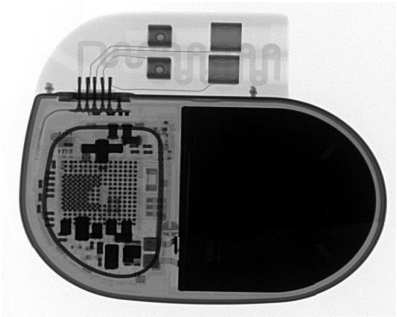
Edora/Evity/Enitra ProMRI® Pacemakers
Technical Manual

BIOTRONIK
excellence for life

Edora/Evity/Enitra ProMRI®

Implantable Pacemakers



X-ray identification

Radiopaque Identification

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

Edora/Evity/Enitra ProMRI®	BIOTRONIK Logo

CAUTION

Because of the numerous available 3.2-mm configurations (e.g., the IS-1 and VS-1 standards), lead/pacemaker compatibility should be confirmed with the pacemaker and/or lead manufacturer prior to the implantation of a pacing system.

CAUTION

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

Contents

1. Device Description 1
2. Indications 3
3. Contraindications 5
4. Warnings and Precautions 7
4.1 Medical Therapy 7
4.2 Storage and Sterilization 8
4.3 Lead Connection and Evaluation 8
4.4 Programming and Operation 9
4.5 Home Monitoring 10
4.6 Electromagnetic Interference (EMI) 11
4.6.1 Wireless Technology 11
4.6.2 Home and Occupational Environments 12
4.6.3 Cellular Phones 13
4.6.4 Hospital and Medical Environments 14
4.7 Pacemaker Explant and Disposal 14
5. Programmable Parameters 15
5.1 Pacing Modes 15
5.1.1 Motion Based Rate-Adaptive Modes 15
5.1.2 CLS Modes 15
5.1.3 Non-Rate-Adaptive Modes 16
5.1.4 Mode Switching 16
5.1.5 Pacing Modes with Triggered Response 19
5.2 Rate Related Functions 19
5.2.1 Basic Rate 19
5.2.2 Rate Hysteresis 20
5.2.3 Scan Hysteresis 21
5.2.4 Repetitive Hysteresis 22
5.2.5 Night Mode 23
5.2.6 Rate Fading 24
5.3 Pulse Specific Features 24
5.3.1 Pulse Amplitude 24
5.3.2 Pulse Width 25
5.4 Automatic Sensitivity Control (ASC) 26
5.4.1 Ventricular Pacing Parameter Options 29
5.5 Timing Features 30
5.5.1 Atrial Refractory Periods 30
5.5.2 Atrial Refractory Period 31
5.5.3 PVARP 31
5.5.3.1 AUTO PVARP 32
5.5.3.2 Ventricular Refractory Period 32
5.5.4 AV Delay 32

5.5.4.1 Dynamic AV Delay 33
5.5.4.2 AV Hysteresis 33
5.5.4.3 AV Repetitive Hysteresis 34
5.5.4.4 AV Scan Hysteresis 34
5.5.4.5 Negative AV Delay Hysteresis 35
5.5.4.6 I-Opt 35
5.5.4.7 AV Opt. Test 36
5.5.5 Ventricular Blanking After Ap 37
5.5.6 Far-Field Protection 37
5.5.7 Safety AV Delay 38
5.5.8 Upper Rate and UTR Response 38
5.6 Lead Polarity 39
5.7 Parameters for Rate-Adaptive Pacing 39
5.7.1 Sensor Gain 40
5.7.2 Sensor Threshold 42
5.7.3 Rate Increase 42
5.7.4 Maximum Activity (Sensor) Rate 43
5.7.5 Maximum Closed Loop Rate 43
5.7.6 Rate Decrease 43
5.8 Management of Specific Scenarios 44
5.8.1 2:1 Lock-In Management 44
5.9 Atrial Upper Rate 44
5.10 Atrial Overdrive Pacing (Overdrive Mode) 45
5.11 Management of Specific Scenarios 46
5.11.1 PMT Management 46
5.11.2 PMT Protection 46
5.11.2.1 PMT Detection and Termination 47
5.12 Adjustment of the PMT Protection Window 48
5.13 Ventricular Capture Control (VCC) 48
5.13.1 Feature Description 48
5.13.2 Capture Control Parameters 49
5.13.3 Search Type 50
5.13.3.1 Algorithm Suspension, Abort and Disabling 53
5.13.4 Ventricular Capture Control Programming 54
5.14 Atrial Capture Control (ACC) 55
5.14.1 Feature Description 55
5.14.2 Search Type 56
5.15 Ventricular Pace Suppression (Vp-Suppression) 57
5.15.1 Feature Description 57
5.15.2 Programmability 57
5.15.3 How the Vp Suppression Algorithm Works 57
5.16 Thoracic Impedance 58
5.17 ProgramConsult® 58
5.18 Home Monitoring 60

5.18.1 Transmission of Information 60
5.18.2 Patient Device 60
5.18.3 Transmitting Data 60
5.18.4 Types of Report Transmissions 61
5.18.4.1 Trend Report 61
5.18.4.2 Event Report 61
5.18.5 Description of Transmitted Data 62
5.18.5.1 IEGM Online HDs 63
5.18.5.2 Periodic IEGM for Home Monitoring Follow-up 63
5.19 MRI 64
5.19.1 MRI Programming 64
6. Diagnostics 67
6.1 Diagnostics Overview 67
6.1.1 General Diagnostic Information 68
6.2 Timing Statistics 68
6.2.1 Event episodes and events 68
6.2.2 Rate histograms 69
6.2.3 AV histogram 69
6.2.4 Pacing trends 69
6.3 Arrhythmia Statistics 70
6.3.1 Atrial Burden 70
6.3.2 Duration of Tachycardia Episode 70
6.3.3 Tachy Episodes/24 h 71
6.3.4 AT/AF Burden 71
6.3.5 Ventricular Response 71
6.4 Heart Failure (HF) Monitor 71
6.4.1 Mean Heart Rate 71
6.4.2 Mean Heart Rate at Rest 72
6.4.3 Heart Rate Variability 72
6.4.4 Patient Activity 72
6.4.5 Thoracic Impedance 72
6.5 24 Hours 74
6.5.1 Rate 74
6.5.2 Percent Paced 74
6.6 More Statistics 74
6.6.1 Event Counters 74
6.6.2 Event Episodes and Events 76
6.6.3 Pulse Amplitude and Threshold 76
6.6.4 Ax-Vs Interval Distribution 77
6.6.5 Sensor Rate 78
6.6.6 Arrhythmia 79
6.6.7 P/R wave trend 80
6.6.8 Lead Impedance Trends with Lead Check 81

6.6.9 Far-field Histogram....82
6.6.10 Vp suppression....83
6.7 IEGMs....84
7. Other Functions/Features....87
7.1 Wandless (RF) Telemetry....87
7.1.1 Establishing Wandless Telemetry....87
7.1.2 Economy Mode....88
7.2 Safe Program Settings....90
7.3 Magnet Effect....90
7.3.1 Automatic Magnet Effect....90
7.3.2 Asynchronous Magnet Effect....90
7.3.3 Synchronous Magnet Effect....90
7.4 Temporary Programming....91
7.5 Patient Data Memory....91
7.6 Position Indicator....92
7.7 Pacing When Exposed to Interference....92
8. Product Storage and Handling....93
8.1 Sterilization and Storage....93
8.2 Opening the Sterile Container....94
8.3 Pacemaker Orientation....94
9. Lead Connection....95
9.1 Auto Initialization....96
10. Follow-up Procedures....99
10.1 General Considerations....99
10.2 Real-time IEGM Transmission....99
10.3 Impedance test....100
10.4 Threshold test....100
10.5 P/R Measurement....102
10.5.1 START (test)....103
10.5.2 Intrinsic Rhythm (test)....103
10.5.3 Mode....104
10.5.4 Sensing test parameters....104
10.5.4.1 Basic Rate....104
10.5.4.2 AV Delay....104
10.5.4.3 Upper Rate....104
10.5.4.4 Pulse Amplitude....104
10.5.4.5 Pulse Width....104
10.5.4.6 Sensitivity....104
10.5.4.7 Pacing Polarity....105
10.5.4.8 Sensing Polarity....105
10.6 AV Opt. Test....105
10.7 Testing for Retrograde Conduction....106

10.7.1 Measuring Retrograde Conduction 107
10.7.2 Requirements for Measurement....107
10.7.3 Follow-up History....107
10.8 Atrial Non-Invasive Programmed Stimulation (NIPS) 108
10.8.1 Description 108
10.8.2 Burst Stimulation 108
10.8.3 Programmed Stimulation....109
10.8.4 Back up Pacing 110
10.8.5 NIPS Safety Features....110
10.9 Optimizing Rate Adaptation 111
10.9.1 Sensor optimization....111
10.9.2 Adjusting the Sensor Gain....112
10.9.3 Adjusting the Sensor Threshold 112
11. Elective Replacement Indication (ERI)....113
12. Explantation 115
12.1 Common Reasons to Explant a Pacemaker 115
13. Technical Data....117
13.1 Modes....117
13.1.1 Rate Adaptation....119
13.1.2 Atrial Capture Control (ACC)....119
13.1.3 Ventricular Capture Control (VCC)....120
13.1.4 Home Monitoring Parameters 120
13.1.5 Additional Functions 121
13.1.6 NIPS Specifications....122
13.2 Programmer 122
13.3 Materials in Contact with Human Tissue 122
13.4 Electrical Data/Battery....123
13.5 Mechanical Data....123
14. Order Information 125
Appendix A....127
Appendix B....131

1. Device Description

Edora/Evity/Enitra ProMRI® pacemakers are BIOTRONIK's state-of-the-art pacing system, providing wandless telemetry communication, intended to simplify implantation and follow-up procedures.

The pacemakers provide two methods of rate-adaptation. Rate-adaptation is achieved through programming of either the unique principle of closed-loop stimulation (CLS) or by motion-based pacing via a capacitive accelerometer.

The basic function of CLS involves the translation of myocardial contractility into patient-specific pacing rates. Specifically, the pacemaker monitors and processes the intracardiac impedance signals associated with myocardial contraction dynamics. Changes in the waveform of this impedance signal are associated with changes in the contraction dynamics of the patient's heart due to the heart's inotropic response to exercise and acute mental stress. By monitoring these changes, the pacemaker can provide a pacing rate that is appropriate and specific to the patient's individual physiologic demands due to exercise and acute mental stress.

For standard motion-based rate-adaptation, the pacemakers are equipped with an accelerometer located within the pacemaker. This sensor produces an electric signal during physical activity of the patient. If a rate-adaptive (R) mode is programmed, then the accelerometer sensor signal controls the stimulation rate.

Edora/Evity/Enitra ProMRI® pacemakers also employs Home Monitoring™ technology, which is an automatic, wireless, remote monitoring system for management of patients with pacemakers. With Home Monitoring, physicians can review data about the patient's cardiac status and pacemaker'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.

Edora/Evity/Enitra ProMRI® pacemakers include two types of wireless technology:

- Inductive coil telemetry link (short range, near-field at 32.768 kHz; for interrogation and programming of the device during follow-ups using the programmer wand)
- RF link (long range, far-field at 403 MHz; for Home Monitoring and wandless telemetry communication used for interrogating and programming the device during follow-ups)

For more information regarding the wireless technology in this device and recommendations for safe and effective operation, refer to Section 4.6.1 of this manual.

Edora/Evity/Enitra ProMRI® pacemakers provide pacing support with a variety of rate-adaptive and non-rate adaptive pacing modes. Pacing capability is supported by a sophisticated diagnostic set.

The Edora/Evity/Enitra ProMRI® pacemakers are designed and recommended for use with atrial and ventricular unipolar or bipolar leads having IS-1 compatible connectors. (Note that IS-1 refers to the International Standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]).

The Edora/Evity/Enitra ProMRI® pacemakers are comprised of single- and triple-chamber devices that are designed to handle a multitude of situations.

Edora/Evity/Enitra SR-T ProMRI®	Single chamber, rate-adaptive, unipolar/bipolar pacing with Home Monitoring
Edora SR ProMRI®	Single chamber, rate-adaptive, unipolar/bipolar pacing
Edora/Evity/Enitra DR-T ProMRI®	Dual chamber, rate-adaptive, unipolar/bipolar pacing with Home Monitoring
Edora DR ProMRI®	Dual chamber, rate-adaptive, unipolar/bipolar pacing

Refer to Chapter 14 of this manual for order information for the Edora/Evity/Enitra ProMRI® devices. The above mentioned pacemakers are MR Conditional devices. Therefore, MR scans are permissible under certain conditions. Refer to the ProMRI® Technical Manual for specific MR conditions of use.

2. Indications

Rate-adaptive pacing with Edora/Evity/Enitra ProMRI® pacemakers is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity.

Generally accepted indications for long-term cardiac pacing include, but are not limited to: sick sinus syndrome (i.e. bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third- degree AV block, and carotid sinus syndrome.

Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual chamber or atrial pacing modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

3. Contraindications

Use of Edora/Evity/Enitra ProMRI® pacemakers are contraindicated for the following patients:

- Unipolar pacing is contraindicated for patients with an implanted cardioverter-defibrillator (ICD) because it may cause unwanted delivery or inhibition of ICD therapy.
- Single chamber atrial pacing is contraindicated for patients with impaired AV nodal conduction.
- Dual chamber and single chamber atrial pacing is contraindicated for patients with chronic refractory atrial tachyarrhythmias.

For a complete discussion of mode-specific contraindications, please refer to Appendix A of this manual.

4. Warnings and Precautions

Certain therapeutic and diagnostic procedures may cause undetected damage to a pacemaker, resulting in malfunction or failure at a later time. Please note the following warnings and precautions:

Rate-Adaptive Pacing Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

High Output Settings High output settings combined with extremely low lead impedance may reduce the life expectancy of the pacemaker to less than 1 year. Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates may lead to premature activation of the replacement indicator.

4.1 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, pacemaker function and stimulation threshold must be checked.

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

Transcutaneous Electrical Nerve Stimulation (TENS) Transcutaneous electrical nerve stimulation may interfere with pacemaker 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 pacemaker/lead system as possible.
- Monitor cardiac activity during TENS use.

Defibrillation The following precautions are recommended to minimize the inherent risk of pacemaker operation being adversely affected by defibrillation:

- The paddles should be placed anterior-posterior or along a line perpendicular to the axis formed by the pacemaker and the implanted lead.
- The energy setting should not be higher than required to achieve defibrillation.
- The distance between the paddles and the pacer/electrode(s) should not be less than 10 cm (4 inches).

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

Lithotripsy Lithotripsy treatment should be avoided for pacemaker patients since electrical and/or mechanical interference with the pacemaker 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 pacemaker.

Electrocautery Electrocautery should never be performed within 15 cm (6 inches) of an implanted pacemaker or lead because of the danger of introducing fibrillatory currents into the heart and/or damaging the pacemaker. Pacing should be asynchronous and above the patient's intrinsic rate to prevent inhibition by interference signals generated by the cautery. When possible, a bipolar electrocautery system should be used.

For 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 pacing system.

4.2 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 pacemaker malfunction (see Section 8.1).

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

FOR SINGLE USE ONLY Do not resterilize the pacemaker or accessories packaged with the pacemaker, 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.

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.

4.3 Lead Connection and Evaluation

The pacemaker requires atrial and ventricular leads with IS-1 compatible connectors. There are no requirements specific to the atrial lead. It is required to use a low polarization ventricular lead for activation of Ventricular Capture Control.

Lead Check The Edora/Evity/Enitra ProMRI® pacemakers have an programmable ON/OFF automatic lead check feature which may switch from bipolar to unipolar pacing and sensing without warning. This situation may be inappropriate for patients with an Implantable Cardioverter Defibrillator (ICD).

Lead/pacemaker Compatibility Because of the numerous available 3.2-mm configurations (e.g., the IS-1 and VS-1 standards), lead/pacemaker compatibility should be confirmed with the pacemaker and/or lead manufacturer prior to the implantation of a pacing system.

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

Lead Configuration Lead configuration determines proper programming of the pacemaker. Pacing will not occur with a unipolar lead if the lead configuration is programmed to bipolar (see Section 9).

Setscrew Adjustment Back-off the setscrew(s) prior to insertion of lead connector(s) as failure to do so may result in damage to the lead(s), and/or difficulty connecting lead(s).

Cross Threading Setscrew(s) To prevent cross threading the setscrew(s), do not back the setscrew(s) completely out of the threaded hole. Leave the torque wrench in the slot of the setscrew(s) while the lead is inserted.

Tightening Setscrew(s) Do not overtighten the setscrew(s). Use only the BIOTRONIK supplied torque wrench.

Sealing System Be sure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle. Failure to do so may result in damage to the plug and its self-sealing properties.

4.4 Programming and Operation

Negative AV Delay Hysteresis This feature insures ventricular pacing, a technique which has been used in patients with hypertrophic obstructive cardiomyopathy (HOCM) with normal AV conduction in order to replace intrinsic ventricular activation. No clinical study was conducted to evaluate this feature, and there is conflicting evidence regarding the potential benefit of ventricular pacing therapy for HOCM patients. In addition, there is evidence with other patient groups to suggest that inhibiting the intrinsic ventricular activation sequence by right ventricular pacing may impair hemodynamic function and/or survival.

Programming VCC If the lead polarization check is not successful, program a shorter pulse width or reduce the starting test amplitude to make the lead polarization check pass. If still unsuccessful, program the pacing pulse amplitude manually.

NIPS Life threatening ventricular arrhythmias can be induced by stimulation in the atrium. Ensure that an external cardiac defibrillator is easily accessible. Only physicians trained and experienced in tachycardia induction and reversion protocols should use non-invasive programmed stimulation (NIPS).

Unipolar/Bipolar All Edora/Evity/Enitra ProMRI® pacemakers can be used with either unipolar or bipolar IS-1 leads.

If the pacing or sensing function is to be programmed to bipolar, it must be verified that bipolar leads have been implanted in that chamber. If either of the leads is unipolar, unipolar sensing and pacing functions must be programmed in that chamber. Failure to program the appropriate lead configuration could result in entrance and/or exit block.

Programmers Use only appropriate BIOTRONIK programmers equipped with appropriate software to program Edora/Evity/Enitra ProMRI® pacemakers. Do not use programmers from other manufacturers.

Pulse Amplitude Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates can lead to premature activation of the replacement indicator.

Pacing thresholds When decreasing programmed output (pulse amplitude and/or pulse width), the pacing threshold must first be accurately assessed to provide a 2:1 safety margin. When using the Ventricular Capture Control feature, the device will automatically set the output to the measured threshold plus the programmed Safety Margin. A new threshold search will occur at scheduled intervals or upon loss of capture.

Electromagnetic Interference (EMI) Active medical devices are subject to electromagnetic interference. In the presence of such interference, telemetry communication may be interrupted and prevent programming.

Intrinsic Rhythm (test) When selecting the Intrinsic Rhythm button, there is no support pacing for the duration the button is depressed. This test should not be performed with pacemaker-dependent patients.

Programming Modifications Extreme programming changes should only be made after careful clinical assessment. Clinical judgment should be used when programming permanent pacing rates below 40 bpm or above 100 bpm.

Short Pacing Intervals Use of short pacing intervals (high pacing rates) with long atrial and/or ventricular refractory periods may result in intermittent asynchronous pacing and, therefore, may be contraindicated in some patients.

OFF Mode Use of the OFF mode should be avoided in pacemaker dependent patients. The OFF mode can be transmitted as a temporary program only to permit evaluation of the patient's spontaneous rhythm.

Myopotential Sensing The filter characteristics of BIOTRONIK pacemakers have been optimized to sense electrical potentials generated by cardiac activity and to reduce the possibility of sensing skeletal myopotentials. However, the risk of pacemaker operation being affected by myopotentials cannot be eliminated, particularly in unipolar systems. Myopotentials may resemble cardiac activity, resulting in pacemaker pulse inhibition, triggering and/or emission of asynchronous pacing pulses, depending on the pacing mode and the interference pattern. Certain follow-up procedures, such as monitoring pacemaker performance while the patient is doing exercises involving the use of pectoral muscles, as well as Holter monitoring, have been recommended to check for interference caused by myopotentials. If sensing of myopotentials is encountered, corrective actions may include selection of a different pacing mode or sensitivity.

Muscle or Nerve Stimulation Inappropriate muscle or nerve stimulation may occur with unipolar pacing when using a non-coated pacemaker.

CLS Rate-Adaptation Under certain circumstances (e.g., EMI, lead dislodgment), the Edora/Evity/Enitra ProMRI® pacemaker may not be able to obtain a usable impedance measurement as required for CLS rate-adaptive pacing. At this point, CLS rate-adaptation will be inactive until the situation is corrected. Rate-adaptation may be programmed to switch to motion based adaptation.

Programmed to Triggered Modes When programmed to triggered modes, pacing rates up to the programmed upper limit may occur in the presence of either muscle or external interference.

Triggered Modes While the triggered modes (DDT, VVT, and AAT) can be programmed permanently, the use of these modes is intended as a temporary setting in situations where maintaining the programming head in place would be impossible or impractical (i.e., during exercise testing or extended Holter monitoring) or as a short term solution to pacemaker inhibition by extracardiac interference. To avoid the potential for early battery depletion, it is important that the triggered modes are not used for long term therapy, and that the pacemaker is returned to a non-triggered permanent program.

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 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 Edora/Evity/Enitra ProMRI® pacemakers 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).

4.6 Electromagnetic Interference (EMI)

The operation of any implanted pacemaker may be affected by certain environmental sources generating signals that resemble cardiac activity. This may result in pacemaker pulse inhibition and/or triggering or in asynchronous pacing depending on the pacing mode and the interference pattern. In some cases (i.e., diagnostic or therapeutic medical procedures), the interference sources may couple sufficient energy into a pacing system to damage the pacemaker and/or cardiac tissue adjacent to the electrodes.

BIOTRONIK pacemakers 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 pacemaker patients. If the patient presumably will be exposed to one of the following environmental conditions, then the patient should be given the appropriate warnings.

Patients should adhere to the following general guidelines regarding EMI:

- Consult with a doctor before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker.
- If the patient becomes dizzy or feels rapid or irregular heartbeats while using an electrical item, release whatever is being touched or move away from the item. The pacemaker should immediately return to normal operation. Consult with a doctor if symptoms do not improve after moving away from the item.

4.6.1 Wireless Technology

The wireless technology incorporated into the Edora/Evity/Enitra ProMRI® devices is defined in 47 CFR 95.601-95.673 (Medical Implant Communication Service). One applicable EMC standard is ISO 14117, and the device has passed all compliance testing. Additionally, the device fulfills Part 15 of the FCC rules and regulations.

An overview of the operating characteristics of the wireless technology is provided in the table below.

Technology	Inductive Coil Telemetry	Radio Frequency (RF)
Uses	Follow-up, programming	Wandless device interrogation and programming during follow-up and Home Monitoring*
Operating Range	0 – 5 cm	0 – 3 meters
Carrier Frequency	32.768 kHz	403 MHz
MedRadio (MICS)		
Modulation	Pulse distance coding, OOK	Binary FSK
Uplink Data Rate	2978 bps	16 kbps
Downlink Data Rate	2978 bps	4 kbps
Effective RF Radiated Output Power	-64.09 dBm EIRP	Less than 25µW EIRP
Field Strength	Less than -50 dBuV/m	Less than 18.2 mV/m

Technology	Inductive Coil Telemetry	Radio Frequency (RF)
Quality of Service	Requires near field (within 5 cm) communication with programmer wand	With a bit error rate less than or equal to 10^{-3} for the system, there is no degradation in the wandless telemetry performance.
Security	Coil communication requires close proximity (less than 10 cm) and patient acceptance.	The wireless wand session can only be started via coil, which requires close proximity (less than 10 cm) and patient acceptance. During wireless wand initiation, the implant and programmer are “paired” via a secondary channel (coil exchange).
Bandwidth	4.71 kHz	Less than 300 kHz
FCC Regulation	47 CFR 15.209(a)	47 CFR Part 95

Table 1: Wireless Communication

* No BIOTRONIK devices can be programmed via Home Monitoring.

To ensure proper Wandless Telemetry operation, please refer to the Electromagnetic Interference section of the Renamic Programmer Technical Manual.

The communication provided by the implant system is robust against EMI. To avoid interference, it is recommended that the distance between the device and programmer is maintained within 3 meters. If the connection deteriorates due to the programmer being too close to an electromagnetic device or radio emitter, unplug the programmer and move the programmer to another location that is free of noise. Reconnect the power cord and reboot the programmer.

In rare cases that the Wandless Telemetry feature ceases operation due to strong electromagnetic interference, communication can be re-established with coil communication (programmer wand) so that the patient follow up can continue nearly seamlessly. Also, the system is designed so that if telemetry is ever lost or interrupted for any reason during programming, the patient is not left in a potentially unsafe partially programmed state.

Wireless security is ensured by a proprietary communication protocol to implantable devices that is security protected by state-of-the-art measures.

4.6.2 Home and Occupational Environments

The following equipment (and similar devices) may affect normal pacemaker 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. If EMI inhibits operation of a pacemaker or causes it to revert to asynchronous operation at the programmed pacing rate or at the magnet rate, moving away from the source or turning it off will allow the pacemaker to return to its normal mode of operation. Some potential EMI sources include:

High Voltage Power Transmission Lines High voltage power transmission lines may generate enough EMI to interfere with pacemaker operation if approached too closely.

Home Appliances Home appliances normally do not affect pacemaker operation if the appliances are in proper condition and correctly grounded and encased. There are reports of pacemaker disturbances caused by electrical tools and by electric razors that have touched the skin directly over the pacemaker.

Communication Equipment Communication equipment such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with pacemaker 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 pacemaker operation if approached too closely.

Electrical Appliances Electric hand-tools and electric razors (used directly over the skin of the pacemaker) have been reported to cause pacemaker disturbances. Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pacemaker operation.

Electronic Article Surveillance (EAS) Equipment such as retail theft prevention systems may interact with the pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary. If the patient experiences symptoms when near an electronic anti-theft or entry control system, they should promptly move away from the equipment. After moving away from the equipment, the cardiac device should resume its previous state of operation.

4.6.3 Cellular Phones

Recent studies have indicated there may be a potential interaction between cellular phones and pacemaker operation. Potential effects may be due to either the radio frequency signal or the magnet within the phone and could include inhibition or asynchronous pacing when the phone is within close proximity (within 6 inches [15 centimeters]) to the pacemaker.

Based on testing to date, effects resulting from an interaction between cellular phones and the implanted pacemakers 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 pacemaker 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.

4.6.4 Hospital and Medical Environments

Electrosurgical Cautery Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause asynchronous or inhibited pacemaker operation. If use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pacemaker and leads as possible.

Lithotripsy Lithotripsy may damage the pacemaker. If lithotripsy must be used, do not focus the beam near the pacemaker.

External Defibrillation External defibrillation may damage the pacemaker. Attempt to minimize current flowing through the pacemaker and lead system by following the precautions.

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

4.7 Pacemaker Explant and Disposal

Device Incineration Never incinerate a pacemaker. Be sure the pacemaker 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 13.

5.1 Pacing Modes

A complete list of pacing modes available for Edora/Evity/Enitra DR-T ProMRI® are shown below.

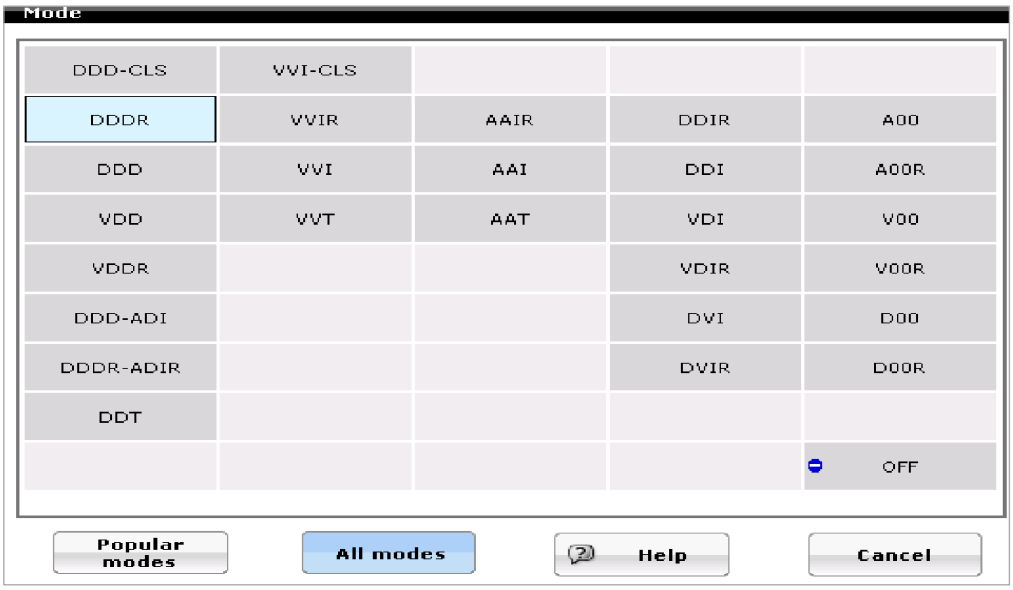


Figure 1: Pacing Modes

NOTE:

Ventricular Capture Control is only available with the following pacing modes: DDD-CLS, VVI-CLS, DDDR, VDDR, VVIR, DDD, VDD, VVI, DDD-ADI, and DDDR-ADIR.

5.1.1 Motion Based Rate-Adaptive Modes

The motion based rate-adaptive modes are designated with an “R” in the fourth position of the NBG pacemaker code on the programmer screen. The rate-adaptive modes function identically to the corresponding non-rate-adaptive modes, except that the basic rate increases when physical activity is detected by the motion sensor.

In demand modes (DDDR, DDIR, DVIR, VDDR, VDIR, VVIR, AAIR), it is possible that the atrial and/or ventricular refractory period can comprise a major portion of the basic interval at high sensor-modulated rates. This may limit the detection of spontaneous events or even exclude their recognition altogether. Further details of this potential occurrence are provided in Section 5.5.1.

Motion based rate-adaptive pacing is also available in non-demand modes (DOOR, VOOR, AOOR). No sensing of intrinsic cardiac signals occur in these modes. Caution should be used as these modes may lead to competition between pacing and intrinsic cardiac signals.

5.1.2 CLS Modes

As explained in the device description, the pacemakers can be programmed to use a unique rate-adaptive principle called Closed Loop Stimulation (CLS) to adapt the patient’s pacing rate.

The device measures electrical impedance by injecting a small AC current between the pacemaker case and the ventricular electrode tip. The induced voltage (which is proportional to the intracardiac impedance) is also measured between pacemaker case and ventricular electrode tip.

CAUTION

Rate-Adaptive Pacing Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

CLS Rate Adaptation Under certain circumstances (e.g., EMI, lead dislodgment), the Edora/Evity/Enitra ProMRI pacemaker device may not be able to obtain a usable impedance measurement as required for CLS rate-adaptive pacing. At this point, CLS rate-adaptation will be inactive until the situation is corrected. Rate-adaptation may be programmed to switch to motion based adaptation.

The DDD-CLS and VVI-CLS mode is functionally equivalent to the DDDR and VVIR pacing modes, respectively. However these modes use the CLS concept to determine the pacing rate variations that are mediated by the body's own cardiovascular control. In these modes, the atrial and/or ventricular refractory periods may comprise a major portion of the basic interval at high rates. This could limit the detection of spontaneous events or even exclude their recognition altogether. However, this phenomenon will not limit the functionality of the mode switch.

Motion based rate adaptive pacing will take over if the CLS pacing algorithm switches into a passive mode.

5.1.3 Non-Rate-Adaptive Modes

Non-rate-adaptive modes that are programmable with the Edora/Evity/Enitra ProMRI® pacemakers perform similarly to earlier generations of BIOTRONIK pacemakers.

5.1.4 Mode Switching

Edora/Evity/Enitra DR-T ProMRI® pacemakers provide Mode switching to change pacing modes as a result of atrial tachycardias. Mode switching is designed to avoid tracking of non-physiologic atrial rates due to paroxysmal atrial tachycardias (PATs). Mode switching is only available in atrial tracking modes DDD(R), VDD(R), DDD-CLS, and DDD(R)-ADI(R).

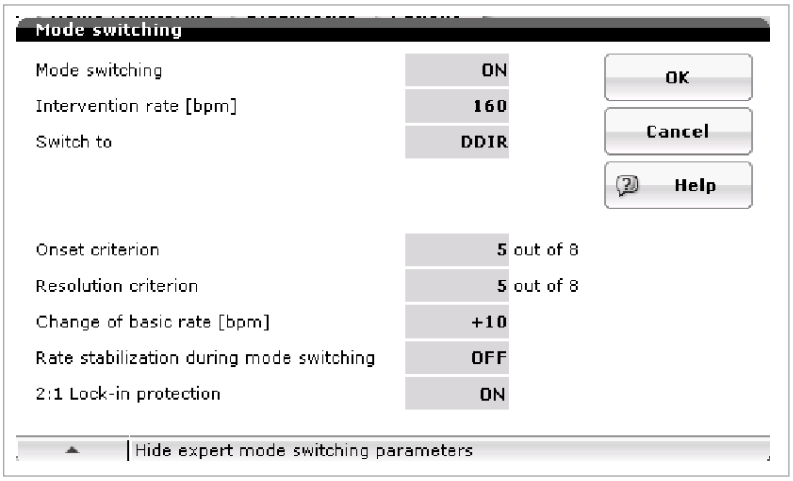


Figure 2: Mode switching screen

Table 2 is a summary of the parameters associated with Mode switching.

Parameter	Range	Default Setting
Mode Switching	ON, OFF	ON
Intervention Rate	100...(10)...250 bpm	160 bpm
Switch to	Dependent on Basic Mode Setting	DDIR
Onset Criterion	3...(1)...8 out of 8	5
Resolution Criterion	3...(1)...8 out of 8	5
Basic Rate during mode Switching	OFF, +5...(+5)...+30	+10
Rate stabilization during mode switching	ON, OFF	OFF
2:1 Lock-in Protection*	ON, OFF	ON

Table 2: Mode switching Parameter Summary

Intervention rate

The Intervention rate is the minimum atrial rate at which Mode switching will occur and is programmable by the user.

Switch to Pacing

Switch to pacing is the mode the device reverts to during Mode switch.

Table 3 shows the choices for Mode switch modes based on the programmed device mode.

Programmed Device Mode	Mode Switch Mode Options	Default Mode for Mode Switch
DDDR-ADIR	DDIR	DDIR
DDD-ADI	DDI,DDIR	DDIR
DDD-CLS	DDIR	DDIR
DDDR	DDIR	DDIR
DDD	DDI, DDIR	DDIR
VDDR	VDIR	VDIR
VDD	VDI, VDIR	VDIR

Table 3: Mode Switch Mode Operations

Onset Criterion

The mode switch onset criterion uses an X of 8 rolling counter with a default X value of 5. This means that 5 out of the last 8 atrial events must be faster than the programmed intervention rate for Mode switch to occur.

The higher the X value, the harder it is to declare Mode Switching. Conversely, the lower the value, the easier it is for Mode Switching to occur.

Atrial oversensing due to far-field events sensed in the atrial channel may lead to inappropriate Mode Switch declaration.

DR-T pacemakers do not use intervals with paced events towards the mode switch count, thereby reducing the risk of inappropriate mode switch due to sensor competition.

* 2:1 Lock-in protection not available in HF-T devices unless BiV pacing is OFF.

Resolution Criterion

The resolution criterion uses an X of 8 rolling counter with a default X value of 5. This means that 5 out of the last 8 atrial events must be slower than the programmed intervention rate for a return to the programmed pacing mode.

The higher the resolution criterion, the harder it is to end a Mode Switching event. Conversely, the lower the value, the easier it is for Mode Switching to end.

Basic Rate during Mode Switching

This refers to the basic pacing rate while mode switching is active. The value selected is added to the programmed basic rate value to become the basic rate during mode switch. By default this value is +10 bpm. If the basic rate is programmed to 60 bpm, then the Basic Rate during mode switching would be 70 bpm (60 bpm +10 bpm).

Rate Stabilization during Mode Switching

This feature is designed to minimize sudden rate changes in the ventricle that can occur with Afib and intact conduction. To minimize the sudden rate changes, DR-T pacemakers use the Rate Fading concept. The device determines a four-beat ventricular rate average and provides ventricular support pacing any time the rate goes below the averaged rate minus 10 bpm.

2:1 Lock-In Protection

For patients who experience atrial flutter, there is a small chance that Mode Switch will not occur due to atrial events falling within the far-field protection window. As a result, inappropriate fast tracking up to the upper tracking rate may occur. The 2:1 Lock-in protection feature is designed to promote Mode Switching and prevent the patient discomfort that may be associated with an inappropriately tracked atrial tachycardia.

2:1 Lock-in Protection behavior is more likely to occur if the far-field protection parameter is programmed too long (greater than 150 ms). This potentially allows every other atrial event to occur in the far-field protection interval.

When the device senses eight consecutive atrial events in the far-field protection window and the ventricular paced response rate is greater than 100 bpm, the AV Delay is extended to a maximum value of 300 ms (AV Delay + FFP interval to a max of 300 ms) for one event. If the event sensed in the FFP window moves with the ventricular paced event during the extension of the AV Delay, it is a cross-talk event due to ventricular pacing. However, if it does not move with the ventricular paced event when the AV Delay is extended, it is a intrinsic atrial event (atrial flutter event)

Additionally, during DDI(R), the AV-delay is set to 100 ms.

Mode Switch Events are recorded in memory and are available to the user through the following diagnostics:

- IEGM Recordings Found in the Recordings Tab
- Mode switch counter in Diagnostics
- Mode switch duration in Diagnostics

Mode switching is available during magnet application after 10 cycles of ASYNC pacing and during ERI.

5.1.5 Pacing Modes with Triggered Response

Pacing modes with triggered response correspond to their respective demand pacing modes, except that a sensed event will not inhibit but will rather trigger a pacing pulse, simultaneously with the sensed event, into the same chamber where sensing has occurred. The demand and corresponding triggered pacing modes are:

Demand:	DDD	VVI	AAI
Triggered:	DDT	VVT	AAT

The DDT triggered pacing mode fixes the AV delay to 150 ms and does not provide a safety AV delay.

Pacing modes with triggered response may be indicated in the presence of interference signals to prevent inappropriate pulse inhibition. They may also have diagnostic application for ECG identification of sense events as an alternative to marker signals. Triggered pacing may also be used for hemodynamic as well as electrophysiologic studies and for termination of tachycardias by non-invasive triggering of pacemaker pulses with chest wall stimuli generated by an external pacemaker.

CAUTION

Programmed to Triggered Modes When programmed to triggered modes, pacing rates up to the programmed upper limit may occur in the presence of either muscle or external interference.

Triggered Modes While the triggered modes (DDT, VVT, and AAT) **can** be programmed permanently, the use of these modes is intended as a temporary setting in situations where maintaining the programming head in place would be impossible or impractical (i.e., during exercise testing or extended Holter monitoring) or as a short term solution to pacemaker inhibition by extracardiac interference. To avoid the potential for early battery depletion, it is important that the triggered modes are not used for long term therapy, and that the pacemaker is returned to a non-triggered permanent program.

5.2 Rate Related Functions

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

5.2.1 Basic Rate

The Basic rate parameter (Figure 3) sets the lower pacing rate for the pacemaker and may be programmed from 30 bpm to 200 bpm. Edora/Evity/Enitra ProMRI® pacemakers will allow pacing lower than the programmed rate when the parameter Hysteresis is enabled. The lowest pacing rate possible with Hysteresis programmed ON is 30 ppm. The Hysteresis parameter is found under Basic rate / Night rate.

Programming conflicts for Basic rate occur when Atrial and/or Ventricular Capture Control is programmed ON. When capture control is programmed ON, the basic rate is limited to 100 bpm.

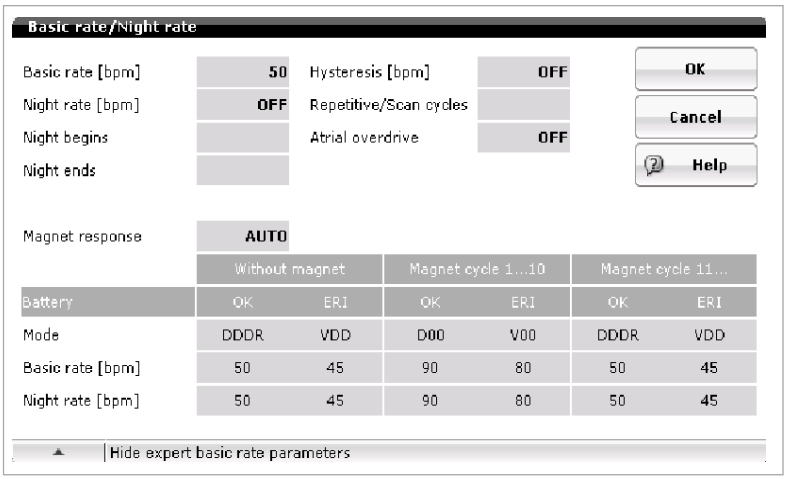


Figure 3: Basic Rate/Night Rate Screen

CAUTION

Programming Modification Extreme programming changes should only be made after careful clinical assessment. Clinical judgment should be used when programming permanent pacing rates below 40 bpm or above 100 bpm.

5.2.2 Rate Hysteresis

Parameter Name	Range	Standard Value	Unit
Rate Hysteresis	OFF, -5...(-5)...-25, -45, -65	OFF	bpm
Repetitive/Scan Hysteresis	OFF, ON (5)	OFF	---

Table 4: Rate Hysteresis Parameters and Ranges

Rate Hysteresis may be programmed to promote intrinsic conduction for patients who can tolerate intrinsic activity below a programmed pacing or sensor-indicated rate. This hysteresis rate becomes the lowest rate permitted before the device begins pacing. Rate hysteresis requires a sensed event in order to activate. Rate hysteresis will remain active as long as the intrinsic activity remains above the programmed hysteresis rate. When the intrinsic rate falls to the hysteresis rate, the device will deliver one paced event at the hysteresis rate and then begin pacing at the programmed basic rate. Pacing will remain at the basic/sensor rate until a new intrinsic event occurs. This new intrinsic event reactivates rate hysteresis. An example is shown in Figure 4. Features such as scan and repetitive hysteresis are available to promote intrinsic activity and are discussed in this chapter.

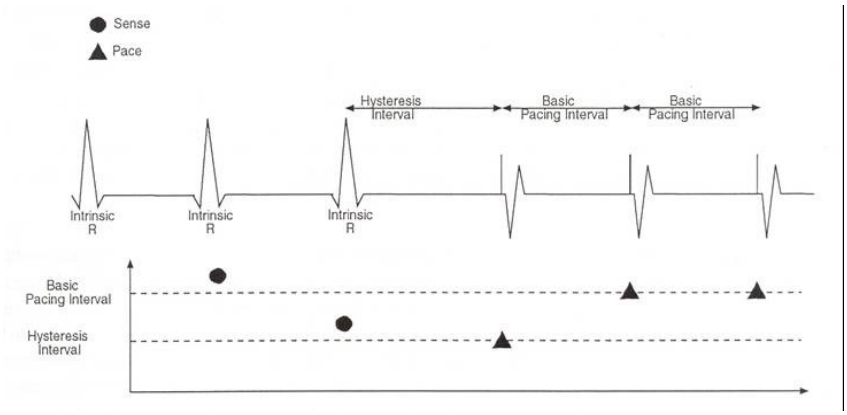


Figure 4: Example of Rate Hysteresis

Repetitive Rate Hysteresis and Scan Rate Hysteresis are Rate Hysteresis enhancements available in the Edora/Evity/Enitra ProMRI® pacemaker families. These features encourage a patient's own rhythm, periodically allowing for, or looking for, intrinsic activity.

NOTE:

If rate adaptation is active, the Hysteresis rate is based on the current sensor-indicated rate and the value of the programmable parameter.

Hysteresis is not available in CLS or DVI, and DVIR modes.

If Hysteresis is used in the DDI mode, the AV delay must be programmed shorter than the spontaneous AV conduction time. Otherwise, stimulation in the absence of spontaneous activity occurs at the hysteresis rate instead of the lower rate.

During night mode the rate will not fall below the programmed night rate even if Hysteresis can take it to a lower rate. Programming conflicts arise when the total decrease in rate is below 30 bpm. Care should be exercised to avoid programming a Night Mode rate and hysteresis that is below what is appropriate and may be tolerated by the individual patient.

5.2.3 Scan Hysteresis

Scan Rate Hysteresis seeks to encourage an intrinsic rhythm during long periods of pacing. The algorithm is enabled after 180 consecutive paced events. Once the 180 paced events are met, the device will pace at the hysteresis rate for up to 5 cycles. If intrinsic activity does not return during that period, pacing will continue at the programmed bradycardia rate or sensor indicated rate, whichever is higher.

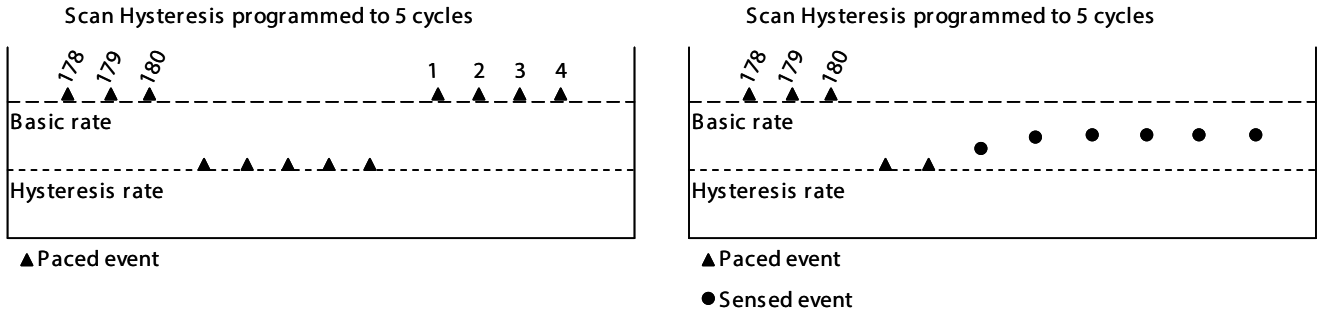


Figure 5: Scan Hysteresis

In the left portion of Figure 5, pacing occurs at the hysteresis rate for the programmed number of five cycles. With no return of intrinsic rhythm, the device resumes pacing at the basic rate. Once pacing begins at the basic rate, the Scan Hysteresis count starts over. The right side of Figure 5 shows a return of intrinsic activity after two paced events at the hysteresis rate. Once the intrinsic rate returns, hysteresis is maintained.

Scan hysteresis has been incorporated to promote intrinsic cardiac rhythm and may reduce pacemaker energy consumption.

NOTE:

Scan Hysteresis can be used during night mode, but it will not take the rate below the programmed night rate.

Scan Hysteresis is only available when Hysteresis is selected on.

After the ASYNC effect following magnet application, hysteresis is available.

5.2.4 Repetitive Hysteresis

When Repetitive Rate Hysteresis is activated (after 180 consecutive sensed events), the feature allows a programmed number of paced events (up to 5) at the hysteresis rate to occur before returning to the programmed basic/sensor rate. This is done to allow return of intrinsic activity in the hysteresis zone. If intrinsic activity is sensed, pacing will be inhibited. If no intrinsic activity returns within the programmed number of events, pacing will resume at the programmed basic rate or sensor rate.

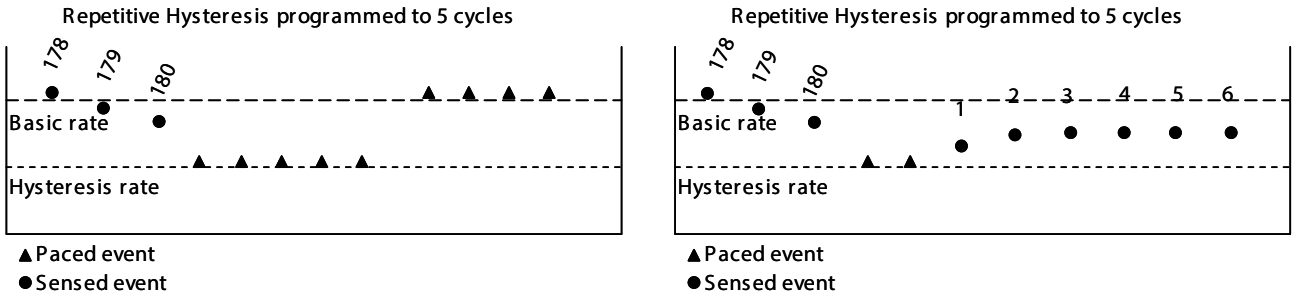


Figure 6: Repetitive Hysteresis

In the left portion of Figure 6, pacing occurs at the hysteresis rate for the programmed number of five cycles. Because there is no return of the intrinsic rhythm, the device restores pacing at the programmed/sensor rate. The right side of Figure 6 shows a return of intrinsic activity after two paced events at the hysteresis rate.

Once the intrinsic rhythm returns, the repetitive hysteresis count begins again. If the intrinsic rhythm falls to the hysteresis rate before the 180 count has been met, the device uses the standard rate hysteresis.

Repetitive hysteresis has been incorporated to promote spontaneous cardiac rhythm and may reduce pacemaker energy consumption.

NOTE:

Repetitive Hysteresis can be used during night mode but it will not take the rate below the programmed night rate.

Repetitive/Scan Hysteresis is only available when a Hysteresis rate is selected.

There is one Standard Hysteresis interval which occurs before the programmable number of Repetitive Hysteresis occur.

5.2.5 Night Mode

Night rate is designed to reduce the pacing rate to emulate the decreased metabolic needs during sleep. When Night Rate is active, the pacing rate automatically decreases during the programmed hours. The Night Rate is programmable from 30 to 200 bpm or OFF as shown in Figure 7.

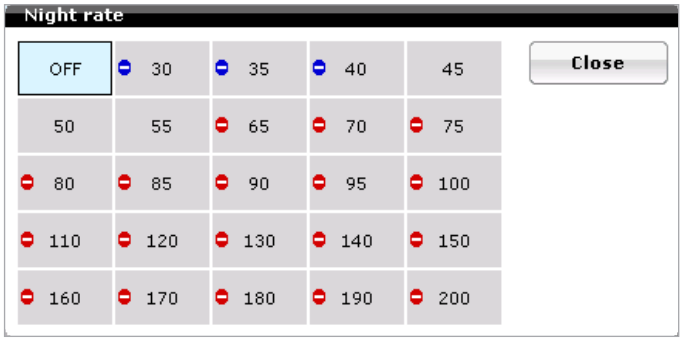


Figure 7: Night Rate Screen

When Night rate is active, the Basic rate is reduced to the Night rate using the Sensor rate Decrease value programmed in the device, even when the sensor is OFF. When Night rate ends, Edora/Evity/Enitra ProMRI® pacemakers use the Sensor rate Increase value to return to the basic rate.

If the sensor is programmed OFF, the device will use the default sensor rate increase/decrease values. The use of sensor increase/decrease values prevents sudden rate changes that may be felt by the patient.

During Night rate, the accelerometer remains active, and the patient will continue to receive the benefit of sensor-driven pacing.

Night rate is NOT available when CLS is active as CLS determines rate requirements for the patient. One may consider reducing the basic rate of the device to optimize the intrinsic rhythm.

Caution should be used in patients who travel across time zones as Night rate is clock-based. Night rate start and stops times are programmable in 10 minute increments.

The red conflicts seen in Figure 7 show that Night Rate cannot be programmed greater than the basic rate value. The value OFF will always correspond to the programmed basic rate of the device.

NOTE:

When Night rate and Rate Hysteresis are programmed, the lowest pacing rate possible is the programmed Night rate. Edora/Evity/Enitra ProMRI® pacemakers do not allow programming less than 30 bpm.

NOTE:

When Night Mode and Ventricular Capture Control are programmed ON simultaneously in VVI(R), VCC will not take the rate below the programmed night rate

Over time, the pacemaker's internal time-of-day clock will exhibit a discrepancy with the actual time (less than 1 hour per year). This will cause a corresponding discrepancy between the programmed bed and wake times and the actual times that the system changes the rate.

The programmer automatically updates the pacemaker time-of-day clock each time the pacemaker is interrogated or programmed.

The actual time when the respective increase or decrease in rate occurs may begin up to 4 minutes after the programmed time because of internal pacemaker timing.

5.2.6 Rate Fading

Rate Fading is intended to prevent a sudden drop in heart rate when the pacemaker transitions from tracking an intrinsic rhythm to pacing due to an abrupt decrease in the intrinsic rate, in order to prevent potential reactions such as dizziness, light headedness, lack of energy and fainting.

With Rate Fading enabled, the pacemaker calculates the Fading Rate, which is a four beat average of the intrinsic rate reduced by 10 bpm. When the intrinsic rate drops considerably (below the Fading Rate), the pacing rate begins at the RF rate and then decreases gradually by the programmable Decay Rate to the Sensor Indicated Rate or Basic Rate.

NOTE:

The Fading Rate cannot exceed the programmed Maximum Activity Rate and cannot increase faster than the RF Rate decrease (programmable in bpm/cycle).

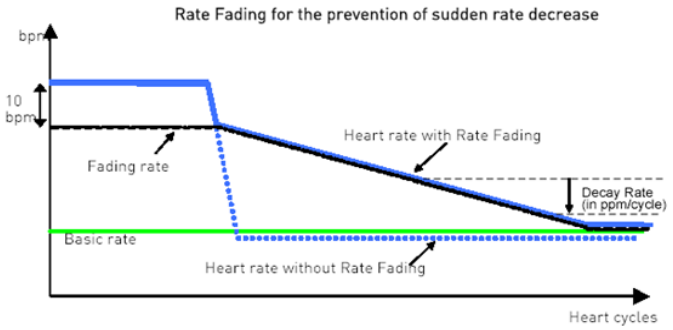


Figure 8: Rate Fading

The Rate Fading feature is available after 10 ASYNC while in magnet mode and disabled at ERI and in backup mode.

5.3 Pulse Specific Features

Features related to the pacing pulse.

5.3.1 Pulse Amplitude

The pulse amplitude can be programmed as shown in Table 5.

Chamber	Range	Default
Atrium	0.2...(0.2)...3.0...(0.2)...6.0...(0.5)...7.5 V	3.0 V
Ventricle	0.2...(0.2)...3.0...(0.2)...6.0...(0.5)...7.5 V	3.0 V

Table 5: Pulse Amplitude Parameters

Pacing outputs can be programmed in each chamber from 0.2 V to 7.5 V if Capture Control is inactive. Caution should be used when programming high outputs for an extended period of time, as this can result in reduced longevity.

Programming the pacing output in the atrial or ventricular channel is not possible when Atrial and Ventricular Capture Control is ON as the programmed output is determined by the device.

NOTE:

When VCC is programmed to ATM, the pulse amplitude cannot be programmed by the user to a value higher than the programmed Maximum VCC Amplitude (Max. Ampl.). When VCC is programmed to ON, the pulse amplitude will be set by the device to the threshold plus the programmed Safety Margin, but never lower than the Minimum VCC Amplitude (fixed at 0.7 V.)

CAUTION

Pulse Amplitude Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates can lead to premature activation of the replacement indicator. If a pulse amplitude of 7.0 V or higher is programmed and high pacing rates are reached, output amplitudes may differ from programmed values.

Programming Modifications Extreme programming changes should only be made after careful clinical assessment. Clinical judgment should be used when programming permanent pacing rates below 40 bpm or above 100 bpm.

5.3.2 Pulse Width

The pulse width can be programmed as shown in Table 6.

Chamber	Range	Default
Atrium	0.1, 0.2, 0.3, 0.4, 0.5, 0.75, 1.0, 1.25, 1.5 ms	0.4 ms
Ventricle	0.1, 0.2, 0.3, 0.4, 0.5, 0.75, 1.0, 1.25, 1.5 ms	0.4 ms

Table 6: Pulse Width Parameters

The selected pulse width determines the duration for which the programmed pulse amplitude will be applied to the heart. The pulse width is independently programmable (0.1 to 1.5 ms) for the atrial and ventricular channels. Pulse width remains constant throughout the service life of the pacemaker.

Edora/Evity/Enitra ProMRI® pacemakers come with nine available Pulse Width choices in each chamber, providing a wide variety of choices for pacing management. The Pulse width options are shown in Figure 9. Pulse widths may be extended, allowing reduction of Pulse amplitude to prevent diaphragmatic stimulation in patients. When ventricular capture control is programmed ON, pulse width programming cannot exceed 0.4 ms.

If a threshold test was performed, the capture threshold value obtained is displayed at the bottom of the Pulse width screen to help guide output programming.

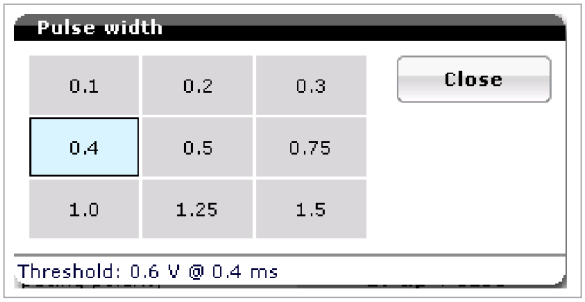


Figure 9: Pulse Width

NOTE:

When VCC is programmed to ON or ATM, the pulse width cannot be programmed to a value higher than 0.4 ms.

5.4 Automatic Sensitivity Control (ASC)

Chamber	Range	Default
Atrium	Auto, 0.1...(0.1)...1.5...(0.5)...7.5 mV	Auto
Ventricle	Auto, 0.5...(0.5)...7.5 mV	Auto

Table 7: Automatic Sensitivity Control Parameters

The parameter “sensitivity” is used to set the pacemaker’s threshold for detecting intracardiac signals. The lower the programmed sensitivity value, the higher the device’s sensitivity.

If intracardiac signals are of low amplitude, a change to a higher sensitivity (lower value) may be necessary. Conversely, if the sensing amplifier is responding to extraneous signals, such as artifact or interference, a change to a lower sensitivity (higher value) may resolve the difficulty. In dual-chamber sensing modes, the sensitivity values for the atrial and ventricular channels are independently programmable.

With unipolar sensing, the lowest sensitivity setting is 0.5 mV in the atrium. Blue conflict icons for the atrial channel shown in Figure 10 show a conflict message, requiring the user to program the lead to a bipolar configuration before the value can be permanently programmed.

A conflict will appear when attempting to program 0.5 mV in the ventricle, as shown in Figure 10, with unipolar sensing. The user is asked to extend the Ventricular Blanking after Ap to resolve the conflict. This is done to reduce the potential of oversensing the atrial pacing spike with unipolar sensing. Once resolved, the user can program 0.5 mV sensitivity in the ventricle.

If a sensing test has been performed, the sensing value is displayed at the bottom of the sensitivity parameter to guide sensing programming of the device.

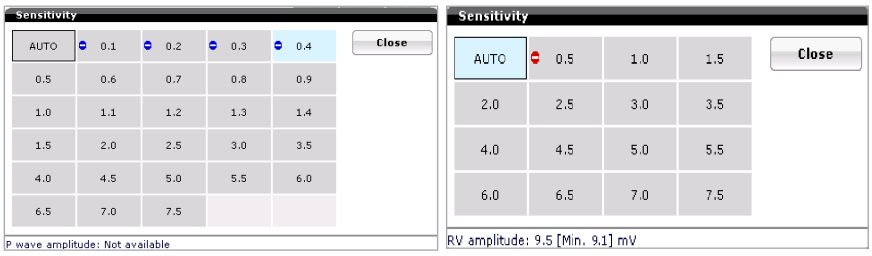


Figure 10: Sensitivity Screens for the Atrium and Ventricle

Automatic Sensitivity Control

The Automatic Sensitivity Control (ASC) feature automatically measures the peak amplitude and adapts the sensing threshold automatically. After every sensed event, the function starts the detection hold-off period and measures the highest peak of the amplitude. After this initial stage, the sensitivity is initially reduced to 50% of the measured peak of the amplitude. At the end of the phase duration, sensitivity is reduced to 25% of the measured peak of the amplitude and maintained until detection of the next event. The sensitivity can never go below the minimum threshold shown below in the sensed event summary.

Atrial and ventricular ASC function for sensed events are the same, except that the Detection Hold-off and Step Duration periods use different values. This is shown in Figure 11.

Sensed Events Summary

	Detection Hold-off	Step Duration	Minimum Threshold
Atrium	101 ms	82 ms	0.2 mV
Ventricle	121 ms	125 ms	2.0 mV

Table 8: Automatic Sensitivity Control Duration Values

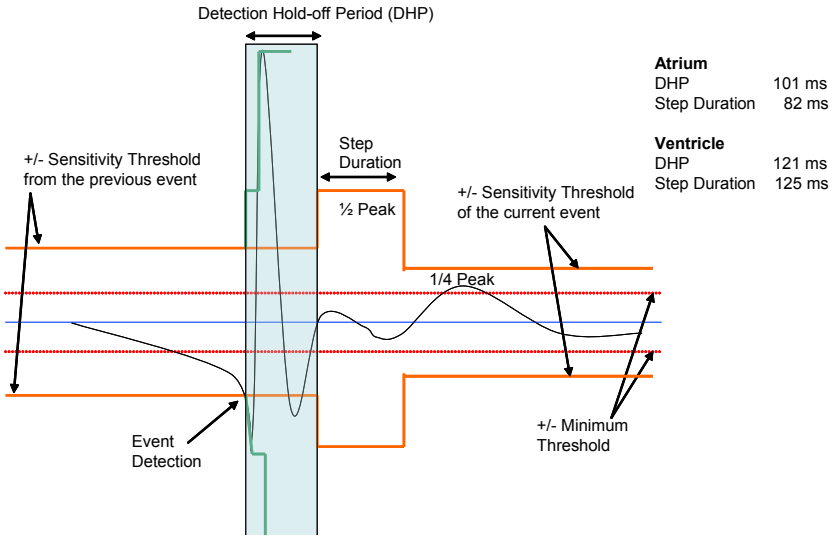


Figure 11: Automatic Sensitivity Control for Sensed Events

Post Paced Event Summary

Following paced events, the Detection Hold-off period is extended slightly in all chambers to prevent oversensing of the paced complex. The step duration is twice that of sensed events to prevent T-wave oversensing.

Atrial and ventricular post-pace sensing function the same except for the Detection Hold-off and Step Duration. The atrial channel provides an additional step if the sensitivity is programmed to 0.2 mV as is shown in Figure 12.

	Detection Hold-off	Step Duration Total	Minimum Threshold
Atrium	120 ms	164 ms (2 x 82 ms)	0.2 mV [1]
Ventricle	200 ms	250 ms (2 x 125 ms)	2.0 mV

Table 9: Automatic Sensitivity Control Values Post Paced Events

1 If the sensing is programmed unipolar, the minimum threshold will be 0.5 mV

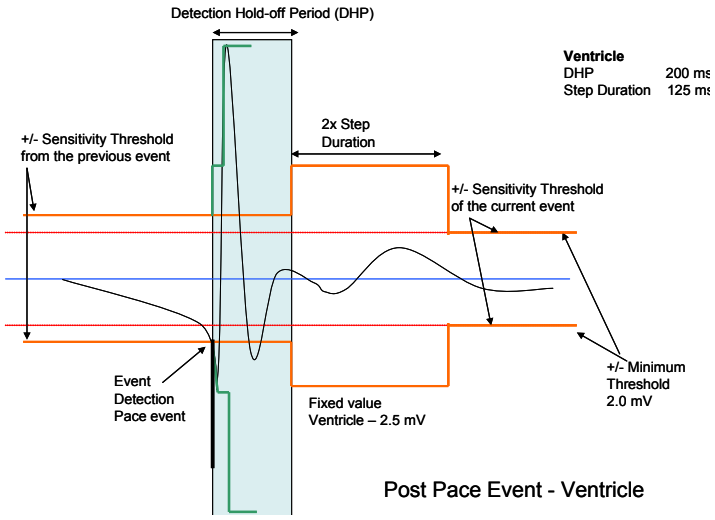


Figure 12: Automatic Sensitivity Control for Ventricular Paced Events

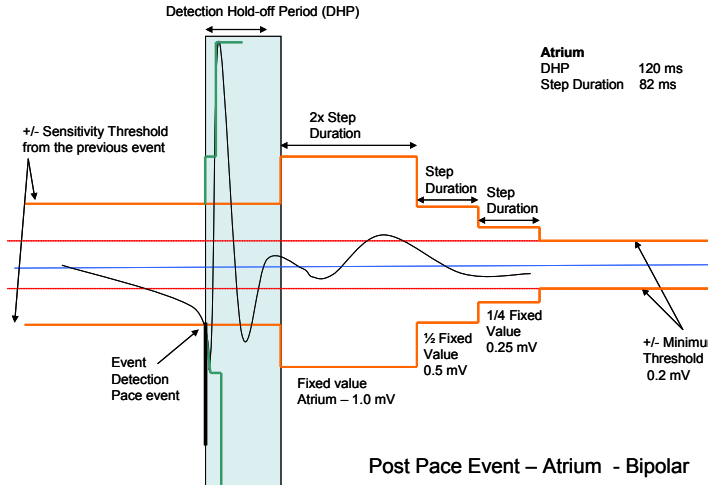


Figure 13: Automatic Sensitivity Control for Atrial Bipolar Paced Events

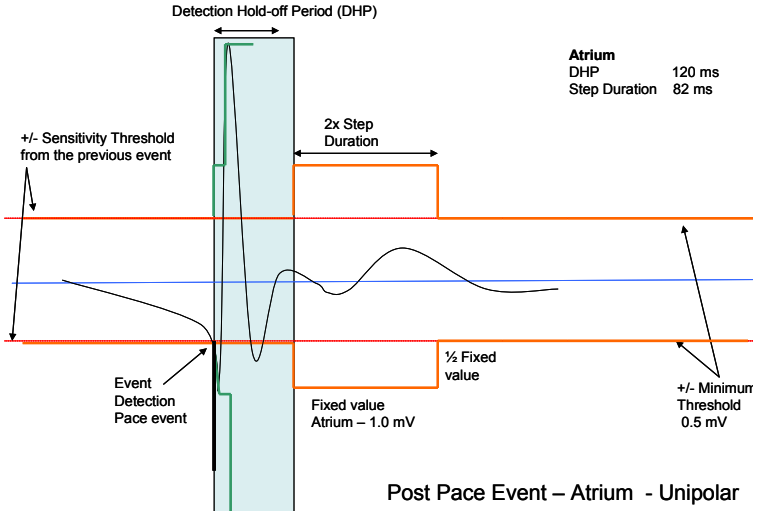


Figure 14: Automatic Sensitivity Control for Atrial Unipolar Paced Events

Ventricular Pacing Overview

Table 10 shows a ventricular pacing overview and applies to bradycardia programming and Mode Switch programming.

Parameter	Range	Default
Ventricular pacing	BiV, RV, LV	BiV
Triggering	OFF, RVs, RVs+PVC	RVs
LV T-wave protection	ON, OFF	ON
Maximum trigger rate	Auto, 90...(10)...160 bpm	Auto
Initially paced chamber	LV, RV	LV
VV Delay after Vp	0...(5)...80...(10)...100 ms	0 ms
VV Delay after Vs	0 ms (fixed)	0 ms

Table 10: Ventricular Pacing Parameters

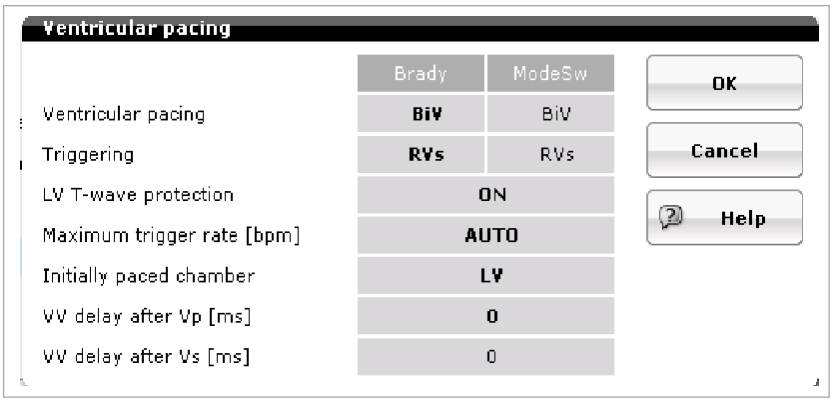


Figure 15: Ventricular Pacing Parameter Screen

5.4.1 Ventricular Pacing Parameter Options

Ventricular Pacing

BiV, RV, LV

Ventricular pacing allows the user to program BiV, RV or LV only pacing, depending on the patient condition. The choice of BiV pacing in this screen applies only to pacing in the permanent pacing mode. Pacing choices for Mode Switch are found in those respective feature areas.

Triggering

OFF, RVs, RVs + PVC

This feature permits triggered pacing when RV sensed events occur, as long as the RV sensed rate does not exceed the Maximum Triggered Rate. When set to the default of AUTO, the trigger rate will be equal to the Upper Tracking Rate +20 bpm. When programmed to RVs and PVC, the device triggers on RVs event, as well as extra systoles (PVC or VES), as long as the rate does not violate the Maximum Trigger Rate.

LV T-wave Protection

ON or OFF

If LV T-wave protection has been activated, Edora, Evity, Enitra HF-T / HF-T QP HF-T devices will detect LVs events and start a left ventricular maximum trigger interval (equal to the upper tracking Interval in ms when programmed to Auto). This feature prevents the delivery of a LV paced event whenever a LV sensed event occurs first. It is also designed to prevent pacing into the sensed refractory period and potentially triggering a tachyarrhythmia. When LV T-wave protection is programmed ON, the device will provide LVs statistics and accurate LVp percentages. If LV T-wave protection is OFF, LVs data is not collected by the device.

Maximum Trigger Rate

Auto, 90 … (10) … 160 bpm

This feature sets the maximum triggered pacing rate to a programmed value, including values above the UTR. The Auto setting is equivalent to the programmed Upper Tracking Rate (UTR) and will automatically change the trigger rate to match changes in UTR programming. Trigger rate pacing applies to permanent pacing and Mode Switch.

Initially paced chamber

LV, RV

Allows the user to program which chamber paces first.

V-V delay after Vp (ms)

0...(5)...80...(10)...100 ms

This parameter allows the user to program the interval between paced events.

V-V delay after Vs (ms)

0 ms (fixed)

When Trigger pacing is programmed to one of the active modes, the Edora, Evity, Enitra HF-T / HF-T QP HF-T device will deliver a LV pace when an RVs and/or PVC occurs below the maximum trigger rate.

5.5 Timing Features

Features related to pacemaker timing cycles.

5.5.1 Atrial Refractory Periods

Immediately upon sensing or pacing, the pacemaker starts a refractory period in the same channel. During the refractory period, intracardiac signals are ignored. This prevents the pacemaker from responding to the depolarization signal or the repolarization signal (T-wave) that might otherwise result in inappropriate inhibition or triggering.

If the pacemaker is programmed to dual chamber sensing, the refractory periods are independently programmable for each sensing channel. There are two refractory periods in the atrium:

- Regular atrial refractory period, which is automatically adjusted by the Auto Aref functionality
- PVARP, which is started with each ventricular pace outside of the AV delay or after a premature ventricular sensed event (PVC). In DDI mode, PVARP is also started with a regular ventricular sense

Note: PVARP after PVC is started after a premature ventricular sensed event (PVC)

CAUTION

Short Pacing Intervals Use of short pacing intervals (high pacing rates) with long atrial and/or ventricular refractory periods may result in intermittent asynchronous pacing and, therefore, may be contraindicated in some patients.

5.5.2 Atrial Refractory Period

The atrial refractory period is set by default to AUTO. This means the atrial refractory period is equal to 225 ms. If the AV Delay is programmed longer than 225 ms, the atrial refractory period is extended to match the AV Delay value.

5.5.3 PVARP

The Post Ventricular Atrial Refractory Period (PVARP) is a function in the pacemaker to help prevent Pacemaker Mediated Tachycardia (PMT), by preventing false classification of a retrograde conduction as an atrial event.

There are 2 different behavior modes of PVARP based on programmed mode, which is described below.

- In P-synchronous modes(e.g. DDD), the PVARP timer is started after : Vp, Vp(WKB), Vp(SW), Vp(BU)
- In R-synchronous modes (e.g. DDI), the PVARP timer is started after: Vp, PVC, Vs.

After a PVC, the parameter PVARP after PVC is automatically extended to PVARP + 150 ms, up to a maximum of 600 ms.

This behavior is shown in Figure 16.

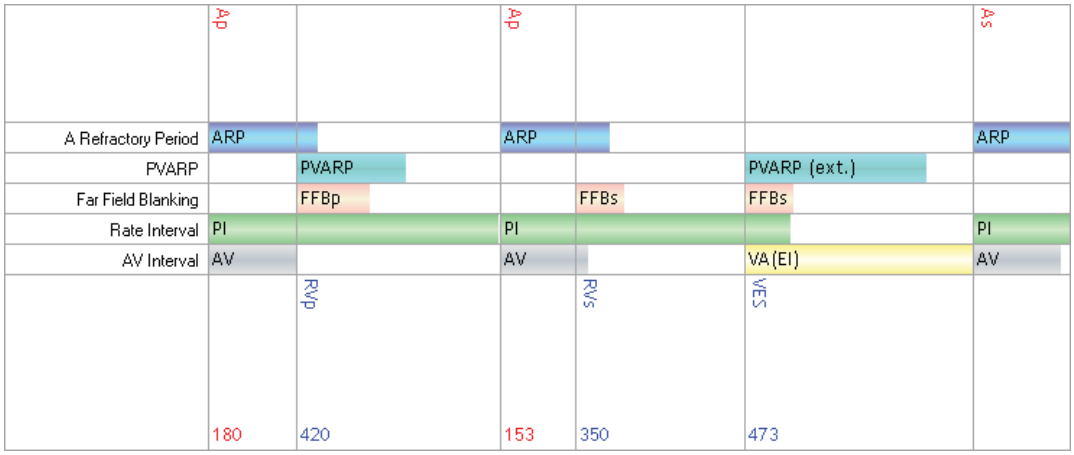


Figure 16: PVARP Timing

Table 11 shows the PVARP parameter values and ranges.

Parameter Name	Range	Standard Value	Units
PVARP	AUTO, 175..(25)..600	225 ms	ms
PVARP after PVC	PVARP + 150 ms to a maximum of 600 ms	375 ms	ms

Table 11: PVARP Parameter Values and Ranges

5.5.3.1 AUTO PVARP

If the PVARP feature is set to AUTO, the algorithm optimizes the PVARP to reduce the incidence of PMT. The nominal values of PVARP value is set to 225 ms, and PVARP after PVC is set to 375 ms.

Once a PMT is detected, the algorithm automatically extends the PVARP and PVARP after PVC by 50 ms, up to the maximum value of 600 ms.

5.5.3.2 Ventricular Refractory Period

200...(25)...500 ms

The right ventricular refractory period is designed to prevent T-wave oversensing, which could result in resetting the Lower Rate timer and causing lower than intended pacing rates. T-wave oversensing could affect pacing rates, as well as statistics. However, caution should be used in programming the right ventricular refractory period too long, as misclassification of appropriate events could result. The right ventricular refractory period is applied to all ventricular events (Vs, Vp and PVC).

5.5.4 AV Delay

Maximum AV Delay Programmable Value	350 ms
Maximum AV Delay Programmable Value with AV Hysteresis	450 ms
I-Opt AV Delay maximum[3]	400 ms

	DR-T Pacemaker	
	Lower Rate AV Delay	Upper Rate AV Delay
Low	180 ms	140 ms
Medium	180 ms	100 ms
High	180 ms	75 ms
Fixed	180 ms	180 ms
Individual	User Defined	User Defined

Table 12: AV Delay Values at the Various AVD Settings

AV Delay Settings

Edora/Evity/Enitra DR-T ProMRI® pacemakers provide three preset AV Delay settings: Low, Medium and High. In addition, the user can program a fixed AV Delay, as well as a user-defined program (Individual). Similar to previous generations of devices, Edora/Evity/Enitra ProMRI® pacemakers allow the user to program individual AV Delay programs. Edora/Evity/Enitra ProMRI® pacemakers provide the option of changing the values on the AV Delay visual display in addition to changing the numeric parameter buttons. By placing the pen over the “o” on the display, the user can slide the value up or down to increase or decrease the AV Delay setting for a particular rate bin.

5.5.4.1 Dynamic AV Delay

20...(5)...350 ms

2 Conflict with Sense compensation will arise as a minimum of 20 ms AV Delay is required

The AV delay defines the interval between an atrial paced or sensed event and the ventricular pacing pulse. If the pacemaker is programmed to a dual chamber sensing mode, an intrinsic ventricular event falling within the AV delay will inhibit the ventricular pacing pulse. If not contraindicated, a longer AV delay can be selected to increase the probability of ventricular output pulse inhibition. Short AV delays are available for testing purposes or if ventricular pre-excitation is desired (i.e., hemodynamic considerations).

Dynamic AV Delay provides independent selection of AV Delays from five rate ranges at pre-set AV Delay values. In addition, the AV Delay after atrial pace events can be differentiated from the AV interval after atrial sense events for dual chamber pacing modes. Dynamic AV Delay is programmable within the following atrial rate ranges at the values specified in Table 13.

	DR-T
Rate Ranges	LOW
below 70 bpm	180 ms
70—90 bpm	170 ms
91—110 bpm	160 ms
111—130 bpm	150 ms
above 130 bpm	140 ms

Table 13: Dynamic AV Delay Settings default settings

In addition the Dynamic AV Delays may be programmed individually for each rate range or a fixed AV delay may be programmed for all ranges.

The AV Delay feature includes an AV shortening option (sensed compensation) for dual chamber pacing modes. The sense compensation can be programmed to OFF and -10…(-5)…-120 ms. When selected, the AV delay after an atrial sense event is the AV delay after an atrial pace minus the sense compensation.

The Dynamic AV Delay is intended to mimic the physiologic, catecholamine-induced shortening of the AV Delay with increasing rate.

5.5.4.2 AV Hysteresis

OFF, Positive, Negative and I-Opt

Positive: Hysteresis - programmable 70, 110, 150 or 200 ms longer than programmed AV Delay

Negative: Hysteresis - 10 … (10) … 150 ms

AV repetitive/scan cycles: OFF, ON

The AV Hysteresis mode choice of Positive is designed to promote intrinsic activity by periodically extending the AV interval to look for intrinsic activity. If intrinsic activity is present, the AV Delay maintains the hysteresis value to allow intrinsic R-waves to conduct. The maximum length the AV Delay can be extended is 450 ms. This will be automatically shortened as the rate increases to ensure appropriate AV conduction.

Negative hysteresis is discussed in Section 5.5.4.5.

I-Opt is discussed in Section 5.5.4.6.

5.5.4.3 AV Repetitive Hysteresis

When AV Repetitive Hysteresis is enabled, the AV delay is extended by a defined hysteresis value after sensing an intrinsic ventricular event. When a ventricular stimulated event occurs, a long AV delay is used for the programmed number of cycles (5). If an intrinsic rhythm occurs during one of the repetitive cycles, the long duration AV delay interval remains in effect. If an intrinsic rhythm does not occur during the repetitive cycles, the original AV delay interval resumes.

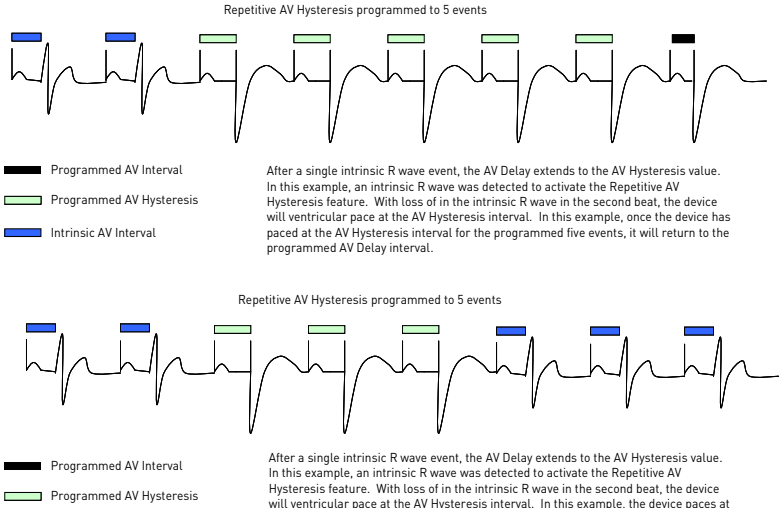


Figure 17: AV Repetitive Hysteresis

5.5.4.4 AV Scan Hysteresis

When AV Scan Hysteresis is enabled, after 180 consecutive pacing cycles, the AV delay is extended for the programmed number of pacing cycles (5). If an intrinsic rhythm is detected within the extended AV delay, the longer AV delay remains in effect. If an intrinsic rhythm is not detected within the number of scan cycles, the original AV delay value resumes.

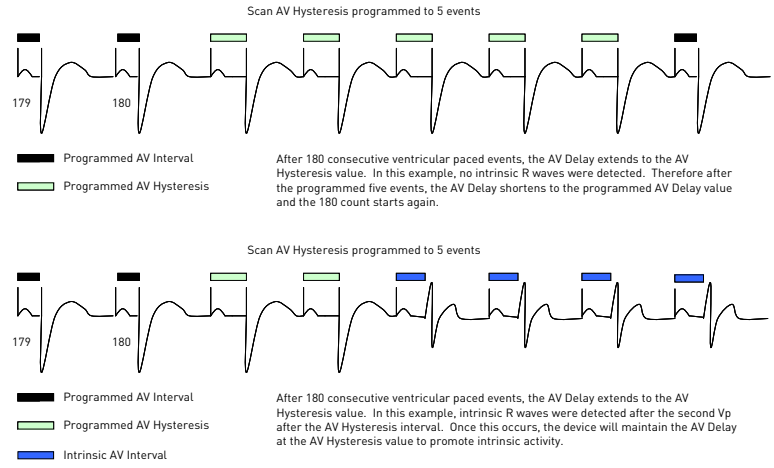


Figure 18: AV Scan Hysteresis

5.5.4.5 Negative AV Delay Hysteresis

With Negative AV Delay Hysteresis, the AV delay is decreased by a defined value after a ventricular event is sensed, thereby promoting ventricular pacing. The Negative AV Delay Hysteresis is limited to a minimum AV Delay of 10 ms.

The normal AV delay resumes after the programmed number of consecutive ventricular paced events (Repetitive Negative AV Delay Hysteresis) elapses.

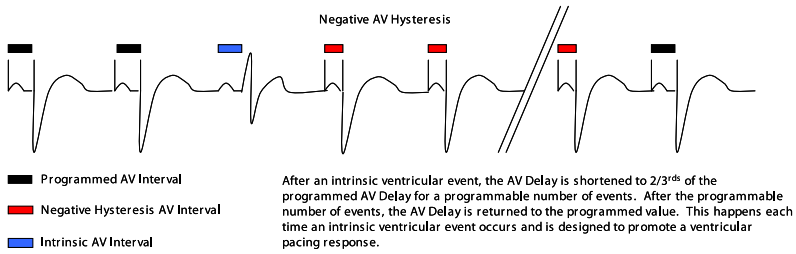


Figure 19: Negative Hysteresis

CAUTION

Negative AV Delay Hysteresis This feature insures ventricular pacing, a technique which has been used in patients with hypertrophic obstructive cardiomyopathy (HOCM) with normal AV conduction in order to replace intrinsic ventricular activation. No clinical study was conducted to evaluate this feature, and there is confl icting evidence regarding the potential benefit of ventricular pacing therapy for HOCM patients. In addition, there is evidence with other patient groups to suggest that inhibiting the intrinsic ventricular activation sequence by right ventricular acing may impair hemodynamic function and/or survival.

5.5.4.6 I-Opt

I-Opt is a one-button feature designed to promote intrinsic activity in the ventricle. When programmed ON, AV Hysteresis is extended to 400 ms, regardless of the programmed AV Delay. As the heart rate increases, I-Opt will eventually shorten to ensure appropriate conduction is maintained, as shown in Figure 20. A combination of high rate and I-Opt can result in a situation where 2:1 block occurs during repetitive hysteresis function.

The Scan and Repetitive Hysteresis values are set to 5 and function as previously described.

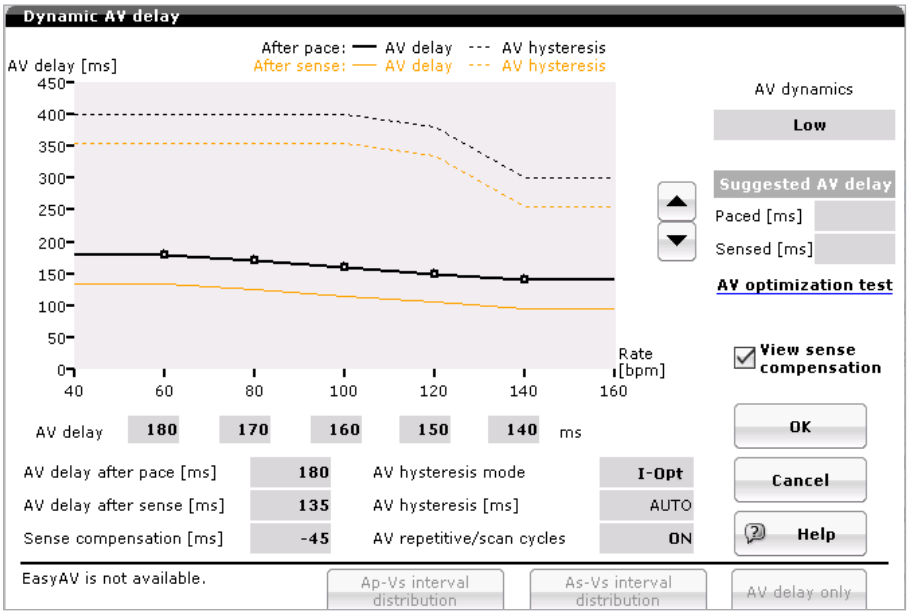


Figure 20: I-Opt

When switching I-Opt ON, the range of values is pre-configured as follows:

Function	I-Opt
AV Hysteresis	400 ms
AV Repetitive/Scan Hysteresis	ON (5)

Table 14: I-Opt Parameters

NOTE:
Activate PMT Protection to prevent pacemaker mediated tachycardia.

5.5.4.7 AV Opt. Test

The AV Opt. Test, designed for patients with AV block and dual chamber pacing modes (e.g. DDD, DDD-BiV), measures P-wave durations for paced and sensed atrial events and provides programming suggestions for the paced and sensed AV-delay. This suggestion attempts to avoid both premature (A-wave truncation; incomplete RV filling) and excessively delayed (E- and A-wave fusion; mitral regurgitation) ventricular pacing following intrinsic and paced atrial events.

The AV Opt. Test can be initiated by the user as part of a device follow-up. This will trigger the implant to send IEGMs from the implant to the programmer, first during intrinsic rhythm, followed by atrial paced rhythm. The programmer analyzes the IEGM signals and extracts the p-wave duration from the different sequences. Based on the measured p-wave durations the software will calculate the mean duration, add 50 ms and display the result as suggested AV-delays. If no intrinsic atrial rate is measured, or if the atrial paced rate violates the upper rate limit, the programmer will use the programmed sense compensation to calculate the corresponding AV-delay suggestion.

After the test procedure has been completed, the user has the option to copy the suggested AV-delay parameters over to the main program screen by pressing the “Accept suggestion” button. In order to activate the updated AV-delay settings, the user must transmit the program to the implant.

The system requires bipolar leads to perform the AV Opt. Test. The test cannot be performed if the heart rate is greater than 100 bpm or if the patient is in Mode Switch. An example of the test page is shown in Figure 21.

The AV Opt. Test does not provide CRT therapy or automatically reprogram the AV-delay settings. AV Opt. is a programmer-based feature. AV Opt. suggests but does not automatically program AV-delay settings based on measuring sensed and paced p-wave durations. CRT clinical studies show that AV delay should be short enough to promote BiV pacing >95% of the time. Controlled clinical studies have failed to show any difference between using device-based features to suggest CRT AV-delay compared to default values or the clinician's best judgement.

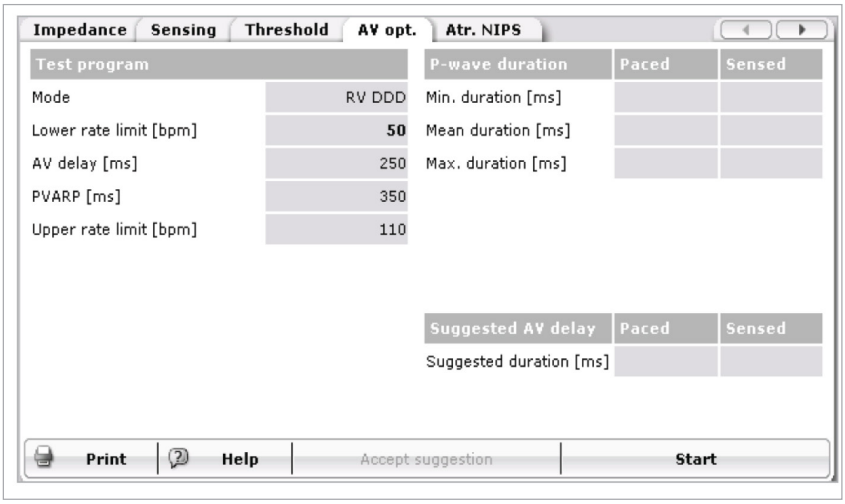


Figure 21: AV Opt. Test

1 Hayes et al. Heart Rhythm 2011

5.5.5 Ventricular Blanking After Ap

The ventricular blanking after Ap (atrial pace) is the period after an atrial pacing pulse during which ventricular sensing is deactivated. It is intended to prevent ventricular sensing of the atrial pacing pulse ("crosstalk"). This parameter is programmable from 30 to 70 ms.

The blanking time shall be as short as possible in order to provide ventricular sensing when a ventricular depolarization could occur.

Crosstalk may be encountered if a shorter blanking time, unipolar ventricular sensing, a higher ventricular sensitivity (lower value) and/or a high atrial pulse amplitude and pulse width are programmed.

5.5.6 Far-Field Protection

Inappropriate mode switches may occur in the presence of atrial oversensing of ventricular events. This scenario is seen when mode switches are recorded in the diagnostics of the pacemaker in the absence of true documented atrial arrhythmias. To aid in diagnosis, a recorded IEGM will demonstrate a rhythmic pattern of a sensed atrial event followed by an atrial refractory event (Ars) at or just following the ventricular event. This may occur with both sensed and paced ventricular events.

The Far-Field Protection in the atrial channel feature affects both sensed and paced events originating from the ventricle and sensed on the atrial channel. The programming resolution for Far-Field Protection is 100 ms to 220 ms following a Vs event, and 100 ms to 220 ms following a Vp event. The

shortest Far-Field Blanking period that will cover the atrial refractory sensed events is recommended to prevent undersensing of true atrial events. Events sensed within this timer are annotated as Ars (FFP) events and are not counted toward Mode Switching.

5.5.7 Safety AV Delay

The safety AV delay (set at 100 ms) applies to the pacing modes DDD-CLS, DDD(R), DVI(R), DDI(R), and DDD(R)-ADI(R).

To prevent ventricular pulse inhibition in the presence of crosstalk, a ventricular pulse will be emitted at the end of the safety AV delay (Figure 22). When pacing is AV sequential at the pre-set safety AV delay, the presence of crosstalk should be considered and appropriate reprogramming performed (lengthen the ventricular blanking time, lower ventricular sensitivity, bipolar configuration, and/or lower atrial pulse energy).

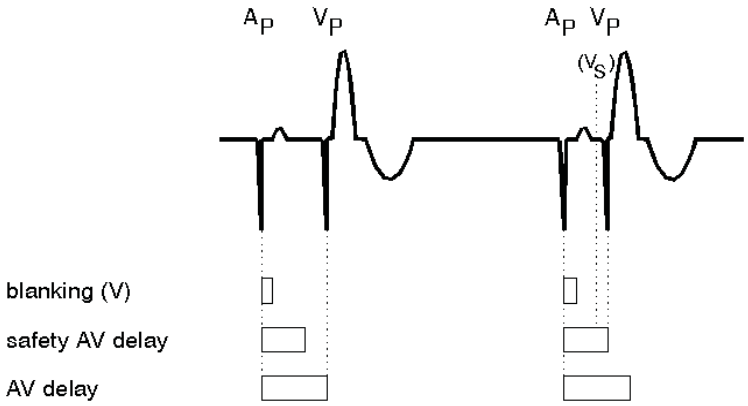


Figure 22: Ventricular Blanking Time and Safety AV Delay (Dual Chamber)

5.5.8 Upper Rate and UTR Response

The upper rate is programmable (up to 200 bpm) for the dual chamber sensing modes [DDD-CLS, DDD(R), VDD(R)], and for all triggered modes (single and dual chamber). The ventricular pacing rate will never exceed the programmed upper rate regardless of the patient's atrial rate.

When the atrial rate surpasses the UTR, one of two different responses may occur, depending on the programmed PVARP value and the AV Delay. Both responses — 2:1 block and Wenckebach — prevent the device from pacing faster than the UTR. The device displays the response, based on the programming, under the Upper rate response feature.

In the Wenckebach zone, ventricular pacing is maintained at UTR as the atrial rate exceeds UTR. Ventricular pacing continues at UTR until the atrial interval falls within PVARP+AV Delay (i.e., until a block mode emerges) or until Mode Switching occurs.

In a 2:1 block zone, the ventricular pacing rate is half the intrinsic atrial rate. The 2:1 ratio between the atrial and ventricular rate is maintained until the atrial rate reaches the Mode Switch Intervention Rate. At a rate greater than this limit, ventricular pacing occurs in a non-tracking mode at the basic (sensor) rate.

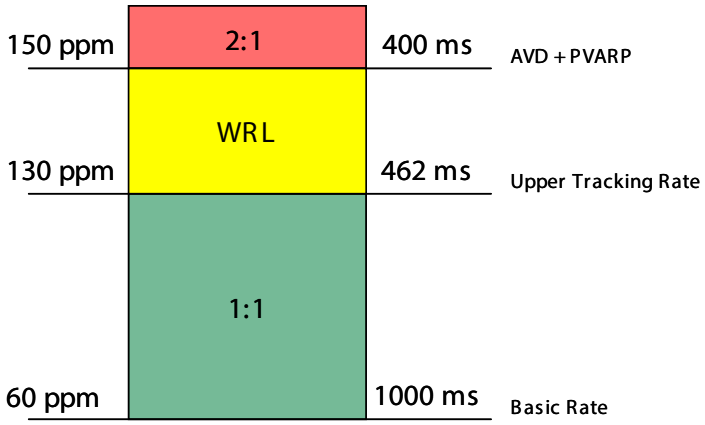


Figure 23: Upper Rate Behavior Example

5.6 Lead Polarity

Chamber Sensed	Range	Default
Atrium	Unipolar, Bipolar	Unipolar
Ventricle	Unipolar, Bipolar	Unipolar
Chamber Paced	**Range**	**Default**
Atrium	Unipolar, Bipolar	Unipolar
Ventricle	Unipolar, Bipolar	Unipolar

Table 15: Lead Polarity Options and Default Settings

The programmed lead polarity determines whether the pacemaker senses or paces in a unipolar or bipolar configuration. Lead polarity can be programmed separately for sensing and pacing in both chambers.

If a bipolar lead is connected to the pacemaker, unipolar or bipolar configuration can be programmed for pacing and sensing. As compared to bipolar pacing, the unipolar pacing pulse has the advantage of being clearly identifiable on the ECG. Unipolar pacing occasionally results in muscle stimulation in the pacemaker pocket or diaphragm.

Bipolar sensing offers an improved “signal-to-noise” ratio due to the decreased susceptibility to interference signals like skeletal myopotentials or EMI, and, therefore, permits programming of higher sensitivities (lower values).

WARNING

Unipolar/ Bipolar All Edora/Evity/Enitra ProMRI pacemaker models can be used with either unipolar or bipolar IS-1 leads.

5.7 Parameters for Rate-Adaptive Pacing

The Edora/Evity/Enitra ProMRI® pacemaker families achieves rate adaptation through programming of either standard motion-based pacing via a capacitive accelerometer or by the means of the principle of closed loop stimulation (CLS) which involves the translation of myocardial contractility into patient-specific pacing rates.

For standard motion-based rate adaptation, the pacemaker is equipped with an accelerometer located on the hybrid circuit of the pacemaker. This sensor produces an electric signal during physical activity of the patient. If a rate-adaptive mode is programmed, then the sensor signal controls the stimulation rate. Sensing and inhibition remains in effect during sensor controlled operation. In the case of high pacing rates, however, the refractory periods may cover a majority of the lower rate interval, resulting in asynchronous operation.

When in CLS mode, the pacemaker monitors and processes the intracardiac impedance signal associated with myocardial contraction dynamics. Changes in the waveform of this impedance signal are associated with changes in the contraction dynamics of the patient's heart due to the heart's inotropic response to exercise. By monitoring these changes, the pacemaker can provide a pacing rate that is appropriate and specific to the patient's physiologic demands.

For a complete list of rate-adaptive pacing modes available in the Edora/Evity/Enitra ProMRI® pacemaker families, see Section 13.1.

The following functions are available for tailoring the motion based rate adaptation to the individual patient except for the maximum closed loop rate, which is relevant to CLS.

Table 16 shows a summary of the parameters associated with rate adaptive pacing.

Parameter Name	Range	Standard Values	Unit
Maximum Activity (Sensor) Rate	80...(10)...180	120	bpm
Sensor Gain	AUTO, Very low, Low, Medium, High, Very high	AUTO	none
Sensor Threshold	Very low, Low, Medium, High, Very high	Medium	none
Rate Fading	OFF, ON	OFF	none
Rate Increase	1, 2, 4, 8	2	bpm/cycle
Rate Decrease	0.1, 0.2, 0.5, 1.0	0.5	bpm/cycle

Table 16: Rate Adaptive Pacing Parameters

5.7.1 Sensor Gain

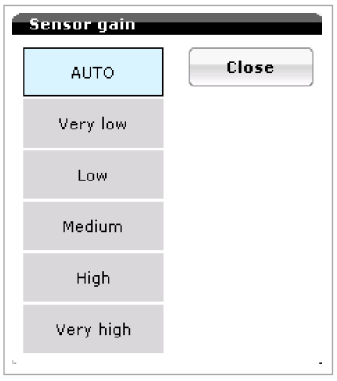


Figure 24: Gain Setting Choices

The sensor gain defines the slope of the linear function between exertion and pacing rate. It designates a factor by which the electric signal of the sensor is amplified prior to the signal processing stages. The programmable amplification permits adaptation of the individually programmed sensor gain to the

desired rate response. The optimum setting is achieved when the desired maximum pacing rate during exertion is reached during maximum exercise levels. The rate increase, rate decrease and maximum sensor rate settings must be checked for their suitability with respect to the individual patient before adjusting the sensor gain.

If the sensor-driven rate is not sufficient at high levels of exertion the sensor gain setting should be increased. The sensor gain should be reduced if high pacing rates are obtained at low levels of exertion. Refer to the sensor statistics or perform a sensor optimization if the rate response is suspected in being inadequate for the patient.

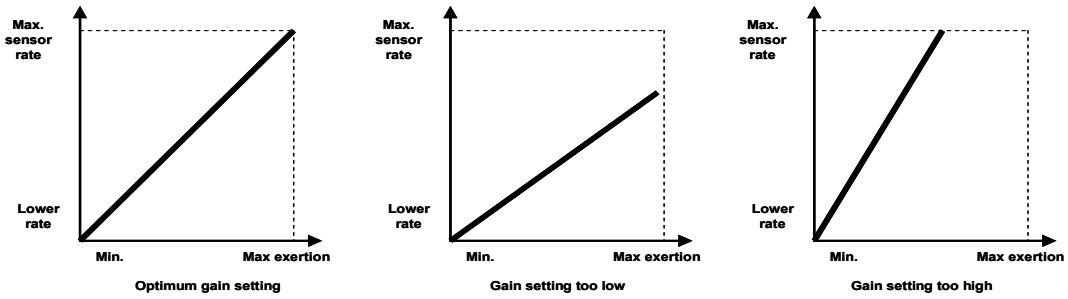


Figure 25: Influence of Sensor Gain on the Rate Response

Edora/Evity/Enitra ProMRI® pacemakers offer an Automatic Sensor Gain setting, which allows the physician to have the Sensor Gain parameter adjusted automatically. This is shown in Figure 24.

When the Automatic Sensor Gain is activated, the pacemaker samples the sensor-indicated rate. The sensor gain will be increased by 10%, if the activity rate does not reach or exceed the programmed activity rate (fixed to 90% of maximum sensor rate) for 30 minutes each day over 7 consecutive days. An increase in gain cannot occur more often than every 7 days. If, during the 24 hour period beginning at midnight, the activity rate reaches or exceeds the programmed activity rate (90% of maximum sensor rate) for one hour, the sensor gain setting is reduced by 10%. A change in the sensor gain only occurs at midnight.

NOTE:

If the reed switch is closed, the accumulated time at maximum sensor rate is reset to zero, and the sensor indicated rate measurement resumes for the period that remains in that day.

The Automatic Sensor Gain function is primarily influenced by the Maximum Sensor Rate setting. Therefore the Maximum Sensor Rate must be appropriately selected.

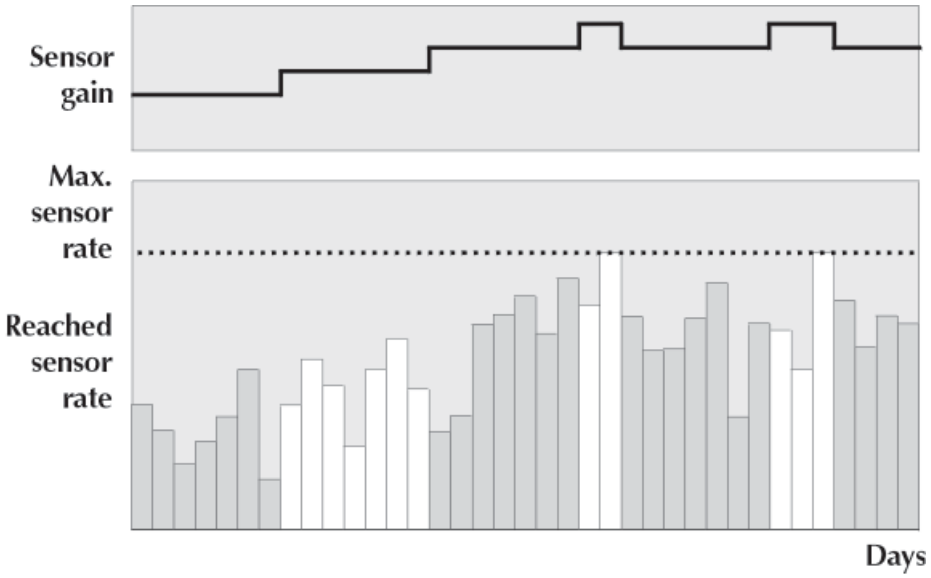


Figure 26: Automatic Sensor Gain

5.7.2 Sensor Threshold

The effects of rate adaptation are limited to sensor signals exceeding the programmable sensor threshold. Sensor signals below this threshold do not affect rate response (Figure 27). The programmable sensor threshold ensures that a stable rate at rest can be achieved by ignoring sensor signals of low amplitude that are not related to exertion.

If the pacing rate at rest is unstable, or tends to stay above the lower rate without activity, the sensor threshold should be increased. The sensor threshold should be reduced if a sufficient rate increase is not observed at a given level of exertion.

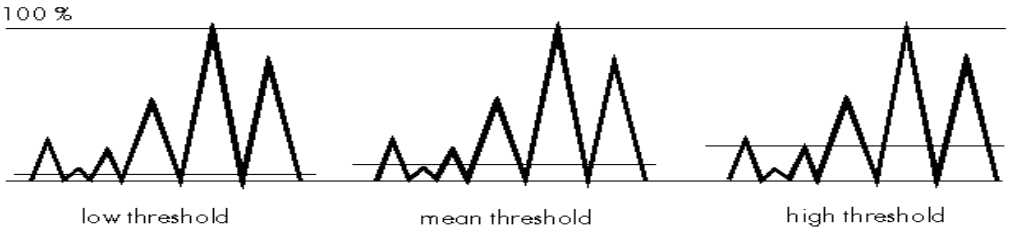


Figure 27: Effect of Sensor Threshold

5.7.3 Rate Increase

The rate increase parameter determines the maximum rate of change in the pacing rate if the sensor signal indicates increasing exertion (Table 17). In DDDR, VDDR, DOOR, VVIR, VOOR, AAIR and AOOR, a rate increase setting of 2 bpm per second increase in pacing rate would take 45 seconds to change from a pacing rate of 60 bpm to 150 bpm.

Increase in Rate (bpm/s)	Time to Increase Rate (seconds)
1	90
2	45
4	23

8	11

Table 17: Rate Increase

In DDIR and DVIR, the rate increase is slightly slower than indicated here (depending on the programmed AV interval). The programmed rate increase setting applies only to the increase in pacing rate during sensor-driven operation and does not affect the pacing rate during atrial triggered ventricular pacing.

5.7.4 Maximum Activity (Sensor) Rate

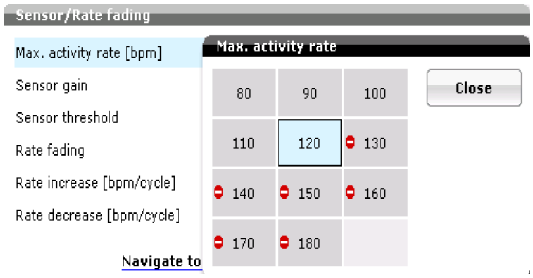


Figure 28: Maximum activity rate

Regardless of the sensor signal strength, the pacing rate during sensor-driven operation will never exceed the programmed maximum sensor rate. The maximum sensor rate only limits the pacing rate during sensor-driven operation and is independent of the rate limit. The maximum sensor rate (programmable up to 180 bpm) must be less than or equal to the programmed UTR.

NOTE:

In the DDIR and DVIR modes, the sensor rates control the ventricular pacing rates independent of the AV Delay.

5.7.5 Maximum Closed Loop Rate

When the pacemaker is programmed to CLS rate adaptation, the pacing rate during CLS-driven operation will never exceed the programmed maximum closed loop rate. The maximum closed loop rate only limits the pacing rate during sensor-driven operation and is independent of the rate limit. The maximum closed loop (programmable up to 180 bpm) must be less than or equal to the programmed UTR.

CAUTION

Programming Modifications Extreme programming changes should only be made after careful clinical assessment. Clinical judgment should be used when programming permanent pacing rates below 40 bpm or above 100 bpm.

5.7.6 Rate Decrease

The rate decrease parameter determines the maximum rate of change in the pacing rate, if the sensor signal indicates decreasing exertion. In DDDR, VDDR, DOOR, VVIR, VOOR, AAIR, and AOOR, the rate decrease setting of 0.5 bpm per second decrease in pacing rate would take 180 seconds to change from 150 bpm to 60 bpm.

Decrease in Rate (bpm/s)	Time to Decrease Rate (seconds)
0.1	900
0.2	450
0.5	180
1.0	90

Table 18: Rate Decrease

The programmed rate decrease setting applies only to the decrease in pacing rate during sensor-driven operation in the primary chamber being paced.

5.8 Management of Specific Scenarios

5.8.1 2:1 Lock-In Management

2:1 Lock-In Management is an expansion to the Mode Switch feature. If the AV delay and far-field protection intervals are programmed such that every second intrinsic atrial event falls within the blanking period and the pacemaker detects an atrial rate that is half of the actual rate, the pacemaker does not Mode Switch during an atrial tachycardia as programmed. With 2:1 Lock-In Management, the tachycardia is detected and confirmed, thereby triggering a Mode Switch.

The 2:1 Lock-In Management feature consists of suspicion, confirmation and termination phases, which are described below:

Suspicion

The pacemaker suspects 2:1 Lock-In when the following criteria are met:

- 8 successive V-pace—A-sense (VpAs) sequences have occurred with an average length shorter than the 2:1 Lock-In VA Length Criterion. This VA Length Criterion is based on the AV delay (AsVp) and far-field protection intervals (FFB).
- The mean deviation of these 8 VpAs intervals is less than the 2:1 Lock-In Stability Criterion, defined as 50 ms.

Confirmation

When the suspicion criteria have been met, the AV delay is increased by the programmed far-field protection interval (up to a maximum of 300 ms. If an atrial event is detected within the AV delay and the detected atrial rate is less than the programmed Mode Switch Detection rate, a 2:1 Lock-In is confirmed.

Otherwise, 2:1 Lock-In is not confirmed, and the AV delay is gradually decreased to the programmed value. The 2:1 Lock-In Management feature is suspended for 120 seconds.

Termination

The pacemaker will immediately mode switch to a non-atrial tracking mode (e.g., DDDR to DDIR) when the confirmation criteria have been met, and then the 2:1 Lock-In Management feature is suspended until the pacemaker mode switches back to the programmed pacing mode.

In order to optimize the programmability of the 2:1 Lock-In Management feature, the far field protection period is programmable to allow the physician to ensure that the protection period is sufficient to recognize cases where a 2:1 lock-in is likely to occur.

5.9 Atrial Upper Rate

OFF, 175, 200, 240 bpm; default - 240 bpm

The atrial upper rate (AUR) prevents atrial pacing from occurring in the vulnerable phase after an atrial sensed event occurring in the PVARP interval, and ensures that the next atrial paced event occurs after the heart's natural atrial refractory period.

To avoid this, an atrial upper rate of 240 bpm (atrial upper interval (AUI), 250 ms) is started after an As(PVARP) event.

The next Ap can only be emitted after the expiration of the AUI. When there are high sensor rates, the atrial pacing is shifted.

NOTE:

Atrial pacing does not occur when mode switching is activated, and when the atrial upper rate is activated in DDI mode at the end of the sensor or basic interval.

5.10 Atrial Overdrive Pacing (Overdrive Mode)

The atrial pacing rate increases after each atrial sensed event that is not classified as an atrial extrasystole, in an attempt to suppress atrial tachyarrhythmias. The overdrive algorithm triggers atrial overdrive pacing and guarantees that pacing occurs at a rate slightly above the intrinsic sinus rate. Atrial overdrive pacing thereby minimizes the number of atrial sensed events. The overdrive mode is available in DDD(R).

The features of Atrial Overdrive pacing include:

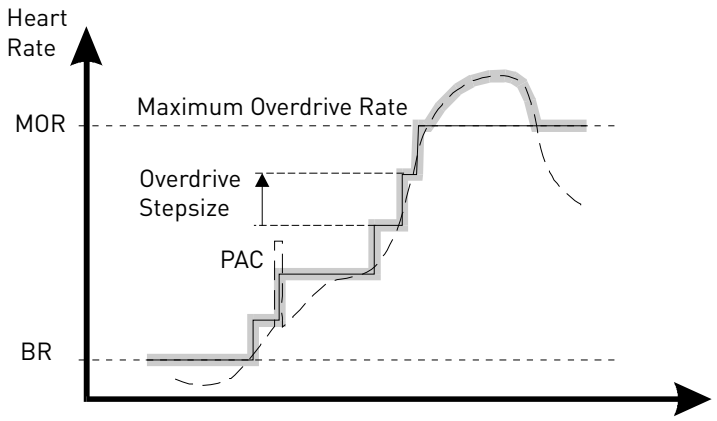


Figure 29: Overdrive Pacing

After every atrial sensed event (non-AES), the pacing rate is increased by a non-programmable 8 bpm rate increase above the intrinsic event. This is shown as the overdrive step in Figure 29. The device will pace at that rate (intrinsic + 8 bpm) for 20 cycles. At the end of those 20 cycles, the device will decrease the pacing rate by 1 bpm/cycle until an intrinsic event is detected. Once an intrinsic event is detected, the device will immediately increase the pacing rate to the new pacing rate (intrinsic rate + 8 bpm).

If an intrinsic event is detected during the 20 cycles of pacing, the device will again increase the pacing rate by 8 bpm and start a new 20-cycle interval up to a maximum rate of 120 bpm or MSR.

Programming of Atrial overdrive pacing requires that the Basic rate to be at least 30 bpm less than the Maximum Overdrive Rate. This also applies when performing an atrial threshold test and may require the user to increase the MSR or turn off Atrial overdrive to perform the atrial threshold test at higher rates.

Protection Function of the Algorithm

Atrial overdrive pacing (Overdrive Mode) consists of different functions that become effective at high atrial rates:

- When the maximum activity rate (MAR, standard setting 120 bpm) is exceeded as with atrial tachycardias, the algorithm is automatically deactivated. If the rate falls below the MAR, the overdrive algorithm is reactivated.
- The function is deactivated when the mean of the atrial rate over a period of twelve hours exceeds the average safety rate ("overdrive average rate limit = OAR"). The average safety rate is determined indirectly from the maximum overdrive pacing rate (MOR minus 10 bpm). If the average safety rate is exceeded, the pacing rate is incrementally reduced to the basic rate. If the average atrial heart rate falls below the average safety rate, the preventive overdrive pacing is reactivated (activation/deactivation only in a 12 hour rhythm).
- If the function is deactivated for a third time because the average safety rate has been exceeded, overdrive pacing remains OFF permanently. The overdrive mode can not be reactivated until after the pacemaker has been programmed.

NOTE:

Atrial Overdrive cannot be programmed when CLS is active.

The feature is found under the Basic rate parameter.

CAUTION

Overdrive Pacing Mode When programming the overdrive pacing mode, check whether the selected program can cause PMT, and whether atrial over drive pacing would result. Corresponding to the measured retrograde conduction time, the PMT protection interval must be programmed to a correct value.

5.11 Management of Specific Scenarios

5.11.1 PMT Management

A PMT is defined as a tachycardia caused by inadvertently tracking retrograde P-waves. The PMT management feature includes PMT Protection/Termination and a programmable PMT detection and termination algorithm.

5.11.2 PMT Protection

Pacemaker-mediated tachycardia (PMT) is normally triggered by ventricular depolarizations that are not synchronized with atrial depolarizations (e.g., VES). The tachycardia is maintained in a retrograde direction by intrinsic VA conduction of the stimulated ventricular depolarization and in an antegrade direction by ventricular pacing of the pacemaker that is triggered by P-waves. It is the objective of the atrial PMT protection interval to not use retrogradely conducted atrial sensed events for pacemaker timing, but only to statistically evaluate them for detection of atrial tachycardia incidents.

To prevent occurrence of a PMT, Edora/Evity/Enitra DR-T ProMRI® pacemakers start an atrial PMT protection interval after each ventricular paced event. If an atrial event is sensed within this PMT protection interval, this will neither start an AV delay nor a basic interval.

PMT Protection is an On/Off feature and is found on the Refractory Period / Blanking Screen. However, it can only be programmed OFF when Auto PVARP is programmed OFF. Once activated, the VA Criterion, nominally set to 350 ms, is programmable from 250...(25)...500 ms.

NOTE:

The default value of PMT protection, when programmed to the automatic setting, is 225 ms after a Vp and 375 ms after a PVC.

5.11.2.1 PMT Detection and Termination

In addition to PMT prevention, Edora/Evity/Enitra DR-T ProMRI® pacemakers contains a programmable PMT detection and termination algorithm. The termination feature will take action in case the prevention was not effective and a PMT is detected. The PMT detection constantly monitors for the presence of a PMT.

The Edora/Evity/Enitra DR-T ProMRI® pacemakers PMT detection/termination algorithm consists of suspicion, confirmation and termination components and is described as follows.

Suspicion

A PMT is suspected when the following criteria are met:

- The heart rate is greater than 100 bpm.
- 8 successive V pace-A sense (Vp-As) sequences have occurred with a length shorter than the VA criterion. This VA criterion is programmable between 250 and 500 ms.
- The mean deviation of these 8 Vp-As intervals is less than the Stability criterion parameter, defined as less than 25 ms.

Confirmation

In order to confirm PMT, one of two actions is taken:

- If the suspected PMT is occurring at the Upper Tracking Interval (UTI), which occurs in most cases, the UTI is increased to the next programmable length by 50 ms.
- If the suspected PMT is occurring at a rate that is slower than the UTI, the programmed AV Delay is shortened to the next programmable length by 50 ms.

In either case, if the measured VA interval remains constant, PMT is confirmed, moving the algorithm to the next phase, PMT Termination.

Interval Length AV Delay Test Method:

Atrial Tracked Rate Interval	AV Delay	Test Method
> UTI	≤ 200 ms	Increase AV Delay by 50 ms
> UTI + 50 ms	> 200 ms	Decrease AV Delay by 50 ms
≤ UTI	Any	Increase UTI by 50 ms
> UTI and ≤ UTI + 50 ms	> 200 ms	Set UTI = Atrial Tracked Rate Interval + 50 ms

Table 19: PMT Confirmation Intervals

Termination

Edora/Evity/Enitra DR-T ProMRI® extends PVARP (Post Ventricular Atrial Refractory Period) to the VA interval + 50 ms.

5.12 Adjustment of the PMT Protection Window

The PMT protection window can be automatically adjusted. This automatic adjustment functions in the following manner:

When the PMT is detected and terminated, the PMT protection interval is extended by 50 ms. The initial values of the PMT protection interval in the automatic setting at 225 ms after Vp and 375 ms after a PVC.

5.13 Ventricular Capture Control (VCC)

5.13.1 Feature Description

The VCC feature periodically measures the capture threshold, and automatically adjusts the pacing output (with a programmable safety margin) when programmed ON. Additionally, the feature continuously assesses ventricular pacing capture on a beat-to-beat basis and responds to any loss of capture with a safety back-up pulse. During the clinical evaluation of the Ventricular Capture Control algorithm, it was demonstrated that use of Ventricular Capture Control can increase device longevity (as compared to standard programming).

Differences in the signal morphology between the polarization artifact and the evoked response signal are used to distinguish capture events from non-capture events. The polarization artifact is the signal caused by the pacing pulse between the pacing electrode and the cardiac tissue. The evoked response signal is the intracardiac signal measured during electrical activation of the myocardium.

Figure 30 shows an example of an evoked response signal and a polarization artifact. After an effective blanking period of 20 ms, the signal is evaluated over the next 60 ms. Several characteristics of the signal falling into this window are evaluated in order to discriminate the evoked response (capture) from polarization artifact (possible non-capture).

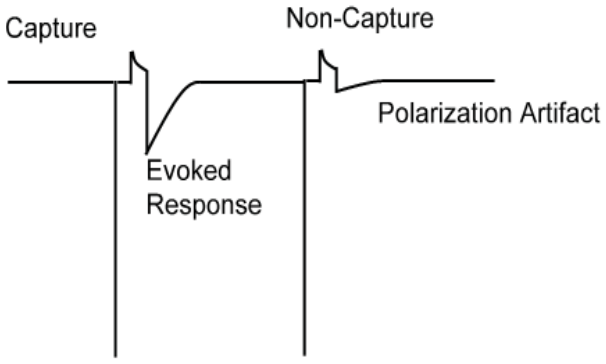


Figure 30: Example of a Capture and a Non-Capture Beat

5.13.2 Capture Control Parameters

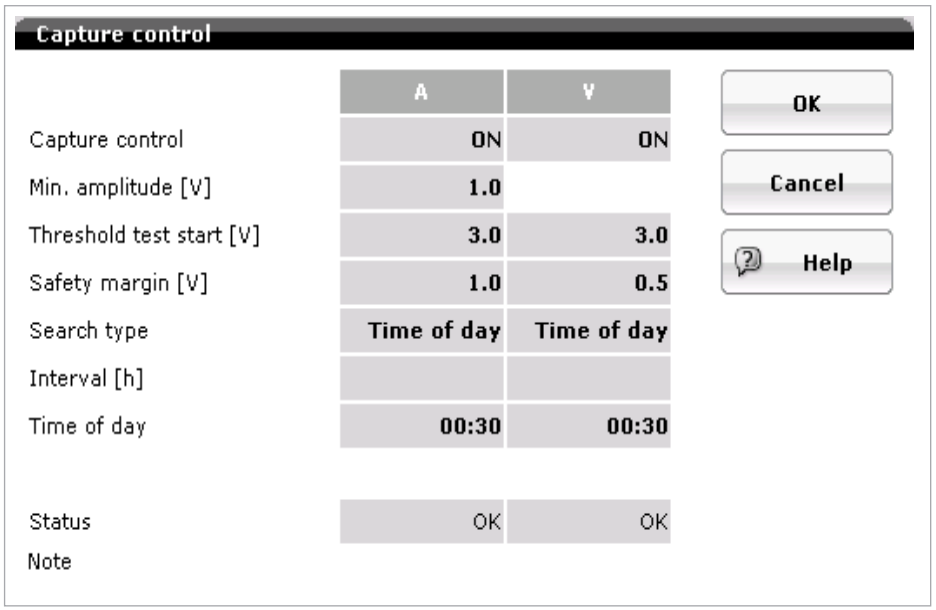


Figure 31: Capture Control Screen

Parameters associated with Ventricular Capture Control are shown in Table 20.

Parameter	Range	Default
Capture Control	ON, ATM, OFF	ON
Threshold Test Start	2.4, 3.0, 3.6, 4.2, 4.8 V	3.0 V
Safety Margin	0.3…(0.1)…1.2 V	1.0 V
Search Type	Time of day, Interval	Time of day
Time of Day	24 hour clock	00:30 A.M.
Interval	0.1, 0.3, 1, 3, 6, 12, 24 hr.	24 hr.

Table 20: Ventricular Capture Control Parameters

Capture Control

OFF, ON, ATM

When Ventricular Capture Control is OFF, the user can manually program the output based on current threshold and physician preference.

When Ventricular Capture Control is ON, the feature will determine the capture threshold, program the output, and provide continuous monitoring to insure capture is present.

The ATM mode differs from Capture Control ON as ATM does not automatically adjust the pacing voltage. ATM instead stores the measured threshold values in the Pacing portion of the Statistics for review, allowing it to be set by the clinician.

Threshold Test Start

2.4 V, 3.0 V, 3.6 V, 4.2 V and 4.8 V, default 3.0 V

This is the starting voltage when Capture Control (ON or ATM) is looking to determine the current threshold. This value should only be changed to a higher value if the patient has high thresholds. This is because the higher the output, the greater the polarization artifact which may cause the Signal Quality Check to fail. This will be discussed in more detail later in this chapter.

Safety Margin

0.3 V...(0.1 V)...1.2 V; default of 0.5 V

This is the amount of pacing output added to the threshold value to ensure capture. This takes into account minor changes in thresholds throughout the day. For example, if the threshold was 0.7 V, the device would add the 0.5 V safety margin to the 0.7 V threshold and program the pacing output to 1.2 V. The lowest the output can be programmed is 0.7 V, regardless of the threshold.

5.13.3 Search Type

Interval Time of Day

This feature determines when the device performs a Ventricular Capture Control test to check the current threshold.

- Interval — Interval starts the next Active Threshold Monitoring test at a programmed time from when the previous threshold test was performed. This time may vary due to retesting programming changes or threshold testing done after loss of capture. By default, it is set to once every 24 hours.
- Time of day — The time of day allows the user to program a specific time of day when the Active Threshold Monitoring test is performed. By default the time is set to 00:30 AM. This may be changed if the patient is sensitive to the pacing test occurring at night and may be set to a time when the patient is awake.

Table 21 contains a list and description of the acronyms and terms pertaining to the VCC feature used in this manual.

Term	Definition
CV	Capture Verification—A component of the VCC feature that provides beat-to-beat classification of capture and non-capture. Used for the RV channel only.
ATM	Automatic Threshold Measurement—A component of the VCC feature that periodically measures the ventricular pacing threshold. ATM can only occur after a successful CV.
Evoked Response	The intracardiac signal measured during electrical activation of the cardiac tissue.
LOC	Loss-of-Capture—The VCC feature classifies loss of capture when a series of ventricular pacing pulses at varying AV delays did not capture (with a maximum of 3 consecutive NC's).
MaxVCCAmp	Threshold test start—This programmable parameter is the maximum voltage setting that VCC will set after a successful CV.
NC	Non-Capture—The VCC feature identifies a non-capture as a single ventricular pacing pulse without capture.
Polarization Artifact	The signal or noise caused by the pacing pulse between the pacing electrode and the cardiac tissue.

Term	Definition
Safety Margin	The safety margin is the difference between the pacing threshold and the programmed pacing amplitude.
SA	Signal Analysis—A component of the VCC feature that periodically determines whether evoked responses are appropriately detected and that pacing artifact is sufficiently small in amplitude. If the SA determines that the signal is not acceptable, then the other portions of the VCC feature cannot be activated.

Table 21: Acronyms and Terms

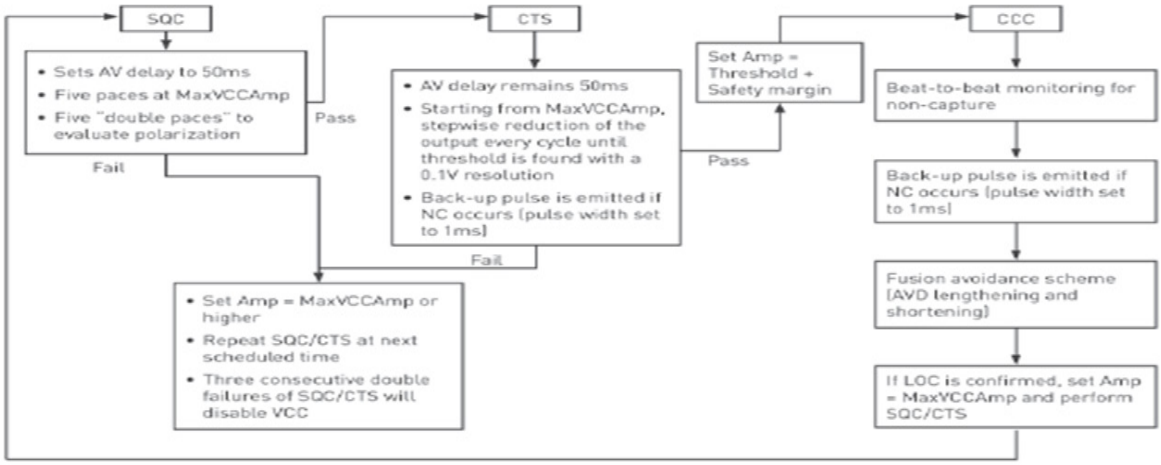


Figure 32: VCC Flow Chart

The feature includes three primary components: Signal Analysis, Capture Threshold Search, and Capture Verification. The following paragraphs describe the operation of these three components (SA, ATM, and CV) of VCC while active in DDD(R) pacing mode. In the other modes (VDD(R) and VVI(R)), there are slight variations in the operation of VCC.

Signal Analysis (SA)

A polarization artifact that is too large may disturb the cardiac signal following the pacing pulse and result in misclassification of the event. Conversely, the evoked response signal may be too small or may not meet the capture criteria, which again may lead to misclassification of the event. Therefore, the SA analyzes the evoked response and the amplitude of the polarization artifact. A successful SA must always be completed before the Capture Threshold Search or the activation of Capture Verification.

- SA is performed in two separate phases. In both phases, the AV delay is shortened to 50 ms after a paced atrial event and to 15 ms after a sensed atrial event to ensure ventricular pacing. First, five ventricular pacing pulses are delivered at MaxVCCAmp, which is the programmable maximum voltage setting (2.4, 3.0, 3.6, 4.2, 4.8 V). If non-capture is detected at the maximum voltage setting, the second phase of the SA is aborted and the test is classified as unsuccessful. In the next phase, five “double” pacing pulses (one pacing pulse followed by another pacing pulse 100 ms later, in the absolute refractory period) are delivered. These pulses are used to verify that the polarization artifact is small enough to distinguish capture from non-capture. If the artifact following the second pacing pulse is higher than a certain limit, then SA is classified as unsuccessful. If necessary, this test can be repeated at a lower maximum voltage setting.
- If the first SA after activating VCC is not completed successfully, VCC is immediately disabled, and the pacing amplitude is programmed to MaxVCCAmp. VCC then requires manual reactivation of the feature with the programmer.
- If the first SA after activating VCC is completed successfully, but subsequent SA’s are not completed successfully, then VCC is suspended, and the pacing amplitude is programmed to the last measured threshold plus the safety margin. The SA will be attempted up to three times. After the 3rd failure, VCC is disabled, and the pacing amplitude is programmed to the MaxVCCAmp plus the Safety Margin of 1.2 V. VCC then requires manual reactivation of the feature with the programmer.

Automatic Threshold Measurement

- The Automatic Threshold Measurement is the component of the VCC feature that measures the ventricular pacing threshold by stepping down the output until non-capture occurs.
- The Automatic Threshold Measurement occurs over a series of cardiac cycles and begins at the threshold test start that decreases until capture is lost. AV delay is shortened to 50 ms after a paced atrial event and to 15 ms after a sensed atrial event to ensure ventricular pacing.
- The pacing amplitude decrements with every paced beat by 0.6 V, until the first non-captured beat. The algorithm then decrements by smaller increments of 0.1 V until the first failed capture, at which point it determines that the capture threshold is preceding value. .
- If two out of three non-capture events are detected, the pacing amplitude is set to the sum of the pacing threshold voltage and the programmed safety margin. If two non-captures are detected when the voltage decrements are greater than 0.1 V, the pacing amplitude is set to the previous amplitude and then the amplitude decrements by 0.1 V until the pacing threshold is determined. When another two non-capture are detected, the previous voltage setting is the pacing threshold.
- The pacing amplitude is then set to the pacing threshold plus a programmable safety margin (0.5 V through 1.2 V in steps of 0.1 V).
- In addition to performing the threshold search after a loss of capture, the search is also conducted at a programmable interval or a specific time during the day to provide an accurate safety margin even with gradual changes in the pacing threshold. Note that a CV initiated by spontaneous loss of capture will reset the timer that triggers the next periodic measurement if the search is programmed to interval.

Capture Verification (CV)

The Capture Verification function is the component of the VCC feature that provides beat-to-beat capture verification. (Not available in the ATM mode or BiV pacing)

- If VCC determines that capture has been maintained, then the pulse amplitude remains at that current setting and no action is required.
- If VCC determines that non-capture (NC) occurred, then a safety back-up pacing pulse is delivered at an increased energy (same output voltage and pulse width extended to 1.0 ms) within 130 ms after the non-captured pacing pulse.
- If a series of ventricular pacing pulses at varying AV delays result in loss-of-capture, a Signal Analysis (SA) and Automatic Threshold Search are initiated to determine the current pacing threshold.
- The algorithm is designed to respond appropriately to fusion beats. In order to discriminate non-capture from fusion, a capture confirmation algorithm varies the AV delay after detection of non-capture in the dual chamber pacing modes. First, fusion is diminished by extending the AV delay. If a second non-capture is detected, the AV delay is returned to the programmed AV delay. If a third consecutive non-capture is detected, loss of capture is confirmed and a Signal Analysis and Automatic Threshold Search are initiated. If the first event was truly fusion, the extended AV delay could allow intrinsic conduction. The AV delay will not return to the normal programmed value until ventricular pacing is required. In case the capture confirmation continues to detect non-captures without detecting 3 consecutive non-captures, the algorithm shortens the AV delay (50 ms after an atrial paced event and 15 ms after an atrial sensed event for up to 2 paced cycles) to confirm the occurrence of non-capture. When VCC and CLS are both enabled, the AV delay is extended after detection of non-capture and then capture confirmation is temporarily disabled while CLS performs an AV Hysteresis Scan.

5.13.3.1 Algorithm Suspension, Abort and Disabling

The VCC feature is inactive until the first SA and CV after programming is completed successfully. The SA/CV sequence is unsuccessful when the SA or CV fail or are aborted. In addition, an SA/CV sequence can be postponed and CV can be temporarily suspended.

The SA/CV sequence will fail when the following events occur:

- Non-capture during SA: non-capture occurs twice in the second through fifth cycles of the SA (at the maximum voltage amplitude setting).
- High polarization artifact during SA: the polarization artifact measured during the SA is too high.
- No non-capture during CV: the threshold search decreases the output to 0.1 V without detecting non-capture.

An ongoing SA/CV sequence will abort when the following events occur:

- Mode Switch: Mode switch has a higher priority than the SA/CV. If Mode switch aborts an SA/CV, the device will be set to high output. After reversion back to the programmed mode, a new SA/CV will be initiated.
- Programmer Wand application: An ongoing SA/CV aborts when a magnet (programmer wand) is applied and the device is then set to high output. After removal of the magnet, a new SA/CV is started.
- Search timer expiration (120 seconds): if the SA/CV takes longer than 120 seconds to be completed (e.g., due to sensing), the SA/CV will be aborted and the device will be set to high output.
- Noise detection: if excessive noise is detected, the initial SA/CV will be aborted and the device will be set to high output.

A SA/CV sequence will be postponed when the following events occur:

- Mode switch is ongoing: If Mode switch is ongoing when an SA/CV is scheduled, the SA/CV will be postponed until reversion back to the programmed mode.
- The presence of a magnet is detected: A scheduled SA/CV is postponed when a magnet (programmer wand) is detected. After removal of the magnet, the SA/CV is started.
- The ventricular rate is higher than 110 bpm: A scheduled SA/CV is postponed when the ventricular rate is higher than 100 bpm. When the ventricular rate drops below 10 bpm, the SA/CV is started.

The continuous capture control (CV) will be suspended and the ventricular pacing amplitude is set to high output when the following events occur:

- The ventricular rate is higher than 110 bpm: CV is suspended while the ventricular rate is higher than 110 bpm. When the ventricular rate drops below 110 bpm, CV is resumed.
- Mode Switch: CV is suspended and the device is set to high output until reversion back to the programmed mode.

The VCC feature will be automatically turned OFF when the following events occur:

- The initial SA/CV sequence after activating VCC failed
- Three subsequent and consecutive failed SA attempts
- The occurrence of 25 Losses of Capture between two consecutive days
- ERI: the device will be set to ERI mode with VCC OFF
- Unipolar lead failure is detected

The occurrence of these unsuccessful, aborted or postponed SA/CV sequences and disabling of the VCC feature are reported in the Status log in the VCC statistics.

5.13.4 Ventricular Capture Control Programming

VCC is programmable to ON, Active Threshold Monitoring (ATM) modes, and OFF. Table 22 provides details about the VCC programmability.

	Programmable Modes for VCC	
VCC Components	ON	ATM
Pulse width programmability	less than or equal to 0.4 ms	
SA and Capture Threshold searches	Yes	Yes
Set output to threshold + safety margin	Yes	No
Capture Verification (CV)	Yes	No

Table 22: VCC Programmability

When programmed to ON, the device will continuously monitor the cardiac signal following the pacing pulse to verify that a depolarization occurred as a result of the pulse. Upon detection of non-capture, the device will issue a back-up pulse at a higher output (pulse width increased to 1 ms) within 130 ms. If loss-of-capture (LOC) occurs, the device will initiate an SA/CV. Additionally, the device will perform regular threshold searches at the programmed time each day. After a successful threshold search, the device will program the pulse amplitude to the threshold plus the programmed Safety Margin. The device will never set the amplitude lower than the fixed minimum VCC Amplitude (Min Ampl.) of 0.7 V.

NOTE:

After programming the Ventricular Capture Control feature to ON or ATM, the device will perform a Signal Analysis and a capture threshold search. This sequence can take up to 2 minutes.

5.14 Atrial Capture Control (ACC)

5.14.1 Feature Description

Automatic atrial threshold measurement can be performed during follow-up using the programmer. The ACC feature periodically measures the pacing threshold and amplitude adjustment in the atrium. The standard setting is one threshold measurement per day, but the user may choose another frequency of measurement. The threshold search is based on the presence or absence of atrial sensing markers generated by the device. The atrium is stimulated at a pacing rate higher then the intrinsic rate to suppress atrial intrinsic events. As soon as the pacing output is lower then the atrial threshold, sensed atrial event will be detected either due to the emerging intrinsic rhythm or due to retrograde conducted events caused by ventricular paces. The detection of sensed atrial activity is used to discriminate between atrial capture and non-capture. The atrial capture control is performed in four steps:

1. Setup-Phase: The device monitors the rate and rhythm condition and determines the actual rate in the atrium immediately before it starts the threshold search. Automatic measurements are allowed if the atrial and ventricular rate is below 110 bpm and no mode switching is active. If these conditions are met, the activation of the capture control algorithm causes a mode switch to DDI with an atrial overdrive pacing of +20 % of the actual determined rate. The Ap-Vp interval will be programmed to 50 ms, to avoid retrograde conduction from the ventricle.
2. Threshold search: The threshold is determined by decreasing the amplitude stepwise at a programmed pulse duration until loss of capture occurs. Loss of capture for one test amplitude is declared if in a test window of five cardiac cycles (5 Ap-Vp intervals) two or more intrinsic atrial events are sensed which indicates unsuccessful pacing.
3. Confirmation phase: The pacing threshold is considered to be confirmed if capture is determined with the first step and loss of capture is confirmed with the second step.
4. Amplitude adjustment: The pacing amplitude is defined by adding the programmed safety margin to the determined threshold.

Parameters associated with Atrial Capture Control are shown in Table 23.

Parameter	Range	Default
Capture Control	ON, ATM, OFF	ON
Minimum Amplitude	0.5...(0.1)...4.8 V	1.0 V
Threshold Test Start	2.4, 3.0, 3.6, 4.2, 4.8 V	3.0 V
Safety Margin	0.5...(0.1)...1.2 V	1.0 V
Search Type	Time of day, Interval	Time of day
Time of Day	24 hour clock	00:30 A.M.
Interval	0.1, 0.3, 1, 3, 6, 12, 24 hr.	24 hr.

Table 23: Atrial Capture Control Parameters

Capture Control

OFF, ON, ATM

When Atrial Capture Control is OFF, the user can manually program the output based on current threshold and physician preference.

When Atrial Capture Control is ON, the feature will determine the capture threshold and program the output based on the capture threshold and programmable safety margin. The device will then perform routine threshold tests based on the programmed scheduled time.

The threshold value is stored in the measured threshold values in the pacing portion of the device statistics as well as in the device follow-up history.

Atrial Capture Control will continue to test for atrial thresholds even when previous attempts have failed. In other words, it will not disable the algorithm unless a lead failure or ERI is detected.

The ATM mode differs from Capture Control ON, as ATM does not adjust the pacing voltage automatically. It does, however, store the measured threshold values in the pacing portion of the Statistics for review and in the follow-up history of the device. In the ATM mode, the clinician controls the pacing output.

Minimum Amplitude

0.5...(0.1)...4.8 V, default 1.0 V.

This is the minimum atrial pacing output to which the device can be automatically programmed, regardless of the measured threshold. The Minimum amplitude can never be programmed higher than the Threshold test start value. This restriction is shown by the symbol.

Threshold Test Start

2.4 V, 3.0 V, 3.6 V, 4.2 V and 4.8 V, default 3.0 V

This is the starting voltage when Capture Control (ON or ATM) is looking to determine the current threshold. This value should only be changed to a higher value if the patient has high thresholds.

Safety Margin

0.5 V...(0.1 V)...1.2 V, default of 1.0 V

This is the amount of pacing output added to the measured threshold value to ensure capture. This takes into account minor changes in thresholds throughout the day. For example, if the threshold was 0.7 V, the device would add the 1.0 V safety margin to the 0.7 V threshold and program the pacing output to 1.7 V. The lowest the output that can be programmed is the Minimum amplitude value, regardless of the threshold.

5.14.2 Search Type

Interval / Time of Day

This feature determines when the device performs a Capture Control test to check the current threshold.

- Interval — Interval starts the next Active Threshold Monitoring test at a programmed time from when the previous threshold test was performed. The interval begins with a permanent program being sent to the device. This time may vary due to retesting or programming changes. By default, it is set to once every 24 hours.
- Time of day — The time of day allows the user to program a specific time of day when the Active Threshold Monitoring test is performed. By default, the time is set to 00:30 A.M. This may be changed if the patient is sensitive to the pacing test occurring at night and may be set to a time when the patient is awake.

5.15 Ventricular Pace Suppression (Vp-Suppression)

5.15.1 Feature Description

Vp-Suppression is a feature that is available in DDD(R)-ADI(R) mode and is not available with biventricular pacing. This feature promotes the intrinsic AV conduction by only pacing the ventricle when intrinsic conduction becomes unstable or disappears. Depending on the presence or absence of AV conduction, the feature is implemented either in the ventricular pacing suppression state ADI(R), which promotes the intrinsic conduction, or in the DDD(R) ventricular pacing state Vp DDD(R), which provides ventricular pacing. Automatic switching capabilities between those two states promote the intrinsic conduction as much as possible without harming the patient. Scheduled Vs searching tests look for intrinsic conduction using an extended AV delay of 450 ms. In order to protect the patient from high ventricular rates, the feature provides Mode Switching independent of the present state of the algorithm. The feature itself becomes suspended for the time of Mode Switching. When Vp-Suppression becomes enabled, the device starts in the Vp-DDD(R) state and looks for intrinsic conduction by starting a Vs-searching. Following any suspension (e.g. Mode Switch), the Vp Suppression feature will resume in Vp-DDD(R) state. The feature provides user programmability with respect to the switching criteria in order to support intrinsic conduction.

5.15.2 Programmability

The Vp-Suppression feature will provide the following programmability as shown in Table 24. Vp-Suppression is available only if DDD(R)-ADI(R) modes is selected.

Parameter	Range	Default
Vp-Suppression feature	On, Off	Off
VpS to DDD(R) x/8 cycles without VS	1,2,3,4	3
DDD(R) to VpS x consecutive Vs	1,2,3,4,5,6,7,8	6

Table 24: Vp-Suppression Parameters

5.15.3 How the Vp Suppression Algorithm Works

Once the algorithm is programmed ON and the wand is removed, a Vs Continuity test is performed with the first intrinsic ventricular event or after 30 seconds of ventricular pacing whichever comes first.

A Continuity test is used to determine whether a stable intrinsic ventricular rhythm is present. During the test, the AV Delay is extended to 450 ms for eight cycles. During those eight cycles, the device looks to determine if six out of eight Vs events occur. If six Vs events occur, Vp Suppression is activated. If six events do not occur, the device will return to the programmed AV Delay and a new search will be performed at a specific time interval. More detail on search intervals will be found in the following section, Intelligent Search.

While the device is in the ADI(R) mode, pacing is available only in the atrium. The AV Delay is set to 450 ms in the background without delivering a pace if the AV Delay timer expires.

Intelligent Search

This feature is designed to prevent frequent searches in patients without stable intrinsic ventricular activity. Each time the search is unsuccessful, the time interval is doubled from the previous interval, up to 128 minutes. After that, the device will search every 20 hours. The rationale for 20 hours is to allow the device to perform searches during different times of the day to improve the chances of success.

Search Time Interval Scheme

30 sec. > 1 min. > 2 min. > 4 min. > 8 min. > 16 min. > 32 min. > 64 min. > 128 min. > 20 hr.

Switching Back to DDD(R)

The following criteria will cause the device to switch back to DDD(R):

- No Vs for two seconds
- Two consecutive cycles without a Vs event
- A programmable number of cycles without a Vs out of eight cycles (Default is three out of eight cycles)

In the presence of a Mode Switch event, the device will switch to the programmed Mode Switch Mode. Once the Mode Switch event is over, the device will switch back to the DDD(R) mode and then initiate the Continuity test for the Vp Suppression algorithm.

If a patient has unstable AV conduction, the algorithm may switch to an ADI(R) mode frequently. The number of times the device can switch to Vp Suppression is limited to 15 attempts per hour. When the limit is reached, the Vp Suppression feature is suspended until midnight (12:00 AM) and will then resume the Continuity test starting with the 30 second search interval.

Interaction of Vp Suppression with other Algorithms

The following events will interrupt the Vp Suppression algorithm:

- Wand application
- PMT Detection
- Mode Switch

The algorithm is disabled when the device enters the ERI state.

5.16 Thoracic Impedance

The thoracic impedance is measured between the distal electrode of the RV lead and the pacemaker housing. 8 measurements per hour are done and these measurements are then averaged. The 24 measurements per day are stored in the device and transmitted via Home Monitoring as a single averaged data point. The Home Monitoring website then displays a trend of the daily average. The same trend of daily TI averages is displayed on the programmer upon interrogation of the pacemaker. The TI trend does not replace assessments that are part of standard of care for the clinical practice. The clinical value of this feature has not been established for the management of patients.

5.17 ProgramConsult®

ProgramConsult® provides clinicians with the option to increase programming efficiency by providing programming suggestions for frequent pacemaker patient conditions and having the capability to store individual programming for future usage (can store up to three individual parameter sets for future programming).

ProgramConsult is not an algorithm but uses preset settings based on the recommendations of the ACC/AHA/HRS guidelines for device based therapy.[3] ProgramConsult only shows recommendations for specific parameter settings to the user and clearly highlights them as modifications to the active permanent program prior to making any changes to device programming.

This feature is part of the programmer parameter section and is located on the main Edora/Evity/Enitra ProMRI® pacemaker programmer screen under the selection Program Sets. Upon selection of ProgramConsult, a sub-window opens with multiple selections depending on the underlying disease. Upon selection of a particular option, the parameter page displays the suggested parameter values in blue color. This indicates the recommended setting changes to the user (from the current settings) so that they can confirm them prior to activation. If desired, modifications can be made prior to transmitting the new program to the pacemaker as an updated permanent program. Table 25 compares the suggested ProgramConsult and standard parameters for different patient conditions with a DR-T ProMRI® pacemaker:

	Standard program	SSS including brady-tachy syndrome	SSS with chronotropic competence	Permanent high-degree AV block	Paroxysmal high-degree AV block	Bradycardia with permanent atrial fibrillation	Dual node disease + permanent AV block	Dual node disease + paroxysmal AV block	Vasovagal syncope	Symptomatic first-degree AV block
Valid for:	DR(-T)	DR(-T)	DR(-T)	DR(-T)	DR(-T)	DR(-T), SR(-T)	DR(-T)	DR(-T)	DR(-T)	DR(-T)
Parameters										
Mode	DDD-R	DDD-CLS	DDD	DDD	DDD	VVI-CLS	DDD-CLS	DDD-CLS	DDD-CLS	DDD
Rate Hysteresis (bpm)	OFF	---	OFF	-10	-10	---	---	---	---	OFF
Rate Hysteresis Rep. Cycles	---	---	---	5	5	---	---	---	---	---
Rate Hysteresis Scan Cycles	---	---	---	5	5	---	---	---	---	---
CLS Vp required	---	No	---	---	---	No	Yes	No	No	---
CLS Resting Rate Control	---	+20	---	---	---	+20	+20	+20	OFF	---
AV Hysteresis	OFF	I-OPT	---	OFF	---	---	OFF	I-OPT	I-OPT	OFF
2:1 Lock-in Protection	ON	ON	ON	ON	ON	---	ON	ON	ON	ON
Mode switch	ON	ON	ON	ON	ON	---	ON	ON	ON	ON
PMT	ON	ON	ON	ON	ON	---	ON	ON	ON	ON
Activate VCC	ON	ON	ON	ON	ON	ON	ON	ON	ON	ON
VCC Threshold start (V)	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
VCC Safety Margin (V)	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
VCC Interval (h)	2:00am	24	24	24	24	24	24	24	24	24
Holter										
High atrial rate	AT	ModeSw	ModeSw	OFF	OFF	OFF	ModeSw	ModeSw	OFF	OFF
High ven. Rate	ON	ON	ON	OFF	OFF	ON	ON	ON	OFF	OFF
Patient trigger	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF
Pre-trigger recording (%)	75	75	75	---	---	75	75	75	---	---
IEGM signal	Filtered	Filtered	Filtered	---	---	Filtered	Filtered	Filtered	---	---
HAR limit (bpm)	200	200	200	---	---	---	200	200	---	---
HVR limit (bpm)	180	160	160	---	---	160	160	160	---	---
HVR counter	8	8	8	---	---	8	8	8	---	---

Table 25: ProgramConsult

3 ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Andrew E. Epstein, John P. DiMarco, Kenneth A. Ellenbogen, N.A. Mark Estes, III, Roger A. Freedman, Leonard S. Gettes, A. Marc Gillinov, Gabriel Gregoratos, Stephen C. Hammill, David L. Hayes, Mark A. Hlatky, L. Kristin Newby, Richard Page, Mark H. Schoenfeld, Michael J. Silka, Lynne Warner Stevenson, and Michael O. Sweeney

5.18 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 implant 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.

The implant's Home Monitoring function can be used for the entire operational life of the implant (prior to ERI) or for shorter periods, such as several weeks or months.

Home Monitoring can be utilized as a functional replacement for in-office follow-up visits and allows the time between routine, scheduled, in-office follow-ups of BIOTRONIK implantable devices to be extended to twelve months or more. Home Monitoring evaluation of implanted devices and patient status is as safe as conventional in-office follow-ups. BIOTRONIK's Home Monitoring system provides early detection of arrhythmic events and of silent, asymptomatic events. Automatic early detection of clinical events by Home Monitoring leads to earlier intervention than conventional in-office follow-ups and improves adherence to scheduled follow-ups.

NOTE:

When ERI mode is reached, this status is transmitted. Further measurements and transmissions of Home Monitoring data are no longer possible.

5.18.1 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).

5.18.2 Patient Device

The patient device (CardioMessenger) is designed for use in or away from the home and is comprised of either a mobile unit and the associated charging station or a stationary unit typically kept at the patients beside. The patient can carry the mobile unit during his or her occupational and leisure activities. The mobile patient device is rechargeable, allowing for an approximate operational time of 24 hours. It receives information from the implant and forwards it via the cellular mobile network or the standard telephone system to a BIOTRONIK Service Center.

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

5.18.3 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.

Use of the Internet for reviewing Home Monitoring data must be in conjunction with the system requirements listed in Table 26.

	System Requirements	System Recommendations (for Optimal Usage)
Screen Resolution	1024 x 768	≥ 1280 x 1024
Internet Bandwidth	200 kB/sec	≥ 200 kB/sec (Broadband internet connection)
PC	800 MHz Pentium processor, 128 MB RAM	N/A
Internet Browser	MS Internet Explorer 7	≥ MS Internet Explorer 7 ≥ Mozilla Firefox 26 ≥ Chrome 21 ≥ Apple Safari 7 JavaScript and cookies must be enabled
Acrobat Reader	Version 8	Version 8 or higher
Communication Channel	Fax (G3) or e-mail	Fax (G3) or e-mail or mobile phone
E-mail Client	UTF-8 Compatible	UTF-8 Compatible

Table 26: System Requirements / Recommendations

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.

5.18.4 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 pacemaker detects certain events, which initiate a report

5.18.4.1 Trend Report

The time of the report transmission is programmable. For periodic messages, the time can be set anywhere between 0:00 and 23:59 hours. It is recommended to select a time between 00:00 and 04:00 hrs.

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.

5.18.4.2 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:

- Atrial Lead Check < 100 +/-50 Ohm and > 2500 +/-500 Ohm
- Ventricular Lead Check < 100+/-50 Ohm and > 2500 +/-500
- VCC Disabled
- ERI detected
- Atrial Capture Control Disabled
- High Ventricular rate
- Atrial tachyarrhythmia persisting beyond a programmable time limit or
- Mode Switch episode persisting beyond a programmable time limit

NOTE:

The attending physician must notify the BIOTRONIK Service Center about which of these events he/she wishes to be informed.

5.18.5 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 implant 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
- Message Creation Date/Time
- Device Serial Number

Leads

- Automatic Threshold Monitoring
- Measured pacing thresholds
- RA enabled/disabled
- RV enabled/disabled
- Date/time of ATM measurement
- Pacing Impedance (RA, RV)
- Sensing Amplitude (RA, RV)

Pacing Counters (Brady)

- AV-Sequences
- Intrinsic Rhythm (AsVs)
- Conducted Rhythm (AsVp)
- Atrial Paced Rhythm (ApVs)

- Complete Paced Rhythm (ApVp)

Atrial Arrhythmia

- Atrial Tachy Episodes (36 out of 48 criteria)
- Counter on AT/AF detections per day
- Atrial Burden per day°
- Ongoing Atrial Episode Time (programmable for 6, 12 or 18 hrs)
- Mode Switching
  - Number of Mode Switches
  - Duration of Mode Switches

Ventricular Arrhythmia

- High Ventricular Rate Counters

Transmitted Device Settings

The primary programmed parameters for the following are sent in the data package:

- Leads—(e.g., Pacing Output, Configuration)
- Brady—(e.g., Basic Rate, UTR, AV-Delays, RV Sensitivity)
- I-Opt—(ON/OFF)
- HM Settings—(e.g., ON/OFF, transmission time (daily), IEGM transmissions ON/OFF, periodic IEGM, ongoing atrial episode, statistics, holter)
- Miscellaneous other information

5.18.5.1 IEGM Online HDs

Pacemakers provide the ability to transmit periodic IEGM Online HD (IEGM and marker data) from the periodic follow-ups as an addition to the current messages.

An IEGM with up to 3 channels (LV, RV and/or RA) are sent in one message.

The following markers are also transmitted: As (including Ars), As (PMT), Ap, RVs/LVs (including RVrs) and RVp/LVp.

The pacemakers include a programmable parameter to disable or enable the IEGM transmission.

5.18.5.2 Periodic IEGM for Home Monitoring Follow-up

The Edora/Evity/Enitra ProMRI® pacemaker families provide the ability to automatically schedule remote follow-ups throught the Home Monitoring Service Center. There are two options available.

1. Fixed Follow-up Intervals (using 30-180 day cycles) from the date of the first scheduled transmission:

Periodic IEGM for HM follow-up					
Cycle duration [days]	30				
	1st date	2nd date	3rd date	4th date	5th date
Transmission date	12/06/2013				

Figure 33: Fixed Follow-up intervals

2. Selection of 5 sequential dates with a minimum time lag of 20 days between any two selected dates.

Periodic IEGM for HM follow-up					
Cycle duration [days]	Selection				
	1st date	2nd date	3rd date	4th date	5th date
Transmission date	12/06/2013	01/13/2014	02/12/2014	03/14/2014	04/13/2014

Figure 34: User defined intervals

5.19 MRI

5.19.1 MRI Programming

The Edora/Evity/Enitra ProMRI® pacemaker families allow the device to be programmed to an asynchronous pacing mode or to the OFF mode when pacing is not required during the procedure. The device provides an AUTO program for MRI procedures.

The AUTO program allows the MRI program to be stored in the device. A sensor in the device recognizes if the patient is in or near the MRI scanner and then automatically activates the stored MRI program. Shortly after the scan is complete, the device reverts to the permanent program.

This feature allows the MRI mode to be programmed in the phsyician's office prior to the scheduled exam.

The AUTO program lasts for up to 14 days (programmable) from the date it is programmed and multiple scans can be performed during that time. Once the timer expires at 11:59 PM of the programmed date, the device will not recognize the scanner and not change to a predefined MRI program.

The Edora/Evity/Enitra ProMRI® pacemaker must always be implanted with MRI compatible leads to ensure system compatibility for an MRI procedure.

A thorough review of the patient and their condition should always be done prior to an MRI procedure.

When selecting the MRI tab, the MRI checklist appears as shown in Figure 35, as well as the current lead values. When the user turns the MRI program ON or AUTO, the mode and rate parameters appear. The Edora/Evity/Enitra ProMRI® DR-T pacemaker allows programming of DOO, AOO, VOO and OFF modes, while the Edora/Evity/Enitra ProMRI® SR-T pacemaker allows programming of either VOO or OFF modes. The basic rate is programmable from 70 to 160 bpm.

The user must check the button stating the patient is approved for MRI scan. Once that is checked, the OK button is accessible. Press the OK button. Press the program button to send the MRI program to the pacemaker.

A test MRI function is available as shown in Figure 36. During the test, the device will show the programmed MRI mode. Stopping the test will take the device back to the permanent program.

MRI mode programming is done from a tab found on the parameters page of the device.

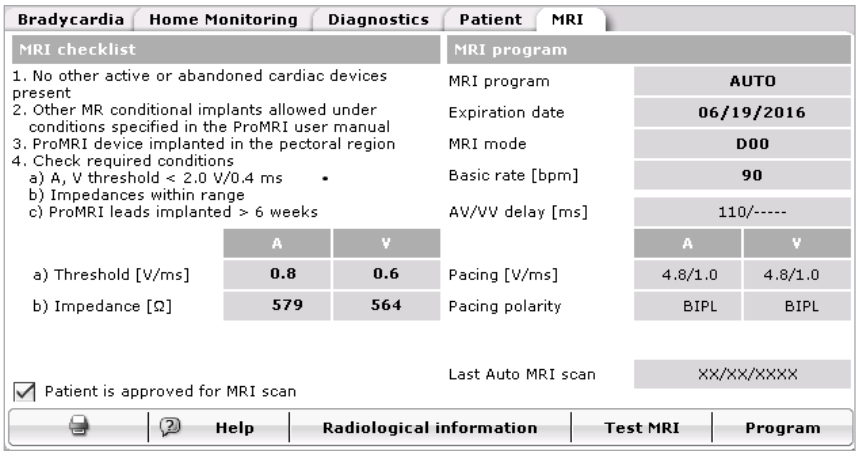


Figure 35: MRI screen

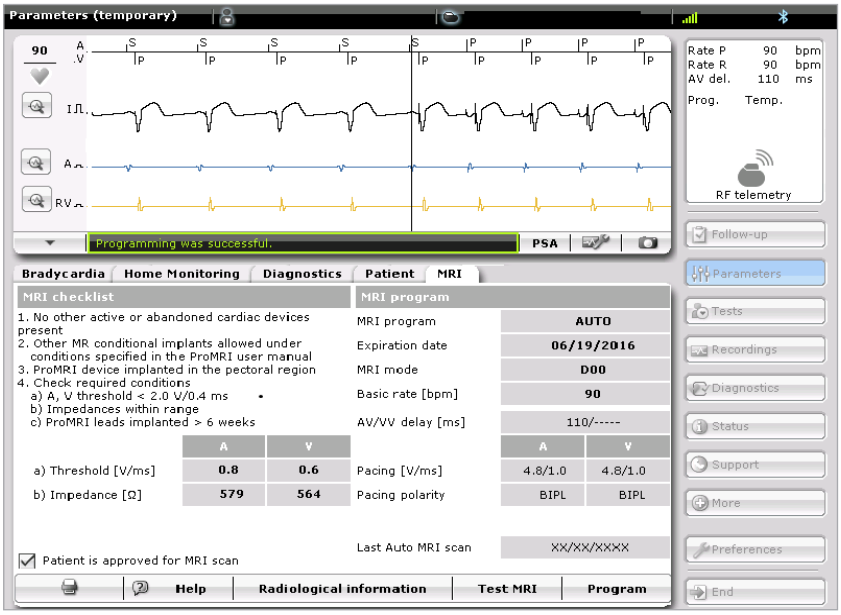


Figure 36: MRI test in progress

6. Diagnostics

6.1 Diagnostics Overview

Edora/Evity/Enitra ProMRI® pacemakers can store a variety of diagnostic information. The various diagnostics consist of such features as rate histograms, event counters, sensor trends, PVC statistics, and activity reports, which are described in the following sections.

Timing

- Event episodes and event
- AV histogram
- Rate histograms
- Pacing trends

Atrial Arrhythmia

- Atrial burden (overall)
- Total number of AT episodes
- Duration
- Tachy episodes / 24 h
- AT/AF burden (daily)
- Ventricular response

Heart Failure Monitoring

- Mean rate
- Heart rate variability
- Patient activity
- Thoracic impedance

24 Hours

- A/V heart rates
- A/V pacing percentages

More Statistics

- Event counters
- Event episodes and events
- Pulse amplitude and threshold
- Ax-Vs interval distribution
- Sensor rate
- Arrhythmia
- P/R wave trend
- Lead impedance trend
- Far-field histogram
- Vp suppression

6.1.1 General Diagnostic Information

The diagnostics 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 pacemaker The counters within the statistic features are reset each time the pacemaker is permanently programmed.

The histogram bars are standardized to a rate class width of 10 bpm to avoid distortion of the rate distribution that would be caused by varying rate class widths. The formula is:

Bar Length =	percentage of total events occurring represented by the events counted in this class x 10
	rate width of this class

6.2 Timing Statistics

Timing statistics presents data collected for event episodes and events, rate histograms, AV histograms and pacing trends for each of the chambers. The data is presented in a graph format with the recording duration found in the rate and AV histogram sections of the page.

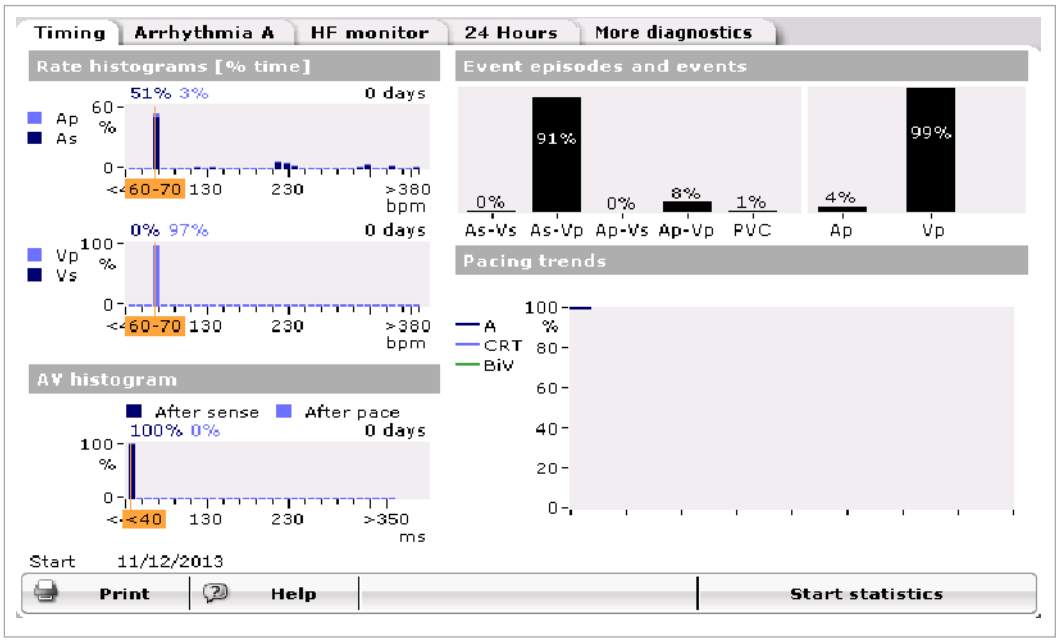


Figure 37: Timing statistics

6.2.1 Event episodes and events

This section presents data collected on the different pacing states of the device; As-Vp, As-Vs, Ap-Vp, Ap-Vs and Vx-Vx. Vx-Vx are ventricular events without an atrial event between.

Event episodes (Brady)

- AV-Sequences
- Intrinsic Rhythm (AsVs)
- Conducted Rhythm AsVp)
- Atrial Paced Rhythm (ApVs)
- Complete Paced Rhythm (ApVp)
- PVC (Vx-Vx)

Pacing Counters (Brady)

- Atrial pace percentage
- Ventricular pace percentage (Vp)

6.2.2 Rate histograms

The Rate histograms show the amount of pacing and sensing for each chamber at different rates. The ventricular data is collected from the RV channel. The heart rate range is divided into 16 segments ranging from less than 40 bpm to greater than 380 bpm.

Key Points:

- The Rate Histogram displays the percentage of paced and sensed events in each rate bin listed along the horizontal axis.
- The Rate Histogram is based on Ap, As, Ars, As(PVARP), Vp, Vs, PVC, and Vrs events.
- Atrial and ventricular rates are plotted on two separate graphs: atrium on the top and ventricle on bottom.
- Paced events are shown in orange and sensed events are light blue.
- A high percentage of atrial events in the upper rate bins may indicate atrial arrhythmias, but could also be due to far-field oversensing.
- Atrial or ventricular events below the basic rate may be due to PVCs resetting the basic rate interval or atrial undersensing.

6.2.3 AV histogram

The AV histogram shows the amount of pacing or sensing response from the ventricular chamber for each AV interval at different rates. The ventricular data is collected from the RV channel. The AV histogram range is adjusted based on the AV delay programming of the device.

6.2.4 Pacing trends

The Pacing trends graph shows the amount of pacing in each chamber per day. The pacing percentage values for the selected day are shown at the top of the graph. Moving the vertical cursor presents data for the selected day. The overall pacing percentage for each day is collected and annotated. The trend collects 240 days of data. After 240 day, the oldest data is overwritten first.

6.3 Arrhythmia Statistics

6.3.1 Atrial Burden

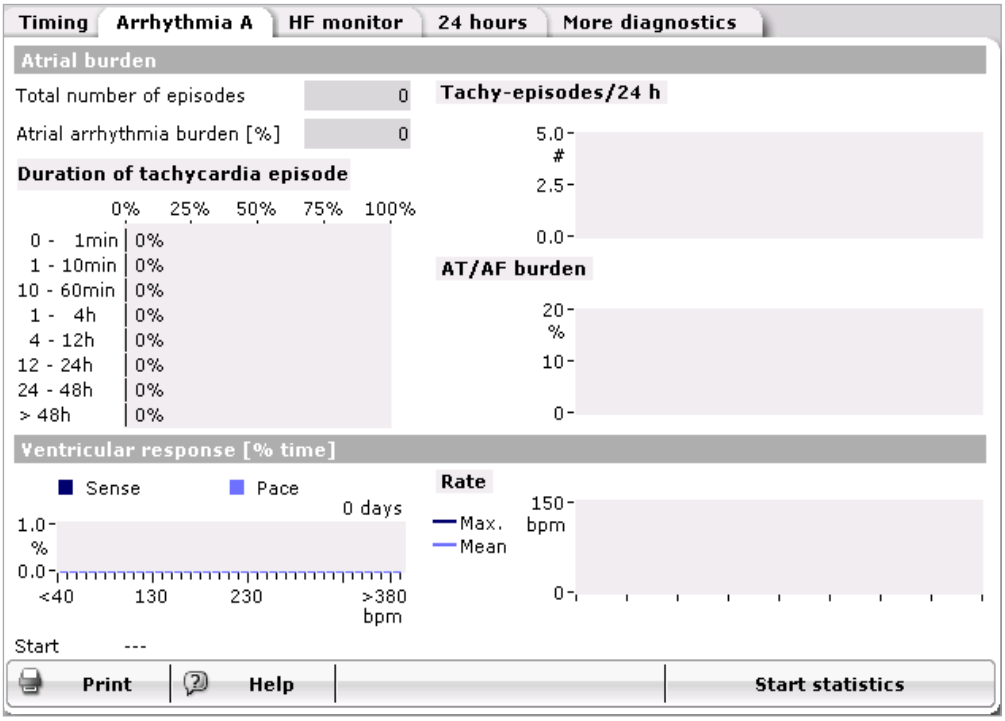


Figure 38: Atrial Arrhythmia

Atrial burden is the percentage of time the patient is in an atrial tachycardia during a given day. The atrial arrhythmia statistic, Figure 38, displays the total number of atrial tachycardias and overall atrial burden. The number of AT events per day and the daily AF burden is also shown on the graph as well as the duration of AT events. The scalar will automatically adjust based on the number and duration of the events. The device will store data for the last 240 days. After 240 days, the device will overwrite the oldest information to make room for current information.

The Atrial burden statistics require the parameter High Atrial Rate (HAR) trigger to be turned ON. The rate that is programmed in the HAR limit becomes the low-rate cut-off value. Atrial burden is not recorded until the 36/48 event above the programmed high atrial-rate criteria is met. Recording is stopped when the termination count of 20/24 is met.

Key Points:

The Atrial Burden diagnostic gives information on atrial arrhythmias throughout the duration of the statistics.

All data is based only on atrial rates above the AT/AF rate (nominally 200 bpm but programmable under the diagnostics parameters).

Percent of Atrial Burden is calculated based on the percentage of time out of the total follow-up duration that the patient was in AT/AF episodes. The atrial burden percentage value is presented as an average daily value.

6.3.2 Duration of Tachycardia Episode

The Duration of tachycardia episode shows the time duration of each AT episode met. The percentage is the number of events in each time bin divided by the total number of events. Knowing the duration of the events can help determine clinical intervention.

6.3.3 Tachy Episodes/24 h

The field represents the number of (atrial) tachycardia episodes per day. The scalar is automatically adjusted to the maximum number of events to occur in a day.

6.3.4 AT/AF Burden

This field represents the amount of time expressed as a percentage per a given day of an atrial tachycardia. The scalar automatically adjusts to the maximum percentage recorded. Each percentage point represents about 14.4 minutes of data.

6.3.5 Ventricular Response

This parameters provides the ventricular rate during AT episodes as well as the percentage of paced and sensed events during AT episodes.

6.4 Heart Failure (HF) Monitor

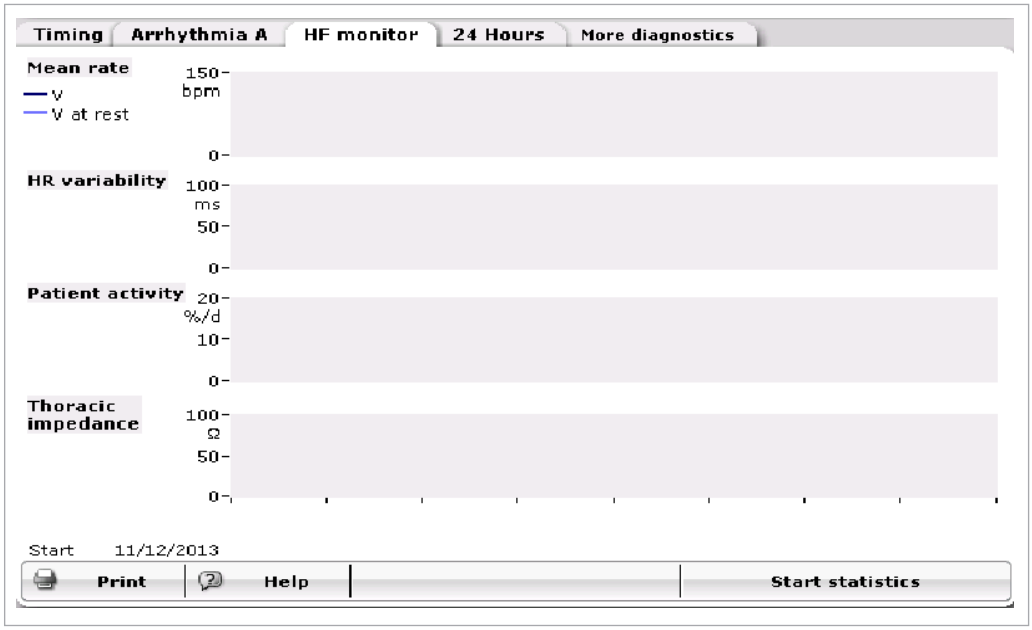


Figure 39: HF Monitor

6.4.1 Mean Heart Rate

The mean heart rate, designated as "V", is calculated based on both ventricular sensed and paced events. All types of events, including VES (PVC) shall be included in the calculation of the mean value. On a daily basis, the device measures and stores the patient's mean heart rate over a 24 hour period and has a value range of 0 to 180 bpm. The daily value is stored for a period of 240 days. After 240 days, new daily values shall replace the oldest daily values. The programmer presents the daily bpm-value in a trend graph for the last 240 days.

6.4.2 Mean Heart Rate at Rest

On a daily basis, the Edora/Evity/Enitra ProMRI® pacemaker measures and stores the patient's resting heart rate (MHRR), shown as "V at rest". Average values are calculated over a defined period. The daily value is based on the smallest mean value in any evaluation window over the resting period. The mean heart rate is calculated based on both ventricular sensed and paced events. All types of events, including VES (PVC) shall be included in the calculation of the mean value.

The MHRR value is measured during a programmed period, defined by a Rest Period Start Time and a Rest Period Duration. The resting period shall be adjustable via the programmer. The MHRR has a value range of 0 to 180 bpm. The daily value (MHRR) is stored for a period of 240 days. After 240 days, new daily values replace the oldest daily values. The programmer presents the daily bpm-value in a trend graph for the last 240 days.

6.4.3 Heart Rate Variability

Heart Rate Variability, which is the standard deviation of the 5-minute mean normal to normal interval over the recorded time is available in the statistics of the Edora/Evity/Enitra DR-T ProMRI®. This is based on the atrial rate (P-P).

6.4.4 Patient Activity

The patient's activity is monitored based on the sensor indicated pacing rate in both, rate adaptive and non-rate adaptive pacing modes. The Edora/Evity/Enitra ProMRI® pacemakers store information about the patient's activity level based on the sensor indicated pacing rate on a daily basis. The device stores the time that the patient is active for each 24-hour period. The time active is defined as the time where the sensor indicated pacing rate is reached.

The sensor indicated pacing rate is the sensor rate above the sensor's threshold. The cumulative daily time when the sensor is active is stored in the device for a period of 240 days. After 240 days, new daily values replace the oldest daily values.

6.4.5 Thoracic Impedance

The thoracic impedance is measured between the distal pacing lead tip of the RV lead and the pacemaker housing. 8 measurements are done every hour and these measurements are then averaged. The 24 measurements per day are then average are stored in the device and transmitted via Home Monitoring. The Home Monitoring website then displays a trend of the daily average. The same trend of daily TI averages is displayed on the programmer upon interrogation of the pacemaker. The TI trend does not replace assessments that are part of standard of care for the clinical practice. The clinical value of this feature has not been established for the management of patients.

Key points:

The heart-rate graph reports mean heart rate (indicated by "V" in the key) and resting heart rate (indicated by "V at rest" in the key).

- Mean heart rate reports the average of the ventricular rate over a 24-hour period (based on Vs, Vp, Vrs, and PVCs).
- The resting heart rate reports minimum ventricular heart rate during the programmed resting period (default beginning at 2:00 AM with a 4-hour duration, programmable under the Diagnostics/HM tab).
- The minimum ventricular heart rate is determined by taking 11-minute averages during the resting period and reporting the lowest of those averages.

Variability is based on the P-P interval, and uses only intrinsic P-P intervals, not atrial paced events.

- Variability is calculated by taking the standard deviation of the 5-minute mean P-P intervals.

Patient activity is available in both rate adaptive and non-rate adaptive pacing modes.

- Data is displayed as the percent of the day (24 hour period) the patient is active.
- Patient activity is present when the device sees motion on the accelerometer.
- Activity is based on the currently programmed sensor threshold.
- If the mode is DDD, activity is measured using a mean sensor threshold.
- Not available in single-chamber devices.

Thoracic Impedance is measured from the distal tip to the pacemaker housing.

- 8 measurements per hour
- Measurements averaged to a single data point
- Thoracic impedance should NOT be used as a stand alone parameter to determine CHF

Variables such as COPD and hypovolemia may affect measurement values

NOTE:

Pocket and or lead revisions may affect the TI trend data. Therefore, the TI trend data should be interpreted cautiously within 6-10 weeks of a revision.

6.5 24 Hours

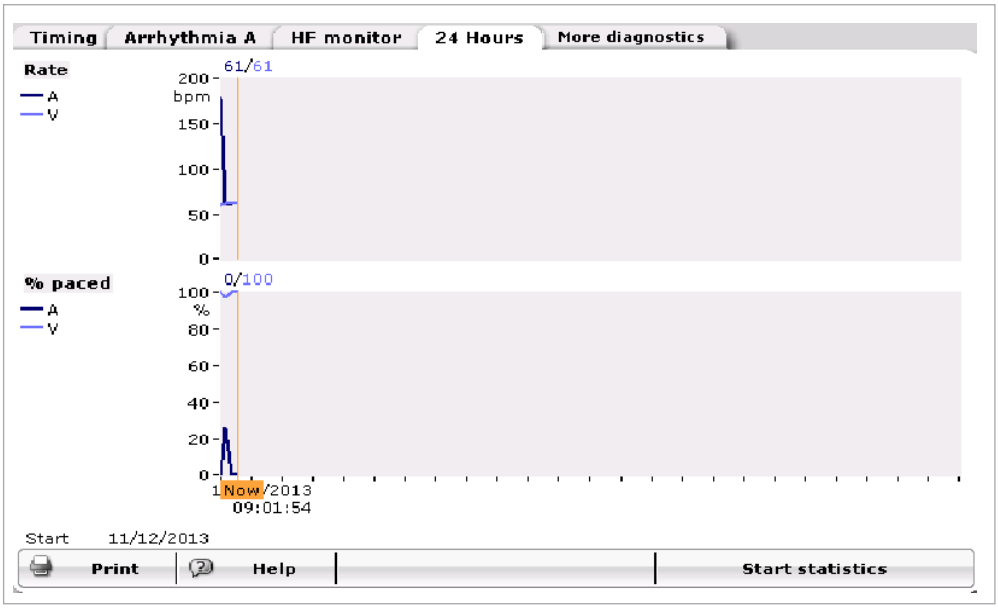


Figure 40: 24 Hours

6.5.1 Rate

The atrial and right ventricular rates are displayed over the last 24 hours prior to interrogation. The data is presented in 11 minute averages

6.5.2 Percent Paced

Presents the paced percentages for all programmed channels.

6.6 More Statistics

6.6.1 Event Counters

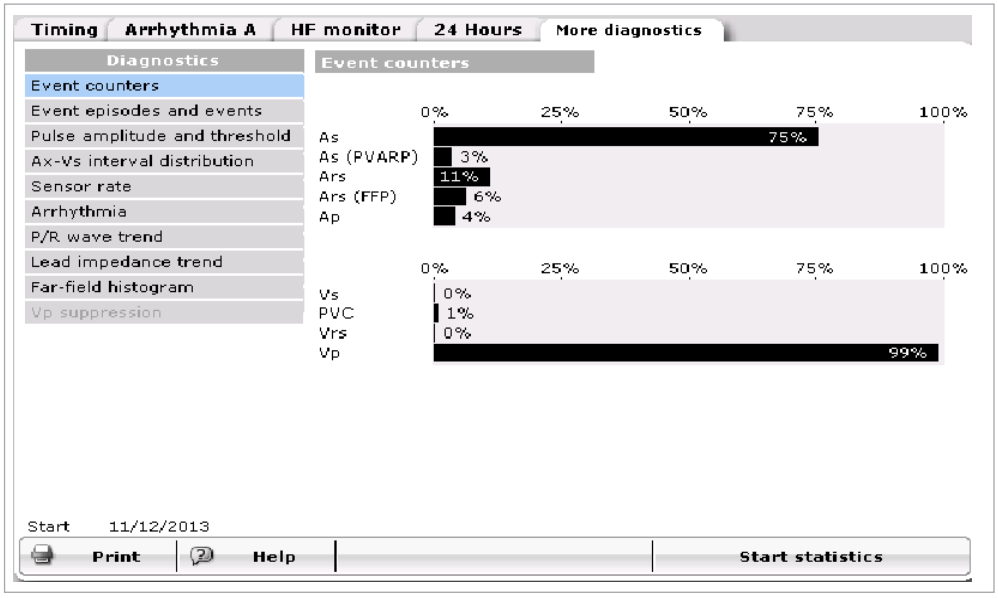


Figure 41: Event counters

In the Event counters, shown in Figure 41, the legend is as follows:

As - refers to atrial sensed events.

As (PVARP) - refers to atrial events occurring during the PVARP period, but outside the FFP period.

Ars - atrial events occurring during the atrial refractory period or during Mode Switching in which the A-A period is less than the programmed atrial refractory period.

Ars (FFP) - events occurring on the atrial channel within the programmed far-field protection period of either ventricular paced or sensed events. Events in this window are not used towards Mode Switching.

Ap - atrial paced events.

Vs - RV sensed events.

PVC - RV extrasystoles (VES).
Edora/Evity/Enitra pacemakers define a PVC as two ventricular events without an atrial event in between. A VT with a slower atrial rhythm will have those events following the atrial events classified as Vs events

Vrs - RV refractory sensed events occurring within the programmed ventricular refractory period of the device.

Vp - RV paced events.

Key Points:

Vrs events are those RV events within 200 ms of the preceding RV sensed event. The 200 ms sensed refractory period is non-programmable.

RVES = Right ventricular extra systole (PVC), defined by the device when the following criteria are met:

- Two ventricular events with no Ap or As in between
- An Ars did not occur within 350 ms of the subsequent Vs event

Ars (PVARP) are those events falling into the PVARP timer and outside the Discrimination after As window. Likely examples of these types of events include non-conducted PAC events or events occurring during Mode Switch.

Ars events are those events occurring during an AV Delay window.

NOTE:

All event counter data are transmitted to the programmer and evaluated there, but not all events are displayed in detail on the programmer.

6.6.2 Event Episodes and Events

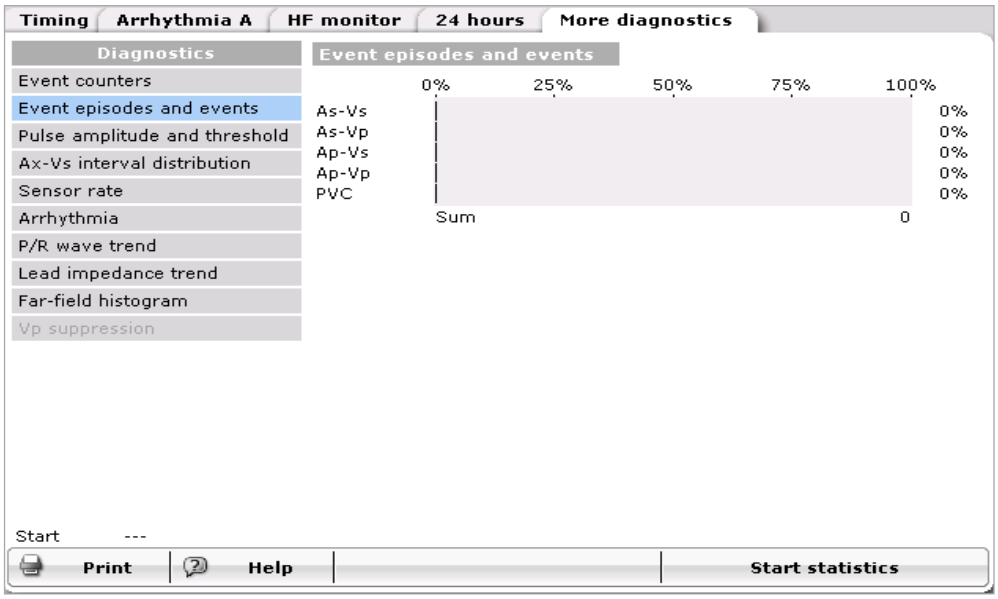


Figure 42: Event episodes and events

The Event episodes and events, shown in Figure 42, presents data collected on the different pacing states of the device; As-Vp, As-Vs, Ap-Vp, Ap-Vs and Vx-Vx. Vx-Vx are ventricular events without an atrial event between.

Event episodes (Brady)

- AV-Sequences (expressed as %)
  - Intrinsic Rhythm (AsVs)
  - Conducted Rhythm (AsVp)
  - Atrial Paced Rhythm (ApVs)
  - Complete Paced Rhythm (ApVp)
  - PVC (Vx-Vx)

Each event is recorded into one of these categories and displayed on this screen. The event episodes are not updated when the patient is in Mode Switch due to the change in device timing.

6.6.3 Pulse Amplitude and Threshold

The Pulse amplitude screen, shown in Figure 43, displays the daily threshold measurements taken in all chambers. This is measured through the ACC/VCC features and is available if the feature is programmed ON. The last threshold test done each day will be displayed on the graph.

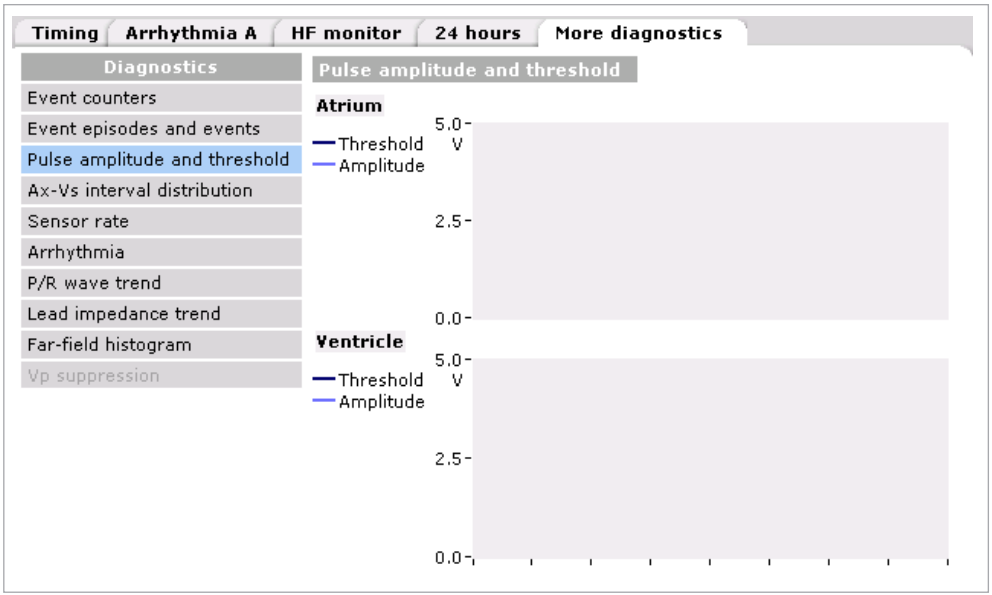


Figure 43: Pulse Amplitude/Threshold Trend

Key Points:

- Pulse amplitude displays the measured threshold for each day throughout the duration of the statistics.
- Pacing threshold measurements can be programmed to ATM or VCC in the device from the parameters screen under the Bradycardia tab.

6.6.4 Ax-Vs Interval Distribution

The Ax-Vs distribution graph provides information regarding the AV intervals at different rates for atrial paced and sensed events. This data can be used to tailor AV Delay programming for the individual patient.

Data is presented in 20 bpm rate bins. The minimum, maximum and mean AV interval for each measured rate bin is displayed on the screen.

In addition, the total number of successful AV hysteresis scans will be displayed if the AV hysteresis feature was turned ON.

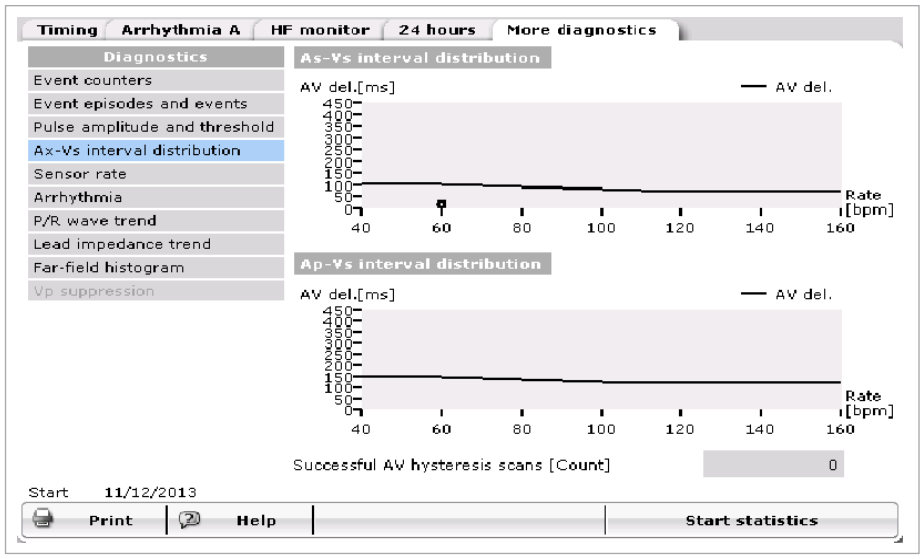


Figure 44: Ax-Vs interval distribution

6.6.5 Sensor Rate

This function records how often the sensor rate is within certain ranges. The rate range is subdivided into 16 rate classes going from 40 to 180, including bins for rates < 40 bpm and rates > 180 bpm. The percentage and total number of sensed and paced events occurring within a rate class is displayed.

Sensor rate recording is independent of the effectiveness of the respective pacing rate, and it is not influenced by inhibition of pacing due to spontaneous events. Rate data are also recorded in non-rate-adaptive modes.

Recording stops when the memory available for recording the sensor rates is full. Recordings can be stored for several years. The frequency distribution of the sensor rates can be displayed as a diagram during follow-up examinations.

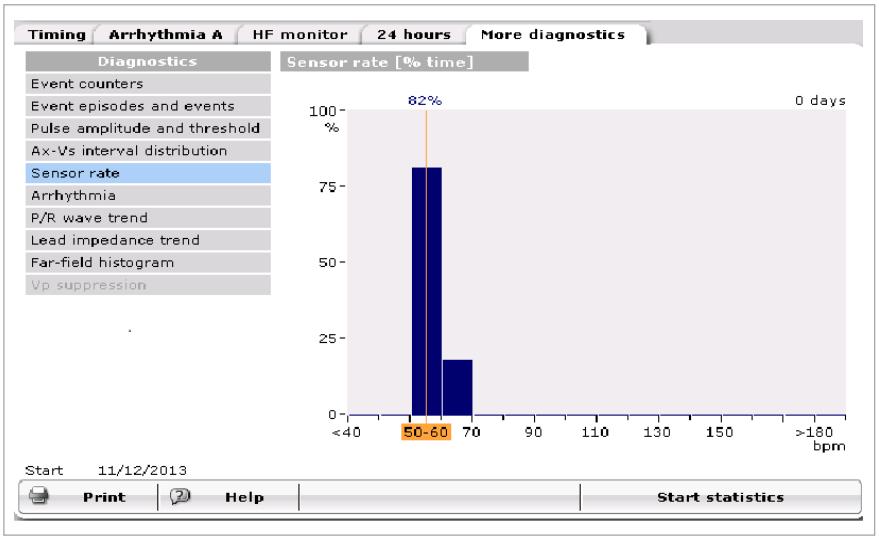


Figure 45: Sensor Histogram

The Sensor rate histogram graph in Figure 45 shows the sensor activity during the recording time. Data is collected even if the device is programmed to a non-sensor mode to demonstrate what the sensor response would have been. In chronotropically incompetent patients, one would expect this

graph to closely match the rate histogram graph. The graph is divided into sixteen 10-beat bins. The duration of recording is displayed on the lower right corner. The user may use the arrow keys, or simply touch on any particular rate within the graph, to review the data. In each bin, the percentage of the time in that particular bin is shown at the top of the graph when that bin is selected.

Key Points:

The Sensor Rate histogram displays the distribution of rates determined by the accelerometer.

The Sensor Rate histogram is updated in R- and non-R-modes.

The Sensor Rate histogram is updated regardless of whether sensor indicated pacing is inhibited by intrinsic events.

6.6.6 Arrhythmia

The atrial arrhythmia section provides the number of mode switches, as well as the longest Mode Switch duration and the longest atrial (AT) episode.

The PVC sequences graph, shown in the ventricular arrhythmia section, provides information related to the number and type of PVC sequences. These sequences include single PVC events, couplets, triplets, runs of 4-8 events and runs of more than eight events.

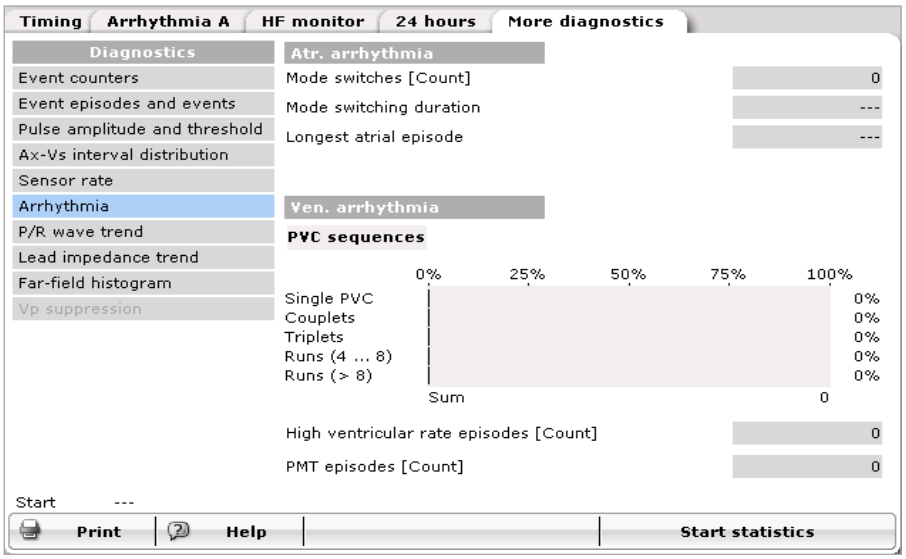


Figure 46: Arrhythmia Screen

The device counts each type of PVC sequence. Each sequence is counted in the sum total below the bar graph in Figure 46. The Sum value is the total number of sequences that have occurred. Each sequence is also given a percentage value; comparing each event sequence against the total number of event sequences.

Mode Switch events that do not meet the HAR criteria of 36/48 will not be counted toward atrial burden or time of occurrence.

The Mode Switch count and the time of occurrence count for AT events may not match for the following reasons:

- Mode Switch events are too short to meet the AT count of 36/48 beats for atrial rate detection criteria
- The patient has SVTs slower than the High Atrial Rate (default 200 bpm).

The Ventricular statistic also displays the total number of HVR events that have occurred.

Key Points:

In order to be counted, PVCs must meet the following criteria:

- Two ventricular events with no Ap or As in between
- An Ars occurring more than 350 ms from the subsequent Vs.

An increase in PVC/h may indicate greater susceptibility to ventricular arrhythmias.

If the patient has a large amount of PVCs causing a low CRT pacing percentage, programming RVES triggering ON may improve the CRT pacing percentage.

A high number of PVCs may indicate atrial undersensing.

NOTE:

PVC events that have an intrinsic atrial event occurring within 350 ms before the Vs event will be classified as an AsVs event and not a PVC. This is due to the As Discrimination feature, which is a hidden feature of the device. This feature is designed to improved event classification but could classify PVC events as As Vs events if an atrial intrinsic event occurs within the 350 ms window (400 ms window if I-Opt is programmed).

NOTE:

If in DDD(R) and atrial undersensing occurs, spontaneously conducted ventricular events are evaluated as PVC events. For this reason, we recommend using the PVC analysis in DDD(R) mode only in conjunction with bipolar sensing and an appropriately high atrial sensitivity.

The interval between two consecutive PVC events must be shorter than 500 ms (i.e., over 120 bpm) for them to be counted. Otherwise, the second PVC will be ignored and the sequence interpreted or terminated. This predominantly eliminates the possibility of PVC events being miscounted as a result of atrial undersensing.

6.6.7 P/R wave trend

Edora/Evity/Enitra ProMRI® pacemakers periodically perform P- and RV-wave amplitude measurements to be displayed later as trend data. A P- and R-wave long-term trend of up to 240 days is available. After the initial timeframe has elapsed, the first data stored is overwritten with new data; therefore, the most recent data are available for review.

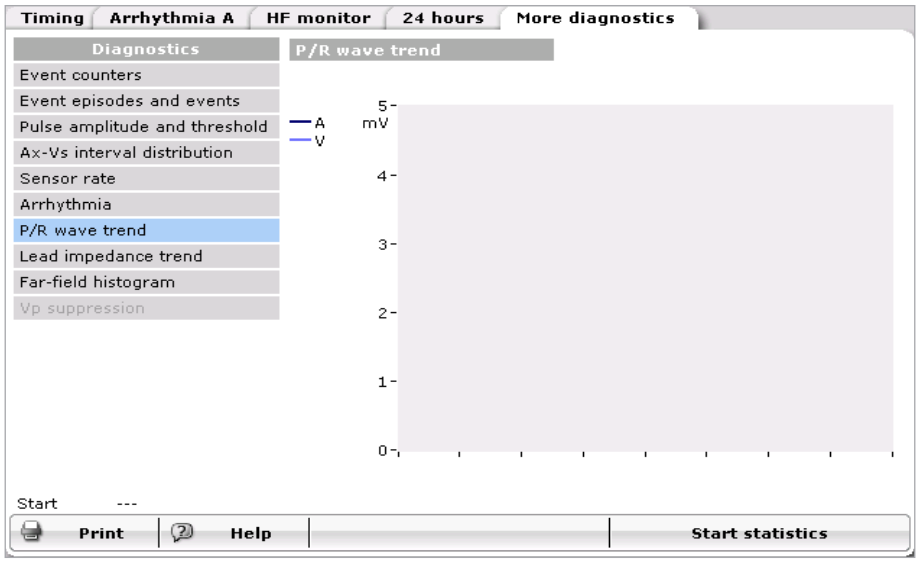


Figure 47: P/R Wave Trend

The P/R wave trend graph shown in Figure 47 shows the sensing results for P- and R-wave measurements. The graph collects daily data for up to 240 days and then overwrites the oldest information.

Each sensed event is measured by the device and the average value over the 24-hour period is displayed on the graph.

NOTE:

Some data may not be displayed if the device is interrogated less than 24 hours after the statistics are restarted.

6.6.8 Lead Impedance Trends with Lead Check

Edora/Evity/Enitra ProMRI® pacemakers can perform lead impedance measurements for the atrial and ventricular leads. These measurements are stored in memory for use in lead impedance trend data as a function of time. The pace current and voltage is measured in order to determine the lead impedance.

Every 30 seconds, the lead impedance measurements are taken and are available for diagnostic trend display. The programmer will display a long-term trend of 240 days.

Impedance trends are always recorded. The lead impedance measurements are used to determine if a lead failure has occurred. The range for normal lead impedance is from 100 to 2500 ohms.

If the Edora/Evity/Enitra ProMRI® pacemaker detects a bipolar lead failure, polarity for the respective lead will automatically be changed to unipolar configuration. A bipolar lead failure is verified if the lead impedance measurement falls outside of the acceptable range for three consecutive readings. When a lead failure has been detected, a message is displayed on the programmer screen at the next follow-up visit in order to notify the physician of the change.

Lead Check is temporarily suspended during magnet application and is inactive during ERI.

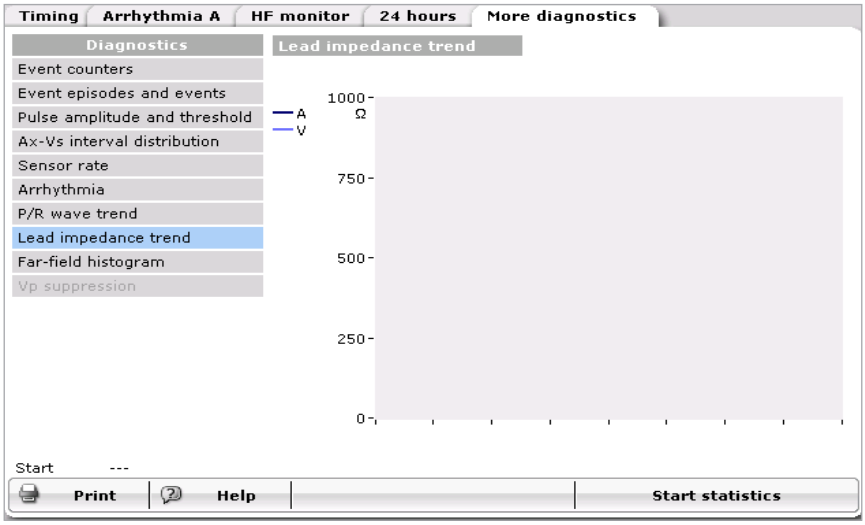


Figure 48: Lead Impedance Trend

The lead impedance trend, shown in Figure 48, displays the impedance data collected since the last time the statistics were restarted. Impedance data is collected throughout the day, and the average value is displayed for the 24-hour period.

The device measures both unipolar and bipolar impedances. If the device is programmed bipolar, the bipolar values will be displayed. If the device is programmed unipolar, the unipolar values will be displayed.

The data trend duration is 240 days. After 240 days, the device will overwrite the oldest data.

Lead check may be turned OFF by the user. Impedances will still be recorded if lead check is OFF. The parameter is found under the Diagnostics tab of the Parameter screen.

6.6.9 Far-field Histogram

The Far-field Histogram provides information related to cross-talk following Vp and Vs events. The range is < 30 ms to > 220 ms for each type of event. The display provides the percentage of far-field events at each value.

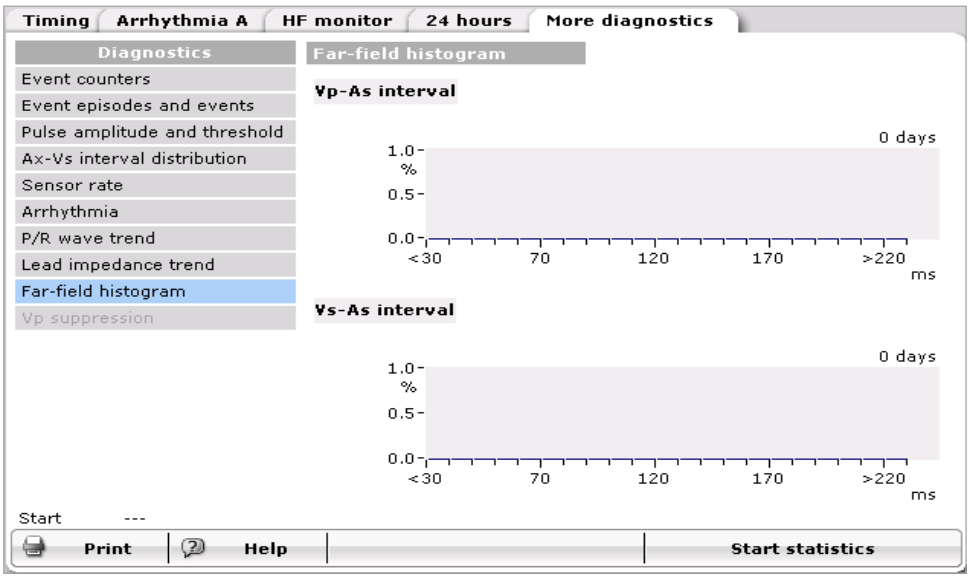


Figure 49: Far-Field Histogram

The Far-field histogram in Figure 49 provides information related to sensed events in the atrium occurring after ventricular paced or sensed events. Data is measured in 10 ms intervals. The maximum value measured is 225 ms after a ventricular paced or sensed event.

The area in gray represents the programmed interval range of the far-field protection parameter. Events outside the programmed far-field protection interval will be shown in the white portion of the graph.

6.6.10 Vp suppression

Vp suppression tracks the number of attempts and successes for enabling the Vp suppression feature. Additionally, the percentage of each day the feature is active is provided.

The graph is not accessible if the feature is not active.

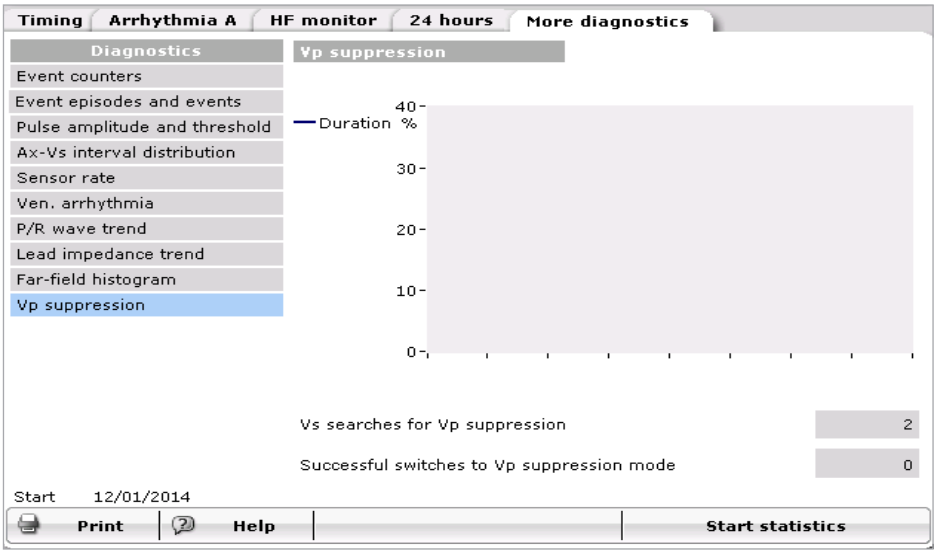


Figure 50: Vp Suppression

PAGE 83

6.7 IEGMs

Edora/Evity/Enitra ProMRI® pacemakers can provide IEGM Snapshots, which are stored intracardiac events based on programmable triggers for later display and review via the programmer screen. The intracardiac events are represented on the programmer screen by event markers. Recordings may be triggered by the following events:

- High atrial rates
- High ventricular rates
- Patient activation (by applying a magnet)
- Mode Switches
- Lead failure (not programmable)

Edora/Evity/Enitra ProMRI® pacemakers can be programmed to store an IEGM on any or all of the events listed above. However, the programmability of the High Atrial Rate and Mode Switch triggers are linked such that only one trigger can be activated at a time. By applying a magnet over the pacemaker for approximately 2 seconds, the current heart rhythm will be instantly recorded. However, Edora/Evity/Enitra ProMRI® pacemakers commit the recording to memory only when the magnet has been removed.

The following intracardiac events are stored with each IEGM:

- Type of IEGM snapshot
- Date and time of IEGM snapshot
- Duration of episode (for Mode Switch and High ventricular rates only)
- Maximum ventricular rate during episode
- Atrial and ventricular IEGMs with marker channels

Edora ProMRI® pacemakers allow a maximum of twenty separate IEGM recordings that each include approximately 10 seconds per event. Evity ProMRI® pacemakers can store up to 12 IEGMs and Enitra ProMRI® provides 4 stored IEGMs.

Upon interrogation of the Edora/Evity/Enitra ProMRI® pacemaker containing stored IEGMs, a list of the stored IEGMs (with date and time stamp) is displayed under the Holter tab as shown in Figure 51. If the number of events triggering a snapshot is greater than the available memory, the IEGMs will be overwritten according to an internal priority list.

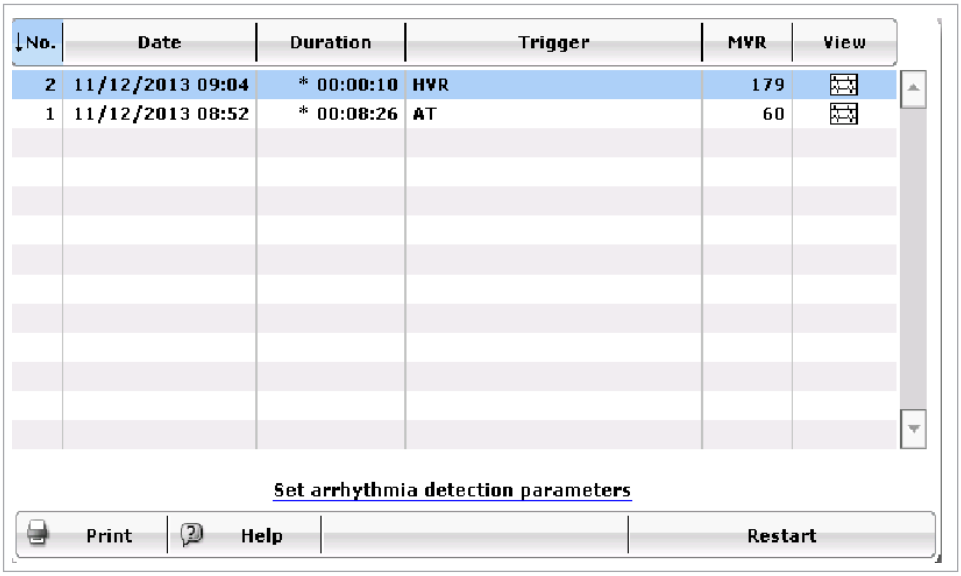


Figure 51: Episode list

An IEGM is not recorded when the programming wand is placed over the pacemaker. However, a patient triggered IEGM will be recorded when a magnet is placed over the pacemaker as with normal transtelephonic monitoring.

An example of a stored IEGM is provided in Figure 52. The IEGM demonstrates AF from an Edora/ Evity/Enitra DR-T ProMRI® pacemaker. The IEGMs from each channel are provided along with the marker channels for each.

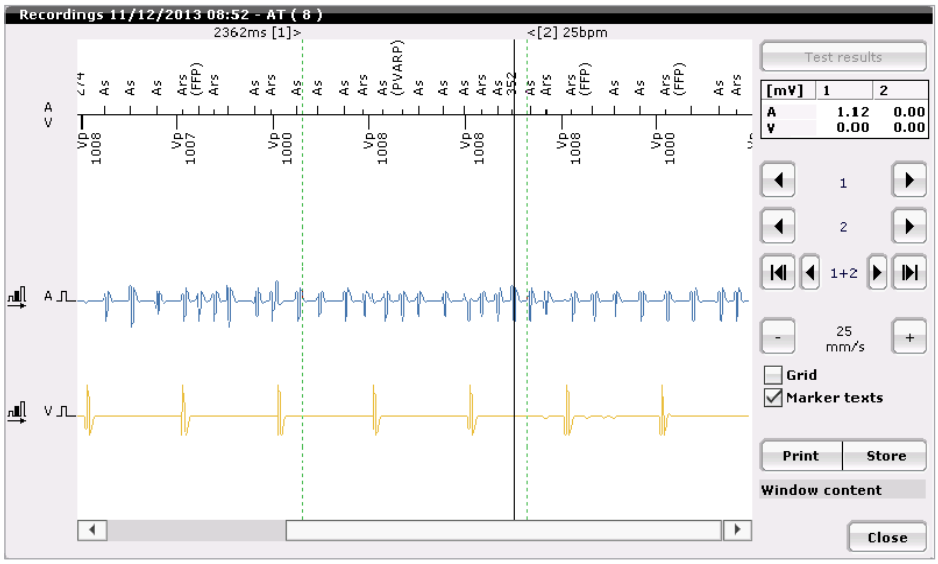


Figure 52: AT episode recording

7. Other Functions/Features

Edora/Evity/Enitra ProMRI® pacemakers offer many additional functions and features to assist the physician in the care of the pacemaker patient.

7.1 Wandless (RF) Telemetry

The pacemakers offer ”wandless” communication between the device and the programmer by using radio frequency (RF) telemetry, in addition to the currently available telemetry used by applying the programming head (PGH) over the implanted device.

Wandless telemetry can be used with the Renamic programmer only.

Prior to initiating a session, look at the upper right hand corner of the programmer screen to determine if RF is enabled. If RF is turned OFF, the programmer will display a green dot above the rate indicator. Additionally, no device picture is shown. An example of this is shown on the right side in Figure 53. When RF is ON, communication bars like that seen on cell phones and a picture of a device transmitting information is shown, as seen in the left side of Figure 53.

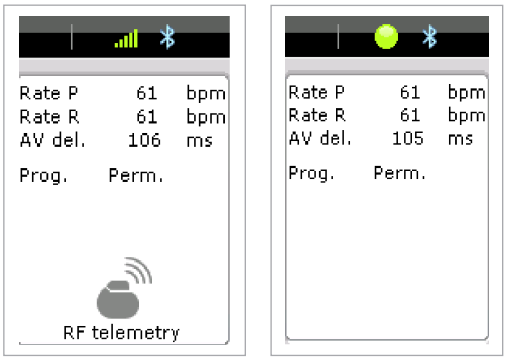


Figure 53: RF ON and OFF

7.1.1 Establishing Wandless Telemetry

To initiate a session using wandless telemetry, place the wand over the device until the message “Programming head can be removed” shown in Figure 53 appears. Once the message appears (typically < 5 seconds) the wand can be removed.

The strength of communication between the programmer and the device is demonstrated by the symbol, found at the upper right hand portion of the programmer screen. The more bars with light green, the better the communication. Conversely, the fewer the green bars, the poorer the communication. To ensure adequate signal strength, place the Renamic programmer within 3 meters (9 feet) of the device. Ideally, there should be no obstacles between the patient and the programmer.

Once RF telemetry has been established, the programming head wand cannot be used again for the duration of the RF telemetry session. In order to indicate this to the user, the LED on the programming head wand will start blinking with an orange light. This notifies the user that there is an active RF telemetry session.

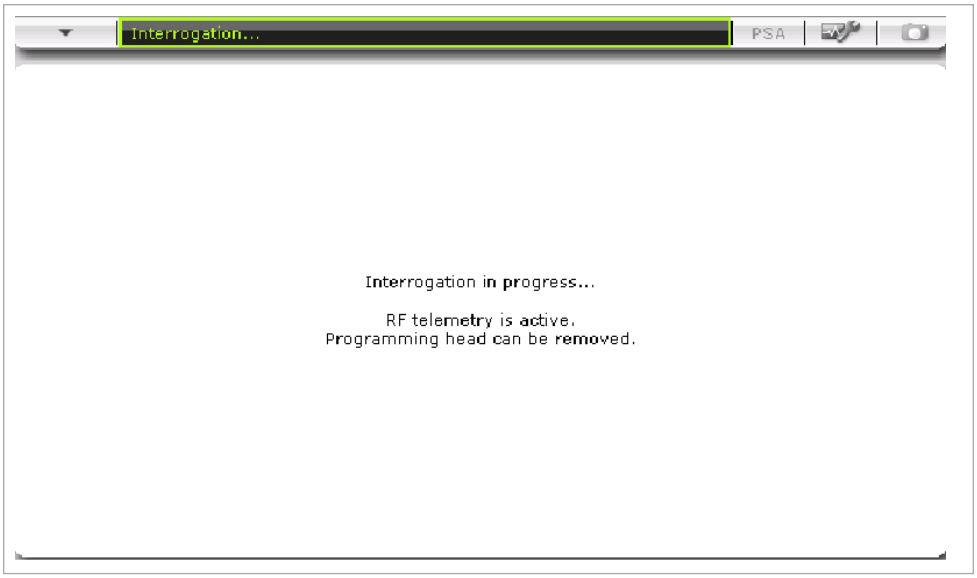


Figure 54: Message for programming wand removal

7.1.2 Economy Mode

To conserve device battery, the system provides an Economy mode. After three minutes of programmer inactivity, the RF telemetry is suspended. When the telemetry is suspended, the IEGMs will not be present on the programmer screen. Each touch of the programmer screen resets the timer.

When the Economy mode screen appears, the patient name will be displayed in the dialog box. In the example shown in Figure 55, “Patient name” and/or device serial number appears. This message prevents potential confusion if more than one patient is in distance of the programmer.

To reactivate RF telemetry, simply press the “Close” button on the screen. The IEGMs will reappear. To conserve the device battery, consider closing the Economy mode box, which ends the Economy Mode, only when you will make a change in the programmer interface.

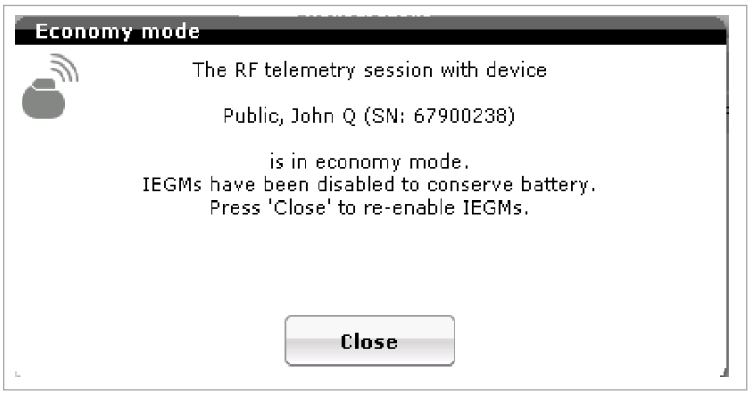


Figure 55: Economy mode message

When ending a follow-up session, end the session by pressing the “End” button on the bottom right programmer screen. A message will appear as shown in Figure 56. This ends the RF telemetry link to the device and prevents the possibility of errant programming.

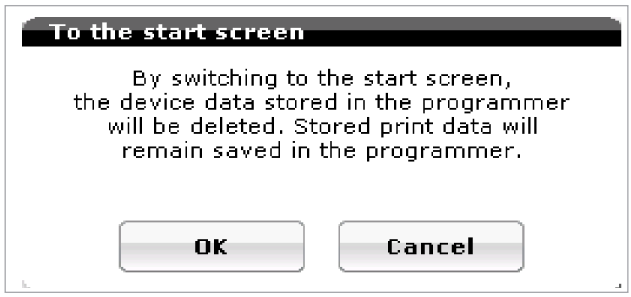


Figure 56: End session message

To switch between RF and wand (PGH) telemetry, go to the Edora/Evity/Enitra ProMRI® tab under the More section. To disable RF telemetry, press the PGH button. If a session is active, a message stating “RF telemetry is deactivated” will appear. To activate RF telemetry, place the wand on the device and press the RF button. A message stating that “RF telemetry is active. Programming head can be removed.” will appear on the screen.

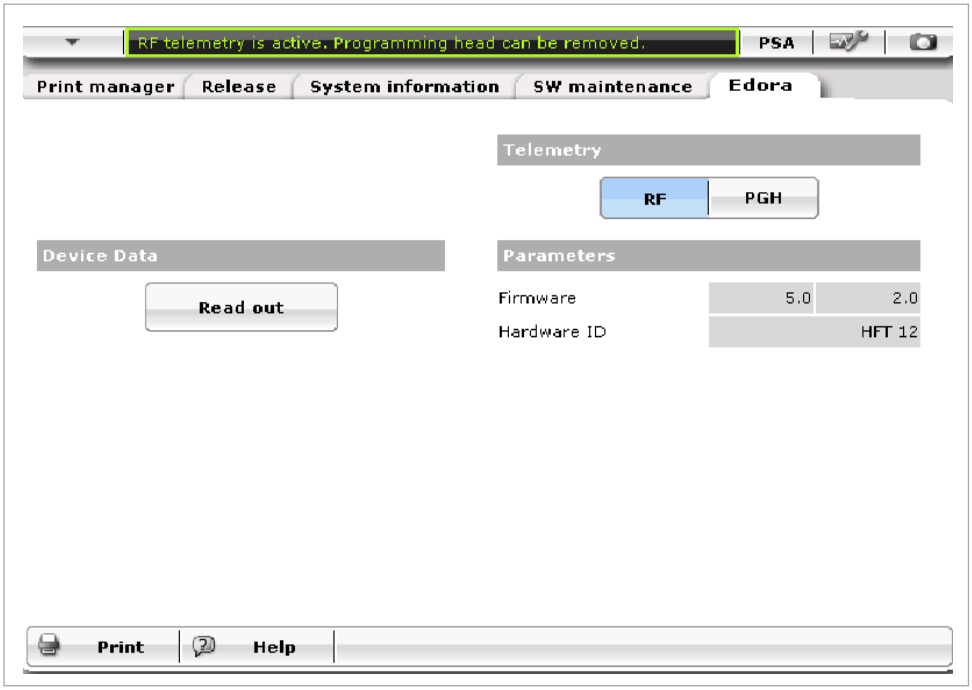


Figure 57: Message for programming wand removal after RF active

Power Consumption Consideration:

Wandless telemetry requires somewhat more power than telemetry via the programming head. Power consumption during 15-minute follow-up with IEGM transmission corresponds to approximately 10 days. As a result:

- Do not establish Wandless telemetry sessions unnecessarily.
- After 3 minutes without input, SafeSync Telemetry switches to the economy mode. In order to re-establish telemetry from the economy mode, select “Close” in the pop-up window with the patient’s name and/or device serial number as shown in Figure 55. To conserve the device battery, consider closing the Economy mode box, which ends the Economy Mode, only when you will make a change in the programmer interface.
- Check the battery capacity of the device at regular intervals.

7.2 Safe Program Settings

Activating the preset values for the Safe Program is a quick and convenient way to provide VVI pacing at a high output setting in urgent situations. Table 27 shows the Safe Program settings for Edora/Evity/Enitra ProMRI® pacemaker devices.

Parameter	Setting
Mode	VVI
Pacing Rate	70 bpm
Amplitude	4.8 V
Pulse Width	1.0 ms
Sensitivity	2.5 mV
Ventricular Refractory Period	300 ms (RV)
Pacing Polarity	Unipolar
Single Chamber Hysteresis	OFF

Table 27: Safe Program Settings

7.3 Magnet Effect

7.3.1 Automatic Magnet Effect

After magnet application the pacemaker paces at 90 bpm for 10 cycles asynchronously. Thereafter, the pacemaker paces synchronously at the programmed basic rate. During asynchronous pacing, the AV interval is reduced to 100 ms.

7.3.2 Asynchronous Magnet Effect

When programmed to asynchronous operation, magnet application results in asynchronous pacing. The pacemaker paces asynchronously at 90 bpm as long as the magnet is over the pacemaker. Upon magnet removal, the current basic interval is completed before the pacemaker reverts to its original operating mode.

If the magnet effect is set to asynchronous, the AV delay is reduced to 100 ms (or the programmed AV delay, whichever is shorter). Shortening of the AV delay to 100 ms during asynchronous AV sequential stimulation is provided to avoid ventricular fusion beats in the presence of intact AV conduction. This allows efficient diagnosis of ventricular capture or failure to capture.

7.3.3 Synchronous Magnet Effect

If the magnet effect is programmed to synchronous operation, magnet application does not affect timing and sensing behavior of the pacemaker. Synchronous operation is of particular importance during follow-up, if sensing and inhibition functions are desired during magnet application.

Trend monitor and event counter operation is interrupted during any magnet application.

7.4 Temporary Programming

CAUTION

OFF Mode – Use of the OFF mode should be avoided in pacemaker dependent patients. The OFF mode can be transmitted as a temporary program only to permit evaluation of the patient's spontaneous rhythm.

A temporary program is a pacing program which remains activated while the programming head is positioned over the pacemaker. Upon removal of the programming head (at least 15 cm away from the pacemaker), the temporary program will be automatically deactivated and the permanent program will again be in effect.

Generally, every pacing program displayed on the programmer screen may be transmitted as a temporary program by pressing the key designated on the programmer keyboard. With few exceptions, this also applies to pacing programs containing a parameter conflict, which cannot be programmed as permanent programs. Temporary programming facilitates follow-up and enhances patient safety. Test programs affecting patient safety, like pacing threshold measurements in a pacemaker-dependent patient, should be activated as a temporary program only.

When interrogating the pacemaker, the permanent program will always be displayed and documented, even though a temporary program was activated during the interrogation.

During temporary program activation, the rate adaptation, trend monitor, and the event counter are always inactive.

7.5 Patient Data Memory

Individual patient data can be stored in the pacemaker'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
- ECG Indication
- Physician
- Implantation Date
- Lead Polarity (A / RV)
- Lead Mode
- Lead Serial Number
- Lead Manufacturer
- Lead Position
- NYHA Class
- LVEF
- Hospital
- City

WARNING

Unipolar/Bipolar – Edora/Evity/Enitra ProMRI pacemakers can be used with either unipolar or bipolar IS-1 leads.

If the pacing or sensing function is to be programmed to **bipolar**, it must be verified that **bipolar leads** have been implanted in that chamber. If either of the leads is **unipolar**, **unipolar** sensing and pacing functions must be programmed in that chamber. Failure to program the appropriate lead configuration could result in entrance and/or exit block.

Symptom, etiology and ECG indication 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, etiology, or ECG indication 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.

7.6 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 pacemaker.

7.7 Pacing When Exposed to Interference

CAUTION

Electromagnetic Interference (EMI) – Active medical devices are subject to electromagnetic interference. In the presence of such interference, telemetry communication may be interrupted and prevent programming.

A sensed event occurring during the interference interval will continuously reset that interval for the corresponding chamber without resetting the basic interval. Depending upon whether the interference (electromagnetic interference, muscle potentials, etc.) is detected by the atrial and/or ventricular channel, atrial and/or ventricular asynchronous pacing at the programmed timing intervals will result for the duration of the interference. The interference interval has a duration of 51 ms.

Depending on the programmed pacing mode and the channel in which electromagnetic interference (EMI) occurs, Table 28 details the resulting pacing modes for the duration of exposure to EMI.

MODE	EMI (A)	EMI (V)	EMI (A+V)
DDD(R)- ADI(R)	DVD(R)	DAD(R)	DOO(R)
DDD-CLS	DVDR	DADR	DOOR
VVI-CLS	---	VOOR	---
DDD(R)	DVD(R)	DAD(R)	DOO(R)
DDI(R)	DVI(R)	DAI(R)	DOO(R)
DVI(R)	---	DOO(R)	---
VDD(R)	VVI(R)	VAT(R)	VOO(R)
VVI(R)	---	VOO(R)	---
AAI(R)	AOO(R)	---	---
DDT	VVT	VAT	VOO
VDI(R)	VVT	VOO	VOO
VVT	---	VOO	---
AAT	AOO	---	---

Table 28: Response to EMI

8. Product Storage and Handling

8.1 Sterilization and Storage

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

The pacemaker 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 pacemaker 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 pacemaker malfunction.

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

CAUTION

FOR SINGLE USE ONLY – Do not resterilize the pacemaker or accessories packaged with the pacemaker, 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.

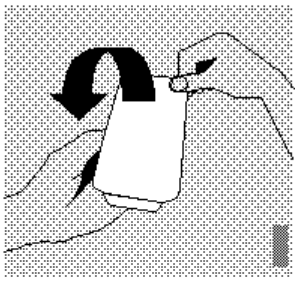
Storage (magnets) – Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid damage to the device.

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

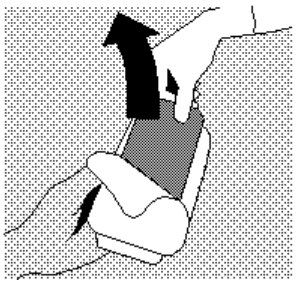
If a replacement pacemaker is needed, contact your local BIOTRONIK representative.

8.2 Opening the Sterile Container

The pacemaker 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.

A torque wrench is included within the blister package of each Edora/Evity/Enitra ProMRI® pacemaker.

8.3 Pacemaker Orientation

The pacemaker may be used in either the left or right side pectoral implants. Either side of the pacemaker can face the skin to facilitate excess lead wrap.

9. Lead Connection

Edora/Evity/Enitra ProMRI® pacemakers have been designed and are recommended for use with bipolar or unipolar leads having an IS-1 connector. The IS-1 configured leads may be placed in one or both chambers of the heart, depending upon model selected.

WARNING

Unipolar/Bipolar – All Edora/Evity/Enitra ProMRI models can be used with either unipolar or bipolar IS-1 leads.

If the pacing or sensing function is to be programmed to **bipolar**, it must be verified that **bipolar leads** have been implanted in that chamber. If either of the leads is **unipolar**, **unipolar** sensing and pacing functions must be programmed in that chamber. Failure to program the appropriate lead configuration could result in entrance and/or exit block.

NOTE:

Connecting systems with a 3.2 mm configuration that do not expressly claim to agree with the IS-1 dimensions generally have to be regarded as incompatible with IS-1 connectors and can only be used with BIOTRONIK products together with an appropriate adapter. For questions regarding lead-generator compatibility, consult your BIOTRONIK representative.

In case of pacemaker replacement, make sure that the existing lead connector and lead are not damaged.

CAUTION

Lead/pacemaker Compatibility – Because of the numerous available 3.2-mm configurations (e.g., the IS-1 and VS-1 standards), lead/pacemaker compatibility should be confirmed with the pacemaker and/or lead manufacturer prior to the implantation of a pacing system.

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

BIOTRONIK recommends the use of bipolar pacing leads with new implants so that all of the programmable parameters of Edora/Evity/Enitra ProMRI® pacemakers are available for use. Edora/Evity/Enitra ProMRI® pacemakers have a self-sealing header. Refer to the following steps when connecting a lead(s) to the pacemaker.

First, confirm that the setscrew(s) is not protruding into the connector receptacle. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.

CAUTION

Setscrew Adjustment – Back-off the setscrew(s) prior to insertion of lead connector(s) as failure to do so may result in damage to the lead(s), and/or difficulty connecting lead(s).

Cross Threading Setscrew(s) – To prevent cross threading the setscrew(s), do not back the setscrew(s) completely out of the threaded hole. Leave the torque wrench in the slot of the setscrew(s) while the lead is inserted.

Rotate the wrench counterclockwise until the receptacle is clear of obstruction. Then connect the pacing leads as described below.

Insert the lead connector pin into the connector receptacle of the pacemaker without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position.

- Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.

CAUTION

Tightening Setscrew(s) – Do not overtighten the setscrew(s). Use only the BIOTRONIK supplied torque wrench.

Sealing System – Be sure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle. Failure to do so may result in damage to the plug and its self-sealing properties.

- Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
- After retracting the torque wrench, the perforation will self-seal. The proximal electrode of bipolar leads is automatically connected. Connect the second lead as described above.
- Pass non-absorbable ligature through the hole in the connector receptacle to secure the pacemaker in the pocket.

NOTE:

Do not lubricate the grommets.

9.1 Auto Initialization

Auto Initialization detects when a pacing lead is connected to the pacemaker at implantation as well as the polarity of the lead is detected. Upon successful detection, the pacemaker automatically initiates several key features. Auto Initialization consists of four phases, which are described below.

1. **Lead detection**

   In order to detect a lead, the Edora/Evity/Enitra ProMRI® pacemaker continuously delivers sub-threshold paces in both the ventricular and the atrial channel to measure the lead impedance. The Edora/Evity/Enitra ProMRI® pacemaker considers a lead “detected” when the measured impedance is within 100 and 2500 Ohms.

2. Detection and Configuration of the Lead Polarity

By default, the Edora/Evity/Enitra ProMRI® pacemaker starts with the unipolar lead measurement and then follows with the bipolar measurement. Pre-programming the device to bipolar prior to lead connection allows for an immediate pacing response. The Edora/Evity/Enitra ProMRI® pacemaker switches the lead polarity to bipolar immediately after a bipolar lead is detected. When the lead impedance is between 100 and 2500 Ohms, the lead connected is classified as bipolar and the sense and pace polarities are set appropriately. The device switches back to unipolar if the lead impedance falls outside this range.

3. 10-Minute Confirmation Phase

A 10-minute confirmation phase is initiated after detection of the lead. The lead impedance measurement is performed alternating between the atrial and ventricular channel. Additional impedance measurements at the end of this phase confirm the lead detection and lead polarity. The impedance measurements need to fall within the range of 100 to 2500 Ohms.

A lead impedance measurement outside this range restarts the confirmation process.

Interrogation of the pacemaker during the confirmation phase results in a message that implant detection is activated. The confirmation phase is terminated and the pacemaker features are activated if it is reprogrammed during this time.

4. Activation of Pacemaker Features

The following pacemaker features are activated after the confirmation phase has been successfully completed:

- Auto Lead Check
- Capture Control
- Statistics
- Rate response
- Collection of patient-specific impedance waveform characteristics for adapting the CLS algorithm to the patient (data does not control the pacing rate until CLS is programmed on)
- PMT Management
- Auto PVARP
- 2:1 Lock-In protection

10. Follow-up Procedures

10.1 General Considerations

The pacemaker follow-up serves to verify appropriate function of the pacing system, and to optimize the parameter settings.

In most instances, pacing system malfunction attributed to causes such as chronic threshold can be corrected by reprogramming the pacemaker. The follow-up intervals are, therefore, primarily determined by medical judgment, taking possible pacemaker dependency into consideration.

The following notes are meant to stress certain product features, which are of importance for follow-up visit. 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.

CAUTION

Programming Modifications – Extreme programming changes should only be made after careful clinical assessment. Clinical judgment should be used when programming permanent pacing rates below 40 bpm or above 100 bpm.

10.2 Real-time IEGM Transmission

The Edora/Evity/Enitra ProMRI® pacemakers provide real time transmission of the intracardiac electrogram (IEGM) to the programmer. During dual chamber operation, IEGMs from the atrium and ventricle can be simultaneously recorded. The IEGMs may be transmitted to the programmer via the programming head positioned over the implanted pacemaker. They are then displayed together with surface ECG and markers on the programmer screen and printed on the ECG recorder. Likewise, intracardiac signals and markers identifying atrial/ventricular paced and sensed events are received via the programming head, and may be displayed on the programmer screen and printed on the ECG recorder.

To determine the amplitudes of intracardiac signals (P-/R-waves) the automatic P/R-wave measurement function may be used.

10.3 Impedance test

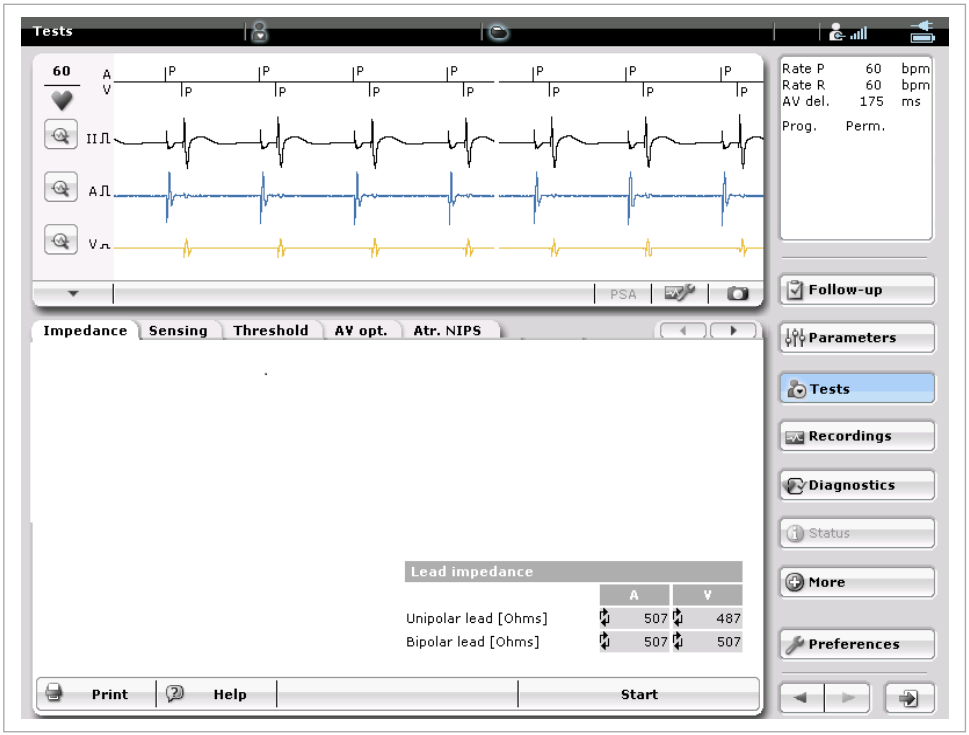


Figure 58: Impedance test

The atrial and right ventricular impedance values are measured in both unipolar and bipolar pacing configurations, as shown in Figure 58.

10.4 Threshold test

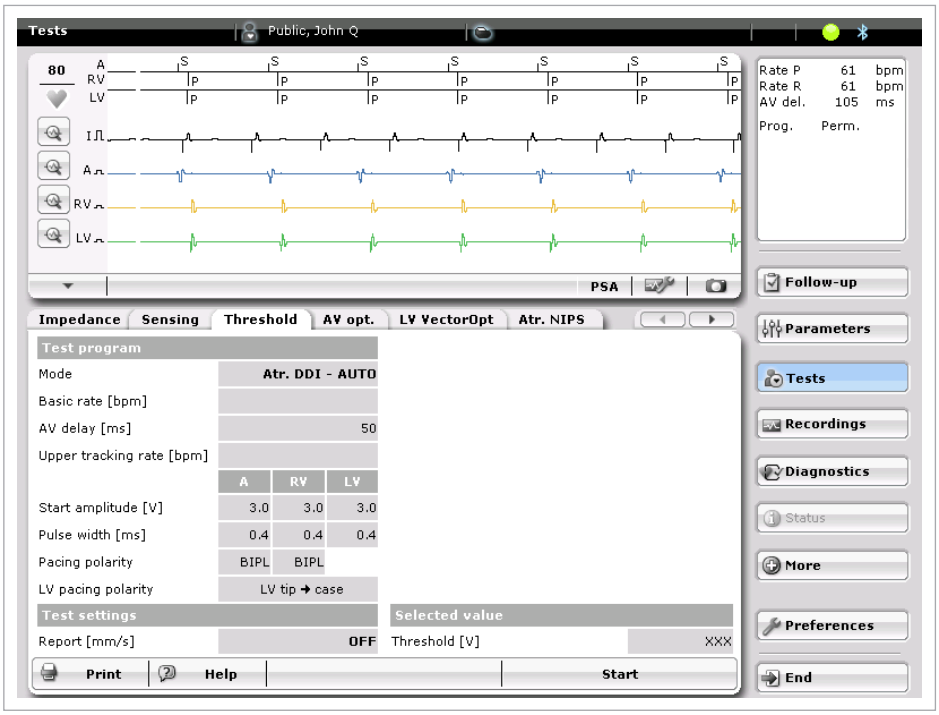


Figure 59: Main Threshold Test Screen

The atrial and ventricular pacing thresholds are determined using a high-precision threshold test found under the Threshold tab, as illustrated in Figure 59. The ventricular threshold test can be performed in the DDD or VVI mode manually at a user-defined rate between 30 and 120 bpm. The ventricular threshold test can also be performed automatically in the DDD, VDD, and VVI modes and will be performed the same way the VCC test is performed.

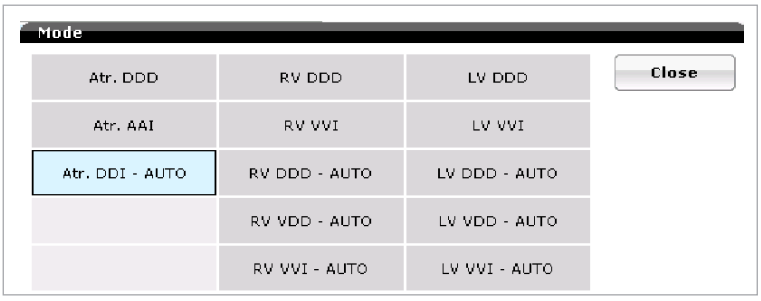


Figure 60: Threshold Test Choices

The atrial test can be performed in the DDD or AAI modes as well as automatically in the DDI mode. Mode options are shown in Figure 60. In addition, the atrial IEGM screen can be displayed during the atrial threshold test by toggling the ECG/IEGM button. Examples of performing the threshold test with ECG or IEGM are shown in Figure 61. As with all screens, the patient's intrinsic rate is displayed in the upper right handiscorner of the screen. The intrinsic rate helps the user select the best pacing rate for the test.

The Edora/Evity/Enitra ProMRI® pacemaker allows real-time changes during the threshold tests. The user can now change any of the values while the test is ongoing. If a value is changed, the device will automatically stop the ongoing test and then restart the test with the new value(s).

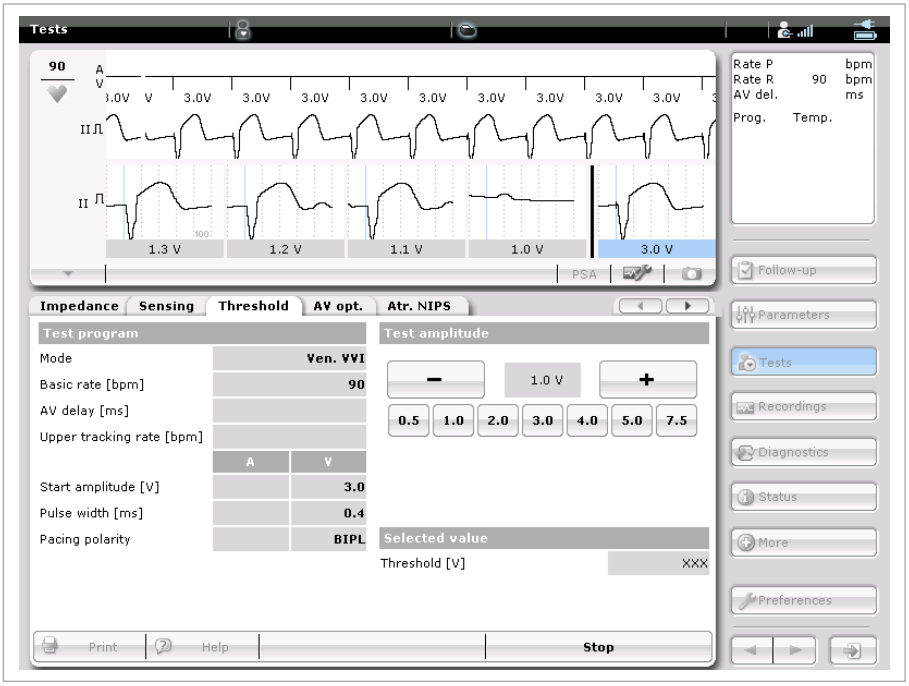


Figure 61: The Pacing Threshold Test In Progress

As the threshold test begins, the selected pacing parameters are transmitted temporarily to the device. These parameters are default parameters (i.e.: the parameters programmed between test parameters) and should be adjusted to guarantee capture. The rate should be programmed above the patient's

intrinsic rate to prevent inhibition. Thereafter, test amplitudes can be decremented until capture is lost; and the threshold is determined. The test amplitude will change only when new amplitudes are selected and the Number of Pulses is programmed to “∞”. Otherwise, a set number of pulses (1-10) will be delivered with each new test amplitude before reverting back to the starting value. The default parameters will be reprogrammed between test selections.

When each test is complete, the user is prompted to enter the threshold value, which is stored for future reference. The ECG strip from the entire test is printed if Report is set to a user-defined printer speed. This is located in the Preference section under Tests. Otherwise, an annotated version of the test can be printed after the test by selecting the “Print” button, which is found in the lower left corner of the screen.

To determine the threshold, the ECG or IEGM must be observed continuously. Based on the measured threshold, the pulse amplitude for the permanent program should be adjusted. Please consult the pertinent medical literature for specific recommendations regarding necessary safety margins.

10.5 P/R Measurement

The Edora/Evity/Enitra ProMRI® pacemakers sensing test is the first test that appears when selecting the Tests button on the right hand side of the programmer screen, shown in Figure 62. The Edora/Evity/Enitra ProMRI® pacemaker provides multiple test modes for sensing as shown in Figure 63. All bolded values can be changed by the user at any time.

When the Sensing test is started, the minimum, mean and maximum values of each chamber measured by the device will be displayed. Typically, there should not be large variations between the minimum, mean and maximum values. If large variations are seen, one should review the strip for premature events (PVCs) or possibly an unstable lead.

The Sensing test is performed via the **START** or **INTRINSIC RHYTHM** button.

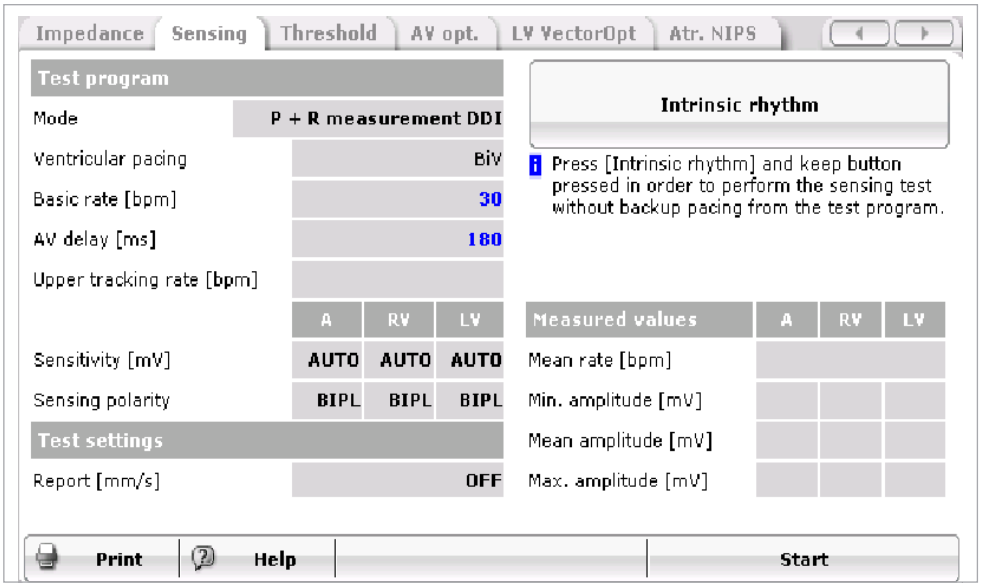


Figure 62: Sensing Test Main Screen

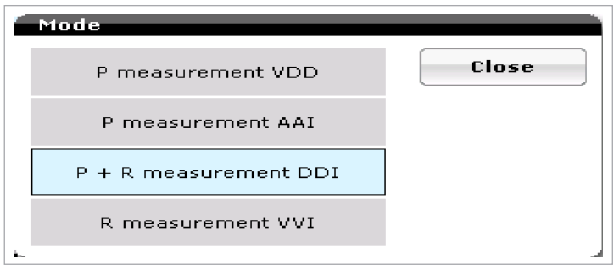


Figure 63: Sensing Test Options

10.5.1 START (test)

The Sensing test is performed in a DDI mode with programmable back-up support pacing when the **Start** button is selected. Atrial values may be given even if the device is programmed in a VVI(R) mode.

The P- and R-wave amplitudes are automatically measured on command using the Start button. During the test, the device uses the temporary pacing program to provide back-up bradycardia support. The amplitude is measured over several beats and is displayed on the programmer screen when the test is complete. An IEGM strip can be printed during the test with Report set to a user-defined printer speed.

10.5.2 Intrinsic Rhythm (test)

The sensing test can also be performed by selecting and holding down the **Intrinsic Rhythm** button. When pressed, **Intrinsic Rhythm** will test for an underlying rhythm but provide no back-up pacing support for the duration the button is depressed. Edora/Evity/Enitra ProMRI® pacemakers will display the measured values on the IEGM screen while the test is in progress.

CAUTION

When selecting the Intrinsic Rhythm button there is no support pacing for the duration the button is depressed. This test should not be performed with pacemaker-dependent patients.

Figure 64: The Sensing Screen with Sensing Test in Progress

10.5.3 Mode

DDI, VVI, AAI and VDD are the available modes for the sensing test

The DDI mode provides programmable pacing support during the test and allows the user to measure atrial and ventricular values simultaneously.

The VVI mode provides programmable pacing support during the test. This mode can be used for patients who can tolerate single-chamber pacing.

AAI mode provides no ventricular pacing support and should not be used for pacemaker-dependent patients.

VDD mode may be used for pacemaker-dependent patients who are symptomatic with non-tracking modes.

Below is a summary of parameters associated with the Sensing test. These are all temporary values activated during the test.

10.5.4 Sensing test parameters

10.5.4.1 Basic Rate

30…(5)…100…(10)…200 bpm.

Default value of 30 bpm. The Edora/Evity/Enitra ProMRI® pacemaker will provide support pacing at the programmed Basic rate during the Sensing test.

10.5.4.2 AV Delay

20...(5)...300 ms

Default of 180 ms with the DDI mode and 50 ms when the VDD mode is selected.

10.5.4.3 Upper Rate

90…(10)…200 bpm

Default of 130 bpm. This is a programmable value only when the VDD mode is selected.

10.5.4.4 Pulse Amplitude

0.2...(0.2)...6.0...(0.5)...7.5 V

Default value is the permanently programmed value.

Independently programmable for each chamber if AUTO test is OFF.

10.5.4.5 Pulse Width

0.1, 0.2, 0.3, 0.4, 0.5, 0.75, 1.0, 1.25, 1.5 ms

Default value is the permanently programmed value.

Independently programmable for each chamber if AUTO test is OFF.

10.5.4.6 Sensitivity

Atrium: Auto, 0.1 - 7.5 mV. Default of Auto

Right Ventricle: Auto, 0.5 - 7.5 mV Default of Auto

Left Ventricle: OFF, Auto, 0.5 - 7.5 mV Default of Auto

Independently programmable for each chamber.

10.5.4.7 Pacing Polarity

Unipolar, Bipolar.

Independently programmable for each chamber if AUTO test is OFF.

10.5.4.8 Sensing Polarity

Unipolar, Bipolar.

Independently programmable for each chamber.

Especially with unipolar sensing functions, the selected sensitivity level should be checked for possible interference from skeletal myopotentials. If oversensing is observed, the programming of a lower sensitivity (higher value), or bipolar sensing function, if the implanted lead is bipolar, should be evaluated.

10.6 AV Opt. Test

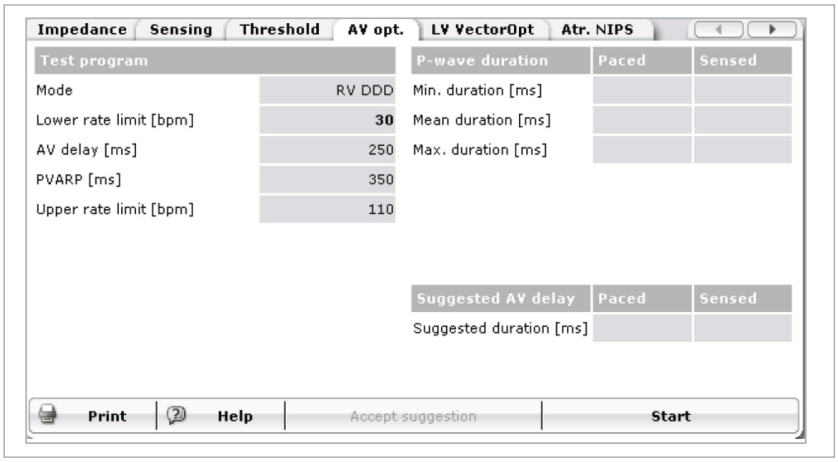


Figure 65: AV Opt. Test

The AV Opt. Test measures p-wave durations for sensed and paced atrial events and provides programming suggestions for the sensed and paced AV-delay. The test is executed in RV DDD mode using a fixed AV-delay of 250ms and PVARP of 350ms. The upper rate limit is set to 110bpm, or to the value of the permanent program if the device is programmed with a lower upper limit. In order to encourage atrial sensing for the first part of the test, the user can adjust the lower rate limit between 30bpm and 90bpm (in steps of 5bpm), with a nominal value of 50bpm.

The AV Opt. Test is initiated by pressing the start button in the lower right corner. This will trigger the implant to send IEGMs to the programmer, first from the intrinsic sinus rhythm, followed by atrial paced rhythm. The programmer will analyze the IEGM signals and extract the p-wave duration from the different sequences. The results (minimum, mean, and maximum duration) of the analysis are displayed on the screen. This allows the user to assess the stability of the p-wave duration. Based on the calculated p-wave duration the software adds 50ms and displays the result as suggested AV-delay. If no intrinsic atrial rate could be measured, or if the atrial paced rate would have violated the upper rate limit, the programmer uses the programmed sense compensation to calculate the corresponding AV-delay suggestion.

After the test procedure has been completed, the user has the option to copy the suggested AV-delay parameters over to the main program screen by pressing the “Accept suggestion” button. In order to activate the updated AV-delay settings, the user needs to transmit the program to the implant.

10.7 Testing for Retrograde Conduction

The Retrograde conduction test is performed in a VDI mode with a programmable ventricular pacing rate.

Figure 66: Retrograde Conduction Test with a Negative Result

Figure 67: Retrograde Conduction Test with a Positive Result

Retrograde conduction from the ventricle to the atrium can be confirmed when a 1:1 relationship with a constant V-A interval is present. The VA interval is the time between the ventricular paced event and the first subsequent atrial sense.

The programmer displays the measured results as the maximum, minimum, and mean retrograde conduction times. If the measured maximum, minimum and mean values are within 25 ms of each other, retrograde conduction is suspected. One may repeat the test to confirm the results.

While the test is being performed, the measured V-A times are displayed on the programmer screen.

10.7.1 Measuring Retrograde Conduction

The Retrograde Conduction measurement is initiated from the Retrograde conduction tab. During the test, the pacemaker operates in VDI mode at a programmable rate that must exceed the heart's intrinsic rate. The V-A interval is measured using the event markers on the IEGM (V pace to A sense). The measurement begins after the START tab is pressed. The first five cycles are not used in the measurement.

10.7.2 Requirements for Measurement

- The programming head must have telemetry contact with the implant for the entire measurement duration. If telemetry contact is interrupted, the measuring process will be aborted. (This is true for all tests.) The values measured up to this point remain displayed.
- Retrograde conduction can only be measured if ventricular pacing and atrial sensing are present.
- The ventricular pacing rate for the retrograde conduction test MUST be greater than the intrinsic atrial rate.

NOTE:

Retrograde conduction may not be present at all rates. If retrograde conduction is suspected, perform the test at different rates.

10.7.3 Follow-up History

Pacemakers can store up to 10 follow-ups. See Figure 68. The first follow-up performed is stored and will not be overwritten to serve as a baseline for future follow-up comparisons. Edora/Evity/Enitra ProMRI® pacemakers store one follow-up per day. If more than one follow-up is performed, the device will retain the most recent data for that day. After 10 follow-ups, the device will overwrite data starting with the second follow-up and continue to overwrite the oldest data.

The Follow History screen is accessed via the main Follow-up screen. The last follow-up icon is in the upper right corner of the follow-up screen.

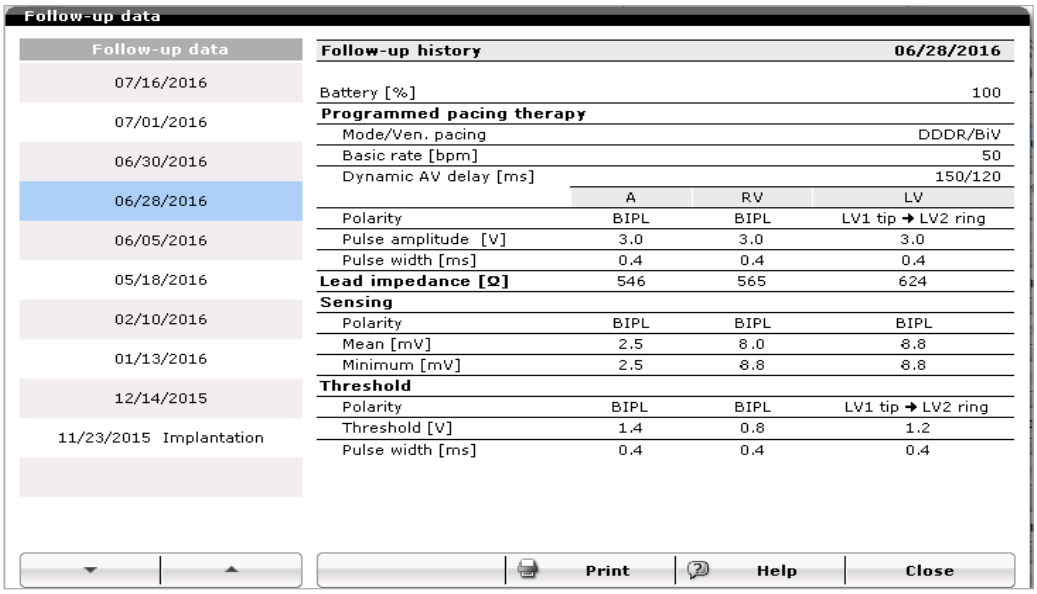


Figure 68: Follow-up History Page

10.8 Atrial Non-Invasive Programmed Stimulation (NIPS)

WARNING

NIPS – Life threatening ventricular arrhythmias can be induced by stimulation in the atrium. Ensure that an external cardiac defibrillator is easily accessible. Only physicians trained and experienced in tachycardia induction and reversion protocols should use non-invasive programmed stimulation (NIPS).

10.8.1 Description

The implanted pacemaker/lead system may be used in conjunction with the programmer to generate externally controlled pacing pulses. Burst Stimulation or Programmed Stimulation may be selected with up to four extra stimuli at pacing rates to 800 bpm.

10.8.2 Burst Stimulation

Parameter	Range	Default
Coupling Interval Interval from last sensed event to the first paced event	None, 80...(10)...2000	None
Burst Rate	125...(25)...800 bpm	250 bpm
Burst Minimum	125...(25)...800 bpm	150 bpm
Burst Maximum	125...(25)...800 bpm	350 bpm
Back-up pacing mode	VOO, VVI	VOO
Basic Rate	30...(5)...100...(10)...200 bpm	60 bpm

Table 29: Burst Stimulation Ranges and Default Settings

Burst Stimulation offers a burst of pacing pulses to the atrium when the programming wand is placed directly over the pacemaker. The duration of the burst is as long as the burst key on the programmer is touched. When the burst key is no longer touched, the program reverts to the backup program. Should the wand be removed, the pacemaker reverts to the permanent program.

Burst Stimulation may be stepped up or down from the nominal value to user-defined high or low limits as long as the selection is touched on the touch screen. When the **Step Up** or **Step Down** key is touched, NIPS is invoked starting at the nominal burst rate and then steps up or down respectively in 10 ms steps. As soon as the step up or step down key is released, NIPS terminates. Subsequent inductions resume at the initially programmed burst rate.

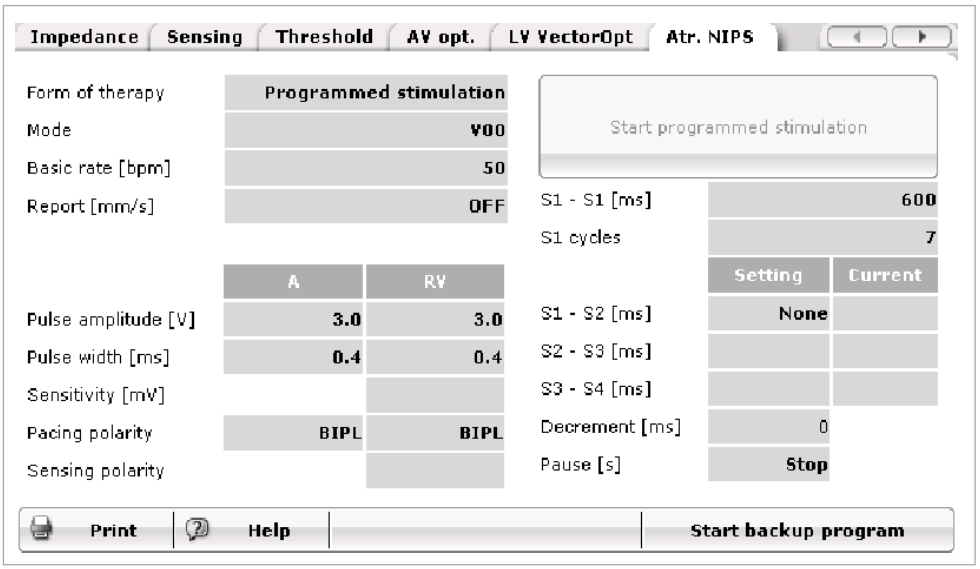


Figure 69: Atrial Burst Stimulation Screen

10.8.3 Programmed Stimulation

Programmed Stimulation offers burst pacing at specifically defined intervals that are user defined. Programmed stimulation offers S1-S1, S1-S2, S2-S3, S3-S4 individual intervals. In addition, up to 10 cycles are available containing a programmable pause of up to 50 seconds. The last selected interval decrements in 0 to 100 ms steps. As with Burst Stimulation, the pacing mode switches to the permanent program when the wand is removed.

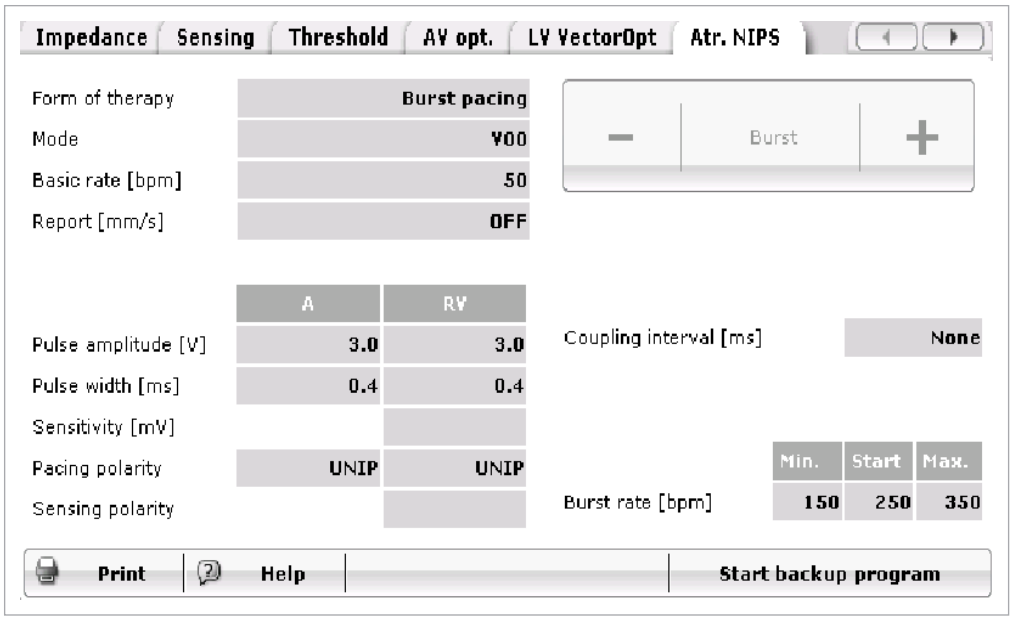


Figure 70: Atrial Burst Stimulation Screen

10.8.4 Back up Pacing

The back up pacing program remains active once NIPS has been selected and remains active during burst or programmed burst stimulation and within this menu. This program remains active until the **Stop** touch key is pressed.

CAUTION

Short Pacing Intervals – Use of short pacing intervals (high pacing rates) with long atrial and/or ventricular refractory periods may result in intermittent asynchronous pacing and, therefore, may be contraindicated in some patients.

10.8.5 NIPS Safety Features

The BIOTRONIK offers the following safety features during NIPS sessions.

- When the battery voltage has reached the Elective Replacement Indicator point (ERI), the NIPS feature is no longer available.
- Atrial pacing support is available to pacemaker dependent patients during burst or programmed burst stimulation through the back up pacing program as long as the wand is within 15 cm of the pacemaker or if RF telemetry is active. Removing the programmer wand or placement to distance greater than 15 cm if RF telemetry is not used from the pacemaker returns the pacemaker to its permanent program.
- NIPS may only be programmed temporarily.

NOTE:

High pacing rates and pulse amplitudes together with wide pulse widths may temporarily decrease the amplitude of the pacing pulse. The pacing pulse must be continuously verified with an ECG to assure effectiveness.

To perform NIPS function, the programmer wand must be placed directly over the pacemaker to enable continuous telemetry.

10.9 Optimizing Rate Adaptation

It is recommended to check the parameters controlling rate adaptation during each follow-up for their individual therapeutic suitability. Any intermediate change in the patient's general well being and cardiac performance since the last follow-up should be taken into consideration. It must be assured that in all cases, the settings for sensor gain, maximum sensor rate, rate increase and rate decrease are well tolerated by the patient.

WARNING

Rate-Adaptive Pacing – Use rate-adaptive pacing with care in patients unable to tolerate increased pacing rates.

Use of the diagnostic functions for recording the pacing and/or intrinsic rate during follow-up and during daily activities facilitates evaluation of the parameter settings for rate adaptation. The rolling mode of the A/V rate trend is particularly useful during follow-up since the time period immediately preceding the follow-up may be evaluated.

When in doubt about the suitability of particular sensor settings for a certain patient, the sensor rate forecast can be utilized to observe the sensor response without the sensor actually controlling the pacing rate. The simulation of the sensor activity can be recorded using the sensor optimization feature.

10.9.1 Sensor optimization

The sensor rate forecast may be used to optimize the rate adaptation parameters without repeated exercise tests. The pacemaker records the sensor rate over a period of 12 minutes. During this time, the pacemaker develops a sensor rate curve. This curve is used to forecast optimal parameters such as the sensor gain, threshold, and maximum sensor rate.

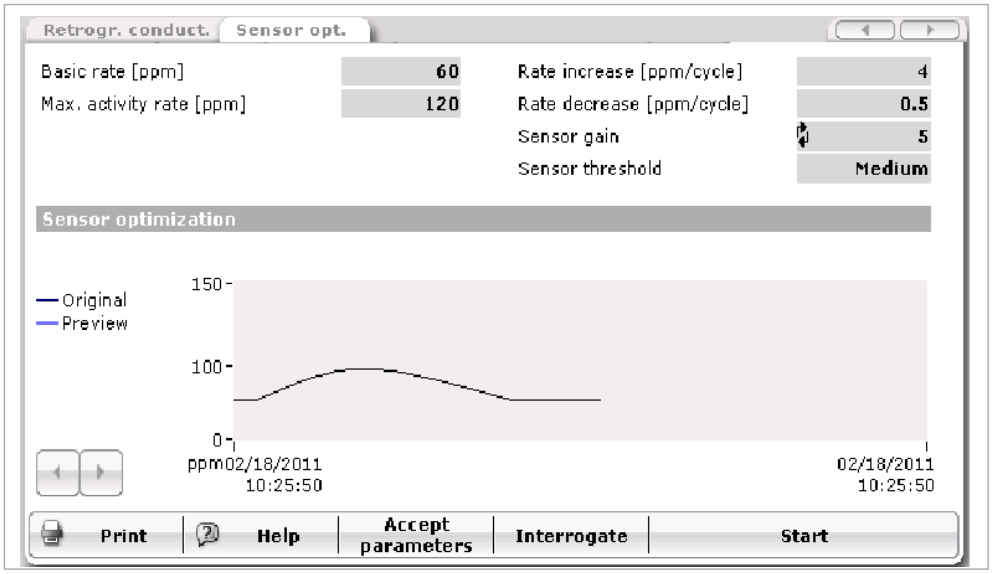


Figure 71: Sensor Optimization

10.9.2 Adjusting the Sensor Gain

The sensor gain controls the change in stimulation rate for a certain change in workload detected by the sensor. An exercise test is recommended in order to achieve a rate response proportional to work load by optimizing the sensor gain. If the pacing rate tends to be too high for the specific amount of work load or if the selected maximum sensor rate is achieved at too low of an exercise level, the sensor gain should be reduced by selecting a lower gain setting. If, on the other hand, rate adaptation is insufficient for a specific amount of workload, selection of a higher gain setting may be indicated. The memory functions can be used to record the pacing rate during exercise.

The sensor rate forecast function facilitates optimization of the rate-adaptive parameters.

10.9.3 Adjusting the Sensor Threshold

The sensor threshold controls the (motion) signal level that has to be exceeded to cause a rate increase. This parameter is meant to assure a stable pacing rate at rest and to prevent rate increases at signal levels not consistent with physical exertion. The sensor gain should be optimized prior to adjusting the sensor threshold. Otherwise, changing of the gain setting will cause changes in the effective threshold.

If rate increase is caused by low level activities, when no rate-adaptation is desired, the sensor threshold setting should be increased by selecting the next higher setting (e.g., low to mean). If, on the other hand, the pacemaker tends to respond only at higher levels of work, a reduction of the sensor threshold may be indicated (e.g., high reduced to mean). It may be useful to record a sensor test trend for evaluation of sensor response. The sensor rate forecast may also be used to tailor the sensor threshold to the patient.

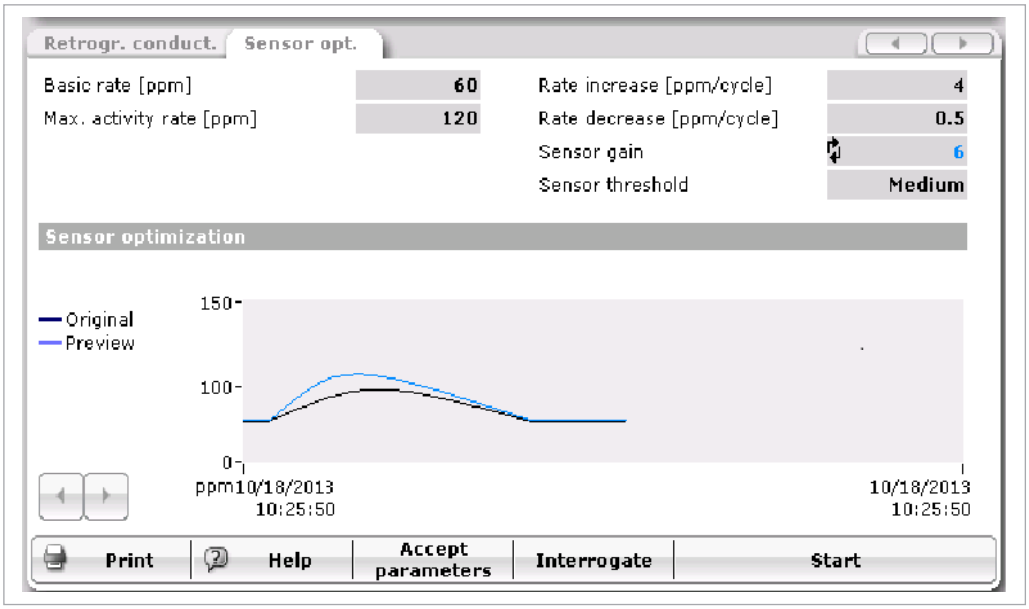


Figure 72: Sensor Optimization with change

11. Elective Replacement Indication (ERI)

The service time of Edora/Evity/Enitra ProMRI® pacemakers vary based on several factors, including battery properties, storage time, lead system impedance, programmed parameters, amount of pacing and sensing required, 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 pacemaker 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, 37°C, and with a lead impedance of 500 ohms). The beginning of the replacement cycle is displayed on the programmer after pacemaker interrogation and appears on the printout. Table 30 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. The rate occurring at ERI depends upon the programmed mode and magnet application.
EOS	End of Service	Identifies the end of the elective replacement indication period.

Table 30: Service Cycle Definitions

The pacemaker indicates the need for replacement by a defined decrease in the programmed rate without a magnet applied. The rate change is dependent on the programmed pacing mode.

The pacing rate decreases by 11% when programmed to DDD(R), DDT(R), DOO(R), VDD(R), VDI(R), VDT(R), VVI(R), VVT(R), AAI(R), AAT(R), or AOO(R).

In DDI(R) and DVI(R) modes, only the V-A delay is extended by 11%. This reduces the pacing rate by 4.5-11%, depending on the programmed AV delay.

The pacemaker indicates the need for replacement by a defined decrease of its rate after magnet application and the programmer displays it upon interrogation of the pacemaker programmed parameters. The magnet rate in all modes decreases as shown in Table 31.

Magnet Mode	Cycles 1-10 after magnet application	After Cycle 10
Automatic	Asynchronous, basic rate at 80 bpm	Synchronized with basic rate reduced by 4.5-11%
Asynchronous	Asynchronous, basic rate at 80 bpm	Asynchronous with basic rate at 80
Synchronous	Synchronized with basic rate reduced by 4.5-11%	Synchronized with basic rate reduced by 4.5-11%

Table 31: Pacemaker Behavior after Reaching ERI

If the pacemaker is programmed to dual chamber pacing, it will switch to single chamber pacing when it reaches the elective replacement indication. The “ERI mode” varies according to the programmed pacing mode and is indicated by the pacemaker.

CAUTION

High output settings combined with very low lead impedance may reduce the life expectancy of the pacemaker to less than 1 year. Programming of pulse amplitudes, higher than 4.8 V, in combination with long pulse widths and/or high pacing rates can lead to premature activation of the replacement indicator

Table 32 shows the expected longevity from BOS to ERI for the Edora/Evity/Enitra ProMRI® pacemakers. The programmer software for the Edora/Evity/Enitra ProMRI® pacemakers provides an estimated time to ERI in months and years that is updated each time the device is reprogrammed. This estimation allows the physician to understand the longevity effects of modifying programmed parameters.

SR-T [1]	
% Pacing	500 Ohms pacing impedance
	RV: 2.5V
50% VVI	14 y 9 m
100% VVI	13 y 0 m

DR-T [2]	
% Pacing	500 Ohms pacing impedance
	A, RV: 2.5V
50% DDD	11 y 4 m
100% DDD	9 y 4 m

Table 32: Nominal Pacemaker Longevity

The remaining expected service time is provided in Table 33 below.

Pacing Program	ERI to EOS in Months
ERI pacing program	6

Table 33: Remaining Expected Service Time

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

1 **SR-T** All longevity calculations based on AAI(R) @ 2.5 V, 0.4 ms, 60 ppm, 100% pacing, 500 Ω, RF-Telemetry: OFF, 15% longevity reduction for Home Monitoring with daily transmissions.

2 **DR-T All longevity calculations based on DDD(R) @ 2.5 V, 0.4 ms, 60 ppm, 100% pacing, 500 Ω, RF-Telemetry: OFF, 15% longevity reduction for Home Monitoring with daily transmissions.**

12. Explantation

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

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

CAUTION

Device Incineration – Never incinerate a pacemaker. Be sure the pacemaker is explanted before a patient who has died is cremated.

Explanted Devices – Return all explanted devices to BIOTRONIK.

12.1 Common Reasons to Explant a Pacemaker

A pacemaker 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; no output/ intermittent output; loss of capture/ sensing; inability to program/interrogate the pacemaker; infection, EOS (normal or premature); system upgrade; physician preference for another pacemaker model; and/ or other reason(s) which may or may not be known to the pacemaker manufacturer. Complications related to other portions of the pacing system (i.e., lead, patient) may also result in pacemaker explant. Table 34 summarizes some of the more common reasons for pacemaker explant.

Source	Cause	Possible Effect
Battery	Premature depletion due to high programmed output or other cause(s) resulting in excessive battery current drain.	Output voltage decrease; rate decrease; loss of capture; increased pulse width; 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.	No output; rate increase, rate decrease; reversion to asynchronous mode; loss of capture and/or sensing Permanent or temporary loss of output; output inhibition; reversion to asynchronous mode with rate change or instability; pacing synchronized to interference; reversion to "Elective Replacement" or electrical reset parameters; inability to program/ interrogate; other damage to circuit components resulting in permanent or temporary parameter changes.
Connector, Setscrew, etc.	Poor connection, intrusion of body fluid.	Excessive current drain; early battery depletion; intermittent or continuous loss of capture and/ or sensing.

Source	Cause	Possible Effect
Leads	Displacement, fracture, loss of insulation integrity.	Intermittent or continuous loss of capture and/or sensing; excessive current drain; early battery depletion.
	Cardiac perforation	The above plus cardiac tamponade; muscle or nerve stimulation.
	Myocardial irritability at time of insertion, e.g., from an acute myocardial infarction	Fibrillation
Patient	Threshold Elevation	Loss of capture and/or sensing.
	Normal medical complication	Infection
	Body rejection phenomena	Fluid accumulation; migration; erosion.
Misc.	Unipolar pacing systems	Inhibition of pacemaker due to sensing of skeletal muscle activity.
	Physician preference	Upgrade to bipolar, dual chamber, rate-adaptive pacemaker, etc.
	Introducer caused	Air embolism or pneumothorax.

Table 34: Common Reasons to Explant a Pacemaker

13. Technical Data

13.1 Modes

DR-T

DDD-CLS (for 8 series only), VVI-CLS (for 8 series only)

DDDR-ADIR (for 8 and 6 series only), DDD-ADI (for 8 and 6 series only), DDD(R), DDI(R), DVI(R), DOO(R), DDT

VDD(R), VDI(R), VVI(R), VOO(R), VVT

AAI(R), AOO(R), AAT, OFF (Temporary only)

SR-T

VVI-CLS (for 8 series only), VVI(R), AAI(R), VVT, AAT, VOO(R), AOO(R), OFF (Temporary only)

NOTE:

Programmability dependent on programmer software utilized.
Bold parameters indicate factory settings.
Parameters specified at 37º C, with a lead impedance of 500 ohms.

Pulse- and Control Parameters

Basic rate

30...(5)...100...(10)...200 bpm

Night rate

OFF, 30...(5)...100...(10)...200 bpm

Rate Hysteresis

OFF; -5...(5)...-25, -45, -65 bpm

Repetitive/Scan Hysteresis

OFF; ON (5)

UTR Response

WRL; 2:1 (automatic selection)

Rate Limitation[5,6,7]

190…220 bpm

Dynamic AV Delay

Low, Medium, High, Fixed, or Individual

AV Delay Values

20…(5)…350 ms in 6 rate bins

AV Delay Hysteresis

OFF; Positive, Negative, I-Opt

AV Scan/Repetitive Hysteresis

OFF; ON

5 The corresponding intervals t correlate with the rates f by the formula t = 60.000 / f (t in ms, f in bpm).
6 In the event of electronic defect.
7 Rate Limitation changes as the Pacemaker approaches End of Service. The Rate Limitation is nominally 190 bpm at Beginning of Service (BOS) and can reach 220 bpm at End of Service (EOS) due to battery depletion.

PAGE 117

Positive AV Hysteresis

70, 110, 150, 200 ms

Negative AV Hysteresis

10…(10)…150 ms

AV safety delay

100 ms

Sense Compensation

Off; -10...(-5)…-**45**…(-5)...-120 ms

Far Field after Vs

100…(10)…220 ms

Far Field after Vp

100…(10)…**150**…(10)…220 ms

Ventricular Blanking after Ap

30…(5)…70 ms

Magnet effect

Automatic; asynchronous; synchronous

Asynchronous Magnet Effect: paces at 90 bpm.

Automatic Magnet Effect; 10 cycles at 90 bpm asynchronous; thereafter synchronous with the programmed basic rate

Synchronous Magnet Effect; synchronous with programmed basic rate

Pulse amplitude

A 0.2...(0.2)...**3.0**...(0.2)...6.0...(0.5)...7.5 V

RV 0.2...(0.2)...**3.0**...(0.2)...6.0...(0.5)...7.5 V

Pulse width

A 0.1; 0.2; 0.3; **0.4**; 0.5; 0.75; 1.0; 1.25; 1.5 ms

RV 0.1; 0.2; 0.3; **0.4**; 0.5; 0.75; 1.0; 1.25; 1.5 ms

Sensitivity

A **AUTO**, 0.1...(0.1)...1.5...(0.5)...7.5 mV

RV **AUTO**, 0.5...(0.5)...2.5...(0.5)...7.5 mV

Refractory period

A AUTO

RV 200…(25)…**250**…(25)…500 ms

PVARP

AUTO, 175…(25)…250…(25)…600 ms

PAGE 118

Mode Switch (X out of 8)

OFF; **ON**

X = 3, 4, **5**, 6, 7, 8 out of 8

Z= 3, 4, **5**, 6, 7, 8 out of 8

Intervention Rate

100...(10)...**160**…(10)…250 bpm

Mode Switch Basic Rate

OFF, +5…(5)…**+10**…(5)…+30

2:1 Lock-In Protection*

OFF; **ON**

Lead Polarity

Pace:	A	**unipolar**; bipolar
	RV	**unipolar**; bipolar
Sense:	A	**unipolar**; bipolar
	RV	**unipolar**; bipolar

13.1.1 Rate Adaptation

Sensor gain

AUTO, Very low, Low, Medium, High, Very high

Sensor threshold

Very low, Low, **Medium**, High, Very high

Rate increase

1, **2**, 4, 8 bpm/cycle

Maximum sensor rate

80...(10)...**120**...(10)...180 bpm

Rate decrease

0.1, 0.2, **0.5**, 1.0 bpm/cycle

Rate fading

OFF; ON

13.1.2 Atrial Capture Control (ACC)

Atrial Capture Control

ON; OFF; ATM (monitoring only)

Minimum Amplitude

0.5…(0.1)…**1.0**…4.8 V

Safety Margin

0.5…(0.1)…**1.0**…1.2 V

* 2:1 Lock-in protection not available in HF-T devices unless BiV pacing is OFF.

Search Type

Interval, **Time of Day**

Interval

0.1, 0.3, 1, 3, 6, 12, **24** hours

Time of Day

00:00 … 23:50 in 10 minute increments, nominal **00:30**

13.1.3 Ventricular Capture Control (VCC)

Ventricular Capture Control

ON, OFF, ATM

Maximum VCC Amplitude

2.4, **3.0**, 3.6, 4.2 4.8 V

Safety Margin

RV - 0.3…(0.1)…**0.5**…(0.1)… 1.2 V

Search Scheduling

Interval, **Time of Day**

Interval

0.1, 0.3, 1, 3, 6, 12, **24** hours

Time of Day

00:00 … 23:50 in 10 minute increments, nominal **00:30**

13.1.4 Home Monitoring Parameters

Home Monitoring

OFF, ON

Monitoring Interval

1 day

Time of the Trend Report Transmission

AUTO, 00:00...(01:00)...23:00 hours

Periodic Transmission

OFF, **30**, 60, 90, 120, 180 days, Selection

Ongoing Atrial Episode

OFF, 6, **12**, 18 hours

Event based IEGM

OFF, **ON**

Patient Trigger

OFF, ON

13.1.5 Additional Functions

NOTE:

Availability of the following functions is dependent upon pacemaker configuration.

- Thoracic Impedance
- AV Optimization
- RF Telemetry
- Temporary Program Activation
- High Precision Threshold test in the range up to 7.5 V
- PAC (pulse amplitude control) system produces consistent pulses
- Real Time IEGM Transmission with markers
- Patient Data Memory
- Sensor Simulation
- Position Indicator for the programmer head
- 24-hour Trend
- Heart Rate Histogram
- Sensor Rate Histogram
- Sensor Test Trend with complete Rate Forecast
- Automatic Sensor Gain with Trend Monitor
- PVC Analysis
- Retrograde Conduction Test
- Mode Switching
- Activity Report
- Event counter
- P-/R-wave Tests with Trend Data
- Night Program
- IEGM Recordings
- Lead Impedance Trends
- Automatic Lead Check
- Rate Fading

PAGE 121

13.1.6 NIPS Specifications

Burst Mode	Burst Chamber	Atrium
Burst stimulation A. Only	Coupling Interval / ms	None, 80...(10)… 2000
	Burst Type	Pushbutton, Ramp
	Burst Range / bpm	125…800
Programmed Stimulation	S1-S1	None, 80...(10)… 2000
	S1 Cycles	0…10
	Extra stimuli	S1-S2, S2-S3, S3-S4
	Extra stimuli range	None, 80...(10)… 1000
	Pause / sec	Stop… 50
	Decrement ms	0…100
Back-up Pacing	Modes	VOO,VVI
	Rate / bpm	30…(5)...100...(10)...200
	Amplitude / V	0.2…(0.2)...6.0...(0.5)...7.5
	Pulse width / ms	0.1, 0.2, 0.3, 0.4, 0.5, 0.75, 1.0, 1.25, 1.5
	Sensitivity (VVI mode only)	AUTO, 0.5...(0.5)...7.5
	Pace Polarity	Bipolar, Unipolar

Table 35: NIPS Specifications

13.2 Programmer

ICS 3000 or Renamic

13.3 Materials in Contact with Human Tissue

Housing: Titanium

Connector receptacle: Epoxy resin

Sealing Plugs: Silicone Rubber

13.4 Electrical Data/Battery

NOTE:

At 37º C, with pacing impedance of 500 Ohms.

Parameter	Edora/Evity/Enitra ProMRI®
Pace	Unipolar/bipolar
Pulse form	Biphasic, asymmetric
Polarity	Cathodic
Input impedance	>10 kΩ (A); >10 kΩ (V)
Power source	$LiMnO_2$ or $LiSVO_2$
Battery voltage at BOS	3.1 V
Conducting surface	33 cm^2
Conducting shape	Ellipsoidal

Table 36: Electrical/Battery Data

13.5 Mechanical Data

Model	Leads	Size	Mass	Volume
Edora/Evity/Enitra 8 SR/SR-T ProMRI®	IS-1	6.5 x 40 x 48 mm	21 g	10 cc
Edora/Evity/Enitra 8 DR/DR-T ProMRI®	IS-1	6.5 x 44 x 48 mm	23 g	11 cc

14. Order Information

Pacemaker Type	Order Number
Edora 8 DR-T	407145
Edora 8 DR	407152
Evity 8 DR-T	407146
Enitra 8 DR-T	407147
Edora 8 SR-T	407157
Edora 8 SR	407164
Evity 8 SR-T	407158
Enitra 8 SR-T	407159
Evity 6 DR-T	407149
Enitra 6 DR-T	407150
Enitra 6 DR	407153
Evity 6 SR-T	407161
Enitra 6 SR-T	407162
Enitra 6 SR	407165

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

Appendix A
Mode-Specific Indications and Contraindications

Rate-adaptive Pacing

Edora/Evity/Enitra DR, DDDR-ADIR, DDIR, DVIR, VDDR, VVIR, DDD-CLS, VVI-CLS, DOOR, VOOR, AOOR, AATR, VDIR

NOTE:

For indications specific to the VDDR mode, see Indications for Use on page 1 (Section 2).

Indications for rate-adaptive pacing may include but are not limited to the following:

- Patients with chronotropic incompetence who have an anticipated moderate or high level of activity and in whom there is a stable atrial rhythm, and for whom DDD, DDI, DVI, VDD, or VVI pacing is also indicated.
- Patients who have persistent VA conduction (dual chamber modes).

These indications include but are not limited to sick sinus syndrome and AV block.

The rate-adaptive modes of the Edora/Evity/Enitra ProMRI® pacemaker families are contraindicated for patients who are known to develop angina or ischemia at accelerated pacing rates. In addition, the rate-adaptive modes are contraindicated in circumstances where the applicable non-rate-adaptive mode is noted as contraindicated in the following text.

Dual Chamber

DDD

The DDD mode is clearly indicated if

- AV synchrony is needed over a broad range of rates, such as
- active or young patients with an adequate increase in atrial rate, and/or
- significant hemodynamic indication, and/or
- previous occurrence of pacemaker syndrome or of a reduction in systolic blood pressure of more than 20 mm Hg under ventricular pacing with pacemaker implantation (regardless of any evidence of retrograde VA conduction).

The DDD mode is **conditionally indicated** in the case of

- a complete AV block or of sick sinus syndrome and stable atrial rate, and/or
- proof that simultaneously setting the atrial and ventricular rates can inhibit tachyarrhythmia or if the pacemaker can be set to a pacing mode suited for interrupting arrhythmia.

The DDD mode is **contraindicated** in the case of

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter, and/or
- inadequate intra-atrial complexes that do not permit safe sensing, and/or
- angina pectoris which would be aggravated by increased heart rates.[8]

DDI

The DDI mode is useful in all cases in which dual chamber pacing is necessary, but where intermittent supraventricular arrhythmias frequently occur.

8 The ACC/AHA Guidelines cannot replace a study of the relevant specialized literature, especially since the indications and contraindications for using particular pacing modes are subject to constant advances in medical knowledge.

DVI

The DVI mode is **clearly indicated** if

- AV sequential contraction is necessary due to symptomatic bradycardia and slow atrial rate, and/or
- a pacemaker syndrome has already been documented.

The DVI mode is **conditionally indicated** for

- frequent supraventricular arrhythmia in which a combination of pacing and medication has proved therapeutically effective, and/or
- the presence of a bradycardia-tachycardia syndrome, presuming that setting the atrial rate and the AV interval with or without accompanying medication stops or prevents supraventricular arrhythmia.

The DVI mode is **contraindicated** for

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter.

Dual Chamber Modes

VDD

The VDD mode is **clearly indicated** for

- ventricular pacing when adequate atrial rates and adequate intracavitary complexes are present. The indication includes the presence of complete AV block when
- the atrial contribution is necessary for hemodynamic optimization, and/or
- a pacemaker syndrome has already occurred or is expected.

The VDD mode is **conditionally indicated** for

- patients with normal sinus rhythms and normal AV conduction, but who intermittently need ventricular pacing.

The VDD mode is **contraindicated** for

- frequent or persistent supraventricular tachyarrhythmia, including atrial fibrillation or flutter, and/or
- inadequate intra-atrial complexes that do not permit safe sensing, and/or
- intact retrograde conduction.

Single Chamber Modes

VVI

The VVI mode is **clearly indicated** for

- all symptomatic bradyarrhythmias, but particularly if
- the atrium does not significantly contribute to the hemodynamics (persistent or paroxysmal atrial flutter or fibrillation, dilated atria).
- there are no grounds for development of pacemaker syndrome through loss of the atrial contribution or through negative atrial contribution.

The VVI mode is **conditionally indicated** for

- symptomatic bradycardia when the simplicity of the pacing system is of crucial significance due to
- senility (for the sole purpose of prolonging life).
- incurable illness.
- great distance from the follow-up care center to the patient‘s home.
- absence of retrograde VA conduction.

The VVI mode is **contraindicated** if

- a pacemaker syndrome is known to exist or if the patient develops particular symptoms during temporary pacing or pacemaker implantation, and/or
- there is a need to maximize the atrial contribution due to
- congestive heart failure, and/or
- a specific need for ventricular rate adaptation.

AAI

The AAI mode is **clearly indicated** for

- symptomatic sino-atrial node dysfunction (sick sinus syndrome), given that adequate AV conduction has been established by an appropriate examination.

The AAI mode is **conditionally indicated** if

- the hemodynamics of patients with bradycardia and symptomatically reduced cardiac output can be improved by raising the heart rate, given that adequate AV conduction has been established by an appropriate diagnostic examination.

The AAI mode is **contraindicated** for

- previously established AV conduction delay or AV block or if diminishing AV conduction has been determined by appropriate tests, and/or
- inadequate intra-atrial complexes that do not permit safe sensing.

Other Modes

In addition to the ACC/AHA guidelines, the modes listed above may have further indications due to medical/technical complications such as electromagnetic interference, sensing defects, fracture of the lead(s), detection of myopotentials, muscle stimulation, etc. The same applies to the asynchronous **DOO(R), AOO(R)** and **VOO(R)** pacing modes derived from the above by restricting the sensing functions. The triggered **DDT, AAT** and **VVT** pacing modes and the **VDI** and **OFF** modes are indicated for diagnostic purposes to assess intrinsic cardiac activity. Use of the **OFF** mode is contraindicated in pacemaker dependent patients.

Appendix B
Known Software Anomalies

Anomaly	Possible Effect on User (Patient or Implant Procedure)
The "Original" and "Preview" printout of parameter "Sensor gain" for the Sensor optimization test does not function as specified. Identical values are printed even if a change was made. Permanent program is not affected	Display/printout of incorrect test program data may cause user confusion
An unexpected programmer shut down requiring a system re-boot may occur in the rare case that the "Start" and "End" buttons on the Retrograde Conduction Test screen are pressed in quick succession.	Unexpected/Unspecified behavior may cause follow-up prolongation
Mismatch of Impedance Measurement and Polarity for the atrial channel at Follow-up printout when programmed to the VDDR mode: BIPL impedance is correctly displayed even though the value is reported with the wrong polarity (UNIP) on the printout.	Display/printout of incorrect diagnostic information may cause user confusion. This only affects the atrial channel in the rarely used VDDR mode.
If the remaining battery capacity goes below the threshold required for a 10 minute wandless telemetry session, the programmer does not display the ERI date during this ongoing session. Autonomous ERI declaration of the implant correctly sets the ERI date and programmer correctly shows no time remaining until ERI.	Display/printout of missing diagnostic information may cause user confusion. Regardless, the user would be present when ERI is declared.
Sensor optimization test may not function during RF communication, since the ongoing follow-up session prevents rate adaptation in the implant (as specified). However, the user might not be aware of the need to terminate the current RF communication session before the sensor optimization can be initiated. During wand communication, lifting the wand was used to start the rate adaptive pacing mode.	Unexpected/Unspecified behavior, but there is no clinical relevance or negative therapeutic/diagnostic implication.
Programmer displays unexpected difference for Time to ERI (6-13mo) between Ventricular Capture Management (VCM) = OFF and VCM = ATM; the higher Time to ERI value for "OFF" is correct for both.	Display/printout of incorrect diagnostic information may cause user confusion, but the displayed value is more conservative.

Edora/Evity/Enitra ProMRI® Pacemakers
Technical Manual

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