BioMonitor

Technical Manual

BIOTRONIK
excellence for life

BioMonitor

Implantable monitors

BioMonitor
X-Ray identification

Radiopaque Identification

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

BioMonitor	VP

CAUTION

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

Contents

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1. Device Description

BioMonitor is a programmable, subcutaneous implantable monitor able to record subcutaneous ECG's and other physiological parameters.

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

The BioMonitor system consists of 3 main components:

BIOTRONIK BioMonitor implantable cardiac monitor - The BioMonitor is a small, leadless device that is typically implanted under the skin, in the chest. The device uses three electrodes on the body of the device to continuously monitor the patient's subcutaneous ECG. The device memory can store up to 13.3 min of subcutaneous ECG (sECG) recordings from automatically detected arrhythmias and up to 22.5 min of ECG recordings from patient-triggered episodes. When a patient experiences symptoms, the sECG recordings can be manually triggered by placing a magnet over the BioMonitor.

Note - The BioMonitor subcutaneous ECG may differ from a surface ECG due to differences in electrode separation and device placement in the body, as well as the differences between subcutaneous and surface contact impedances.

As shown in Figure 1, the BioMonitor has three input channels A, B and C, which receive different projections of the mean heart signal. Each channel uses a single pair of electrodes

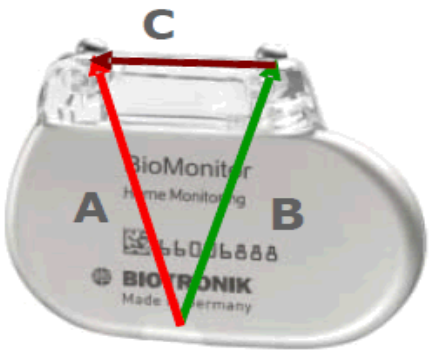


Figure 1: Input channels

BioMonitor detects subcutaneous ECG from each of its three vectors. 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 4Hz – 40Hz, which is designed to retain morphological features of a typical ECG while still rejecting large low frequency artifacts and baseline drift.

The three sensed cardiac signals are combined into a single channel, shown in Figure 2. This increases the signal to noise ratio by smoothing some of the random noise associated with each channel, while emphasizing the QRS complexes.

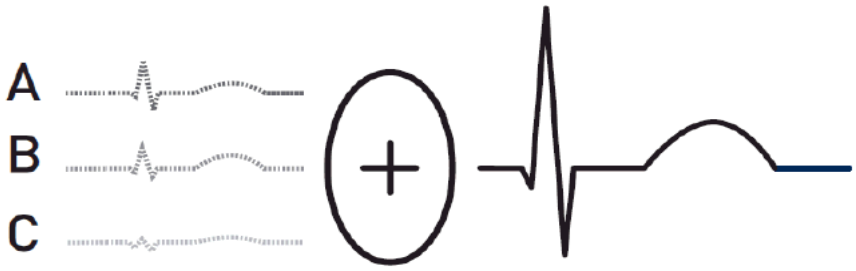


Figure 2: Single channel sECG

BIOTRONIK Renamic / ICS 3000 Programmer – The programmer is used to set up the BioMonitor 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 to BIOTRONIK's Home Monitoring Service Center.

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

- 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

3. Contraindications

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

4. Warnings and Precautions

Certain therapeutic and diagnostic procedures may cause undetected damage to an implantable 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 MRI CONDITIONS FOR USE

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

- The cardiac monitor is labeled and certified MR conditional.
- 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.
- The patient does not have a fever.
- The device system has been implanted for at least 6 weeks.
- The device is located in the patient's chest area.

4.2 MRI Scanner Limitations

The MRI scanner has to meet the following conditions:

- Use of a clinical MRI scanner with a closed tube, cylindrical magnets and a static magnetic field strength of 1.5T.
- The slew rate of the MRI scanner's gradient fields should not exceed 200 T/m/s per axis.
- For the head and the extremities, local transmitter and receiver coils are approved for use in addition to the local receiver coils. Only local receiver coils may be used for the thorax.

4.3 Restrictions during the MR Scan

The following conditions must be met during the MR scan:

- The MR scan must only be performed with the patient in dorsal position.
- The mean specific absorption rate (SAR) for the whole body as displayed by the MRI scanner must not exceed 2.0W/kg.
- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- Continuously monitor the patient's hemodynamics during the entire MR scan using at least one of the following parameters: blood oxygen saturation, blood pressure or ECG. Note: the ECG function integrated in the MRI scanner is often not approved for patient monitoring. Therefore, only use devices which are approved for patient monitoring in an MRI environment.

4.4 Implanted Pacemakers and Defibrillators

The BioMonitor 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 may be affected by the paced heart rhythm.

4.5 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, implantable cardiac monitor function must be checked.

Therapeutic Diathermy Equipment - Use of therapeutic diathermy equipment is to be avoided for implantable cardiac monitor patients due to possible heating effects of the implantable cardiac monitor and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the implantable 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 implantable 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 implantable cardiac monitor as possible.
- Monitor cardiac activity during TENS use.

Defibrillation - The following precautions are recommended to minimize the inherent risk of implantable 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 implantable cardiac monitor
- The energy setting should not be higher than required to achieve defibrillation.

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

Lithotripsy - Lithotripsy treatment should be avoided for implantable cardiac monitor patients since electrical and/or mechanical interference with the implantable 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 implantable cardiac monitor.

Electrocautery - Electrocautery should never be performed within 15 cm (6 inches) of an implantable cardiac monitor because of the danger of introducing fibrillatory currents into the heart and/or damaging the implantable cardiac monitor. 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.

4.6 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 implantable cardiac monitor malfunction (see Section 8.1).

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

FOR SINGLE USE ONLY - Do not resterilize the implantable 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 (magnets) - Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) 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.

4.7 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 implanted 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 system through an active telephone link.
- The CardioMessenger cannot establish a connection to the implanted 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 implantable 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.

4.8 Electromagnetic Interference (EMI)

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

BIOTRONIK implantable cardiac monitors have been designed to significantly reduce susceptibility to electromagnetic interference (EMI). However, due to the variety and complexity of sources creating interference, there is no absolute protection against EMI. Generally, it is assumed that EMI produces only minor effects, if any, in implantable 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.

4.8.1 Home and Occupational Environments

The following equipment (and similar devices) may affect normal implantable 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 implantable cardiac monitor operation if approached too closely.
- **Home Appliances** - Home appliances normally do not affect implantable cardiac monitor operation if the appliances are in proper condition and correctly grounded and encased. There are reports of implantable cardiac monitor disturbances caused by electrical tools and by electric razors that have touched the skin directly over the implantable 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 implantable 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 implantable cardiac monitor operation if approached too closely.

- **Electrical Appliances** - Electric hand-tools and electric razors (used directly over the skin of the implantable cardiac monitor) have been reported to cause implantable cardiac monitor disturbances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with the implantable cardiac monitor operation.
- **Electronic Article Surveillance (EAS)** - Equipment such as retail theft prevention systems may interact with the implantable cardiac monitor devices. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.

4.8.2 Cellular Phones

Recent studies have indicated there may be a potential interaction between cellular phones and implantable 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 implantable cardiac monitor.

Based on testing to date, effects resulting from an interaction between cellular phones and the IMPLANTABLE CARDIAC MONITORs have been temporary. Simply moving the phone away from the implanted device will return it to its previous state of operation. Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made.

Patients having an implanted 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 implanted 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 implanted device.
- Patients should hold the phone to the ear opposite the side of the implanted device. Patients should not carry the phone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted 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 implant.

4.8.3 Hospital and Medical Environments

Electrosurgical Cautery - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may inhibit implantable cardiac monitor sensing operation. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the implantable cardiac monitor as possible.

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

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

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

4.9 Implantable Cardiac Monitor Explant and Disposal

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

Explanted Devices - Return all explanted devices to BIOTRONIK.

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 Diagnostics

The Diagnostics page, shown in Figure 3, 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. Each of these will be discussed in greater detail in this section.

Figure 3: Main Diagnostic screen

5.1.1 Atrial Fibrillation (AF)

The Atrial fibrillation menu (Figure 4) allows the user to program AF detection ON or OFF as well as set the detection criteria.

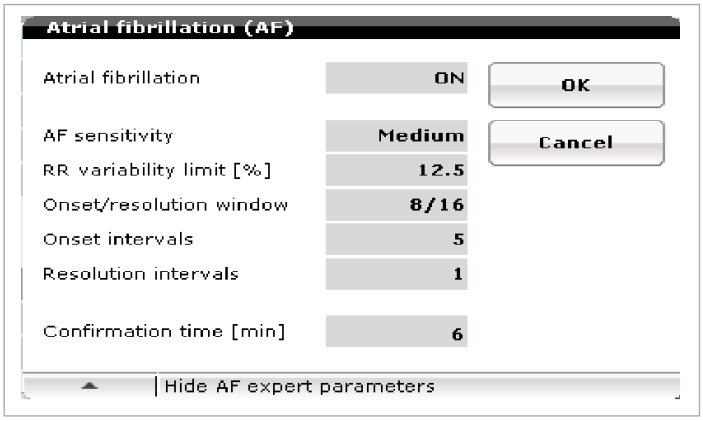


Figure 4: AF menu

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

Atrial fibrillation

o Programmable ON or OFF

AF sensitivity

o Low, Medium, High

Allows the user to preset select 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.

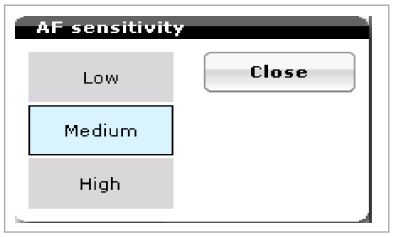


Figure 5: AF sensitivity

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.

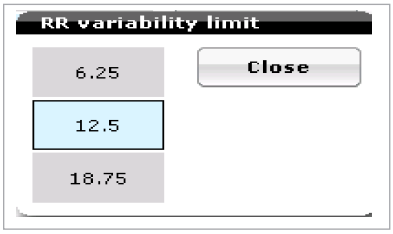


Figure 6: RR variability limit

Onset/Resolution window

The number of cycle lengths used to determine detection and termination of AF. Figure 7 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 criteria is met.

A Resolution criteria 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.

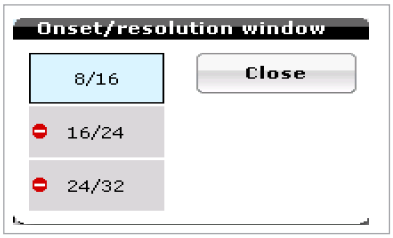


Figure 7: Onset/Resolution window

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.

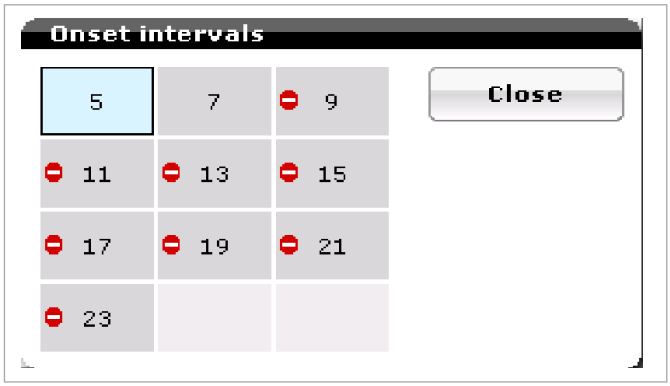


Figure 8: Onset intervals

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.

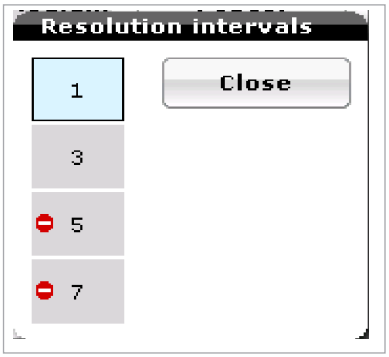


Figure 9: Resolution intervals

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.

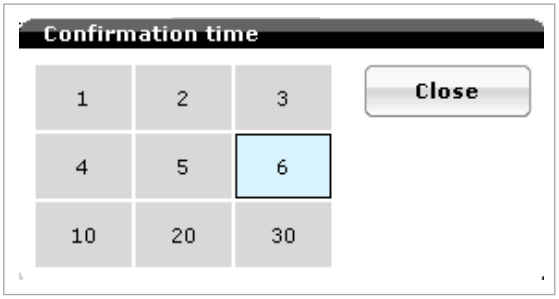


Figure 10: Confirmation time

5.1.2 High ventricular rate (HVR)

BioMonitor 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.

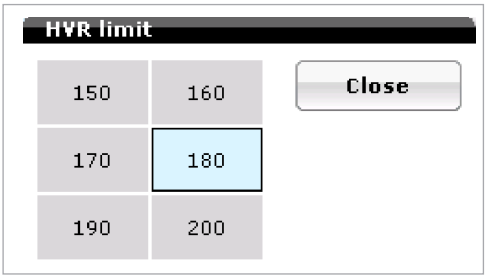


Figure 11: HVR limit

HVR counter

This parameter value represents the lowest 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.

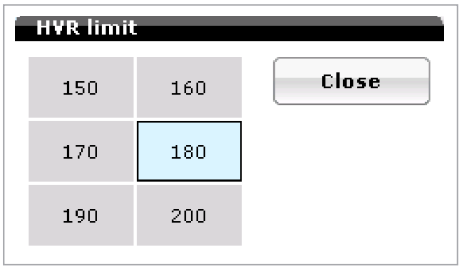


Figure 12: HVR counter

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.

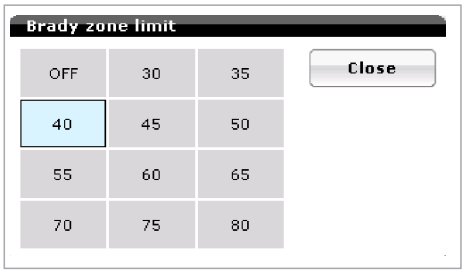


Figure 13: Bradycardia zone limit

Bradycardia duration

This parameter value represents the duration in seconds that the average heart rate is below the programmed bradycardia zone limit for the device to confirm bradycardia is present.

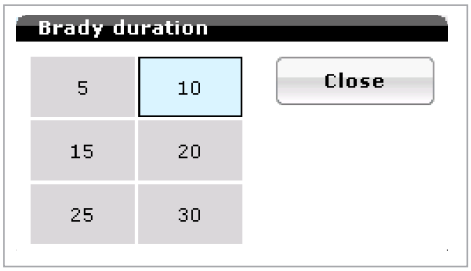


Figure 14: Brady duration

Brady rate decrease

This parameter value represents the percentage in rate decrease that triggers a bradycardia 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).

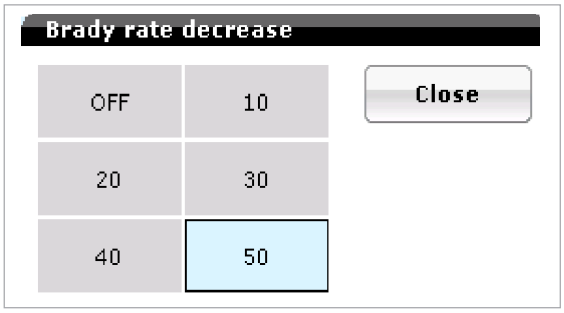


Figure 15: Brady rate decrease

Bradycardia sensitivity

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

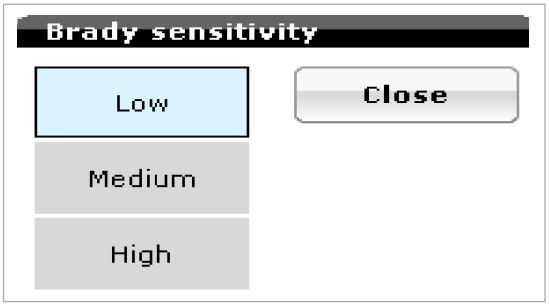


Figure 16: Brady sensitivity

Baseline intervals

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

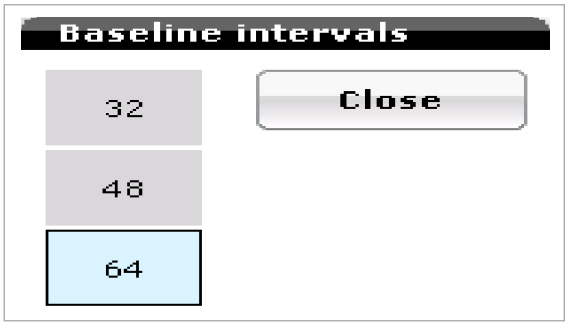


Figure 17: Baseline intervals

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.

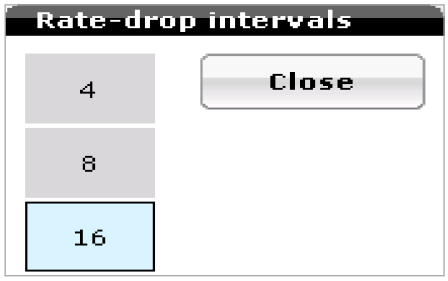


Figure 18: Rate-drop intervals

5.1.4 Asystole duration

Asystole duration

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

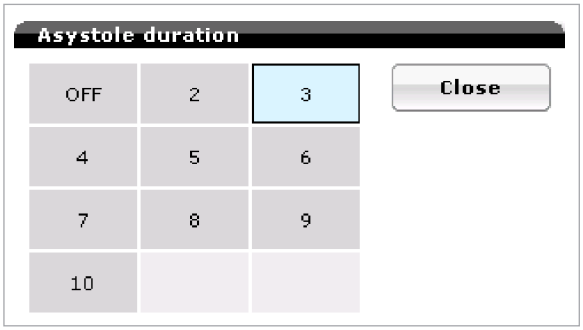


Figure 19: Asystole duration

5.1.5 Patient trigger

Patient trigger

This is an ON/OFF feature which allows a patient to record an sECG by passing a magnet over the device.

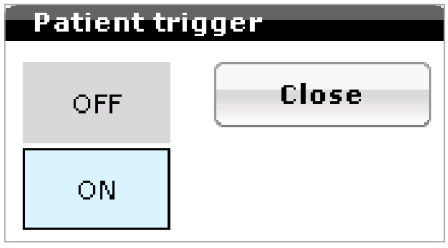


Figure 20: Patient trigger

5.1.6 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.

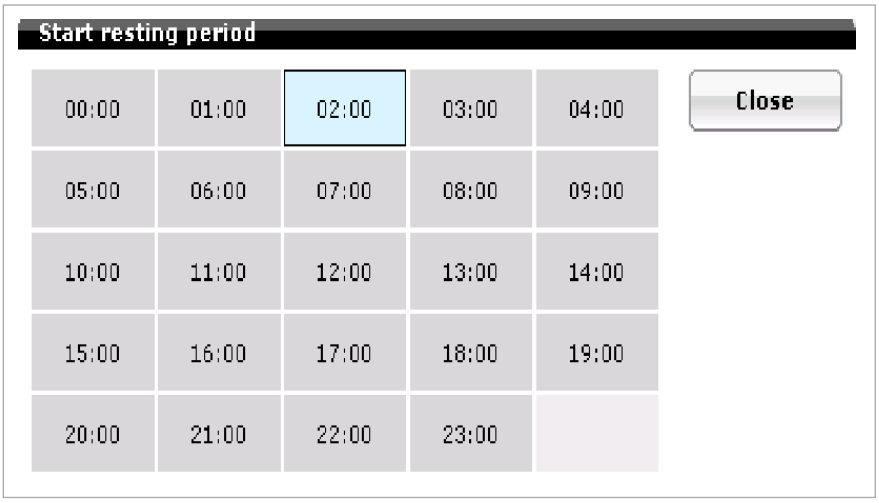


Figure 21: Start resting period

Resting period duration

The Resting period duration parameter is the time duration the data is collected for the Rate trend diagnostic. BioMonitor 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.

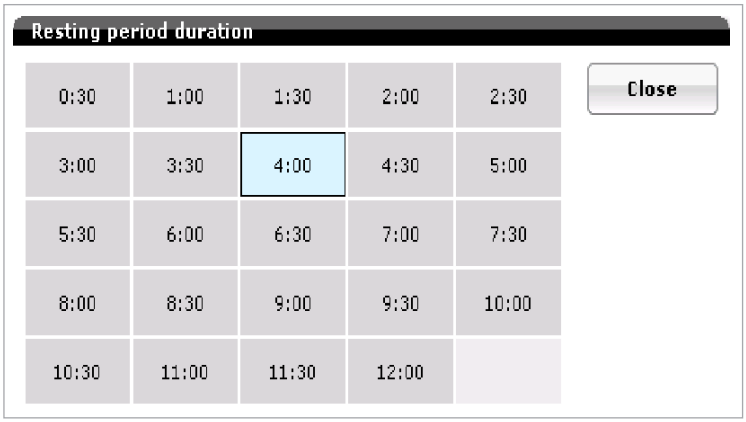


Figure 22: Resting period duration

5.2 Home Monitoring (HM)

The availability of parameters and parameter values is determined by the software used for programming/ interrogating the implantable 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 will transmit all non-urgent data and a daily trend report between 1:00 A.M and 2:00 AM 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 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 23: Time of transmission

5.2.4 Periodic subcutaneous electrocardiogram (sECG)

The BioMonitor can send up to 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 24.

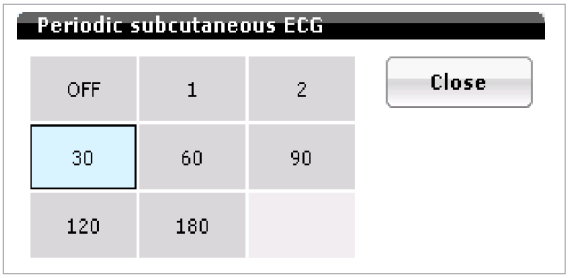


Figure 24: Periodic Subcutaneous ECG

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 25: Last message

5.2.6 HM episode trigger

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

HM episode trigger	
High ventricular rate (HVR)	ON
Bradycardia	ON
Asystole	ON
Patient trigger	ON

Figure 26: 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 five digit 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.

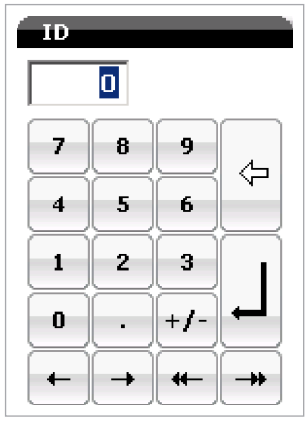


Figure 27: Patient ID

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 40 characters for the first name, as well as for the last name. Enter the patient's name and select the enter key.

Figure 28: First name

Figure 29: 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 30. 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 30: Date of birth

5.3.4 Gender

This section allows the user to select the patients gender.

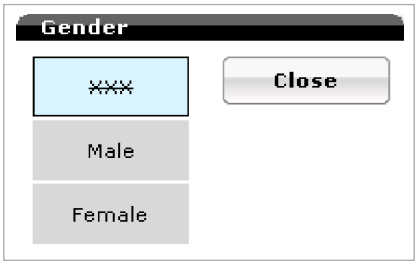


Figure 31: Gender

5.3.5 Date of implant

The implantation date is entered by the user.

Figure 32: 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 19 characters are available to add hospital and city information.

Figure 33: Hospital, City

5.3.7 Physician

The physician name can be added. As with the patient name, up to 19 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 34: Physician

5.3.8 NYHA

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

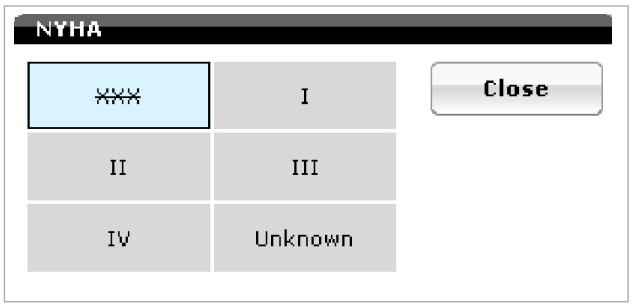


Figure 35: NYHA

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.

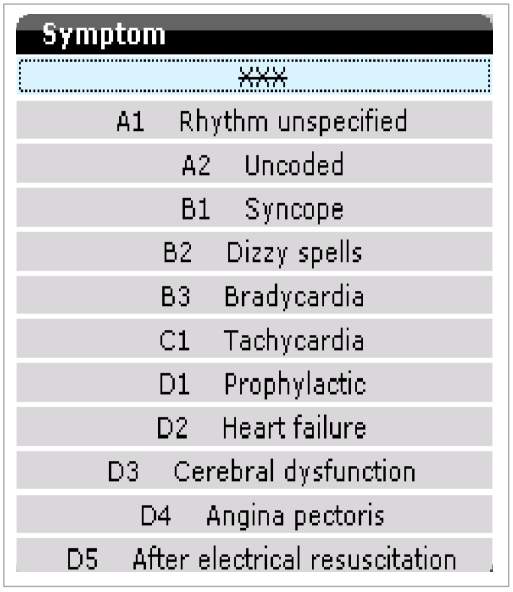


Figure 36: Symptom

5.3.10 Etiology

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

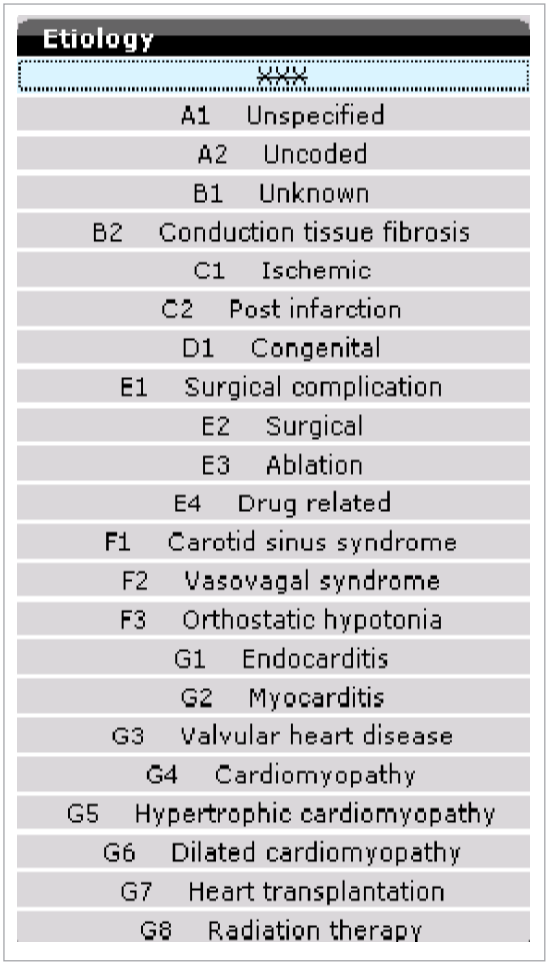


Figure 37: Etiology

6. Diagnostics

6.1 Diagnostics Overview

BioMonitor 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
- Asystole
- Patient trigger

Sensing

- R -wave trends
- Noise duration trend

AF Details

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

6.1.1 General Statistical Information

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

The counters within the statistic features do not operate when a magnet is applied to the implantable monitor.

The counters within the statistic features are reset each time the implantable 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 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.

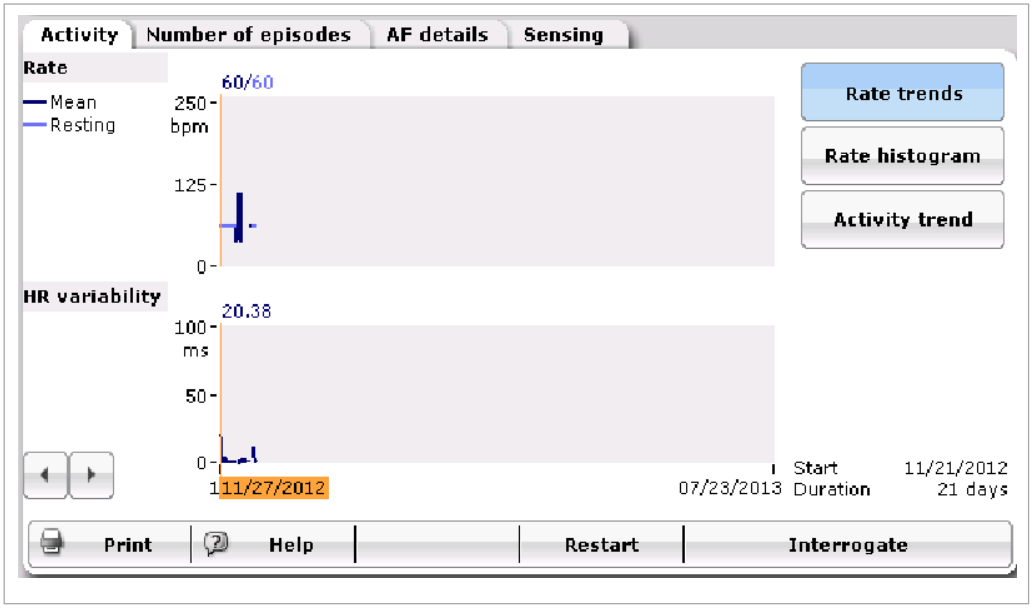


Figure 38: Rate trends

6.2.2 Rate Histogram

The Rate histogram shown in Figure 39, provide the percentage of activity in each rate bin for the BioMonitor. Rate bins are divided into 10 bpm increments.

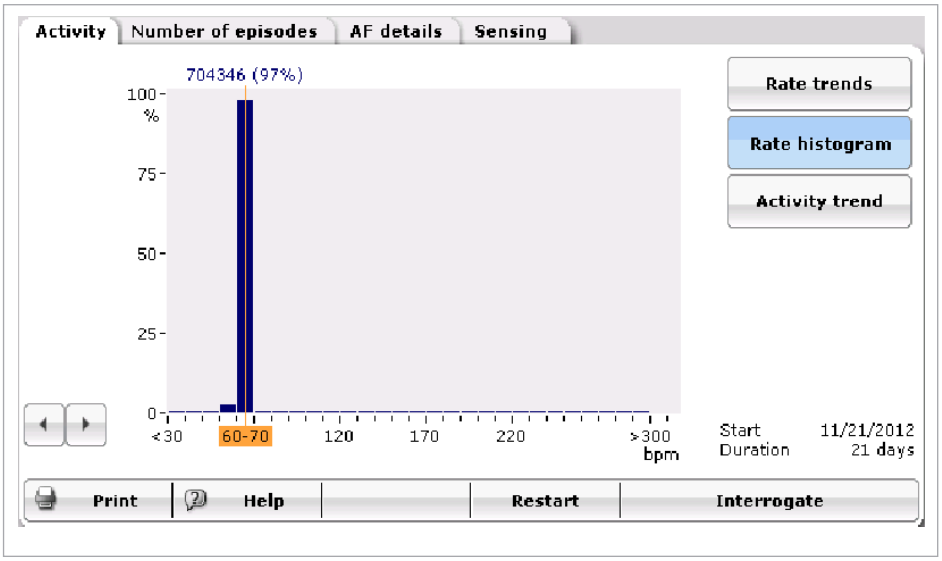


Figure 39: Rate histogram shows the percentage of activity in each rate bin

6.2.3 Activity trend

The Activity trend, shown in Figure 40, displays the daily percentage of activity as detected by the motion sensor of the device.

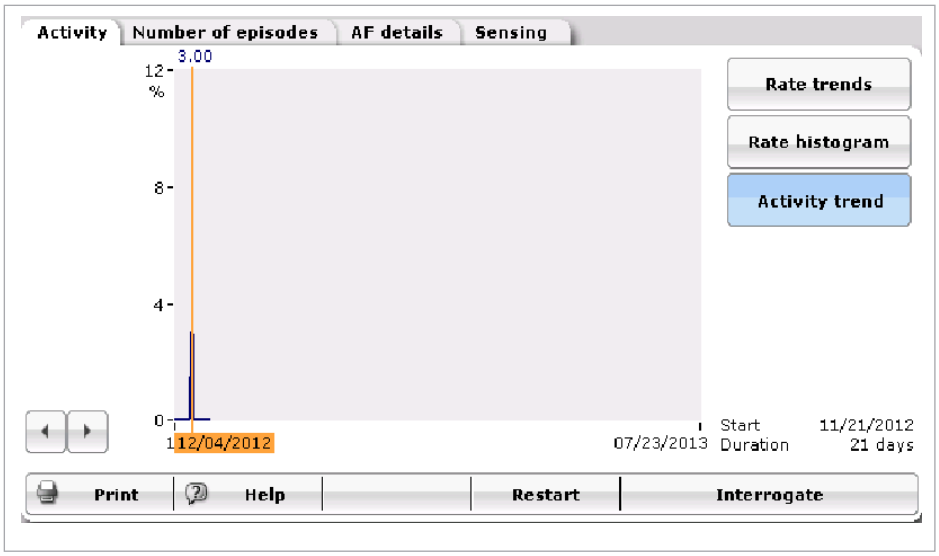


Figure 40: Activity trend

6.3 Number of episodes

The number of episodes, Figure 41, displays the total number of events that occurred since the previous follow-up.

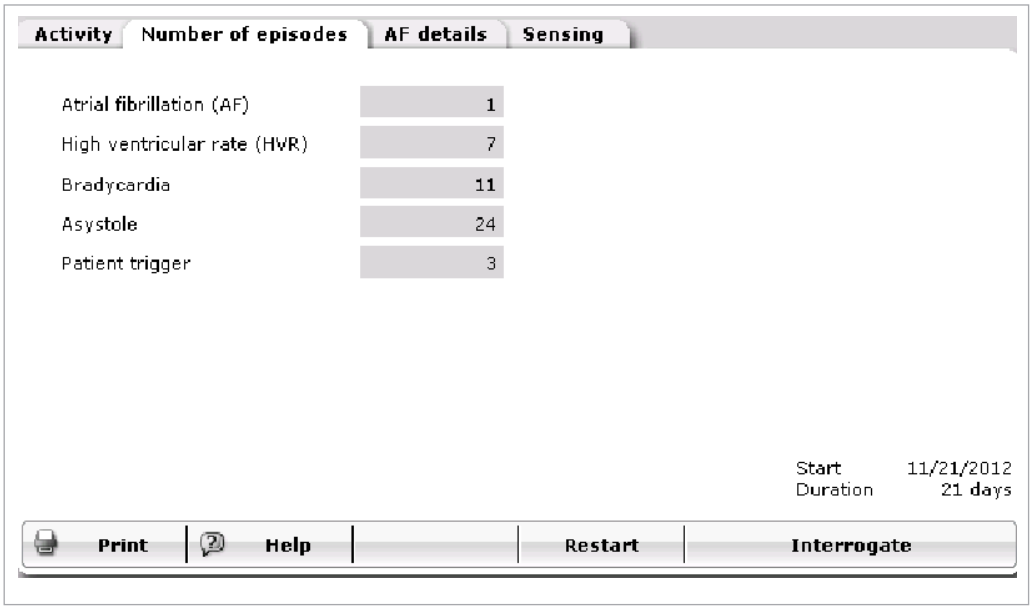


Figure 41: Number of episodes

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.

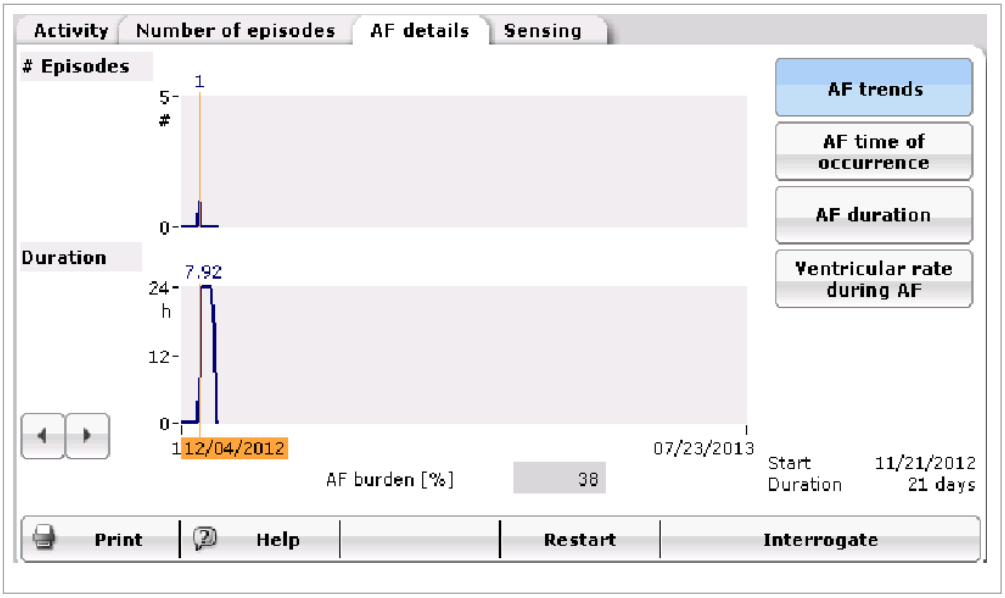


Figure 42: AF trends

6.4.2 AF time of occurrence

The Time of occurrence, shown in Figure 43, 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.

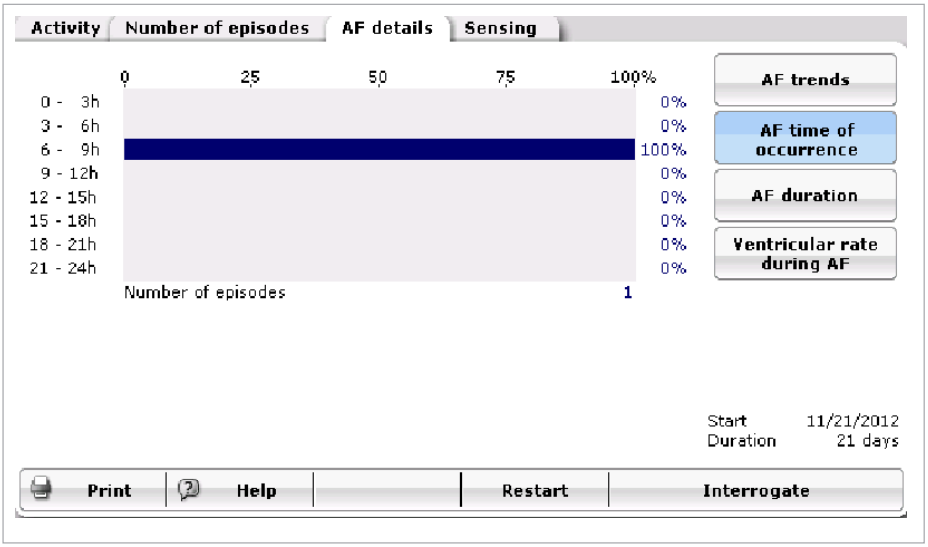


Figure 43: Time of Occurrence

6.4.3 AF duration

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

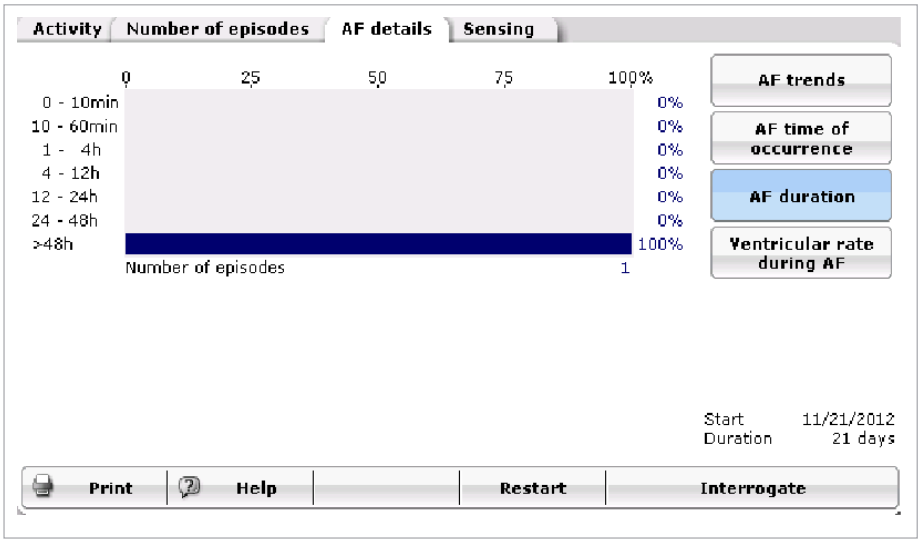


Figure 44: AF duration

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 difference may imply that ventricular rate is more stable during AF.

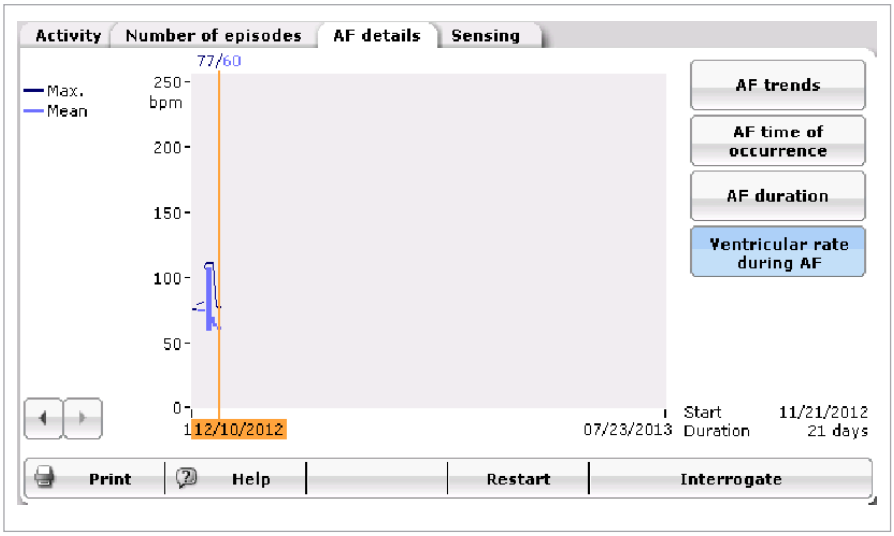


Figure 45: Ventricular rate during AF

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.

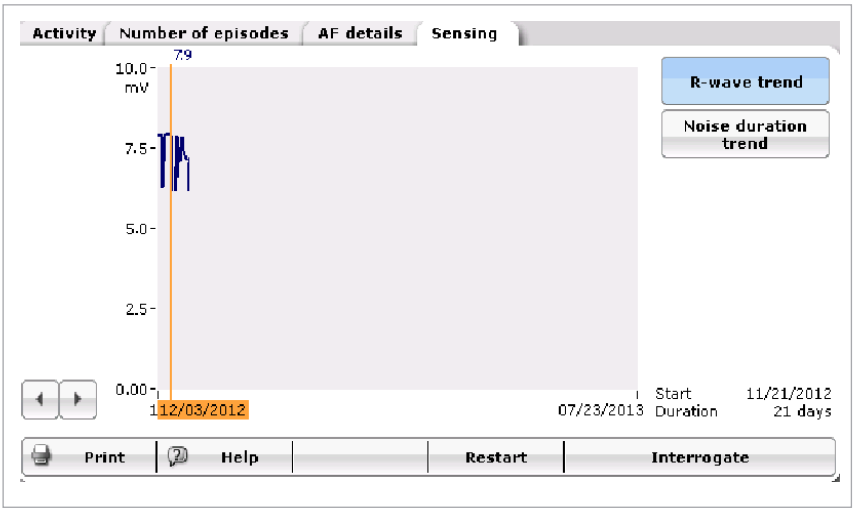


Figure 46: R-wave trend

6.5.2 Noise duration trend

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

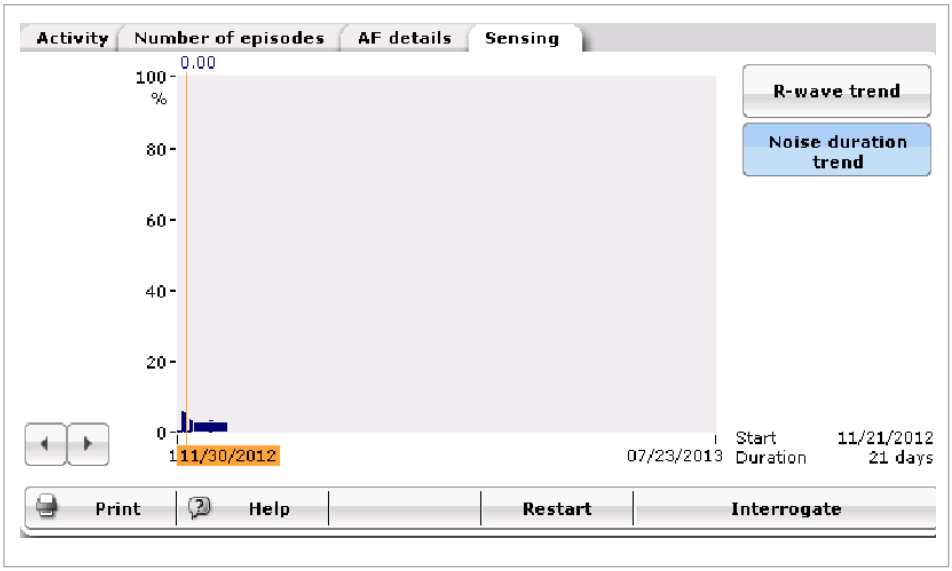


Figure 47: Noise trend duration

7. Other Functions/Features

BioMonitor implantable 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 implant to the physician. Home Monitoring can be used to provide the physician with advance reports from the BioMonitor 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 implant transmits information with a small transmitter, which has a range of about 6 feet (2 meters). The patient's implant data are sent to the corresponding patient device in configurable periodic intervals.

The minimal distance between the implant and the patient device must be 6 inches (15 cm).

7.1.2 Patient Device

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 implant'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 implant 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 implant 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 detects certain events, which initiate a report. These events include

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 implant and the transmission is initiated at the designated time.

Event Report

When certain cardiac and technical events are detected by the implant, 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 following data are transmitted by the Home Monitoring system, when activated. In addition to the medical data, the serial number of the implant is also transmitted.

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 is also transmitted.

Device Status & Home Monitoring Settings

Containing device and message identifying values that pertain to the implant 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 Magnet Effect

Device data collection is not suspended with magnet application.

7.3 Patient Data Memory

Individual patient data can be stored in the implantable monitor's memory. The stored data is automatically displayed upon each interrogation. The amount of data stored is determined by the software version being used. 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.

7.4 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 implantable monitor.

CAUTION

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

8. Product Storage and Handling

8.1 Sterilization and Storage

The implantable 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 implantable monitor. The box contains a double container with the implantable monitor and product documentation.

The implantable 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 implantable 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 implantable monitor is dropped onto a hard surface, return it to BIOTRONIK.

CAUTION

FOR SINGLE USE ONLY – Do not resterilize the implantable 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.

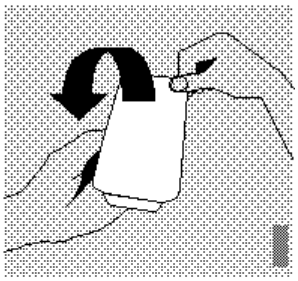
Storage (magnets) – Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid damage to the device.

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

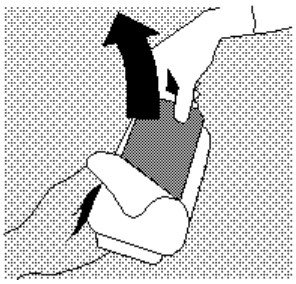
If a replacement implantable monitor is needed, contact your local BIOTRONIK representative.

8.2 Opening the Sterile Container

The implantable 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 Implantable monitor orientation

The implantable monitor should be used with left-side pectoral implants. Either side of the implantable monitor can face the skin.

9. Follow-up Procedures

9.1 General Considerations

The implantable monitor follow-up serves to monitor and provide information related to the patients 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 implantation by pressing the **[Transmit/Program]** button.

9.2 Real-time sECG Transmission

The implantable 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 implanted monitor. They are then displayed together with surface ECG and markers on the programmer screen and printed on the ECG recorder. Likewise, sECG signals and markers identifying ventricular sensed events are received via the programming head, and may be displayed on the programmer screen and printed on the ECG recorder.

9.3 Follow-up page

The follow-up page shown in Figure 46 provides information including the implant and last follow-up date, the device status, number of the diagnostics recordings and Home Monitoring status.

Figure 48: Follow-up page

The ECG and sECG signal display may be adjusted to make viewing easier by pressing on the  icon shown in Figure 48.

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.

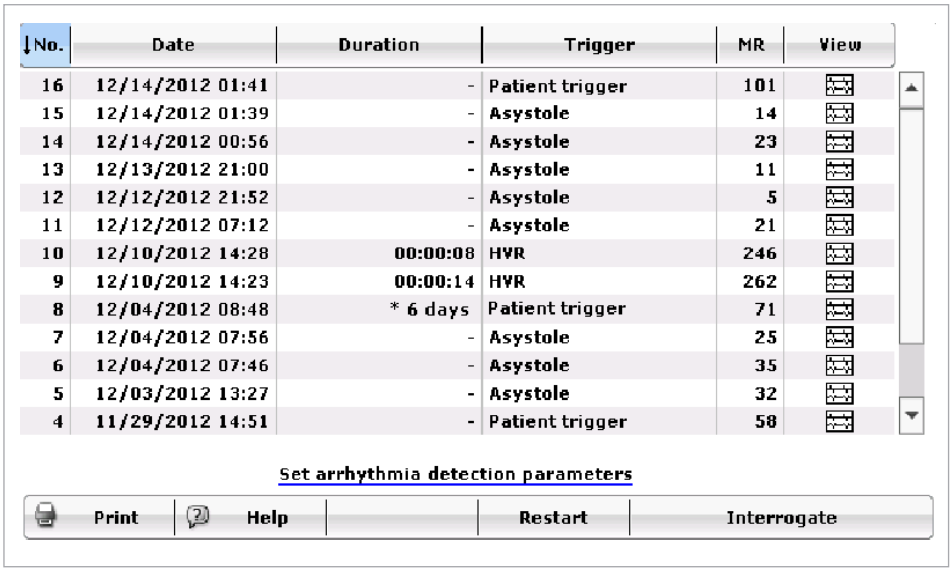


Figure 49: Recordings page

9.5 SECG

BioMonitor can store up to 35.8 minutes of sECGs. The types of sECG recording include HVR, Bradycardia, Asystole and Patient triggered events.

If sECG snapshots of all arrhythmias 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
Patient trigger	3	Oldest, two most recent
High Ventricular Rate	3	Oldest, most recent, longest
Bradycardia	3	Oldest, most recent, longest
Asystole	3	Oldest, most recent, longest

Examples of the different recordings are provided in the following sections. Figures 50-53 are for demonstration purposes only and are not clinically derived.

9.5.1 Atrial fibrillation

Figure 48 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.

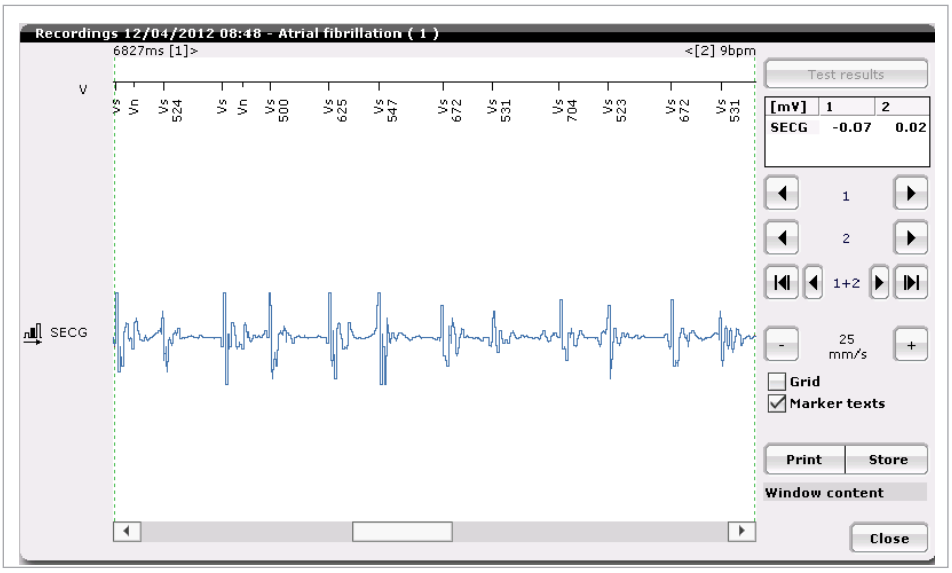


Figure 50: Atrial fibrillation sECG

9.5.2 High ventricular rate

Figure 49 shows an example of a high ventricular rate SECG. The black vertical bar indicates when the HVR criteria was met.

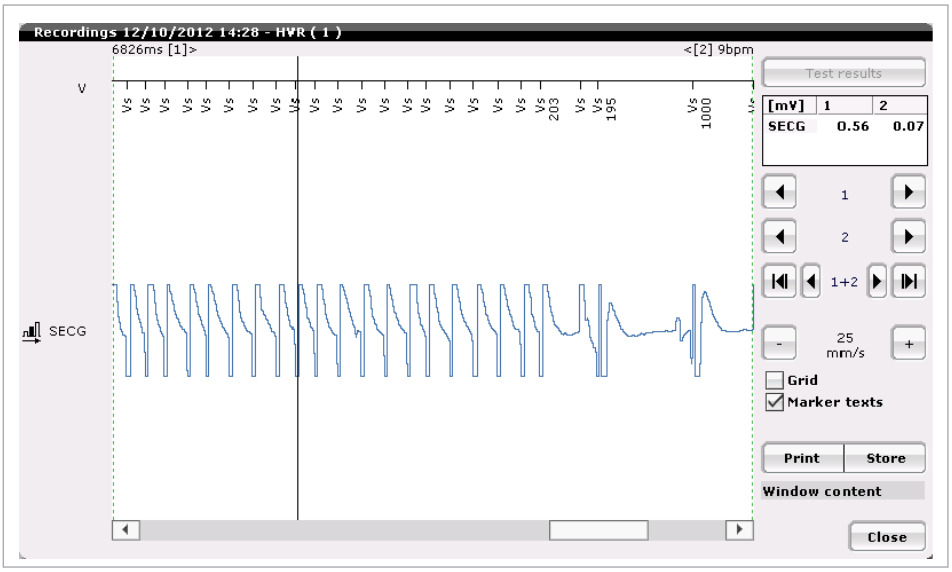


Figure 51: High ventricular rate SECG

9.5.3 Bradycardia

Figure 49 shows an example of a bradycardia recording.

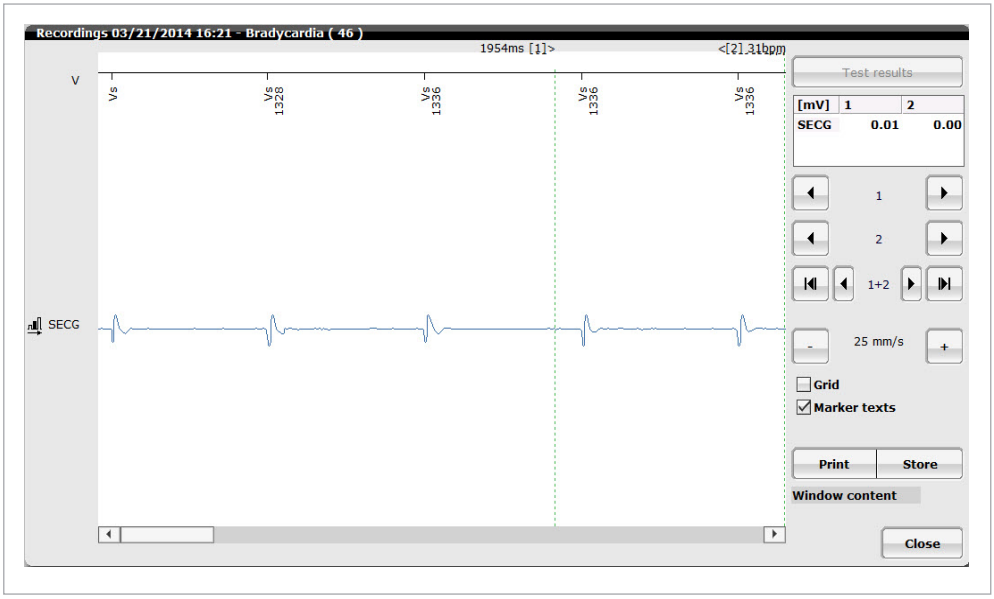


Figure 52: Bradycardia

9.5.4 Asystole

Figure 51 shows an Asystole recording.

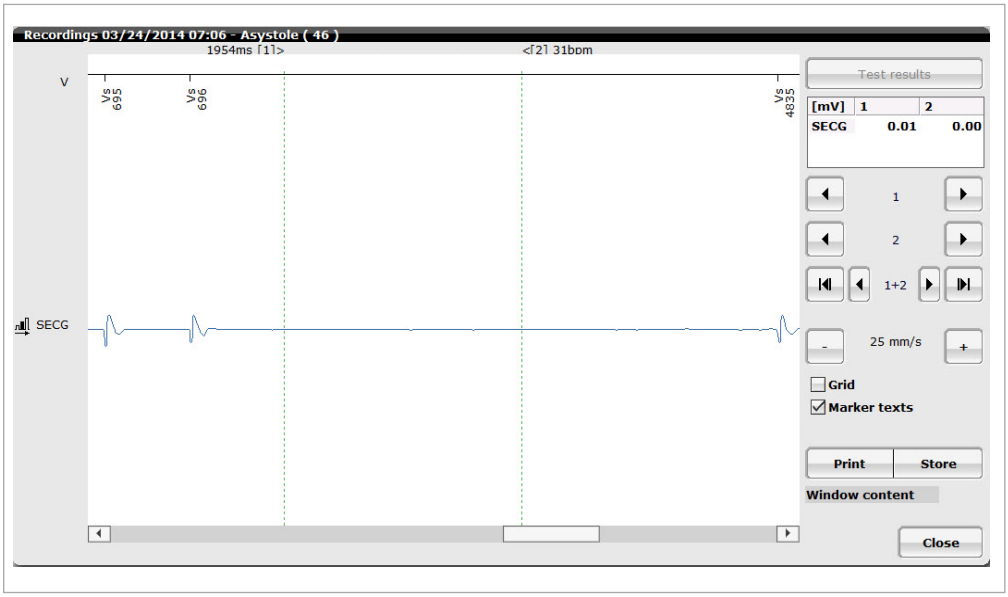


Figure 53: Asystole

9.5.5 Patient trigger

Figure 54 shows a sECG recording from a patient trigger event.

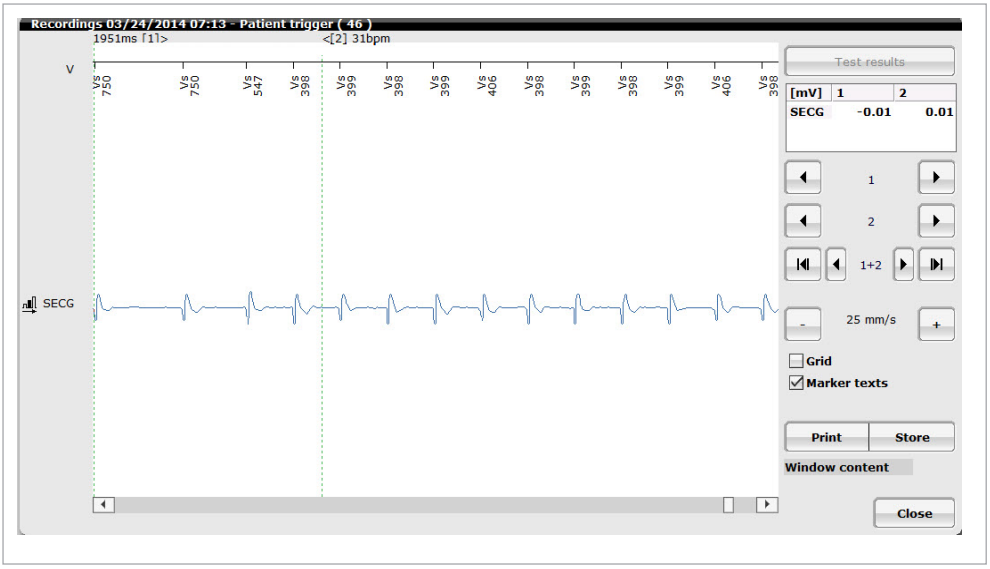


Figure 54: Patient trigger

10. Elective Replacement Indication (ERI)

The service time of BioMonitor 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 implantable 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 implantable monitor interrogation and appears on the printout. Table 2 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 as determined by a programmer message
EOS	End of Service	Identifies the end of the elective replacement indication period.

Table 2: Service cycle definitions

Table 3 shows the expected longevity (in months) from BOS to ERI for the BioMonitor implantable monitors. The programmer software for the BioMonitor implantable monitors provides a fuel gauge to provide information related to the battery status.

Implantable monitor	Standard (BOS - ERI) in Months
BioMonitor	48

Table 3: Nominal BioMonitor longevity

The remaining expected service time is provided in Table 4 below.

Monitor Program	ERI to EOS in Months
ERI	2

Table 4: Remaining Expected Service Time

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

11. Implantation/Explantation

11.1 Implantation

The BioMonitor 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.

The BioMonitor should be implanted in the left side pectoral region. Implant the BioMonitor using standard aseptic techniques.

1. Create a subcutaneous pocket that is slightly smaller that the BioMonitor to minimize device movement.
2. Place the BioMonitor into the pocket with the lettering facing upward.
3. To further minimize device movement, use the suture holes on the header of the device to secure it to the underlying tissue.

11.2 Explantation

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

The implantable monitor should be explanted before the cremation of a deceased patient.

CAUTION

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

Explanted Devices – Return all explanted devices to BIOTRONIK.

11.3 Common Reasons to Explant a Implantable monitor

An implantable monitor may be explanted emergently or at a physician's discretion at any time subsequent to an implant procedure. Reasons for explant include, but are not limited to: patient death; loss of sensing; inability to program/interrogate the implantable monitor; infection, EOS (normal or premature); system upgrade; physician preference for another implantable monitor model; and/or other reason(s) which may or may not be known to the implantable monitor manufacturer. Complications related to other portions of the implantable monitor system (i.e., patient) may also result in implantable monitor explant. Table 5 summarizes some of the more common reasons for implantable monitor explant.

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 5: Common reasons to explant a implantable monitor

12. Technical Data

12.1 Parameters

12.1.1 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

12.1.2 High Ventricular rate

HVR

ON; OFF

HVR Limit

150, 160, 170, **180**, 190, 200

HVR Count

4, 8, 12, 16, **32**, 64

12.1.3 Bradycardia

Brady zone limit

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

Brady duration

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

Brady rate decrease (%)

OFF, 10, 20, 30, 40, 50

Brady Sensitivity

Low, Medium, High

Baseline intervals

32, 48, **64**

Rate-drop intervals

4, 8, **16**

12.1.4 Asystole duration

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

12.1.5 Patient trigger

ON; OFF

12.1.6 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

12.1.7 Home Monitoring

Home Monitoring

ON; OFF

Time of transmission (hh:mm)

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

Period subcutaneous ECG

OFF, 1, 2, **30**, 60, 90, 120, 180 days

12.2 Programmer

ICS 3000 or Renamic

12.3 Materials in Contact with Human Tissue

Housing: Titanium

Header: Epoxy resin

Sealing Plugs: Silicone Rubber

Device coating: Silicone

Electrodes: Fractal Iridium

12.4 Electrical Data/Battery

NOTE: At 37° C

Parameter	BioMonitor
Input impedance	>10 kΩ (A); >10 kΩ (V)
Power source	QMR or $LiMnO_2$
Battery voltage at BOS	QMR 3.0 V $LiMnO_2$ 3.1 V
Conducting surface (coated)	7 cm^2
Conducting shape (coated)	Ellipsoidal Flattened

12.5 Mechanical Data

Model	Size	Mass	Volume
BioMonitor	7.1 x 42.7 x 53.3 mm	26 g	12.5 cc

13. Performance Data

QRS Clinical Study Results

The performance (sensitivity and positive predictive value (PPV)) of QRS detection in BioMonitor was assessed in a clinical study including 36 patients implanted with a BioMonitor. The study design used paired comparison of BioMonitor subcutaneous electrograms (sECG) to 3-electrode Holter surface electrograms (ECG), the gold standard. Simultaneously-recorded electrograms were obtained outside the clinical setting while the patient performed activities of daily living.

QRS detection performance was calculated by comparing BioMonitor detections to the gold- standard detections of the simultaneous Holter recordings. Results of the QRS analysis are shown in Table 5.

Number of patients participating	76
QRS complexes analyzed	107, 795
QRS detection sensitivity	99.5%; 95% CI [99.0% – 99.7%]
QRS detection PPV	97.8%; 95% CI [97.0% – 98.4%]

Table 5: QRS Detection Performance in Clinical Study.

Arrhythmia Bench Testing Results

Bench testing performance analysis was completed utilizing publicly-available datasets from PhysioNet1. The objective of this analysis was to assess the performance of high ventricular rate (HVR), bradycardia, and asystole detection algorithms in BioMonitor on test clips with the natural variability and unexpected arrhythmias of true clinical data. Physician reviewed and annotated recordings were used to create a clip database containing segments of the recordings using 10 minutes of ECG data prior to the annotated arrhythmia (required) and 10 minutes following the annotation, (if available).

A total of 380 clips containing tachycardia (high ventricular rate), bradycardia, asystole, and sinus rhythm were replayed through the BioMonitor via an emulator platform. All clips were physician annotated by PhysioNet, allowing assessment of true positive, false positive, and false negative rates of the algorithms. True or false status was assessed by comparing the physician annotation for each clip to the corresponding arrhythmia detections (true positives, false positives) or lack of arrhythmia detection (false negative) by the BioMonitor. The results of these analyses are summarized in Table 6.

	Sensitivity (%)	PPV (%)
Bradycardia	83.3	100.0
Asystole	96.4	100.0
High Ventricular Rate	81.4	100.0

Table 6. Performance of BioMonitor Arrhythmia Detection of PhysioNet databases

13.1 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. Fifty (50) 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 50 participants, 27 showed at least one true AF episode during the two-day Holter period. A total of 131 AF episodes were annotated from 2132.9 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 1 summarizes the mean episode sensitivity and a mean episode PPV.

Sensitivity (%) ± SD	PPV (%) ± SD
94.3 ± 14.7	73.7 ± 40.3

Table 6: Mean BioMonitor AF detection performance statistics.

14. Order Information

Implantable monitor Type	Order Number
BioMonitor	394 119

FCC Statement: (FCC ID: QRIPRIMUS): 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

BioMonitor

Technical Manual

M4154-B 03/15

MN026r1 3/10/15

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