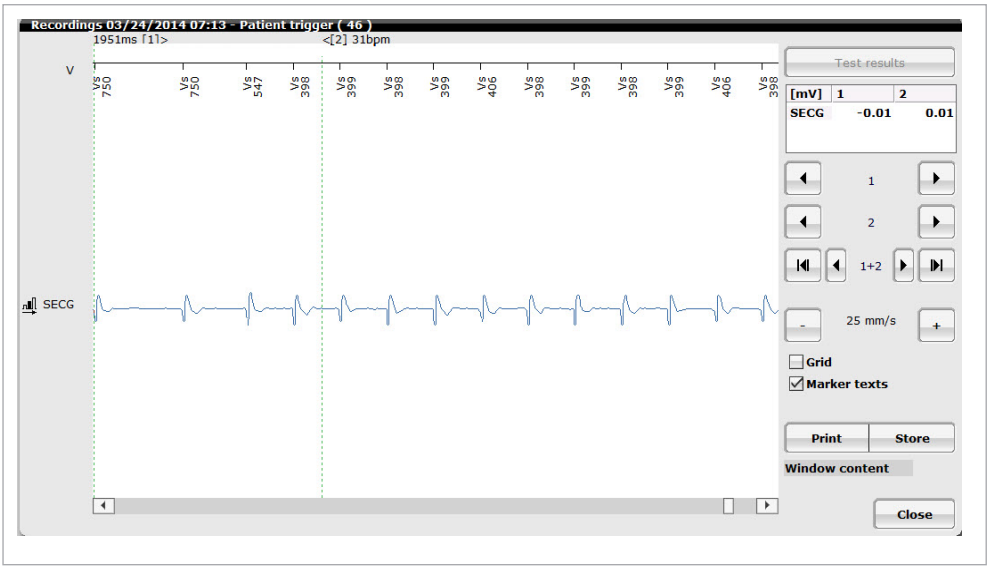


Figure 57: Patient trigger

This page left intentionally blank

10. Elective Replacement Indication (ERI)

The service time of BioMonitor 2 may vary based on several factors, including battery properties, storage time, programmed parameters and circuit operating characteristics. Service time is the time from beginning of service (BOS) to the end of service (EOS). To assist the physician in determining the optimum time for insertable monitor replacement, an elective replacement indicator is provided that is activated when the battery cell capacity drops to a predetermined level. The following table defines the different service cycles (at standard settings at 37°C). The beginning of the replacement cycle is displayed on the programmer after insertable monitor interrogation and appears on the printout. Table 3 shows the service cycle definitions.

Abbreviation	Service Cycle	Definition
BOS	Beginning of Service	Normal service cycle; battery in good condition
ERI	Elective Replacement Indication	Identifies the time of elective replacement indication
EOS	End of Service	Identifies the end of the elective replacement indication period.

Table 3: Service cycle definitions

Table 4 shows the expected longevity (in months) from BOS to ERI for the BioMonitor 2 insertable monitors. The programmer software for the BioMonitor 2 insertable monitors provides a fuel gauge to provide information related to the battery status.

Insertable monitor	Standard (BOS - ERI) in Months
BioMonitor 2	48

Table 4: Nominal BioMonitor 2 longevity

The remaining expected service time is provided in Table 5 below.

Monitor Program	ERI to EOS in Months
ERI	2

Table 5: Remaining Expected Service Time

All service intervals, including the above-cited nominal insertable monitor longevity, are based on considerations that consider the battery discharge behavior and the hybrid circuit properties including current consumption and replacement indicator.

This page left intentionally blank

11. Insertion/Removal

11.1 Insertion

The BioMonitor 2 is packaged in two plastic containers, one within the other. Each is individually sealed and then sterilized with ethylene oxide. Due to the double packaging, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed on the sterile field.

The BioMonitor 2 system uses a specialized insertion tool set, consisting of the components FIT-Fast Insert Tool 1 (FIT1), the pocket creation tool (Figure 58a) and FIT-Fast Insert Tool 2 (FIT2), the lead support tool (Figure 58b). The set allows easy sub-dermal insertion. Design features enable creation of a snug pocket for the BioMonitor 2, provide an ergonomic contour for the physician, and properly support the flexible lead during insertion.

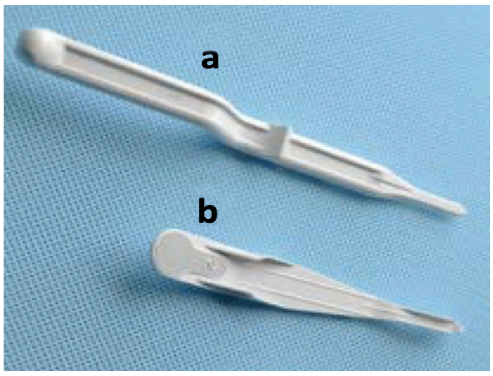


Figure 58: FIT Tools for BioMonitor 2 insertion

The BioMonitor 2 was developed to be inserted in a subcutaneous pocket, preferably in or around the left side of the chest. Recommended locations are areas where minimal device movement due to positional changes or body and arm movement is expected, e.g. location between the suprasternal notch and the left nipple, generating an approximately 45° rotation from the midline (Figure 59, position A) or the left parasternal region (Figure 59, position B). Alternatively, a left sub-mammary position can be used (Figure 59, position C).

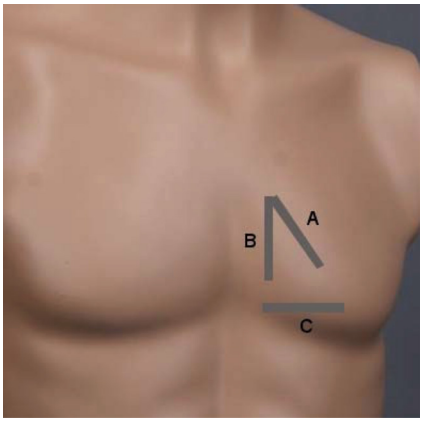


Figure 59: Possible Positions for BioMonitor 2

In the selected anatomical position, local anesthetic agent is injected, before a small incision through the skin is made, avoiding damage to any underlying musculature. The incision should be approximately 1.5 cm wide. The pocket tool (FIT1) is advanced within a sub-dermal plane until the thumb stop approaches the incision, as shown in Figure 60. After withdrawing the FIT1 a suitable pocket for the cardiac monitor remains.

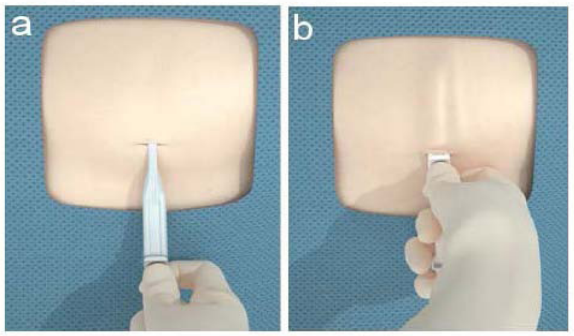


Figure 60: Insertion of the FIT 1 Tool

The BioMonitor 2 is placed into the preformed recess on the FIT2 and clipped in by pressing the flexible lead body into the guide beneath the undercut (Figure 61 and Figure 62, position a). Then it is inserted in a two-step approach: First the BioMonitor 2 is gripped with the thumb on top of the device until it is inserted to the welding line (Figure 62, position b). In a second step the device is pushed in with the thumb resting behind the device (Figure 62, position c). Both, the FIT2 with the BioMonitor 2, are inserted together straight into the pre-shaped pocket.

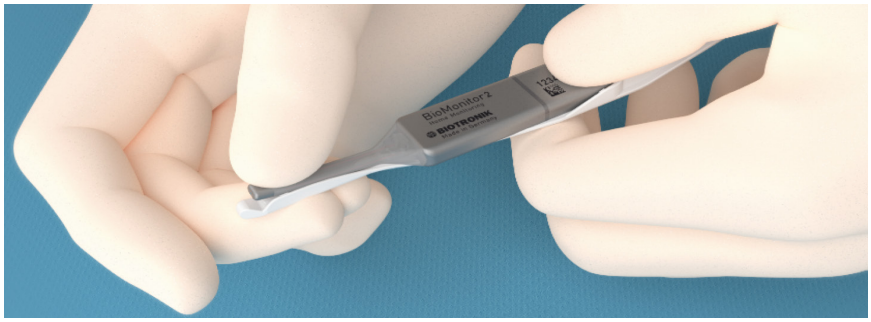


Figure 61: Placement of the BioMonitor 2 in FIT2 and fixation of flexible part

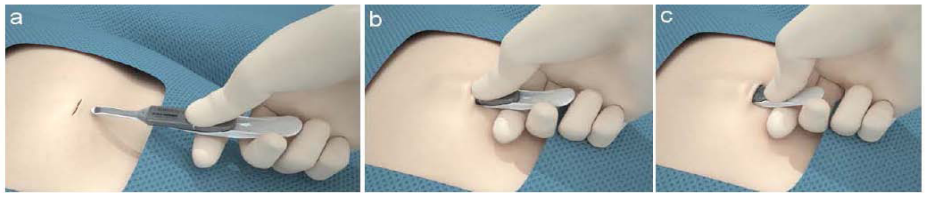


Figure 62: Insertion of the BioMonitor 2

While sliding the support tool FIT2 out of the pocket finger pressure is applied to the BioMonitor 2 to keep the implant in place (Figure 63). For incision closure standard clinical practice is advised. Protection of the wound from environmental influences according to hospital guidelines finalizes the insertion procedure of BioMonitor 2.

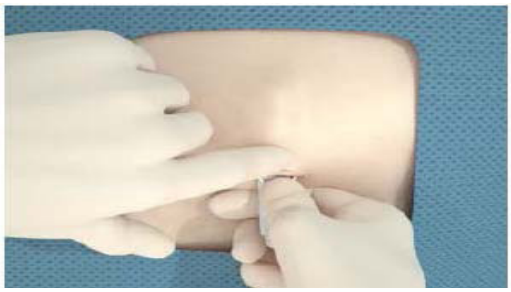


Figure 63: Sliding out the Support Tool (FIT 2)

11.2 Removal

Removed cardiac monitors or removed accessories may not be reused. Removed cardiac monitors can be sent either to the local BIOTRONIK representative or the BIOTRONIK home office for expert disposal. If possible, the removed cardiac monitor should be cleaned with a sodium-hyperchlorine solution of at least 1% chlorine and, thereafter, washed with water prior to shipping.

The insertable monitor should be removed before the cremation of a deceased patient.

CAUTION

Device Incineration – Never incinerate a removed cardiac monitor. Be sure the insertable cardiac monitor is explanted before a patient who has died is cremated.

Removed Devices – Return all removed devices to BIOTRONIK.

11.3 Reasons to Remove an Insertable Monitor

An insertable monitor may be removed emergently or at a physician's discretion at any time subsequent to an implant procedure. Reasons for removal include, but are not limited to: patient death; loss of sensing; inability to program/interrogate the inserted monitor; infection, EOS (normal or premature); system upgrade; physician preference for another insertable monitor model; and/or other reason(s) which may or may not be known to the insertable monitor manufacturer. Complications related to other portions of the insertable monitor system (i.e., patient) may also result in insertable monitor removal. Table 6 summarizes some of the more common reasons for insertable monitor removal.

Source	Cause	Possible Effect
Battery	Premature depletion or other cause(s) resulting in excessive battery current drain.	Inability to program/interrogate; sensing difficulty.
Circuitry	Electrical parameter changes due to shorts, opens, or component parametric drift Electromagnetic Interference (EMI) from large power tools, industrial equipment, electrocautery, defibrillation, radiation therapy, RF ablation therapy, etc.	Reversion to "Elective Replacement" or electrical reset parameters; inability to program/ interrogate; other damage to circuit components resulting in permanent or temporary parameter changes.
Patient	Normal medical complication	Infection
	Body rejection phenomena	Fluid accumulation; migration; erosion.
	Physician preference	Upgrade to an implantable cardiac pacemaker or implantable cardioverter defibrillator.

Table 6: Common reasons to remove an insertable monitor

12. Remote Assistant

12.1 General Information on the Remote Assistant

The Remote Assistant is an accessory for the BioMonitor 2 that allows patients to manually trigger the recording of an ECG.

Press the trigger key on the Remote Assistant to send a signal to the BioMonitor 2. If the BioMonitor 2 successfully receives the signal, it will record and store an ECG. The Remote Assistant indicates a successful or unsuccessful recording using the behavior of the signal transmission LED before it automatically turns off.

The Remote Assistant is powered by two batteries that are non-replaceable due to the design of the device.

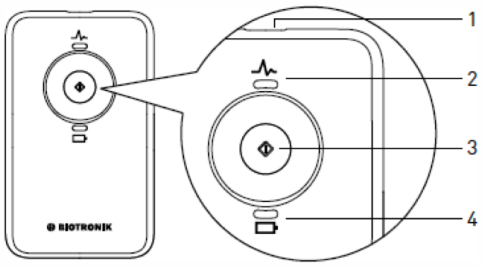
12.2 Remote Assistant Functional Testing

The Remote Assistant is supplied for immediate use. However, check the Remote Assistant for visible damage before use. A manual function test may also be performed:

- Hold the Remote Assistant and press the trigger key. The signal transmission LED briefly lights up yellow.
- Then observe the behavior of the signal transmission LED.
  If the LED lights up continuously green or flashes yellow and turns off after a short time, the Remote Assistant is undamaged, and you can use it immediately.

  If the LED exhibits other or no behavior, do not use the device. Contact BIOTRONIK Technical Services (800-284-6689) for further instructions.

12.3 Getting to Know the Remote Assistant



Item	Symbol	Description
1	–	Hanger
2		Signal transmission LED
3		Trigger key
4		Battery indicator LED

12.4 Triggering a Manual Recording

1. The patient holds the Remote Assistant over his or her chest at the location where the BioMonitor 2 was implanted.

2. The trigger key is pressed and held on the device in this position for at least three seconds.

   The device emits an acoustic signal, and the signal transmission LED lights up continuously yellow for approximately of three seconds.

3. If the recording has been successfully triggered in the BioMonitor 2, the signal transmission LED lights up continuously green for a maximum of 30 seconds before the device automatically turns off. If the signal transmission LED flashes yellow, no recording was triggered in the BioMonitor 2.

12.5 Battery LED Indicator Explained

Battery indicator LED:

LED behavior	Explanation
LED is not lit	The battery in the Remote Assistant has sufficient capacity.
LED flashes yellow	The battery's capacity is only sufficient for another approx. 20 trigger attempts.
LED is continuously lit yellow	The device is defective or the battery's capacity is depleted.

12.6 Signal Transmission LED Explained

Signal transmission LED:

LED behavior	Explanation
LED is continuously lit yellow	The trigger key has been pressed.
LED flashes yellow	Recording in the BioMonitor 2 was not successfully triggered.
LED is continuously lit green	Recording in the BioMonitor 2 was triggered successfully.

13. Technical Data

13.1 Parameters

13.1.1 Atrial Fibrillation

Atrial Fibrillation

ON; OFF

AF Sensitivity

Low, **Medium**, High

RR variability

6.25%, **12.5%**, 18.75%

Onset/Resolution window

8/16, 16/24, 24/32

Onset intervals

5, 7, 9, 11, 13, 15, 17, 19, 21, 23

Resolution intervals

1, 3, 5, 7

Confirmation time

1, 2, 3, 4, 5, **6**, 10, 20, 30

13.1.2 High Ventricular rate

HVR

ON; OFF

HVR Limit

110...(10)... **180**, 190, 200

HVR Count

8, 12, **16**, 20, 24, 32, 64

13.1.3 Bradycardia

Brady zone limit

OFF; 30...(5)...**40**...(5)...80 bpm

Brady duration

5, **10**...(5)...30 seconds

13.1.4 Sudden rate drop (SRD)

SRD rate decrease (%)

OFF, 20...(10)...70

SRD Sensitivity

Low, **Medium**, High

Baseline intervals

48, **64**, 128, 256

Rate-drop intervals

8, **16**, 32

13.1.5 Asystole duration

OFF; 2, **3**...(1)...10 seconds

13.1.6 Patient trigger

ON; OFF

13.1.7 Resting rate period

Start resting period (hh:mm)

00:00, 01:00, **02:00**...(01:00)...23:00

Resting period duration (hh:mm)

00:30, 01:00...(00:30)...**04:00**...(00:30)...12:00

13.1.8 Home Monitoring

Home Monitoring

ON; OFF

Time of transmission (hh:mm)

Std.; 00:00...(00:30)...23:30

Period subcutaneous ECG

OFF, 1, 7, **30**, 60, 90, 120, 180 days

13.2 Programmer

ICS 3000 or Renamic

13.3 Materials in Contact with Human Tissue

Housing: Titanium

Device coating: Silicone

Electrodes: Titanium

13.4 Electrical Data/Battery

NOTE: At 37° C

Parameter	BioMonitor 2
Power source	$LiMnO_2$
Battery voltage at BOS	3.1 V

13.5 Mechanical Data

Model	Size	Mass	Volume
BioMonitor 2	88.4 x 15.2 x 6.2 mm Rigid portion 55.5 x 15.2 x 6.2 mm	10.1 g	5 cc

This page left intentionally blank

14. AF Detection Study Results

In order to evaluate BioMonitor AF detection performance, clinical data was collected in a single-center, prospective, nonrandomized study. The ability of BioMonitor to detect episodes of AF was quantified in comparison with the gold standard, expert-annotated, external Holter ECG recorder. Sixty-six (66) participants with suspected paroxysmal or persistent atrial fibrillation who had been implanted with a BioMonitor were additionally equipped with an external Holter ECG recorder. Of these 66 participants, 39 showed at least one true AF episode during the two-day Holter period. A total of 146 AF episodes were annotated from 2898 hours of Holter ECG data.

False positive AF episodes (i.e., non-AF periods falsely detected as AF by BioMonitor), resulting in positive predictive values less than 100%, were predominantly associated with episodes of ectopic beats.

False negative AF episodes (i.e., true AF episodes undetected by BioMonitor), resulting in sensitivity values less than 100%, were mainly attributed to R-R interval variability that did not exceed the BioMonitor-programmed limit of 12.5% for a sufficient fraction of intervals. All of these FN patients had AF documented by the BioMonitor in another episode and were thus identified as AF positive patients.

Table 7 summarizes the mean episode sensitivity and a mean episode PPV.

Sensitivity (%) ± SD	PPV (%) ± SD
95.4 +/- 13.3	76.6 +/- 38.7

Table 7: Mean BioMonitor AF detection performance statistics.

14.1 BioMonitor 2 Pilot Study Results

The objective of this study was to provide clinical data of the insertion procedure and the sensing quality of BIOTRONIK's second generation of Insertable Cardiac Monitor (ICM) BioMonitor 2. Data of 30 patients from 5 Australian clinical sites from December 18, 2014 through July 06, 2015 are included in this summary.

There were 22 male and 8 female subjects enrolled with a mean age of 63 years. The most common indications for insertion of the BioMonitor 2 were syncope and symptomatic or asymptomatic atrial fibrillation.

The median time between first skin cut to final successful positioning of BioMonitor 2 was 2.5 minutes. The mean time of the entire implantation procedure was 9.9 minutes. Inserting investigators evaluated the tunneling procedure with the FIT 1 tool related to the needed force and grip on the tool, which resulted in a rating of good or acceptable in 83% and 100% of the cases respectively. The FIT 2 tool was evaluated by the inserting investigator for implant loading, insertion, removal and overall handling. All assessment were good or acceptable.

The mean R-wave amplitude at the 1-week and 1-month follow-up visit was 0.7 ± 0.4 mV and 0.8 ± 0.4 mV respectively. The results show significant superiority to the mean R-wave amplitude of the predecessor BioMonitor (0.3 mV). The mean noise burden was 1.3 ± 2.3 % and 2.3 ± 3.1 % at the 1-week and 1-month follow-up respectively. The results are significantly improved compared to the predecessor device (5.5%). Five patients reported pain in the pocket during the first week after implantation. Medical treatment was not needed. One patient had a wound infection which was treated with oral antibiotics.

The results demonstrate safety and efficacy of the insertion procedure and the study device.

14.2 BioInsight Study Results

The BioInsight study was designed to evaluate the safety and feasibility of performing the BioMonitor 2 insertion procedure in an office setting. All subjects enrolled in the study had an approved indication for continuous arrhythmia monitoring with an ICM and were implanted with a US market released BIOTRONIK BioMonitor 2. The primary objective was to characterize all insertion procedure-related adverse events requiring additional invasive intervention to resolve though the 90-day follow-up. Secondary objectives included characterization of all insertion procedure-related adverse events not included in the primary objective, characterization of the insertion procedure, and characterization of device functionality post-insertion.

Of 82 subjects enrolled at 6 study sites in the U.S., 77 patients underwent an insertion procedure in an office setting. All insertion procedure attempts were successful. There were no reported adverse events that met the criteria for primary objective 1; therefore, the rate of all insertion procedure-related adverse events that required additional invasive intervention to resolve is 0%, 95% CI: (0.0%, 5.0%). Only two adverse events were reported and both were classified as insertion procedure-related that did not require additional invasive intervention to resolve. The overall event rate for all reported adverse events was 2.7%, 95% CI: (0.3%, 9.5%) and is similar to in-office ICM insertion rates reported in literature. The average R-wave amplitude was 0.77 ± 0.5 mV at insertion and 0.67 ± 0.3 mV at 90 days. The average noise burden was 2.5 ± 4.64 % at wound check and 2.7 ± 5.79% at 90 days. Daily BIOTRONIK Home Monitoring® transmissions for 76 subjects showed stable R-wave amplitudes and noise burden through the 90-days post-insertion with an overall average of 0.68 mV and 2.7%, respectively.

15. Order Information

Insertable monitor Type	Order Number
BioMonitor 2-AF	398 493
BioMonitor 2-S	398 494

FCC Statement: (FCC ID: QRIBM2): This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) this device must accept any interference received, including interference that may cause undesired operation

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

(800) 547-0394 (24-hour)
(800) 291-0470 (fax)
www.biotronik.com

M4183-C 11/19

MN058r3 11/18/19

BIOTRONIK
excellence for life