Rivacor ProMRI®
Family of ICDs and CRT-Ds
Technical Manual

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CAUTION

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

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Figure 1: Rivacor ProMRI® ICDs and CRT-Ds

Rivacor ProMRI® Specifications	
Battery Voltage	3.2 +/- 0.1V
Maximum Shock Energy	40 joules stored
X-ray Identification	
Rivacor ProMRI® Models	
VR-T Models	One DF4
DR-T Models	One DF4, One IS-1
HF-T QP Models	One IS-1, One IS4, One DF4
Materials	
Housing	Titanium
Header	Epoxy Resin
Sealing Plug	Silicone

Table 1: Rivacor ProMRI® Specifications

Detailed technical specifications are provided in Section 14.

Chapter 1: General

1.1 System Description

The Rivacor ProMRI® family of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) detect and treat ventricular tachyarrhythmias and provide rate adaptive bradycardia pacing support. The HF-T version of Rivacor ProMRI® provides cardiac resynchronization therapy (CRT) through biventricular pacing. The products are designed to collect diagnostic data to aid the physician's assessment of a patient's condition and the performance of the implanted device.

The Rivacor ProMRI® family of devices provides therapy for ventricular tachyarrhythmias with a sophisticated range of programmable anti-tachycardia pacing (ATP), and/or defibrillation therapy features. The shock polarity and energy may be programmed to tailor the therapy to appropriately treat each patient's tachyarrhythmias. The ICDs/CRT-Ds provide shock therapies with programmable energies from 2 to 40 joules.

The Rivacor ProMRI® DR-T and CRT-D ICDs can provide therapy for atrial tachyarrhythmias using a programmable range of anti-tachycardia pacing (ATP), and/or HF burst therapy features.

The Rivacor ProMRI® family of ICDs/CRT-Ds includes the following members:

- **Rivacor ProMRI® HF-T QP** - provides three-chamber rate adaptive bradycardia pacing support, including biventricular pacing via the right and left ventricular quadripolar pacing lead. The left ventricular quadripolar pacing lead allows the physician to determine the optimal pacing position for CRT therapy while minimizing pacing output to maximize device longevity. The QP CRT-D uses the atrial and right ventricular sensing/pacing leads to provide enhanced atrial and ventricular tachyarrhythmia discrimination through BIOTRONIK's SMART Detection® algorithm.
- **Rivacor ProMRI® DR-T** - provides dual-chamber rate-adaptive bradycardia pacing support. The ICD uses atrial and ventricular sensing/pacing leads to provide enhanced atrial and ventricular tachyarrhythmia discrimination through BIOTRONIK's SMART Detection® algorithm.
- **Rivacor ProMRI® VR-T** - provides single-chamber rate-adaptive bradycardia pacing support as well as tachyarrhythmia detection and therapy.

Rivacor ProMRI® DF4 models have one DF4 port [Reference ISO 27186:2010]. Additionally the Rivacor ProMRI® DR-T DF4 models have one IS-1 port. The Rivacor ProMRI® HF-T QP has one IS-1 port and one IS4 port and one DF4 port [Reference ISO 27186:2010]. Throughout this manual, "HF-T" includes the HF-T and HF-T QP Devices.

External devices that interact with and test the implantable devices are also part of the ICD/CRT-D System. These external devices include the ICS 3000 Programmer with the Implant Module, the Renamic Programmer with PSA Module, or the Reliaty Pacing System Analyzer for acute lead testing. The ICS 3000 or Renamic programmer is used to interrogate and program the Rivacor ProMRI® ICD/CRT-Ds.

The ICDs and CRT-Ds referenced in this manual are MR Conditional devices. Therefore, MR scans are permissible under certain conditions. Refer to the ProMRI® System Technical Manual or www.biotronikusa.com/promri for specific MR conditions for use and to confirm the approved ProMRI® device-lead combination. The ProMRI® device is also identified on the packaging by the following MR Conditional symbol.

All Rivacor ProMRI® ICD/CRT-D devices can be used with the BIOTRONIK Home Monitoring® system. The Home Monitoring System enables wireless automatic transmission of information about a patient's cardiac status from the implanted device to the physician remotely.

The Rivacor ProMRI® devices provide the ability to schedule remote follow-up appointments via the Home Monitoring Service Center. This feature will allow programming of remote follow-up transmissions without needing to bring the patient into the office for device programming.

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 regard 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.

BIOTRONIK Home Monitoring® has been shown to improve patient outcomes. Home Monitoring provides automatic, daily updates of multi-parameter information received from implanted cardiac devices. Timely review of this data by medical professionals with subsequent patient contacts and therapeutic interventions have demonstrated improved clinical outcomes and mortality in ICD and CRT-D patients with heart failure (see G. Hindricks et al., The Lancet, vol. 384, August 16, 2014). The patients managed with BIOTRONIK Home Monitoring experienced a significant mortality advantage (1-year all-cause mortality of 3.4% versus 8.7% in the control group ($p = 0.004$)).

Rivacor devices 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 402-405 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 Appendix B of this manual.

1.2 Indications for Use

ICDs:

The Rivacor ProMRI® family of implantable cardioverter defibrillators (ICDs) is intended to provide ventricular tachycardia pacing and ventricular defibrillation for automatic treatment of life-threatening ventricular arrhythmias.

CRT-Ds:

The Rivacor ProMRI® CRT-Ds are indicated for use in patients with all of the following conditions:

- Indicated for ICD therapy
- Receiving optimized and stable congestive heart failure (CHF) drug therapy
- Symptomatic CHF (NYHA Class III/IV and LVEF ≤35%); and
- Intraventricular conduction delay (QRS duration ≥130 ms)

1.3 Contraindications

The Rivacor ProMRI® devices are contraindicated for use in patients with the following conditions:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as:
  - Acute myocardial infarction
  - Digitalis intoxication
  - Drowning
  - Electrocution
  - Electrolyte imbalance
  - Hypoxia
  - Sepsis
  - Patients with incessant ventricular fibrillation (VF) and ventricular tachycardia (VT)
  - Patients whose only disorder is bradycardia arrhythmia or atrial arrhythmias

1.4 Warnings and Precautions

Electrical Isolation To prevent inadvertent arrhythmia induction, electrically isolate the patient during the implant procedure from potentially hazardous leakage currents.

Left Ventricular Lead Systems BIOTRONIK CRT-Ds may be implanted with any legally marketed, compatible LV lead. Compatibility is defined as:

- IS-1 pacing connector
- IS4 pacing connector for QP models. IS4 refers to the international standard ISO 27186:2010. Compatibility with St. Jude Quartet IS4 lead has been demonstrated through chronic in-vivo animal GLP testing.
- Active or passive fixation technology
- Insertion and withdrawal forces as specified by ISO 5841-3 (IS-1)

ICD Lead Systems BIOTRONIK IS-1/DF4 IS4/DF4 ICDs/CRT-Ds may be implanted with any legally marketed, compatible ICD lead. Compatibility is defined as:

- IS-1 pacing and sensing connector(s)
- IS4 pacing and sensing connector for QP models
- DF4 pacing/shock coil connector
- Integrated or dedicated bipolar pacing and sensing configuration
- Active or passive fixation technology
- Single or dual defibrillation shock coil(s)
- High-energy shock accommodation up to 40 joules
- Insertion and withdrawal forces as specified by ISO 5841-3 (IS-1) DF-1

Resuscitation Availability – Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, induce and convert the patient's ventricular tachyarrhythmias.

Unwanted Shocks – Always program ICD Therapy to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or to the person handling the device during the implant procedure.

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

Blanking after RV pace – Extending this value too long may lead to delays in arrhythmia detection. Consult Advanced Product Support prior to extending this value.

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.

1.4.1 Sterilization, Storage, and Handling

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

Do not drop If an unpacked device is dropped on a hard surface during handling, electronic parts could be damaged. Use a replacement device and return the dropped device to BIOTRONIK.

Re-sterilization Do not re-sterilize and re-implant explanted devices.

Storage (temperature) Store the device between 5° to 45°C (41°-113°F) because temperatures outside this range could damage the device.

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

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

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

1.4.2 Device Implantation and Programming

Blind Plug A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high-energy therapy.

Capacitor Reformation Infrequent charging of the high-voltage capacitors may extend the charge times of the ICD/CRT-D. The capacitors are reformed automatically at least every 6 months. For further information, please refer to Section 9.3, Capacitor Reformation.

Connector Compatibility ICD/CRT-D and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD/CRT-D system. For further information, please refer to Appendix A.

ERI (Elective Replacement Indicator) Upon reaching ERI, the battery has sufficient energy remaining to continue monitoring for at least three months and to deliver a minimum of six maximum energy shocks. After this period (EOS), all tachyarrhythmia detection and therapy is disabled. Bradycardia functions are still active at programmed values until the battery voltage drops below 1.75 volts.

Magnets Positioning of a magnet over the ICD/CRT-D will suspend tachycardia detection and treatment. The minimum magnet strength required to suspend tachycardia treatment is 1.5 mT. When the magnet strength decreases to less than 1 mT, the magnet sensor is reopened.

Programmed Parameters Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Programmers Use only BIOTRONIK ICS 3000 or Renamic programmers to communicate with the device.

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

Defibrillation Threshold Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Manual Shocks User-commanded shocks may be withheld if the ICD/CRT-D is already busy processing a manual command or the Battery Status is low.

Charge Time When preparing a high-energy shock, the charge circuit stops charging the capacitors after 20 seconds and delivers the stored energy as shock therapy. After the device reaches ERI, the stored energy may be less than the maximum programmable energy for each shock.

Shipment Mode The shipment mode is a factory set mode that controls the charge current of automatic capacitor reformations. This mode controls the charge current to avoid temporary low battery readings.

The shipment mode is deactivated with transmission of a permanent program to the implant followed by a valid RV lead impedance measurement obtained by the programmer.

Shock Therapy Confirmation Programming CONFIRMATION to OFF sets the shock delivery to defibrillation instead of cardioversion when programmed ON. This may increase the incidence of the ICD/CRT-D delivering inappropriate shocks.

Shock Impedance If the shock impedance is less than 25 ohms (25 Ω), reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has measured shock impedance of less than 25 ohms (25 Ω). Damage to the device may result.

Negative AV Hysteresis This feature ensures 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.

1.4.3 Lead Evaluation and Connection

Gripping Leads Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.

Kinking Leads Do not kink leads. This may cause additional stress on the leads that can result in damage to the lead.

Liquid Immersion Do not immerse leads in mineral oil, silicone oil, or any other liquid.

Short Circuit Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD/CRT-D system.

Far-Field Sensing Far-field sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/ sensing parameters, and maximum sensitivity settings. If it is necessary to modify the Far-field Blanking parameter, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending the parameter unnecessarily may cause under sensing of actual atrial or ventricular events.

Suturing Leads Do not suture directly over the lead body as this may cause structural damage. Use the appropriate suture sleeve to immobilize the lead and protect it against damage from ligatures.

Tricuspid Valve Bioprosthesis Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

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 the 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 while the lead is inserted.

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

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

Capping Leads If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.

1.4.4 Follow-up Testing

Defibrillation Threshold Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Resuscitation Availability Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Safe Program Pressing the "Safe Program" key on the programmer or programmer head immediately sends the safe program to the ICD/CRT-D.

Shipment Mode ICDs are set to an energy-saving mode prior to implantation. These devices use less current and conserve more battery during shipment mode compared to prior ICD generations. IEGMs are not available in Shipment mode. Shipment mode can be deactivated by sending a permanent program to the implanted device.

1.4.5 Pulse Generator Explant and Disposal

Device Incineration Never incinerate the ICD/CRT-D due to the potential for explosion. The ICD/CRT-D must be explanted prior to cremation.

Explanted Devices Return all explanted devices to BIOTRONIK.

Unwanted Shocks Always program ICD Therapy to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or to the person handling the device during the procedure.

1.4.6 Hospital and Medical Hazards

Electromagnetic Interference (EMI) signals present in hospital and medical environments may affect the function of any ICD/CRT-D or pacemaker. The ICD/CRT-D is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this, or any other, ICD/CRT-D.

The ICD/CRT-D system should have detection and therapy disabled (OFF) prior to performing any of the following medical procedures. In addition, the ICD/CRT-D should be checked after the procedures to assure proper programming:

Diathermy Diathermy therapy is not recommended for ICD/CRT-D patients due to possible heating effects of the pulse generator and at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system.

Electrocautery Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible (at least 6 inches (15 cm)).

External Defibrillation The device is protected against energy normally encountered from external defibrillation. However, any implanted device may be damaged by external defibrillation procedures. In addition, external defibrillation may result in permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. When possible, observe the following precautions:

- Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted device and the heart.
- Set the energy to the minimum level required to achieve defibrillation.
- Place the paddles as far as possible away from the implanted device and lead system.
- After delivery of an external defibrillation shock, interrogate the ICD/CRT-D to confirm device status and proper function.

Lithotripsy Lithotripsy may damage the ICD/CRT-D. If lithotripsy must be used, avoid focusing near the ICD/CRT-D implant site.

Radiation High-radiation sources such as cobalt 60 or gamma radiation should not be directed at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Radio Frequency Ablation Prior to performing an ablation procedure, deactivate the ICD/CRT-D for the duration of the procedure. Avoid applying ablation energy near the implanted lead system whenever possible.

Hyperbaric Oxygen Therapy (HBOT) Hyperbaric oxygen therapy (HBOT) for patients with BIOTRONIK CRM devices is not recommended due to the potential for damage or impaired function of the implant after exposure. The physician should conduct a risk-benefit analysis if HBOT treatment is necessary. The ICDs specified in this manual have been tested to be in compliance with ISO 14708-2:2012, where the device is exposed to 40 cycles test up to 450kPa.

1.4.7 Home and Occupational Hazards

Patients should be directed to avoid devices that generate strong electromagnetic interference (EMI) or magnetic fields. EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the ICD/CRT-D to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD/CRT-D operation: electric arc or resistance welders, electric melting furnaces, radio/television and radar transmitters, power-generating facilities, high-voltage transmission lines, and electrical ignition systems (of gasoline-powered devices) if protective hoods, shrouds, etc., are removed.

1.4.8 Cellular Phones

Testing has indicated there may be a potential interaction between cellular phones and BIOTRONIK ICD/CRT-D systems. Potential effects may be due to either the cellular phone signal or the magnet within the telephone and may include inhibition of therapy when the telephone is within six inches (15 centimeters) of the ICD/CRT-D, when the ICD/CRT-D is programmed to standard sensitivity.

Patients having an implanted BIOTRONIK ICD/CRT-D who operate a cellular telephone should:

- Maintain a minimum separation of 6 inches (15 centimeters) between a hand-held personal cellular telephone and the implanted device.
- Set the telephone to the lowest available power setting, if possible.
- Patients should hold the phone to the ear opposite the side of the implanted device.
- Patients should not carry the telephone in a breast pocket or on a belt over or within 6 inches (15 centimeters) of the implanted device as some telephones emit signals when they are turned ON, but not in use (i.e., in the listen or stand-by mode). Store the telephone in a location opposite the side of implant.

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs/CRT-Ds have been transitory. The potential adverse effects could include inhibition or delivery of additional therapies. If electromagnetic interference (EMI) emitting from a telephone does adversely affect an implanted ICD/CRT-D, moving the telephone away from the immediate vicinity of the ICD/CRT-D should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs/CRT-Ds is not possible due to the disparate nature of EMI.

1.4.9 Electronic Article Surveillance (EAS)

Equipment such as retail theft prevention systems may interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than necessary.

1.4.10 Home Appliances

Home appliances normally do not affect ICD/CRT-D operation if the appliances are in proper working condition and correctly grounded and shielded. There have been reports of the interaction of electric tools or other external devices (e.g. electric drills, older models of microwave ovens, electric razors, etc.) with ICDs/CRT-Ds when these tools are placed in close proximity to the device.

1.4.11 Home Monitoring

All Rivacor ICD/CRT-D devices can be used with BIOTRONIK's Home Monitoring® system. The Home Monitoring System enables wireless automatic transmission of information about a patient's cardiac status from the implanted device to the physician remotely.

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 unplugged or damaged and is not able to connect to the Home Monitoring system through an active telephone link or cellular network.
- The CardioMessenger cannot establish a connection to the implanted device
- The telephone or cellular network is not operational or the patient lives in a geographical area not covered by landline or cellular networks.
- 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.

Use in Cellular Phone Restricted Areas The CardioMessenger (transmitter/receiver) should not be utilized in areas where cellular phones are restricted or prohibited (i.e., commercial aircraft). Cellular or telephone network outages (including poor signal strength) prevent reliable connections.

1.5 Potential/Observed Effects of the Device on Health

1.5.1 Potential Adverse Events

The following are possible adverse events that may occur relative to the implant procedure and chronic implant of the ICD/CRT-D:

- Air emboli
- Allergic reactions to contrast media
- Arrhythmias
- Bleeding
- Body rejection phenomena
- Cardiac tamponade
- Chronic nerve damage
- Damage to heart valves
- Device migration
- Elevated pacing thresholds
- Extrusion
- Fluid accumulation
- Hematoma
- Infection
- Keloid formation
- Lead dislodgment
- Lead fracture/ insulation damage
- Lead-related thrombosis
- Local tissue reaction / fibrotic tissue formation
- Muscle or nerve stimulation
- Myocardial damage
- Myopotential sensing
- Pacemaker mediated tachycardia
- Pneumothorax
- Pocket erosion
- Thromboembolism
- Under sensing of intrinsic signals
- Venous occlusion
- Venous or cardiac perforation

In addition, patients implanted with the ICD/CRT-D system may have the following risks. These are the same risks related with implantation of any ICD/CRT-D system:

- Acceleration of arrhythmias (speeding up heart rhythm caused by the ICD/CRT-D)
- Dependency
- Depression
- Fear of premature battery depletion (fear that battery will stop working before predicted time)
- Fear of shocking while awake
- Fear that shocking ability may be lost
- Anxiety about the ICD/CRT-D resulting from frequent shocks
- Imagined shock (phantom shock)
- Inappropriate detection of ventricular arrhythmias
- Inappropriate shocks
- Potential death due to inability to defibrillate or pace
- Shunting current or insulating myocardium during defibrillation with external or internal paddles

There may be other risks associated with this device that are currently unforeseeable.

For the observed adverse events and information on clinical studies, please see the Clinical Study Summary pamphlet.

1.6 Patient Selection and Treatment

1.6.1 Individualization of Treatment

- Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- Determine whether the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.
- Direct any questions regarding individualization of patient therapy to your BIOTRONIK representative or BIOTRONIK Advanced Product Support at 1-800-547-0394.

The prospective patient's size and activity level should be evaluated to determine whether a pectoral or abdominal implant is suitable. It is strongly recommended that candidates for an ICD/CRT-D have a complete cardiac evaluation, including EP testing, prior to device implant to gather electrophysiologic information, including the rates and classifications of all the patient's cardiac rhythms. When gathering this information, delineate all clinically significant ventricular and atrial arrhythmias, whether they occur spontaneously or during EP testing.

If the patient's condition permits, use exercise stress testing for the following:

- Determine the maximum rate of the patient's normal rhythm.
- Identify any supraventricular tachyarrhythmias.
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of pulse generator implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affect the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

If another cardiac surgical procedure is performed prior to implanting the pulse generator, it may be preferable to implant the lead system at that time. This may prevent the need for an additional thoracic operation.

1.6.2 Specific Patient Populations

Pregnancy If there is a need to X-ray the device, care should be taken to minimize radiation exposure to the fetus and the mother.

Nursing Mothers Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

Geriatric Patients Most (about 71%) of the patients receiving a CRT-D or ICD in the clinical studies were over the age of 60 years (see Clinical Studies Summary pamphlet).

Handicapped and Disabled Patients Special care is needed in using this device for patients using an electrical wheel chair or other electrical (external or implanted) devices.

1.7 Patient Counseling Information

Persons administering cardiopulmonary resuscitation (CPR) may experience the presence of voltage on the patient's body surface (tingling) when the patient's CRT-D/ICD system delivers a shock.

A patient manual is available for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of the device. (For additional copies of the patient manual, contact BIOTRONIK at the address listed in this manual.)

1.8 Evaluating Prospective CRT-D/ICD Patients

The prospective ICD/CRT-D implant candidate should undergo a cardiac evaluation to classify any and all tachyarrhythmias. In addition, other patient specific cardiac information will help in selecting the optimal device settings. This evaluation may include, but is not limited to:

- Evaluation of the specific tachycardia rate(s)
- Confirmation and/or evaluation of any supraventricular arrhythmias or bradyarrhythmias
- Evaluation of various ATP and cardioversion therapies
- Presence of any post-shock arrhythmias, and
- Evaluation of the maximum sinus rate during exercise.

If a patient's drug regimen is changed or adjusted while the CRT-D/ICD is implanted, additional EP testing may be required to determine whether detection or therapy parameter settings are relevant and appropriate.

Empirical changes to the detection or therapy parameters should be assessed based on patient safety. Some changes may necessitate a re-assessment of sensing, pacing, or arrhythmia conversion treatment. Thorough technical knowledge of BIOTRONIK CRT-D/ICDs, additional CRT-D/ICD experience, and individual medical judgment will aid in determining the need for additional testing and follow-up.

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Chapter 2: Programmer

The Renamic and ICS 3000 programmers may be used to communicate with the Rivacor ProMRI® family of ICDs. When the programmer is turned ON, the screen shown in Figure 2 is seen. The devices able to be interrogated with the programmer software can be viewed by selecting the Device list button at the bottom of the screen.

> **Note –** The images of the user interface (in the form of screenshots) represent the interface at the time at which this technical manual was created. These images are intended exclusively for illustrative purposes, and details may deviate from the software actually provided.

The Renamic programmer provides both RF telemetry and wand communication with the Rivacor ProMRI® ICD. The ICS 3000 provides communication with the Rivacor ProMRI® ICD through use of a programming wand.

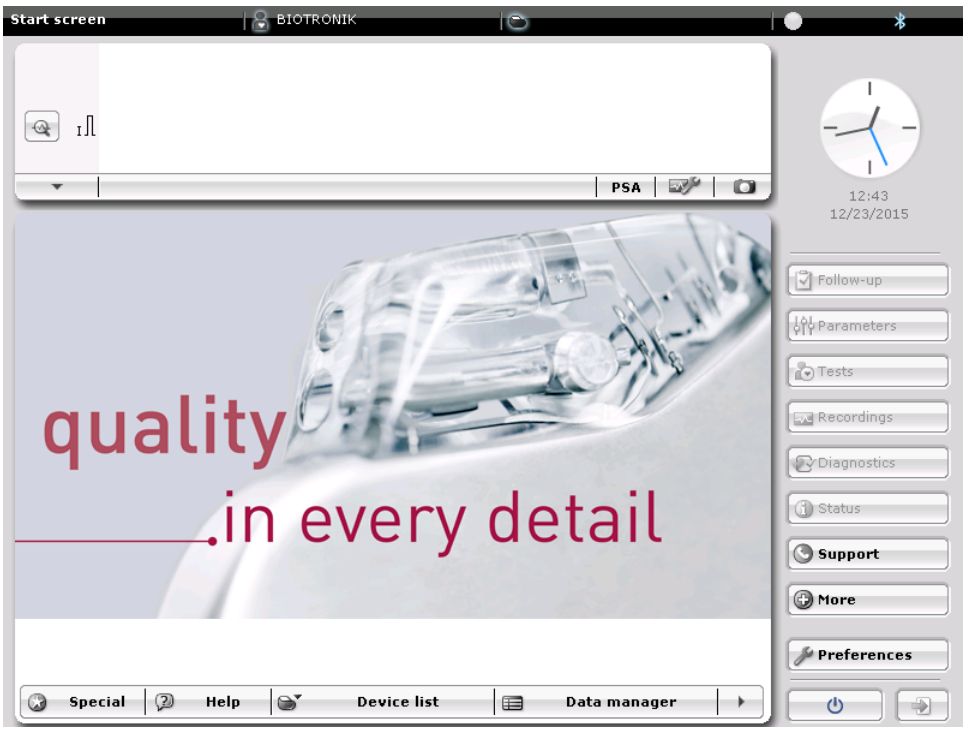

Figure 2: Start up programmer screen

2.1 Device Programming

The Rivacor ProMRI® family feature set is presented under the following sub-headings: Tachyarrhythmia Detection and Therapy, Bradycardia/CRT Therapy, Home Monitoring, Diagnostics and MRI. EP Test Functions and Follow-up testing can be accessed through the Tests button. The features apply to all members of the Rivacor ProMRI® family, except where specifically referenced differently.

CAUTION

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

2.2 Master Switch Behavior

Programming the Rivacor ProMRI® devices does not automatically turn the tachycardia detection/therapy ON. The Master Switch must be turned ON and the Status Indicator must show Enabled, as shown in Figure 3.

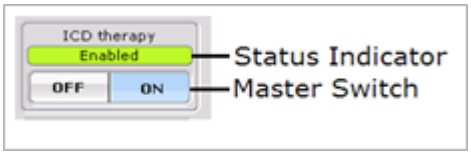

Figure 3: Master switch

Three colors are used for the Status Indicator of the Master Switch: Green = full detection and therapy options available

Yellow = limited detection and therapy options available

Red = no therapy options are available or the status is unclear

Figure 4 shows the different message options that are available with the Rivacor ProMRI® series ICD.

Figure 4: Master switch options

The following sections provide a summary of the Master Switch options and behavior.

2.2.1 Enabled

Tachyarrhythmia detection is enabled, as shown in Figure 5.

All tachyarrhythmias that will be detected according to the permanent programmed detection criterion including atrial monitoring episodes.

All tachyarrhythmias will be treated as therapy sequences are programmed.

This status should be confirmed upon completion of a follow-up or implant unless otherwise indicated.

Figure 5: Master switch enabled

2.2.2 Disabled

Tachyarrhythmia detection is disabled, as shown in Figure 6.

All tachyarrhythmias will be disregarded by the device detection. No programmed therapy will be delivered.

The user is able to deliver emergency and manual shocks or manual ATP.

When leaving an interrogation session of an ICD with this status, the user must acknowledge on a dialog box that the device is programmed in a disabled mode.

Figure 6: Master switch disabled

2.2.3 Temporarily Active

Temporarily active, as shown in Figure 7, is used for the temporary DFT test. Tachyarrhythmia detection is enabled for temporary VF zone only.

All VF tachyarrhythmias will be treated with shock therapy sequences as programmed in the temporary program on the DFT screen.

The user is able to deliver emergency and manual shocks or manual ATP.

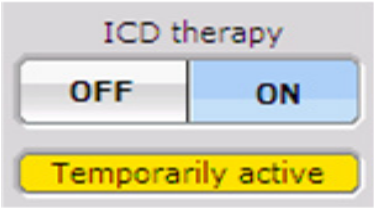

Figure 7: Master switch temporarily active

2.2.4 Temporarily Inactive

Temporarily inactive, as shown in Figure 8, is used for temporary testing such as Sensing, Pacing threshold, Retrograde conduction, and Impedance test, as well as for Atrial NIPS.

All tachyarrhythmias will be disregarded by the device detection.

The user is able to deliver emergency and manual shocks or manual ATP.

Figure 8: Master switch temporarily inactive

2.2.5 Pending

The programmer does not know the status of the Master Switch because telemetry interference during an ongoing ICD session interrupts the connection; e.g., slipping wand or EMI. This may also be seen when initial wand placement over the device occurs as the programmer is establishing contact with the device.

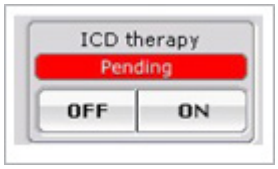

Figure 9: Master switch pending

WARNING

Unwanted Shocks – Always program ICD Therapy to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or to the person handling the device during the implant procedure.

2.3 RF Telemetry

The Rivacor ProMRI® models offer "wandless" communication between the device and the programmer by using radio frequency (RF) telemetry, in addition to the available telemetry used by applying the programming head (PGH) over the implanted device. This function is called RF Telemetry.

RF Telemetry can be used with the Renamic programmer.

When interrogating an Rivacor ProMRI® ICD and RF telemetry is OFF, the dot will become green. An example of this is shown on the left side in Figure 10. When RF telemetry is ON, communication strength bars like that seen on cell phones and a picture of a device transmitting information is shown below the master switch, as seen in the right side of Figure 10.

Figure 10: Examples of RF OFF and RF ON

2.3.1 Establishing RF Telemetry Contact

To initiate a session using RF Telemetry, place the wand over the device until the message "Programming head can be removed" shown in Figure 11 appears. Once the message appears (typically < 2 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 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 three meters (9 feet) of the device. Ideally, there should be no obstacles between the patient and the programmer.

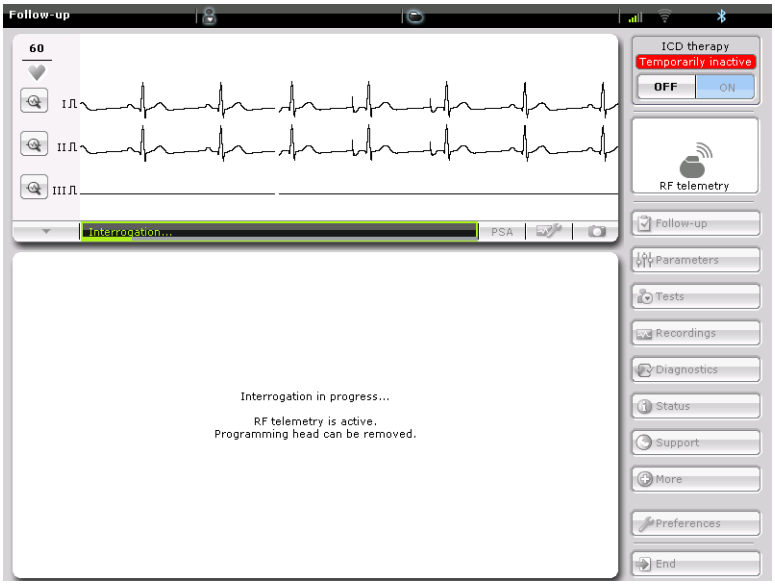

Figure 11: Session initiation message

Once RF telemetry has been established, the programming head 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 will start blinking with an orange light. This notifies the user that there is an active RF telemetry session.

2.3.2 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 12, "Patient name" 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.

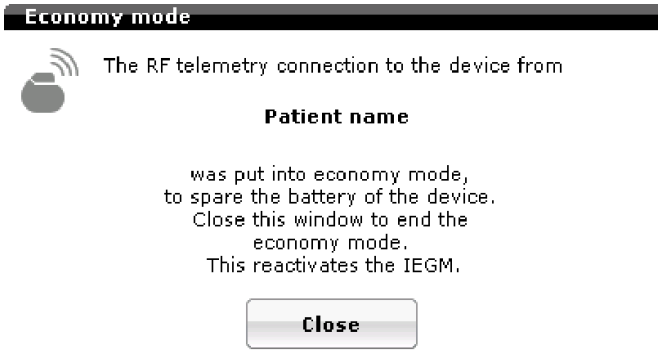

Figure 12: Economy mode message

2.3.3 Ending a Follow-up Session

Always end a follow-up session by pressing the "End" button on the screen, as shown in Figure 13. This ends the RF telemetry link to the device and prevents the possibility of errant programming.

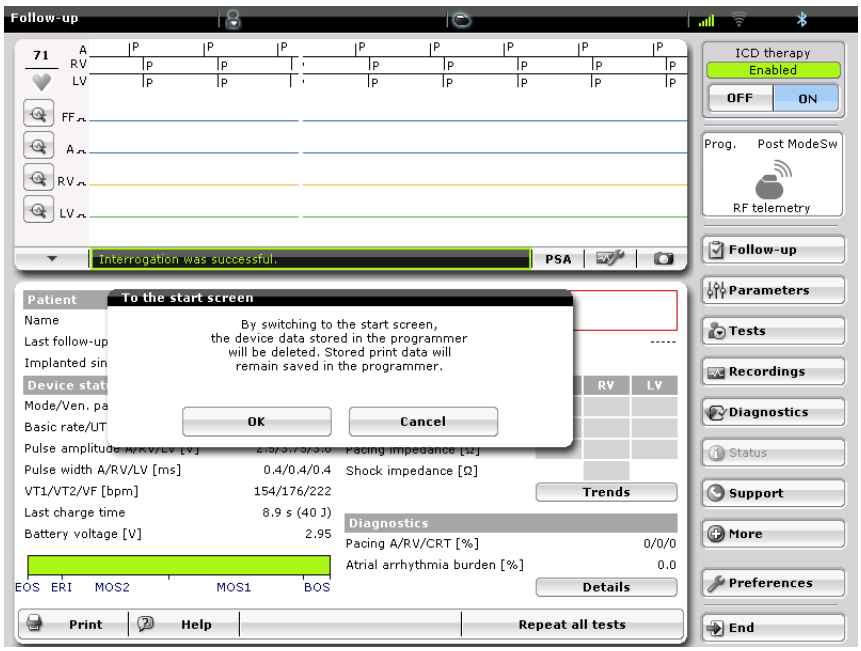

Figure 13: End session

2.3.4 Switch between RF and Wand

To switch between RF and wand (PGH) telemetry, go to the Rivacor ProMRI® tab under the More section. To disable RF telemetry, apply the PGH over the device and 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.

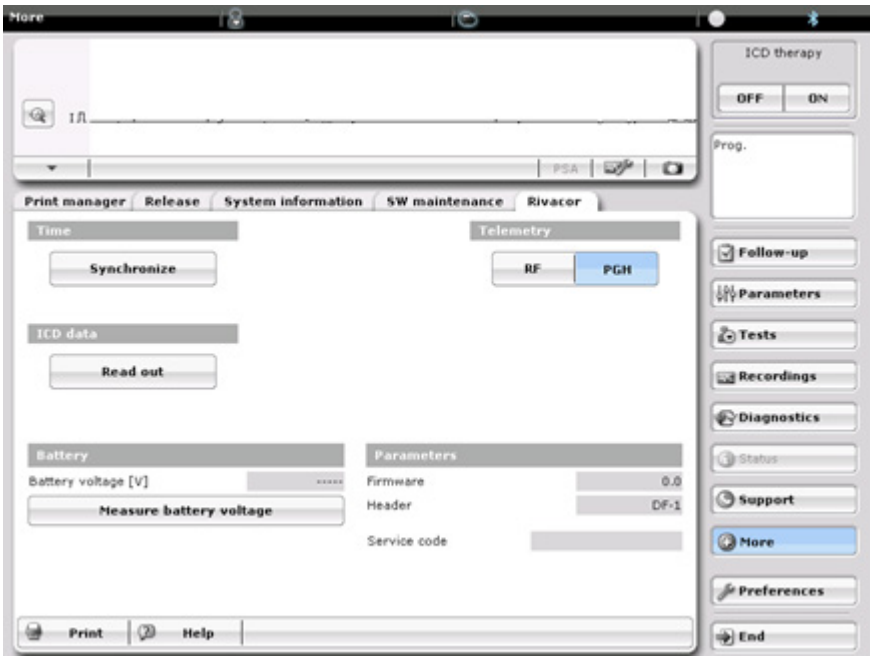

Figure 14: Switch between PGH and RF Telemetry

2.3.5 Power Consumption Consideration

RF Telemetry requires somewhat more power than telemetry via the programming head. Power consumption during a 3 hour implantation procedure corresponds to approximately seven days of service time and consumption during 20-minute follow-up corresponds to approximately three days. As a result:

- Do not establish RF Telemetry sessions unnecessarily.
- After three minutes without input, RF Telemetry switches to the economy mode. To re-establish RF Telemetry from the economy mode, select "Close" in the pop-up window with the patient's name, as shown in Figure 12. 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.

2.4 Programmer Functions

2.4.1 Far-Field IEGM for Threshold Testing (Leadless ECG)

Leadless ECG allows for an alternative to ECG and IEGM for the threshold testing without the external/ surface ECG leads. The far-field IEGM can be used to replace surface ECG leads during threshold testing. There is now an option to select between conventional surface ECG signals (I, II, or III) or leadless ECG (FF IEGM) as display options. Figure 15 shows the far-field option.

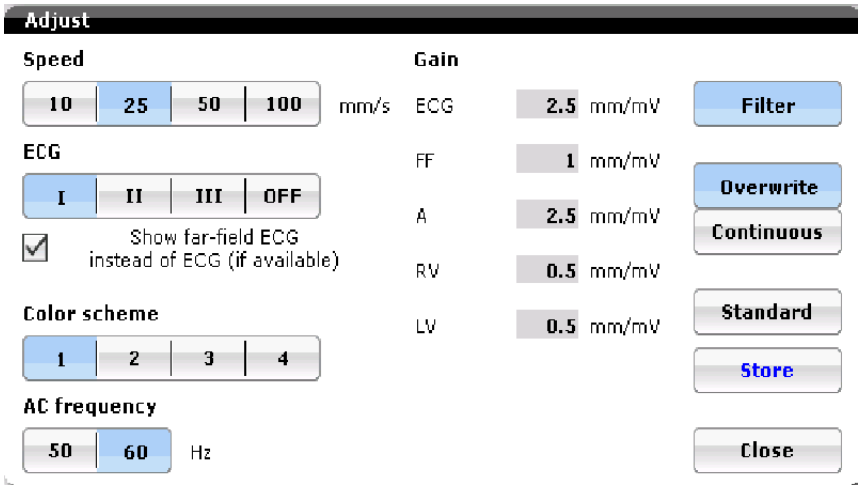

Figure 15: Far-field IEGM option screen

2.4.2 Real-time IEGM Transmission

The Rivacor ProMRI® ICDs provide real-time transmission of the intracardiac electrogram (IEGM) to the programmer. IEGMs from the atrium and ventricles can be simultaneously recorded with a bandwidth of 18 to 80 Hz in the atrium and 24 to 100 Hz in the ventricle. Depending on the device, the following channels are simultaneously recorded:

- During single-chamber (VR-T) operation, far-field and RV electrograms are available.
- During dual-chamber (DR-T) operation, far-field, RA, and RV electrograms are available.
- During triple-chamber (HF-T) operation, far-field, RA, RV, and LV electrograms are available.

A real-time IEGM can be viewed in most programmer screens when the wand is placed over the ICD or when RF Telemetry is established. The surface ECG is continuously displayed in the Overview screen, the Sensing screen, and the EP test functions module. Real-time IEGMs are available in the EP tests and sensing/impedance screens. 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 wand or RF Telemetry session, and may be displayed on the programmer screen and printed on the ECG recorder.

The IEGM can be printed to document sensing, inductions, and therapy. The printout will show the ventricular markers, one ECG channel, and the atrial and ventricular IEGMs. In the case of a VR-T or DR-T device, the IEGM will display a far-field electrogram. This far-field signal is measured from the distal shock coil to the can.

Figure 16 shows IEGM marker annotations compared to the ECG box. A pace marker is represented by a full dash. A sense marker is represented by a half-length dash, while a refractory sense marker is represented by a quarter-length dash.

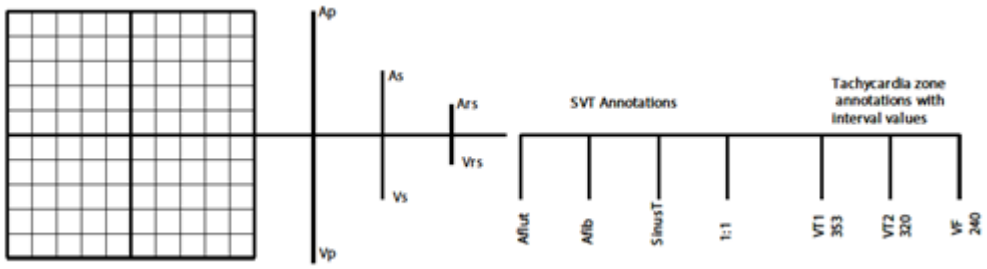

Figure 16: IEGM markers

The freeze icon located on the main screen, as seen in Figure 17, may be used to capture a snapshot of the IEGM. Electronic calipers (vertical dotted lines) will appear with the snapshot, allowing the user to measure intracardiac distances. Calipers can be adjusted by touching the vertical dotted lines on the screen (Figure 18) or by using the arrows on the right side of the screen.

Figure 17: The freeze ECG page

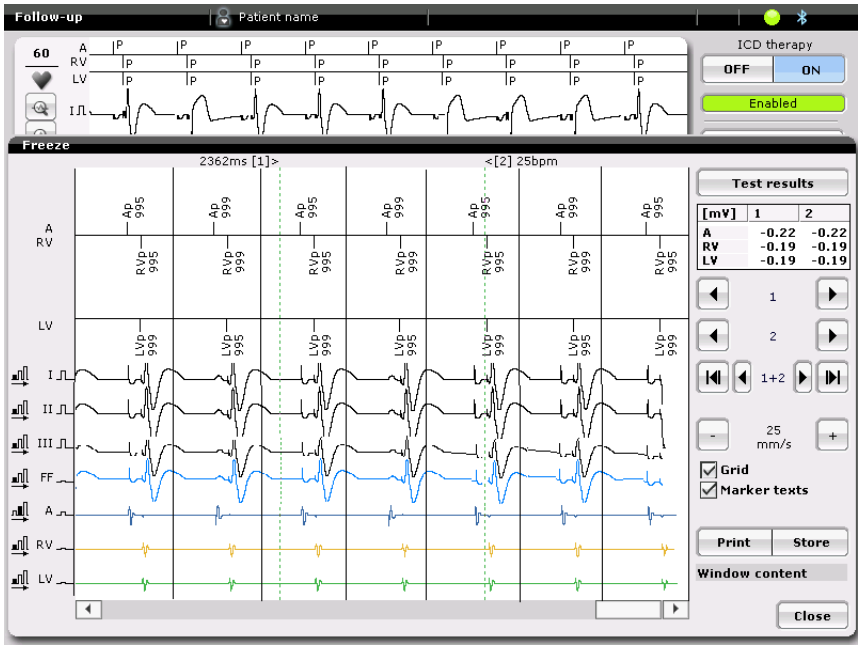

Figure 18: The freeze ECG page with one-second gridlines

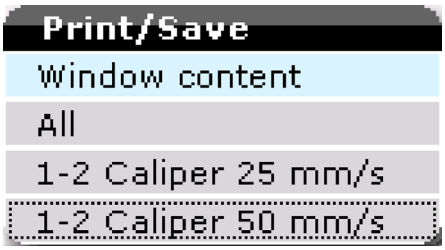

Figure 19: Window content

The programmer is capable of storing the last 60 seconds of temporary memory when the Freeze icon is selected. This information can be printed by the user. The Print/Save options are opened when pressing on "Window Content," found on the bottom-right corner of the programmer screen, as shown in Figure 19. Whichever option is selected is the portion of the information that can be printed or stored in the programmer.

There are four choices for printing and storing to the programmer:

1. Window Content – prints only what is visible on the screen.
2. All – prints all 60 seconds of information.
3. 1-2 Caliper 25 mm/s prints only the information between the electronic calipers at 25 mm per second paper speed.
4. 1-2 Caliper 50 mm/s prints only the information between the electronic calipers at 50 mm per second paper speed.

The IEGMs are printed by pressing the print button in the bottom right corner of the screen. The Store button below the Window content stores the frozen information to the programmer for later viewing. The table in the upper-right portion of the screen shows the signal amplitude that crosses the calipers. The Close button turns off the freeze and returns the programmer to standard function.

2.4.3 Additional Programmer Functions

Additional programmer functions are available to enhance follow-up and troubleshooting for devices. The heart rate is also found in the upper-left side of the screen, next to the heart icon.

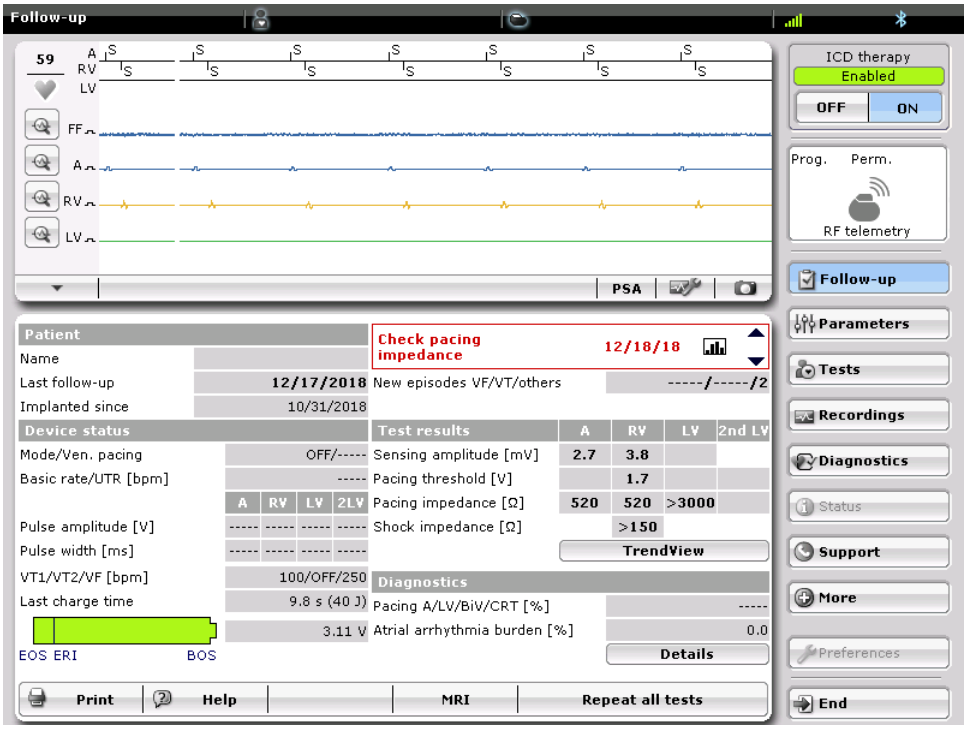

Figure 20: Main follow-up screen

Immediately to the left of the freeze icon (Figure 21) is an adjust icon. This enables a pop-up menu, allowing the user to change screen sweep speed, display color scheme, ECG display for testing, gains for the ECG and IEGMs, as well as the display mode. Any of these can be changed without rebooting the programmer.

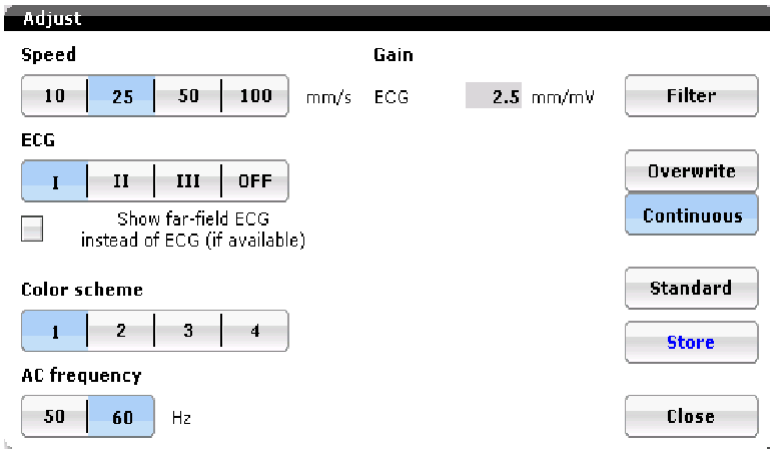

Figure 21: Adjust screen

2.4.3.1 Speed

Adjusts the sweep speed of the display.

2.4.3.2 ECG

Selects the ECG lead to be visualized during testing. A check box beneath the ECG section allows the user to use the far-field signal instead of the ECG for devices that use a far-field signal.

2.4.3.3 Color scheme

Changes the color scheme of the ECG/IEGM display to white-on-black or black-on-white.

2.4.3.4 AC Frequency

Allows the user to choose 50 Hz or 60 Hz frequency to be filtered out. 60 Hz is recommended.

2.4.3.5 Gain

Another method to adjust the size of the on-screen signal for ECGs, IEGMs, and Far-field signals.

2.4.3.6 Overwrite / Continuous

Two options are available for choosing how data crosses the screen. The Overwrite mode brings new information in from the right side of the screen. The Continuous mode brings new information in from the left side of the screen.

2.4.3.7 Standard

Resets the settings to a standard default.

2.4.3.8 Stores

Stores into memory any changes made by the user.

2.4.4 Preferences

Preferences may be stored to optimize the programmer's setup for an individual office or clinic. These programmer options can be adjusted via the Preferences button accessed under More. Preferred settings include parameters for the Fast follow-up, threshold and amplitude tests, as well as ECG, Print, and System settings.

2.4.4.1 Follow-up Preferences

The Follow-up screen, as shown in Figure 22, allows the user to select which tests are performed automatically by the programmer during a follow-up. Not all devices have the capabilities shown on this screen.

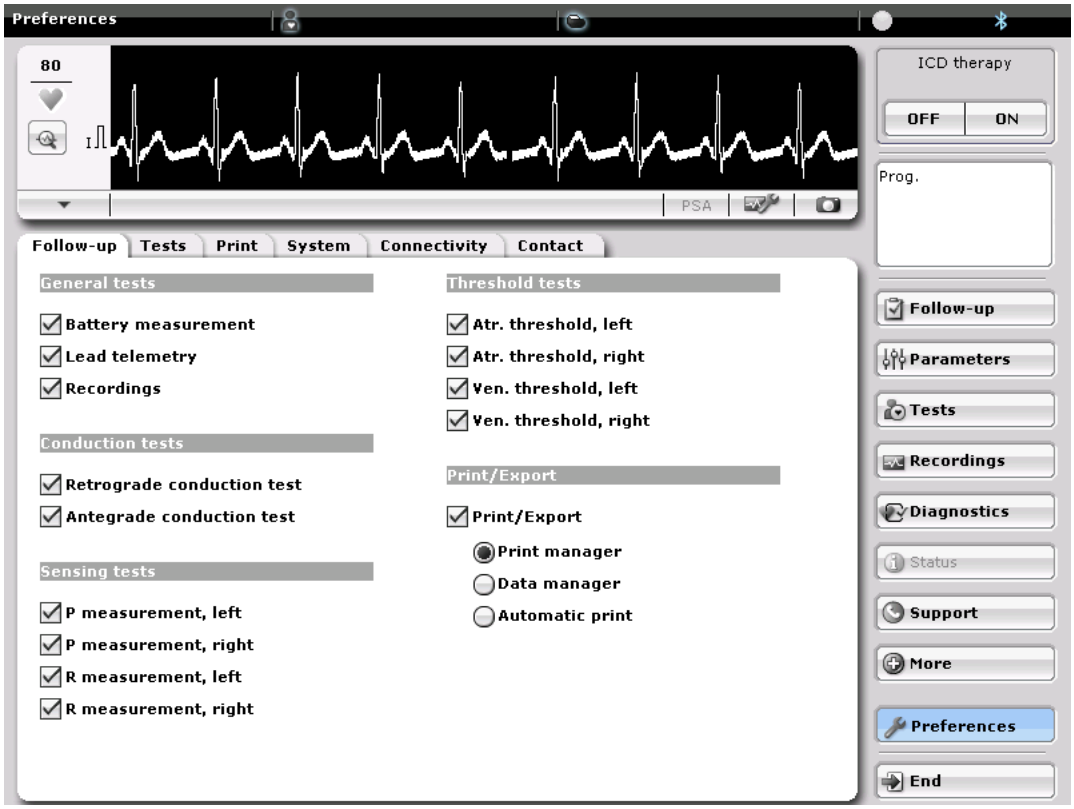

Figure 22: Follow-up preferences screen

2.4.4.2 Test Preferences

The Test Preferences screen, shown in Figure 23, allows the user to preset tests in the programmer for follow-up and testing purposes. These values will become the default value each time the programmer is turned ON. These values can be manually changed by the user at any time.

Each time the programmer is turned ON, the stored preferences that appear on this page are used for follow-up testing. The user can override the stored preference value at any time by making the desired change in the specific test screen.

Figure 23: Test preferences screen

2.4.4.3 Print Preferences

The print preference screen, shown in Figure 24, permits the user to set up four custom printing scenarios for follow-up data. Each of these can be individually labeled. Simply select the follow-up data to be printed by touching the box to place an "X" in it or by deselecting a box to prevent the data from being printed. These preference selections will be printed when the user prints data from the print manager or data manager.

Figure 24: Print preference screen

The four default name choices of A-D can be changed by the user to tailor to a specific physician or clinic preference. For example, by pressing on letters A-D under Standard, an alphanumeric keyboard appears, allowing the user to change the title name to the print package, as shown in Figure 25.

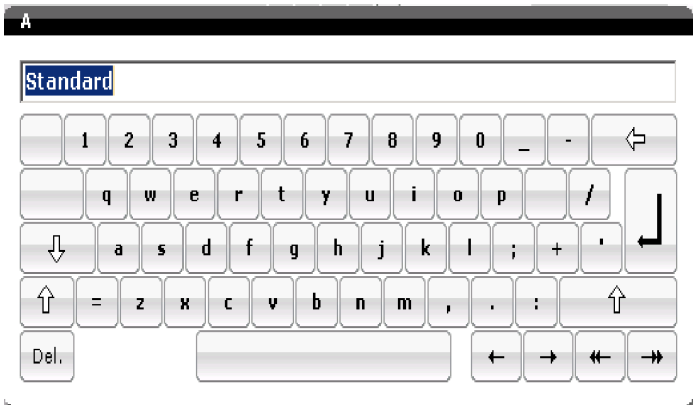

Figure 25: Alphanumeric keyboard

Below the print package names, the user can select the Standard or default print package for a follow-up (Figure 26). This can be overridden by the user at any time.

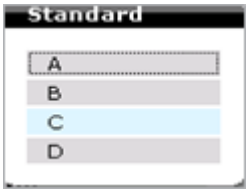

Figure 26: Print package default choices

When connecting an external printer to the programmer, press the Search for button, shown in Figure 27, to allow the programmer to locate and connect to the external printer. Connect the printer first, and then boot-up the programmer to allow the programmer to look for printer drivers during the boot-up process.

Figure 27: Printer type

2.4.4.4 System Preferences

The system preference screen, shown in Figure 28, allows the date and time of the programmer to be set. Additionally, several other basic programmer functions can be set on this screen.

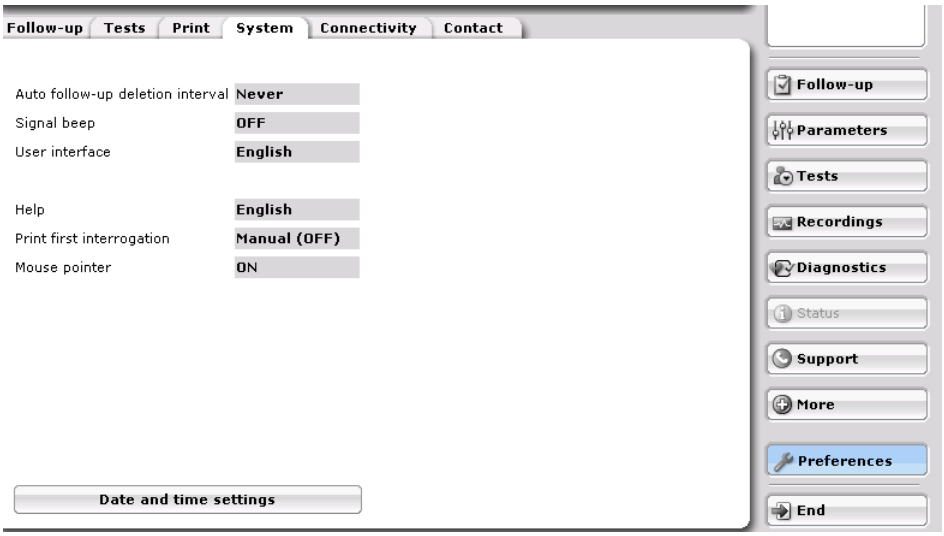

Figure 28: System preference screen

The programmer can be adjusted to daylight saving time (DST) by programming DST ON.

The time zone can be set to the local time by selecting the time zone and choosing the time zone in which the programmer is located (Figure 29). GMT stands for Greenwich Mean Time.

NOTE:

The ICS 3000 programmer displays programmer battery parameters, as well as a Start battery maintenance button.

Figure 29: Time zone

Signal beep provides an audible tone when selecting parameters or making programming changes when the signal beep feature is ON.

Print first interrogation provides an automatic option that prints the permanent parameters when the device is first interrogated. A setting of manual requires the user to press the print button if a printout is desired.

For ICS 3000 programmers only:

- Brightness refers to how bright the screen will be when the operating module is disconnected from the base. The choices are Bright, Normal and Economy. Selecting bright will use more energy and reduce the time the Operating Module can be disconnected from the base.
- Battery maintenance requires approximately four hours.

2.4.4.5 Connectivity

If Interrogation in the section "RF telemetry" is set to "ON", the programmer automatically establishes the RF telemetry with the RF-capable device after the programming wand is placed over the device.

2.4.5 Print Manager

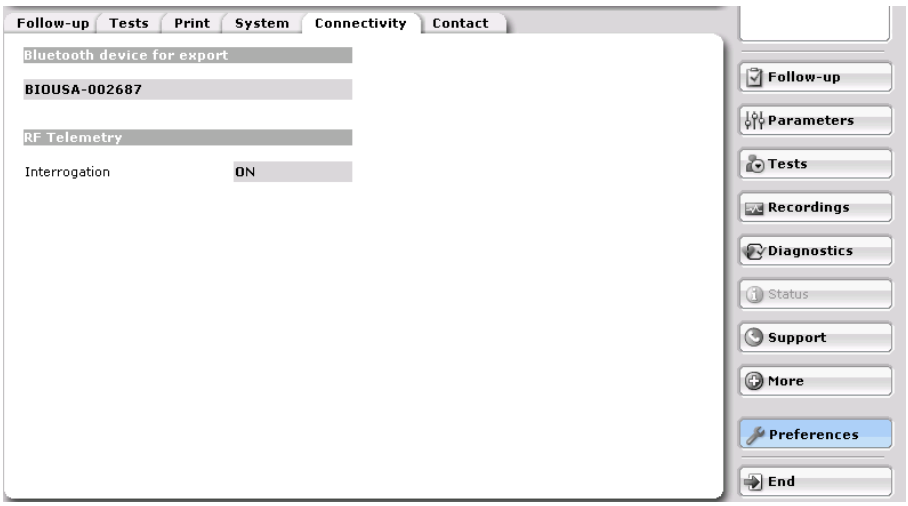

Figure 30: Connectivity screen

The programmer has a print manager, which allows for a simplified printing process. All previous follow-ups for the interrogated device are listed on the left side of the screen below the Print manager tab. The last follow-up is highlighted. The user can simply access any previous follow-up by selecting the data.

The data collected for each follow-up is shown under Follow-up data. By selecting Preview, the user can review data prior to printing. The user has the option to manually override the data to be printed, as well as to preview data prior to printing.

The user can select which data is to be printed by selecting the Preference choice. By default, these are named Standard, min, B + Statistics, and All. These can be renamed under the Preferences print screen.

Selecting the internal printer will send the printouts to the Renamic or ICS 3000 printer, while selecting external will send the report to an attached external printer. The programmer will recognize many HP DeskJet printers.

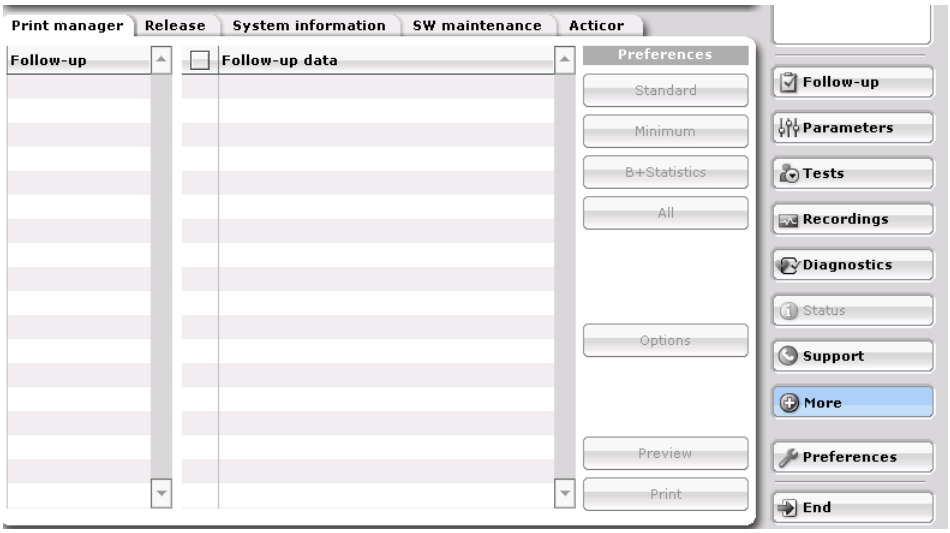

Figure 31: Print manager screen

When pressing the Preview button, shown in Figure 31, the screen shown in Figure 32 appears. The upper-left corner of the Preview screen shows arrows to allow the user to view previous follow-ups for that device stored on the programmer. Below the arrows is patient information, along with device serial number and date of the follow-up being viewed.

The data for the currently viewed follow-up is shown on the left side of the screen. The highlighted blue data is shown in the center of the screen. Simply pressing any of the follow-up data field choices will display that information.

The user can print the entire follow-up based on the print preference by pressing the print follow-up on the lower-right corner of the screen.

Print view only will print the currently viewed data on the programmer screen.

If an external printer is connected, the user can choose to print to the programmer printer or the external printer by pressing Internal or External.

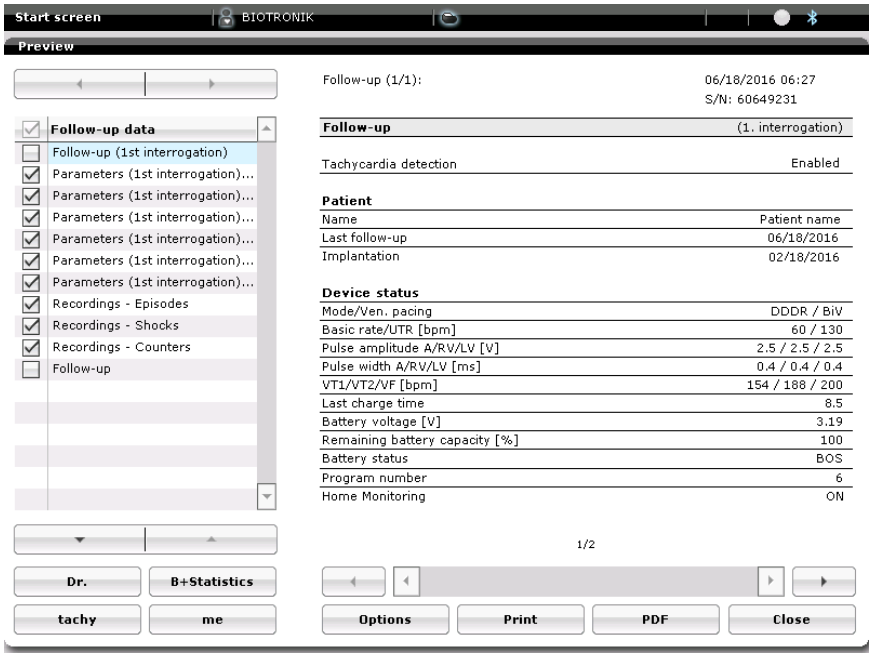

Figure 32: Preview screen

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Chapter 3: Programming Overview

3.1 General Overview

The Follow-up screen, shown in Figure 33, is the first screen displayed following interrogation of the Rivacor ProMRI® ICD/CRT-D. It is confirmed the device has been successfully interrogated by the appearance of the patient name, device name, and serial number on the right side of the Follow-up header bar located at the top of the screen. Furthermore, below the ECG/IEGM portion of the screen is an information status bar that provides information related to interrogation (i.e., "Interrogation was successful") and testing status.

The Master switch and device status are shown in the right upper portion of the screen.

The bottom of the screen reveals a Print button for printing a follow-up summary. Pressing the Last follow-up under the Patient section accesses previous follow-up information. The device can store follow-up data for 11 follow-ups. If multiple follow-up procedures are performed in a given day, only one set of follow-up data can be stored per day. The most recent value for a given test will be stored.

The Repeat all tests button repeats follow-up tests. The freeze button (camera icon) freezes 60 seconds of ECG and IEGM data that can be printed or stored into the programmer.

The programmer navigation buttons are found on the right side of the screen and are available at all times from the programming screen. These buttons include: Follow-up, Parameters, Tests (i.e., pacing and defibrillation tests), Recordings and Diagnostics. More information (pacing and defibrillation tests and additional programming options) will be detailed in this chapter.

The programmer interface includes link buttons that take the user directly to specific data or test screens. These include Episodes (if present), Sensing, Threshold, Impedance, Trends, and Details (Diagnostics). In addition, picture icons, such as those shown under the Event header, take the user directly to the data page covered by the icon.

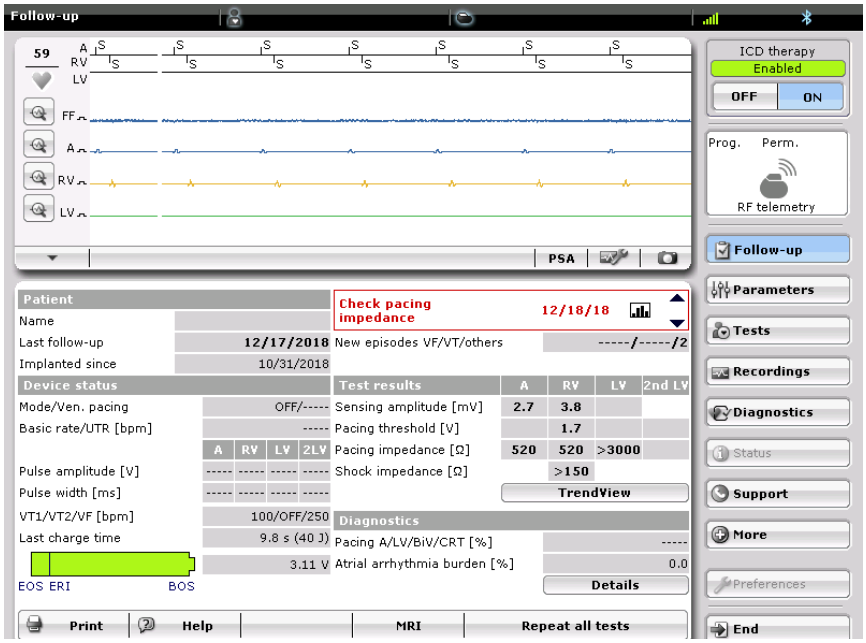

Figure 33: Main Follow-up Page

3.2 Parameters Overview

3.2.1 Bradycardia/CRT Parameters

The Bradycardia/CRT Screen allows the user to program parameters related to the bradycardia function of the device. Each of these parameters is described in this section.

Figure 34: The Bradycardia/CRT screen and Sensing Parameters

3.2.1.1 Mode

Figure 35 shows the available modes for Rivacor ProMRI® DR-T or Rivacor ProMRI® HF-T ICD. The Rivacor ProMRI® VR-T provides VVI-CLS, VVI(R), VOO and OFF mode.

The DOO/VOO mode choices require the user to turn OFF detection and therapy.

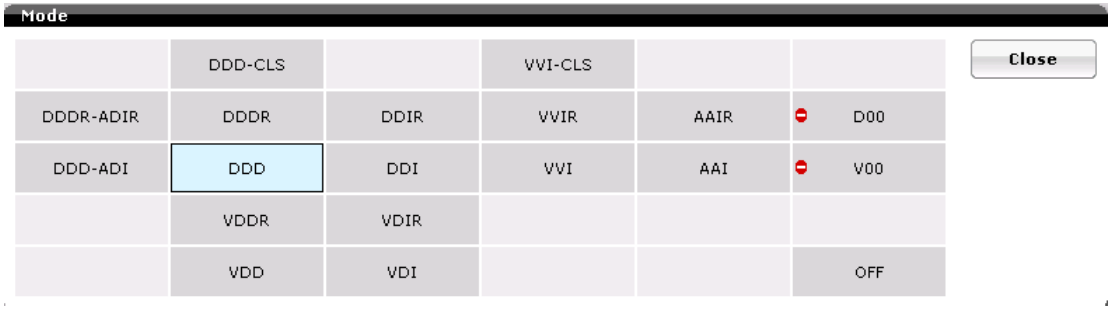

Figure 35: Pacing mode choices in dual-chamber and HF-T ICDs

3.2.1.2 Basic Rate and Night Rate

Basic Rate: 30 ... (5) ... **60** ... (5) ... 100 ... (10) ...160 bpm

Night Rate: **OFF**; 30 ... (5) ... 100 bpm

Night Begins: 22:00

Night Ends: 06:00

NOTE:

The clock only appears once a Night Rate is selected.

The basic rate and the night rates cannot be programmed less than 30 bpm. If Night Rate is programmed ON, Rate Hysteresis will not function during that time. Rate response will override the night rate and pace the heart at the sensor indicated rate if the patient becomes active during that time.

3.2.1.3 Rate Hysteresis

Rate Hysteresis: **OFF**, -5 ... (-5) ... -25, -45, -65 bpm

Scan/Repetitive Hysteresis: **ON (10 fixed)**, OFF

NOTE:

A combination of Basic Rate and Hysteresis Rate can never be less than 30 bpm. Repetitive and Scan Hysteresis values only appear when a Rate Hysteresis value is selected.

3.2.1.4 CLS *(Not applicable in Rivacor 5)*

The Rivacor ProMRI® ICD/CRT-D measures electrical impedance by injecting a small AC current between the ICD housing and the right ventricular electrode tip. The induced voltage (which is proportional to the intracardiac impedance) is also measured between the ICD housing and the right 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 Rivacor ProMRI® ICD may not be able to obtain a useable 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 modes are functionally equivalent to the DDDR and VVIR pacing modes, respectively. However, these modes use the CLS algorithm 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.

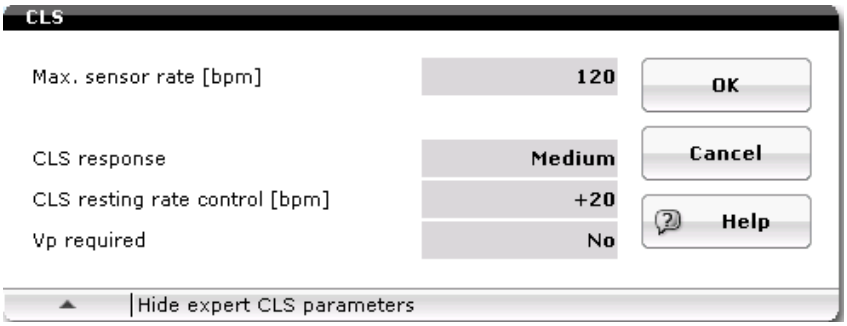

Figure 36: CLS parameter screen

3.2.1.4.1 Max Sensor Rate

80 ... (10) ... **120** ... (10) ... 160 bpm

This is the maximum atrial paced rate the device will allow when using CLS. This rate must be at least 10 beats lower than the Upper Tracking Rate.

3.2.1.4.2 CLS response

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

Used to determine the pacing distribution when CLS is programmed ON.

3.2.1.4.3 Resting Rate Control

OFF, +10 ... (+10) ... +50 bpm, default +20 bpm

Used to limit the pacing rate while the patient is at rest.

3.2.1.4.4 Vp Required

Yes, **No**

Adjusts the AV interval to update the algorithm information for paced and sensed events. This parameter may be turned to Yes if the patient has slow or no underlying intrinsic activity. Vp Required is set to Yes and is non-programmable in CRT-Ds with BiV pacing enabled.

3.2.1.5 Max sensor rate

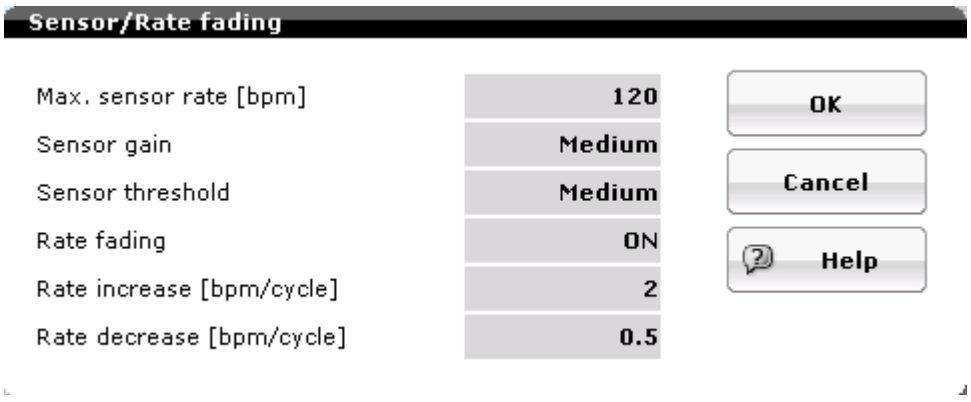

Figure 37: Max sensor rate screen

3.2.1.5.1 Max Sensor Rate

80 ... (10) ... **120** ... (10) ... 160 bpm

This is the maximum atrial paced rate the device will allow when using the accelerometer of the device. This rate must be at least 10 beats lower than the Upper Tracking Rate.

3.2.1.5.2 Sensor Gain

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

This refers to the rate of increase and decrease. Very high provides a more aggressive change in heart rate in response to demand; while Very low provides a less aggressive response.

AUTO is designed to tailor the sensor gain to a patient's activity level by making automatic changes based on patient activity level. This feature should not be used in the case of low-activity-level patients, as the sensor gain can change over time and become too aggressive.

Sensor gain will increase in value (more response) if the patient has not reached 90% or more of their max sensor rate for 60 minutes in a seven-day period. Conversely, the device decreases the value (less response) if the patient has reached 90% or more of their max sensor rate for 30 minutes in a 24-hour period.

3.2.1.5.3 Sensor Threshold

Very Low, Low, **Medium**, High, Very High

This feature determines how sensitive to motion the accelerometer is to determine rate. This should only be changed when a patient's heart rate does not respond to changes in the Sensor Gain.

3.2.1.5.4 Rate Fading

ON, OFF

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 Fading Rate and then decreases gradually by the programmable Rate Decrease to the Sensor Indicated Rate or Basic Rate.

3.2.1.5.5 Rate Increase

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

The speed of rate increase with sensor activity.

If the Rate Increase is set at the default of 2 bpm, the heart rate increases 2 bpm every new cycle until the sensor pacing rate is met. If the current rate is 60 bpm and the sensor indicated rate is 100 bpm, it would take 20 cycles to achieve a rate of 100 bpm (100 – 60 = 40/2 bpm/cycle = 20 cycles).

3.2.1.5.6 Rate Decrease

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

The speed of rate decrease as the sensor rate decreases.

If the Rate Decrease is set at the default of 0.5 bpm, the heart rate decreases 0.5 bpm every new event until the sensor pacing rate is met. If the current rate is 100 bpm and the sensor indicated rate is 60 bpm, it would take 80 cycles (events) to achieve a rate of 60 bpm (100 – 60 = 40/0.5 bpm/cycle = 80 cycles).

3.2.1.6 Upper Tracking Rate

90 ... (10) ... **130** ... (10) ... 170 bpm Wenckebach Response

The Wenckebach response zone is the distribution of rates between the Upper Tracking Rate and the calculated 2:1 response rate. The resulting behavior is a prolongation of the AV interval until

a P-wave is not tracked. The occurrence of Wenckebach is dependent on atrial rate and device programming. When the atrial interval decreases to less than the combined AV Delay/PVARP intervals, a 2:1 response occurs.

The 2:1 response is determined by the following formula:

60,000 ms divided by the ((AV Delay plus PVARP) minus Sense Compensation) For example:

AV Delay – 200 ms PVARP – 250 ms

Sense Compensation -30 ms

60,000 ms divided by ((200 ms+ 250 ms) – 30 ms) = 143 bpm

143 bpm is the maximum Wenckebach limit. Once the atrial rate goes faster than 143 bpm, the device will go to a 2:1 response.

NOTE:

The Upper Tracking Rate can be programmed into a tachycardia zone for the Rivacor ProMRI® DR-T ICD. However, for the Rivacor ProMRI® HF-T ICD, the Upper Tracking Rate cannot be programmed into a tachycardia zone if the maximum trigger rate is greater than the VT2 zone rate.

NOTE:

The Wenckebach window and 2:1 block rate can be affected if LV pace first is chosen. NOTE that PVARP is started with the RV paced event. This applies only to HF-T devices.

3.2.1.7 Mode Switching

Figure 38 shows the Mode Switch screen. Each of the screen parameters will be discussed.

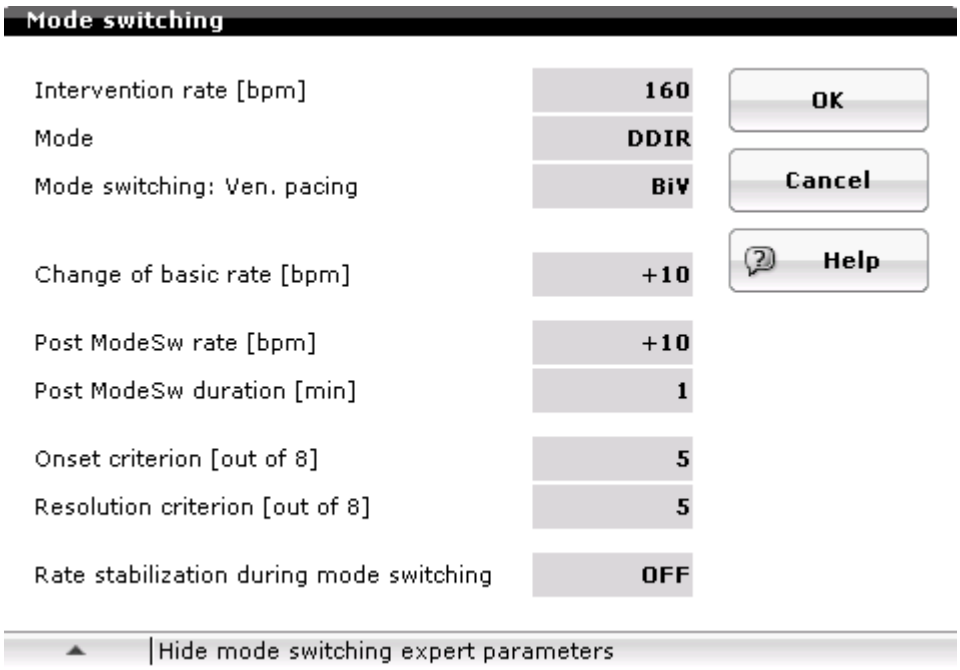

Figure 38: Mode Switch Screen

3.2.1.7.1 Intervention Rate

OFF, 120 ... (10) ... **160** ... (10) ... 200 bpm

The Intervention Rate is the atrial rate above which intervals will count toward Mode Switch. The nominal value is 160 bpm.

3.2.1.7.2 Mode

DDIR, DDI

The Mode that the device Mode Switches to when programmed DDD(R). If the device is programmed VDD(R), the device will Mode Switch to VDI(R).

3.2.1.7.3 Mode switch: Ventricular pacing (Rivacor HF-T only)

BiV, RV

Allows the user to choose between BiV and RV pacing during a Mode Switch episode. See Section 3.2.1.9 for more detailed information regarding the additional parameters found in this section.

3.2.1.7.4 Change of Basic Rate

OFF, +5 ... (+5) ... **+10** ... (+5) ... +30 bpm

The change of basic rate value is the amount added to the Basic Rate when Mode Switching occurs. For example, if the device is programmed to 60 bpm and the Change of Basic Rate is +10, the Mode Switch Rate will be 70 bpm while Mode Switch is present. This is designed to increase the cardiac output by providing higher pacing rates and reducing patient symptoms during Mode Switch. Once the Mode Switch is terminated, the rate will decrease back to the basic rate or the post mode switch response rate using Sensor rate decrease criteria.

3.2.1.7.5 Post Mode Switch Response

OFF, +5 ... (+5) ... **+10** ... (+5) ... +50 bpm

This feature is designed to suppress recurrence of atrial arrhythmias immediately after Mode Switching by increasing the pacing rate for a limited (programmable) time.

3.2.1.7.6 Post Mode Switch Duration

1 ... (1) ... 30 minutes

The duration of the Post Mode Switch Response rate change. Once the Post Mode Switch rate expires, the device will decrease the rate to the basic rate using the Sensor decay rate.

3.2.1.7.7 Onset Criterion

3, 4, **5**, 6, 7 or 8

The number of events out of a sliding window of eight that must exceed the Intervention Rate in order for the device to Mode Switch.

3.2.1.7.8 Resolution Criterion

3, 4, **5**, 6, 7 or 8

The number of events out of a sliding window of eight that must be below the Intervention Rate for the device to revert to permanently programmed pacing.

3.2.1.7.9 Rate Stabilization

OFF or ON

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, Rivacor ProMRI® ICDs 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.

3.2.1.8 Ventricular Pace Suppression (Vp Suppression)

Vp-Suppression is a feature available in DDD(R)-ADI(R) modes 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.

3.2.1.8.1 Pacing Suppression

1, 2, 3, 4, 5, **6**, 7 or 8

The number of consecutive ventricular sensed events needed during the Continuity test for the device to change to the Vp Suppression mode

3.2.1.8.2 Pacing Support

1, 2, **3**, 4 out of 8 cycles

The number of paced ventricular events out of the last eight cycles for the device to turn off the Vp Suppression feature

3.2.1.9 Ventricular Pacing (CRT-D devices only)

There are seven for HF-T and 10 for HF-T QP sub-parameters found under this menu.

1. Ventricular Pacing – **BiV** or RV
2. CRT AutoAdapt - **OFF**, AVadapt, ON
3. Triggering – OFF, **RVs**, RVs + PVC
   When triggering is programmed ON, the device will trigger a BiV paced event when an RV sensed event occurs. RVs is a sensed RV event following an AV Delay. PVC is an extrasystolic event that can trigger a BiV pace as long as it does not violate a tachycardia zone or the programmed maximum trigger rate.
4. LV T-wave protection – **ON** or OFF – When programmed ON, inhibits LV pacing in the presence of a sensed LV event within the max trigger rate period. When the feature is turned OFF, the device will not sense intrinsic LV events or withhold pacing. Additionally, no LV sense diagnostic data are collected.
5. Maximum Trigger Rate – **UTR + 20**, 90 ... (10) ... 160 bpm The user can select a max trigger rate for BiV pacing.
6. Initially paced chamber – **LV** or RV
7. VV delay after Vp - **0** ... (5) ... 100 ms

For HF-T QP devices, additional parameters are available:

8. MultiPole pacing
9. Pacing Sequence
10. LV-2nd LV delay [ms] - **0**...[5]...100ms

NOTES:

Max Trigger rate cannot be programmed into a VT/VF zone. A conflict message will appear informing the user of the conflict.

VV delay is fixed to 0 ms if CLS is programmed ON.

Trigger pacing for PVCs is not available when CLS is programmed ON.

3.2.1.9.1 CRT AutoAdapt *(Not applicable in Rivacor 5)*

OFF, ON, AV Adapt

The CRT AutoAdapt algorithm continuously and dynamically adapts CRT pacing method and AV

delays. By promoting intrinsic RV conduction, CRT AutoAdapt reduced RV pacing and increases device longevity for patients with normal AV conduction. For more information see Section 7.9.8.

3.2.1.10 AV Delay

The Rivacor ProMRI® ICD/CRT-D devices provide three preset values for AV Delay; Low, Medium and High. In addition, the user can program a fixed AV Delay, as well as a user-defined program Individual. Unlike previous generations that used rate bins to determine AV Delay, Rivacor ProMRI® ICDs allow the user to select a Lower Rate AV Delay, as well as an Upper Rate AV Delay, to calculate an AV Delay in a linear fashion. The device automatically calculates what the AV Delay value is for a given heart rate. In Rivacor ProMRI® HF-T devices, the AV Delay is calculated based on which chamber is paced first.

3.2.1.10.1 AV Delay Settings

Dynamic AV Delay Default (ms) for Rivacor ProMRI®

Dynamic AV Delay Default (ms) for Rivacor ProMRI® HF-T			
Rate	Low	Medium	High
60 bpm – Lower Rate	150	140	130
130 bpm – Upper Rate	120	100	80
Dynamic AV Delay Default (ms) for Rivacor ProMRI® DR-T			
Rate	Low	Medium	High
60 bpm – Lower Rate	180	180	180
130 bpm – Upper Rate	140	100	80

Table 2: Dynamic AV Delay Default (ms) for Rivacor ProMRI®

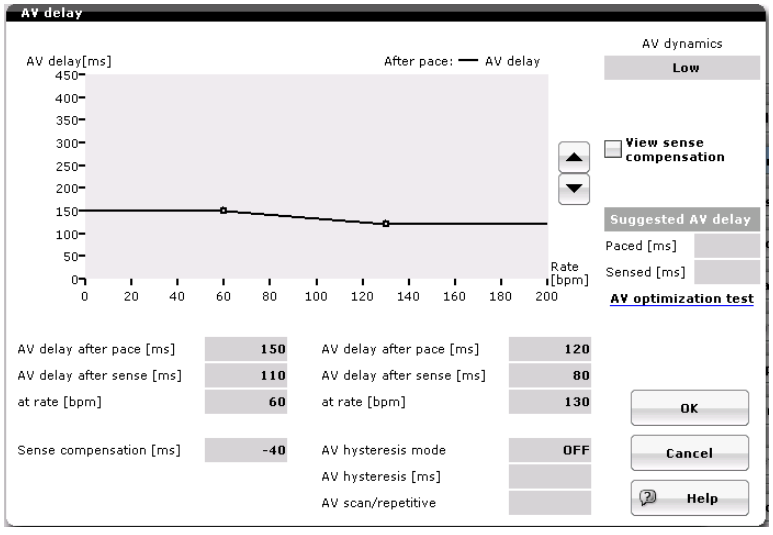

Figure 39: AV Delay screen

3.2.1.10.2 Sense Compensation

OFF, -5 ... (-5) ... **-40** ... (-5)... -120 ms

This feature is designed to help ensure that the physiologic AV delay intervals (atrial filling times) are the same from Ap to Vp as it is from As to Vp.

NOTE:

Conflicts occur if the AV Delay minus Sense Compensation is less than 40 ms.

3.2.1.10.3 Safety Window

Fixed at 100 ms

This parameter refers to the safety pace window, ensuring that non-physiologic events do not inhibit ventricular pacing. This is especially important in pacemaker-dependent patients.

Safety pacing requires an atrial paced event to occur and does not occur following an atrial sense event.

AV Hysteresis Mode

OFF, Positive, Negative, I-Opt (Rivacor ProMRI® DR-T ICDs)

Positive:	AV Hysteresis – 70, 110, 150, 200 ms
	AV Scan/Repetitive - OFF, ON (5)
Negative:	AV Hysteresis – 10 ... (10) ... 50...(10)...150 ms AV Repetitive – 180 (fixed)
I-Opt	AV Hysteresis – 400 ms
	AV Scan/Repetitive - ON (5)

The Positive Hysteresis mode is designed to promote intrinsic activity by periodically extending the AV interval looking for intrinsic activity. If intrinsic activity is present, the AV Delay maintains the extended value to allow intrinsic R-waves to occur.

Negative Hysteresis is designed to promote ventricular pacing in the presence of hypertrophic cardiomyopathy (HCM) by shortening the AV Delay when a sensed R-wave occurs. This feature can also be used in CRT patients to maximize AV Delays to promote better filling times (longer AV Delays) while maintaining pacing.

When Negative hysteresis is programmed ON, the device shortens the AV Delay by the programmed negative hysteresis value for 180 cycles. After 180 cycles, the AV Delay will revert to the programmed value.

I-Opt is a one-button feature designed to promote intrinsic activity by periodically extending the AV interval to 400 ms looking for intrinsic activity. If intrinsic activity is present, the AV Delay maintains the extended value to allow intrinsic R-waves to occur. This feature is available in the Rivacor ProMRI® DR-T ICDs.

3.2.1.11 Pulse Amplitude and Width

Pulse Amplitude

0.5 ... (0.25) ... **3.5** ... (0.25) ... 4.0 ... (0.5) ... 6.0, 7.5 V for all chambers Pulse Width

0.4, 0.5, 0.75, 1.0, 1.25, 1.5 ms for all chambers. 0.4 ms is required for ATM/VCC.

3.2.1.12 Atrial Capture Control (ACC)

Capture control; OFF, ATM, **ON**

Threshold test start: 2.5 ... (0.5) ... **3.5** ... (0.5) ... 5.0 V

Minimum Amplitude: 0.5, 0.75, **1.0** ... (0.25) ... 4.0 V

Safety margin; 0.5, **1.0** or 1.2 V

Active Threshold Monitoring (ATM) tracks the pacing threshold without reprogramming the pacing output.

3.2.1.13 Right/Left Ventricular Capture Control (VCC)

Capture control; OFF, ATM, **ON**

Threshold test start: 2.5 ... (0.5) ... **3.5** ... (0.5) ... 5.0 V

Minimum Amplitude: **1.0** ... (0.25) ... 4.0 V

Safety margin: **1.0** or 1.2 V (0.5V available in LV Capture Control)

3.2.1.14 Sensing

Chamber	Right Atrium	Right Ventricle	Left Ventricle*
	Standard (Std.)	Standard (Std.)	Standard (Std.)
Sensing parameter options	OFF (Inactive)	Enhanced T-wave Suppression (TWS)†	OFF (Inactive)
		Enhanced VF Sensitivity (VFS)†	
Minimum threshold	0.2 ... (0.1)... **0.4** ... (0.1) ... 2.0 mV	0.5 ... (0.1) ... **0.8** ... (0.1) ... 2.5 mV	0.5 ... (0.1) ... **1.6** ... (0.1) ... 2.5 ... (0.5) ... 5.0 mV

The Standard sensitivity settings are ideal for most patients. However, when special sensing issues arise, the right-ventricular sensitivity may be programmed to Enhanced VF Sensitivity or Enhanced T-wave Suppression. The Minimum threshold in the atrium may be adjusted between 0.2 mV and 2.0 mV, while the Minimum threshold in the right ventricle may be adjusted between 0.5 mV and 2.5 mV, and up to 5.0 mV in the left ventricle.

Turning the Right Atrial channel to OFF (inactive) disables all atrial related features. In essence, the device will function as a VVI(R) device.

Turning the Left Ventricular channel OFF (inactive) results in the loss of LV sensing and LV statistical information.

Any changes made in the default sensing parameters will result in the term "Ind." (individual) appearing for the chamber in which the changes were made.

NOTE:

Enhanced VF Sensitivity and Enhanced T-wave Suppression are available only for the right ventricle. In Heart Failure (HF) devices, the left ventricular options are Standard or OFF.

* Applies to CRT-D devices only

† These choices are preset programs and will override previous sensing parameter changes

3.2.1.15 Refractory period / Blanking

3.2.1.15.1 PVARP

Auto, 175 ... (25) ... **225** ... (25) ... 600 ms

PVARP is used to prevent pacemaker-mediated tachycardia by not allowing retrograde atrial events to be tracked by the device. Retrograde conduction should be confirmed before making any programming changes. Generally, PVARP should be 15-20 ms longer than the measured retrograde conduction time. Caution should be used when programming an extended PVARP to ensure appropriate tracking of antegrade atrial events.

NOTE:

Programming long PVARP values in combination with long AV Delays will result in reduced 1:1 tracking by the device.

3.2.1.15.2 Auto

When Auto PVARP is programmed, the PVARP is programmed to 175 ms and the PVARP after PVC is set to 325 ms.

Auto is an option that will automatically adjust the PVARP value when a PMT occurs. Following a PMT, the device will extend PVARP by 50 ms.

3.2.1.15.3 PVARP Extension

PVARP extension allows the user to turn OFF PVARP following Vp and PVC events. This may be useful to prevent misclassification of intrinsic atrial events that occur closely after a Vp or PVC event.

3.2.1.15.4 PVARP after PVC

PVARP after PVC is a nonprogrammable parameter that is used to prevent PMT following PVC events by adding a fixed value of 150 ms to the programmed PVARP for that PVC event. The maximum value is 600 ms. By default, this value is 375 ms.

3.2.1.16 Far-field Protection After Vs

OFF, **AUTO** 25 ... (25) ... 225 ms

Provides an atrial blanking period after a Vs event to prevent oversensing in the atrial channel. If set to AUTO, the interval shall be shortened to 25 ms from 75 ms after two consecutive sense events in a VT or VF zone. The interval will return to 75 ms upon termination or short termination.

3.2.1.17 Far-field Protection After Vp

50 ... (25) ... **75** ... (25) ... 225 ms

Provides an atrial blanking period after a Vp event to prevent oversensing in the atrial channel.

3.2.1.18 PMT Protection

ON, OFF

This algorithm is designed to break a PMT by extending a refractory period and detects PMT by changing the AV Delay after the device has sensed eight consecutive events in which the Ventricular pace to Atrial sense interval is less than the VA Criterion value. The algorithm requires the following criteria to initiate:

- Rate greater than 100 bpm with Vp
- VA Criterion met
- Stability criteria of 25 ms met

3.2.1.18.1 VA Criterion

250 ... (10) ... **350** ... (10) ... 500 ms

The Vp to As interval that the atrial event must be within in order for the PMT algorithm to initiate, along with the rate and stability criteria.

3.2.2 Tachycardia

3.2.2.1 Atrial Detection

100 ... (10) ... **200** ... (10) ... 250 bpm

This parameter allows the user to define a minimal atrial rate to record an atrial arrhythmia IEGM. In order for an atrial IEGM to be recorded, the device needs to detect 36 out of 48 of the most recent atrial events greater than the programmed value. Recording is terminated when 20 out of 24 events are less than the programmed value. This parameter is located on the Tachycardia page of the programmer screen.

3.2.2.2 Ventricular Detection

Ventricular detection, redetection, and termination parameters are set up in the Detection screen of the device. This screen is accessed by selecting any of the detection zone input fields that are located immediately to the right of the zone field. The rate limits defining each tachyarrhythmia zone are programmed on the Overview screen or the individual zone screens. VT zones not used are programmed to OFF. The Detection Counters, Redetection Counters, detection enhancements (i.e., SMART Detection®, Onset and Stability) and Sustained VT timers are located in the Detection screen.

Figure 40 shows an example of the basic Detection screen. In this case, three tachyarrhythmia zones are programmed. A VT1 zone is programmed typically for ventricular rates between 133 and 154 bpm, a VT2 zone is typically programmed for ventricular rates between 154 bpm and 200 bpm, and a VF zone is typically programmed for rates equal to or greater than 200 bpm. In addition, SMART Detection® defaults ON for DX, dual chamber and CRT-D devices with Onset and Stability of 20% and 12%, respectively. When SMART Detection® is OFF in both VT zones, the Sustained VT timer is active with a default setting of OFF.

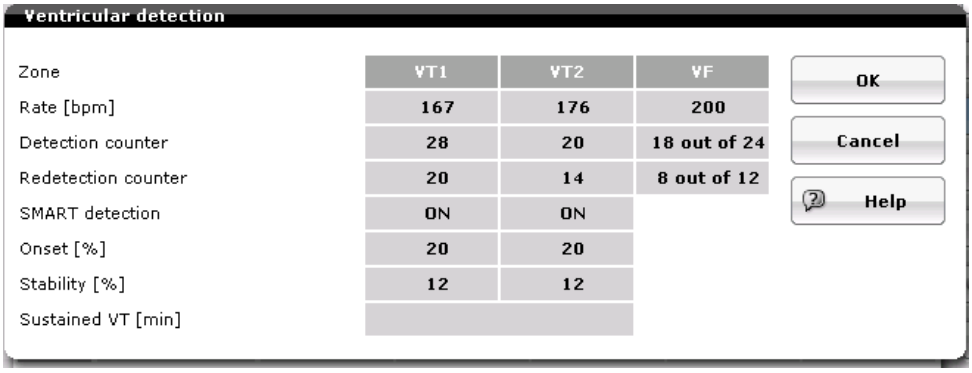

Figure 40: Ventricular detection screen

3.2.2.2.1 Detection Rate

VT1: **OFF**, 100 – 222 bpm or 270 – 600 ms

VT2: **OFF**, 120 – 222 bpm or 270 – 500 ms

VF: 150 – 250 bpm or 240 – 400 ms; Default **200 bpm (300 ms)**

VT1 is the lowest zone for programming; therefore, when programming multiple zones, the rate must be lower than the VT2 zone or VF zone.

NOTE:

When programming a VT zone, a VF zone must be programmed ON.

3.2.2.2.2 Detection Counter

VT1: 10 ... (2) ... **28** ... (2) ... 100

VT2: 10 ... (2) ... **20** ... (2) ... 80

Initial VF: 6 out of 8, 8 out of 12, 10 out of 14, 12 out of 16, 16 out of 20, **18 out of 24**, 20 out of 26, 22 out of 30, 24 out of 30, 30 out of 40

This parameter determines the minimal number of VT events for each zone that must be counted to initiate VT/VF detection and therapy delivery. The VT counters use an up/down counter for criteria. The VF counter uses an X out of Y counter.

3.2.2.2.3 Redetection Counter

VT1: 10 ... (2) ... **20** ... (2) ... 50

VT2: 10 ... (2) ... **14** ... (2) ... 40

VF: 6 out of 8, **8 out of 12**, 10 out of 14, 12 out of 16, 16 out of 20, **18 out of 24**, 20 out of 26, 22 out of 30, 24 out of 30

This parameter determines the minimal number of VT events for each zone that must be counted to redetect VT/VF and prompt therapy delivery. The Redetection Counter value for a VT1 zone must be greater than the redetection counter of the VT2 zone.

3.2.2.2.4 SMART Detection®

ON, OFF

This feature can be programmed on in the VT1 zone and/or the VT2 zone. This feature is discussed in detail in Section 3.4. When SMART Detection® is ON, SMART® Redetection is automatically ON, as well.

3.2.2.2.5 Onset

SMART Detection® ON – 4 ... (4) ... **20** ... (4) ... 32%

SMART Detection® OFF – OFF, 4 ... (4) ... **20** ... (4) ... 32% The Onset value applies to both VT zones.

3.2.2.2.6 Stability

8 ... (4) ... **12** ... (4) ... 48% - with SMART Detection®

8 ... (4) ... **12** ... (4) ... 48% or

8 ... (4) ... **48** ms when SMART Detection® is OFF

The Stability value applies to both VT zones, as well as detection and redetection.

3.2.2.2.7 MorphMatch

OFF, ON or Monitoring

Uses morphology to differentiate SVT from VT. SMART Detection® must be turned OFF if programmed to ON or Monitoring.

MorphMatch compares the morphology of sinus events against those events seen in a tachycardia zone to differentiate SVT from VT.

MorphMatch threshold Low, Standard, High

When MorphMatch is programmed to Monitoring or ON, the MorphMatch threshold allows the user to program the VT sensitivity. A Low setting would make sensitive to VT detection, while a high setting would make the device more specific to VT detection.

MorphMatch is not available in CRT-D devices unless SMART Detection® and CRT pacing are OFF.

3.2.2.2.8 Sustained VT

OFF, 1, 2, 3, 5, 20 or 30 minutes

This parameter is the override parameter for SVT detection. If a patient is in an SVT for a period of time, the device will verify the arrhythmia (by rate alone) and deliver therapy after a programmed period of time. This is viewed as a safety net for single-chamber devices that may have difficulty in distinguishing VT from SVT (i.e., Afib with rapid conduction vs. VT).

3.2.2.2.9 Forced Termination Timer

Fixed at 1 minute

This parameter terminates an SVT episode following VT therapy after one minute. It will reset all therapy and start a new episode. If the patient is in an SVT when the Forced Termination timer expires, a new SVT episode will begin. This parameter is hidden.

3.2.2.2.10 Programming the VT1 detection lower than the UTR

The Rivacor ProMRI® ICDs allow programming of the Upper Tracking Rate (UTR) into the VT1 zone. The exception is in Rivacor ProMRI® HF-T amd HF-T QP devices that do not allow programming of BiV triggered events higher than a programmed Tachycardia zone. This function is particularly helpful for patients who experience slow, sustained, symptomatic VT (100 bpm – 120 bpm), have active lifestyles in which their sinus rate goes above this rate range, and require a higher UTR. With this programming, more athletic patients have the freedom to exercise at higher heart rates with the continued protection of arrhythmia detection provided by SMART Detection®.

NOTE:

Keep in mind the following important information regarding programming: ATP initiated during sinus rhythm can have, in vulnerable patients, a pro-arrhythmic effect and induce a faster VT or VF.

3.2.2.3 Atrial Therapy *(Not applicable in Rivacor 5)*

The Rivacor ProMRI® ICDs allow programming of atrial ATP or HF burst for termination of atrial arrhythmias. Back-up pacing support is programmable.

Figure 41: Atrial therapy screen

3.2.2.3.1 Atrial ATP

Burst, Ramp

The device allows for a single ATP delivery or burst or ramp ATP. Back-up pacing is available.

3.2.2.3.2 Atrial HF Burst

OFF, HF Burst

Burst frequency and duration are programmable. Back-up pacing is available.

3.2.2.3.3 Back-up stimulation (pacing support)

OFF, 70 or 90 bpm

Provides VVI back-up pacing for Atrial ATP and VOO back-up for HF Burst.

3.2.2.4 Ventricular Therapy

The VT1, VT2, and VF therapies are programmed in separate screens. In each VT zone, two ATP sequences and one shock sequence can be programmed. The therapy is delivered sequentially from ATP1 to ATP2 in VT1 and VT2. Programmed shock therapy follows ATP in each VT zone. In the VT and VF zones, six to eight shocks may be programmed. The first and second shock energies are programmable; the remaining shocks are at maximum shock energy. Figure 42 shows an example of a VT therapy screen.

Figure 42: VT therapy screen

3.2.2.4.1 Ventricular ATP

Burst, Ramp

The device allows for two ATP scheme for each zone. There is no hierarchy for ATP programming, allowing the user to program any combination of ATP therapy

3.2.2.4.2 Ventricular Pacing (HF-T devices only)

RV, BiV

BiV pacing for ATP may be a better option for therapy if the VT origin is left-sided.

3.2.2.4.3 Number S1

1 ... (1) ... **5** ... (1) ... 15

This sets the number of stimuli delivered for each ATP attempt.

3.2.2.4.4 Add S1

ON, OFF

This parameter adds an additional paced ATP event for each new therapy delivery.

3.2.2.4.5 R-S1 Interval

70 ... (5) ... **80**, 88, 90, 95%; (88% default for ATP One-Shot)

Applies to all ATP schemes. This sets the paced interval based on the last interval average.

3.2.2.4.6 S1 Decrement

5 ... (5) ... **10** ... (5) ... 40 ms

Used when Ramp ATP is programmed. This parameter sets the amount of decrement between pacing pulses during therapy delivery.

3.2.2.4.7 Scan Decrement

OFF, 5 ... (5) ... 40 ms

This parameter sets the amount of S1 decrement between therapy attempts.

3.2.2.4.8 Minimum Interval

200 ms for all zones, including ATP One-Shot

The minimal pacing interval the device will allow for ATP therapy delivery. This limit prevents the device from pacing too fast and initiating VF. Applies to all programmed schemes within a zone. This parameter is hidden and non-programmable.

3.2.2.4.9 ATP Optimization

ON, **OFF**

Applies to all programmed schemes within a zone. Counts the number of successes of each programmed attempt and then delivers ATP based on the most successful ATP first, then in descending order of success. If ATP attempts have the same number of successes, they will be delivered in order of programming. ATP attempts that accelerate a rhythm will be blocked until the the next in-office follow-up.

NOTE:

ATP therapy parameter reprogramming will clear the ATP Optimization memory.

3.2.2.4.10 ATP Help

Displays the programmed ATP schemes as programmed. The VT interval can be changed to show what the ATP scheme will be, based on a specific interval. This screen cannot be printed.

3.2.2.4.11 Shock Therapy

OFF, 1, 2, 6, **8** shocks per VT zone 6 or 8 shocks for the VF zone

The first two shocks for each zone are programmable. The remaining shocks are at maximum output. ATP therapy should always be followed by shock therapy if ATP therapy is ineffective.

3.2.2.4.12 Confirmation

ON, OFF

Programmable by zone if the check box "Configure zones separately" is selected. Otherwise, confirmation in the VT zones will be the same as the VF zone.

When programmed ON, the first shock in uncommitted. If shock therapy is delivered, the next shock is uncommitted. If shock therapy is aborted, the next shock is committed. Shown below are different scenarios of confirmation.

Shock #	1	2	3	4	5	6	7	8
Confirmation programming	U	U	U	U	U	U	U	U
First shock D	D	U	U	U	U	U	U	U
First shock A	A	C	U	U	U	U	U	U
Third shock A	D	D	A/D	U	U	U	U	U
Fifth shock A	D	D	D	D	A/D	U	U	U

A = Aborted
C = Committed D - Delivered
U = Uncommitted
A/D = Aborted/Delivered. When a shock is aborted, the delivered shock is the same count in the sequence. For example, if the third shock is aborted, the next shock delivered in the episode will be the third in the sequence, rather than skipping to the next shock in the sequence.

NOTE:

The device can never abort two shock deliveries in a row, other than induction testing. Wand application or RF telemetry with an induction suspends the rule of aborting two consecutive shocks.

3.2.2.4.13 Polarity

Normal, Reversed, Normal Alternating, Reversed Alternating Applies to all shocks in a zone and can be different between zones.

3.2.2.4.14 Waveform

Biphasic, Biphasic 2, Biphasic Alternating, Biphasic 2 Alternating

Applies to all shocks within a zone and may be programmed differently for each zone.

3.2.2.4.15 Shock Path

RV to proximal Coil/Can, RV to Can, RV to proximal Coil

This allows the user to program multiple pathways for patients and is used as an additional tool for patients with high DFTs. The programmer will prompt the user to select a "release" button if selecting the RV to proximal Coil option to ensure that a dual-coil lead is implanted.

3.2.2.4.16 ATP One-Shot

Applies to the VF zone only.

This feature allows the delivery of a single ATP before charging only if the fixed 12% Stability Criteria is met during initial detection. If ATP therapy breaks the arrhythmia, the shock charging will abort. The programming of this ATP is the same as described above. This feature is automatically disabled if ATP One-shot fails in four consecutive attempts. When VF detection zone detection counters are programmed to 16 out of 20 or higher and Early ATP One shot programmed to ON with a long VF count, the device will deliver the programmed ATP One shot therapy when 12 out of 16 events, plus stability are met.

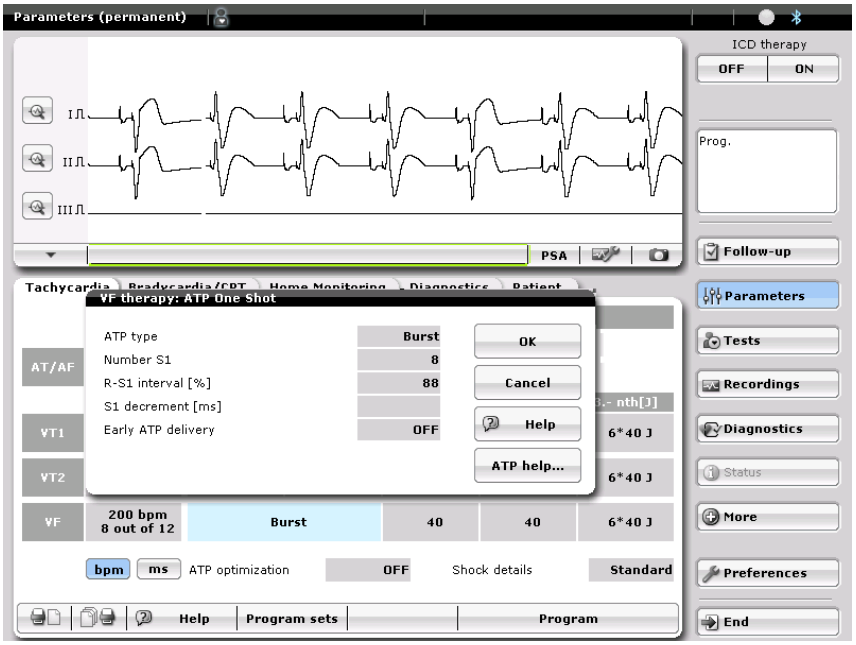

Figure 43: VF Therapy Screen showing ATP One-shot

ATP One-Shot programming options

Parameter	Burst	Ramp
Attempts	One Only	
Ventricular pacing	**RV**, BiV (CRT-D only)	
Number of S1	1 ... (1) ... **8** ... (1) ... 15	
R-S1 Interval	70 ... (5) ... 85, **88**, 90, 95%	
S1 Decrement	N/A	5 ... (5) ... 10 ... (5) ... 40 ms
Early ATP	**OFF**, ON	

Table 3: ATP One-Shot programming options

3.2.3 BIOTRONIK Home Monitoring®

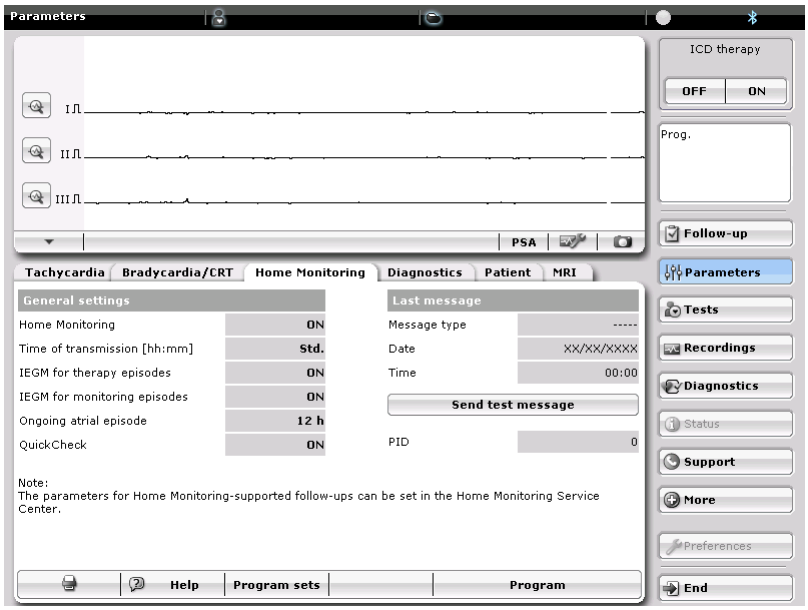

Figure 44: Home Monitoring screen

The Home Monitoring screen, shown in Figure 44, allows the user to set up the transmission time for Home Monitoring as well as the recording of IEGM information for Home Monitoring transmission and QuickCheck.

3.2.3.1 Home Monitoring

ON, **OFF**

The user can program the device to transmit or not.

3.2.3.2 Time of Transmission

Clock based (24 hour clock) Standard; 00:00 ... (01:00) ... 23:00 hh:mm

The selection Standard uses the device serial number to calculate a transmission time between 01:00 AM and 02:00 AM. Otherwise, the user can select a time the device transmits information to the Service Center. It is generally recommended that transmissions occur while the patient is asleep as this provides the best chance the patient is in range of the CardioMessenger.

NOTE:

Always verify the programmer time prior to programming the transmission time as the device time is based on the current programmer time.

3.2.3.3 IEGM for Therapy Episodes

ON, OFF

When programmed ON, the device will transmit the IEGM stored during a therapy episode to the service center.

3.2.3.4 IEGM for Monitoring Episodes

ON, OFF

When programmed ON, the device will transmit the Monitoring Zone IEGM to the service center.

3.2.3.5 Ongoing Atrial Episode

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

The device will send a message plus IEGM to the service center after a programmed time to alert the physician that the patient is in an ongoing atrial arrhythmia.

3.2.3.6 QuickCheck *(Not applicable in Rivacor 5)*

OFF, **ON**

The physician will be able to trigger a QuickCheck Request through the Home Monitoring Service Center. The device will send a full data download including any new triggered IEGMs and a real-time periodic IEGM to the Home Monitoring Service Center.

3.2.4 Diagnostics

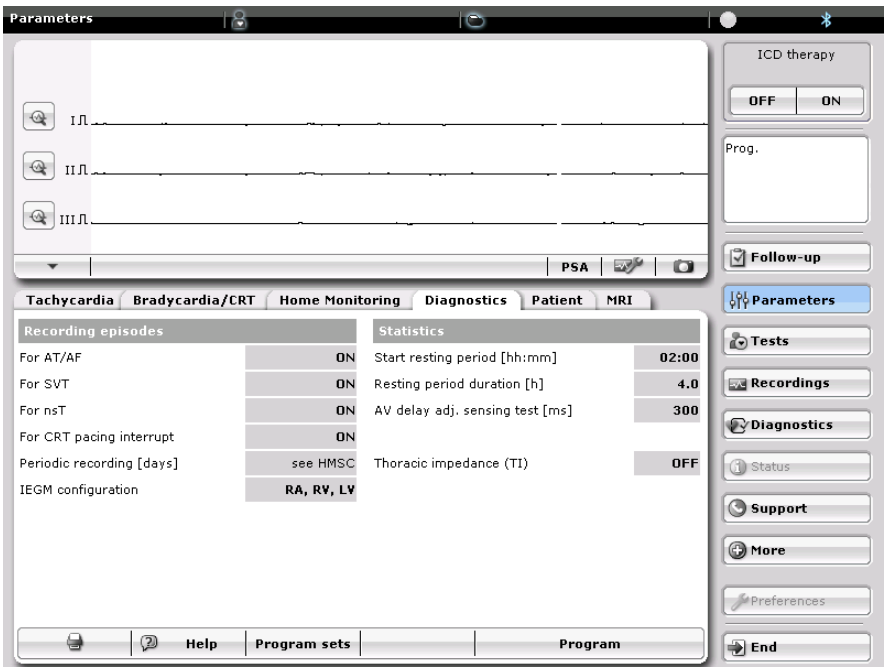

Figure 45: Diagnostics screen

3.2.4.1 Recording Episodes

For AT/AF:

OFF, **ON**, Advanced ON *(Advanced ON not applicable in Rivacor 5)*

This allows the user to record atrial tachyarrhythmias into the Holter based on the programmed rate selected in the Tachycardia tab of the device. Selecting Advanced ON doubles the prehistory time of the recording (approximately 1 min), allowing the user to view more information related to the onset of the arrhythmia.

For SVT:

OFF, **ON**

This parameter stores IEGM data for SMART Detection® SVTs such as AFib, AFlut, SVT and 1:1.

For nsT (non-sustained tachycardia):

OFF, **ON**, ON (<220ms)

This parameter stores IEGM data if the nsT recording is activated the device will recognize short fast ventricular intervals that are too short to fulfil the tachy detection counters. These fast ventricular intervals will trigger an IEGM recording and be counted in the statistics.

If the nsT recording is set to OFF, neither the IEGMs are recorded nor the statistics updates.

3.2.4.2 Periodic Recording

Programmable via the Home Monitoring Service Center

This parameter provides the capability to send periodic IEGMs without enabling Home Monitoring. The default value is 90 days. It can be used as diagnostic support for the normal heart rhythm of the patient at regular in-office follow-ups if needed.

3.2.4.3 IEGM Configuration (HF-T devices only)

RA, RV, LV; FF, RV, LV; RA, RV, FF

This parameter determines the IEGM configuration for the episode recordings in a CRT-D because the storage is limited to 3 channels only. ECG lead (FF) can be used alternatively to RA or LV IEGM.

3.2.4.4 Start Resting Period

Clock based; 00:00 ... (01:00) ... **02:00** ... (01:00) ... 23:00 hh:mm

This parameter determines the Heart Rate at Rest start time, as programmed by the user. Generally, it is recommended to program the time while the patient is at rest or asleep in order to get a more accurate measurement of the true resting heart rate for the patient.

3.2.4.5 Resting Period Duration

0.5 ... (0.5) ... **4.0** ... (0.5) ... 12 h

This parameter determines the duration for the calculation of the mean heart rate at rest. During this time, the device will measure the mean heart rate in 10-minute windows. The lowest value recorded during this time will be displayed on the HF monitor diagnostics.

3.2.4.6 AV Delay Adjustment Sensing Test

OFF, **300 ms**

Extends the AV Delay during the automatic sensing test to promote intrinsic activity in the ventricle and allow sensing values to be measured. Feature may be turned off in patients with no AV conduction (CHB) or high-grade AV Block.

3.2.4.7 Thoracic Impedance (TI)

ON, **OFF**

The thoracic impedance is measured between the distal shock-coil of the RV lead and the ICD housing. Up to 64 measurements are taken every hour, and these measurements are then averaged.

The 24 measurements per day are averaged and stored in the device and transmitted daily via Home Monitoring as a single average point per day. 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 ICD. 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.

3.2.5 Patient

This section allows the user to add patient, physician, hospital, and lead information. This information is stored in the device and can be accessed with any compatible programmer. The data in this section can be modified at any time.

3.2.5.1 Patient Data ID

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

Figure 46: ID Number

First Name/Last Name

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

Enter the patient's name and select the enter key.

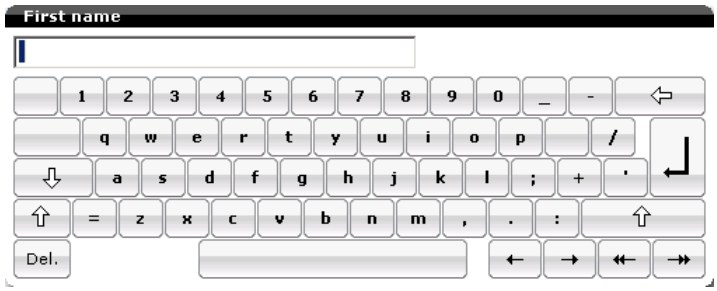

Figure 47: First Name

Figure 48: Last Name

Date of Birth

This section allows the user to input the patient's birth date. The birth date is entered as MM/DD/YYYY, as shown in Figure 49. When initially accessed, the current day will be displayed. The date can be changed using the following methods:

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

Once the date is entered, select the OK button.

Figure 49: Date of Birth

Gender

This section allows the user to select the patient's gender.

Figure 50: Gender

Symptom

This section allows the user to select the symptom related to the patient. Only one choice can be selected. The selection will appear on the main patient page.

Figure 51: Symptom

ECG Indication

This section allows the user to select an ECG indication related to the patient. Only one option can be selected. The selection will appear on the main patient page.

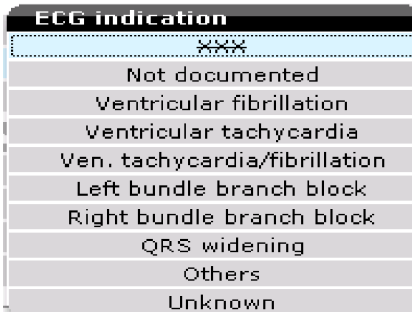

Figure 52: ECG Indication

Etiology

This section allows the user to select one etiology related to the patient. The selection will appear on the main patient page.

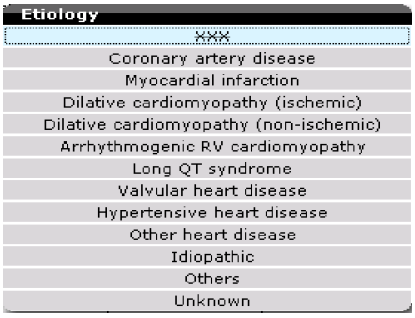

Figure 53: Etiology

Date of Implant

The implantation date is automatically added after implantation when valid impedance values are measured by the device. This refers to the device implantation date. The lead implantation date can be manually entered in the lead section.

Hospital and City

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

Figure 54: Hospital, City

Physician/Phone

The physician's name and phone number can be added. The Physician name can be entered in the left-side box and the phone number on the right-side box. As with the patient name, up to 40 characters are available to add physician information. It is a good idea also to add the physician's first name to help prevent confusion.

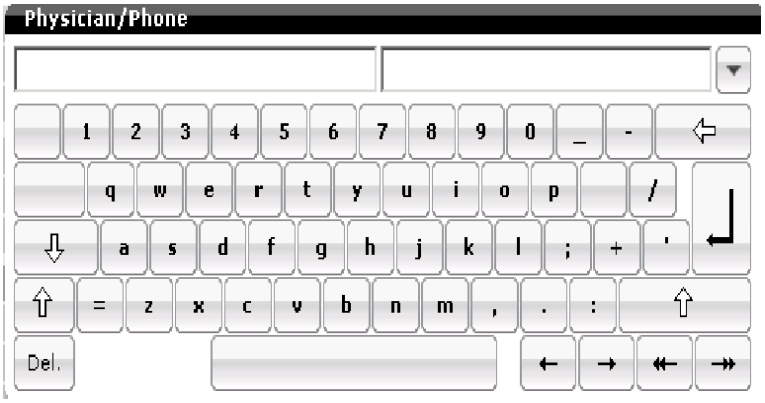

Figure 55: Physician information

Remark

Free text remarks can be entered into the device. Up to 42 characters (including spaces) can be entered.

Figure 56: Remark

LVEF

This refers to the left ventricular ejection fraction. Here the user can select the LVEF, if known.

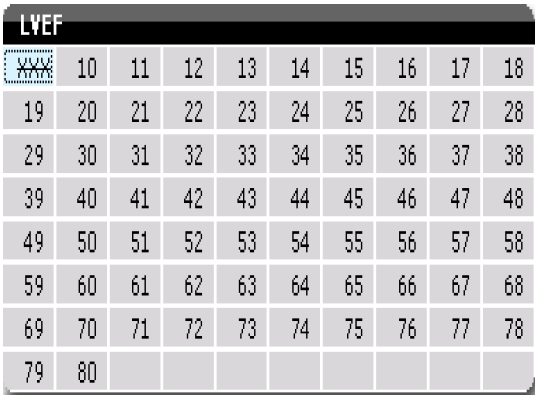

Figure 57: LVEF

NYHA

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

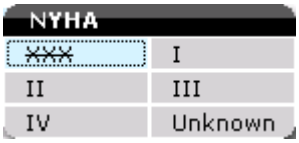

Figure 58: NYHA

Lead Information

Rivacor ProMRI® series allows atrial and ventricular lead information to be added to the device memory.

Lead Model

The lead model number can be entered here using both letters and numbers.

Figure 59: Lead Model

Lead Serial Number/Manufacturer

This box allows the user to input the lead serial number and select the lead manufacturer.

Figure 60: Lead serial number/Manufacturer

Type

The polarity of the lead can be added for the atrial and ventricular leads.

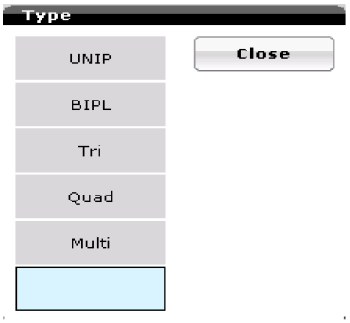

Figure 61: Lead type

Implantation

This box allows the user to enter the implantation date of the leads.

Figure 62: Implantation date

Brady / Tachy Channels

This box allows the user to choose the channel to which the lead is connected for bradycardia and tachycardia positions.

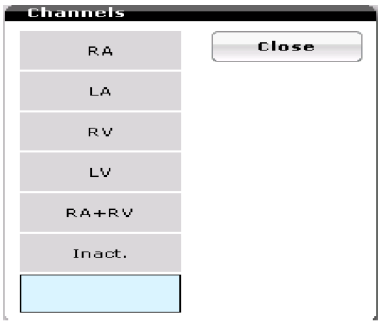

Figure 63: Brady channel

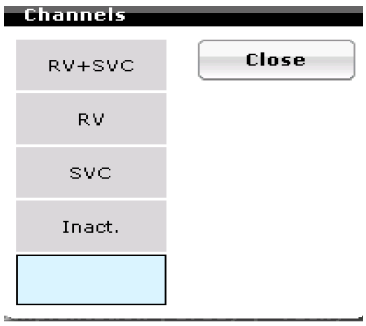

Figure 64: Tachy channel

Import

This feature is located at the bottom of the Patient tab page. This feature allows the user to import most patient information from the current device to a new device at the time of a replacement. NYHA and EF are not copied over as these values usually change with time. When pressing the import button, the user is taken to the data manager screen. The user can select the current patient device. When a device is selected, the OK button appears. Pressing OK will copy the patient data from the old device and move it into the new device. Review the information to ensure nothing has changed and press the Program button to save the data in the new device.

3.2.6 Patient Data Import

Patient and device information stored in the patient's existing implant can be automatically imported into the new implant rather than manually entering in the data. There are three steps to follow:

1. Interrogate the existing device
2. Interrogate the new implant
3. Select the "Import" button at the bottom of the Patient tab

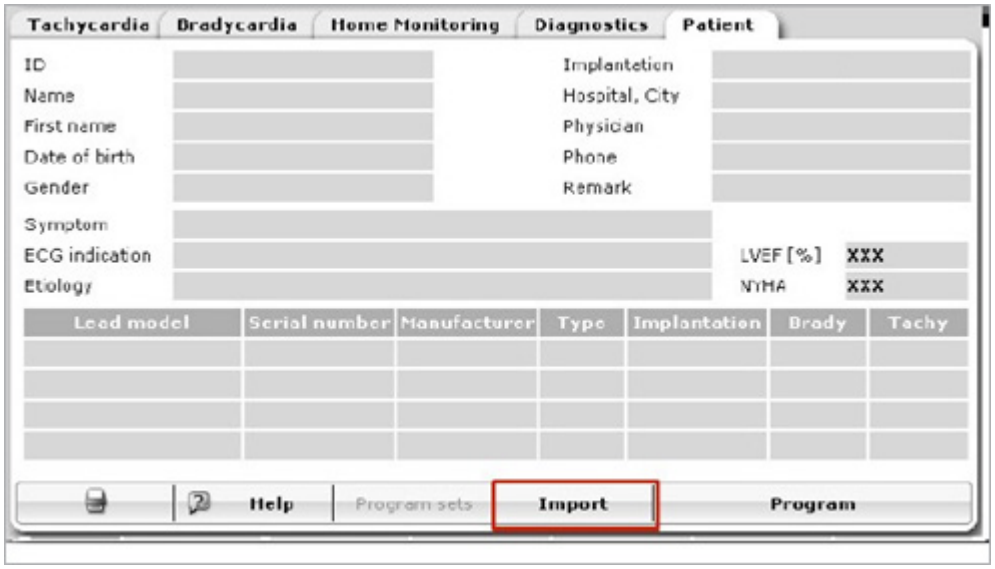

Figure 65: After interrogating the new device, selecting the Import button at the bottom of the Patient tab pulls up a list of previous device interrogations from the programmer.

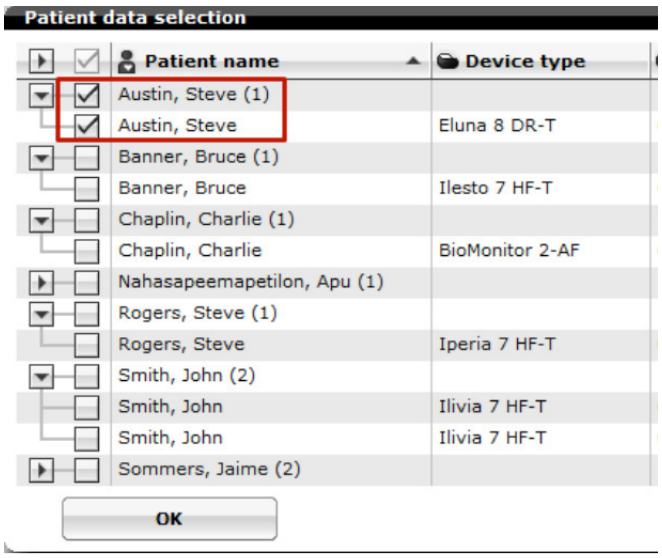

Figure 66: Selecting the follow-up from the previous implant and selecting the OK button will import patient and device data onto the patient tab of the new device.

3.3 Conflict Manager

Rivacor ProMRI® ICD software includes programming rules that result in parameter conflicts when selected values lead to unsafe or illogical parameter combinations. The programmer will not transmit parameters with conflicts present. However, the software includes a Conflict Manager, which displays a Conflict button with each conflict. When the button is selected, a pop-up editing window reveals a short message to guide reprogramming.

An example showing the Conflict Manager is shown in Figure 67. In this case, the VT1 zone and Max Sensor Rate program overlap. To resolve the conflict, the Max Sensor Rate must be programmed to a lower rate relative to the VT1 zone, as indicated by the message. Once the rates are properly adjusted and the Close button is pressed, the pop-up window and the Conflict button disappears, revealing the Overview screen.

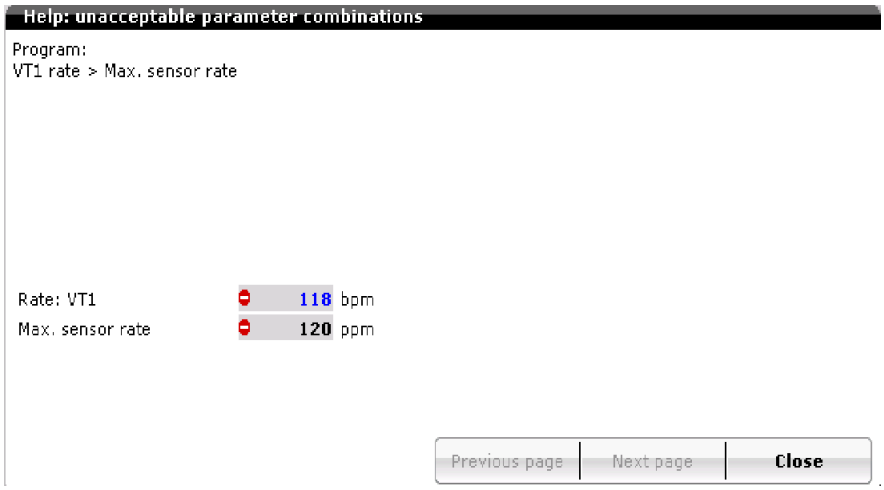

Figure 67: The Conflict Manager screen

3.4 MRI Programming

3.4.1 MRI Program

OFF, ON, AUTO

These parameters allow the user to program the device for an MRI procedure provided the entire ICD system meets the system criteria and radiological considerations for MRI are met. A checklist is provided as shown in Figure 68.

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

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 physician'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 programmed time has expired, the device will not recognize the scanner and not change to a predefined MRI program.

The mode and rate parameters appear when the user turns the MRI program ON or AUTO.

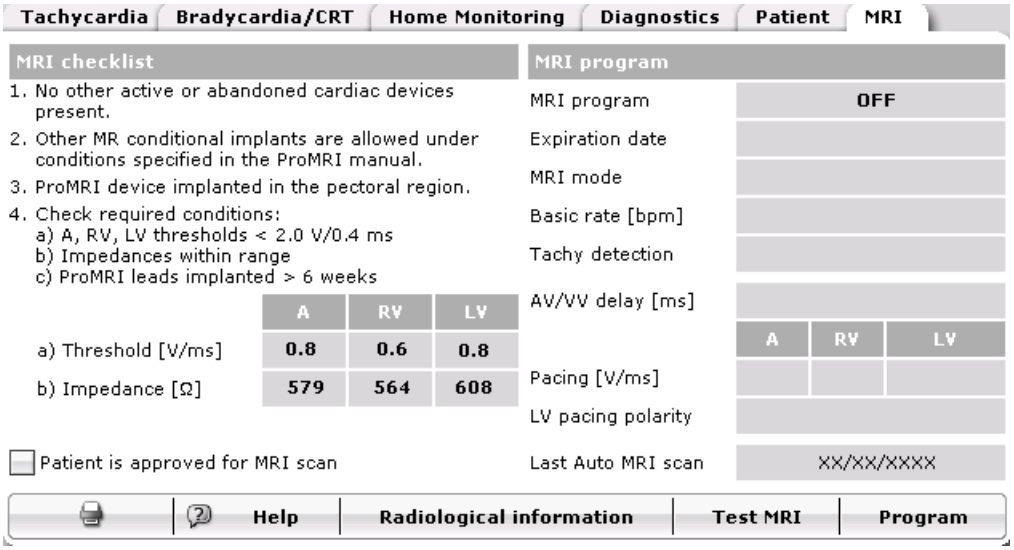

Figure 68: Main MRI screen

3.4.1.1 MRI Modes

OFF, DOO/BiV, DOO, VOO/BiV, VOO

This allows the user to program the pacing mode while in the MRI mode. The user has the option of four asynchronous modes or no pacing, if the patient has an adequate underlying rhythm.

It is important to note that tachycardia therapy is disabled and the device is no longer sensing events when the device is in the MRI mode.

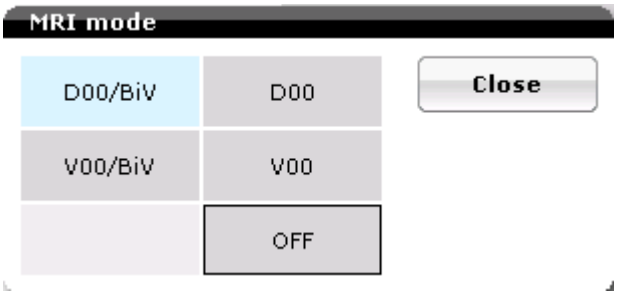

Figure 69: MRI modes

3.4.1.2 MRI Expiration Date

When AUTO is selected, this date reflects when the 14 day clock expires and when the patient will no longer automatically switch to an MRI mode for a MRI procedure. The user does have the option of reducing the 14 day window by selecting expiration date and choosing a date for the AUTO time to be over. The AUTO setting remains enabled through the end of the expiration date (11:59 pm).

3.4.1.3 MRI Mode Rate

70 ... (5) ... 100 ... (10) ... 160 bpm

This allows the user to select the rate during an MRI if an asynchronous mode is selected.

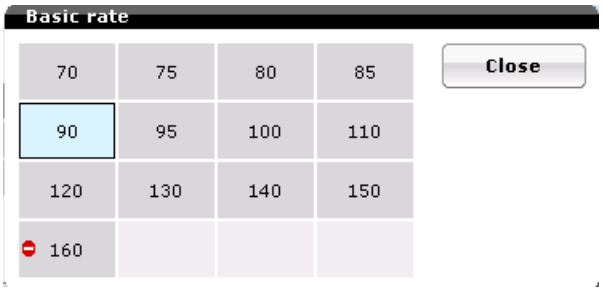

Figure 70: MRI mode rate options

3.4.1.4 LV Pacing Polarity

MRI scans require true bipolar pacing polarities to be programmed. A conflict message will appear if the RV coil or Can is currently programmed and prompt the user to make a change to resolve the conflict for the MRI scan.

3.4.1.5 Last Auto MRI scan

The date of the last AUTO MRI scan is displayed.

3.4.1.6 MRI Program Message

The user must check the box, "Patient is approved for MRI scan". Once it is checked, press the Program button at the bottom of the screen. After pressing the program button, a warning message will appear telling the user that the MRI program will disable tachycardia detection and therapy. Press the OK button to accept the conditions and permanently program the device to the MRI mode.

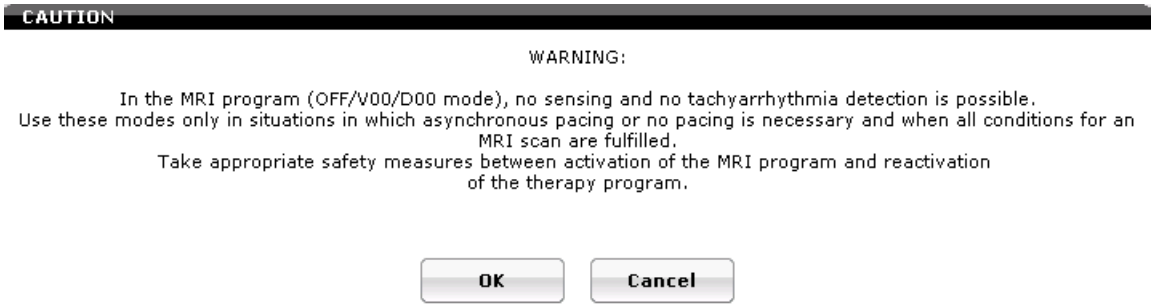

Figure 71: MRI program warning message

Chapter 4: Sensing

To ensure that appropriate ICD therapy is delivered, ventricular tachycardia and fibrillation must be distinguished from normal sinus rhythm and supraventricular tachycardias. This is accomplished by proper device sensing.

Sensing options in the Rivacor ProMRI® ICD/CRT-D devices

	Right Atrium	Right Ventricle	Left Ventricle*
Sensing Option	Standard (Std)	Standard (Std)	Standard (Std)
	OFF (Inactive)	Enhanced T-wave Suppression (TWS)	OFF (Inactive)
		Enhanced VF Sensitivity (VFS)	
Range (Default)	0.2 – 2.0 mV (**0.4 mV**)	0.5 – 2.5 mV (**0.8 mV**)	0.5 – 5.0 mV (**1.6 mV**)

Table 4: Sensing options in the Rivacor ProMRI® ICD/CRT-D devices

4.1 Sensing (Automatic Sensitivity Control)

Because the cardiac signals that the ICD must measure may vary in amplitude with different rhythms, the sensing threshold cannot be static in an ICD. Therefore, the Rivacor ProMRI® ICD utilizes Automatic Sensitivity Control (ASC) to automatically adjust the atrial and ventricular sensing threshold. In the Standard setting, each peak R-wave in a single-chamber ICD and P/R-wave in a dual-chamber ICD resets an upper threshold (UT) and a lower threshold (LT). The thresholds decay slightly over time, based on a preset sensitivity setting.

Programming of sensing options in the Rivacor ProMRI® ICD

Parameter	Right Atrium	Right Ventricle	Left Ventricle*
Upper Threshold†	25%, **50**%, 75%	**50**%, 75%	**50**%, 75%
Lower Threshold	**25**%	**25**%, 50%	**25**%
Upper Threshold duration after sensing		110, 150 ... (50) ... **350** ... (50) ... 500 ms	110, 150 ... (50) ... **350** ... (50) ... 500 ms
Upper Threshold duration after pacing		110, 150...(50)...**400**... (50)...500 ms	110, 150 ... (50) ... **400** ... (50) ... 500 ms
Blanking after atrial pace	100 ... (10) ... **140** ... (10) ... 350 ms	40, **50** ... (10) ... 100 ms	**100** ms
Blanking after RV pace	N/A	100 ... (10) ... **120** ... (10) ... 350 ms	50 ... (10) ... **80** ... (10) ... 100 ms
Blanking after LV pace	N/A	50 ... (10) ... **80** ... (10) ... 100 ms	100 ... (10) ...**120**... (10)... 350 ms

Table 5: Programming of sensing options in the Rivacor ProMRI® ICD

Default values are in bold.

* HF-T devices with LV sensing set to Standard

4.1.1 Atrial Sensitivity in Dual-Chamber and HF-T ICDs

The Rivacor ProMRI® DR-T and HF-T ICDs have two sensitivity settings in the atrium: Standard and OFF. The Standard atrial setting is recommended for all patients and works similarly to the ventricular Standard setting. In the Standard setting, each P-wave is tracked and used to reset the upper and lower thresholds. Figure 72 shows an example of atrial ASC. The upper threshold (UT) is set to 50% of the peak P-wave amplitude. The Upper threshold after sense/pace is fixed at 350 ms. Following the Hold of upper threshold, sensing decreases to the lower threshold (LT), which is equal to 25% of the measured P-wave. The lower threshold (LT) decays 12.5% every 156 ms until the Minimum Threshold is reached or until the next event, sensed or paced.

The OFF setting deactivates the atrial channel for sensing, pacing, SMART Detection®, atrial IEGM, and Holter recording. The Inactive setting may be used in cases in which the atrial lead signal is no longer required.

NOTE:

Do not use Inactive setting without consultation.

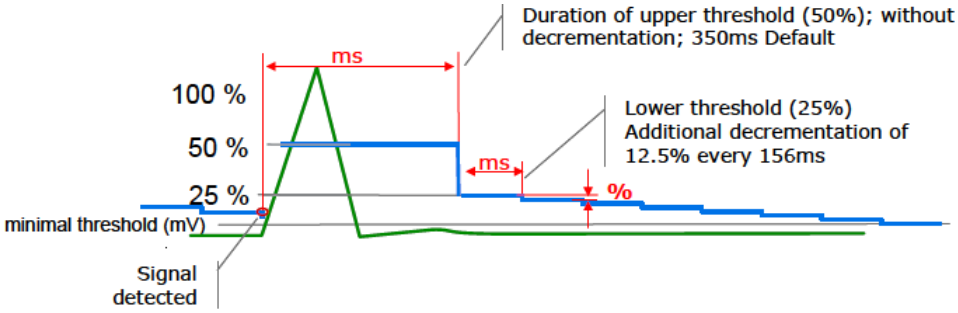

Figure 72: Automatic Sensitivity Control (ASC) in the atrium

4.1.2 Right Ventricular Sensitivity

In the right ventricle, three different sensitivity settings can be programmed based on patient needs: Standard (Std); Enhanced T-wave Suppression (TWS); and Enhanced VF Sensitivity (VFS). The Standard setting is ideal for most patients. Enhanced T-wave Suppression should be programmed for patients who experience T-wave oversensing during normal sinus rhythm. Enhanced VF Sensitivity should be programmed for patients with fine VF or when signal dropout occurs resulting in significant undersensing of VF events when using the Standard setting. Details of each setting are described in the following sections.

NOTE:

With HF-T devices, the settings only apply to the Right Ventricular Channel. Sensitivity choices for the Left Ventricular Channel are Standard and Inactive only.

Summary of RV sensitivity settings

	Standard	TWS	VFS
Upper Threshold	50%	75%	50%
Lower Threshold	25%	25%	25%
UT duration (sense)	350 ms	350 ms	110 ms
UT duration (pace)	400 ms	400 ms	110 ms
High pass filter	24 Hz	32 Hz	32 Hz

Table 6: Summary of RV sensitivity settings

4.1.2.1 Standard Sensitivity

In the Standard ventricular setting, each R-wave is measured and used to reset the upper and lower thresholds. The Upper threshold (UT) duration after sensing is set to 50% of the peak R-wave amplitude. Following the Upper threshold duration after sensing, the device sets the lower threshold (LT) to 25% of the measured R-wave for 156 ms. The device will continue to decrement 12.5% of the measured R-wave value every 156 ms or until the minimum threshold is reached or until a new R-wave occurs.

The right ventricular minimum threshold is nominally programmed to a default value of 0.8 mV and is programmable from 0.5 mV to 2.5 mV. The MT is a fixed minimum threshold sensing value. The Rivacor ProMRI® ICD will not allow sensing below the programmed value.

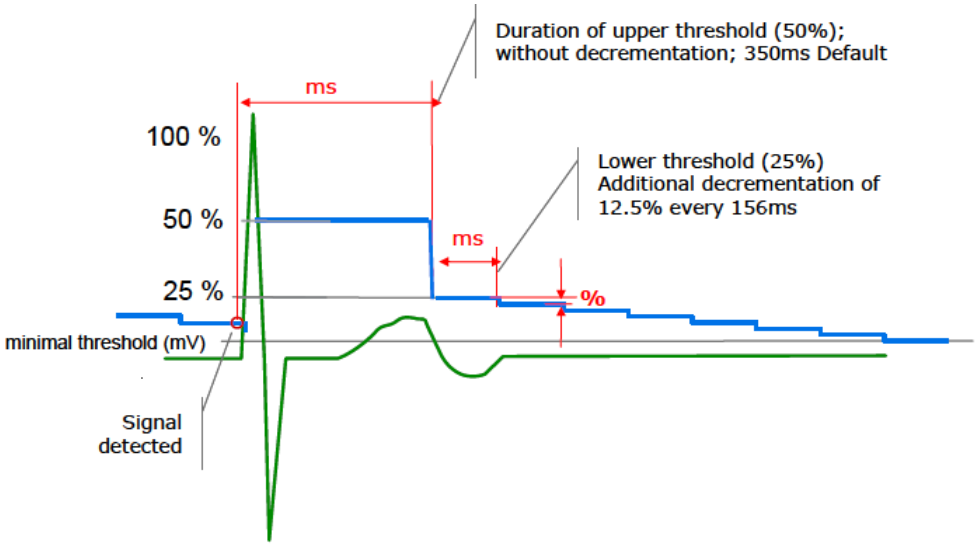

Figure 73: Automatic Sensitivity Control (ASC) with standard sensitivity (right ventricle)

Figure 73 illustrates ASC with the Standard sensitivity programmed. The R-wave is tracked and determined to be 8.0 mV at its peak. The amplitude is measured in the first 110 ms of detection of the complex. Following the sensed event the upper threshold (UT) is set to 4.0 mV (i.e., 50% of the measured R-wave). After the Upper threshold duration after sensing, the device decreases sensing to the lower threshold (LT). It remains at the lower threshold for 156 ms and then decrements 12.5% every 156 ms afterward. However, the minimum threshold (i.e., maximum sensitivity) is never violated.

The 12.5% decrement is measured from the previous setting. For example, if the lower threshold was 2.0 mV, the next decrement would be 1.75 mV. The one after that would be 1.53 mV (1.75 x 87.5%) and so on.

The Upper threshold duration after sensing may be extended in patients with T-wave oversensing due to Long QT syndrome.

4.1.2.2 Enhanced T-wave Suppression (TWS)

If oversensing of the T-wave complex occurs during normal sinus rhythm, then Enhanced T-wave Suppression may be programmed. With Enhanced T-wave Suppression, two parameters are automatically changed with programming TWS: high pass filtering is increased from 24 Hz to 32 Hz to reduce low-frequency signal components such as T-waves and respiratory artifacts; and the upper threshold (UT) is increased to 75% of the measured R-wave.

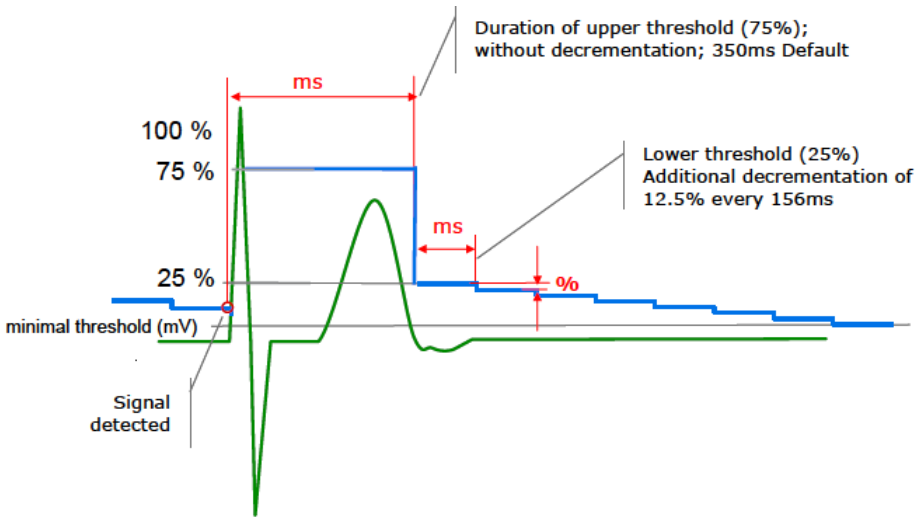

Figure 74: Enhanced T-wave suppression

NOTE:

While Enhanced T-wave Suppression can eliminate T-wave oversensing, the setting should be used with caution if the R-wave signal amplitude is small (e.g., less than 4 mV). Detection of VF should be retested when the sensitivity setting is reprogrammed.

NOTE:

While Enhanced T-wave Suppression is typically used for oversensing seen after sensed R-waves, this feature can also be used for T-wave oversensing following paced events due to the change in the filtering of the incoming signal.

4.1.2.3 Enhanced VF Sensitivity (VFS)

The Enhanced VF Sensitivity was specifically designed to improve VF detection when the VF signal amplitude is small or alternating, which can lead to undersensing during detection. Two adjustments are made to ASC with this setting: the Hold of Upper Threshold is decreased to 110 ms; and the high pass filter is changed from 24 Hz to 32 Hz. Both adjustments ensure that the threshold approaches the minimum threshold more quickly compared to the Standard setting. If undersensing is still present, the minimum threshold may also need to be adjusted. As with standard ASC, the minimum threshold value cannot be violated. Figure 75 illustrates Enhanced VF Sensitivity.

NOTE:

While Enhanced VF Sensitivity can help with undersensing, the setting should be used with caution, as oversensing of the intrinsic complex may occur. Detection of VF should be retested when the sensitivity setting is reprogrammed.

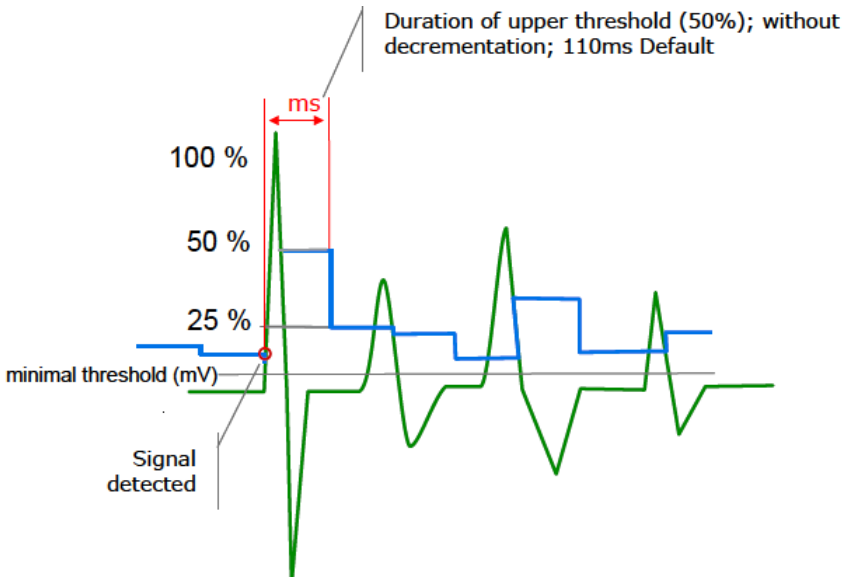

Figure 75: Automatic Sensitivity Control (ASC) with enhanced VF sensitivity

4.1.2.4 ASC and Pacing

ASC for paced events functions similarly following sensed events. Following the Blanking after RV pace period, the ventricular threshold will default to 50% of the measured event until 400 ms has expired (including the blank post pace period) and then will decrease to 25% of the measured event.

An example of this behavior is shown in Figure 76.

By default, the blank post pace period is set to 120 ms. The user can program a specific value from 100 ms to a maximum of 350 ms through the use of a release code.

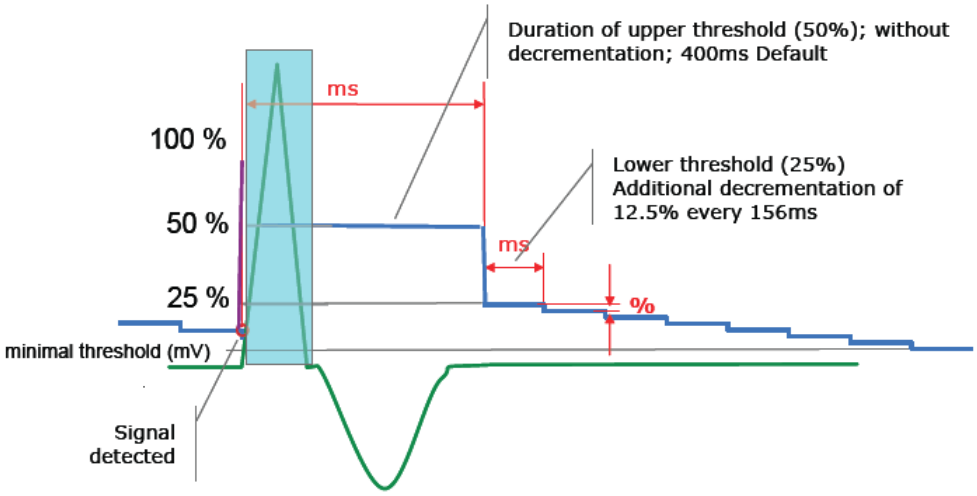

Figure 76: Automatic Sensitivity Control (ASC) with ventricular pacing - default

An additional option following post-paced events is available to program the sensing threshold following the blank after RV pacing period to a specific value. When Post pace T-wave is programmed ON, the post pace threshold defaults to 3 mV (Figure 77). This feature may be used when the patient has small amplitude R-waves (< 4 mV).

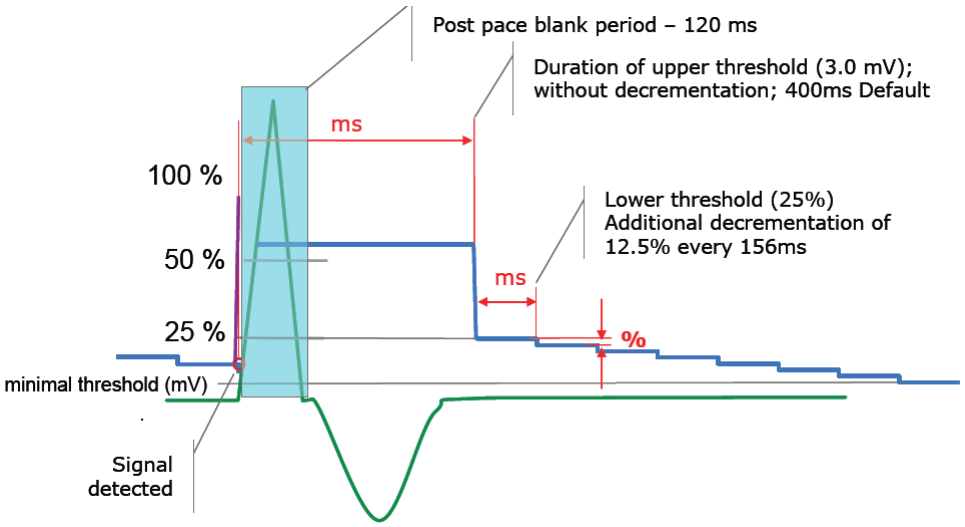

Figure 77: Post pace T-wave suppression

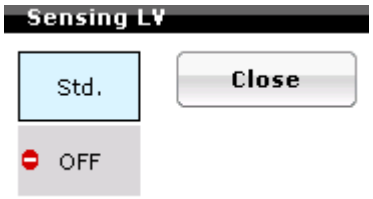

Figure 78: LV sensing options

4.1.3 Left Ventricular Sensitivity in Rivacor ProMRI® HF-T ICDs

The Rivacor ProMRI® ICD has two sensitivity settings in the left ventricle: Standard and OFF (Figure 79). In the Standard ventricular setting, each R-wave is measured and used to reset the upper and lower thresholds. The Upper threshold (UT) duration after sensing is set to 50% of the peak R-wave amplitude. Following the Upper threshold duration after sensing, the device drops to a 25% value for the lower threshold duration. The device will continue to decrement 12.5% of the measured R-wave value every 156 ms or until the minimum threshold is reached or until a new R-wave occurs.

The Inactive setting deactivates the LV channel for sensing and does not provide diagnostic recording of LV sensing measurements.

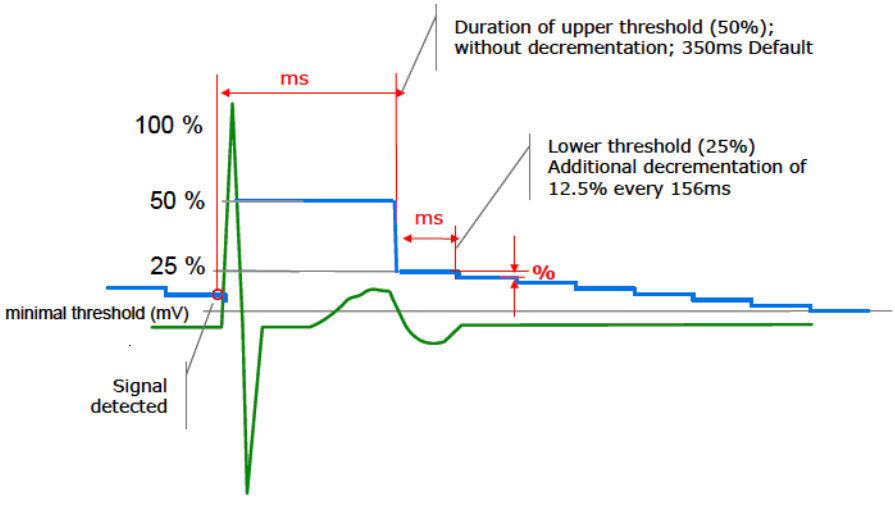

Figure 79: Automatic Sensitivity Control (ASC) in the LV channel

4.2 Far-Field Protection

Figure 80 shows the main screen for Far-field Protection. This feature is used to prevent oversensing of crosstalk events to prevent inappropriate therapies or mode switching.

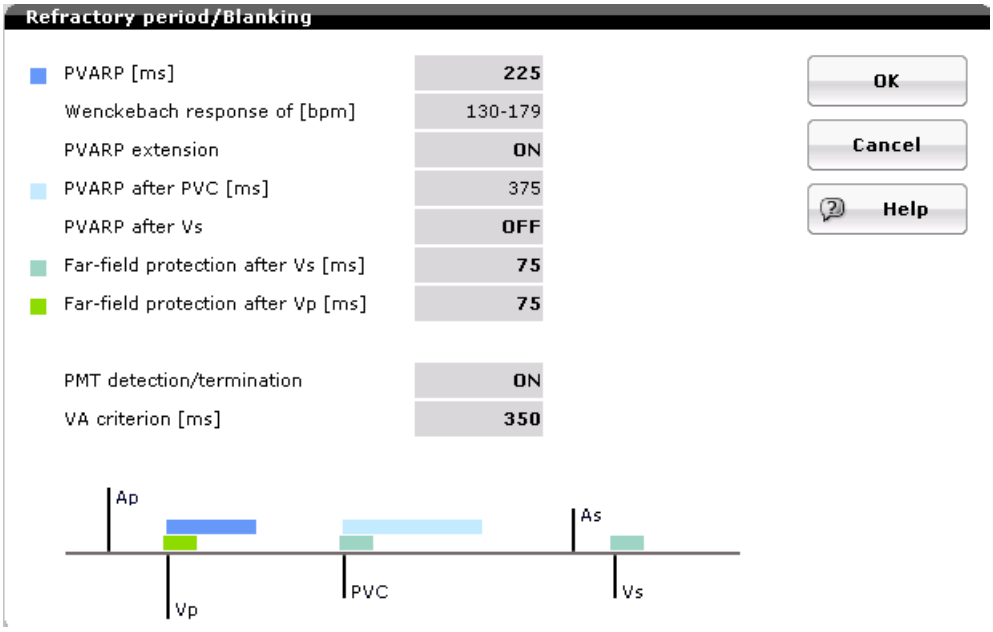

Figure 80: Far-field parameters screen

In Rivacor ProMRI® ICDs, this parameter is a true blank period, meaning that the signals that occur during this timer are not sensed by the device. As a result, there will be no marker channel events during this time period, and events are not recorded in the device diagnostics.

4.2.1 Far-Field Protection after Ventricular Sensed (Vs) Events

Parameter Range: OFF; **AUTO**; 25...(25) ...225 ms

Far-field protection after Vs is a parameter used to address oversensing in the atrial channel that occurs from ventricular sensed events. Oversensing in the atrial channel can result in inappropriate mode switching and inaccurate statistical counts. In some cases, it can also affect SMART Detection®.

Far-field protection after Vs initiates an atrial blanking period with each ventricular sensed event. As seen in Figure 81, blanking in the atrial channel occurs before and after each ventricular sensed (Vs) event. When the far-field protection parameter is programmed at the default value of 75 ms, 16 ms of blanking is applied before the Vs event and the remaining 59 ms is applied after the Vs event.

When reprogramming this parameter, measure the VA interval and remember that 16 ms is applied before the event when selecting a new value. For example; if the VA interval was measured at 110 ms. The selection of 125 ms would provide 16 ms prior to the event and 109 ms after the event. Therefore, the choice of 150 ms would be more appropriate.

It is important to note that while this parameter will prevent oversensing from ventricular sensed events, it will not alter the morphology of the IEGM.

NOTE:

All parameter choices will have a pre-event blanking period of 16 ms prior to the event and the remainder post event.

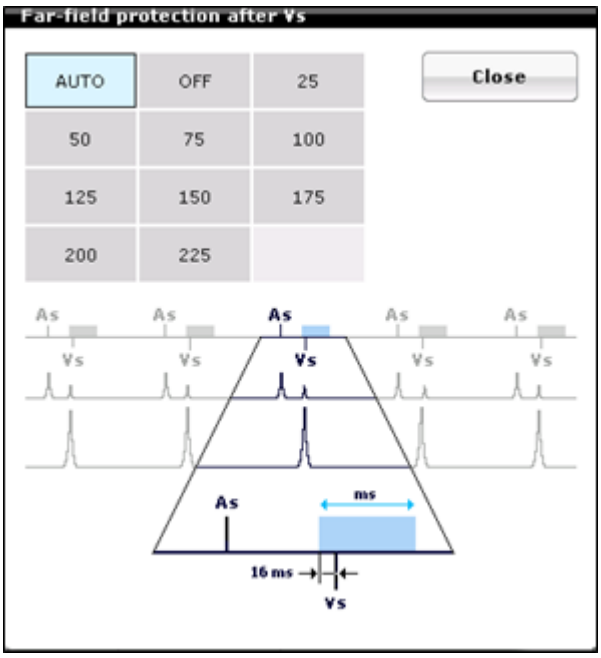

Figure 81: Far-field protection after Vs. The picture demonstrates a 16 ms pre-event non-programmable blanking period that is separate (fixed) from the programmable choices.

The Far-field protection parameter is found in the Bradycardia tab.

AUTO Far-field protection after Vs will adjust the Far-field protection window when the ventricular rates fall into the VT/VF zones.

If SMART detection is enabled, Far-field Protection after RV sense will be reduced to 25 ms once the second consecutive ventricular event falls into the VT/VF zone. This allows atrial events to be sensed and recognized for appropriate SMART classification. The Far-field protection (FFP) after RV sense will remain at 25 ms for the duration of the episode, and will then return to the nominal value of 75 ms at termination/short termination.

This feature is nominally active, and can be turned off by setting a fixed value for FFP after RV sense instead of AUTO.

NOTE: The Auto FFB may lead to an elevated number of mode switches.

4.2.2 Far-Field Protection after Ventricular Paced (Vp) Events

Parameter Range: 50, **75** ... (25) ... 225 ms

Far-field protection after Vp is a parameter used to address oversensing in the atrial channel that occurs from ventricular paced events. Oversensing in the atrial channel can result in inappropriate mode switching and inaccurate statistical counts.

Far-field protection after Vp initiates an atrial blanking period with each ventricular paced event. As seen in Figure 82, blanking in the atrial channel occurs before and after each ventricular paced (Vp) event. When the far-field protection parameter is programmed at the default value of 75 ms, 16 ms of blanking is applied before the Vp event, and the remaining 59 ms is applied after the Vp event.

When reprogramming this parameter, measure the VA interval and remember that 16 ms is applied before the event when selecting a new value. For example; if the VA interval was measured at 110 ms. The selection of 125 ms would provide 16 ms prior to the event and 109 ms after the event. Therefore, the choice of 150 ms would be more appropriate.

It is important to note that while this parameter will prevent oversensing from ventricular paced events, it will not alter the morphology of the IEGM.

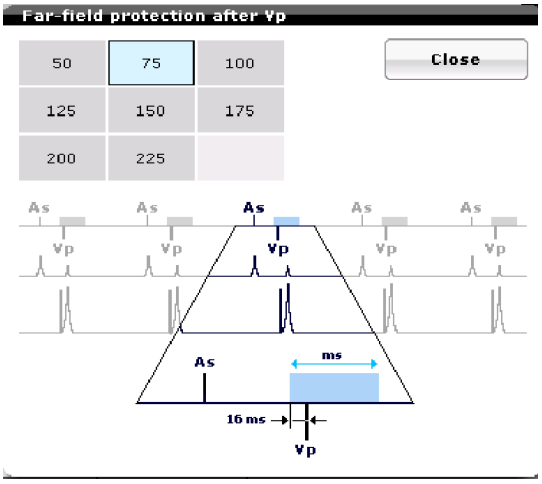

Figure 82: Far-field protection after V Pace in the atrial channel. The picture demonstrates a 16 ms pre-event non-programmable blanking period that is separate (fixed) from the programmable choices.

In Figure 83, Far-field oversensing is occurring. NOTE the atrial refractory sense (Ars) post ventricular pace (Vp). In Figure 84, the far-field sensing of post-ventricular paced events (Vp) has been corrected by extending the Far-field Protection after Vp. The atrial refractory sense (Ars) markers following the ventricular pace (Vp) markers in the atrial marker channel are gone, which means that the device is no longer sensing the ventricular signal on the atrial channel, even though the complex is still visible on the strip.

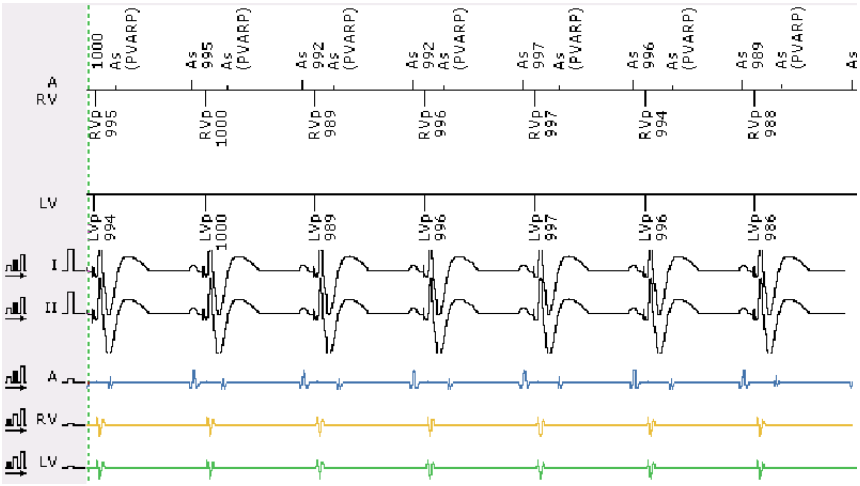

Figure 83: Atrial oversensing IEGM

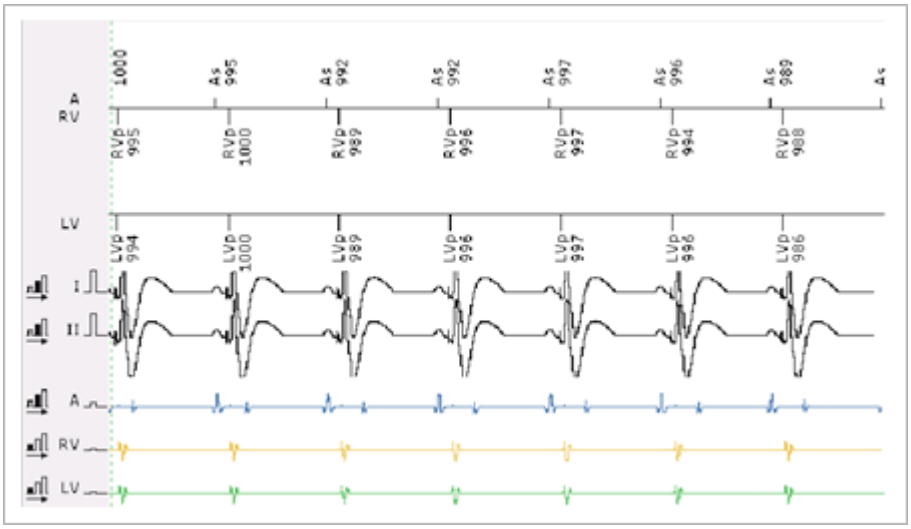

Figure 84: Atrial channel oversensing corrected IEGM

NOTE:

Should the 75 ms Far-field protection default value not prevent Far-field oversensing, thoroughly analyze the IEGM before making any programming changes. It is important to determine the exact lengthening required to eliminate far-field sensing, as too much blanking can negatively interfere with the X and Z counters for appropriate Mode Switch function and statistics, as well as potentially affecting SMART Detection® when addressing oversensing with ventricular sensed events.

4.3 Safety Pacing

To protect the patient from inappropriate inhibition of needed ventricular pacing due to oversensing (crosstalk or noise seen as a Vs event), Rivacor ProMRI® provides a feature called Safety pacing. Safety pacing provides a ventricular pace (Vp) at an AV Delay of 100 ms (fixed value). As seen in Figure 85, the fourth atrial pace (Ap) is being sensed on the ventricular channel, causing the triggering of Safety pacing. NOTE the presence of a Vs event preceding the Vp event. Safety pacing only occurs following an atrial paced event. Safety pacing is not possible following an atrial sense event.

Should this occur during an implantation, it is advisable to consider relocating the atrial lead. In a chronic system, a common corrective action is to reduce the atrial pacing amplitude, if possible, while maintaining a 2:1 safety margin. One may consider a combination of pulse amplitude and pulse width to maintain an adequate pacing safety margin.

If neither of these solutions corrects the crosstalk, the next option is to lengthen the parameter Blanking after A Pace value found in the Details section of the Bradycardia page (Figure 84). Blanking after A Pacing parameter for the RV channel is programmable from 40 to 100 ms with a default setting of 50 ms.

In the Rivacor ProMRI® HF-T device, safety pacing will provide Biventricular pacing with V-V timing at 0 ms, provided Biventricular pacing is programmed ON.

The Rivacor ProMRI® ICD will not display the safety pace value on the AV Delay screen as did previous generations of devices.

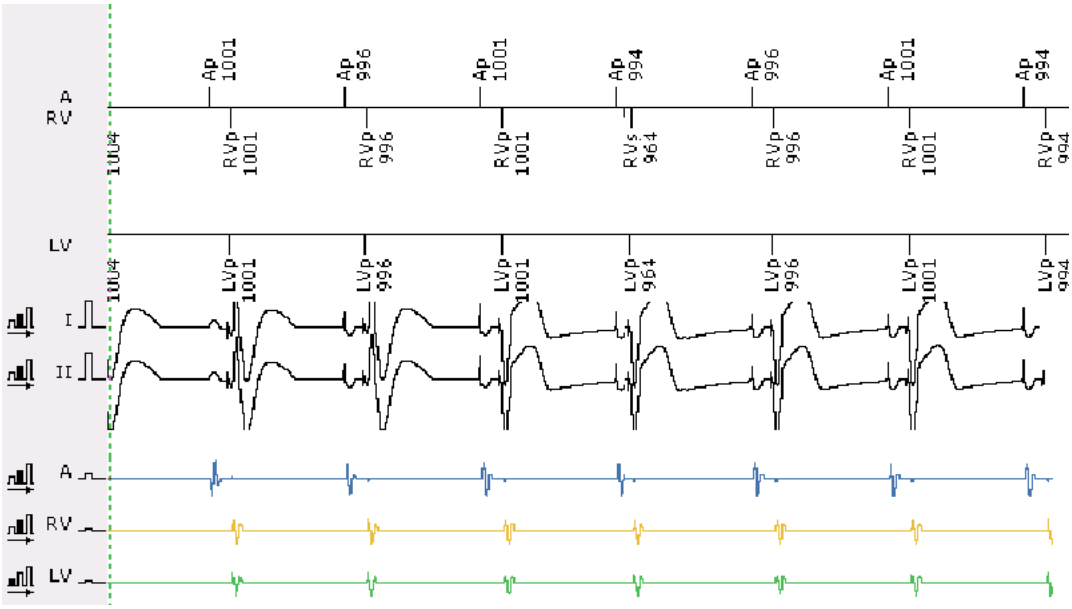

Figure 85: Example of safety pacing

4.4 Blanking after Pacing

Blanking after pacing

Parameter	Right Atrium	Right Ventricle	Left Ventricle
Blanking after atrial pace	100 ... (10) ... **140** ... (10)...350 ms†	40, **50** ... (10) ... 100 ms	100 ms
Blanking after RV pace	N/A	100 ... (10) ... **120** ... (10)... 350 ms†	50...(10)...**80**... (10)...100 ms
Blanking after LV pace	N/A	50 ... (10) ... **80** ... (10) ... 100 ms	100 ... (10) ... **120** ... (10) ... 350 ms†

Table 7: Blanking after pacing

† Accessible by BIOTRONIK personnel only

4.4.1 Blanking after Atrial Pace

Blank after atrial pace in the Right atrium. When the device delivers an atrial pace, the atrial channel is blanked for 140 ms to prevent oversensing the pace artifact.

4.4.2 Blank after Atrial Pace in the Right Ventricle

This feature is designed to prevent sensing of the paced atrial artifact from being sensed in the ventricle, resulting in Safety pacing. This screen is found under Sensing details on the Bradycardia screen.

Use the Blank after Atrial Pacing parameter to correct Safety pacing (Figure 86):

1. To determine the appropriate setting, measure from the Ap to the Vs marker; then add 10 ms to allow for minor variations in duration.
2. If the crosstalk is intermittent, programming to the next higher value should correct the problem.

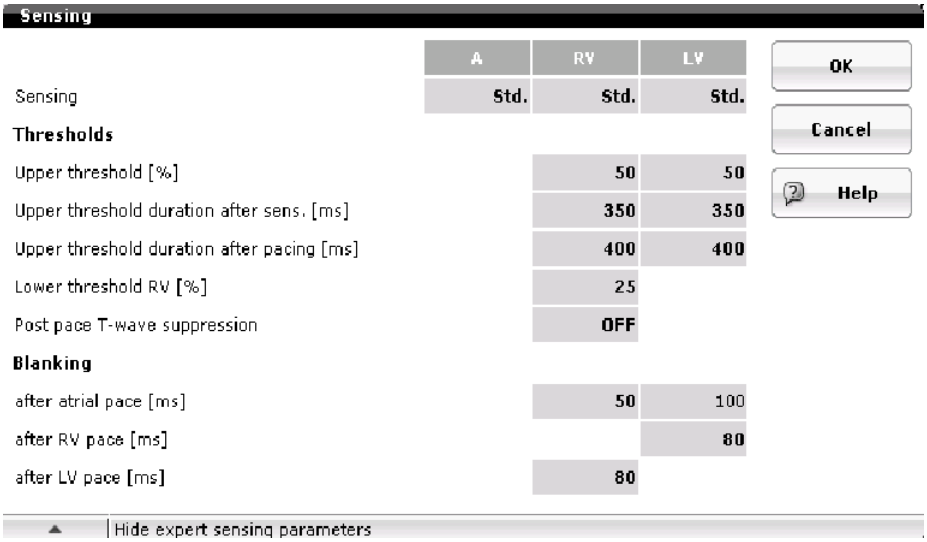

Figure 86: Sensing details screen

NOTE:

The sensing details screen, among others, has an arrow in the bottom-left corner to open or reduce the window. A message to hide or show additional parameter options is listed to the right of the arrow.

4.4.3 Blank after Atrial Pace in the Left Ventricle

Following an atrial paced event, the left ventricle is blanked for 100 ms (fixed) to prevent oversensing that may lead to inhibition of LV pacing.

4.4.4 Blanking after RV pace

Blanking after RV pace in the RV channel. This in-channel blanking period prevents oversensing of the pacing pulse and the depolarized event that could lead to inhibited pacing and changes in device timing.

Blanking after RV pace in the LV channel. This prevents oversensing in the LV channel that may lead to inhibition of LV pacing.

CAUTION

Blanking after RV pace – Extending this value too long may lead to delays in arrhythmia detection. Consult Advanced Product Support prior to extending this value.

4.4.5 Blanking after LV Pace (HF-T device only)

Blanking after LV pace in the RV channel:

This prevents oversensing in the RV channel that may lead to inhibition of RV pacing if the initially paced chamber is the left ventricle.

Blanking after LV pace in the LV channel:

This in-channel blanking period prevents oversensing within the LV channel that may lead to inhibition of LV pacing for the subsequent event.

4.5 Discrimination after As

Parameter Range: 250 ... (50) ... **350** ... (50) ... 800 ms

Discrimination after As is a feature used to promote proper device timing and is found in the Sensing details screen via code release. If an RV sensed event occurs within 350 ms of an Ars event, the Rivacor ProMRI® assumes the RVs event to be a response to the atrial (Ars) event. As a result, the Rivacor ProMRI® will consider the event to be an AsVs event, rather than an Ars event followed by a PVC, and will be annotated that way in the statistics of the ICD. This will provide a more accurate PVC count and event timing.

An example of Discrimination after As is shown in Figure 87.

NOTE:

If I-Opt is programmed ON in an Rivacor ProMRI® DR-T, the device will use 400 ms as the Discrimination after As value.

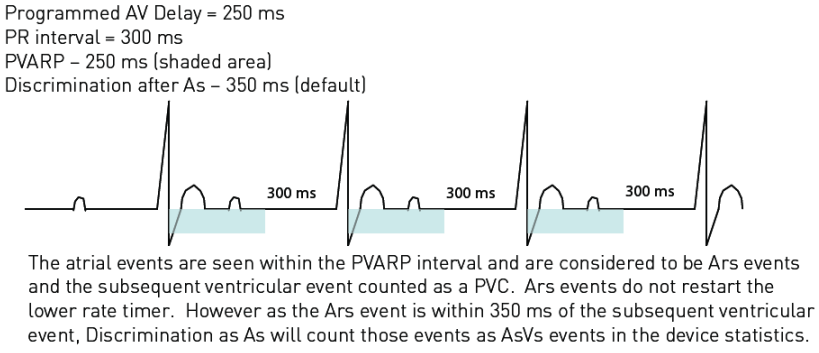

Figure 87: Discrimination after As

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Chapter 5: Detection

Initial Ventricular Arrhythmia Detection:

To ensure that appropriate ICD therapy is delivered, ventricular tachycardia and fibrillation must be distinguished from normal sinus rhythm and supraventricular tachycardias. This is accomplished by proper device sensing, as well as appropriate detection.

Detection activation/deactivation:

Detection is activated and deactivated via the ICD Therapy field in the upper right corner of the programmer screen, with the Master Switch. When the device is disabled, tachyarrhythmia detection and therapy are inhibited, and the upper right corner will display "disabled". Refer to Section 2.1 for more information about the Master Switch.

5.1 Ventricular Tachyarrhythmia Detection

The Rivacor ProMRI® ICDs/CRT-Ds detect and measure the rate of sensed cardiac signals to discriminate ventricular tachyarrhythmias from supraventricular tachycardias, sinus rhythm, or sinus bradycardia.

This is accomplished through programmable rate detection parameters in the device. When a tachyarrhythmia is present, the ICD/CRT-D classifies the arrhythmia and delivers the programmed therapy. If a tachyarrhythmia continues following the first therapy attempt, then the

ICD/CRT-D will redetect the tachyarrhythmia and deliver subsequent therapies as necessary.

WARNING

Unwanted Shocks – Always program ICD Therapy to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or to the person handling the device during the implant procedure.

Classification of cardiac signals is accomplished primarily by measuring the cardiac cycle length (R-R, P-R and P-P). In addition, the ICD/CRT-D can also utilize abrupt changes in rate or irregularity of the cardiac signal to further differentiate ventricular tachyarrhythmias. Each detected ventricular tachyarrhythmia is classified into one of the following zones:

- VT1 Lower rate ventricular tachycardia
- VT2 Higher rate ventricular tachycardia
- VF Ventricular fibrillation

Each rhythm class is programmable to a separate rate with the zone limit defining the lowest rate in each class. The upper rate limit of each class is equal to the zone limit of the next higher class, creating a continuous range of rate classes.

5.1.1 Ventricular Tachycardia Zone Classifications

There are up to three programmable ventricular tachyarrhythmia zones in the Rivacor ProMRI® family of ICDs: two ventricular tachycardia zones (VT1 and VT2) and a single ventricular fibrillation zone (VF).

SMART Detection® or Ventricular-Only Detection (i.e., SMART Detection® = OFF) is used only for ventricular tachycardia (VT) detection with an up/down counter. An "X out of Y" detection count is used for VF detection.

5.1.1.1 Ventricular-Only Detection

As its name implies, Ventricular-only detection (i.e., SMART Detection® = OFF), uses only information obtained from the ventricular sensing lead. Specifically, ventricular rate (or interval), Stability and Sudden Onset are used for rhythm classification. Therefore, Ventricular-only detection relies on the standard enhancement criteria used in single-chamber ICDs.

In its most basic form, Ventricular-only detection uses an interval count and rate/interval cut-off as criteria. This means that any time the rhythm crosses the programmed detection interval, Rivacor ProMRI® will classify the event as VT. Detection enhancements such as Onset, Stability and MorphMatch can be added to help discriminate VT from SVT. These detection enhancements are sometimes referred to as "therapy inhibitors," as both interval count and the programmed detection enhancement criteria must be met to classify an arrhythmia.

5.1.1.2 SMART Detection® for Dual-Chamber AV Discrimination

When SMART Detection® is programmed ON, information from the atrial and ventricular chambers of the heart is used for ventricular tachycardia classification. The algorithm is specifically designed to detect VT while withholding therapy upon detection of an SVT. The algorithm performs classification on a beat-to-beat basis. Classification begins after the cycle length is measured and determined to lie within the programmed VT zones. Thereafter, a series of tests are performed to determine whether the arrhythmia is atrial or ventricular in origin. SMART Detection® can be programmed in both VT zones (VT1 and VT2) or only in the VT1 zone. SMART Detection® can be programmed in the VT2 zone (only) if a VT1 zone is programmed with SMART Detection® OFF. However, the user is required to use Onset and Stability in the VT1 Zone.

By default, SMART Detection® and SMART Redetection are ON when a VT Zone is programmed.

5.1.1.3 VF Detection

Initial detection and redetection in the ventricular fibrillation (VF) zone relies on a single X out of Y detection criterion. Initial VF detection and VF redetection may be programmed separately in the Rivacor ProMRI® ICDs. The Rivacor ProMRI® ICD provides 10 options for VF detection and 9 options for redetection.

Details describing VT and VF detection are shown in Figure 88 and will be discussed in this chapter.

VF	Initial Detection = X of Y (10 options) Redetection = X of Y (9 options)
VT2	Initial Detection = SMART Detection® or Ventricular-only Detection* Redetection = SMART Redetection® or Interval count with stability
VT1	Initial Detection = SMART Detection® or Ventricular-only Detection* Redetection = SMART Redetection® or Interval count with stability
Sinus	Sinus events decrement the tachycardia counters by -1

Figure 88: Summary of detection

* Ventricular-only detection includes interval count, Onset and/or Stability, MorphMatch and a Sustained VT Timer

5.1.1.4 Sliding Averages

While not a specific criteria of Ventricular-only or SMART Detection®, the Rivacor ProMRI® ICD uses 4-beat sliding rate averages for several of its calculations. With SMART Detection®, the devices use sliding averages to compare atrial and ventricular rate to: determine whether the atrial and ventricular rates are equal or not, used with Multiplicity to determine the N:1 ratio; and Stability, to determine whether the atrial and ventricular rates are stable. An example is shown in Figure 89.

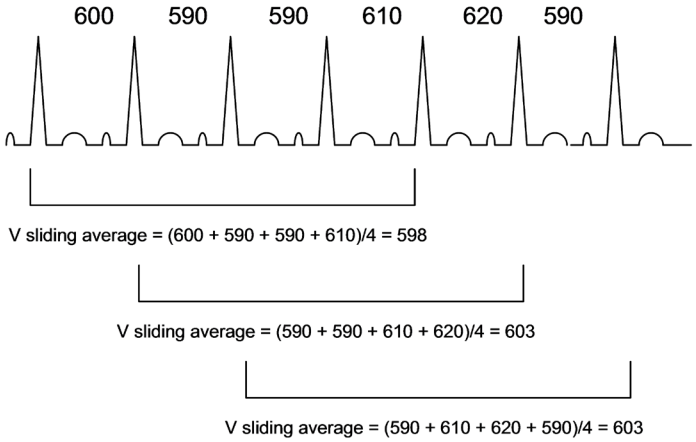

Figure 89: Calculation of sliding averages

A variant of sliding averages is used in both Ventricular-only and SMART Detection® for Onset. In this case, the devices compare the most recent four-beat average versus the previous four-beat average to determine if the Onset criteria were met. This is discussed further in the Onset section of this chapter.

5.1.2 Ventricular-Only VT Detection

When a VT zone is programmed, the Ventricular-only detection algorithm uses a programmable VT Counter and standard detection enhancements used in rate-only ICDs (i.e., Stability, Sudden Onset and MorphMatch). As the name implies, Ventricular-only Detection (i.e., SMART Detection® programmed OFF) uses only ventricular information. Detection relies on simple up/down counters (i.e., a VT1 Counter and a separate VT2 Counter), ventricular rate, and single-chamber enhancements.

5.1.2.1 Rate Only

When Rate only is used, detection is met when the programmed number of intervals exceeds the programmed detection count.

Each time an interval is faster than the programmed VT zone rate (interval), the VT Counter increments by one (+1). Conversely, the VT Counter decrements by one (-1) when an interval is slower than the programmed rate for that zone.

All intervals faster than the VT1 detection rate (including VT2 and VF intervals) also increment the VT1 counter. All intervals faster than the VT2 detection rate (including VF intervals) increment the VT2 counter. Intervals slower than the defined detection zones decrement the counter for that zone.

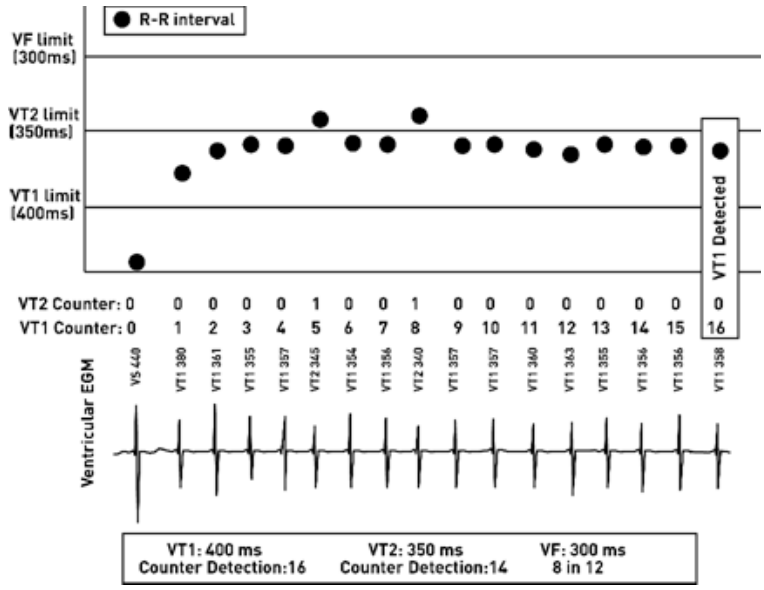

Figure 90: Rate-only detection of VT1

An example of rate-only VT1 detection is shown in Figure 90. In this case, there are three tachyarrhythmia zones programmed (i.e., VT1, VT2, and VF). VT detection begins with the first short interval (i.e., the first interval that falls into the VT1 zone). The VT1 Detection Counter increments with each interval shorter than the VT1 limit of 400 ms, including intervals that fall into the VT2 zone. The VT2 Detection Counter increments with each interval shorter than the VT2 limit of 350 ms and decrements with each interval longer than the VT2 limit. VT1 detection is declared and therapy delivered when the VT1 Detection Counter reaches the programmed value of 16.

5.1.2.2 Stability

Stability is a detection enhancement to assist in determining whether a tachyarrhythmia is ventricular tachycardia or atrial fibrillation with a rapid ventricular response. Stability refers to the stability of R-R intervals (not patient hemodynamics). Monomorphic ventricular tachycardia (mVT) demonstrates a stable R-R interval, while in atrial fibrillation the R-R intervals are unstable. Stability is evaluated on a beat-to-beat basis. Stability is used for detection and redetection.

The Stability criterion (Figure 91) is satisfied for a given ventricular interval when the difference between the current interval and each of the three preceding intervals is less than the programmed Stability limit. The default Stability limit of 12% is optimal and generally should not be reprogrammed. Changing the stability value in a VT1 zone will also change it in the VT2 zone, if programmed.

When an unstable event occurs, the tachycardia counters are reset to zero. However, to prevent therapy delays when long detection counters are programmed, the device will decrement the VT counter by 20. In the case of the detection count being at less than twenty when the unstable event occurs, the device will reset the counter to zero.

Reprogramming Stability may result in delivery of inappropriate therapy for supraventricular tachyarrhythmias. Programming a larger value can result in therapy delivery for AFib, while programming a smaller value may result in inhibition of therapy for VTs which may be slightly unstable.

NOTE:

Unstable events reset the VT counters to zero, or minus 20 when long detection counts are programmed, potentially delaying therapy.

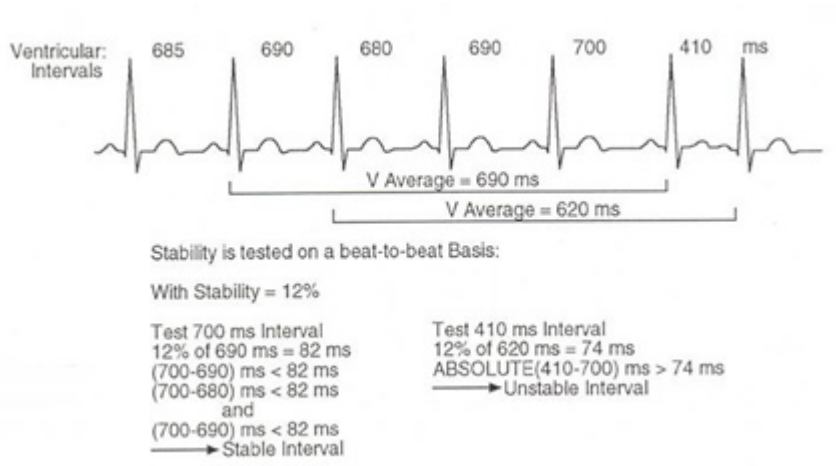

Figure 91: Calculation of stability

5.1.2.3 Sudden Onset

Sudden Onset is a detection enhancement used to determine whether a tachyarrhythmia is ventricular or sinus in origin. Spontaneous ventricular tachycardias typically demonstrate a sudden change in rate, while sinus tachycardias change rate slowly over time. Sudden Onset is programmed to a default value of 20% and is available in the VT1 and VT2 zones in Rivacor ProMRI®. The Onset value applies to both VT1 and VT2 zones.

In the Rivacor ProMRI® ICD, Onset confirmation is activated when the current sliding four-interval average is faster than the previous four-interval average by programmed Onset criteria value. Once the first fast event that meets Onset criteria occurs, the device uses that interval and the next three additional intervals to determine a new four-interval average and compares that new average against the previous four-interval average. This is designed to prevent single fast events declaring Onset and delivering inappropriate therapy. As shown in Figure 92, Onset is satisfied only when the difference between the current four-interval average and the previous 4-interval average exceeds the Sudden Onset value.

NOTE:

Onset applies to the ventricular chamber only.

NOTE:

Once Onset is met, it is declared for the entire episode, including redetection.

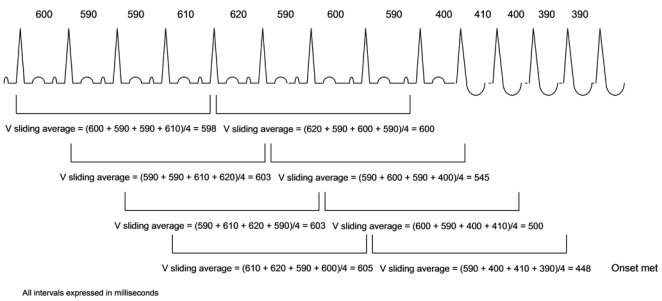

Figure 92: Calculation of onset

5.1.2.4 MorphMatch

MorphMatch is a detection enhancement using far-field signal morphology to differentiate SVT from VT. Therefore, it is only available when the device is programmed to ventricular-only sensing/detection modes and is recommended for single-chamber ICDs or dual-chamber ICDs which may experience inconsistent atrial sensing. MorphMatch is programmable in both the VT1 and VT2 zones.

MorphMatch compares the signal morphology of sinus events to events seen in the VT zone. If the events in the VT zone are determined to be a true VT event, the Morphology counter is incremented by +1. An event determined to be a sinus tachycardia event will not change the count. When the Morphology counter is lower than 1/2*VT counter, the episode is declared as SVT.

MorphMatch is programmable ON, OFF, or Monitoring. If Monitoring is activated, the device will monitor for VT, but will not use morphology (MorphMatch) criteria to classify VT. Rather, the programmed Onset and Stability criteria will be used to classify the event as either SVT or VT.

MorphMatch provides an additional parameter called MorphMatch threshold. This parameter changes the sensitivity of MorphMatch. The programmable values are Low, Standard and High. Changing the threshold value to Low will make it less sensitive for SVT and more likely the arrhythmia will be declared a VT. Conversely, changing the setting to High will make it more sensitive for SVT and more likely the arrhythmia will be declared a SVT. This should not be changed from the nominal unless there is evidence to support changing the parameter set.

5.2 Ventricular Tachyarrhythmia Detection Criteria for SMART Detection®

Ventricular-Only Detection algorithm uses a VT Counter and the standard detection enhancements used in rate-only ICDs (i.e., Stability and Onset). SMART Detection® is a much more sophisticated detection algorithm that relies on several key criteria to distinguish supraventricular tachycardias (SVTs) from ventricular tachycardia's (VTs). These criteria include: atrial rate, ventricular rate, atrial stability, ventricular stability, sudden onset, multiplicity, as well as AV regularity and AV trend. Each of these terms is defined below as they apply to the Rivacor ProMRI® ICD.

As multiple criteria are being used for SMART Detection®, the acronym **STORRM** can be helpful to remember the criteria used for AV discrimination detection.

S – Stability

T – Trend

O – Onset

R – Rate

R – Regularity

M – Multiplicity

Each is described in greater detail throughout the rest of this chapter.

5.2.1 Stability

Stability is a key component of SMART Detection®. With SMART Detection® ON, Stability is checked on a beat-to-beat basis in the atrium and the ventricle. Although the calculation for Stability is determined independently in both chambers, the same default of 12% Stability is used for each chamber.

An interval is considered stable when the difference between the current interval and each of the three preceding intervals is less than the Stability limit (Figure 93).

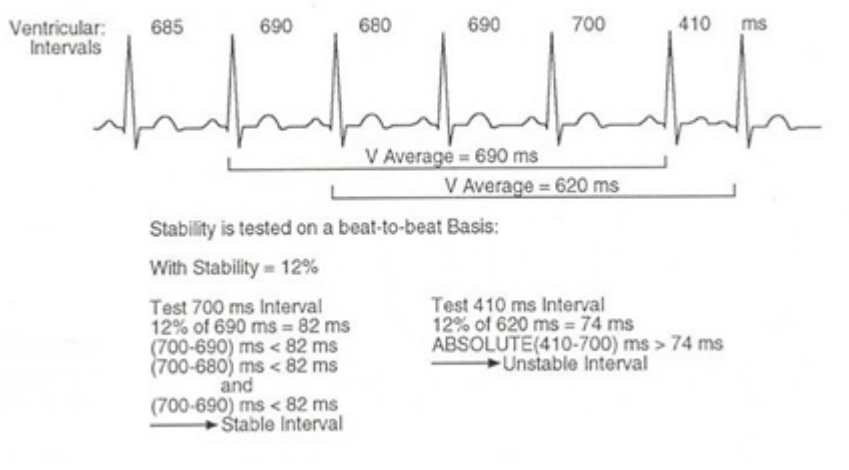

Figure 93: Calculation of ventricular stability with SMART Detection®

5.2.2 Trend AV

To determine whether a consistent pattern between the atrial and ventricular rhythms (AV association) is present, SMART Detection® measures AV trend (Figure 94).

When the atrial and ventricular rates are stable and equal, SMART Detection® determines whether an AV trend exists. With each new ventricular interval, the algorithm checks to see whether the four most recently measured AV intervals are in strict increasing or decreasing order (i.e., AV n < AV n-1< AV n-2 < AV n-3 or AV n > AV n-1> AV n-2 > AV n-3). This strict order defines AV creep or AV trend indicative of AV dissociation.

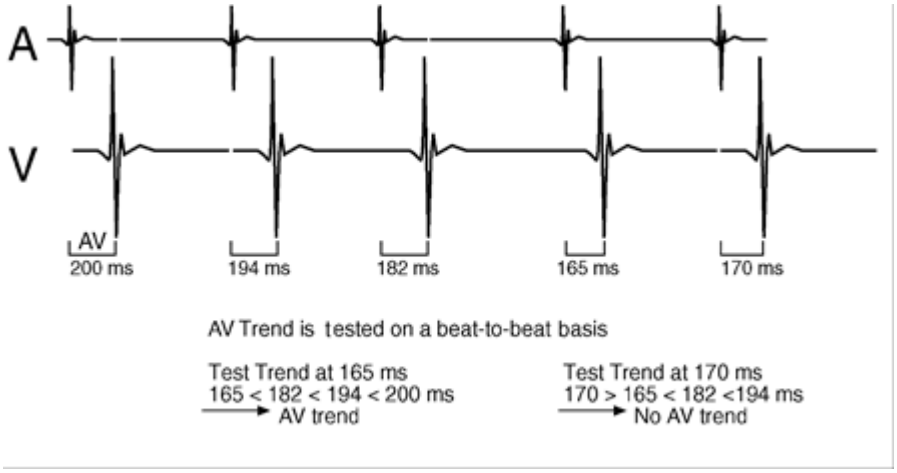

Figure 94: Calculation of AV trend

5.2.3 Sudden Onset

Sudden Onset is used in the SMART Detection® algorithm when the atrial and ventricular rhythms are stable and equal in rate to distinguish ventricular tachycardia from slow onset sinus tachycardia. By default, Sudden Onset is programmed at 20%.

Onset is programmable. Caution should be used when considering making a programming change. In the Rivacor ProMRI® ICD, Onset confirmation is activated when an event meets the Onset criteria. Once the first fast interval (in a tachycardia zone) meeting Onset criteria occurs, the device uses that interval and the next three additional intervals to determine a new four-interval average and compares that new average against the previous four-interval average. This function of Onset is designed to prevent single fast events (PVCs) from declaring Onset and providing inappropriate therapy to the patient.

Onset is satisfied only when the difference between the current four-interval average and the previous four-interval average exceeds the Sudden Onset value (Figure 95).

NOTE:

Sudden Onset is applied in the ventricular chamber only.

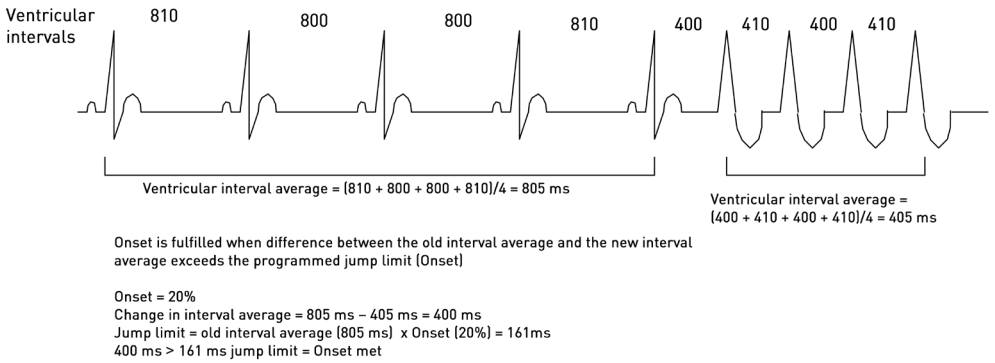

Figure 95: Calculation of sudden onset

5.2.4 Rate (Interval)

SMART Detection® uses a sliding average of intervals (Figure 96) (both in the atrium and ventricle) to compare the overall atrial and ventricular rates. This is used in SMART Detection® to determine whether the rates in the atrium and the ventricle differ from each other. The sliding average is calculated using the four most recently measured intervals in each chamber of the heart. With each new interval, the average is recalculated, deleting the oldest interval from the average and incorporating the most recently measured interval. In this way, the device has a window over time to assess atrial and ventricular rates.

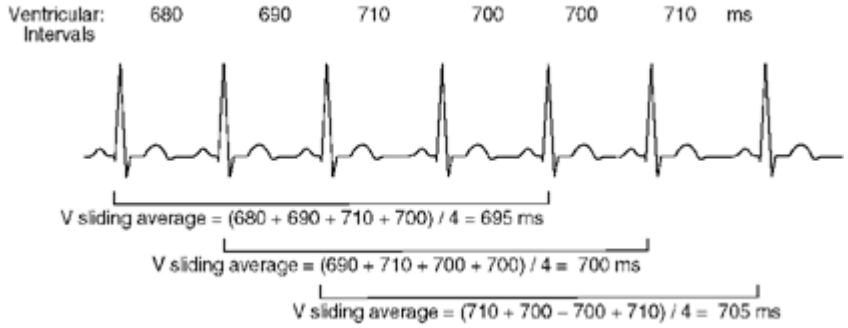

Figure 96: Calculation of the ventricular sliding average

5.2.5 Regularity (AV)

To determine whether a consistent pattern between the atrial and ventricular rhythms (AV association) is present, SMART Detection® measures AV regularity (Figure 97).

An AV interval is determined to be regular if the interval does not differ from the three preceding AV intervals by more than the AV limit. In other words, the device compares the current AV interval against the three previous without averaging. The AV limit is a predetermined value equal to one-half of the Stability limit, or 6%, by default.

In Figure 97, the Stability limit was 50 ms, making the AV Regularity limit 25 ms.

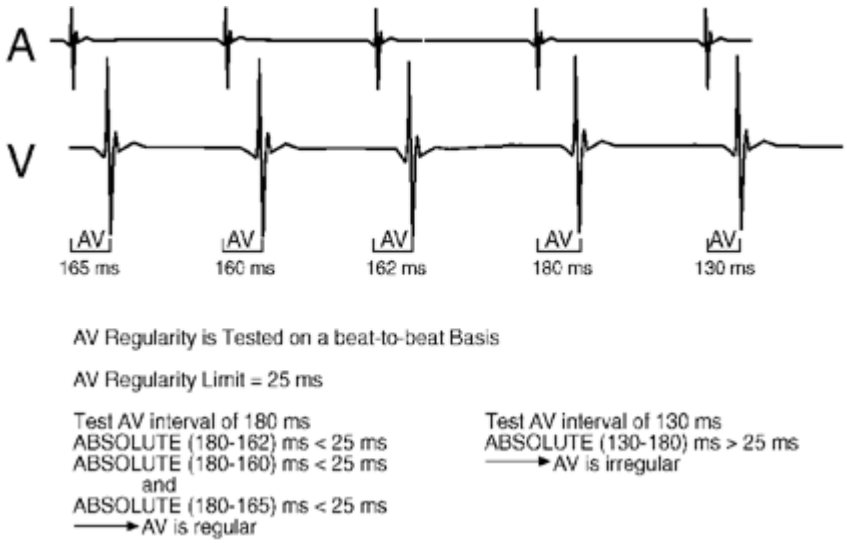

Figure 97: Calculation of AV regularity

5.2.6 Multiplicity

To determine whether atrial flutter is present, SMART Detection® looks for a consistent N:1 pattern (i.e., 2:1, 3:1, 4:1, etc.). An N:1 pattern, called Multiplicity, is confirmed when the average ventricular interval is found to be a multiple of the average atrial interval (with a tolerance of +/- 12 ms to allow for minor normal variances). Multiplicity, like all SMART Detection® criteria, is evaluated on a beat-to-beat basis.

Figure 98 shows how Multiplicity is evaluated. The ventricular average calculated on the fifth ventricular event is 500 ms. The corresponding atrial average is 250 ms. Consequently, Multiplicity is established for this event. As detection continues, each new interval is tested to determine whether the 2:1 pattern exists. (Remember, the tolerance for multiplicity is 12 ms. For example, if the atrial average is 250 ms then the ventricular interval must be between 488 ms and 512 ms to meet the 2:1 Multiplicity criteria.)

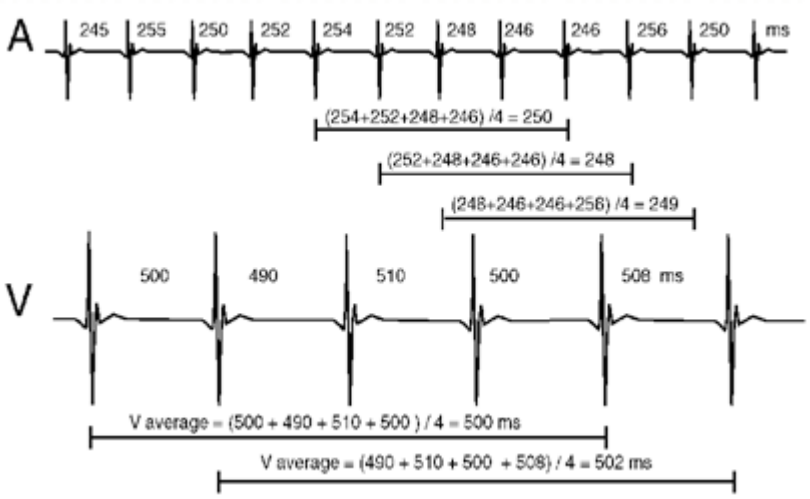

Figure 98: Calculation of Multiplicity

5.3 SMART Detection®

SMART Detection® is one of the most sophisticated detection algorithms available for the discrimination of ventricular tachycardia (VT) and supraventricular tachycardia (SVT). SMART Detection® (Figure 99) is designed to increase detection specificity (i.e., to increase the likelihood that atrial tachycardia is not declared a VT) without sacrificing sensitivity (i.e., the ability to detect and treat all VTs with therapy).

This translates into improved patient comfort and care from reduced inappropriate therapies. With SMART Detection®, inappropriate shocks for SVT are minimized without compromising accurate VT detection and therapy. Clinical studies demonstrated that SMART Detection® provided 100% sensitivity and 94% specificity.

Each time an interval is found to lie within one of the programmed VT zones, SMART Detection® follows a series of decisions to determine whether the interval meets the criteria for a VT count or an SVT count. VT intervals affect VT counters, while SVT intervals affect an SVT Counter. VT intervals are labeled with a VT1 or VT2 marker. SVT intervals are marked by one of four labels: AFib for atrial fibrillation, AFlut for atrial flutter, SinusT for sinus tachycardia, or 1:1 for atrial tachycardia.

Additional steps in the SMART tree, highlighted in yellow, determine between a biarrhythmia, a monomorphic VT with retrograde and a sinus tachycardia by evaluating the ventricular rate, AV regularity and VA interval lengths (Figure 99).

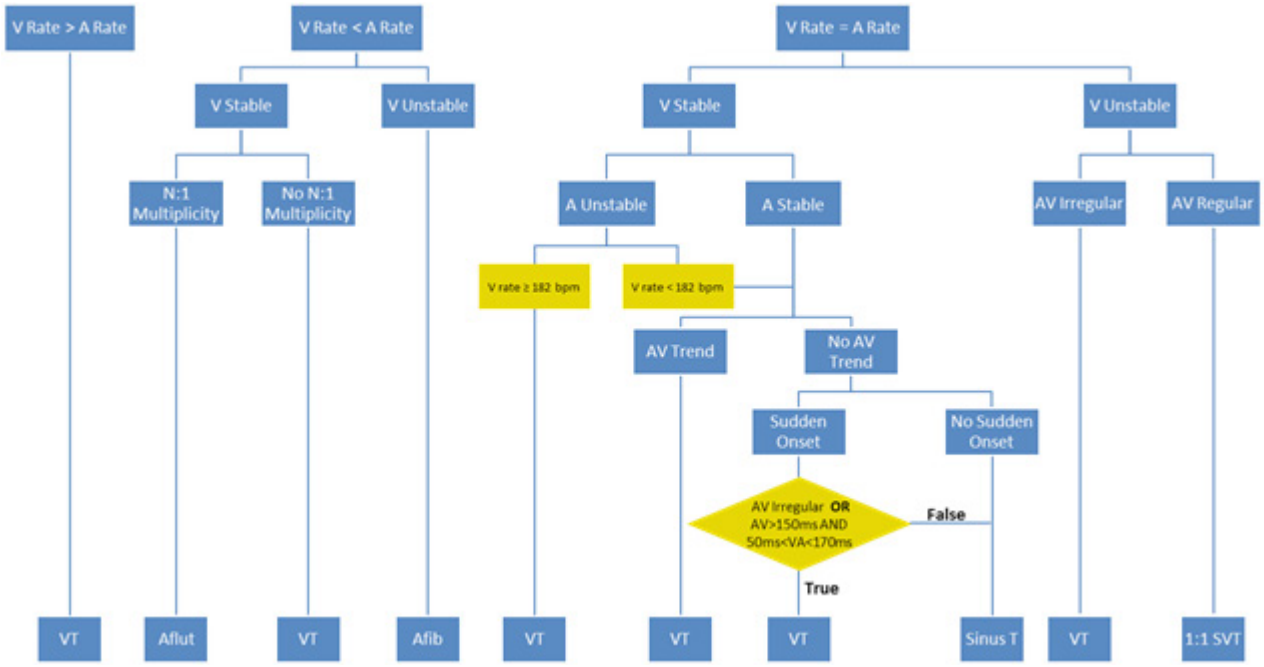

Figure 99: The SMART Detection® decision tree.

Most tachyarrhythmias will occur when the ventricular rates are not equal to the atrial rates. Monomorphic VT, atrial flutter, and atrial fibrillation are identified by these portions of the decision tree.

When ventricular and atrial rates are equal, discrimination of tachyarrhythmias is more difficult.

SMART Detection® uses two separate programmable VT Counters (i.e., one counter for VT1 and one counter for VT2). When the VT criteria are met and the interval lies in the VT1 zone, the VT1 counter increments by one (the VT2 counter is unaffected). When VT criteria are met and the interval lies within the VT2 zone, the VT1 and VT2 counter increment by one (i.e., since a VT2 interval is shorter/faster than the VT2 and VT1 limit, both counters increase). VF intervals "freeze" the VT counters.

SVT intervals decrement the VT counters. For initial detection, SMART Branch #2 (Aflutter) decrements the VT counter by one (-1), Branch #4 (Afib) decrements the VT counter by four (-4), Branch 8 (Sinus Tachycardia) decrements by 1/2 and Branch 10 (1:1 Unstable atrial tachycardia) decrement the VT counter by 1/4. For SMART® Redetection, the same counters are used as in initial SMART Detection®, except for Branch 10, which is decremented by 3/4 and Branch 8 which is decremented by 1/4. A summary of how different SVT events affect the VT counter is shown below.

Effects on VT Counters

	Atrial Flutter	Atrial Fibrillation	Sinus Tachycardia	1:1
Initial Detection	-1	-4	-1/2	-1/4
Redetection	-1	-4	-1/4	-3/4

Table 8: Effects on VT Counters

An SVT is declared when the SVT criterion are met. The detection criterion for SVT is twice the VT zone count. For example, if the VT1 zone is set to 16 intervals, it will take 32 SVT intervals in the VT1 zone for an SVT episode to be declared.

5.3.1 SMART Detection® Decision Examples

5.3.1.1 Detection of Monomorphic VT or Polymorphic VT (Branch 1)

Determining monomorphic VT (mVT) or polymorphic VT (pVT) is relatively simple because SMART Detection® can rely solely on the rate criteria.

When an mVT or pVT occurs alone (i.e., without an accompanying atrial arrhythmia or without retrograde conduction), discrimination is based on a comparison of rates - the ventricular rate is faster than the atrial rate. In general, a monomorphic VT has a slow atrial rate, an elevated ventricular rate, and a "regular" QRS morphology and regular R-R intervals. A polymorphic VT has a slow atrial rate and an elevated ventricular rate, but the QRS signal may vary in shape and amplitude.

5.3.1.2 Discrimination of Atrial Flutter (Branch 2)

Typically, VT is difficult for discrimination algorithms to identify when it occurs in the presence of an ongoing atrial arrhythmia. In the worst case scenario, VT could go unrecognized and untreated. However, SMART Detection® distinguishes these arrhythmias by carefully comparing atrial and ventricular rates and analyzing the relationship between intervals to classify VT without delay.

When SMART Detection® measures an interval in the VT zone and determines that the atrial rate is greater than the ventricular rate, a biarrhythmia or a supraventricular tachycardia (SVT) is suspected.

To classify the rhythm further, SMART Detection® looks at ventricular stability and multiplicity.

If the atrial rate is faster than the ventricular rate, and an N:1 relationship exists between the atrial and ventricular rates (i.e., there is a 2:1, 3:1, or 4:1 ratio within in a tolerance of +/- 12 ms), then the ventricular interval is classified as an atrial flutter beat and labeled with an AFlut marker. In other words, the algorithm assumes that the accelerated ventricular rate results from atrial flutter with some degree of AV block. An AFlut interval will decrement the VT Counter by one (-1).

5.3.1.3 Atrial Tachycardia or Fibrillation with VT (Branch 3)

Using SMART Detection®, a biarrhythmia (i.e., a concurrent atrial and ventricular arrhythmia) is identified along several branches of the SMART Detection® decision tree. The biarrhythmia in this section occurs when the atrial rate is greater than the ventricular rate, the ventricular rate is stable, and multiplicity cannot be established. When these conditions are met, a VT with concurrent atrial tachycardia or atrial fibrillation is identified. Each beat will be marked with a VT marker (Figure 102).

This branch uses the same criterion as described for the discrimination of atrial flutter in the previous section. However in this case, N:1 criterion was not met and the device declares the arrhythmia a VT.

5.3.1.4 Atrial Fibrillation (Branch 4)

Atrial fibrillation has more than one focus and by nature is irregular or chaotic with atrial intervals of varying lengths. In turn, these atrial intervals are conducted irregularly to the ventricles. SMART

Detection® identifies irregular conduction and declares atrial fibrillation when the atrial rate is greater than the ventricular rate and the ventricular intervals are unstable. Each ventricular interval is marked with an AFib marker. Therapy is withheld for the episode, and an IEGM is stored.

NOTE:

An event declared as Atrial Fibrillation will decrease the VT counter by four (-4) to reduce the potential of delivering inappropriate therapy.

5.3.1.5 VT with an Unstable Atrial Arrhythmia (Branch 5)

Once SMART Detection® identifies equal atrial and ventricular rates, atrial and ventricular stability is tested. In this branch, SMART uses other criteria to determine between VT or SVT by evaluating the ventricular rate. If the ventricular rate is stable, the atrial rate is unstable and the ventricular rate is greater than or equal to 182 bpm, the rhythm is disassociated and classified as a VT. If the ventricular rate is less than 182 bpm, atrial stability is considered fulfilled and the remaining SMART criteria in Branches 6, 7 and 8 are used to determine between VT or Sinus Tachycardia (Figure 99). During redetection, SMART will ignore the "Vrate ⩾ 182 bpm and Vrate < 182 bpm" criteria (shown in yellow in Figure 99) and only use atrial and ventricular stability to classify a VT event.

5.3.1.6 Concurrent Atrial Tachycardia with VT (Branch 6)

When atrial and ventricular rhythms are stable and equal in rate, several different rhythms may exist. If an AV Trend exists, (i.e., successive AV intervals are present in strict increasing or decreasing length), the atrial and ventricular rhythms are close in rate, but disassociated. The small but consistent difference between the atrial and ventricular rate causes the AV interval to gradually shrink or expand over time.

If the atrial rate is unstable with the ventricular rate less than 182 bpm, the algorithm will shift to Branch 6 and assess AV Trend. If AV trend exists, SMART will classify the rhythm as VT. If AV trend doesn't exist, the algorithm will continue to assess the rhythm using Branch 7 and Branch 8 criteria. As mentioned previously, SMART will ignore the "Vrate < 182 bpm" criteria during redetection and use AV Trend to classify a VT event.

5.3.1.7 Distinguishing VT from Sinus Tachycardia (Branch 7 and Branch 8)

When atrial and ventricular rates are equal and stable with no AV trend, SMART Detection® branches out to identify two different rhythms; monomorphic VT (mVT) with 1:1 retrograde conduction and sinus tachycardia (ST). If Sudden Onset is met, SMART will evaluate AV stability OR AV and VA intervals. If the AV interval is unstable, indicating AV disassociation, SMART will classify the beat as monomorphic VT with retrograde. If the AV interval is greater than 150 ms AND the VA interval is between 50 ms and 170 ms, SMART will classify the rhythm as VT. If none of these criteria are met, the algorithm will move to Branch 8 and label the rhythm as ST.

Since the ventricular rate may increase gradually in ST, SMART Detection classifies the rhythm as ST if the ventricular and atrial rates equal, if both atrial and ventricular rates are stable, if there's no AV trend and if Sudden Onset is not met. SMART Detection® identifies the rapid change in heart rate with the Sudden Onset criteria to distinguish monomorphic VT with retrograde conduction from ST. SMART will decrease the VT counter by -1/2 for any ST detection. During redetection, SMART will classify a beat as ST only if ventricular and atrial rates are stable, if there is no AV Trend and if Sudden Onset is not met. The criteria in yellow (Figure 99) will not be used during redetection.

5.3.1.8 Polymorphic VT with Retrograde Conduction (Branch 9)

Usually polymorphic VT occurs at higher rates than monomorphic VT. In addition, the QRS morphology and the rate are variable. When polymorphic VT is conducted back to the atrium on a beat-to-beat basis, instability in the ventricle is introduced into the atrium. Since the retrograde conduction is consistent and the intervals are unstable, the AV intervals become irregular

5.3.1.9 Multifocal AT with Antegrade Conduction (Branch 10)

In this SMART Detection® branch, as in the last, the ventricular rhythm is unstable, while the average atrial and ventricular rates are equal. However, now the AV intervals are regular or stable. This regularity suggests a direct AV association between the atrial and ventricular rhythms. In other words, the rhythm originates in the atrium, and therefore the rhythm is irregular atrial tachycardia with 1:1 antegrade conduction. In this case, each beat is labeled with a 1:1 marker, and therapy is appropriately withheld. An episode of atrial tachycardia is declared after twice the programmed VT Count is met.

5.3.2 Sustained VT Timer

A Sustained VT timer can be programmed as a "safety net" to override Onset and Stability in initial ventricular-only VT detection. The Sustained VT timer begins with the detection of a fast interval (i.e., an interval that falls into the VT or VF zones). When the timer expires, the rhythm is reevaluated using the single-chamber redetection criteria (i.e., using the Redetection Count without detection enhancements of Onset or Stability). If the redetection criterion is met, therapy is delivered based on what zone the tachyarrhythmia was met. The timer resets with arrhythmia termination. The parameter may be programmed between 1 minute and 30 minutes (default = OFF). A message is provided to show that detection was met due to the Sustained VT timer expiring.

Figure 100: Episode detail message for Sustained VT

SMART Detection® must be programmed OFF for the Sustained VT Timer value to appear.

While the Sustained VT value defaults to OFF, it is generally recommended to use the feature only when using Ventricular-only detection criteria.

NOTE:

When the Sustained VT Timer expires with two VT zones programmed, therapy is based on which VT Redetection Counter is satisfied (i.e., If the VT1 Redetection Counter is met, VT1 therapy is delivered. If the VT2 Redetection Counter is met, VT2 therapy is delivered).

5.4 VF Detection

The Rivacor ProMRI® ICD has a single VF zone. VF detection/redetection is based on the Interval/Rate limit and an "X out of Y" criterion. If X intervals within a rolling window of Y intervals are shorter (i.e., the rate is faster) than the VF detection Interval/Rate limit, then VF is declared and therapy delivered. The default setting for "X out of Y" is 18 out of 24. There are ten programmable options available in the Rivacor ProMRI® family for initial detection. The shortest setting is 6 out of 8 intervals and the longest is 30 out of 40 intervals. The default for redetection is 8 out of 12 intervals and the longest duration choice of 24 out of 30 intervals.

Values in which programming is not permitted will have a symbol in front of the value.

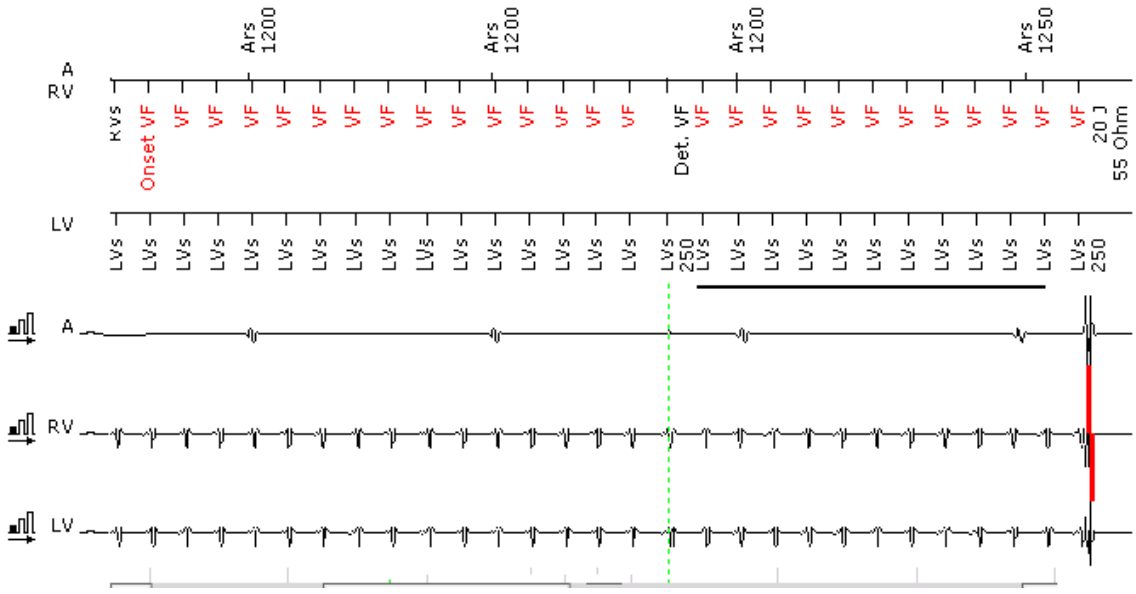

Figure 101: IEGM example of VF detection

Figure 101 shows an example of VF detection. In this example, the VF zone is programmed to 16 out of 20 events at an interval of 300 ms, or 200 bpm. One Vs event is seen after the first VF marker, shown in red. A sliding window of 12 intervals is continuously monitored for VF. VF is declared when 16 out of 20 intervals are found to be 300 ms or less. The green vertical line shows when the device declared VF. Below the VF markers, a bar appears that shows the device is charging to treat the VF.

5.4.1 VF Detection Hysteresis

This is used when a single therapy zone is used and only applies during charging. This feature is designed to prevent a shock from being aborted if 3/4 events occur outside the programmed detection zone by extending the VF zone by 60 ms. Confirmation must be programmed ON for this feature to be enabled.

5.5 Ventricular Tachyarrhythmia Redetection

Redetection begins after the first therapy in any arrhythmia zone is delivered. Thereafter, the redetection criteria are used to evaluate the cardiac signal until termination is declared or until all programmed therapy has been delivered. VT redetection uses programmable VT1 and

VT2 Redetection Counters. The VT Redetection Counters must be programmed to a smaller value compared to initial detection to speed redetection. However, to ensure appropriate detection in the VF zone, the Redetection Counters cannot be programmed below the "X" of the X in Y criteria for VF detection. Nominally, the Redetection Counter is programmed to 20 for the VT1 zone and 14 for the VT2 zone. VT redetection uses up/down counters, as with initial detection. VF redetection uses "X out of Y" criteria, as with initial VF detection.

5.5.1 SMART® Redetection

SMART® Redetection is automatically ON when SMART Detection® is programmed. It is used after VT therapy delivery to withhold further therapy if the delivered VT therapy resulted in an SVT. VT redetection with SMART® Redetection ON is based on the programmable Redetection Count; however, the counters are changed. A VT interval will increment the counter +1, a VF interval "freezes" the counter, and a Sinus interval decrements the counter by -1. SVT events will decrement the counter as in initial SMART® Redetection. The exception of behavior with SMART Detection® ON is Branch #10, which decrements by 3/4. SMART® Redetection will not use the discriminators "Vrate ⩾ 182 bpm and Vrate < 182 bpm" or the "AV unstable or AV and VA interval" criteria as shown in yellow in Figure 99. The Sustained VT timer is not utilized when SMART® Redetection is ON, but rather a Forced Termination timer is used. An Example of SMART® Redetection is shown in Figure 102.

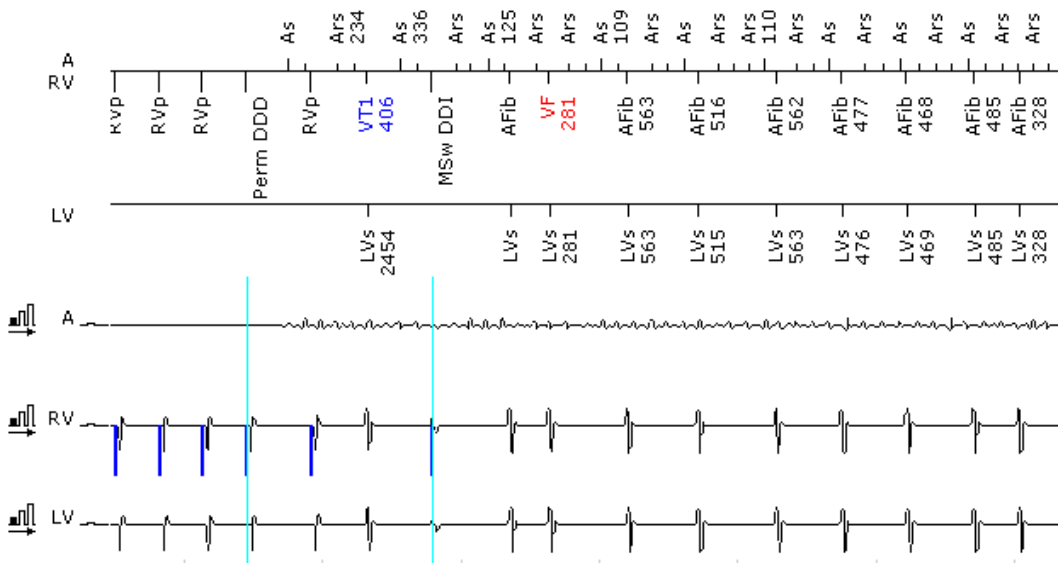

Figure 102: SMART® Redetection

Figure 102 shows a detected VT treated with ATP. The result of the therapy was atrial fibrillation. Because SMART® Redetection is ON, no therapy will be delivered while the AFib continues.

5.6 Ventricular Tachyarrhythmia Termination

Tachyarrhythmia termination is based on a non-programmable "X out of Y" termination criterion of 12 in16. Termination is declared when twelve intervals out of a sliding window of 16 intervals are longer (i.e., the rate is slower) than the lowest programmed cutoff interval/rate limit with therapy. If

12 long intervals are measured before the first window of 16 intervals, termination is declared with the twelfth interval. Following termination, detection starts anew, and all programmed therapy is available for treatment.

If a VT Monitoring Zone is programmed, intervals in the VT Monitoring Zone count toward termination and do not count towards redetection. For example, a VT Monitoring Zone is programmed to 130 bpm, a VT2 zone at 150 bpm and a VF zone at 200 bpm. Termination of the arrhythmia will occur when 12 of 16 events are slower than the VT 2 zone (150 bpm). This behavior is appropriate, as there is no therapy programmed for a VT Monitoring Zone.

5.6.1 Forced Termination Timer

The purpose of the Forced Termination timer is to reset therapies after a successful ventricular arrhythmia termination results in an SVT. In this way, all programmed therapies will be available should the arrhythmia revert back to a VT/VF.

If an SVT occurs after successful termination of VT/VF and SMART® Redetection is used, no therapy will be delivered for the SVT during redetection. If the SVT remains when the Forced Termination timer expires, the device will declare the end of the episode. If the VT/VF returns before the Forced Termination timer expires, the arrhythmia will be treated with the next programmed therapy.

When the Forced Termination timer expires, the current event is logged as terminated and all therapy is reset. A message stating "Term" will appear at the end of the IEGM recording, as shown in Figure 104. The device will then record a new SVT episode provided the SVT is still present and SVT IEGM storage is ON.

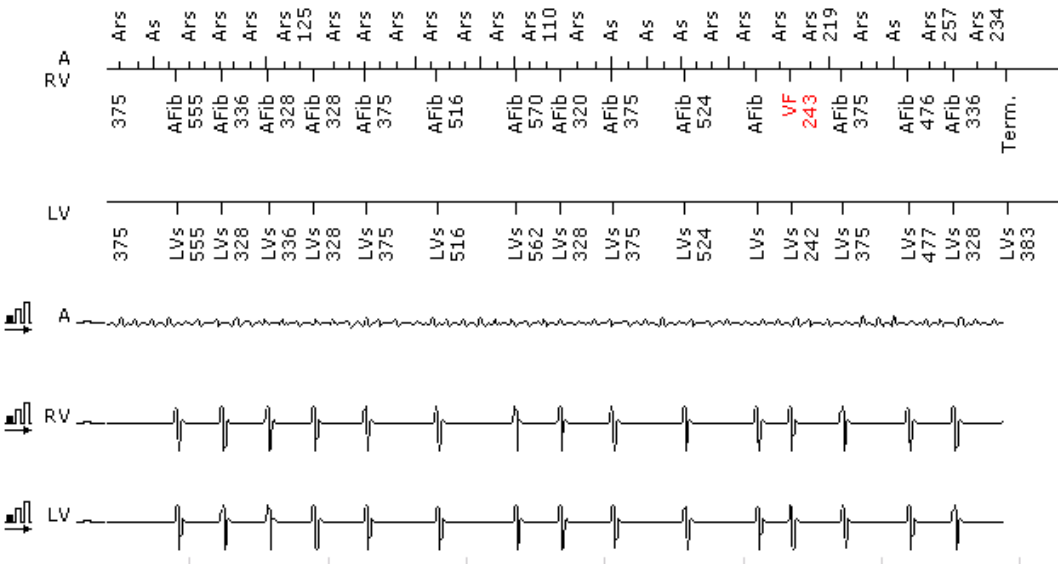

Figure 103: Example of forced termination with annotation

In addition to the annotation of the IEGM, the episode details will also provide a Forced Termination message.

Figure 104: Forced termination message in the episode details

The Forced Termination timer is set to one minute and is neither programmable nor visible on the programmer screen.

5.7 Monitoring Zones

In addition to programming ATP and/or shocks for VT zones, the user may program the Rivacor ProMRI® ICD with a monitoring zone in the VT1 zone only. A monitoring zone cannot be programmed in the VT2 zone.

The monitoring zone may be used to look for non-sustained VTs. Monitoring zones are programmed the same as standard VT1 zone programming except that ATPs and therapy energies are not provided. Monitoring zone programs may also include the programming of SMART Detection®, as well to look for SVTs that may not be previously known.

To program a VT1 monitoring zone, select the monitoring zone rate or interval and the detection count criterion. Ensure that all ATPs and energies are turned OFF.

NOTES:

Trigger pacing in Rivacor ProMRI® HF-T CRT-Ds cannot be programmed into a monitoring zone. There is no reduction in longevity using a monitoring zone.

Chapter 6: Tachyarrhythmia Therapy

The Rivacor ProMRI® ICDs/CRT-Ds offer a variety of therapy options that can be tailored to meet a patient's specific atrial or ventricular therapy requirements. Anti-tachycardia pacing (ATP) therapies can be combined with defibrillation therapies to provide a broad spectrum of tachyarrhythmia treatment options for ventricular tachyarrhythmias. ATP therapies and HF burst options are available for atrial tachyarrhythmias in the Rivacor ProMRI® DR-T and CRT-D devices.

Atrial therapy programming for Rivacor ProMRI® DR-T and CRT-D

Zone	ATP	Therapy programming
AT	OFF, Burst, Ramp	Burst - programmable number of S-1 and P-S1 interval Ramp - programmable number of S-1, P-S1 interval and S1 decrement Back-up pacing available
AF	OFF, HF Burst	Programmable frequency and duration Back-up pacing available

Table 9: Atrial therapy programming for Rivacor ProMRI® DR-T and CRT-D

6.1 Atrial Anti-tachycardia Therapies *(Not applicable in Rivacor 5)*

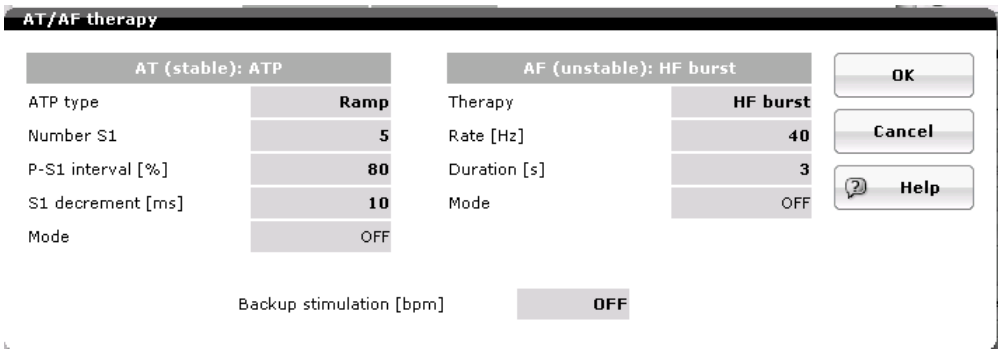

Figure 105: Atrial therapies screen

6.1.1 ATP Schemes

OFF, Burst, Ramp

Atrial ATP is a feature that allows the physician to program a single ATP therapy for a stable rhythm in the AT Zone. The rhythm in the AT zone must be regular (+/- 40 ms), such as atrial flutter or sinus tachycardia.

In general, ATP therapies consist of a series of pacing pulses delivered in predetermined (adaptive) intervals. In theory, ATP pulses are delivered to interrupt the atrial flutter or sinus tachycardia to slow the atrial rate.

The Rivacor ICD/CRT-D allows one atrial ATP attempt per episode in an attempt to terminate the atrial tachycardia.

6.1.2 HF Burst

OFF, HF Burst

HF burst is an option for atrial therapy that allows the physician to program a train of very fast atrial pacing pulses in an attempt to terminate atrial fibrillation. The physician can program the rate, expressed in hertz (Hz), as well as duration (in seconds).

6.2 Ventricular Antitachycardia Pacing Therapy (ATP)

Ventricular therapy programming for Rivacor ProMRI®

Zone	ATP 1	ATP 2	Shock 1	Shock 2	Shock 3 - Nth	Shocks per zone
VT1	OFF, Burst, Ramp	OFF, Burst, Ramp	OFF, 2-40 J	OFF, 4-40 J	OFF, 4*40 J; 6*40 J	0, 1, 2, 6 or 8
VT1	OFF, Burst, Ramp	OFF, Burst, Ramp	OFF, 2-40 J	OFF, 4-40 J	OFF, 4*40 J; 6*40 J	0, 1, 2, 6 or 8
VF	OFF, Burst, Ramp	N/A	2-40 J	4-40 J	4*40 J; 6*40 J	6 or 8

Table 10: Therapy programming for Rivacor ProMRI®

6.2.1 ATP Schemes

Burst, Ramp

ATP Enhancements: Add S1, Scan Decrement

In general, all ATP therapies consist of a series of pacing pulses delivered in predetermined (adaptive) intervals. In theory, ATP pulses are delivered to interrupt reentrant tachycardias. As a result, ATP is most effective in terminating slow, monomorphic, re-entrant VTs. An ATP scheme is considered least aggressive (least likely to terminate) and safest (least likely to accelerate the rhythm) when the pulse number is low and the intervals are fixed. Conversely, an ATP scheme is considered the most aggressive (most likely to terminate) and potentially dangerous (most likely to accelerate) when the pulse number is high and the intervals are varied. The device does not differentiate the hierarchy of ATP programming in the device. This allows the user to program ATP therapies to meet a specific patient's needs.

The Rivacor ProMRI® ICD can be programmed to deliver ATP in the configuration schemes of Burst or Ramp. ATP enhancements of Add S1 and Scan decrement are available. The Rivacor ProMRI® ICD allows the programming of two ATP schemes per VT zone, in any combination. The pulse amplitude and pulse width for all ATP pulses is 7.5 V and 1.5 ms, respectively, while the pacing mode is VOO. The pacing configuration for ATP can be programmed in either the RV or BiV configuration in HF-T devices. In HF-T devices, the user may program one ATP to deliver RV only pacing and the other to deliver BiV pacing.

The ATP Type, Number of Attempts, Number of S1 pulses, and R-S1 Interval parameters define each ATP scheme. In addition, the S1 Decrement, S1-S2 Interval, and Add S1 parameters can be programmed as shown below in Table 11.

Ventricular ATP programming options

ATP Type	Burst	Ramp
Attempts	OFF, 1 ... (1) ... 10	OFF, 1 ... (1) ... 10
Ventricular pacing (HF-T only)	RV, BiV	RV, BiV
Number of S1	1 ... (1) ... 15	1 ... (1) ... 15
Add S1	ON/OFF	ON/OFF
R-S1 Interval	70 ... (5) ... 85, 88, 90, 95%	70 ... (5) ... 85, 88, 90, 95%
S1 Decrement	N/A	5...(5)...40 ms
Scan Decrement	OFF, 5 ... (5) ...40 ms	OFF, 5 ... (5) ... 40 ms

Table 11: ATP programming options

ATP Programming

The R-S1 interval is programmed as an adaptive value of the last interval average. The R-S1 interval equals the S1-S1 interval; the S1-S1 interval cannot be programmed independently. If the rate of an arrhythmia increases or decreases between detection and redetection in the adaptive ATP mode, the ATP intervals will adapt to the new arrhythmia interval.

Typically, the ATP interval most likely to cause termination is just shorter (faster rate) than the interval length of the arrhythmia. Therefore, it is often desirable to program ATP intervals that are tachycardia-specific, which is the adaptive mode expressed as a percentage – nominally at 80%. For ATP One-shot, the adaptive percentage is 88%.

Burst

An ATP Burst scheme is the simplest of ATP forms. It is a series of pulses whose S1-S1 interval is constant. The S1-S1 interval may change between successive trains if the ventricular tachyarrhythmia rate changes.

Figure 106 shows a Burst ATP scheme. The initial S1-S1 interval and the R-S1 interval are calculated to the same value based on the intrinsic R-R average of 400 ms. More precisely, the R-S1 interval and S1-S1 interval are both calculated to 320 ms, or 80% of 400 ms.

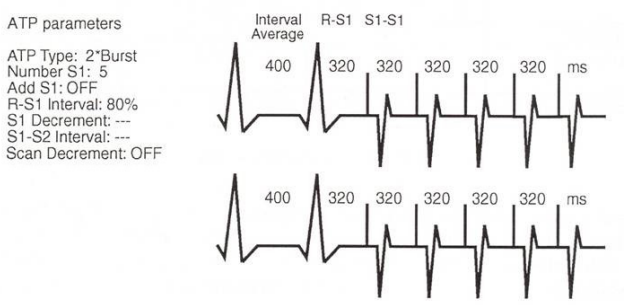

Figure 106: Burst ATP scheme

Ramp

An ATP Ramp scheme is a series of pulses whose S1-S1 intervals vary within a single train. To modify the S1-S1 interval, the S1 Decrement is programmed. For example, when the S1 Decrement is programmed to 20 ms, the S1-S1 interval shortens by 20 ms with each successive pulse within the train.

The Ramp scheme in Figure 107 consists of two attempts with five ATP pulses. The R-S1 interval and first S1-S1 are 80% of the R-R average of 400 ms, which equals 320 ms. Since the S1 Decrement is programmed to 10 ms, the second S1-S1 is 10 ms less than 320 ms (320 -10 = 310 ms). The third S1-S1 interval is 10 ms less than the second interval (310 – 10 = 300 ms). The final interval is 10 ms less than the third interval (300 – 10 = 290 ms).

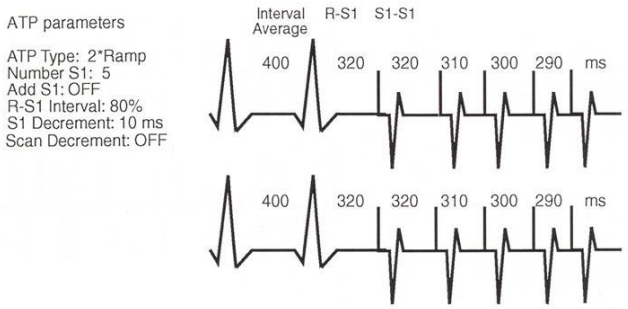

Figure 107: Ramp ATP scheme

ATP Enhancement - Scan Decrement

The Scan Decrement ATP enhancement can be programmed with each ATP scheme available. When Scan Decrement is programmed with the Burst and Ramp options, the R-S1 and S1-S1 intervals decrease by the programmed amount between each successive ATP attempt within a given VT episode. Figure 108 and Figure 109 illustrate a 10 ms Scan Decrement with a Burst and Ramp scheme. For the second Ramp shown, note that the S1 Decrement is based on the newly calculated R-S1 and S1-S1 intervals.

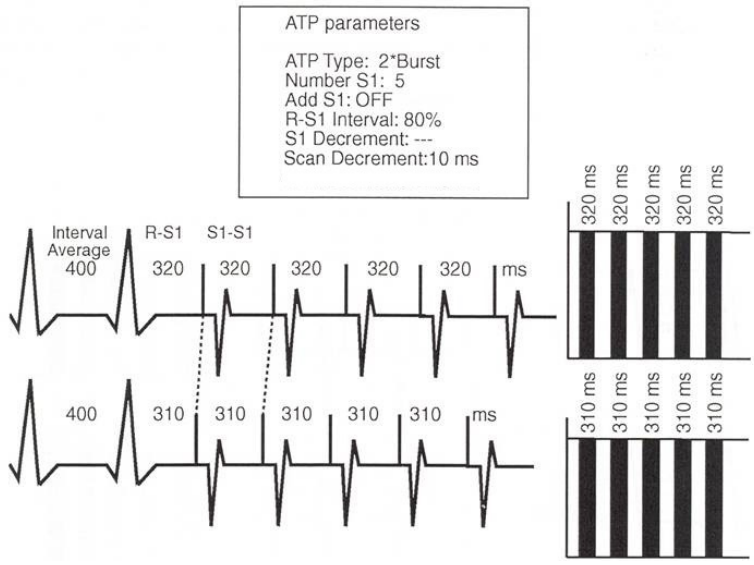

Figure 108: The Scan Decrement programmed with a Burst ATP scheme

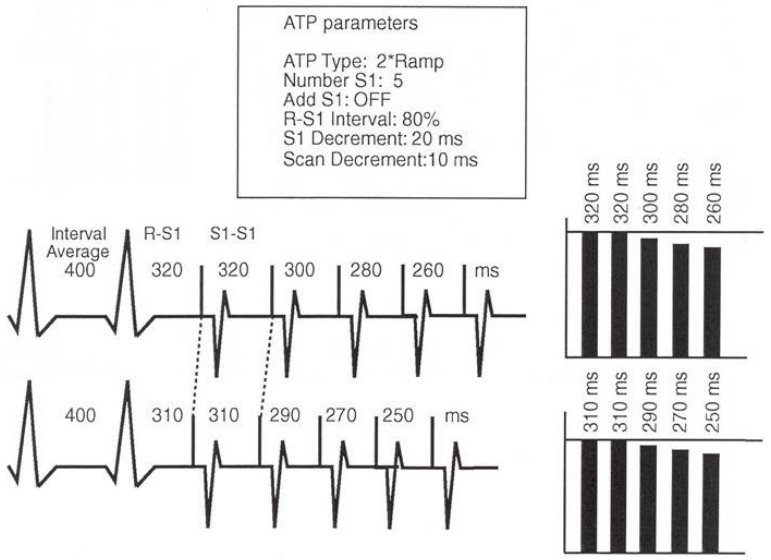

Figure 109: The Scan Decrement programmed with a Ramp ATP scheme

ATP Enhancement - Add S1

Add S1 is programmed ON by default in the Rivacor ProMRI® ICD. When Add S1 parameter is programmed ON, the number of S1 pacing pulses increments by one with each successive ATP delivery. The new S1-S1 interval length is dependent on the programmed ATP parameters and the optional scan parameter (if applicable).

6.2.2 ATP One-Shot

Default **ON** with Burst ATP, S1 to 8 paced events, R-S1 interval at 88%.

ATP One-Shot is a feature that allows the physician to program a single ATP therapy for a stable rhythm in the VF zone prior to charging. The rhythm in the VF zone must be regular (12%), such as a stable monomorphic VT. Once the ATP is delivered, charging begins. During charging, the device looks to see if the arrhythmia has terminated (Figure 110). If termination has occurred, charging is aborted once three sinus intervals (out of four) occur.

ATP One-Shot allows the user to select different types of ATP to be delivered (Figure 111). Additionally, the user can select the same options as can be programmed for standard ATP delivery. The minimum pacing interval for ATP One-Shot is 200 ms, the same as the minimum pacing interval for VT ATP.

Within the ATP One-shot screen, an option for early ATP delivery is available. When VF detection counters of 16 out of 20 or greater are programmed, turning on early ATP delivery will result in ATP therapy delivery when 12 out 16 events + stability criteria are met. If unsuccessful, the VF counters will continue until met. Once met, the device will charge to deliver shock therapy.

6.2.2.1 Early ATP Delivery for ATP One-shot

When long VF detection counts are programmed, the device allows the option of programming early ATP to provide therapy before the full detection count is met. When early ATP is programmed ON with a long VF count, the device will deliver the programmed ATP One-shot therapy when 12 out of 16 events, plus stability, are met.

If the tachycardia is not terminated with the ATP therapy, the device will charge when the programmed VF criteria is met. ATP pulses will not count towards the VF count.

NOTE:

ATP One-Shot is disabled after four consecutive unsuccessful attempts. To re-enable ATP One-Shot, simply interrogate the device again with a programmer.

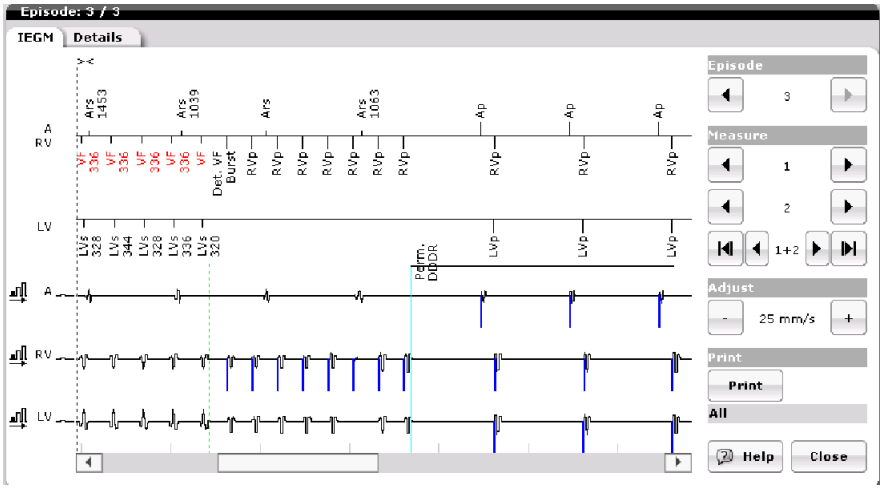

Figure 110: Example of ATP One-Shot

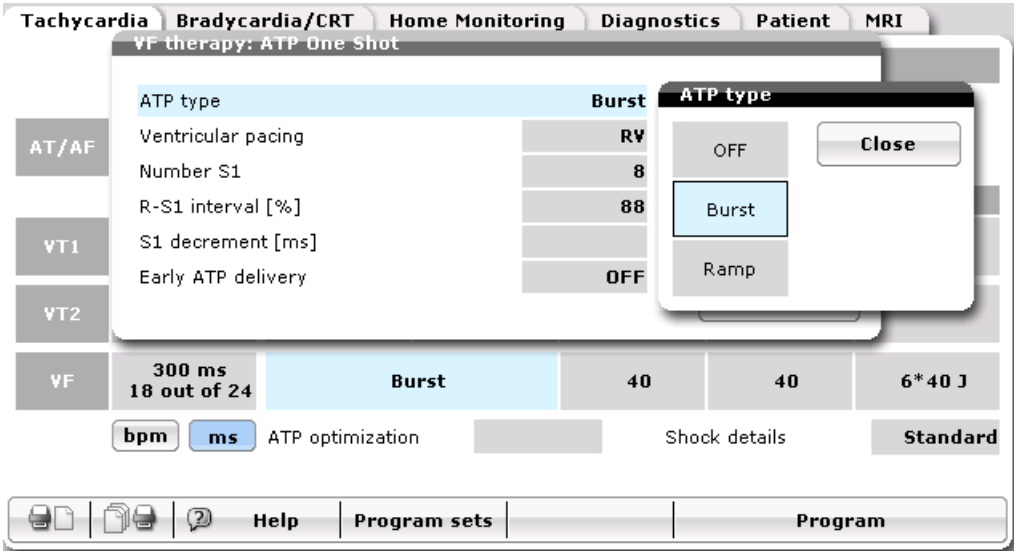

Figure 111: ATP One-Shot type options

6.2.3 ATP Optimization

ON, **OFF**

Located on the bottom center of the tachycardia screen and only programmable when an ATP is programmed.

ATP Optimization counts the number of successes for each programmed ATP scheme and assigns future ATP delivery based on the highest success counts for each attempt on the highest success count per sequence to the lowest. Optimization potentially limits ineffective ATP attempts and reduces time to effective therapy. ATP Optimization applies to all programmed VT zones.

If Ramp ATP therapies were programmed with four attempts, the device counts the number of successes for each attempt. For example if ATP1 had three successes, ATP2 had one success, ATP 3 had four successes and ATP 4 had zero successes, the sequence for the next therapy would be ATP3>APT1>ATP2>ATP4.

ATP Optimization is programmed in the Tachycardia section. The parameter choices will not appear unless an ATP scheme has been programmed. While ATP Optimization cannot be programmed separately for VT1 and VT2, a successful ATP scheme is independently determined for each zone when the parameter is activated. Delivered shock therapy and device reprogramming will reset a stored ATP scheme. ATP Optimization blocks any ATP scheme that accelerated a rhythm until at follow-up ATP parameters are adjusted or are unblocked.

NOTES:

In VT zones, the ICD/CRT-D stores successful ATP therapies only. The stored information includes not only the number of the ATP therapy (e.g., ATP2), but also the successful configuration in detail (for example: Burst; R-S1 Interval: 320 ms, S1-S1 Interval: 320 ms; etc.).

If an ATP attempt accelerates the rhythm, that ATP attempt will not be used in subsequent VT therapy deliveries.

6.2.4 ATP Help

Found on VT1, VT2, and VF (with ATP One-shot ON) screens

ATP Help is a useful tool to assist the physician in choosing and confirming appropriate ATP programming. When the ATP Help button is pressed, a histogram is displayed on the programmer screen for ATP therapy in the given VT zone. The histogram displays the intervals for each scheme programmed. Placing the cursor over a bar will provide the interval for a given event.

The displayed intervals are based on the programmed zone interval. This interval may be changed to reflect the VT rate for a given patient. To change the interval, select the current VT interval value on the "help" page. A pop-up screen will appear. Chose a specific VT interval. The screen will update to show current values.

An example depicting an ATP Burst and Ramp is shown in Figure 112. To prevent ATP intervals from becoming too short (due to programming of the adaptive parameters) and promoting tachyarrhythmias, a Minimum (ATP) Interval is used. In the Rivacor ProMRI® ICD family, the Minimum Interval for the ATP 200 ms for all zones, including the ATP One-Shot used in the VF zone. The Burst is programmed with five S1 pulses and Add S1 programmed ON. The interval lengths are labeled based on a VT rate of 370 ms (as highlighted in the upper center portion of the graph).

The value shown above the cursor indicates the interval based on programming and a specific VT value.

The arrow keys allow the user to move the cursor left and right to view a specific value throughout the ATP schemes.

The thin black horizontal line on the screen indicated the programmed minimum ATP interval of the device. By default, the minimum ATP interval is 200 ms for all zones including the VF zone.

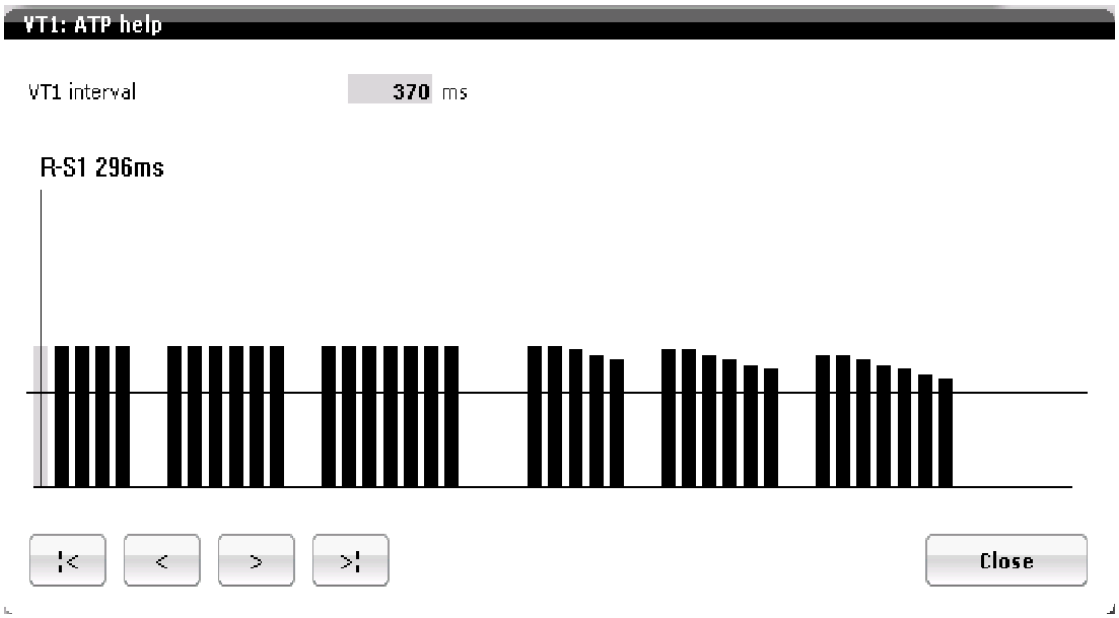

Figure 112: ATP Help

6.2.5 Minimum ATP

To prevent ATP intervals from becoming too short (due to programming of the adaptive parameters) and promoting tachyarrhythmias, a Minimum (ATP) Interval is used. In the Rivacor ProMRI® ICD family, the Minimum Interval for ventricular ATP is 200 ms for all zones, including the ATP One-Shot used in the VF zone.

If an ATP pulse within an ATP scheme is calculated such that the S1-S1 interval violates the Minimum Interval (i.e., is shorter than the programmed minimum), the ATP pulse will be delivered at the Minimum Interval and not the calculated interval.

6.3 Ventricular Shock Therapy

VT1: OFF, 1,2, 6 or **8** shocks, First two shocks with programmable output
VT2: OFF, 1,2, 6 or **8** shocks, First two shocks with programmable output
VF: 6 or **8,** First two shocks with programmable output

Shock therapy programming by zone for Rivacor ProMRI® ICD/CRT-D

	VT1	VT2	VF
Programmable shocks per zone	0, 1, 2, 6 or 8	0, 1, 2, 6 or 8	6 or 8
Maximum programmable energy stored (delivered)	0 J (36.9 J)	40 J (36.9 J)	40 J (36.9 J)
Confirmation*	ON/OFF	ON/OFF	ON/OFF
Polarity*	Normal, Reverse, Alternating starting with Normal, Alternating starting with Reverse	Normal, Reverse, Alternating starting with Normal, Alternating starting with Reverse	Normal, Reverse, Alternating starting with Normal, Alternating starting with Reverse
Waveform*	Biphasic, Biphasic 2, Biphasic alternating, Biphasic 2 alternating	Biphasic, Biphasic 2, Biphasic alternating, Biphasic 2 alternating	Biphasic, Biphasic 2, Biphasic alternating, Biphasic 2 alternating
Shock pathway (applies to all zones)	RV→SVC/Can, RV→Can, RV→SVC		

Table 12: Shock Therapy programming by zone for Rivacor ProMRI® ICD/CRT-D

The Rivacor ProMRI® ICD will allow programming of one to eight shocks in the VF zone for induction testing. This is done through the temporary VF therapy section of the DFT screen.

6.3.1 Standard Biphasic Shock Waveform

For the biphasic shock, the initial charging voltage is 100%, the phase switching voltage is equal to 40% of the initial voltage, and the cutoff voltage is 20% of the initial voltage. The voltage used is automatically calculated based on the programmed shock energy.

Because the waveform is voltage-controlled, the pulse width of each phase varies with the shock lead impedance — the larger the impedance, the longer the pulse width. For a standard biphasic shock waveform, the pulse width maximum limit equals 23 ms for the first shock phase and 17 ms for the second phase.

Sixty percent of the initial voltage is delivered in phase 1 (i.e., (100 - 40) / 100 = 60% delivered) — also defined as tilt. Fifty percent of the remaining energy is delivered in phase two (i.e., (40 - 20) / 40 = 50% delivered) — also defined as tilt. Therefore, the waveform may be described as a voltage-controlled shock with a (fixed) 60/50 tilt.

* Confirmation, Polarity and Waveform can be all programmed based on VF zone programming or independently programmed when checking the Configure zones separately box on the Shock details screen.
† Dual coil lead needs be confirmed for this pathway.

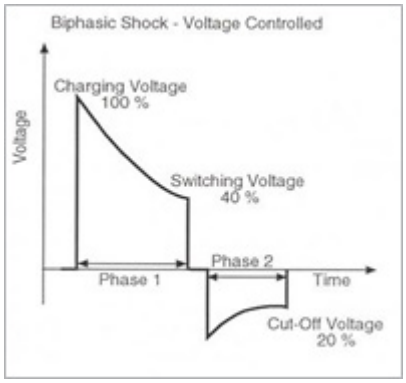

Figure 113: Rivacor ProMRI® ICD Biphasic Shock Waveform

6.3.2 Biphasic 2 Shock Waveform

For a biphasic 2 waveform, the initial charging voltage is 100%, the switching voltage is equal to 40% of the initial voltage, and the cutoff voltage for phase 2 is time-controlled at 2 ms. The voltages are automatically calculated based on the programmed energy.

The Biphasic 2 programmable shock waveform option offers an additional option for lowering defibrillation thresholds. A study by Merkely et al, showed that the Biphasic 2 waveform may help lower DFTs in patients on Class III antiarrhythmic drugs*.

Refer to Table 13 for a summary of shock waveforms offered in Rivacor ProMRI® ICDs.

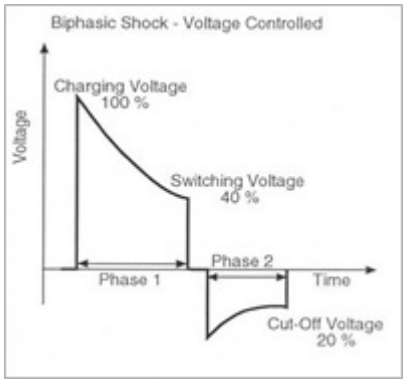

Figure 114: Biphasic 2 shock waveform

Rivacor ProMRI® Shock Waveforms

Shock Waveform		Phase 1 (Voltage)	Phase 2 (Voltage/Time)
Biphasic	Start	100%	40%
	End	40%	20%
Biphasic 2	Start	100%	40%
	End	40%	2 ms

Table 13: Rivacor ProMRI® Shock Waveforms

* Merkely B et al. 2001. Jour of Cardiovascular Electrophysiology, 12(7).

The shock waveform programming choices described in Table 13 are shown in Figure 115.

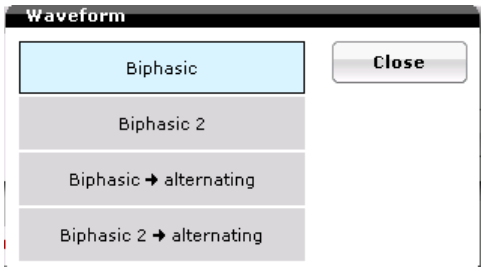

Figure 115: Shock waveform programming choices

6.3.3 Maximum Capacitor Charge Time

The maximum capacitor charge time (i.e., capacitor reformations and defibrillation shocks) is 20 seconds. This means that after charging for 20 seconds, the ICD will deliver the energy that is stored in the capacitors, regardless of whether it is fully charged. This could result in delivering less energy for a tachycardia episode than was programmed for the device.

An excessive charge time may be associated with component failure or depleted battery, and the physician or sales representative is alerted that further device analysis is necessary.

6.3.4 Uncommitted Shocks (Confirmation ON by default)

Independently programmable by zone when Configure zones separately is selected.

Rhythm classification continues through the charging period when shock Confirmation is programmed to ON. If the device detects three slow intervals (i.e., sinus or brady events) out of four during charge, then the device aborts shock therapy. The device then begins the redetection/termination process.

If one fast event is seen after charging but before three slow events are seen, the shock is delivered 30 ms after the tachyarrhythmia event.

Confirmation in Rivacor ProMRI® ICDs applies to all shocks within the programmed VT or VF zone. Confirmation can be separately programmable for each therapy zone.

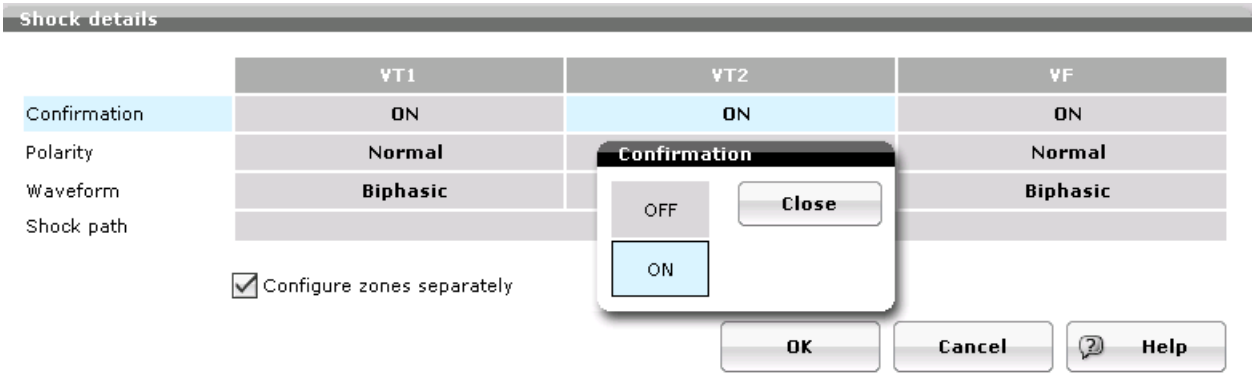

Figure 116: Confirmation

When programmed ON, the first shock in the detected tachycardia zone is uncommitted. Each time a shock is delivered, the next therapy automatically becomes uncommitted. Each time a shock is aborted, the next shock is automatically committed. From the third shock on, when a shock is aborted, the next delivered shock will be the same in the sequence. For example, if the third shock was aborted, the

next delivered shock will be the third programmed shock of the sequence. The device will not allow two aborted shocks in a row to occur. This is a safety feature, should intermittent undersensing of a tachyarrhythmia be present, to prevent therapy inhibition.

Aborted charge energy is slowly released and may take up to 10 minutes to bleed off. Redetection and shock therapy delivery before the stored energy has bled off may result in a shorter charge time. This is due to a "topping off" of the capacitors as opposed to a full programmed energy charge. The symbol to display the "topping off" of the capacitor is the "^" symbol, which is shown on the shock table page.

Figure 117 shows five different shock scenarios for an uncommitted shock. Shock is delivered in the first three cases, since the abort conditions are not satisfied. In each instance, the shock delivery occurs on a tachyarrhythmia event. The last two examples show aborted shocks.

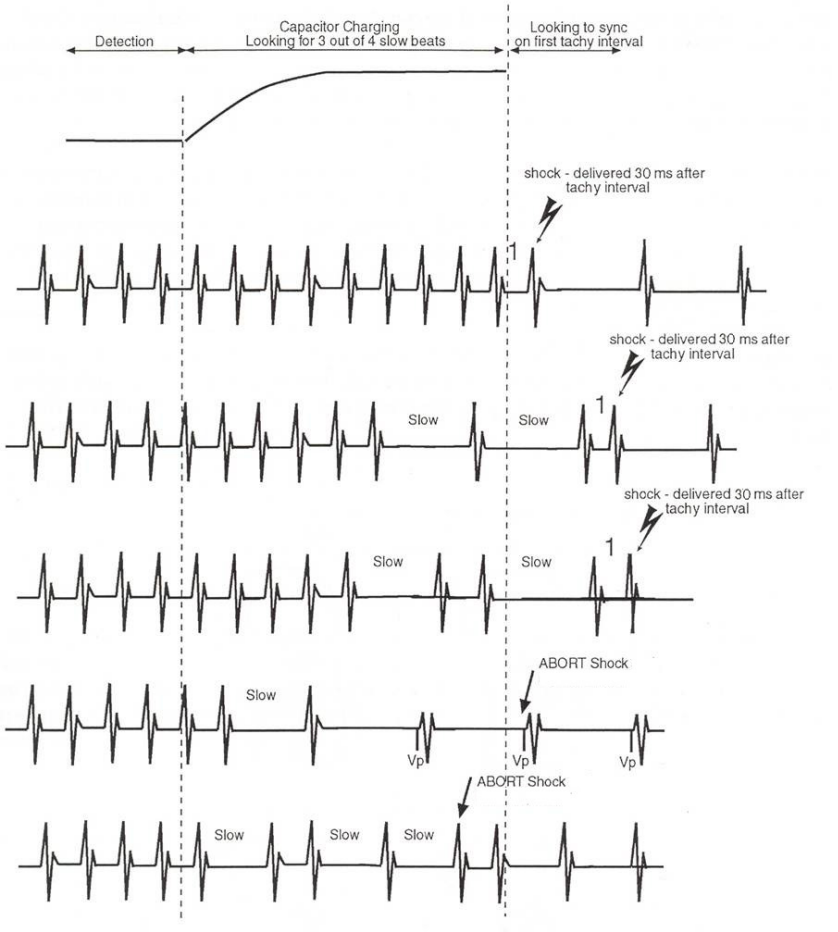

Figure 117: Shock delivery with Confirmation programmed ON

NOTE:

Pacing events, as well as sinus events, are seen as "slow" events. Therefore, if the rhythm breaks during charging and pacing results, shock therapy aborts after three paced beats.

6.3.5 Committed Shocks (Confirmation OFF)

Independently programmable by zone when Configure zones separately is selected.

A committed shock is a shock delivered after detection and charge. There is no attempt to recheck or verify the rhythm prior to shock delivery. The device tries to synchronize with the first ventricular event (sensed or paced). However, if synchronization is not possible, the device delivers the shock asynchronously within two seconds.

Rivacor ProMRI® Shock Types

Shock Type	Confirmation	Shock Delivery
Committed	OFF	R-wave synchronization attempted Shock can NOT be aborted/dumped
Uncommitted	ON	R-wave synchronization attempted Shock aborted/dumped if 3 out of 4 intervals are slower than the slowest tachy therapy zone during the charge One fast tachy event after charging is required to deliver energy

Table 14: Rivacor ProMRI® Shock Types

6.3.6 Shock Polarity

Normal, Reversed, Normal alternating or Reverse alternating

Independently programmable by zone when Configure zones separately is selected.

The shock polarity refers to the direction of current flow between electrodes during shock delivery. The Shock Polarity parameter is programmable to Normal, Reversed, or Normal/Reverse alternating within each tachyarrhythmia zone (e.g., it can be programmed for all shocks within VT1, VT2 and the VF zone). Because the shock polarity can significantly affect defibrillation thresholds in some patients, the DFT may be tested in more than one configuration.

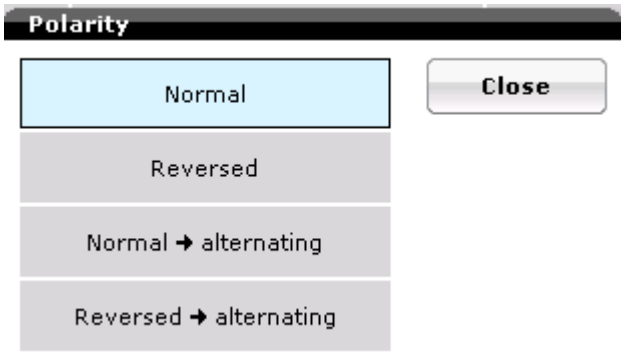

Figure 118: Polarity choices

When a single-coil lead is implanted and polarity is programmed to Normal, current flows from the active can — the anode — to the distal shock coil — the cathode. When the polarity is programmed to Reversed, the current flows from the distal shock coil to the active can. This reverses the polarity of the two shock phases in the biphasic waveform so the first phase is negative and the second phase positive.

When a dual-coil lead is implanted and the polarity programmed to Normal, then current flows from the "hot can" to the ventricular apex, as well as from the proximal shock coil to the ventricular apex. The active can and the SVC coil are always electrically tied together. If the configuration is Reversed, current flows in the opposite direction.

When programmed to Normal alternating, the device starts with Normal polarity and will alternate between Normal and Reversed. Reversed alternating with start with Reversed polarity first, then alternate between Reversed and Normal.

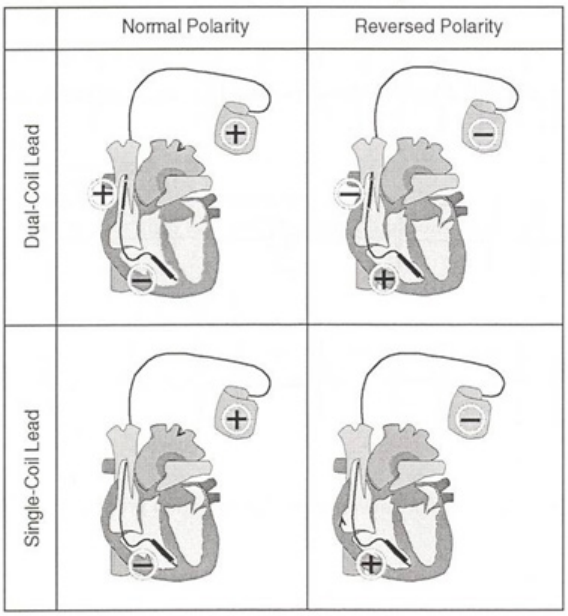

Figure 119: Normal and Reversed shock polarities

6.3.7 Shock Pathway Programming for the Rivacor ProMRI® Series ICD/CRT-D

The Rivacor ProMRI® ICD/CRT-Ds allow the user to program different shock vectors to provide additional options for patients with high DFTs. The device provides shock pathway configurations, as seen in Figure 120. If selecting the RV to SVC option, a release button will appear, asking the user to select "release". This is designed to remind and prevent users from selecting this option when a single-coil lead is implanted.

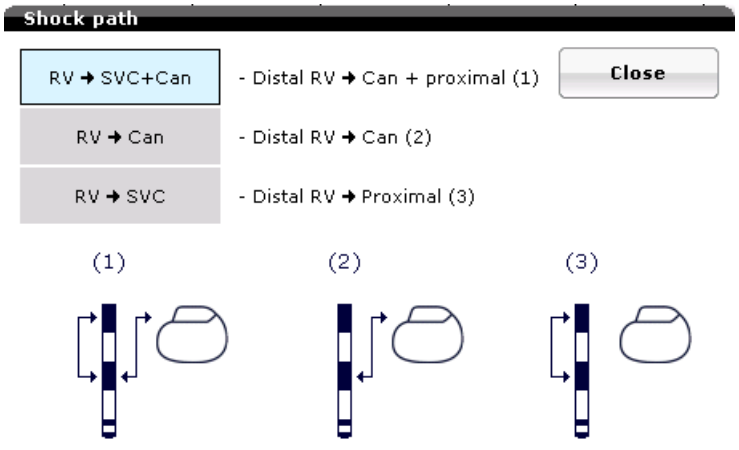

Figure 120: Programmable Shock pathways

6.4 Therapy Progression

Progressive Course of Therapy is automatically enabled (ON) whenever a VT Zone therapy is activated.

Therapy within an episode will always be delivered more aggressively with Progressive Course of Therapy. Once shock therapy is delivered, all ATP therapy in the VT zone is suspended, allowing therapy to progress to programmed shock therapy. As illustrated in Figure 132, if shock therapy is delivered and redetection occurs within a slower zone (with the shock energy less than or equal to that of the first shock), then therapy will continue with the next greater output shocks through termination.

The full complement of shocks is available in the lower zone. In the scenario shown in Figure 121, each zone has six shocks programmed. If the 25 joule shock in the VF zone results in a VT1 tachycardia, the device will be able to deliver six shocks in the VT1 Zone for a total of seven shocks for the episode.

If a shock has already been delivered within an episode and redetected in a zone with ATP only, the ATP will be delivered, as long as the ATP scheme has not led to acceleration earlier in the episode. Therefore, programming an "ATP only" zone instead of "monitor only" will allow slow VTs to only be treated by ATP. It will also aim to treat slow VTs caused by previous shock delivery.

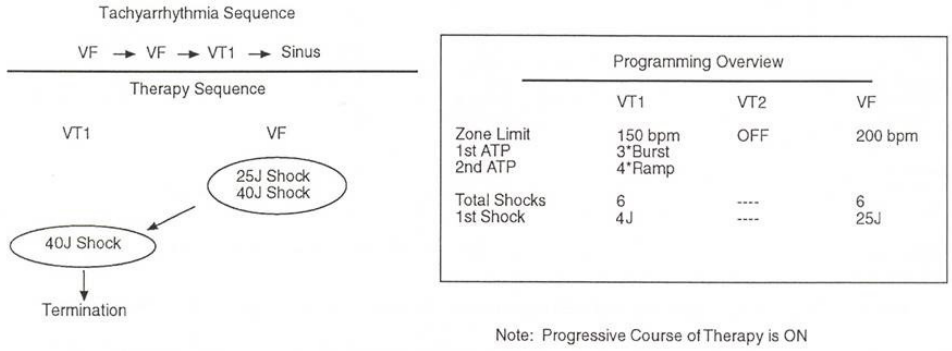

Figure 121: Therapy sequence with Progressive Course of Therapy

6.5 Post-Shock Pacing

Nominal Settings:

For VVI mode, 60 bpm, 10-second duration, 7.5 volts @ 1.5 ms (non- programmable).
For DDI mode, 60 bpm, AV Delay 140 ms, 10-second duration, 7.5 volts @ 1.5 ms (non-programmable), RV pacing.

Post shock pacing	
Post-shock duration	OFF, **10 s**, 30 s, 1 min, 2 min, 5 min, 10 min
Post-shock mode	**DDI**, VDI
Post-shock basic rate (bpm)	30 ... (5) ... **60** ... (5) ... 100 ... (10) ... 160 bpm
Post-shock AV delay (ms)	50 ... (10) ... **140** ... (10) ... 350 ms (DR-T and HF-T)
Post-shock ventricular pacing	**RV**, BiV (Rivacor ProMRI® HF-T)

Table 15: Post shock pacing

A one-second post-shock blanking period follows each shock delivery (i.e., blanking does not follow aborted shocks). During the blanking period there is no detection, which limits possible polarization effects being sensed as an arrhythmia. At the conclusion of the post-shock blanking period, Post-Shock Pacing begins.

Post-Shock Pacing is delivered in the DDI mode when the Normal Pacing mode is DDD(R), DDI(R), or AAI(R). The Post-Shock mode is VDI when the Normal Pacing mode is VDD(R) or VDI(R). When the Normal Pacing mode is VVI(R), the Post-Shock mode is VVI.

The Post-Shock Pacing duration is programmable in time between OFF and 10 minutes, with a default of 10 seconds. After the Post-Shock Pacing period is complete, normal bradycardia pacing resumes. (See Figure 122)

The Rivacor ProMRI® HF-T allows biventricular pacing to be programmed during the post-shock period.

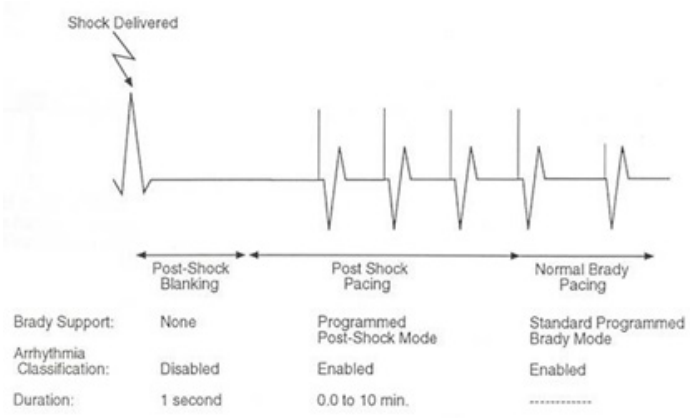

Figure 122: Post-Shock Blanking and Pacing

NOTE:

If the Post-Shock pacing rate is programmed higher than the basic rate, the pacing rate will gradually decrease using the sensor rate decrease value once the post-shock pacing time has expired. This prevents sudden drops in pacing rates.

6.5.1 Shock Energy

The Rivacor ProMRI® ICDs/CRT-Ds are designed to charge to the energy selected on the programmer screen, but similar to all other commercially available ICDs/CRT-Ds, the actual therapy delivered is somewhat less depending on several factors including the shock lead impedance. The first two shock energies in each therapy class are programmable between 2 joules and maximum energy for the first shock and 4 joules and maximum energy for the second shock. The energy of the second shock is always greater than the first shock. The remaining shock energies will be delivered at maximum programmable energy.

Actual energy delivered for each programmable shock energy is approximately equal to the "Energy Delivered" for the high-energy Rivacor ProMRI® models in Table 16.

Delivered Shock Energy

Programmed Energy (joules)	Approximate Delivered Energy (joules)
1	0.8
2	1.7
3	2.6
4	3.4
5	4.3
6	5.2
7	6.1
8	7.0
9	8.0
10	8.4
11	10.0
12	10.2
13	11.1
14	12.0
15	12.8
16	14.0
18	15.6
20	17.1
22	19.2
24	21.0
25	22.0
26	22.8
28	24.5
30	26.4
32	28.4
34	30.1
35	31.3
36	32.4
38	34.1
40	36.4

Table 16: Delivered Shock Energy (Rivacor ProMRI®)

CAUTION

Shock Impedance - If the shock impedance is less than 25 ohms (25 Ω), reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has measured shock impedance as less than 25 ohms. Damage to the device may result.

Defibrillation Threshold - Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Shock Therapy Confirmation - Programming CONFIRMATION to OFF may increase the incidence of the ICD/CRT-D delivering inappropriate shocks.

Chapter 7: Bradycardia Therapy

The Rivacor ProMRI® ICDs/CRT-Ds have independently programmable single-, dual- and triple-chamber and post-shock pacing functions. The post-shock bradycardia parameters may be programmed to higher rates or output values for the period following a delivered shock, without significantly compromising the longevity of the ICD/CRT-D for patients who require chronic bradycardia pacing. The post-shock programmable values are presented in Section 7.11 and differ from the normal bradycardia pacing support values.

7.1 Bradycardia Pacing Modes

The available bradycardia pacing modes for each device in the Rivacor ProMRI® ICD/CRT-D family are listed in Table 17.

Rivacor ProMRI® Pacing Modes

Mode	Rivacor ProMRI® HF-T and HF-T QP	Rivacor ProMRI® DR-T	Rivacor ProMRI® VR-T
DDDR	X	X	N/A
DDD-CLS*	X	X	N/A
VVI-CLS*	X	X	X
DDDR-ADIR	X	X	N/A
DDD-ADI	X	X	N/A
DDIR	X	X	N/A
VDDR	X	X	X
VDIR	X	X	X
AAIR	X	X	N/A
VVIR	X	X	X
DDD	X	X	N/A
DDI	X	X	N/A
VDD	X	X	X
VDI	X	X	X
DOO	X	X	N/A
VOO	X	X	X
AAI	X	X	N/A
VVI	X	X	X
OFF	X	X	X

*CLS not applicable in Rivacor 5

Table 17: Rivacor ProMRI® Pacing Modes

The basic rate timer is started by a sensed or paced event. A sensed event outside of the refractory period inhibits pacing and resets the lower rate time; in the absence of a sensed event, a pacing pulse will be delivered at the end of the lower rate interval.

The pacing modes with an "R" indicate rate-adaptive pacing controlled by a motion-based capacitive sensor. These modes are functionally the same as the corresponding non-rate-adaptive modes, except that the pacing rate is increased based on physical activity.

7.2 Basic and Hysteresis Rates

Basic Rate: 30 ... (5) ... **60** ... (5) ... 100 ... (10) ... 160 bpm (DR-T, HF-T and HF-T QP)

Basic Rate: 30 ... (5) ... **40** ... (5) ... 100 ... (10) ... 160 bpm (VR-T)

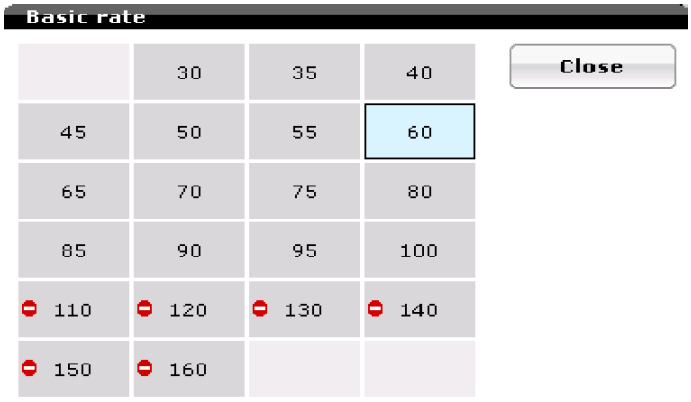

Figure 123: Basic Rate

Rate Hysteresis: **OFF**, -5 ... (-5) ... -25, -45, -65 bpm

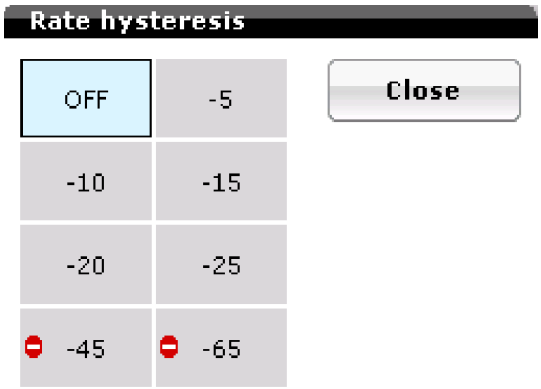

Figure 124: Rate Hysteresis

Both a Basic Rate and a Hysteresis Rate may be programmed for normal bradycardia pacing. The Hysteresis Rate, lower than the Basic Rate, is the lowest intrinsic rate permitted before the device begins pacing. With a hysteresis rate programmed, two escape intervals are created. The first escape interval is controlled by the lower rate timer and begins after paced events. The second escape intervals are determined by the hysteresis escape interval and after intrinsic events (Figure 125).

The Basic Rate may be programmed between 30 and 160 bpm, while the Hysteresis Rate may be programmed between -5 and -65 bpm (or to OFF).

NOTE:

A conflict message appears if the combination of the Basic Rate and the Hysteresis Rate is less than 30 bpm.

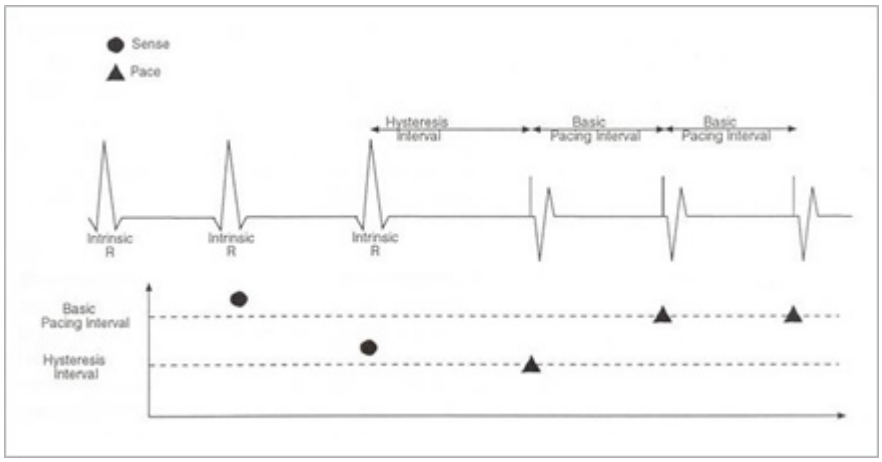

Figure 125: The Basic and Hysteresis intervals with VVI pacing

7.2.1 Scan and Repetitive Rate Hysteresis

Scan/Repetitive Hysteresis: OFF; ON at 10 events (non-programmable)

Both Scan and Repetitive Rate Hysteresis are available in the Rivacor ProMRI® ICD. These features encourage a patient's own rhythm, periodically allowing for or looking for intrinsic activity.

Scan Rate Hysteresis searches for a spontaneous rhythm during long periods of pacing. The algorithm is activated after 180 consecutive paced events. After this time, the device will pace at the slower hysteresis rate for 10 consecutive beats. If intrinsic activity does not occur above the hysteresis rate, then pacing will continue at the programmed bradycardia rate.

When Repetitive Rate Hysteresis is activated and pacing has been inhibited for at least 180 beats and the rate drops to the hysteresis rate, the device will pace consecutively for 10 beats at the slower hysteresis rate. If intrinsic activity is found, pacing will be inhibited until the rate falls again below the hysteresis rate. If no intrinsic activity is present, pacing will resume at the programmed basic rate.

NOTE:

Scan and Repetitive hysteresis are not independently programmable.

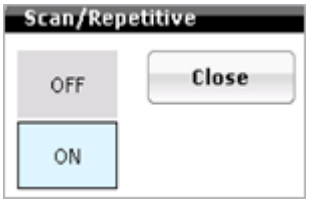

Figure 126: Scan/Repetitive Hysteresis choices

NOTES:

If rate adaptation is active, the Hysteresis rate is based on the current sensor-indicated rate minus the Rate Hysteresis value. 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. Night Rate is the limit for the Hysteresis when Night Mode is active. 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 are below what is appropriate and may be tolerated by the individual patient.

Repetitive and Scan Hysteresis are only available when Hysteresis is selected ON. There is one Standard Hysteresis interval which occurs before the programmable number of Repetitive Hysteresis.

7.2.2 Night Rate

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

To reduce the pacing rate to match decreased metabolic needs during sleep, the Rivacor ProMRI® ICD can be programmed to Night Rate. When Night Rate is active, the base pacing rate automatically decreases during the programmed nighttime hours. The Night Rate is programmable from 30 to100 bpm. When Night Rate is started, the base pacing rate will be reduced by the rate sensor decrease value to the Night Rate value.

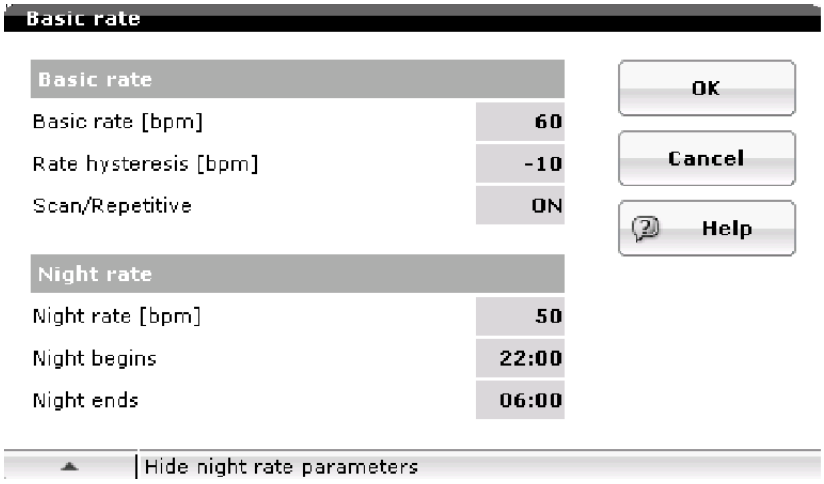

Figure 127: Night rate screen

NOTES:

During the Night Program, Rate Hysteresis is limited to the night rate mode. All AV hysteresis options remain as programmed. The Night Program remains in effect in Magnet mode.

The Night Mode time is based on the programmer clock. Therefore, the programmer time should be checked prior to device programming. If a patient travels across different time zones, the Night Mode time may require adjustment.

7.3 I-Opt

Programmable from the AV hysteresis parameter screen in the Rivacor ProMRI® DR-T ICD Max AVD – 400 ms (fixed)

Scan/Repetitive Hysteresis – ON (at 5 events, non-programmable)

I-Opt (intrinsic optimization) is a feature found in the Rivacor ProMRI® DR-T ICD to promote ventricular intrinsic rhythm. The feature is found under the AV hysteresis parameter when an atrial tracking mode is selected. When programmed, the hysteresis AV Delay is set to a fixed value of 400 ms, regardless of programmed AV Delay. It uses the AV Hysteresis functions as described in Section 7.3, with fixed scan and repetitive AV hysteresis values of 5.

NOTE:

This feature is not available in the Rivacor ProMRI® VR-T/HF-T devices.

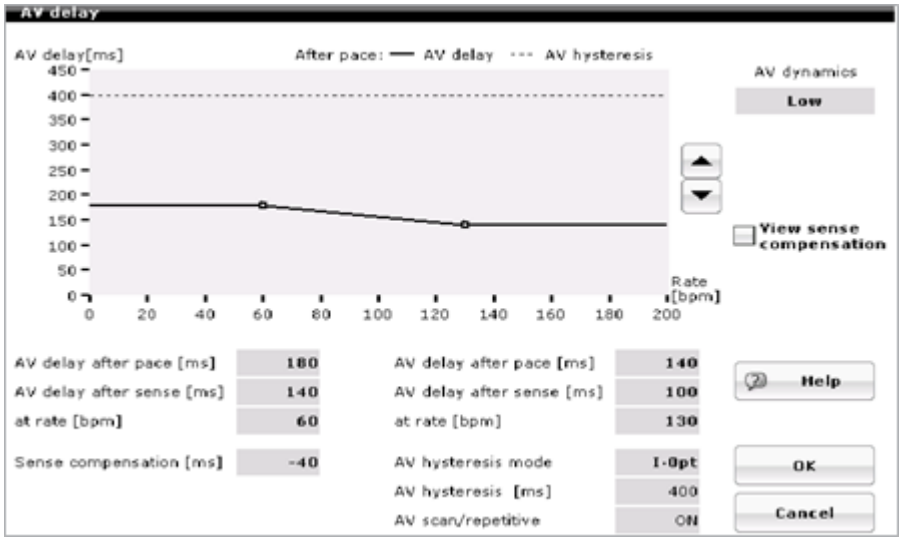

Figure 128: AV Delay Screen with I-Opt ON

7.4 Closed Loop Stimulation (CLS) *(Not applicable in Rivacor 5)*

The Rivacor ProMRI® ICD/CRT-D family 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 translation of myocardial contractility into patient-specific pacing rates.

When in CLS mode, the pulse generator 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 pulse generator can provide a pacing rate that is appropriate and specific to the patient's physiologic demands.

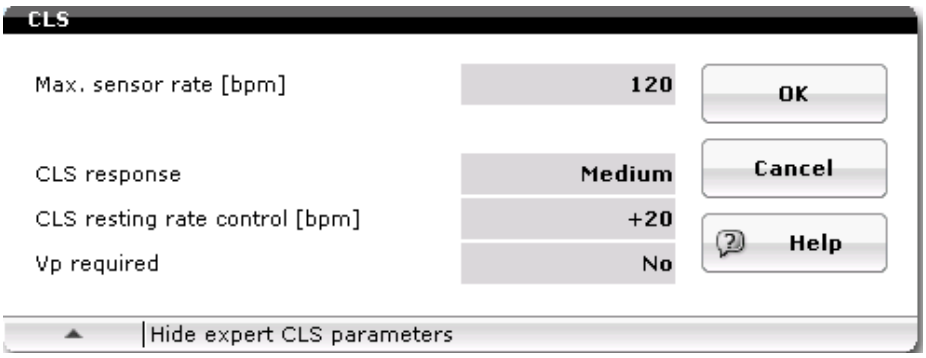

Figure 129: CLS Parameter Screen

7.4.1 Maximum (CLS) Sensor Rate

80 ... (10) ... **120** ... (10) ... 160 bpm

The maximum CLS sensor rate is the highest pacing rate that may be achieved with sensor activity and should be programmed based on the patient's activity level. This value must be less than the programmed Upper tracking rate value.

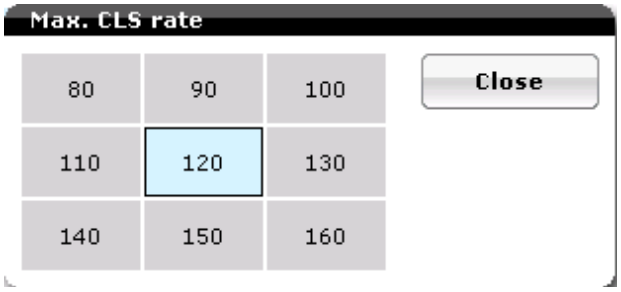

Figure 130: CLS Sensor Rate Screen

7.4.2 CLS Response

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

CLS response determines the rate curve for a patient based on their activity. While medium works well for most patients, inactive patients may require a lower setting, while more active patients may require a higher setting.

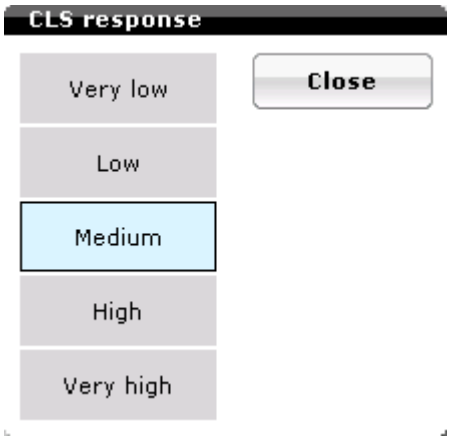

Figure 131: CLS Resting Rate Control

7.4.3 CLS Resting Rate Control

OFF, +10, **+20** ... (+10) ... +50 bpm

This is the maximum allowable rate increase (compared to basic rate), if the accelerometer does not recognize any physical motion/movement.

7.4.4 Vp Required

Yes, **No**

This parameter allows the device to update the CLS algorithm for paced and sensed events. When programmed to No, the device modulates the AV interval to ensure the algorithm is using current data. Vp required to yes may be selected in patients complete heart block as no underlying rhythm may be present.

7.5 Rate Adaptation Using an Accelerometer

The Rivacor ProMRI® ICD/CRT-D uses a capacitive accelerometer as its activity sensor. The sensor drives the generator to pace according to a patient's physical demands (i.e., the higher the demand, the higher the pacing rate). The sensor rate can be optimized for each patient by specifying both a Sensor gain and Sensor threshold.

7.5.1 Maximum Sensor Rate

80 ... (10) ... **120** ... (10) ... 160 bpm

The maximum sensor rate is the highest pacing rate that may be achieved with sensor activity and should be programmed based on the patient's activity level. This value must be less than the programmed Upper tracking rate value.

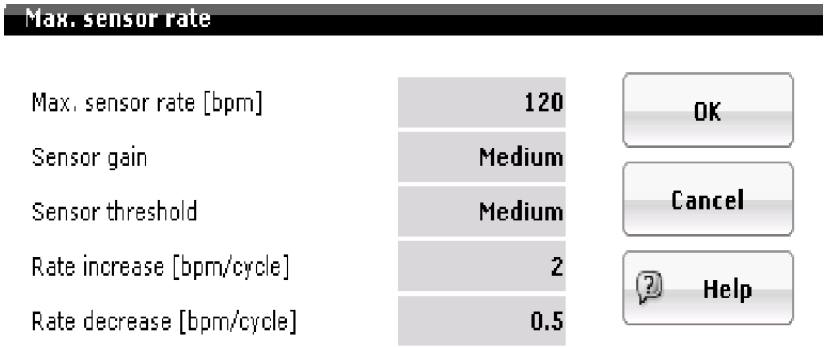

Figure 132: Sensor Parameter Screen

7.5.2 Sensor Gain

Auto, Very low, Low, **Medium**, High, Very High

NOTE:

Numbers in parenthesis are not shown on the programmer screen. The Sensor Gain, also known as response factor, defines how much the sensor signal is amplified before it is transformed to a rate change. The Sensor Gain can be programmed to Auto or to a fixed setting. When the Sensor Gain is Very low (1.3), a great deal of exertion is needed to cause a significant change in sensor output and a subsequent change in the pacing rate. When the Sensor Gain is Very high (26), little exertion is needed to increase the sensor output. Ideally, the gain should be programmed so that the maximum desired pacing rate during exercise occurs at a maximum exertion level.

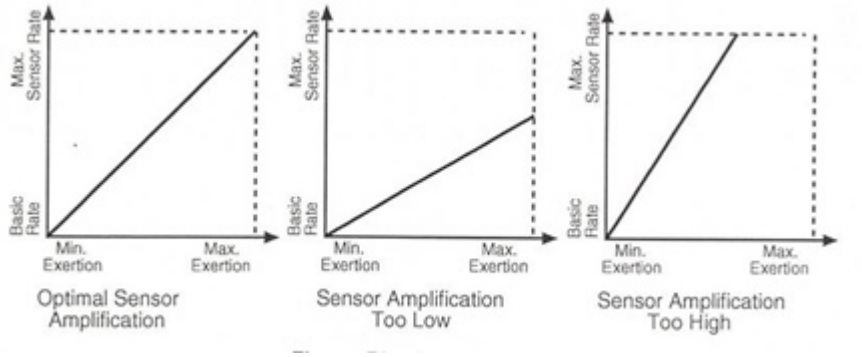

Figure 133: Sensor Gain

When the Sensor gain is programmed to Auto, the sensor is designed to adjust the gain setting automatically based on the patient's activity level. The gain will increase in value (more aggressive) if the patient has not reached 90% or more of the maximum sensor rate for 60 minutes in a seven-day period. If the criterion is met, then the sensor gain is reduced by one gain setting. Conversely, if 90% of the maximum sensor rate is reached for 30 minutes within a 24-hour period, the gain decreases by one setting (less sensitive). See Figure 145 for an example of Automatic Sensor Gain.

NOTE:

This feature is not recommended for patients who exhibit little or no physical activity as their pacing rate can change dramatically with sudden movement due to the change in sensor gain.

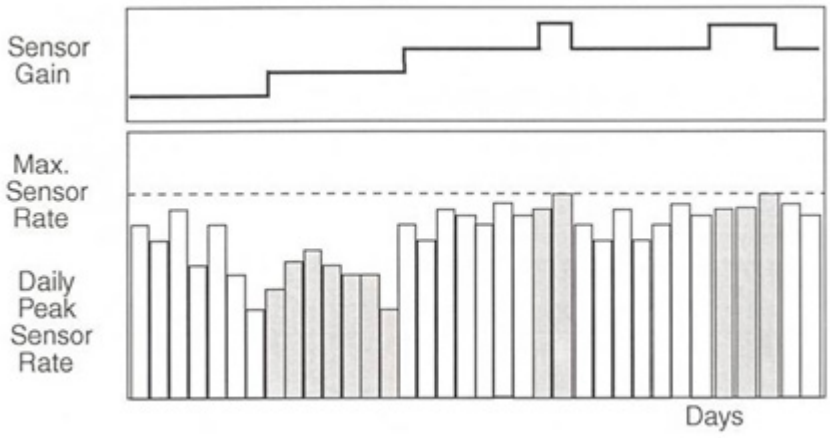

Figure 134: Auto Sensor Gain

7.5.3 Sensor threshold

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

The device ignores all activity that occurs below the sensor Threshold. In other words, the Threshold defines the lowest sensor input that initiates a change in the pacing rate. The basic rate will be used for pacing at rest when the threshold is programmed optimally.

7.5.4 Rate Increase/Decrease

The Rate Increase and Rate Decrease parameters work with Sensor Gain to determine how quickly the pacing rate increases or decreases with changes in the sensor output. There are four different Rate Increase settings (1, 2, 4, or 8 bpm/cycle) and four different Rate Decrease settings (0.1, 0.2, **0.5** or 1.0 bpm/cycle).

7.6 Upper Rate Behavior

90 ... (10) ... **130** ... (10) ... 170 bpm

In atrial-tracking pacing modes (i.e., DDD(R) and VDD(R) modes), the upper tracking rate (UTR) defines the fastest rate that the device tracks an intrinsic P-wave on a 1:1 basis. The upper tracking rate can be programmed into a tachycardia zone in the DR-T device. The UTR cannot be programmed into a tachycardia zone with the HF-T ICD unless LV pacing is turned OFF.

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 (pacing) Wenckebach — prevent the device from pacing the ventricle faster than the programmed UTR.

In the pacing Wenckebach scenario, ventricular pacing is maintained at UTR as the atrial rate exceeds UTR. Ventricular pacing continues at the 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 scenario, the ventricular pacing rate is half the atrial rate, as every other atrial event falls into the refractory period. 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 sensor indicated rate or basic rate.

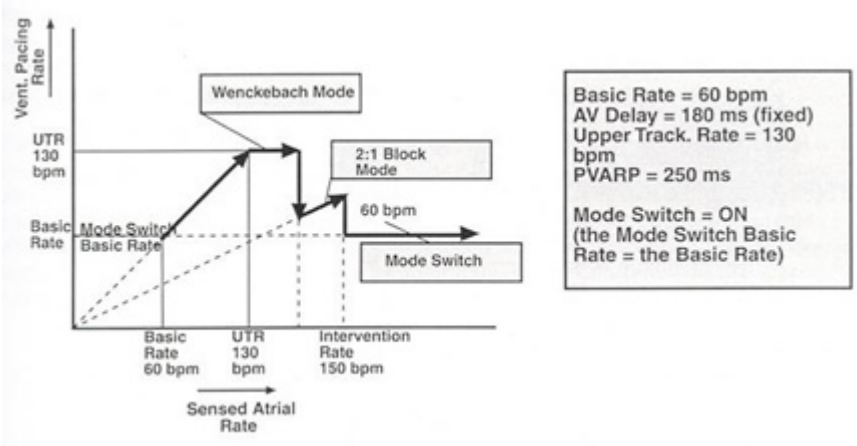

Figure 135: Upper Rate Behavior

Figure 135 shows an example of upper rate behavior in the Rivacor ProMRI® ICD. In this case, the Basic Rate equals 60 bpm and the UTR equals 130 bpm. Therefore, the intrinsic atrial rhythm is tracked on a beat-to-beat basis up to 130 bpm. Because the AV Delay is fixed at 180 ms and PVARP equals 250 ms, Wenckebach pacing occurs between 130 bpm (i.e., UTR) and 140 bpm (i.e., 140 bpm = 430 ms =180 ms + 250 ms). Between 140 and 150 bpm, a block pattern emerges in which every other atrial beat is tracked. At 150 bpm, Mode Switch occurs and ventricular pacing begins at 60 bpm.

NOTE:

In this example, there is no separate Mode Switching Basic Rate programmed. When Mode Switching occurs, the rate equals the Normal Basic Rate. If the Change of Basic Rate is programmed, the pacing rate during Mode Switching will the programmed Basic Rate plus the Change of Basic Rate value.

7.7 Mode Switching

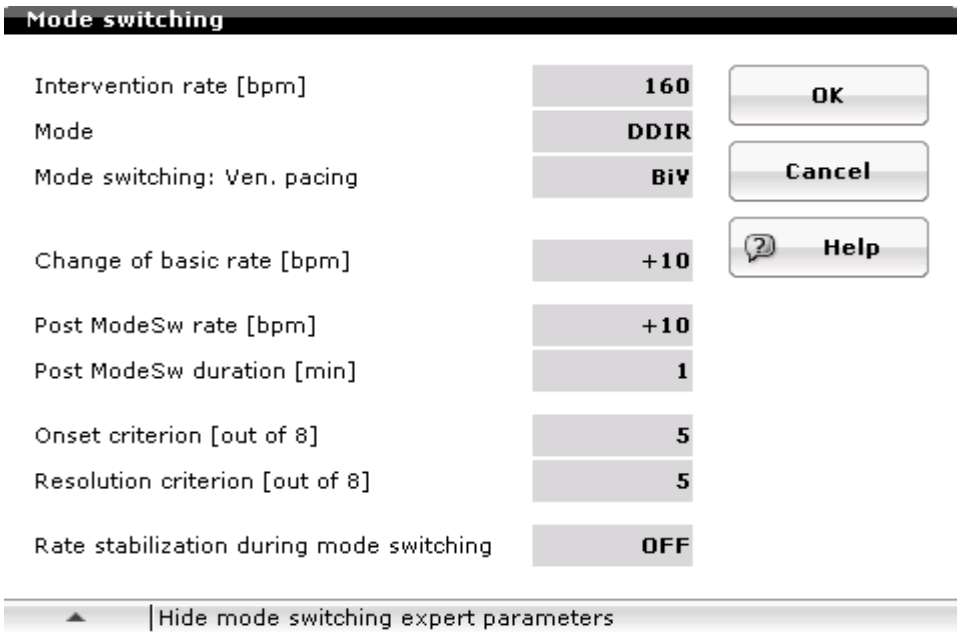

Figure 136: Mode Switching Screen

Mode Switching is designed to avoid tracking of the atrial signal during atrial tachyarrhythmias. In the presence of a high atrial rate, the normal bradycardia mode is automatically reprogrammed to a non-atrial tracking mode. The Intervention rate is the rate at which Mode Switching will occur. The range is OFF; 120 ... (10) ... **160** ... (10) ... 200 bpm. In other words, based on standard programming it would take five out of the last eight atrial events having a rate of at least 160 bpm to initiate Mode Switching.

NOTE:

The Intervention rate will not be used for the atrial diagnostic.

The modes available during Mode Switching are shown in Table 18 below. The default setting is in bold.

Mode Switching

Programmed Mode	Programmable Mode Switch Mode
DDDR, DDD-CLS	**DDIR**, DDI
DDD	**DDIR**, DDI
VDDR	**VDIR**, VDI
VDD	**VDIR**, VDI

Table 18: Mode Switching

Mode Switching is triggered based on the Intervention Rate and Activation/Deactivation criterion. The Intervention Rate defines the minimal atrial rate required for an automatic change to the non-tracking Mode Switch Mode. An "X out of Y" criteria is used to control the time of the mode switch. The X variable can be programmed between 3 and 8. The Y variable is always 8 intervals.

These are shown in Table 19.

Activation/Deactivation Criterion

Mode Switch	X value	Y value
Activation Criteria	3, 4, 5, 6, 7, 8	8
Deactivation Criteria	3, 4, 5, 6, 7, 8	8

Table 19: Activation/Deactivation Criterion

The Mode Switching automatically reverts to the Normal Bradycardia pacing mode when the atrial rate falls below the Intervention Rate. The time of reversion is based on the Criteria for Deactivation, an X out of Y criterion. The X value can be defined by the user (i.e., it is programmable between 3 and 8).

The Y value is fixed at 8 intervals.

7.7.1 Change of Basic Rate

Programmable OFF; +5 ... (+5) ... **+10** ... (+5) ... +30 bpm

When the Rivacor ProMRI® mode switches, the basic pacing rate during Mode Switching is the permanently programmed basic rate plus the change in basic rate value. For example, if the Rivacor ProMRI® was programmed to a basic rate of 60 bpm, the Mode Switch pacing rate would be 70 bpm.

In Rivacor ProMRI® HF-T devices, parameters such as Ventricular pacing, LV T-wave protection, and Triggering are programmable.

7.7.2 Post Mode Switch Rate and Duration

Post Mode Switch Rate: OFF, +5 ... (+5) ... **+10** ... (+5) ... +50 bpm (above base rate)

Post Mode Switch Duration: **1** ... (1) ... 30 minutes

The Post Mode Switch rate is designed to reduce the likelihood of recurrence of atrial tachyarrhythmias by overdrive pacing the atrium for a programmed period of time. After the time has expired, the pacing rate will decrease to the permanently programmed pacing rate by the rate decrease value.

7.7.3 Rate Stabilization During Mode Switching

OFF, ON

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, Rivacor ProMRI® ICDs 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.

7.8 Ventricular Pace Suppression (Vp Suppression)

Programmable parameters for Vp Suppression:

Parameter	Range	Default setting when Vp Suppression is ON
Pacing Suppression	1 ... (1) ... 8	6
Pacing Support	1, 2, 3, 4 out of 8 cycles	3

7.8.1 Overview

Ventricular pace suppression is designed to reduce the amount of right ventricular pacing by effectively changing the mode from DDD(R) to ADI(R) if stable ventricular activity is detected by the device.

Vp Suppression is activated by selecting DDD(R) - ADI(R) mode. Once the mode is selected, Vp Suppression will display ON in the main parameter screen.

When the ON parameter is selected, a pop-up box with the parameters Pacing suppression and Pacing support will appear when the parameter is selected (Figure 137).

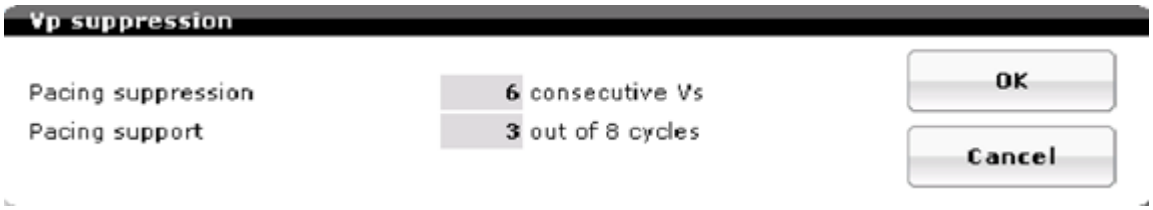

Figure 137: Vp Suppression

The Vp suppression parameter determines how aggressive the algorithm will be in switching to the ADI(R) mode. The default setting is six with a programmable range of 1-8 events. This means the device requires six consecutive Vs events before the device switches to the ADI(R) mode. In this mode, the device is able to pace in the atrium and sense in both chambers.

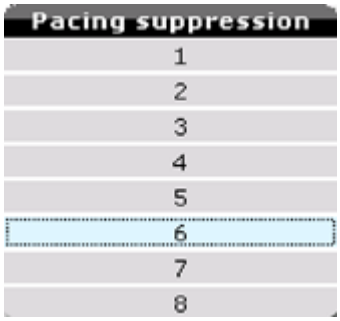

Figure 138: Pacing Suppression

The Pacing support parameter determines how many events out of the previous eight events (X/8) may not have intrinsic ventricular conduction (AxVs) in response to the atrial event before ventricular support pacing resumes. The default setting is three events out of the last eight cycles. This means that if more than three of eight events do not have a sensed ventricular response to an atrial event, the device will revert to the DDD(R) mode at the programmed AV Delay values. Additionally, the device will switch back to DDD(R) if no ventricular sensing occurs.

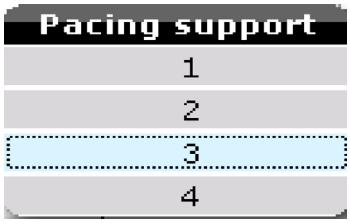

Figure 139: Pacing Support

7.8.2 How the Vp Suppression Algorithm Works

Once the algorithm is programmed ON, a Vs Continuity test is performed with the first intrinsic ventricular event (Figure 140) or after 30 seconds (Figure 141), whichever comes first.

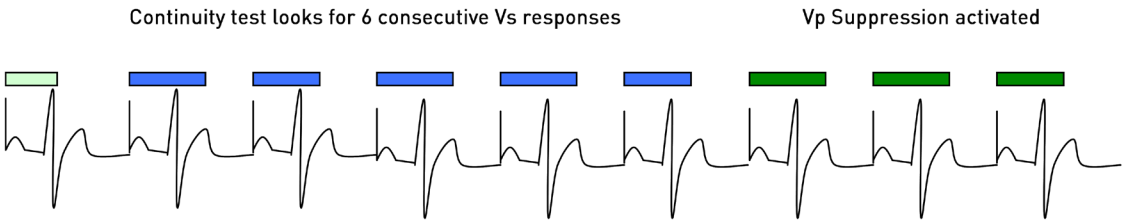

Figure 140: Continuity test starting with a Vs event

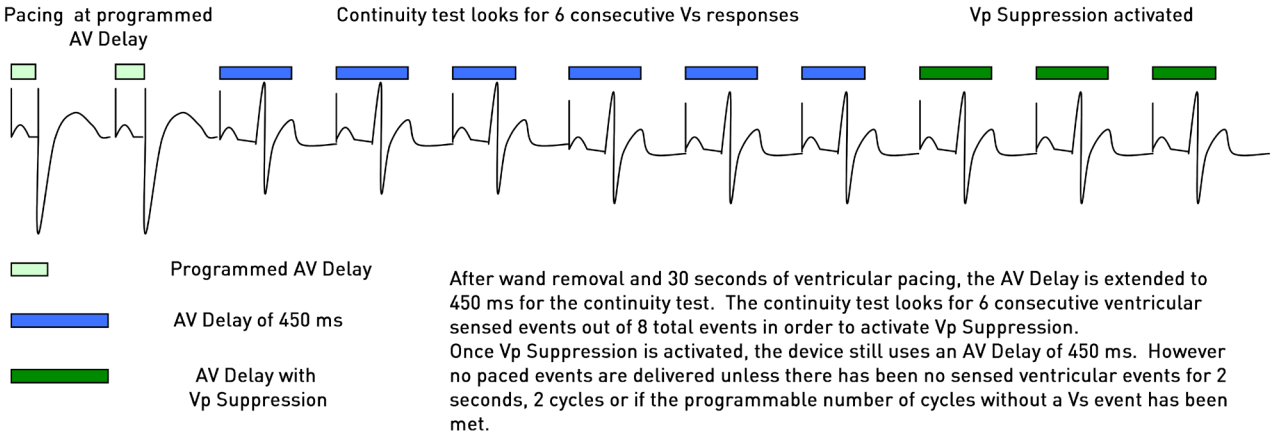

Figure 141: Continuity test starting with a Vp event

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 (Figure 142) at a specific time interval. More detail on search intervals will be found in the following section, Intelligent Search.

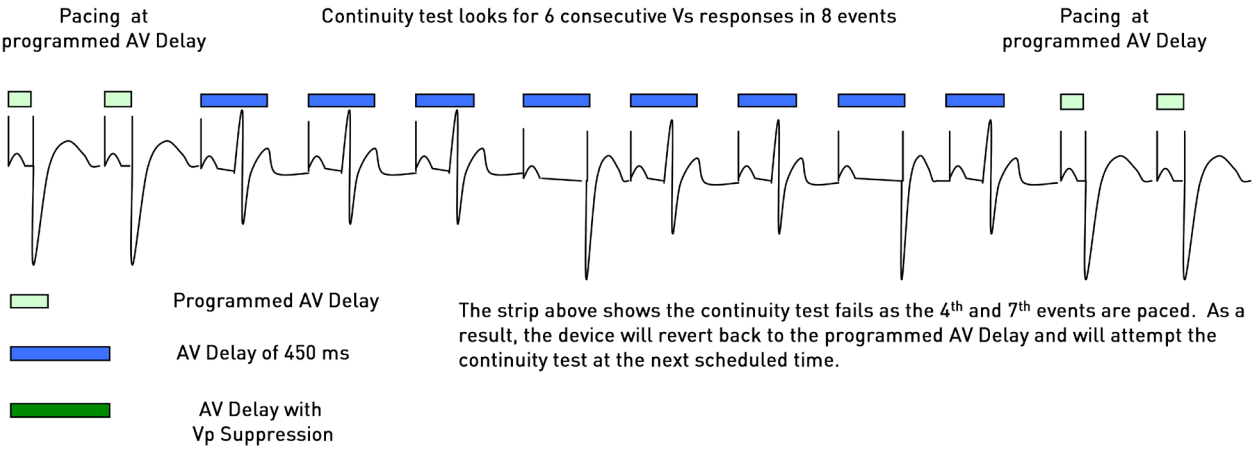

Figure 142: Example of an unsuccessful Continuity test for Vp Suppression

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.

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) An example of the device switching back to a DDD mode is shown in Figure 143.

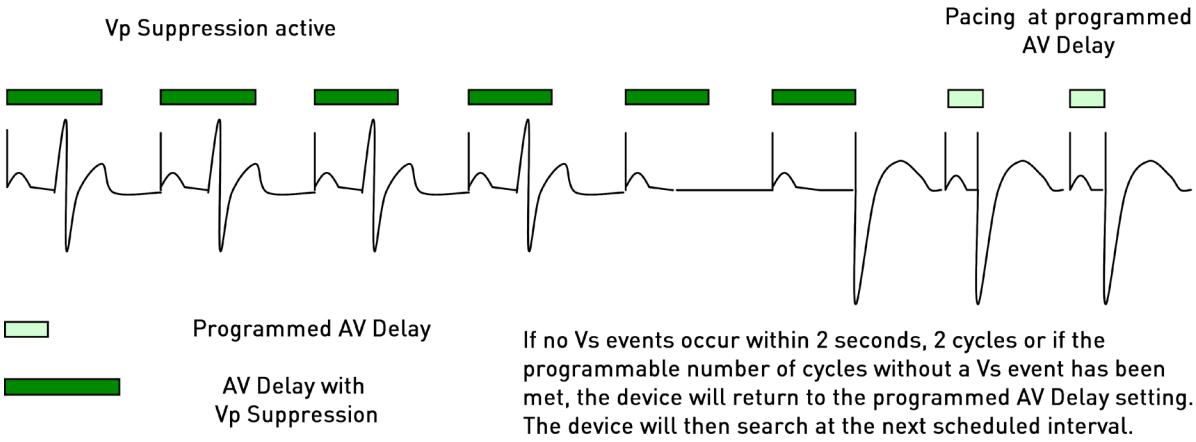

Figure 143: Reversion to DDD(R) mode

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:

- Tachycardia Episodes
- ACC/VCC
- PMT Detection
- Mode Switch

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

7.9 Ventricular Pacing (HF-T Devices Only)

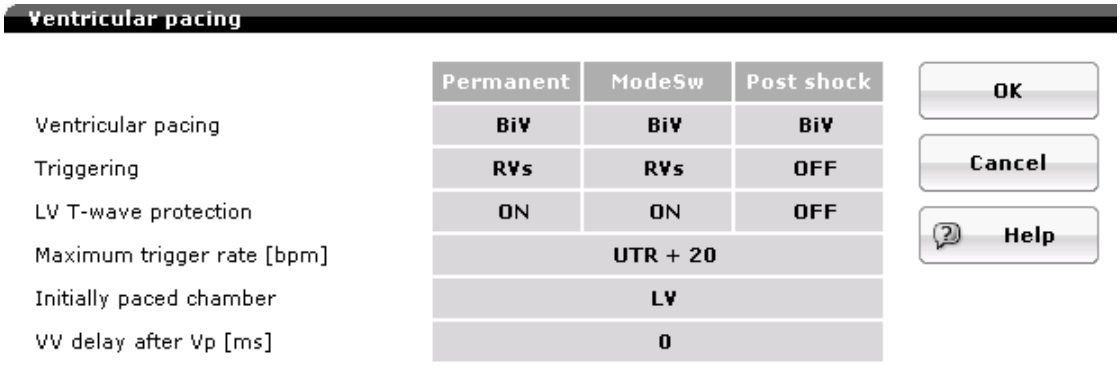

Figure 144: Ventricular pacing screen for HF-T devices

7.9.1 Ventricular Pacing

The Rivacor ProMRI® HF-T provides the option for BiV or RV pacing. These can be independently programmable for the permanent, Mode Switch, and Post-shock pacing.

7.9.2 Trigger Pacing

Programmable RV sense, RV sense + PVC or OFF. The Rivacor ProMRI® HF-T provides the option for trigger pacing of RV sensed events and/or PVCs. These options can be used to maximize CRT pacing. Trigger pacing cannot be programmed into a tachycardia zone.

7.9.3 LV T-wave Protection

Programmable ON or OFF. This feature is designed to prevent LV pacing into vulnerable periods of depolarization, preventing potential arrhythmias. Should LV T-wave protection be turned OFF, no LV sense statistics will be gathered by the device.

7.9.4 Maximum Trigger Rate

Programmable UTR + 20, 90 ... (10) ... 160 bpm. This value determines the maximum LV pacing rate. It is recommended the highest value be programmed to maximize CRT pacing. A conflict message will occur if trying to program the trigger rate value into a tachycardia zone.

7.9.5 Initially Paced Chamber

LV or RV. The programming of RV or LV first allows the physician to program the chamber in which pacing starts first to produce the best hemodynamic outcome for the patient. This value is fixed to LV if DDD-CLS is programmed.

7.9.6 V-V Delay After Vp

Programmable 0 ... (5) ... 100 ms. The programming of V-V interval allows the physician to program the V-V interval to produce the best hemodynamic outcome for the patient. This value is set to 0 ms if DDD- CLS is programmed ON.

7.9.7 MultiPole Pacing (MPP) for HF-T QP Only *(Not applicable in Rivacor 5)*

With MultiPole pacing, devices implanted with a quadripolar LV lead can deliver two left ventricle stimuli to different sites.

MultiPole pacing was studied on CRT non responders, defined as patients who have received BiV pacing (without MPP) and have demonstrated (1) worsening of their NYHA class or (2) have been hospitalized for HF despite receiving BiV pacing. MultiPole pacing was also studied in patients who have received BiV pacing (without MPP) for greater than 6 months without incremental benefit. MPP is not recommended as initial programming but is normally programmed on after optimizing BiV pacing and lack of response is demonstrated.

BIOTRONIK conducted the MPP Post-Approval study to evaluate the effectiveness of the MultiPole pacing feature. The study demonstrated the MPP feature was able to convert a percentage of CRT non-responders to responders. For detailed results, please see the Clinical Study Summary pamphlet.

NOTE:

Programming MultiPole Pacing ON reduces the estimated device longevity by approximately 10%. Three ventricular paces are delivered within each cardiac cycle: one on the right ventricle and two on the left ventricle. Pacing output and interventricular delays can be independently programmed. Two pacing sequences can be programmed: LV – 2nd LV – RV or RV – LV – 2nd LV.

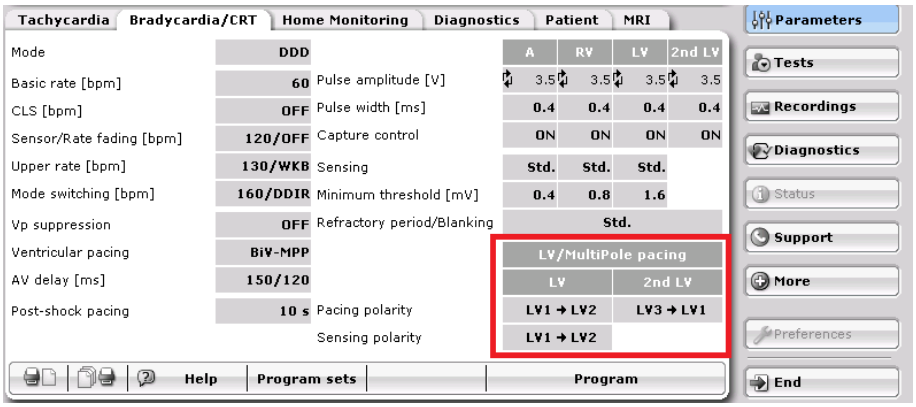

Figure 145: MultiPole settings are found on the bottom-right of the parameter screen

Twenty pacing configurations are available for both LV paces, however LV and 2nd LV pacing vectors must have different polarities. Pulse amplitude and pulse width are independently programmable for both LV and 2nd LV stimuli and can be adjusted within the usual limits (Figure 146). The LV pacing vector can be programmed differently than the sensing vector.

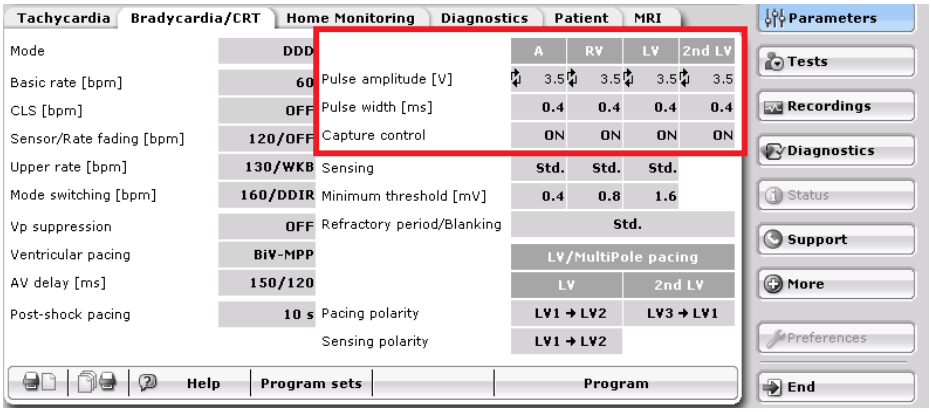

Figure 146: Each LV pace output is independently programmable.

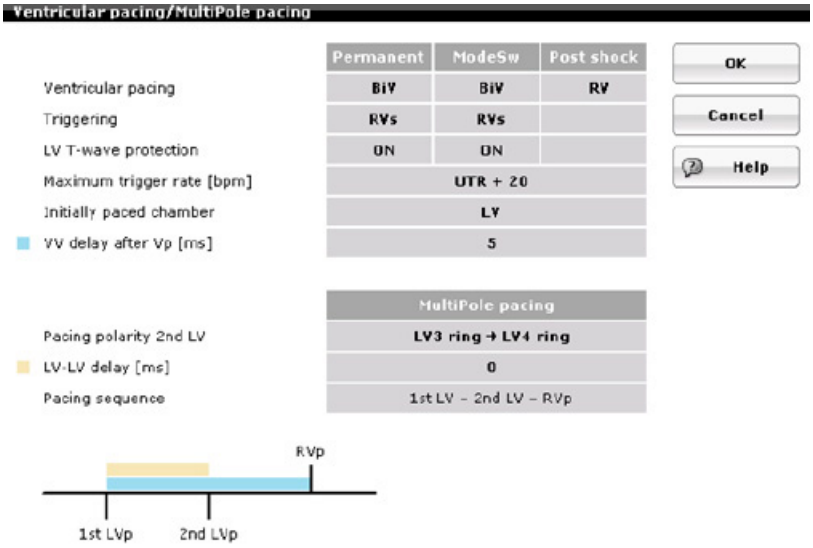

Figure 147: Once a second LV polarity is selected, in addition to the V-V delay, the LV-LV delay can be programmed from the ventricular pacing window.

As mentioned, the pacing sequence is determined by the initially paced chamber. For example, if LV is the initially paced chamber, then after the second LV pace, the device will RV pace. The following are rules that govern timing of these sequences.

7.9.7.1 LV First

If the LV is selected as the initially paced chamber, the minimum V-V delay is 5 ms AND the LV-LV delay (0-50 ms) must be lower than the programmable V-V delay (5-100 ms). For example, if LV is the first paced chamber and the V-V delay is set at 20 ms, the LV-LV delay can be programmed from 0 to 15 ms. The second LV pace always follows the LV pace, therefore a sequence like LV-RV-2nd LV is not allowed.

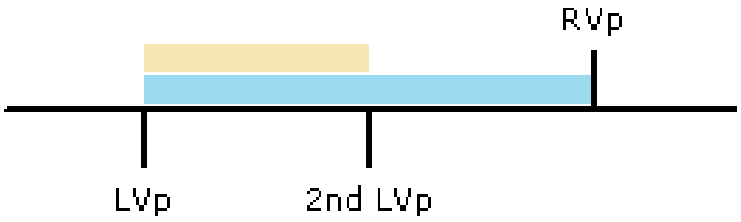

Figure 148: The 1st LV pace must be followed by the 2nd LV pace. The LV-LV delay must be less than the V-V delay.

7.9.7.2 RV First

If the RV is selected as the initially paced chamber, both V-V and LV-LV delays can be independently programmed however the sum of the V-V (0-100ms) and LV-LV delay (0-50ms) must be less than 100 ms.

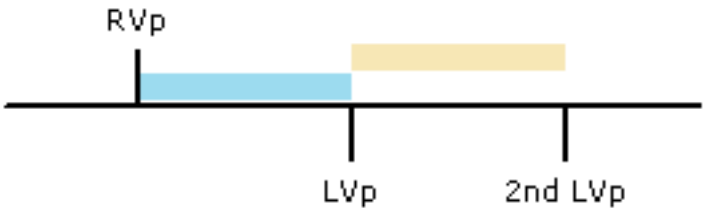

Figure 149: When the RV is the initially paced chamber, the sum of the V-V and LV-LV delays must be less than 100 ms

Additional Notes:

- LV capture control is available for the 2nd LV pace. *(Not applicable in Rivacor 5)*
- CLS is not available in combination with MPP
- If Triggering is enabled, the LV response will follow the programmed MPP path

7.9.8 CRT AutoAdapt *(Not applicable in Rivacor 5)*

The CRT AutoAdapt feature is intended for use in all CRT patients with intact AV conduction and atrial heart rate less than 100bpm. There is no current data to support superiority of CRT AutoAdapt to conventional BiV pacing and it is not known if this feature will turn a non-responder into a responder or improve CRT response. The CRT AutoAdapt algorithm continuously and dynamically adapts the CRT pacing method and AV delays. By promoting intrinsic RV conduction, CRT AutoAdapt may reduce RV pacing and increase device longevity for patients with normal AV conduction and atrial heart rates less than 100bpm. CRT AutoAdapt can be turned ON under the permanent BiV settings as seen in Figure 150.

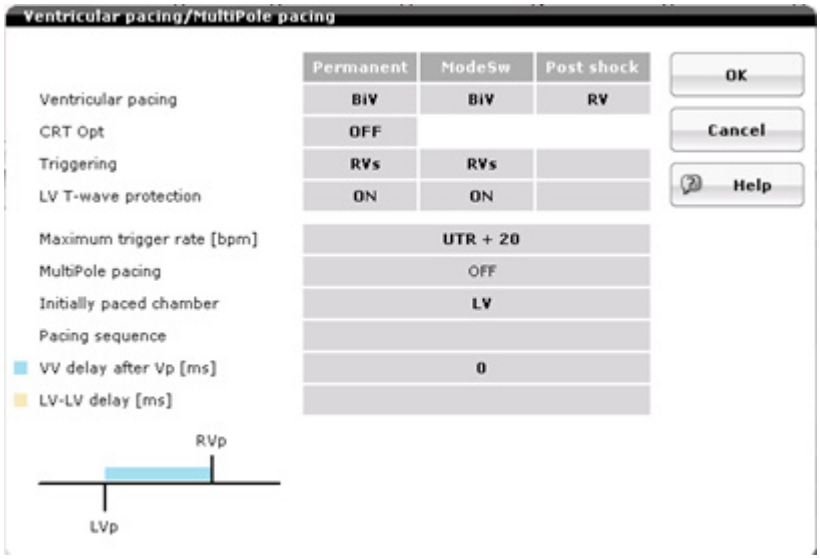

Figure 150. The CRT AutoAdapt algorithm is programmable under the ventricular pacing parameters screen.

When CRT AutoAdapt is ON, the device must be programmed to DDD(R) with ventricular pacing set to BiV and AV Hysteresis OFF.

CRT AutoAdapt can be programmed to "AVadapt" to enable AV adaptation only, or "ON" to enable AV adaption with a possible LV Only pacing state. If CRT AutoAdapt is set to "ON" LV Capture Control must be set to "ATM" or "ON" to ensure appropriate capture monitoring when in the LV Only state. This is also the case if MultiPole Pacing is enabled so both the 1st and 2nd LV Polarities must have Capture Control set to "ATM" or "ON".

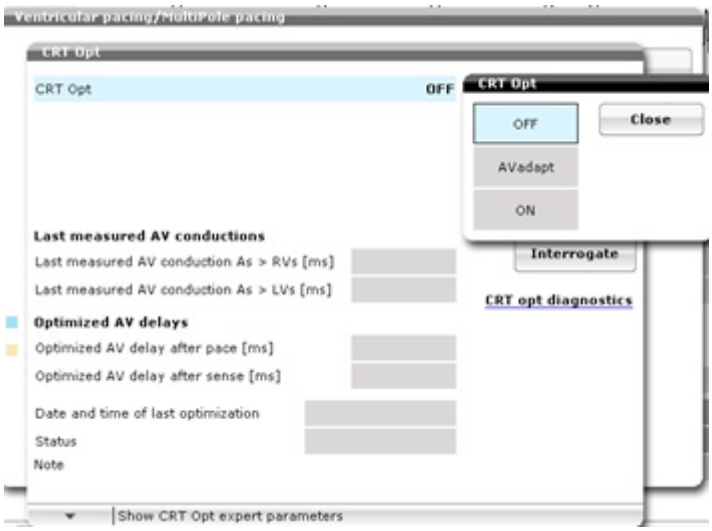

Figure 151: Programming CRT AutoAdapt to "OFF", "AVadapt" or "ON"

CRT AutoAdapt has four possible states that dictate pacing and timing behavior:

1. CRT AutoAdapt BiV Adaptive AV state: The device uses the programmed BiV pacing settings except for an adaptive AV delay and the CRT AutoAdapt VV delay after pace. The VV delay in the CRT AutoAdapt BiV Adaptive AV state will be limited to a maximum of 40ms.
2. CRT AutoAdapt LV Only State: In this state, the device provides LV-only pacing, except for periodic LV threshold measurement, which utilizes right ventricular pacing. This state also uses an adaptive AV delay.
3. CRT AutoAdapt Suspended: Device uses permanent programmed BiV pacing settings, AV and VV delays.
4. CRT AutoAdapt BiV state: Device uses permanent programmed BiV pacing settings AV and VV delays.

Conduction Test

Once enabled, CRT AutoAdapt will begin in the CRT AutoAdapt BiV state and will start the AV conduction test with the next As or Ap event by setting the absolute AV delay to 300 ms after a paced event (plus Sense Compensation after a sensed event, where Sense Compensation is a programmable offset to provide a similar PR interval whether atrial depolarization is accomplished by pacing or intrinsic activity). The AV conduction test will not run again until one minute (test interval time) has passed. The test interval time doubles and resets pending certain outcomes. The maximum test interval possible is 17 hours.

The AV conduction test measures one cardiac cycle for the As/Ap to RVs time called the RV-AV delay, and the As/Ap to LVs time called the LV-AV delay. If the measured Ax-LV or Ax-RV delays are not within expected bounds, the test will end and the device will enter the CRT AutoAdapt BiV state. If there are RVp, LVp, or safety pacing following the atrial event, the test will end and the test interval will double.

If the RV-AV delay is less than the LV-AV delay and CRT AutoAdapt is set to "ON" and the last measured LV threshold is valid, the test shall stop, the test interval will be reset and started, and the device will increment the LV only counter by 1. If the counter reaches 3 consecutive LV only decisions, the device will enter the CRT AutoAdapt LV Only state. In this state, the device provides LV-only pacing, except for periodic LV threshold measurement, which utilizes right ventricular pacing. This state also uses an adaptive AV delay. If three consecutive LV-only decisions are not met, the device will be in the CRT AutoAdapt Adaptive BiV state.

If the RV-AV delay is equal to the LV-AV delay or CRT AutoAdapt is set to "AVadapt" and the RV-AV delay is less than the LV-AV delay, or CRT AutoAdapt is set to "ON", and the last measured LV threshold is invalid, the test shall stop, the test interval will be reset and started, and the device will enter the CRT AutoAdapt BiV Adaptive AV state. In this state, the device uses the programmed BiV pacing settings except for an adaptive AV delay and the CRT AutoAdapt VV delay after pace, which limits the VV delay to a maximum of 40 ms.

If the RV-AV delay is greater than the LV-AV delay, the device shall reset the test interval, and enter the CRT AutoAdapt BiV state. This state uses the permanent programmed BiV pacing settings including VV interval and AV delays.

Adaptive AV Delay Calculation

If the device enters the CRT AutoAdapt BiV Adaptive AV state or the CRT AutoAdapt LV Only State, the device will use an adaptive AV delay calculated as follows from the results of the conduction test:

1. First the device uses the minimum of either the measured RV-AV or LV-AV delay as the Measured AV delay
2. If the measured AV delay in the conduction test started with an Ap:

    a. The calculated AV delay after pace is equal to either the Measured AV delay – a nonprogrammable 40ms offset, or the "CRT AutoAdapt Adaptive AV Reduction" multiplied by the Measured AV delay, whichever value is lower.

    b. The calculated AV delay after sense is equal to the calculated AV delay after pace + Sense Compensation.
3. If the measured AV delay started with an As:

    a. The calculated AV delay after sense is equal to either the Measured AV delay – a nonprogrammable 40ms offset, or the "CRT AutoAdapt Adaptive AV Reduction" multiplied by the Measured AV delay, whichever value is lower.

    b. The calculated AV delay after pace is equal to the calculated AV delay after sense – Sense Compensation.
4. The mean value of the calculated AV delay and the two previously adapted AV delays is used for the adapted AV delay.

5. The adapted AV delay after pace is limited by the "Adaptive AV lower limit" or "Adaptive AV lower limit" plus sense compensation for after sense. Adaptive AV lower limit is a programmable value and will be discussed later in this section.

NOTE: Once CRT AutoAdapt is turned ON, the current permanent AV delay after pace will be used as the two previously adapted AV delays.

Expert Options

NOTE: These parameters are only available by hitting the "show CRT AutoAdapt expert parameters" drop down in the bottom of the CRT AutoAdapt window.

CRT AutoAdapt Adaptive AV Reduction: The percentage of the intrinsic AV conduction time that the device would use to set the Adapted AV delay. Reducing this value results in a shortened Adapted AV delay while increasing it will bring the adapted value closer to the sensed conduction value. This can be programmed from 0.5 ... (0.1) ... 0.9 as seen in the figure below.

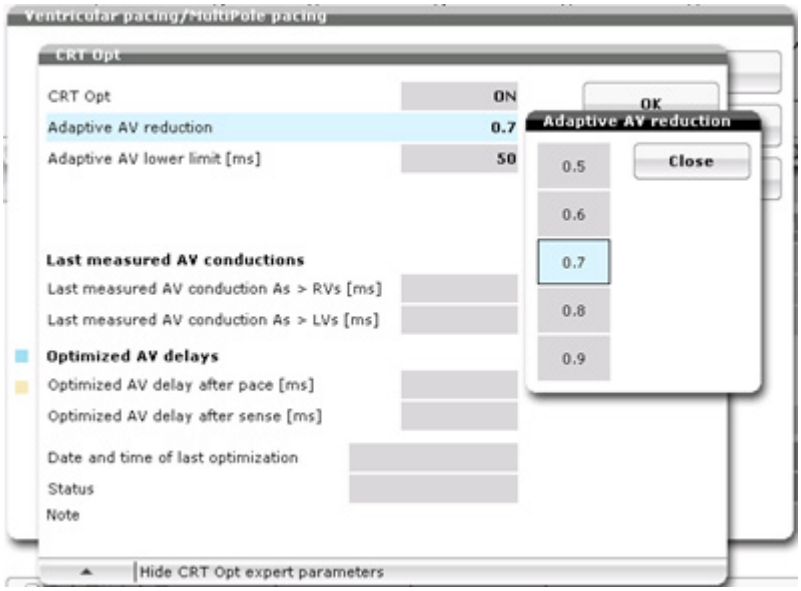

Figure 152: Programming options for Adaptive AV Reduction

CRT AutoAdapt Adaptive AV Lower Limit: This parameter provides the lowest value for the CRT AutoAdapt algorithm to ensure there is an effective AV delay. The adapted AV delay after pace cannot go below the chosen value, and the adapted AV delay after sense cannot go below the set value plus sense compensation. The value is programmable from 50 ... (10) ... 150 ms.

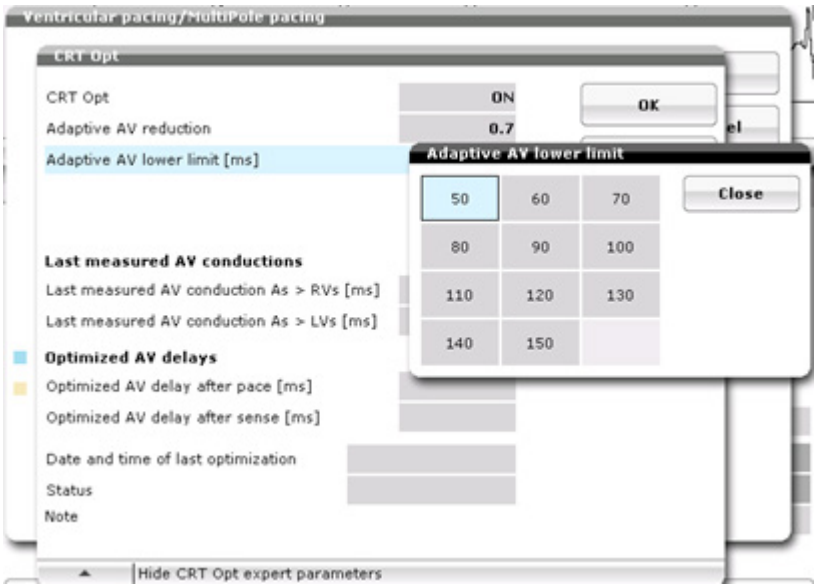

Figure 153: Programming options for Adaptive AV lower limit [ms]

Suspension of CRT AutoAdapt

The CRT AutoAdapt algorithm shall suspend when the following conditions are met:

- Ongoing VT/VF episode with programmed therapy (NOTE: Monitoring episodes shall have no effect to the CRT AutoAdapt algorithm)
- Ongoing Mode Switching
- Ongoing Post Mode Switch Rate
- Ongoing Postshock Pacing
- Automatic Sensing Test
- Automatic Threshold Test (Including ATM mode)
- MRI Program

The device will suspend CRT AutoAdapt until both the end of the particular condition listed above and the test interval elapses.

The CRT AutoAdapt Menu

The programmer will provide the following status information on the CRT AutoAdapt parameters screen:

- The last measured AV conductions for both the RV-AV delay and the LV-AV delay and if they were measured after As or Ap
- The adapted "Optimized" AV delays after sense and pace
- The date and time of last optimization
- The current status of the algorithm (OFF, LV only state, BiV Adaptive AV state, BiV state, Suspended State)
- A notes field which will display additional information if the CRT AutoAdapt is in the Suspended/BiV state.

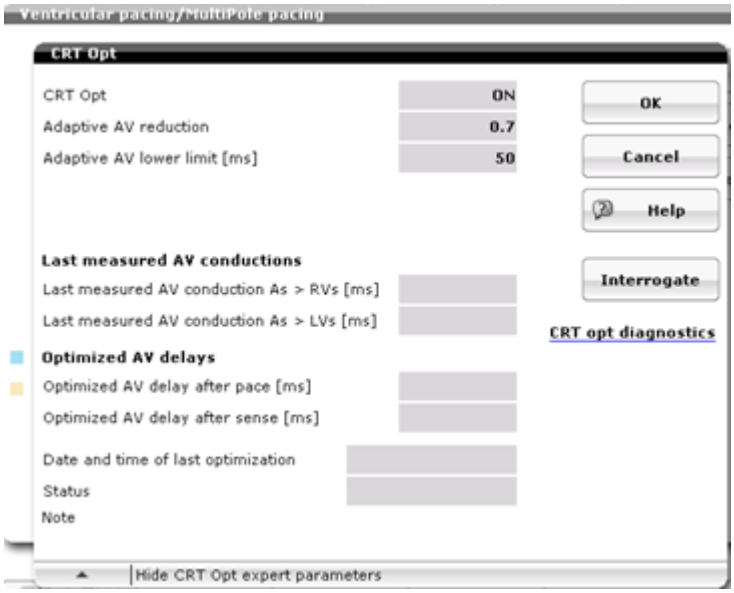

Figure 154: CRT AutoAdapt Expert Parameters

The percentage of time in each pacing state and the Adapted AV delay values will be displayed under the More Diagnostics tab. For more information on CRT optimization diagnostics, please go to Section 8.2.6.9.

7.10 Dynamic AV Delay

Rivacor ProMRI® Dynamic AV Delay

	Dynamic AV Delay Default (ms) for Rivacor ProMRI® HF-T		
Rate	Low	Medium	High
60 bpm – Lower Rate	150	140	130
130 bpm – Upper Rate	120	100	80
	Dynamic AV Delay Default (ms) for Rivacor ProMRI® DR-T		
Rate	Low	Medium	High
60 bpm – Lower Rate	180	180	180
130 bpm – Upper Rate	140	100	80

Table 20: Rivacor ProMRI® Dynamic AV Delay

The AV Delay is the interval between an atrial event and the following ventricular event. During normal intrinsic activity, the PR interval (i.e., the intrinsic AV Delay) shortens as the heart rate increases, producing a ventricular filling time that is proportionate to the ventricular ejection time.

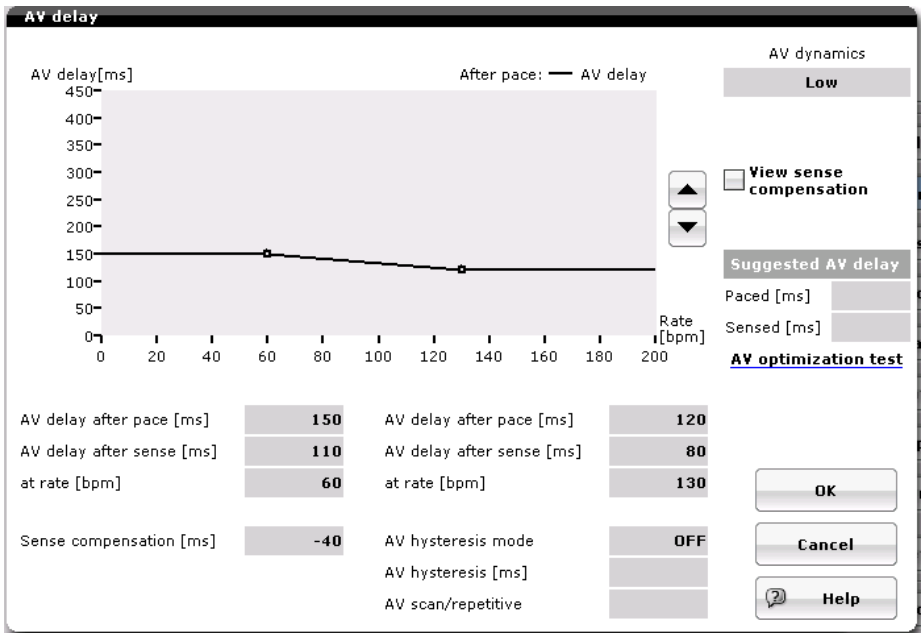

Figure 155: Dynamic AV Delay

Dynamic AV Delay automatically adjusts the AV interval based on the current heart rate. There are three different pre-defined settings (Low, Medium, and High), as shown in Table 20. In addition, the AV Delay may be Fixed across all heart rate bins, or Dynamic, which allows the user to customize the AV Delay for each heart rate zone — this is referred to as Individual on the programmer screen.

In addition to changing the numerical values, AV Delays and Rates for AV Delay changes can be made on the screen by selecting the small circles (Figure 155) on the graph with the pen and sliding it up and down to change AV Delay, or left to right to change the rate at which AV Delays will change.

7.10.1 Positive AV Hysteresis with Scan/Repetitive

Positive Scan/Repetitive Hysteresis: OFF; **ON** at 5 events (non-programmable)

This function should not be used in Rivacor ProMRI® HF-T because it could encourage intrinsic ventricular activity and impact the effects of CRT pacing therapy.

With AV Hysteresis ON, the AV Delay is extended to the programmed hysteresis delay after every Vs event to encourage intrinsic conduction;

- If a Vs event is detected, the extended AV delay remains intact.
- If no Vs event is detected, the AV delay returns to its original programmed setting.
- AV Extension programmable: 70, 110, 150, or 200 ms

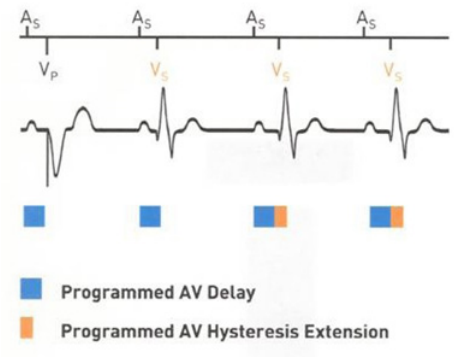

Figure 156: AV Hysteresis

By adding the Repetitive enhancement, the extended AV delay remains in effect for five repetitive cycles to help maintain intrinsic conduction. A Vs event triggers the first AV delay extension and starts the counter at zero.

During a Repetitive Sequence (refer to Figure 157):

- Each Vs event will reset the repetitive counter and initiate the extended AV delay. (see green arrow in Figure 157)
- If no Vs event occurs, the AV delay remains extended until the repetitive count of Vp is met.

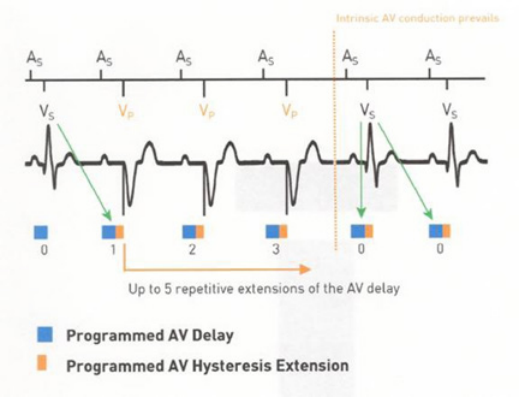

Figure 157: Repetitive Hysteresis

By adding the Scan enhancement, after 180 consecutively paced cycles, the AV delay is extended for five pacing cycles

- Each Vs event will reset the scan counter and initiate the extended AV delay (see green arrow in Figure 158).
- If no Vs event occurs, the AV delay remains extended until the scan count is met.

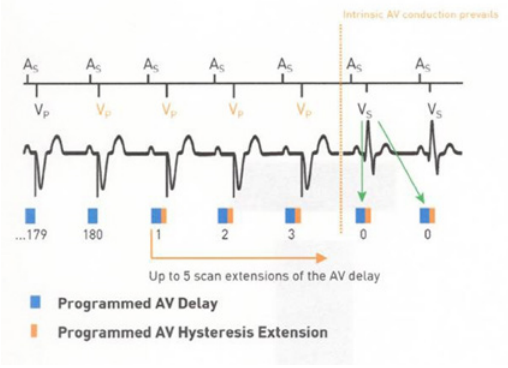

Figure 158: AV Scan Hysteresis

To program Positive AV Hysteresis ON:

1. Press AV hysteresis mode to select Positive hysteresis.
2. Select the AV Hysteresis value desired. The choices are 70, 110, 150, 200 ms.
3. AV scan/repetitive is automatically ON when Positive hysteresis is selected.

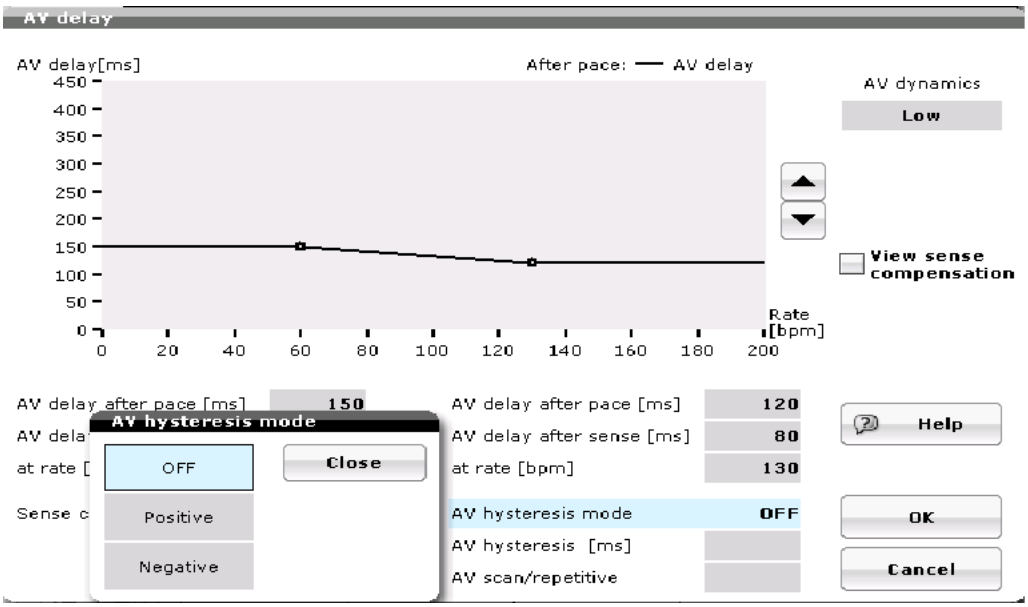

Figure 159: Dynamic AV delay screen with AV hysteresis choices

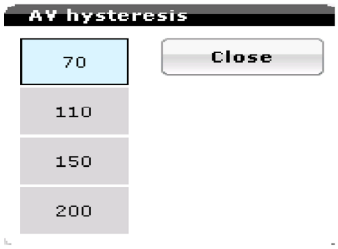

Figure 160: AV hysteresis

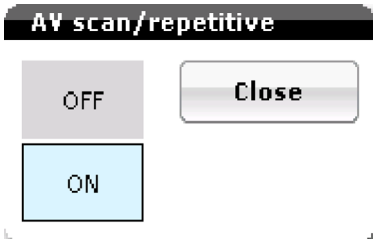

Figure 161: AV scan/repetitive

7.10.2 Negative AV Hysteresis

AV Hysteresis: 10 ... (10) ... **50** ... (10) ... 150 ms

The intent of Negative AV Hysteresis (Figure 162) is to reduce the chance of intrinsic activity occurring in patients with hypertrophic cardiomyopathy (HCM) or heart failure patients when trying to optimize the AV Delay for maximum cardiac output and high (bi-)ventricular pacing percentages. The feature allows the user to program a shorter AV Delay (10-150 ms) when intrinsic activity breaks through to maintain pacing. After 180 paced ventricular events at the shortened AV Delay, the device returns to the programmed AV Delay. This feature is not required in patients with third-degree heart block or post AV nodal ablation, as there is little risk of intrinsic activity occurring.

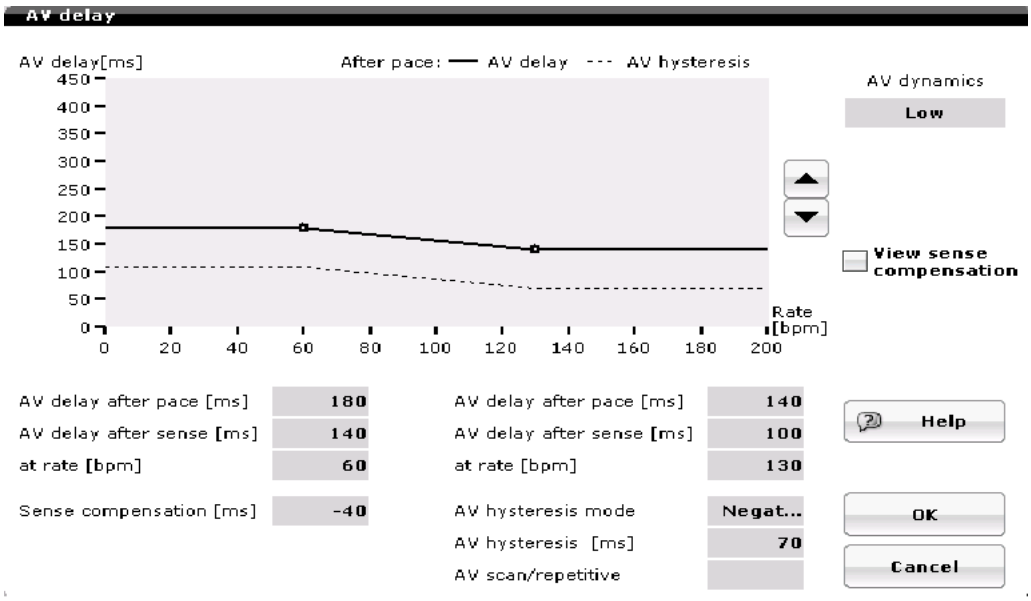

Figure 162: Negative AV Hysteresis

CAUTION

Negative AV Hysteresis – This feature ensures ventricular pacing, a technique that 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

7.10.3 Sense Compensation

OFF, -5 ... (-5) ... **-40** ... (-5) ... -120 ms

When Sense Compensation is activated, the AV Delay following an atrial sensed event differs from the AV Delay following an atrial paced event. The AV Delay after a sensed event is shortened by a programmed value (i.e., between -5 and -120 ms) to provide a similar PR interval, whether atrial depolarization is accomplished by pacing or intrinsic activity. Sense Compensation is programmed in the AV Delay window.

7.11 Post-shock Pacing

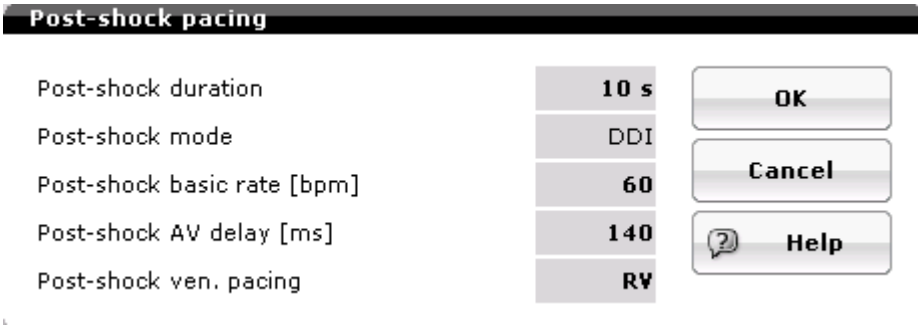

Figure 163: Post-shock pacing screen

7.11.1 Post-shock Duration

OFF, 10 s, 30 s, 1, 2, 5, or 10 minutes. The Rivacor ProMRI® ICD/CRT-D provides duration options post-shock duration pacing up to 10 minutes. During post-shock pacing, the pacing outputs are 7.5 V at 1.5 ms.

7.11.2 Post-shock Mode

The post-shock pacing mode depends on the permanent pacing mode.

7.11.3 Post-shock Basic Rate

30 ... (5) ... 60 ... (5) ... 100 ... (10) ... 160 bpm. Allows the physician to program a post-shock pacing rate different than the permanent pacing rate.

7.11.4 Post-shock Ventricular Pacing

RV pacing for non-HF-T devices. HF-T devices have the option of RV only and BiV pacing.

7.12 Capture Control

7.12.1 Atrial Capture Control (ACC)

Capture control; OFF, ATM, **ON**

Threshold test start: **Programmed output value**

Key numbers for Atrial Capture Control (ACC)

Test Rate	20% higher than the intrinsic rate
AV Delay/Mode	The AV Delay is shortened to 50 ms in the DDI mode
Test cycle	Each test cycle consists of five paced atrial event
Loss of capture determination	Loss of capture is determined when at least two sensed events occur in the test cycle period.
Step down interval	0.6 V until loss of capture, returns to the last captured output. Then the device steps down in 0.1 V increments until threshold is determined. Threshold is confirmed by testing 0.3 V above and 0.3 V below the last capture value

Table 21: Key numbers for Atrial Capture Control (ACC)

Active Threshold Monitoring (ATM) tracks the pacing threshold without reprogramming the pacing output.

7.12.1.1 Overview of How Atrial Capture Control Functions

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 than the intrinsic rate to suppress atrial intrinsic events. As soon as the pacing output is lower than 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. 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 rates are below 110 ppm 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 22.

Parameter	Range	Default
Capture Control	ON, ATM, OFF	ON
Minimum Amplitude	0.5 ... (0.25) ... 4.0 V	1.0 V
Capture Test Start	2.5 ... (0.5) ... 5.0 V	3.5 V
Safety Margin	0.5, 1.0, 1.2 V	1.0 V

Table 22: Atrial Capture Control Parameters

7.12.1.2 Atrial Capture Control Parameters

7.12.1.2.1 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.

7.12.1.2.2 Minimum Amplitude

0.5 ... (0.25) ... 4.0 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 .

7.12.1.2.3 Threshold Start Test

2.5 .. .(0.5) ... 5.0 V, default 3.5 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.

7.12.1.2.4 Safety Margin

0.5, 1.0, 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.

7.12.2 Ventricular Capture Control

Capture control; OFF, ATM, **ON**

Threshold test start: 2.5 ... (0.5) ... **3.5** ... (0.5) ... 5.0 V

Minimum Amplitude: **1.0** ... (0.25) ... 4.0 V

Safety margin; 0.5 V*, **1.0 V,** 1.2 V

*Available in LV capture control only

Key numbers for Ventricular Capture Control (VCC)

Signal Quality Check	Five single-paced events followed by five double-paced events 100 ms apart
AV Delay	The AV Delay is shortened to 15 ms post atrial sense and 50 ms post atrial pace to ensure capture.
Back-up pulse	Occurs at 100 ms after the loss of capture event
Back-up pulse output	Current programmed output + 0.6 V at 1.0 ms pulse width. When performing the LV threshold test, V-V delay is set to 50 ms with the LV first. The RV paced event is always delivered throughout the test so an LV back-up pulse is not required.
Step down interval	0.6 V until loss of capture, returns to the last captured output and steps down 0.1 V

Table 23: Key numbers for Ventricular Capture Control (VCC)

Active Threshold Monitoring (ATM) allows the user to track the pacing threshold without reprogramming the pacing output. The test is performed in the same manner as Ventricular Capture Control (VCC) except for the final step of reprogramming the pacing output.

7.12.2.1 Overview of How Ventricular Capture Control Functions

When VCC is programmed ON or to ATM, the device starts by performing a Signal Quality Check (SQC).

The purpose of the SQC is to verify that the ventricular capture and non-capture signals are adequate for reliable capture determination. Amplitude and morphology of the ventricular evoked response may vary significantly between patients. This poses a problem for accurately identifying capture versus non-capture morphologies. Also affecting the ability of the capture threshold algorithm is the ability to distinguish between an evoked response (true ventricular systole) and polarization artifacts produced by the pacing lead. The VCC algorithm analyzes signal morphology characteristics to differentiate capture from non-capture by measuring positive and negative signal amplitudes, location and polarity of the zero crossing, and various integrals of the signal at different times. The signal evaluation occurs during a specific window. There is a 16 ms blanking period immediately following the paced event. Following the blanking period, a 60 ms detection window and a 20 ms decision window occurs.

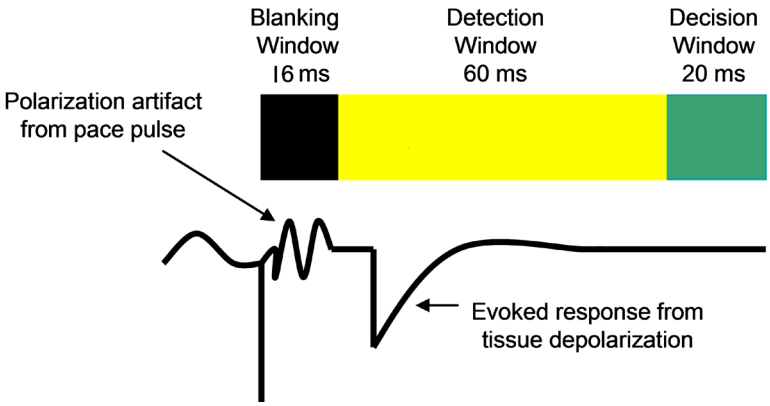

Figure 164: Signal Evaluation

7.12.2.1.1 Signal Quality Check (SQC) and Capture Threshold Search (CTS)

When the VCC or ATM algorithm is activated, an SQC and a CTS sequence are initiated. The progression of this sequence is shown by a message displayed at the bottom of the programmer screen. The programmer wand must be in place during the initial SQC/CTS initialization. The SQC/ CTS is initiated as long as the average ventricular rate is less than 110 bpm (the SQC Rate limit). (The preset rate limit is used to avoid overdrive pacing at higher rates, interaction with other pacemaker features that occur at higher rates, and to prevent pacing into the intraventricular baseline variations that occur at the end of T-waves.) The SQC begins by setting the pacing amplitude to Threshold Test Start value and shortening the AVD to 15 ms or 50 ms in order to force ventricular pacing. The selection of AVD is determined by the patient's current pacing status. A 15 ms AVD will be used if there is atrial tracking or the patient's intrinsic rhythm is inhibiting the atrial pacing. For the pacemaker dependent patient, a 50 ms AVD provides forced ventricular pacing. In the single-chamber Rivacor ProMRI® device or if another member of the Rivacor ProMRI® family is programmed to a single-chamber mode, the pacing rate will be set at 10 beats above the intrinsic ventricular rate. The SQC is divided into two separate phases, the first to evaluate capture and the second to evaluate lead polarization artifact. In phase 1, five paced cycles are delivered to evaluate capture using the evoked response. In phase 2, the five cycles are for evaluation of the lead polarization artifact in order to differentiate capture from non-capture.

The first ventricular pacing event of SQC is ignored in order to allow the system to stabilize to the altered pacing amplitude. (The cycle that is ignored will have a slightly longer AVD.) On the second to fifth cycles of the capture phase of SQC, capture or non-capture determinations are made. Back-up pulses are delivered if non-capture is present. Immediately following the first phase of SQC, the second phase is started. Five secondary pulses are delivered at 100 ms after each of the next five ventricular paces (Figure 165). These paces fall into the absolute refractory period of the ventricle. Based on the polarization of the non-capture second paces, the maximum polarization artifact is determined.

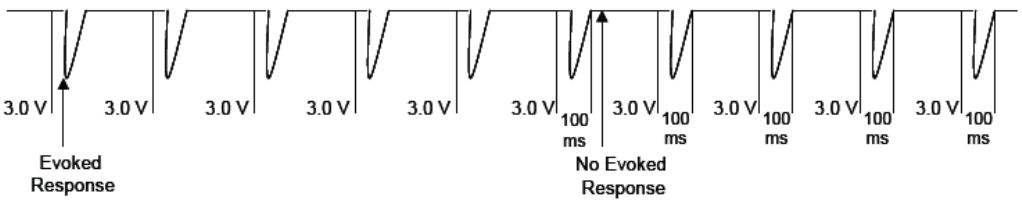

Figure 165: Signal Quality Check

To pass the SQC phase of ATM/VCC initialization, the phase 1 paced events must be retrospectively classified as 'capture' by phase 2. The SQC starts at the Threshold Test Start value and represents the worst-case polarization artifact, and therefore, the resulting worst-case evoked response signal.

If any non-capture events occur during the capture phase or if the polarization amplitude violates the pre-set threshold, the SQC attempt is unsuccessful. If the first SQC attempt is unsuccessful upon initialization, the VCC algorithm is set to pending and repeated. The SQC/CTS sequence generally takes less than one minute.

7.12.2.1.2 Capture Threshold Search

The purpose of the Capture Threshold Search (CTS) is to determine the minimum ventricular pacing amplitude that will capture the heart to a resolution of 0.1 V. The pacing threshold is defined as the maximum non-capture voltage at X.X volts + 0.1 V. In the VCC ON mode, the CTS resets the final pacing voltage at completion of the CTS. However, the lowest output that can be set is 1.2 V regardless of the measured output.

NOTE:

In the ATM mode, the threshold is recorded in the Ventricular Pacing Threshold histogram, but is not used to adjust the pacing amplitude.

CTS is always initiated following a successful completion of the SQC sequence. The applicable AVD is maintained from the SQC. The pacing amplitude begins at the Threshold Test Start value and decreases by 0.6 V of the currently programmed amplitude every ventricular pacing event. Once the

amplitude is lost, the device will return to the last captured value and decrease the output by 0.1 V until the threshold is determined. At the 0.1 V decrement interval, the device will deliver a second paced pulse when a loss of capture occurs to verify the threshold. If the second pulse delivery captures, the device will deliver a third paced pulse. If two out of three paced events capture, the device will step down to the next value. See Figure 166 for an example of Capture Threshold Search.

If a single non-capture is detected, a back-up pulse is delivered 100 ms after the non-capture event at the current programmed output + 0.6 V and 1.0 ms pulse width. The back-up pulse results in a resetting of the lower rate timer (LRT). Once determined, the pacing amplitude is reset to the threshold plus the programmable safety margin (1.0 V standard).

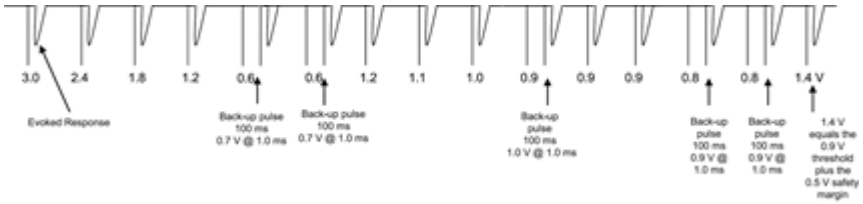

Figure 166: Capture Threshold Search

7.12.2.1.3 Key Points about ATM/Capture Control

- ATM/VCC is a programmable ON/OFF feature available in the Rivacor ProMRI® device family.
- ATM/VCC requires the Pulse Width to be programmed to 0.4 ms or less.

- ATM/VCC measurements are performed once daily, 40 minutes before the programmed HM transmission time. If the first attempt fails, a second attempt will occur 30 minutes later or 10 minutes before the HM transmission.
- A back-up pace pulse occurs up to 100 ms after loss of capture in the RV channel only. The back-up pulse is at +0.6 V above the last output and 1 ms pulse width.
- When LV ATM/VCC is performed, the V-V interval is temporarily changed to 50 ms. This means the RV channel will pace 50 ms after the LV channel so a back-up pulse is not required. RV pacing will occur at all times during the test, regardless of whether LV capture occurred.
- ATM does NOT permanently modify the programmed pacing outputs.
- ATM/VCC will not be performed if the heart rate is 110 bpm or within 10 bpm of the UTR.
- ATM/VCC in single-chamber ICDs is done by pacing at 10 bpm above the intrinsic rate.
- The AV Delay is shortened to 50 ms following an Ap; 15 ms following an As event.
- When LV ATM/VCC is programmed ON, the LV pacing is only programmable to LV Tip to LV Ring, LV Tip to RV Ring or Unipolar. Conflict messages will appear informing the user if the LV pacing configuration is using the LV ring first.

NOTE: RV and LV Capture Control is available in DDI mode. The device will confirm the LV threshold if the device captures at the measured threshold +0.3 V and loses capture at the measured threshold -0.3 V. This is similar to the ACC threshold confirmation test.

7.12.2.1.4 LV Capture Control in 2nd LV pace *(Not applicable in Rivacor 5)*

LV Capture Control is available for the 2nd LV pace in devices.

LV Capture Control parameters can be independently programmed between the 1st and 2nd LV pace.

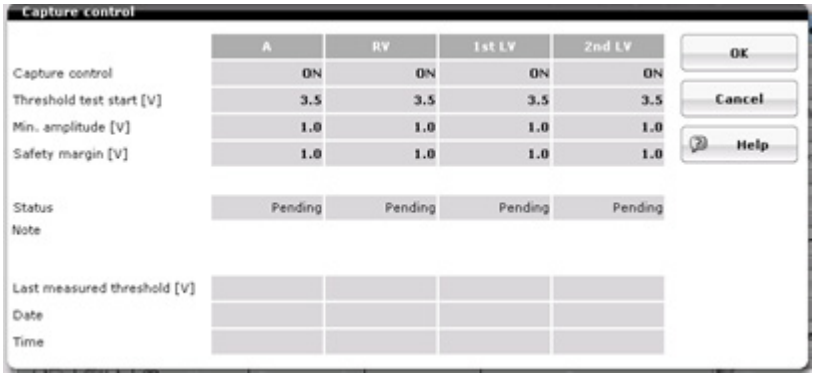

Figure 167: Programming LV Capture control from the Bradycardia screen

The 2nd LV Capture Control will execute a Signal Quality Check (SQC) and a Capture Threshold Search (CTS) identical to Capture Control in the RV and LV. The Capture Control can be set to ATM or ON. When programmed to ATM, the device will monitor and report the threshold values without changing the outputs. When programmed to ON, the device will automatically adapt the pacing amplitude for the 2nd LV pace.

NOTE: LV Capture Control needs to be set to ATM or ON for both the 1st and 2nd LV when CRT AutoAdapt is ON.

7.13 PMT Protection

ON or OFF

VA criterion: 250 ... (10) ... 350 ... (10) ... 500 ms

Located under the Refractory period/Blanking parameter of the Bradycardia section.

Under certain conditions, retrograde conducted atrial events may be tracked by the device and lead to Pacemaker Mediated Tachycardia (PMT). These retrograde atrial events may occur following a premature ventricular beat, loss of atrial capture, or a prolonged AV Delay. PMT Protection is an optional bradycardia algorithm (programmed ON or OFF) designed to terminate a PMT.

The PMT termination algorithm looks for eight consecutive AsVp events greater than 100 bpm in which the VA interval is less than the programmed PMT VA criterion (default 350 ms). Additionally, the algorithm looks at stability to determine if the atrial intervals are stable (< 25 ms). If these conditions are met, the PVARP extension is activated. This extension is equal to the programmed VA interval + 50 ms. Thus, a subsequent atrial event that falls within the longer refractory period will not be tracked and PMT will be broken.

* Applies to HF-T (CRT) devices only
† These choices are preset programs and will override previous sensing parameter changes

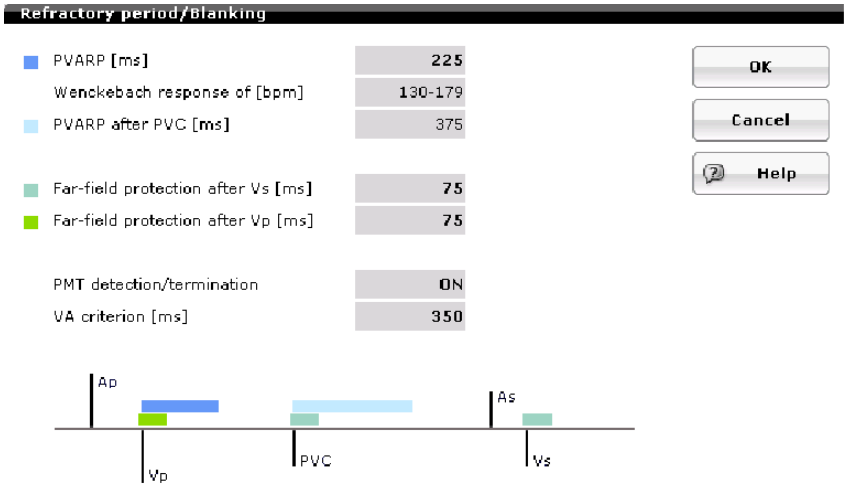

Figure 168: PMT Protection

7.14 LV channel programming for pacing polarity

The Rivacor ProMRI® HF-T QP devices provide 20 choices for LV pacing polarity. Pacing polarity choices are shown in Figure 169.

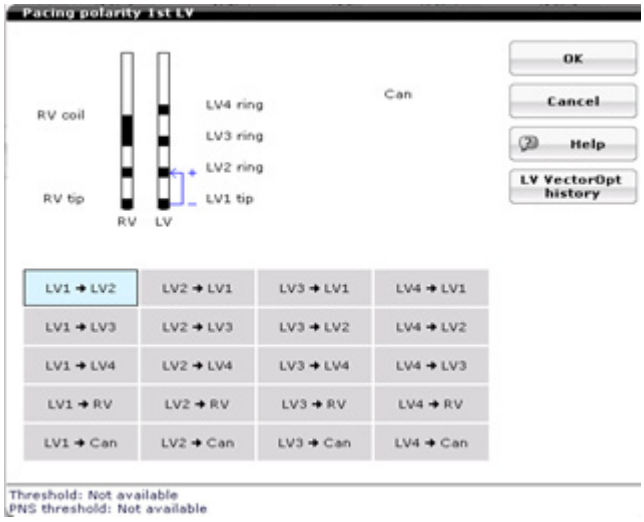

Figure 169: LV Vector Options in Rivacor HF-T QP devices

All Rivacor ProMRI® HF-T QP devices provide seven choices for LV sensing. LV sensing polarities include: LV1-> LV2, LV2-> LV3, LV3-> LV4, and LV1 -> Can, LV2-Can, LV3 -> Can and LV4 -> Can. It is important for CRT AutoAdapt and MPP that the independent LV sensing polarity is matched to the the LV pacing polarity of the 1st LV vector.

7.15 LV QP channel programming for pacing and sensing polarity

The Rivacor ProMRI® HF-T QP devices provide 20 choices for LV pacing polarity.

Pacing Polarity		
LV1 Tip	→	LV2 Ring
LV1 Tip	→	LV4 Ring
LV2 Ring	→	LV1 Tip
LV2 Ring	→	LV4 Ring
LV3 Ring	→	LV2 Ring
LV3 Ring	→	LV4 Ring
LV4 Ring	→	LV2 Ring
LV1 Tip	→	RV Coil
LV2 Ring	→	RV Coil
LV3 Ring	→	RV Coil
LV4 Ring	→	RV Coil
LV1 Tip	→	Can
LV1 Tip	→	LV3 RIng
LV2 Ring	→	LV3 Ring
LV2 Ring	→	Can
LV3 Ring	→	LV1 Tip
LV3 Ring	→	Can
LV4 Ring	→	LV2 Ring
LV4 Ring	→	LV3 RIng
LV4 Ring	→	Can

Figure 170: LV QP pacing polarity choices

The Rivacor ProMRI® HF-T QP provides 7 choices for LV sensing polarity.

Sensing Polarity		
LV1 Tip	→	LV2 Ring
LV1 Tip	→	Can
LV2 Ring	→	LV3 Ring
LV2 Ring	→	Can
LV3 Ring	→	LV4 Ring
LV3 Ring	→	Can
LV4 Ring	→	Can

Figure 171: LV QP sensing polarity choices

7.16 Rate Smoothing (non-programmable)

Rate Smoothing is a hidden feature to prevent sudden rate changes and is utilized for Mode Switching, Night rate, following Post Shock duration, and Post Mode Switch Duration. It uses the same attack and decay rates as the sensor, regardless of whether the sensor is turned ON. For example, if the Post mode switch rate is 70 bpm, the basic rate is 60 bpm and the rate decrease is 0.5 bpm/cycle, it would take 20 cycles for the rate to decrease from 70 bpm to 60 bpm.

7.17 Bradycardia Noise Mode

Initial Noise interval of 110 ms, retrigger interval of 10 ms

Each ventricular event starts a blanking period. A ventricular sense starts a ventricular sense blanking, and a pace starts a ventricular paced blanking period. During blanking, there is no sensing or rhythm classification. In addition, a sensed event also starts a noise window of 110 ms. The noise window will be retriggered if a sensed event is seen within the window. Continuous retriggering of the noise window will result in asynchronous pacing at the lower rate.

All devices with atrial sensing provide the same initial noise interval in the atrium.

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Chapter 8: Diagnostics

8.1 Tachycardia Diagnostics

8.1.1 Recording Memory

Various device information is available within the Recording memory. The Recording memory can be configured a number of different ways, depending on the physician's preference. Up to 60 minutes of IEGM storage is available

8.1.1.1 Episode List

Detailed information about each individual episode is presented as a table of events ordered from most recently delivered to the first delivered. Each IEGM segment can be viewed from the episode detail sub-menu by selecting the IEGM button (icon). From this screen, an IEGM can be expanded and scrolled to assist in a more accurate IEGM interpretation by enabling a closer examination of specific segments.

The ICD/CRT-D stores a variety of useful diagnostic data about tachyarrhythmia episodes, which may be used to optimize tachyarrhythmia detection and therapy parameters. This diagnostic data includes detection counters; therapy counters, last delivered ATP and shock therapy, shock data memory, therapy history, and stored intracardiac electrograms.

Color codes are used for the different zone detections. Red indicates a VF zone event, blue indicates a VT zone event and black indicates a SVT or AT/AF event, Periodic IEGM episodes or other events. The description column provides information related to the type and number of therapies provided or events such as periodic recordings. For example in Figure 172, episode 10 states "1 shock, induced". This means that one shock was delivered during induction testing. Furthermore, one can see at a glance how fast the atrial (PP) and the ventricular (RR) rhythm were before the episode and how fast they are after termination. Pre-detection information about the rhythm is found on the left side of the description column and post-termination information on the right side.

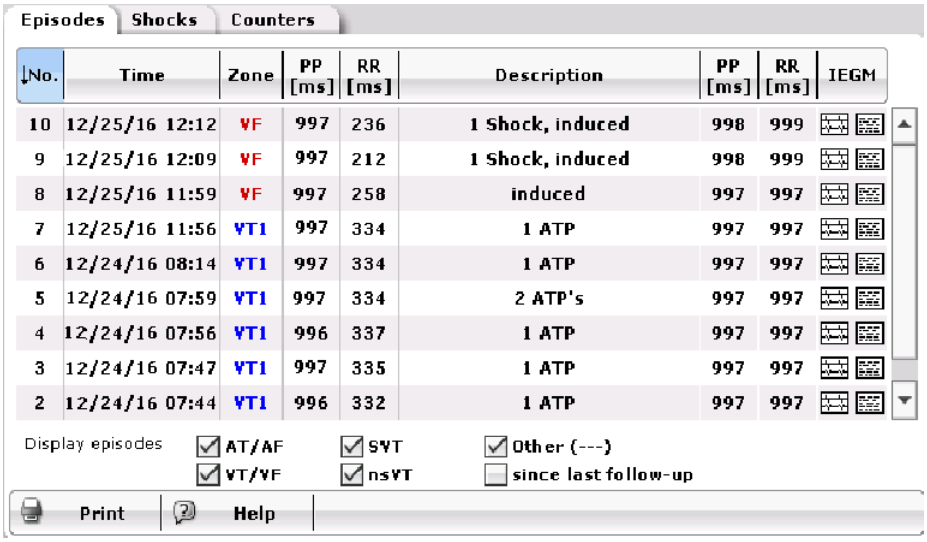

Figure 172: Episode list

8.1.1.2 Episode Details

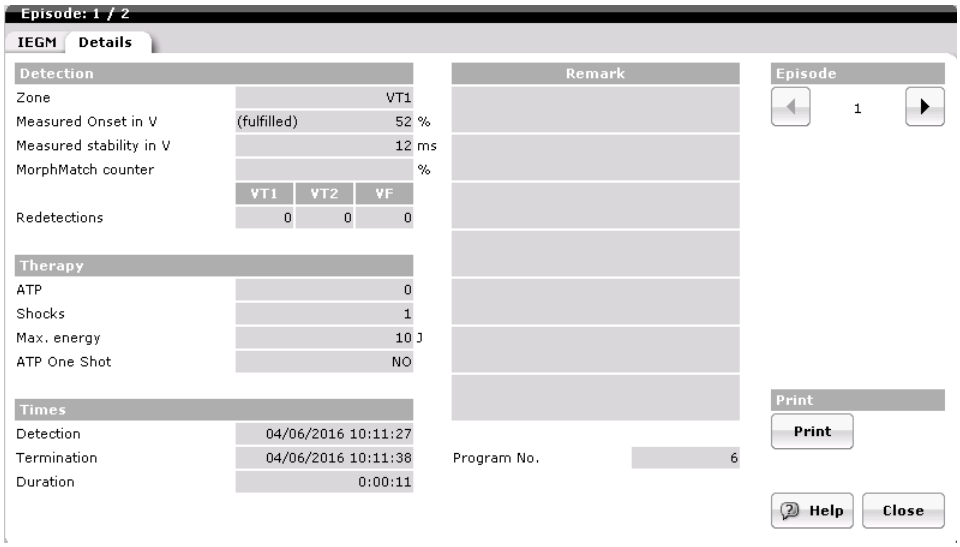

Figure 173: Episode details

The Details Icon provides detection and therapy specifics for each episode. The time and date of the episode are noted in the bottom left, along with the duration of the episode and the time of termination. Similarly, the measured stability (in milliseconds) is shown for the last 4 R-R intervals prior to detection in the upper left portion of the panel. The number of redetections in each zone provides acceleration and deceleration information.

8.1.1.3 Stored IEGM

The ICD/CRT-D can store up to 60 minutes of triple-chamber intracardiac electrograms (IEGMs) including the history and prehistory of the following events regarding AT/AF, VT/VF, SVTs, nsT and technical IEGMs.

- Time
- Zone
- Descriptions
- Episode details
- PP and RR intervals (before detection and termination, displayed only in the episode list)
- IEGMs

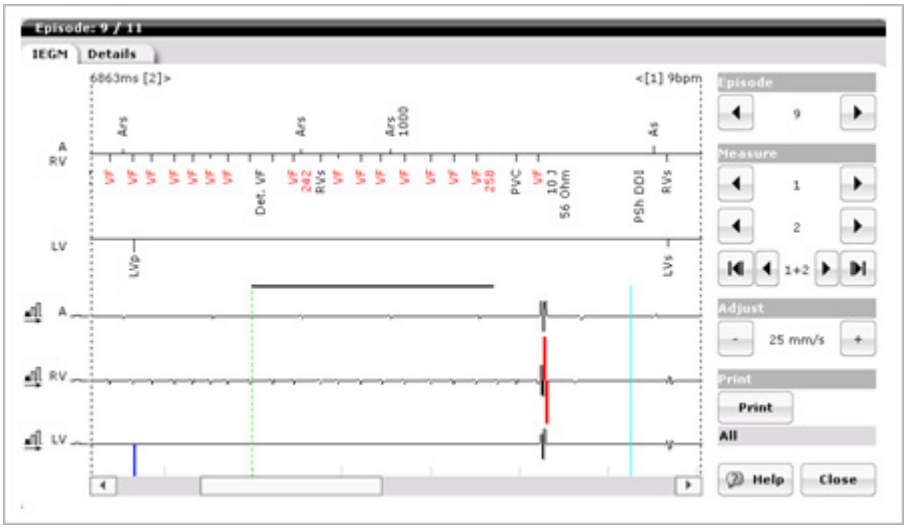

Figure 174: Stored IEGM viewed on the programmer

The Rivacor ProMRI® DR-T ICD provides atrial and ventricular IEGM recordings as well as far-field recordings. The Rivacor ProMRI® HF-T CRT-D provides three channels of electrograms in three programmable offerings: atrial, right and left ventricular IEGMs; atrial, right ventricle, far-field; and far-field, right and left ventricle. All ventricular tachyarrhythmia recordings (i.e., VT1, VT2, and VF episodes) are triggered when detection occurs and includes the predetection as well as the preterminiation IEGM. A maximum recording time of up to four minutes, including prehistory and termination, is stored. Up to 45 seconds of IEGM, including up to 30 s of prehistory and up to 15 s termination for SVT events, can be stored.

For a VT or VF episode, an IEGM episode in its entirety from pre-history to termination can be viewed on-screen by pressing the IEGM Icon from the Episode List. On-screen annotations include pace/sense markers (e.g., Vp/Vs), zone labels (e.g., VT1, SVT), interval measurements, and therapy markers (e.g., Burst ATP).

SVT episodes will provide IEGMs for the onset of the SVT and termination of the episode.

8.1.1.4 Shocks

The device history regarding high energy shocks is presented in a table format with the following information:

- Shock Number
- Date
- Time
- Energy
- Charge time
- Impedance
- Type of shock/Remark

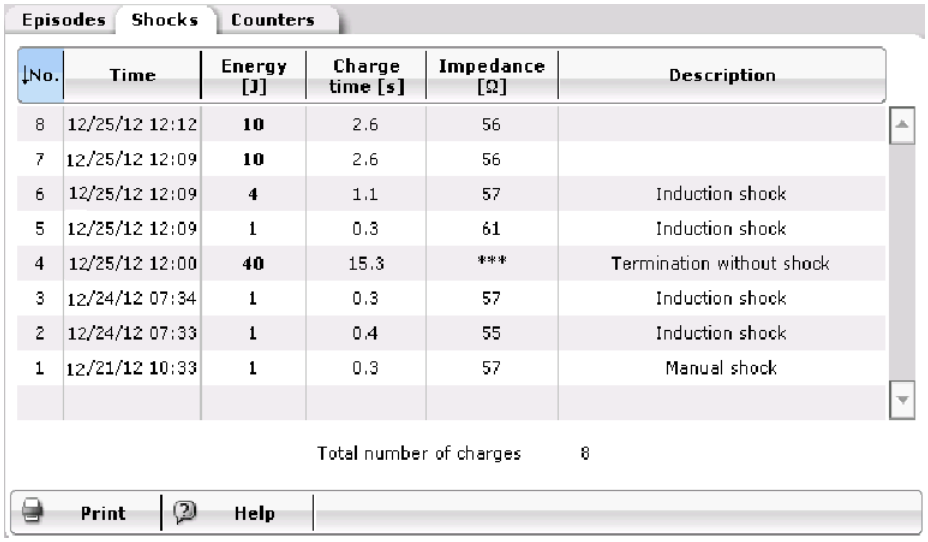

Figure 175: Shock table

In the Recordings screen, a table summarizing all shock therapy is displayed under the Shocks tab. The table gives the date and time stamp, energy, charge time, and the shock lead impedance for each shock. An additional field (Description) is provided to note induced, manual, or aborted therapy. The total number of charges occurring over the life of the device is shown at the bottom of the screen.

Delivered shocks will provide a charge time and a shock impedance value. Aborted shocks will provide a charge time but no impedance value as the energy was not delivered. Aborted energies are not dumped by the device after the episode immediately, but rather bleed off over several minutes. If a new episode resulting in shock delivery occurs before the stored energy bleeds off the device, the user may see "^40" in the energy column for the delivered shock. Additionally, a shorter charge time than expected may be shown.

8.1.1.5 Counters

The device history regarding several therapy and detection parameters is presented in the "Counters" screen. For detection and SVT details, this screen contains both the number of events since the last ICD/CRT-D follow-up and totals since the device was implanted. The available parameters include:

Detection Episodes (since last follow-up and since implantation)

- Atr. Monitor
- Atr. Therapy
- SVT
- VT1 SVT Details
- AFlut
- AFib
- VT2
- VF
- VT1 Monitor
- Sinus T
- 1:1

Therapy Episodes (since last follow-up and since implantation)

- Successful ATP Therapies in VT and ATP One-Shot
- Unsuccessful ATP Therapies in VT and ATP One-Shot
- Successful Shock Therapies
- Unsuccessful Shock Therapies
- Delivered ATP Therapies in VT and ATP One-Shot
- Delivered Shock Therapies

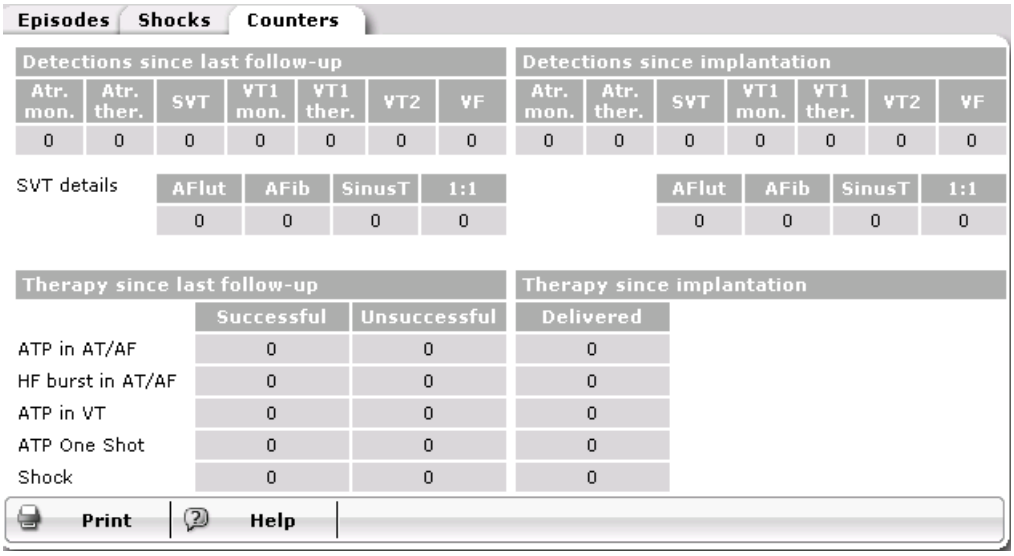

Figure 176: Counters

Tachyarrhythmia therapy and detection counters are found under the Counters tab. Detection counters in the upper panel include the number of initial detections in each tachyarrhythmia zone since the last follow-up and since implantation of the device. Detection counters include VT1 Therapy, VT1 Monitoring, VT2, VF, Atrial, and SVT detections. In the second panel, the SVT detections are classified into separate types of SVT rhythms based on SMART Detection®. SVT types include AFib (atrial fibrillation - SMART branch 4); AFlut (atrial flutter - SMART branch 2); Sinus T (sinus tachycardia - SMART branch 8); 1:1 SVT (one-to-one atrial tachycardia - SMART branch 10).

The therapy counters appear in the bottom column and give the total number of successful and unsuccessful ATP and shock therapies since the last follow-up. Also included are the therapies delivered since implantation (i.e., over the life of the device). These numbers may help the physician optimize patient therapy.

8.1.1.6 Statistics for ATP Optimization

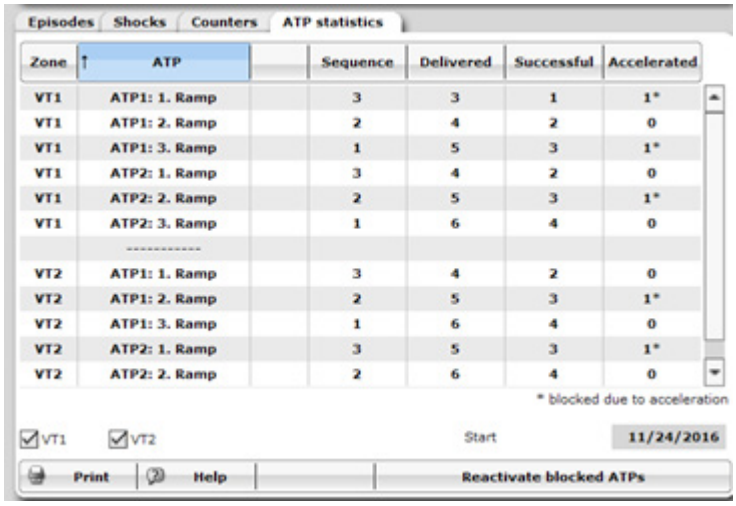

Figure 177: Statistics for ATP Optimization under the Recordings screen

The ATP statistics tab, located on the Recordings screen, will show information on the success of each ATP scheme. The table will contain columns for the following information:

- Programmed ATP attempts grouped into each VT zone
- Sequence: Sequence of the ATP attempt within their VT zone
- Delivered: The number of times ATP was delivered
- Successful: How often the ATP led to termination of the episode
- Accelerated: How often the ATP led to acceleration of the rhythm and therefore disabled by ATP optimization

If, due to ATP Optimization, all ATP attempts are disabled in a VT zone, the programmer will show an alert on the Follow-up screen and on Home Monitoring Service Center. Any ATP events that have been disabled can be re-enabled by selecting "Reactivate blocked ATPs" at the bottom of the screen. When this button is pressed, a confirmation message will appear.

8.2 Bradycardia Diagnostics

The Diagnostics button contains data related to bradycardia therapy. This data includes timing data, arrhythmia information, heart failure statistics, 48 hour pacing and rate trends, sensor data and other diagnostic information. Trend data are collected for 240 days. After 240 days, the data is overwritten on a first-in, first-out basis.

Trends will be marked at the day of follow-up with "F" at a follow-up session without reprogramming or with "P" at a follow-up session with reprogramming. Histogram statistics and counter will be restarted after every follow-up with automatic interrogation.

To restart all statistics, click the Start statistics button at the bottom of the statistics screen on the programmer. With either method, a message at the bottom of the screen will confirm "Programming was successful."

After diagnostics are restarted, the previous data will still be displayed under the diagnostics screen until the device is reinterrogated by returning to the implant list.

Data is not collected during the time of temporary testing during a follow-up session.

8.2.1 Timing Data

Rivacor devices have two tabs with Timing data labeled Timing and Timing 2 displayed under Diagnostics. The Timing tab contains Event episode, event statistics (i.e., percent timing sequences and percent atrial; right ventricular CRT and BiV pacing) as well as pacing trends for atrial, right ventricular, left ventricular, CRT and BiV pacing.

The Timing 2 tab displays the Rate histograms for atrial and ventricular events and the AV histogram

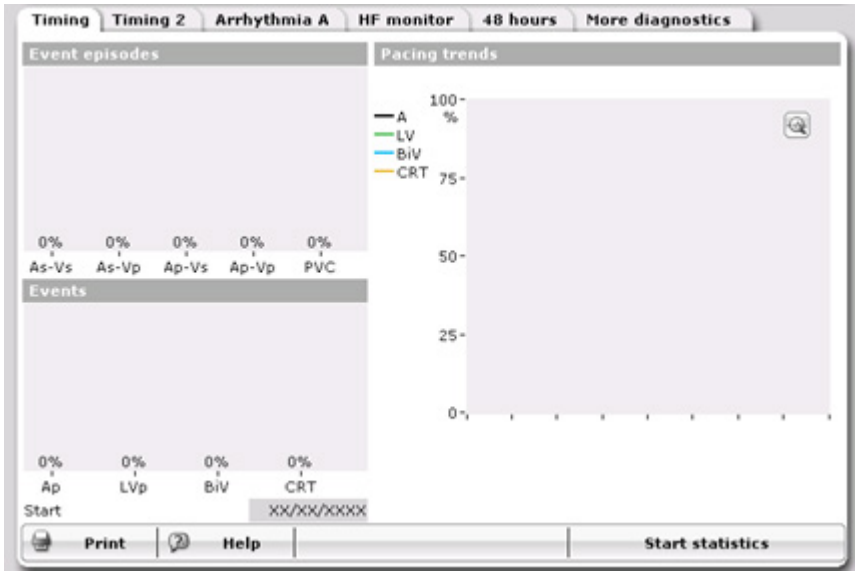

Figure 178: The Timing statistics screen

8.2.2 Timing Statistics

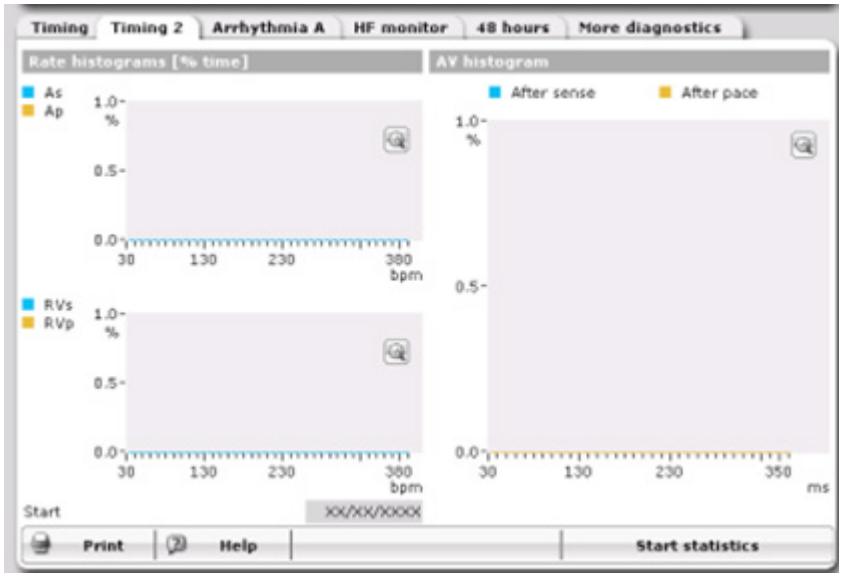

Figure 179: The Timing 2 statistics screen

The ICD/CRT-D stores a variety of useful diagnostic data of the bradycardia history as described in the following sections.

8.2.2.1 Event Episode and Events

Event Episode and Events statistics are located under the first Timing tab. This section presents data collected on the different pacing states of the device; As-Vp, As-Vs, Ap-Vp, Ap-Vs and PVC.

Event episodes (Brady)

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

Pacing Counters (Brady)

- Atrial pace percentage
- RV pace percentage and LV pace percentage (CRT-D)
- CRT pace percentage (HF-T devices only)
- BiV pace percentage (HF-T devices only)

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.

8.2.2.2 Pacing Trends

The Pacing trends graphs 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 days, the oldest data is overwritten first.

8.2.2.3 Rate Histograms

The Rate histogram shows the amount of pacing and sensing for each chamber at different rates. The ventricular data is collected from the RV channel. In the Rivacor devices, this data is displayed in the Timing 2 tab.

The heart rate range is divided into 16 segments ranging from 30 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), RVp, RVs, PVC, and RVrs 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. Printed programmer versions are black and white.
- 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.

8.2.2.4 AV Histograms

AV histograms are located in the Timing 2 tab in Rivacor devices. 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.

8.2.3 Atrial Arrhythmia Data

The Atrial arrhythmia tab provides information related to Atrial Burden and Ventricular reaction. Atrial burden is the amount of time the heart is in an atrial tachyarrhythmia, while Ventricular reaction is the ventricular rate response to the atrial tachyarrhythmia.

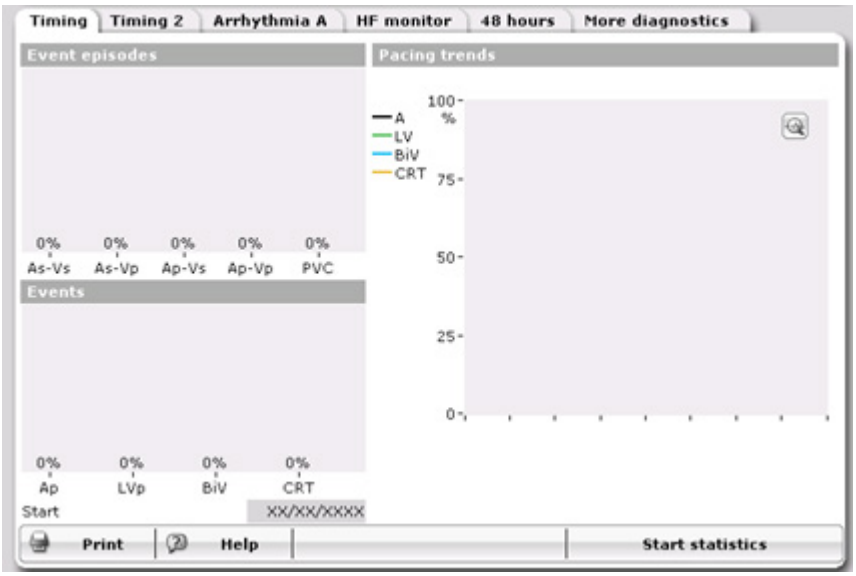

Figure 180: The Atrial arrhythmia screen

8.2.3.1 Atrial Burden

The Atrial burden section provides information for the following:

8.2.3.2 Total Number of Episodes

This represents the number of atrial tachycardia episodes that have occurred since the last follow-up. Ongoing atrial episodes are not counted in this number.

8.2.3.3 Atrial Arrhythmia Burden Percentage

This represents the average daily atrial burden since the last time the diagnostics were reset. Each percentage point represents about 14.4 minutes of data/day.

8.2.3.4 Duration of Tachycardia Episode

The duration of each episode is placed into the appropriate time bin and displayed as a percentage. For example, if the 0-1 minute bin shows 10%, it means that 10% of all episodes occurred in that bin. It does not represent the duration time.

8.2.3.5 The Number of (atrial) Tachycardia Episodes in a 24-hr Period

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.

8.2.3.6 Stress Duration per Day Expressed in a Percentage

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.

8.2.3.7 Ventricular Reaction

The Ventricular reaction graph provides information about the value of the mean and maximum ventricular rates during atrial tachyarrhythmia events. It also provides information as the percentage of paced and sensed events during the atrial tachyarrhythmia events.

Key Points:

- The Ventricular Reaction diagnostic gives information on the ventricular rate and pacing percentages during an AT/AF episode.
- The diagnostic is based on all Vs, Vp, PVC, and Vrs events.
- Ventricular reaction data will not be plotted continuously since data for this diagnostic is only collected during an AT/AF episode.
- The graph shows the percentage of ventricular events during AT/AF falling into each rate bin.

8.2.4 HF Monitor

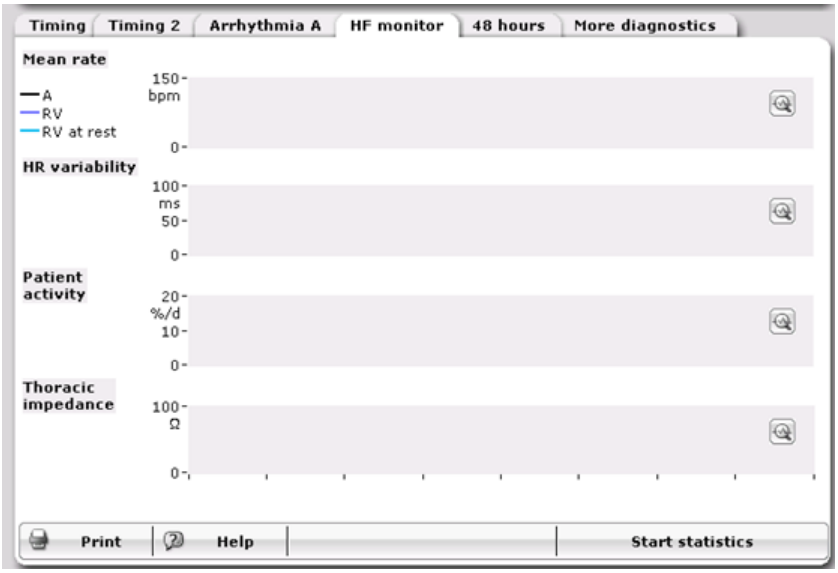

Figure 181: HF Monitor diagnostic

8.2.4.1 Rate

The top of the graph in the HF Monitor tab displays Mean Heart Rate and Mean Heart Rate at Rest. Mean Heart Rate is designated by the "RV," and the Mean Heart Rate at Rest is designated by "RV at Rest". Mean Heart Rate at Rest is a measurement of the lowest heart rate during a programmed measuring period. The heart rate is calculated based on 10-minute intervals beginning at the programmable Starting Resting Period. The device uses the lowest single average taken during the recording period. For accurate daily measurements, do not program the Starting Resting Period and Resting Period Duration to overlap the transmission time for Home Monitoring periodic transmission.

8.2.4.2 Heart Rate Variability

In addition, the HF Monitor statistics show the amount of heart-rate variability and patient activity. With Heart Rate Variability, the higher the number the more variability is present. With successful CRT therapy, one would expect both of these statistics to show increased activity. This feature is not available in the Rivacor ProMRI® VR-T, as HR Variability is based on P-P intervals.

8.2.4.3 Patient Activity

Patient activity is defined as any time the sensor moves off of baseline (programmed lower rate value) and not necessarily when sensor pacing occurs, such as the case when the patient's intrinsic rate is greater than the sensor indicated rate.

8.2.4.4 Thoracic Impedance

Thoracic impedance is measured between the distal shock-coil of the RV lead and the ICD housing. Up to 64 measurements are taken every hour and these measurements are then averaged. The 24 measurements per day are averaged and stored in the device and transmitted daily via Home Monitoring as a single average point per day. 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 ICD. 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 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 "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 four-hour duration, programmable under the Diagnostics tab).
- The minimum ventricular heart rate is determined by taking 10-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
- Data is displayed as a single data point per day.

- Should not be used as a stand-alone parameter to assess CHF in patients.
- Hypovolemia, COPD and other factors can affect thoracic impedance calculations.
- Data collected within the first 30 days after implantation generally should not be used because issues such as small hematomas and expected post-surgical swelling affect the measurements.

8.2.5 48 Hours

48 Hours presents a snapshot of the most recent 48 hours of rate, atrial burden and paced percentages. Each data point shown is a 10-minute average of the data collected. This allows the user to see more detailed, short term data to look for sudden changes in rates, burden or pacing percentages.

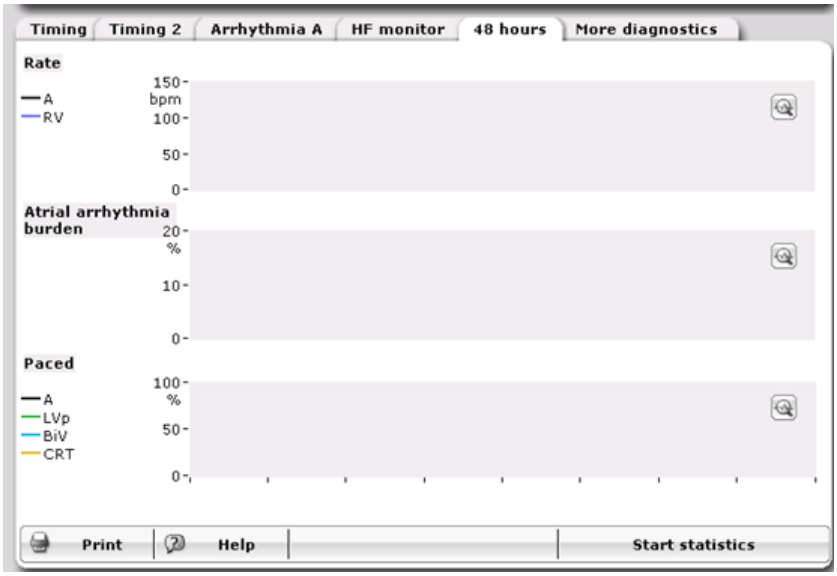

Figure 182: 48 Hours

8.2.5.1 Rate

The atrial and right ventricular rates are displayed over the last 48 hours prior to interrogation.

8.2.5.2 Atrial arrhythmia burden

Presents atrial burden data for the last 48 hours prior to interrogation.

8.2.5.3 Paced

Presents the paced percentages for all programmed channels.

8.2.6 More statistics

8.2.6.1 Event Counters

In the Event Counters, the legend is as follows: As - refers to atrial sensed events

As (PVARP) - refers to atrial event occurring during PVARP

Ars - typically refers to events occurring during the AV Delay or during Mode Switching Ap - atrial paced events

RVs - refers to RV sensed events

PVC - refers to RV extrasystoles

RVrs - refers to RV refractory sensed events. These are events that occur within 200 ms of the previous RV event and are non-programmable.

RVp - refers to RV paced events LVs - refers to LV sensed events LVp - refers to LV pacing

LVrs - refers to LV refractory events. These are events that occur within 200 ms of the previous LV event and are non-programmable.

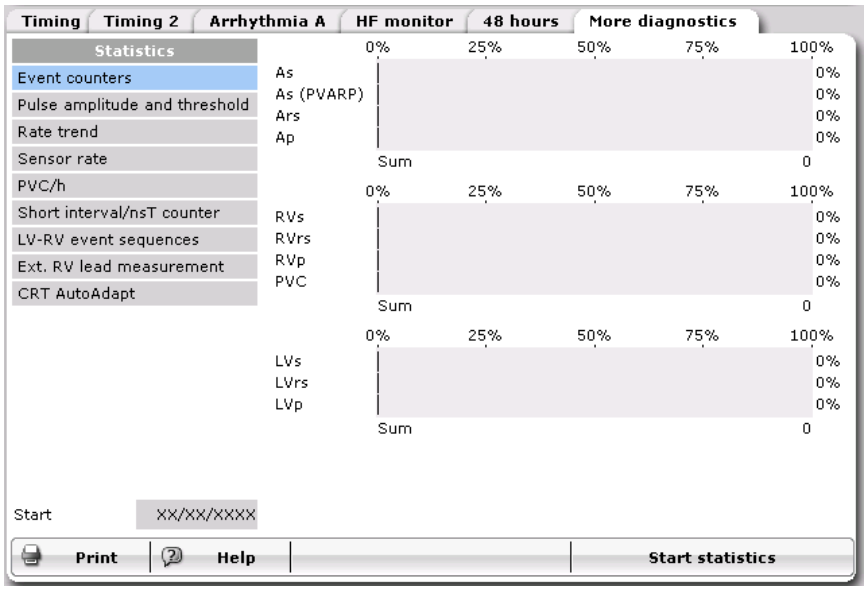

Figure 183: Event Counters screen

The number of Mode Switching episodes, detected PMTs and Safety window pacing are also listed on this page.

Key Points:

- With LV T-wave protection turned OFF, the LV pace will show 100% because intrinsic LVs events will not restart the Maximum Trigger Rate. LV sense statistics will still be available even if LV T-wave Protection is OFF.
- RVrs events are those RV events within 200 ms of the preceding RV sensed event. The 200 ms sensed refractory period is non-programmable. LVrs is also 200 ms.
- PVC = Right ventricular extra systole, 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.

8.2.6.2 Pulse Amplitude and Threshold

The Pulse amplitude and threshold screen, shown in Figure 184, displays the daily threshold measurements taken in the RV and LV chambers. This is measured through the ACC/VCC feature and is available if the feature is programmed to ACC/VCC. If the device is an HF-T QP and LV CC is active for the second LV pace, the threshold data will be displayed here as well. If programmed to ATM or OFF this diagram shows the fixed programmed amplitude for the RA, LV and RV channel. This measurement is taken once daily 40 minutes prior to the programmed Home Monitoring transmission time. If the test could not be completed, a second attempt 10 minutes prior to HM transmission will occur.

If Home Monitoring is OFF, the device uses the default transmission time.

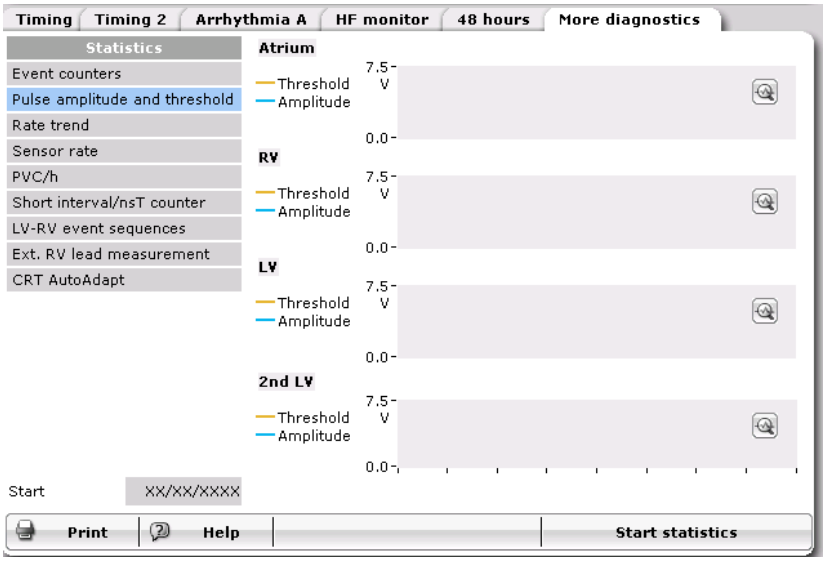

Figure 184: Pulse amplitudes

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/CRT tab.
- The test is performed daily, 40 minutes prior to the Home Monitoring transmission time. If the first attempt is unsuccessful, a second attempt will occur 10 minutes prior to the Home Monitoring transmission.

8.2.6.3 Rate trend

The Rate trend statistic shows the heart rate and percentage of pacing in each chamber for 240 days. The oldest data is overwritten as new data is collected. The ventricular data is collected from the RV channel.

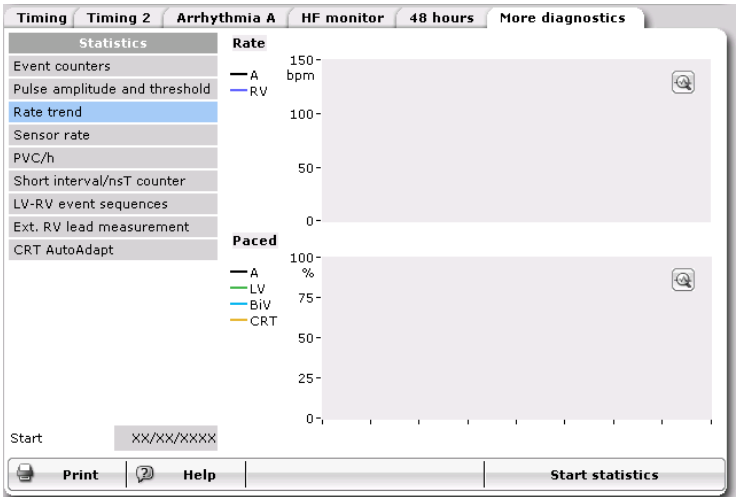

Figure 185: Rate trend

Key Points:

- The Rate Trend shows the rate of each chamber plotted separately for the duration of the statistics.
- The Rate Trend is based upon As, Ap, Ars, As(PVARP), Vs, Vp, PVC, and Vrs events.
- The Paced Trend shows the percentage of paced events in each chamber for the duration of the statistics.
- This diagnostic is useful to assess any changes to the patient's state of pacing, dependency on the device, or occurrence of arrhythmias.
- An overall increase in average heart rate may indicate worsening heart failure.
- Rate trend collects a single data point for each day.
- After 240 days, the oldest data are overwritten.

8.2.6.4 Sensor rate

The Sensor rate page displays sensor histogram data and the rate/sensor trend. The sensor histogram shows the percentage of time the sensor rate lies within given heart rate bins — regardless of whether the sensor is used. The heart rate range is divided into a total of 16 bins in groups of 10 bpm.

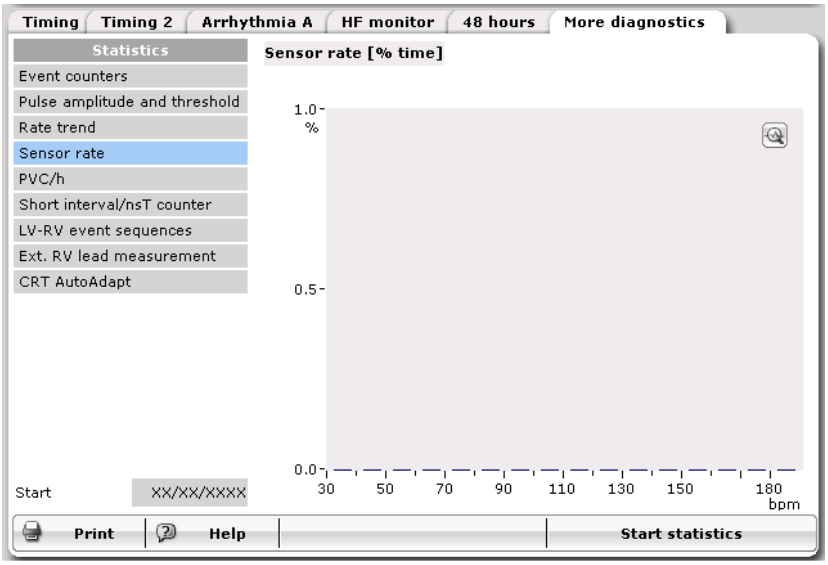

Figure 186: Sensor rate

The Sensor histogram collects information regarding sensor activity whether the sensor is turned ON or not.

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.

8.2.6.5 PVC/h

The PVC/h statistic shows the average number of PVCs per hour for each 24-hour period.

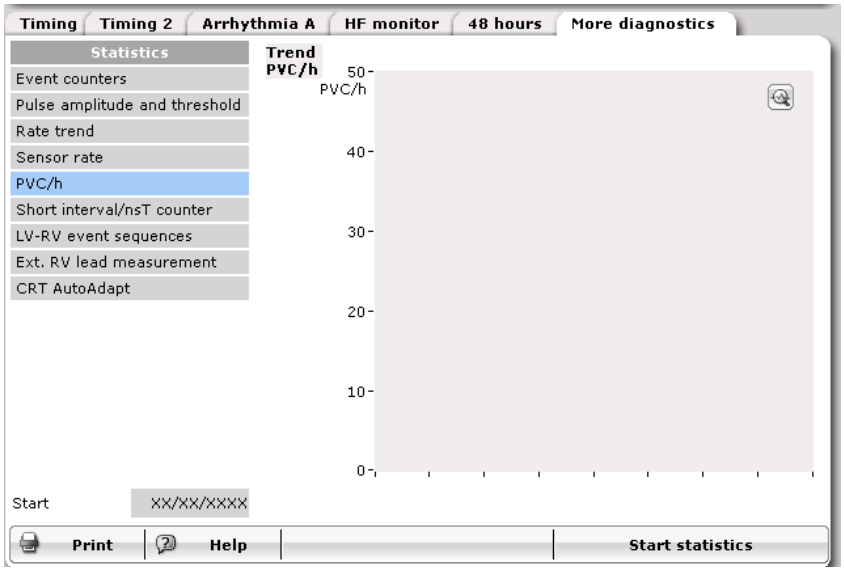

Figure 187: PVC/h graph

Key Points:

- The PVC/h diagnostic displays the average PVCs per hour each day throughout the duration of the statistics.
- 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 could be an indicator of worsening heart failure.
- 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.
- The scalar will automatically adjust based on the number of PVCs occurring.
- Collects a single data point for each day.
- After 240 days, the oldest data are overwritten.

8.2.6.6 Short Interval/nsT Counter

These graphs show the number of non-sustained VT events and short interval (noise) events on a daily basis. Non-sustained VT events are those VT episodes that are 6 or more fast beats in duration, but do not meet the VT/VF detection counter for therapy. Short intervals are those events that are considered non-physiologic in nature based on their intervals. These short intervals may indicate a lead issue.

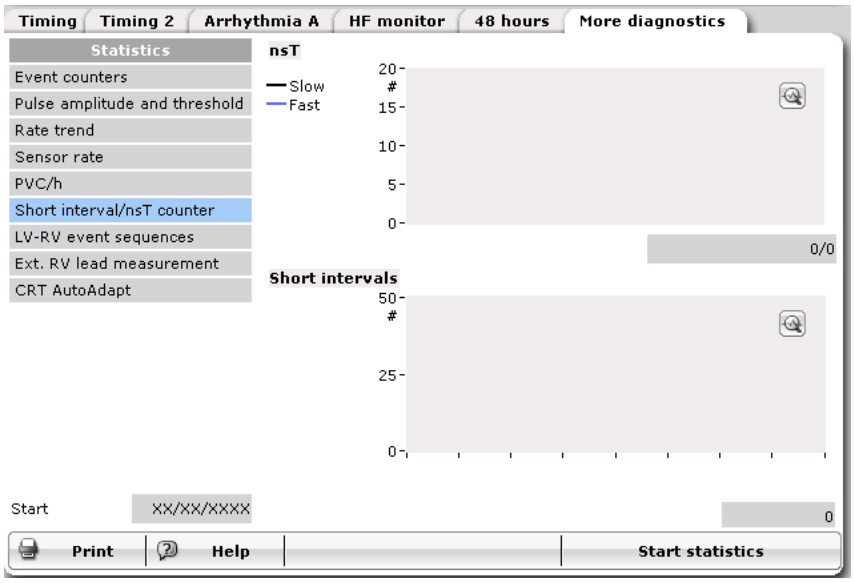

Figure 188: Short interval/nsT graph

Key Points:

- nsT episodes are short runs (6 beats or more) that do not meet the programmed VT/VF therapy counters and may indicate a worsening cardiac condition.
- IEGMs for nsT episodes may be programmed ON.
- Short intervals may indicate lead noise and eventually require intervention to address.

8.2.6.7 Event Sequences (HF-T devices only)

This page provides the percentage of each of the different states of pacing and the percentage of BiV pacing in HF-T devices. In HF-T devices, event sequences involving synchronizable RV and LV events are displayed in one graph. The graph provides more information on the RV and LV pacing states including the percentage of time the device is RVs without LVp, RVp without LVp and other event sequences (Figure189)

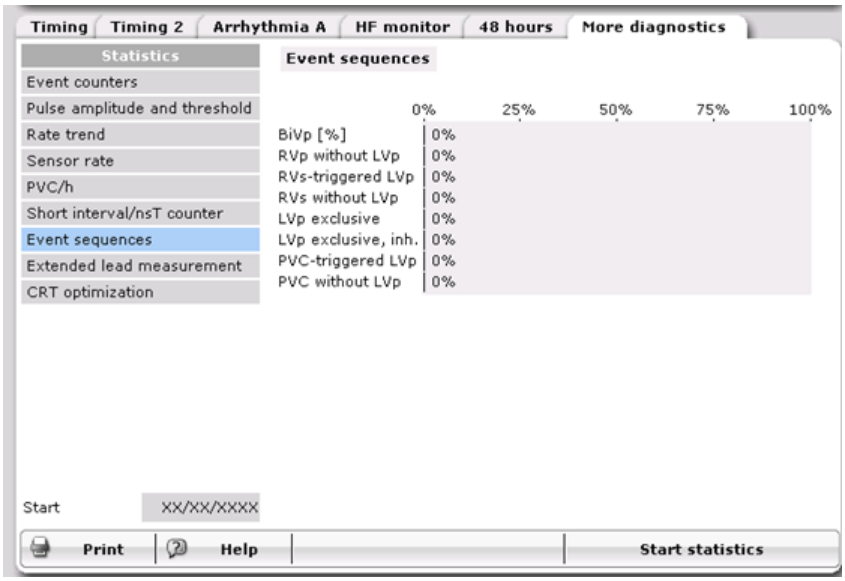

Figure 189: Event sequences in HF-T devices

8.2.6.8 Extended lead measurement

Extended Lead Measurement is a non-programmable feature that records lead impedance measurements for the following vectors:

- RV-Coil -> Can
- RV-Coil -> RV-Tip
- RV-Ring -> Can
- RV-Ring -> RV-Tip
- SVC-Coil -> Can
- SVC-Coil -> RV-Coil

The device will take hourly impedance measurements for each vector. The daily mean impedance value for each vector will be stored in an impedance trend as shown below.

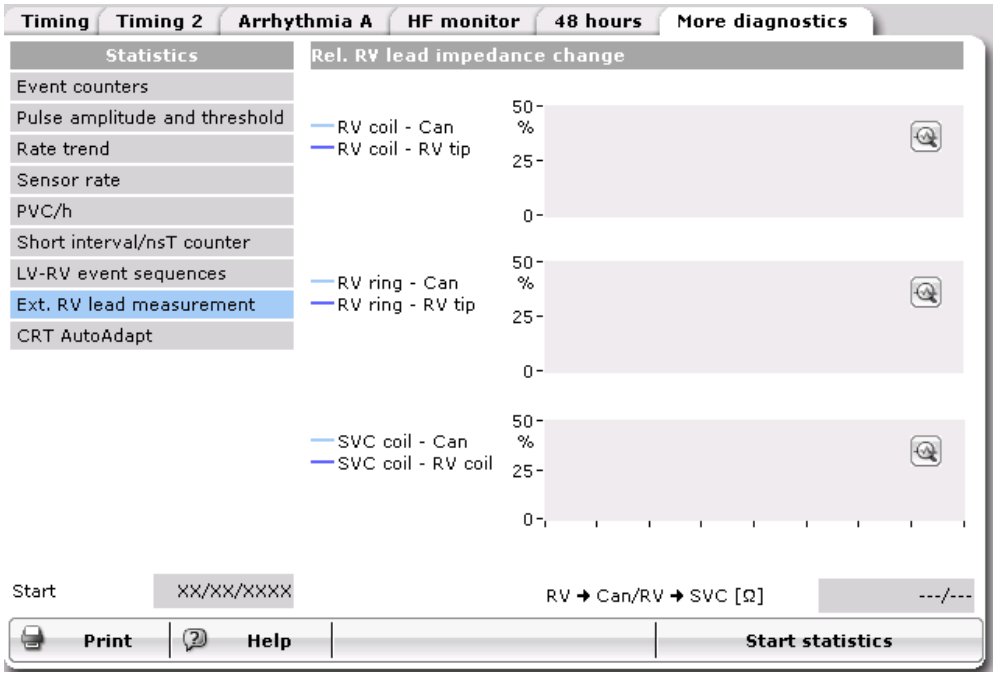

Figure 190: Impedance trends are stored under More diagnostics

The programmer statistics will display the lead impedance trend for each vector. The displayed trend values will be calculated as the difference of the daily mean value to the average of the last 16 values.

8.2.6.9 CRT AutoAdapt (HF-T devices only) *(Not applicable in Rivacor 5)*

The programmer will display the following information on the more diagnostics screen (NOTE: this can also be reached by clicking the CRT AutoAdapt Diagnostics link from the parameters page):

- A histogram displaying the pacing status broken down into LV adaptive, BiV programmed and BiV adaptive as a percentage vs time. This information can be used to access CRT AutoAdapt functionality by seeing how much time the algorithm is spending in each state.
- A histogram showing the Adaptive AV delay values in ms for both after pace and after sense vs time. This information can be used to see how the adapted AV delay is changing over time.

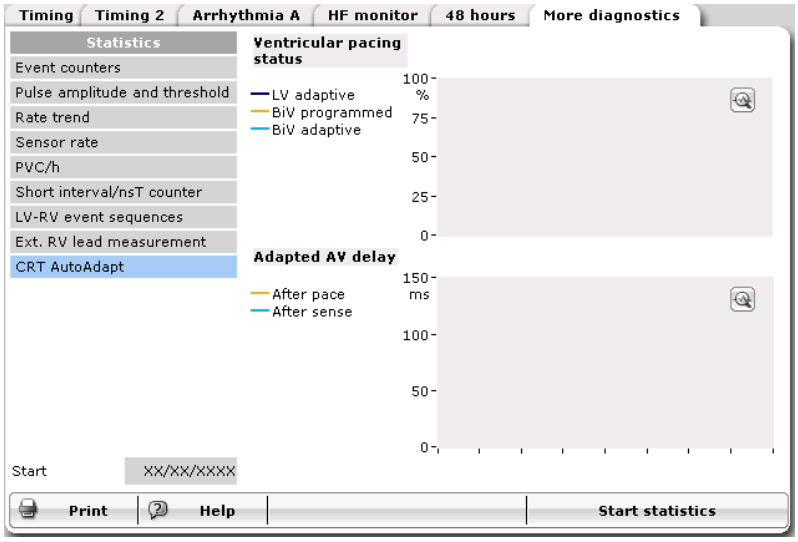

Figure 191: CRT AutoAdapt Diagnostics

Chapter 9: Additional Features

9.1 BIOTRONIK Home Monitoring®

When active, Home Monitoring enables the exchange of information about a patient's cardiac status from the implant. The information is transmitted to the Home Monitoring Service Center (HMCS), where the physician may log in to review. The HMSC can be used to provide the physician with advance reports from the implanted device and process them into a graphical and tabular format that is accessible via the internet platform HMSC. This information may help the physician optimize the therapy process, possibly providing earlier notification of clinically relevant events to help guide future therapy.

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 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 data is automatically collected and reported on a daily basis.

The implanted device's Home Monitoring function can be used for the entire operational life of the implanted device (prior to EOS).

NOTE: When ERI mode is reached, this status is transmitted. All measurements and transmissions are unaffected. When End of Service (EOS) is reached and transmitted, further measurements and transmissions of Home Monitoring® data are no longer possible.

9.1.1 Transmission of Information

The implanted device transmits information with a small transmitter, which has a range of about 2 meters (6 feet). The patient's implant data are sent to the CardioMessenger, at least every 24 hours. The transmissions may also be activated by the detection of a cardiac event, as programmed. The types of transmissions are discussed in Section 2.4.3.3.

9.1.1.1 CardioMessenger

The CardioMessenger patient device is designed for use in the home and is comprised of a stationary device or a mobile device that comes with an associated charging accessary. The stationary device remains on the patient's bedside table at all times. The mobile device can be carried by the patient during his or her occupational and leisure activities. The mobile patient device is rechargeable, allowing for an operational time of approximately 24 to 48 hours, if needed. CardioMessenger devices receive information from the implanted device and forward it via a telephone or cellular network to the Home Monitoring Service Center. For additional information about the CardioMessenger, please refer to the device's technical manual.

9.1.1.2 Transmitting Data

The implant's information is digitally formatted by the Home Monitoring Service Center and is processed into a tabular format (CardioReport) that is accessible via the internet platform HMSC. The CardioReport notification is available via BIOTRONIK's secure Internet connection. Reports are available depending on the type of report transmission—periodic or event triggered. This CardioReport, which is adjusted to the individual needs of the patient, contains current and previous implant data. An intracardiac electrogram (IEGM) is included for the latest tachycardia episode (VT/VF). The Internet site allows the physician to "program" the HMSC on how the notification for event information is supplied; either by SMS message, on the internet platform, and/or via email. Once the message is received, the physician can view the information through the Internet site.

The periodic/event trigger criteria are specific to the particular device and can additionally be individually customized for each patient. These notifications can be sent to the attending physician via SMS or email.

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 24. Additionally, Table 24 provides system specifications that are recommended for optimizing usage of the Internet.

System requirements / recommendations

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 11	⩾ MS Internet Explorer 11 (recommended) ⩾ Mozilla Firefox 56 ⩾ Google Chrome 62 ⩾ Apple Safari 11 ⩾ MS Edge 41 JavaScript and cookies must be enabled.
Acrobat Reader	Version 8	Version 8 or higher
Communication Channel	E-mail	E-mail or mobile phone

Table 24: System Requirements/recommendations

9.1.1.3 Types of Report Transmissions

When the Home Monitoring function is activated, the transmission of information from the implant can be triggered as follows:

- Daily report – the time period (daily) initiates the transmission (IEGM included if not yet sent)
- Event report – certain event reports can be programmed to have an IEGM included each time that they are transmitted. The device records and transmits up to 45 seconds of patient presenting IEGM at the time interval programmed.
- Periodic IEGM report – The periodic IEGM report is a transmission triggered by a preprogrammed trigger entered in the HMSC. This transmission contains an IEGM of up to 30 sec. as well as the content of the daily transmission information including statistic/trend data.
- Programmer triggered report – a test message transmitted upon request of the physician in the clinic.
- QuickCheck- The device will send a full data download including any new triggered IEGMs and a real-time periodic IEGM to the Home Monitoring Service Center within 15 minutes of triggering the QuickCheck Request. The patient must sit by the monitor once the physician initiates the request. *(Not applicable in Rivacor 5)*

Daily Report

The time of daily Home Monitoring Report transmission is programmable via the programmer.

For periodic messages, the time can be set anywhere between 0:00 and 23:00 hours or may be programmed to Standard (default). When the device is set to Standard (Std.), the device transmits a message between 01:00 and 02:00 hours, dependent on the serial number of the device. It is recommended to select a time between 00:00 and 04:00.

Periodic Report with IEGM

The Rivacor ProMRI® ICDs and CRT-Ds can be programmed to transmit Periodic IEGMs with the daily Home Monitoring through the Home Monitoring Service Center as part of the Remote Follow-up feature.

Event Report

When certain cardiac and technical events occur, a report is automatically generated. This information is described as an "event report."

The implant supports the following automatic event triggers:

- Termination of VT/VF Episode (not Termination of a Monitoring episode, SVT episode or Episodes during temporary program)
- Ongoing Atrial Monitoring Episode lasting longer than the programmed time (6, 12 or 18 hours) The following event triggers are also supported and are only evaluated at daily transmission time. These event triggers can convert the daily trigger to an event trigger:
  - Impedance out-of-range for A, RV, LV, shock lead (painless measurement)
  - Atrial Therapy Episodes
  - Special Device Status
  - EOS
  - Back-up mode

- ERI
- Master Switch V Off
- Emergency Brady Active

Additional messages

The following triggers are also supported:

- First ineffective maximum energy shock detected
- Initial detection SVT
- Percent of ventricular sensing below set limit
- ERI

Programmer Triggered Report

With the device status screen, it is possible to test the ICD/CRT-D's Home Monitoring capabilities during device implantation or follow-up. To do this, the CardioMessenger must be within range of the Rivacor ProMRI® ICD/CRT-D and powered ON. From the device's Home Monitoring tab, press the Send test message button.

QuickCheck *(Not applicable in Rivacor 5)*

The Rivacor ProMRI® ICD/CRT-D will have the ability to trigger an on demand device data download to the Home Monitoring Service Center via the patients CardioMessenger SMART. QuickCheck is programmable and can only be enabled if Home Monitoring is turned ON. The physician is able to trigger a QuickCheck Request through the Home Monitoring Service Center. The device will send a full data download including any new triggered IEGMs and a real-time periodic IEGM to the Home Monitoring Service Center within a maximum of 15 minutes (usually in 3-4 minutes) of triggering the QuickCheck Request. The patient must sit by the monitor once the physician initiates the request.

9.1.1.4 Description of Transmitted Data

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

Device Status and Home Monitoring Settings

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

- Device Serial Number
- Battery status voltage and Date of Measurement
- Max. charge time since last follow-up
- Device Status
  - Master switch (e.g., ICD Therapy ON or OFF)
  - Standard error flags
  - Implantation Date
- MRI Activation
- Data of last Shock
  - Impedance and Date of last Shock delivered
  - Shock Energy

- Complete Shock Recording
- Message Creation Date/Time
- Date/Time of End of last Monitoring Interval
- Date and time of Last Follow up and Program Counter
- Current ROM/RAM Version Information
- Current Consumption for ERI calculation (done by the Service Center)

Leads

- Automatic Threshold Monitoring
  - Measured RV pacing threshold
  - Measured LV pacing threshold
  - Measured LV2 pacing threshold
  - Measured RA pacing threshold
  - Current Pulse Amplitude (RA, RV, LV, LV2)
- Pacing Impedance (RA, RV, LV, LV2)
- The mean daily pacing impedance is the mean of up to 24 values per day. HMSC calculates mean values since last follow-up.
- Sensing Amplitude (RA, RV, LV)
  - Mean of four daily measurements
  - Minimum of four daily measurements
- Painless Shock Impedance
  - The mean daily painless shock lead impedance is the mean of up to 24 values per day.
- Impedance and Date of last Shock delivered
- Number of short RV intervals

Pacing Statistics (Brady)

- AV Sequences
  - Intrinsic Rhythm (AsVs)
  - Conducted Rhythm (AsVp)
  - Atrial Paced Rhythm (ApVs)
  - Complete Paced Rhythm (ApVp)
  - VV sequence (Vx Vx) [%]
- Ap, RVp [%]

Pacing Statistics (CRT)

- Lvp, BiVp, CRTp [%]
- Statistics related to CRT AutoAdapt
  - Adaptive BiV pacing [%]

    - Programmed BiV pacing [%]
    - Adaptive LV pacing [%]
    - Mean adapted AV delay after pace [ms]
    - Mean adapted AV delay after sense [ms]
- LV RV Sequences
    - BiVp (RVp LVp or LVp RVp
    - RVs LVp
    - RVp no LVp, RVs no LVp (LV T wave protection ON)
    - LVp, no LVp (LV pacing only)
    - PVC LVp (Triggering: RVs+PVC)
    - PVC no LVp (LV T wave protection ON)
- Number of PMT episodes per day

Atrial Arrhythmia

- Atrial Burden per Day
- Duration of longest atrial Episode
- Mean and max. Heart Rate during AT/AF
- Number of atrial Episodes per Day
- Number of Mode Switches per Day
- Life-Time Counter of atrial monitoring Episodes
- Life-Time Counter of atrial therapy Episodes
- Ongoing Atrial Episode Time (programmable for 6, 12 or 18 hrs)
- Atrial Therapy Counts
- Lifetime Counter of Detections in SVT
    - Number of SVT by SMART
    - Number of SVT without SMART

Ventricular Arrhythmia

- Lifetime Counters
    - Detections in VT1, VT2, VF,Episodes during temporary program (induction)
    - SVT total
    - Started + successful ATP in VT
    - Started + successful ATP One Shot in VF
    - Started + cancelled + successful Shocks
    - Ineffective maximum energy shocks
- Date, Time and Number of Last Episode (number as in episode listing in Recordings)
- Non-sustained tachycardias per day
- Number of Mean PVC/h per day ("per Day" is referenced to the Monitor Interval Duration)

Heart Failure Monitoring (all data based on Monitoring Interval)

- Heart Rate
  - Mean atrial heart rate
  - Mean ventricular heart rate
  - Mean ventricular heart rate at rest
- Heart Rate Variability
  - Atrial SDANN per day (5 min periods of As As)
- Patient Activity
  - % Duration per day (from Sensor)
- Thoracic Impedance
  - Hourly mean of up to 64 measurements/hour

Transmitted Device Settings

The currently 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)
- CRT (e.g., Configuration, VES Triggering, VV delay)
- I OPT (ON/OFF)
- AV Delay Adjust setting (ON/OFF)
- Ventricular Tachycardia Detection (e.g., Zone limits, SMART Detection®, Sustained VT)
- Ventricular Tachycardia Therapy (e.g., ATP Schemes, Shock path and energies)
- HM Settings (e.g., ON/OFF, transmission time (daily), IEGM transmissions ON/OFF, HM Follow up, ongoing atrial episode, statistics and recordings)

System Information

Information is also added by the CardioMessenger to the message from the implant. This information contains the following data:

- CardioMessenger Serial Number
- Technical Parameters for Troubleshooting

9.1.1.5 IEGM Online HD

The Rivacor ProMRI® ICDs/CRT-Ds provide the ability to transmit up to 4 IEGMs Online HD (high definition) (IEGM and marker data) from the most recent SVT / VT / VF / AF / nsT / Technical Trigger episodes as an addition to the current messages.

An IEGM with up to three channels (RV, LV, RA or Far-Field) are sent in one message, depending on the number of IEGM channels programmed in the Holter configuration.

If an episode is terminated each IEGM Frame contains at least 8 sec of pre-detection IEGM and at least 8 sec of pre-termination IEGM

If the episode is not terminated each IEGM Frame shall contain at least 10 sec of pre-detection IEGM The IEGMs delivered for specific events are as follows:

- For VT/VF therapy episodes both pre-detection and pre-termination parts are sent (at least 8 sec + 8 sec), because HM is triggered after termination detection.
- If AF, SVT, VF, or VT monitoring episodes are terminated, both pre-detection and post-detection parts are sent if the episode is terminated. If it is not yet terminated only a pre-detection part is sent.
- If an ongoing atrial episode fulfills a programmed time duration criteria, a message is triggered to provide the physician with the information, including an IEGM, early on.
- For the periodic IEGM only one part is available. Such recordings are performed right before a periodic message, and after each interval as configured.

The Rivacor ProMRI® ICD/CRT-D may transmit the following data from the Episode List with the IEGM message:

- Episode Number
- Date and time of initial detection
- Date and time of termination
- Indication of magnet application (induced episode and forced termination)
- Zone of initial detection
- Number of delivered ATP and shocks during this episode
- Number of redetections per zone
- SMART Detection® settings (VT zones activated)
- SMART path (for SVT)
- Duration of episode

The IEGM also contains the following rhythm markers: As, Ars, Ap, Vs, Vrs, Vp, VT1, VT2, VF, and the SMART Detection® rhythm markers Aflut, SVT, Afib, SinT and 1:1.

The IEGM Online HD for up the four episodes are stored in the device in an IEGM data buffer. The firmware updates the IEGM transmission buffer before the first IEGM transmission episode. IEGM data from a VT/ VF episode is available after Termination detection of an episode. If the Holter configuration records an SVT IEGM episode, the IEGM data from an SVT episode is available after Termination detection of an episode. An IEGM message is transmitted with daily, periodic IEGM, and episode messages (unless already sent).

An IEGM is not sent with programmer triggered and ROM/EOS messages.

The Rivacor ProMRI® ICD/CRT-D includes a programmable parameter to disable or enable the IEGM transmission. The default value is "enabled."

9.1.1.6 Scheduling Remote Follow-up

The Rivacor ProMRI® ICDs/CRT-Ds provide the ability to automatically schedule remote follow-ups via the Home Monitoring Service Center. From the patient's Home Monitoring page, the user can enable or disable remote scheduling. When Remote Scheduling is enabled, the physician decides when to receive the first Remote follow-up as well as subsequent transmissions. These additional transmissions can be programmed by a set interval of days, a specific day of the week closest to the programmed interval or specific calendar days selected by the physician. A Periodic IEGM is sent as part of the remote follow-up data.

NOTE:

The patient must be registered to Home Monitoring to allow programming of remote follow-ups.

9.2 Thoracic Impedance

Thoracic impedance is measured between the distal shock-coil of the RV lead and the ICD housing. Up to 64 measurements are done every hour and these measurements are then averaged. The 24 measurements per day are stored in the device and transmitted daily 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 ICD. 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.

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 an implant or revision procedure.

9.3 Capacitor Reformation

Shock charge times may be prolonged if the high-voltage capacitors remain uncharged for an extended period of time. Conditioning (or reforming) the capacitors by periodically charging them will help assure shorter charge times for those patients that do not regularly receive shock therapy. The Rivacor ProMRI® devices automatically re-form the capacitors after every six months and the reformation is performed at midnight. The capacitor reformation clock is reset following an automatic or manual capacitor reform. Any device initiated maximum charging of the high voltage capacitors also resets the automatic reformation clock (i.e., shock therapies).

An automatic or manually initiated capacitor reform fully charges the capacitors and then allows the capacitors to discharge slowly. No shock will be delivered to the patient. Throughout the re-formation process the ICD/CRT-D will provide bradycardia pacing support and tachyarrhythmia sensing and detection as programmed. If a tachyarrhythmia is detected during capacitor reformation, the process is aborted and therapy is available if required.

CAUTION

Capacitor Reformation - Infrequent charging of the high voltage capacitors may extend the charge times of the ICD/CRT-D. The capacitors are automatically reformed.

Figure 192: The manual capacitor reformation page

9.4 Asynchronous Pacing Modes

The Rivacor ProMRI® models offer the following asynchronous pacing modes for use during medical procedures:

- VOO – asynchronous pacing in the ventricle
- DOO – asynchronous pacing in the atrium and ventricle with a fixed AV delay for conduction between chambers. The Rivacor ProMRI® HF-T provides BiV pacing as a default when programmed to the VOO/DOO modes.

Tachyarrhythmia detection is deactivated when using these asynchronous modes in Rivacor ProMRI® devices.

The asynchronous modes are intended for use during medical procedures, such as cautery. In patients with inadequate intrinsic rhythm, the pacemaker should be reprogrammed to an asynchronous mode during the procedure in order to prevent inhibition by electromagnetic interference. Thus, the asynchronous modes VOO and DOO are intended to prevent possible inhibition by electromagnetic interference during invasive intervention (such as during electrocauterization).

The patient must be monitored when asynchronous pacing modes are used. The asynchronous modes VOO and DOO can only be set if tachyarrhythmia sensing is deactivated. However, this would leave the patient without sensing and therefore without ICD therapy. Thus, during the use of asynchronous modes:

- Continually monitor the patient
- Keep an external defibrillator ready

Chapter 10: Implantation Testing, EP Test Functions and Follow-up

All tests related to an ICD implant and follow-up are located on the Tests screen. These tests include: P/R amplitude measurements, pacing impedance, retrograde conduction test, threshold (pacing), DFT test, and ATP test. Additional EP test functions are also available with the Rivacor ProMRI® family of ICD/CRT-Ds, including extensive testing of defibrillation thresholds as well as the ability to verify the effectiveness of anti-tachycardia pacing and defibrillation shocks. Each of these tests is described in this chapter.

Marker Annotations

The Rivacor ProMRI® ICD provides multiple-sized marker annotations on ECGs and IEGMs to differentiate events from a bradycardia timing perspective. Shown below are examples of the different marker annotations. The SVT annotations are available on stored episodes only.

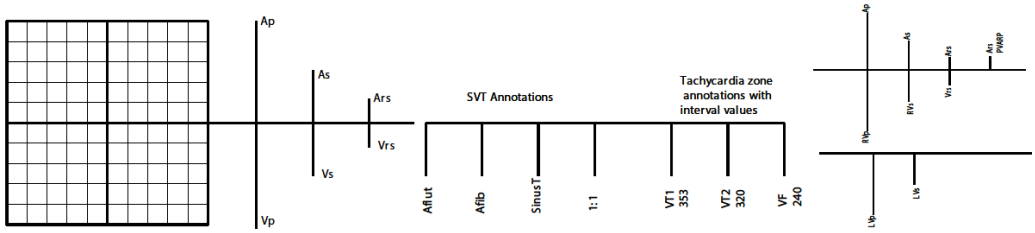

Figure 193: Marker Annotations

NOTE:

In the Rivacor ProMRI® devices, unused sensed events can occur in any chamber. They will be annotated as Ars or Vrs events. These events are not used for bradycardia timing cycles. However, these intervals are used for mode switching and/or tachyarrhythmia detection.

NOTE:

Tachyarrhythmia detection/therapy is temporarily disabled while the sensing, threshold, retrograde and impedance tests are active. Once the specific test is complete, detection/therapy is active again.

10.1 P- and R-Wave Measurements

Sensing test may be performed via the Start or Intrinsic Rhythm buttons.

10.1.1 Start (test)

The sensing test is performed in a VDI mode with a programmable back-up support pacing when the START button is selected for all channels. Thus atrial values will be given even if the device is programmed in a VVI(R) mode.

When the Tests button is selected, the Sensing screen is revealed, the P- and R-wave amplitudes are automatically measured on command using the Start button. During the tests, the device uses the temporary pacing program to provide backup bradycardia support. The intrinsic amplitudes

are measured over several beats and are displayed on the programmer screen when the test is complete. The user has an option to print an IEGM strip during the test via the Report button on the left side of the screen.

10.1.2 Intrinsic Rhythm (test)

The sensing test can be performed by selecting and holding down the Intrinsic Rhythm button. The test ends when the button is released.

NOTE:

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

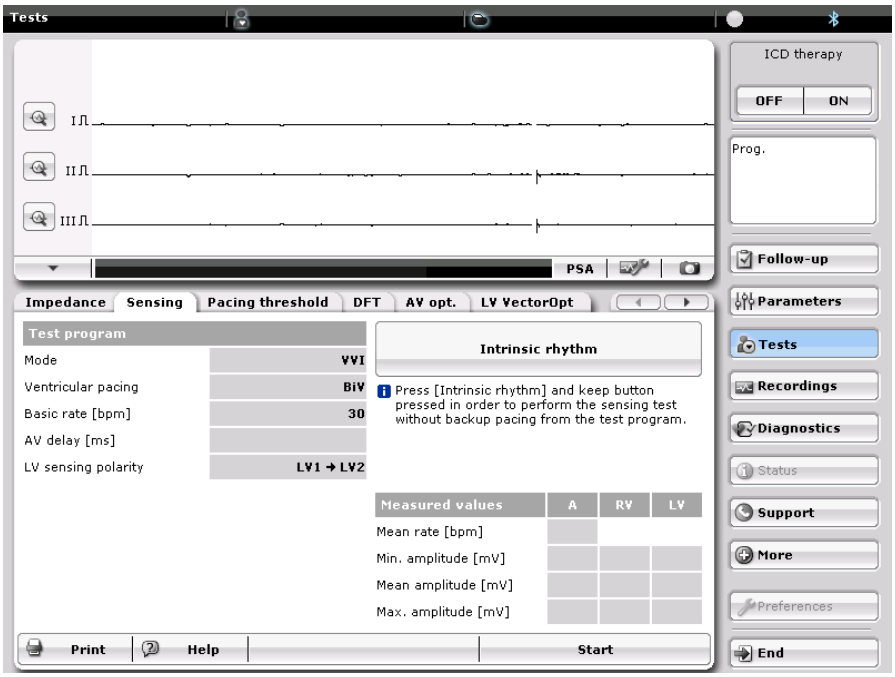

Figure 194: The Sensing screen

10.1.2.1 Back-up Pacing Mode

OFF, **VVI**, AAI and VDD

The OFF mode provides no pacing support during the test and should not be used for pacemaker dependent patients.

AAI mode provides no ventricular pacing support and should not be used for patients with high-grade or complete heart block.

VDD mode may be used for pacemaker-dependent patients who suffer from pacemaker syndrome.

10.1.2.2 Ventricular Pacing

(HF-T devices only) BiV or RV

10.1.2.3 Basic Rate

30 ... (5) ... 100 ... (10) ... 160 bpm

10.1.2.4 AV Delay

100 ms

This is a fixed value available only when the VDD mode is selected.

10.1.2.4 LV Sensing Polarity

Programmed polarity

NOTE:

During the sensing test, PVARP is set to 200 ms if PVARP is set to AUTO.

10.2 Pacing Lead Impedance

Performed independent of the programmed mode using subthreshold outputs. The user can select the desired LV pacing polarity for the test.

Atrial value may be given even though the device is permanently programmed in a VVI(R) mode.

Figure 195: Performing the Impedance Test

Atrial and ventricular pacing lead impedance can be used to determine whether the pacing leads are electrically sound. The pacing impedance is the total resistance to current flow along the lead, across the lead-tissue interface, and into the tissue. A large impedance value (e.g., greater than 3000 ohms) may indicate lead fracture. A small impedance value (e.g., less than 200 ohms) may indicate an insulation break.

The pacing impedances are measured from the Impedance tab found under the Tests button. To measure the impedance, simply press the Start button at the bottom of the screen. The word TEMP (temporary) appears on the marker channel when the test has started and across the bottom of the screen the phrase "Lead detection in progress. Please wait ..." appears with a status bar under the IEGM. Additionally, the device status will be temporarily changed to "Temporarily inactive" while the test is active and returns to "Enabled" when the test is complete. After the button is pressed, a series of subthreshold pacing pulses are delivered. The programmer measures the voltage drop from the leading edge to the trailing edge of the delivered pulses and automatically calculates impedance from the measured voltage drop. The calculated value is immediately displayed on the

programmer screen. When the test is complete, the term Perm appears on the marker channels. The impedance test displays the Shock Impedance first and then the atrial and ventricular pacing impedances. Atrial impedance measurements may be difficult to obtain in patients with atrial fibrillation at the time of testing. Increasing the sensing threshold value (decrease sensitivity) to force atrial pacing may help in forcing atrial pacing in order to obtain impedance. Be sure to change the sensing threshold back if it is changed for the test.

The Impedance test allows the user to program any LV pacing polarity in order to determine the pacing polarity in different configurations.

10.3 Retrograde Conduction Test

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

Figure 196: Retrograde conduction test.

10.3.1 Measuring Retrograde Conduction

The Retrograde Conduction test 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 in the IEGM (V pace to A sense). The measurement begins after the Start tab is pressed.

The programmer displays the results as the maximum, minimum, and average retrograde conduction time (RCT), and the measured V-A times are displayed on the marker channel. Generally, if the min, mean and max times are within 25 ms, retrograde conduction is suspected. The timing values shown are equal to the time between the ventricular pace and the first subsequent atrial sense event.

Retrograde conduction from the ventricle to the atrium can be confirmed when a 1:1 relationship at a constant V-A interval is present.

Requirements for Measurement

1. Telemetry contact (wand or RF) must be maintained with the ICD 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.
2. Retrograde conduction can only be measured if ventricular pacing and atrial sensing are present.
3. The ventricular rate for the test MUST be greater than the atrial rate.

NOTE:

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

10.3.2 Programming to prevent PMT

If Retrograde conduction is confirmed, extending the PVARP value by 10-15 ms greater than the RCT interval can cover the retrograde events. Caution should be used, as this will reduce the 2:1 block point for bradycardia pacing.

10.4 Pacing Threshold Test

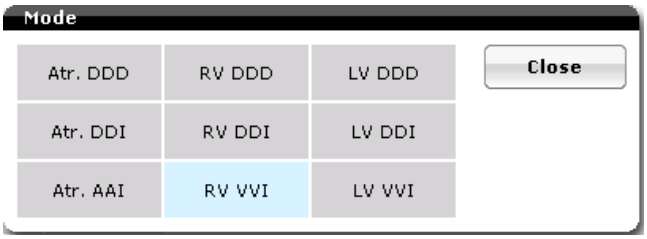

Figure 197: Threshold Test Choices with Rivacor ProMRI® HF-T

The atrial and ventricular pacing thresholds are determined using the threshold tests found under the Threshold tab. The right and left (HF-T only) ventricular threshold test can be performed in the DDD, DDI or VVI mode at a user-defined rate between 30 and 160 bpm. The atrial threshold test can be performed in the DDD, DDI or AAI. Auto threshold tests in the RV and LV channels using the same algorithm as the ATM/VCC tests can also be selected. In addition, the atrial IEGM screen can be displayed during the atrial threshold test by changing the parameter from Test settings. As with all screens, the patient's intrinsic rate is displayed on the screen. The intrinsic rate helps the user select the best pacing rate for the test.

Rivacor ProMRI® devices allow real-time changes during the threshold tests. The user can change any of the values while the test is ongoing.

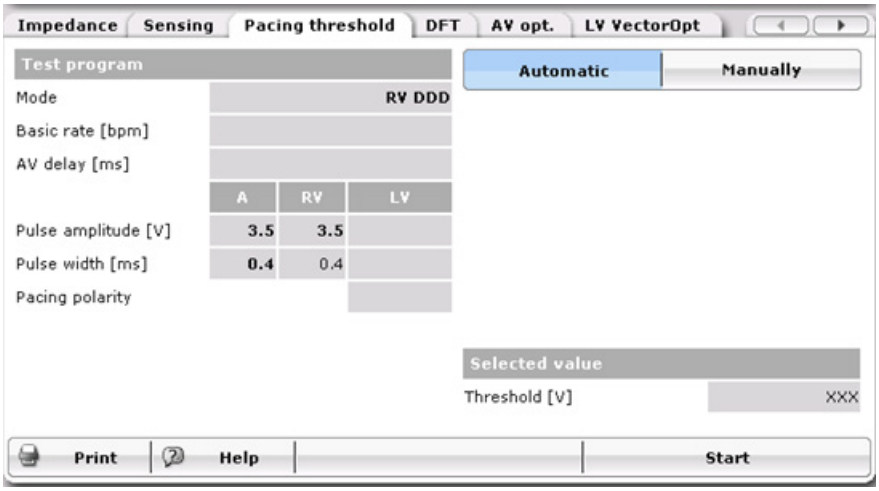

Figure 198: The Pacing threshold test using the Automatic option

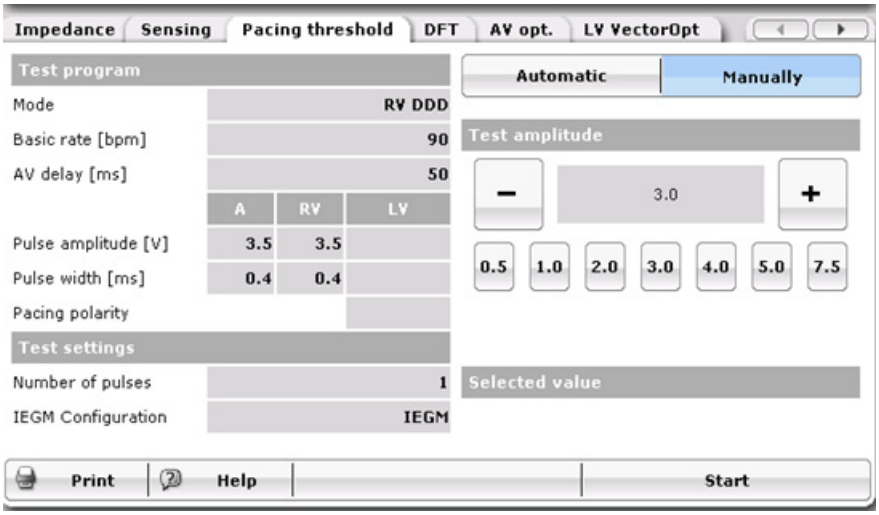

Figure 199: The Pacing threshold test using the Manual option

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 Number of Pulses is programmed to "∞". Otherwise, a set number of pulses (1-10) will be delivered with each new test amplitude selected before reverting back to the starting value. The default parameters will be reprogrammed between test selections.

When each test is complete, the threshold value is entered into the programmer for future reference. An annotated version of the test can be printed after the test by selecting the "Print" button found in the lower left-hand corner of the screen.

10.5 AV Optimization Test

AV optimization is a feature which measures AV intervals for paced and sensed atrial events and provides programming suggestions for paced and sensed AV delay programming. This may provide the opportunity to improve cardiac hemodynamics and modulate the efficacy of cardiac resynchronization therapy (CRT). This is implemented as part of a follow-up test in the device. In this test, the device measures the mean, minimum and maximum P-wave durations for paced and sensed events. The device then offers suggested paced and sensed AV Delay setting options, which the user can accept or select manual options.

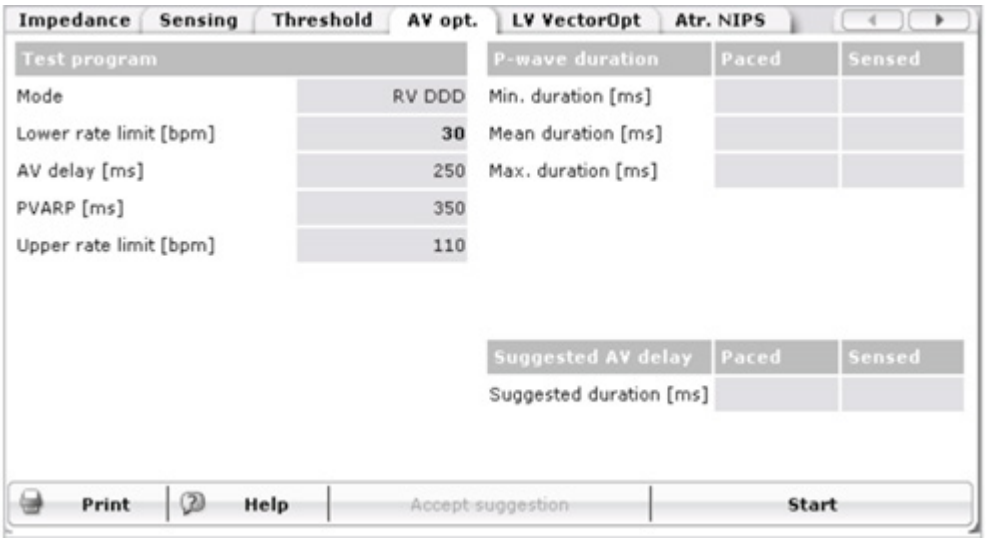

Figure 200: AV Opt Test

10.6 LV VectorOpt

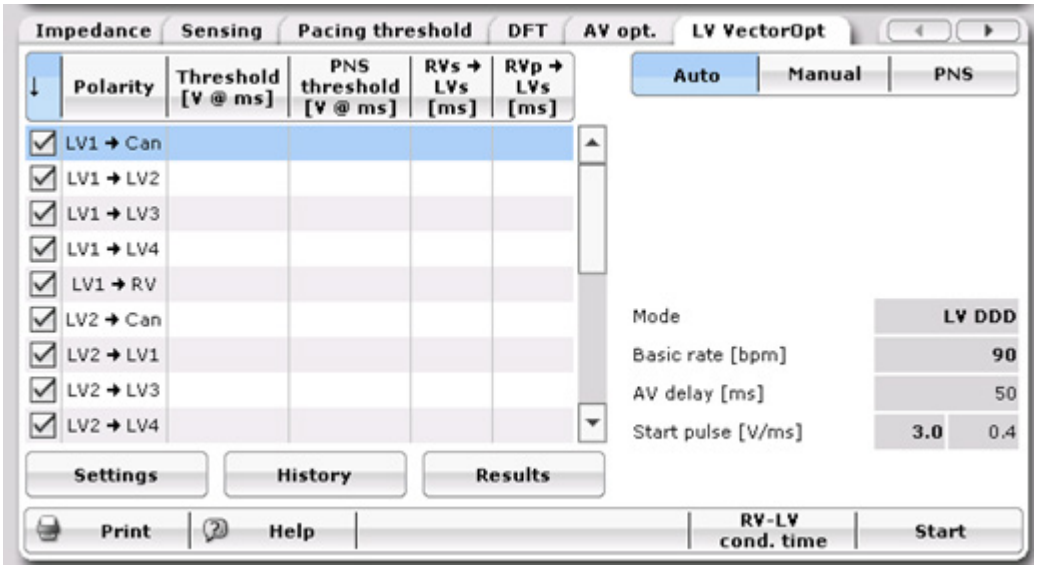

Figure 201: LV Threshold testing

LV VectorOpt is used to measure LV thresholds in various pacing configurations to determine the pacing thresholds and phrenic nerve stimulation (PNS) thresholds in each configuration. The results are displayed for each pacing configuration measured to allow comparisons to determine the best pacing vector for the patient.

10.6.1 Auto LV VectorOpt

In addition to the manual LV VectorOpt test, Auto LV VectorOpt can perform LV threshold measurements automatically. This test starts a temporary program and automatically measures the thresholds of up to 20 polarity vectors. The user can measure all 20 vectors or select a subset of pacing vectors as shown in Figure 202.

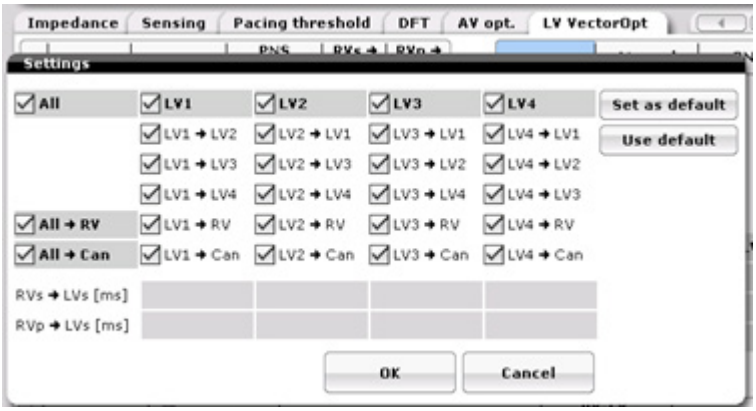

Figure 202: Selecting LV pacing vectors for LV VectorOpt

The Auto LV VectorOpt test will first determine if the pacing vector has an in-range impedance measurement. If the impedance is out-of-range (<200 Ohms or >3000 Ohms), the measurement of the current pacing vector will be cancelled and the test will move to the next LV pacing vector.

The threshold test is performed similarly to the ventricular capture control algorithm. The device will perform a signal quality check (SQC) for each pacing vector. The purpose of the SQC is to determine if capture and non-capture amplitudes are adequate by measuring positive and negative signal amplitudes, location and polarity of the zero crossing, and various integrals of the signal at different times. Once SQC is successful, the device will perform the threshold test by initially pacing with the threshold test start value and decreasing the voltage step-by-step until non-capture. The threshold will decrease depending on programmable start amplitude. If the start amplitude is greater than or equal to 1.2 V, the threshold will decrease by 0.8 V until non-capture. If the start amplitude is less than 1.2 V, the threshold will decrement by 0.2 V until non-capture. The last effective test amplitude will be recorded as the threshold.

After all vectors have been tested, the temporary program will stop and the threshold and impedance results of every vector will be saved on the measurement LV VectorOpt page.

Parameters

Mode:
LV DDD, LV DDI, LV VVI

Basic Rate:
30 ... (5) ... 100 bpm
100 ... (10) ... 160 bpm

Start Amplitude:
Programmable threshold test start value
Range: 0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0, 7.5 V

10.6.2 RV-LV Conduction Time (QP Devices Only)

The RV-LV Conduction Time test measures both the RVp to LVs and RVs to LVs conduction times. This test allows for the user to measure the real intrinsic conduction time from the right to the left ventricle in addition to the RVp forced conduction time measurement.

To program, the user can select whether they want to measure RVp to LVs, RVs to LVs, or both. This test is only available in DDD/VVI RV-only modes with LV sensing. After the test runs, the results will be saved to the measurement page as shown in Figure 203.

Figure 203. RV-LV conduction time measurements

The programmer displays the results for the RV-LV Conduction test, PNS testing, and Threshold testing by selecting the results button on the LV VectorOpt page. Previous results can be viewed by selecting the history option at the bottom of the page

10.7 Defibrillation Threshold Testing (DFT)

Defibrillation threshold testing is performed from the DFT Test screen. These tests allow the physician to assess defibrillation thresholds and to verify adequate and appropriate detection and sensing during induced arrhythmias. As DFT tests are performed, the ventricular signal is continuously evaluated via the real-time IEGM signal on the programmer screen. The DFT Test screen as it appears when you enter the test page is shown in Figure 204.

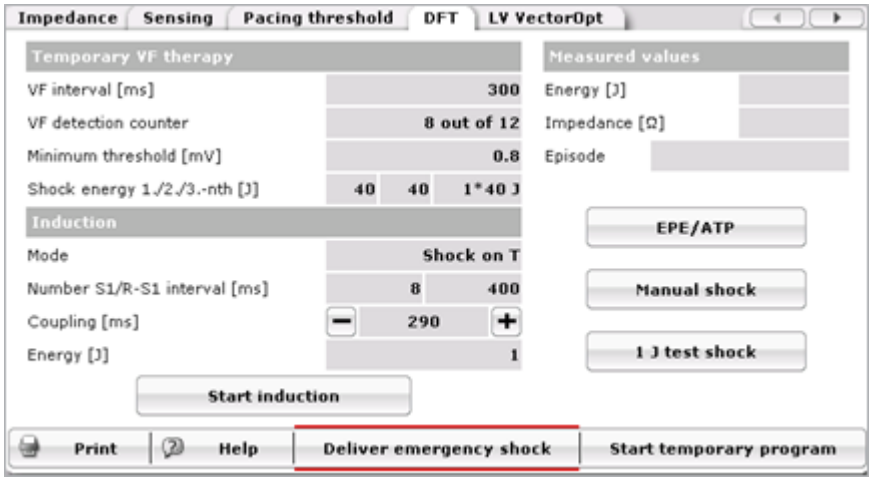

Figure 204: The Rivacor ProMRI® DFT Test screen

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

The DFT Test screen is organized left-to-right in order of use during testing. On the upper left of the screen is the Temporary VF therapy program. This allows the device to use the selected values on the screen without having to permanently program changes to the device. The user can change the VF zone rate, minimum threshold, detection counters and shock energy output and number of programmed delivered shocks.

Below the temporary VF therapy section is the Induction section. Here the user can select the induction mode of Shock-on-T or HF Burst.

The upper-right portion of the screen provides information related to the delivered energy, shock impedance and the date and time of the last recorded episode. A link to the last episode is also provided if a successful episode termination occurred.

Below the measured values are buttons to access manual ATP (EPE/ATP), deliver a manual shock and deliver a one-joule(1 J) test shock. These will be discussed in greater detail throughout this chapter.

10.7.1 Induction

The Start induction button is located on the bottom left portion of the screen. Two different induction schemes are available: Shock-on-T and HF Burst. If the rhythm is not converted by the device after induction, an emergency shock can be delivered via the Deliver Emergency Shock button found on the bottom center of the screen or Manual shock button located at the right lower portion of the screen. The manual shock energy should be set to a rescue energy level in the case of ventricular undersensing.

Manual ATP may also be delivered in the event VT is induced through the EPE/ATP screen.

CAUTION

Manual Shocks – User-commanded shocks may be withheld if the ICD/CRT-D is already busy processing a manual command or the Battery Status is low.

NOTE:

The emergency shock and manual shocks are delivered with confirmation OFF.

10.7.2 Shock Lead Impedance

Before an arrhythmia is induced during DFT testing, shock lead connections and lead integrity should be checked. This can be done by performing an impedance test from the impedance tab or by delivering a 1 J test shock. As with pacing lead impedance, shock impedance values can indicate poor connector contact, lead fractures, or insulation failures.

Acute shock impedance values should be greater than 25 Ω and less than 100 Ω, although the programmer will measure up to 150 Ω. If the impedance is less than 25 Ω, increasing the distance between electrodes through repositioning may increase impedance. However, the device can be damaged if a shock is delivered with very low impedances. Therefore, the pulse generator should not be implanted with a lead system with impedances less than 25 Ω. If impedance is greater than 150 Ω, shock therapy is likely to be ineffective. No damage will be done to the device during shock delivery in this case; however, the amount of the energy to the patient may not be the programmed amount.

1 J Test Shock

This test shock may be performed before device testing to ensure shock lead integrity if the painless shock impedance is not performed. After the 1 J test shock is delivered, the shock impedance can be viewed and verified by viewing the measured values portion of the DFT page.

To ensure the 1 J test shock does not induce VF, the Rivacor ProMRI® ICD times the shock after a three pulse pacing train. Pacing is delivered in a VOO mode. The pace train default for the 1 J test shock is 500 ms (default) but is programmable (200-500 ms) if the intrinsic interval is faster. This may be done to prevent the shock delivery from occurring in the vulnerable period and inducing VT/VF. The shock is delivered into the absolute refractory period of the last paced event.

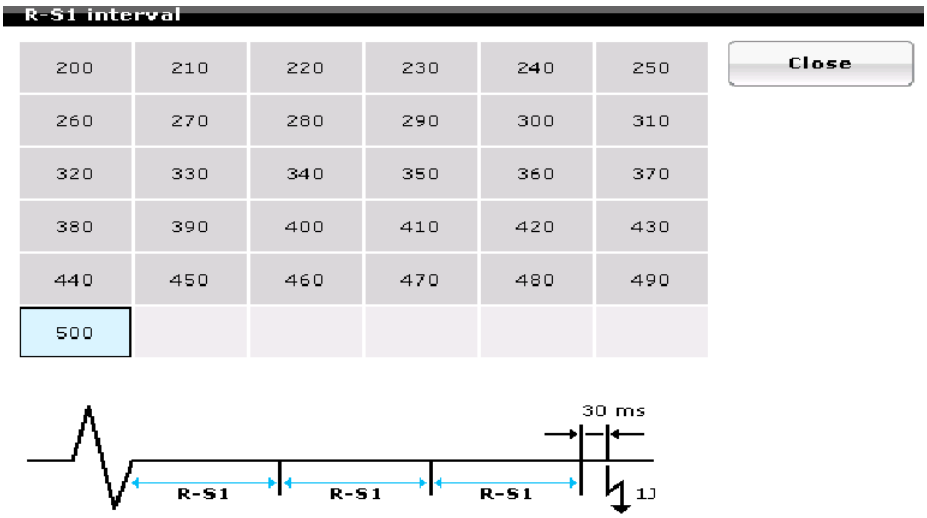

Figure 205: R-S1 interval options for 1 J test shock

Figure 206: DFT screen with 1 J Test Shock being delivered

As seen in Figure 206, the ICD will deliver three ventricular pacing pulses (500 ms; 7.5 V @ 1.5 ms) as well as a 1 J shock following a 30 ms delay after the third ventricular paced pulse. Should the user try to deliver the test shock while the device ICD therapy is OFF, a caution message is displayed to require the user to activate ICD therapy before the test shock can be delivered. This assures the device is enabled and protects the patient should the 1 J test shock induce VF.

NOTE:

When the test shock is administered, VF detection is required to be active.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

To improve ease of implantation, VT and VF markers displaying tachyarrhythmia detection appear at the level of the marker channel as detection occurs. In addition, a charge bar marks the progress of charging when shocks are delivered. The DFT Test screen as it appears after a Shock-on-T induction is shown below in Figure 207.

Figure 207: The DFT Test screen during induction testing

10.7.2.1 Wand Application / RF Telemetry

Placing the wand over the ICD allows for communication — including real-time IEGM transmission — between the device and the programmer. Wand application does NOT inhibit tachyarrhythmia detection and therapy. This applies to the standard wand application over the device as well as use of the RF telemetry mode.

When the programmer-initiated session is active, detection remains activated.

NOTE:

Placing an external magnet over the device will have no effect during the active session.

Once initiated, emergency shocks or manual therapies cannot be diverted.

10.7.3 Defibrillation Threshold Testing

There are two methods used to evaluate the DFT. The first method is to precisely define the DFT using a step-down test to conversion failure. Figure 208 illustrates an example of step-down DFT testing.

The example begins by evaluating conversion efficacy at 30 J. If a 30 J shock does not successfully convert the induced arrhythmia, the system must be modified (e.g., the lead position or polarity should be changed) until a 10 J safety margin can be met. If the 30 J shock is successful, a second arrhythmia is induced and a conversion is tested at 20 J. If the 20 J shock is successful, the procedure continues until the induced rhythm cannot be converted. The lowest energy that successfully converts the rhythm defines the DFT.

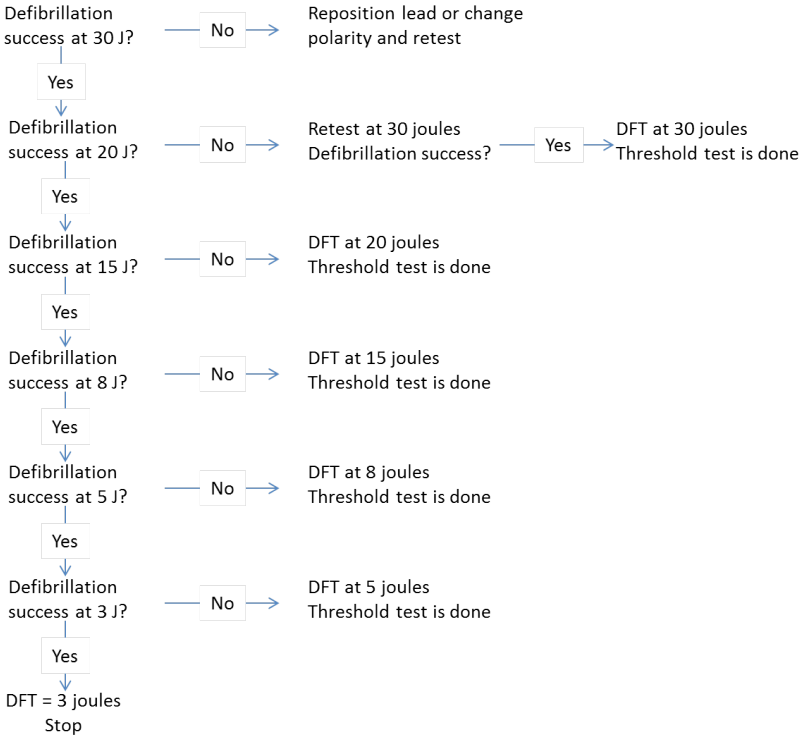

Figure 208: Step-down DFT test

The second testing method is to determine only if an adequate safety margin exists. Standard practice for all ICD implants dictates that an induced fibrillation should be successfully converted twice by a shock that is 10 J less than the maximum energy output of the device. (See Figure 209)

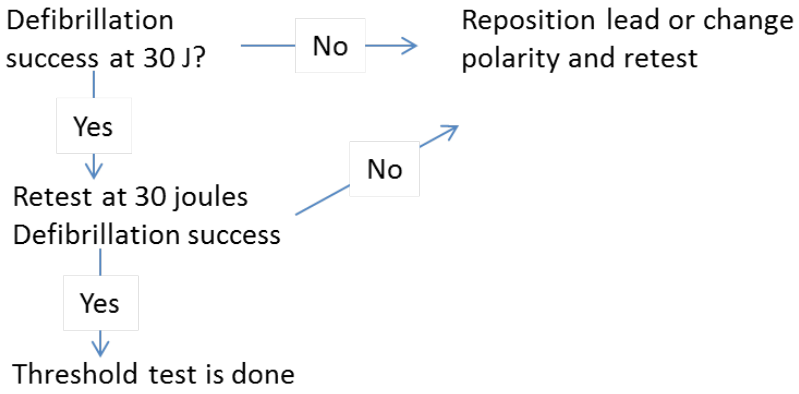

Figure 209: Safety Margin Test

10.7.4 Arrhythmia Induction Types

The Rivacor ProMRI® devices can be programmed to induce arrhythmias for DFT testing using two different induction schemes: Shock-on-T or HF Burst. Induction success depends on the patient and on the induction type. Shock-on-T is usually most effective for inducing ventricular fibrillation.

The Rivacor ProMRI® series provides an on-screen clock located on the induction screen displaying the time since last induction.

NOTE:

All induction schemes use a VOO pacing mode.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Manual Shocks – User-commanded shocks may be withheld if the ICD/CRT-D is already busy processing a manual command or the Battery Status is low.

10.7.4.1 Shock-on-T

Number S1: 1-25 events; Default 8

R-S1 Interval: 300 ... (10) ... 600 ms; Default **400 ms**

Coupling Interval: 200 ... (10) ... 400 ms; Default **290 ms**

Energy: OFF, 1 J to maximum output of the device (40 J); Default **1 J**

The Shock-on-T-wave induction scheme begins with a train of pacing pulses. The number of paced pulses (i.e., Number S1) and the coupling interval (i.e., R-S1 Interval.) are programmable. Generally, the coupling interval R-S1 is programmed between 300 and 450 ms with the number of S1 pulses between 4 and 8 pulses.

Following the train, there is a timed shock coupling period and then shock delivery. The shock coupling period and the shock energy are programmable. To increase the probability of induction success, shock coupling should be programmed to target the vulnerable period of the cardiac cycle (i.e., the time just prior to the peak of the T-wave, usually 290 to 310 ms). In cases of a left bundle branch block, one may need to extend the coupling interval to find the vulnerable period to induce VF. The shock energy rarely needs to be reprogrammed from its default value of 1 J.

Figure 210: Shock-on-T Induction (the shock waveform for induction is biphasic)

10.7.4.2 HF Burst

Duration: 1, 2, 3 or **4 seconds**; Default 4 seconds. HF Burst can be delivered for an extended time by holding the START button down.

Burst Rate: 10 ... (5) ... 40 Hz; Default **40 Hz**

Another type of fibrillation induction can be accomplished using an HF (high frequency) Burst. This scheme consists of a large number of pulses delivered in rapid succession over a user-defined period of time. The Burst Rate can be programmed between 10 and 40 Hz with durations of 1, 2, 3 or 4 seconds. Hertz (Hz), in this case, means the number of paced pulses delivered per second by the Rivacor ProMRI® ICD. If 40 Hz is selected, the device will deliver 40 paced pulses per second to the patient.

The Start button is accessed when the Start VT/VF Induction button is pressed. HF Burst impulses are delivered at the maximum pacing energy of 7.5 V at 1.5 ms.

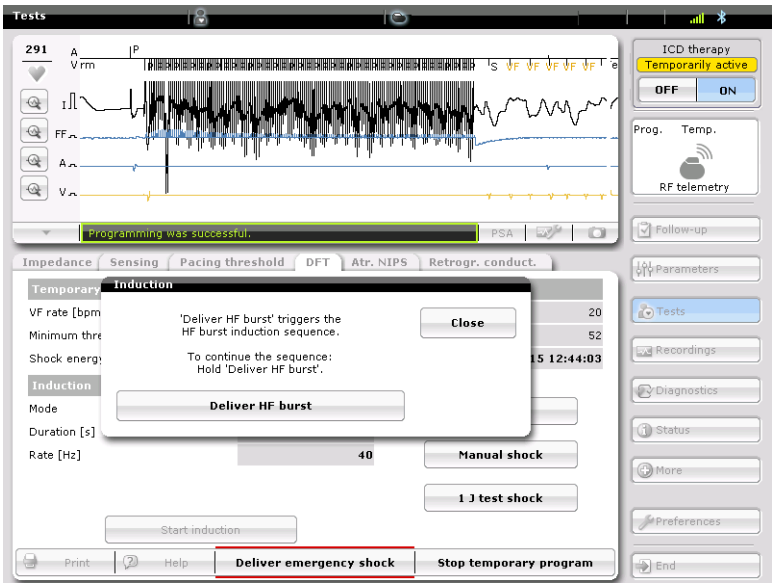

Figure 211: HF Burst induction

10.7.5 Manual Therapy

10.7.5.1 Non-Invasive Programmed Stimulation Testing (NIPS)

Available in the EPE/ATP section of the DFT screen.

Type: **Ramp**, Burst or Burst + PES, Rapid pacing

Ventricular pacing: **RV** or BiV (HF-T only)

Number S1: 1 ... (1) ... 25; Default **5**

R-S1 Interval: 70% ... (5%) ... 95%, 200 ... (10) ... 600 ms; Default **80%**

S1 Decrement: 5 ... (5) ... 40 ms (Ramp Only); Default **10 ms**

S1- S2 Interval: 70% ... (5%) ... 95%, 200 ... (10) ... 600 ms (Burst + PES only); Default **290 ms**

S2- S3 Interval: **OFF**, 70% ... (5%) ... 95%, 200 ... (10) ... 600 ms (Burst + PES only)

S3- S4 Interval: **OFF**, 70% ... (5%) ... 95%, 200 ... (10) ... 600 ms (Burst + PES only)

The plus (+) and minus (-) buttons make it easy to adjust the stimulus intervals for EPE.

Caution should be used when using NIPS. An external defibrillator and other emergency equipment should always be available.

NOTE:

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

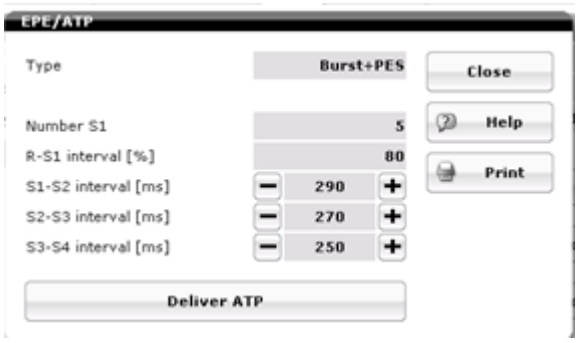

Figure 212: Example of NIPS using Burst + PES induction

10.7.5.2 Manual Shock

Energy: **1-40** joules

Polarity: **Normal** or Reversed

Waveform: **Biphasic** or Biphasic 2

Manual ATP therapy and manual shock therapy can be delivered from the DFT Test screen regardless of the magnet mode. Each therapy type is delivered with the press of the Deliver ATP or Deliver Shock button. Pressing either button will result in a new screen asking the user to confirm therapy delivery.

When a manual shock is delivered, the Polarity and Energy may be adjusted to meet the specific needs of the patient or the particular situation at the time of delivery. The manual shock is delivered with Confirmation = OFF.

Burst, Ramp, and Burst + PES ATP therapies are available for manual ATP delivery. (A Burst + PES scheme is shown in Figure 216)

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Manual Shocks – User-commanded shocks may be withheld if the ICD/CRT-D is already busy processing a manual command or the Battery Status is low.

10.7.6 Atrial Non-Invasive Programmed Stimulation Testing (NIPS)

To perform the NIPS testing, the programmer wand must be placed directly over the pulse generator to enable continuous telemetry or wandless telemetry session initiated.

NOTE:

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

10.7.6.1 Atrial NIPS

Atrial Burst Stimulation

Parameter	Range	Default
Burst Rate Start	30 ... (10 ... 800 bpm	250 bpm
Burst Minimum	30 ... (10) ... 250 bpm	150 bpm
Burst Maximum	250 ... (10) ... 800 bpm	350 bpm
Back-up pacing mode	OFF, VVI at basic rate value	OFF
Basic Rate	30 ... 120 bpm	60 bpm

Table 25: Atrial Burst Stimulation

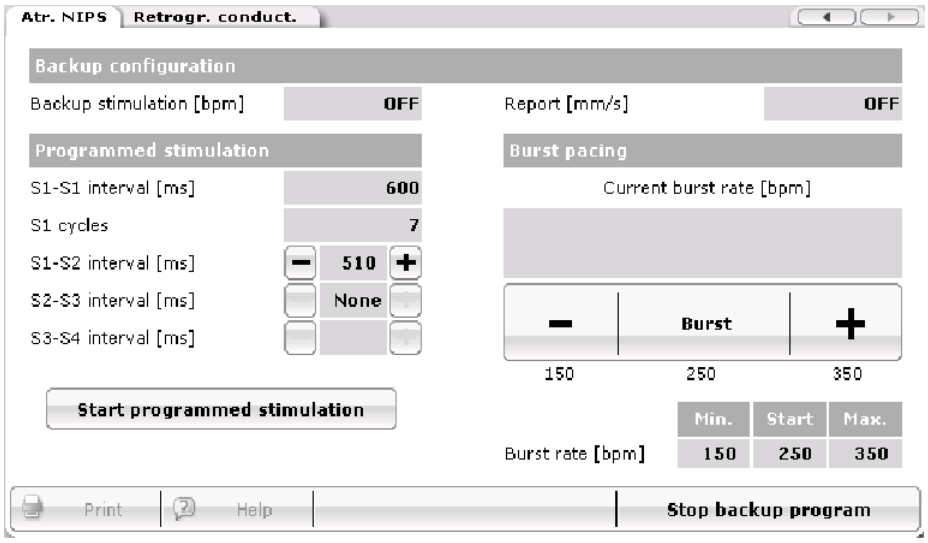

Figure 213: Atrial NIPS Screen

Burst Stimulation, shown in Figure 213, offers a burst of pacing pulses in the atrium up to a rate of 800 bpm. The duration of the burst is as long as the burst key on the programmer is pressed.

When the burst key is no longer pressed, the program reverts to the back-up program. Should the wand be removed or the telemetry session ended, the pulse generator reverts to the permanent program.

The upper and lower rates for Burst Stimulation may be adjusted by changing the following parameters:

- Burst rate: the initial rate when burst pacing is started
- Burst minimum: sets the lower rate of burst pacing
- Burst maximum: sets the upper rate of burst pacing

In addition to setting the rate for burst pacing, the following parameters can also be programmed for back-up pacing support:

- Mode: the user can choose either OFF or VVI at the selected rate mode for back-up pacing
- Basic rate: sets the back-up pacing rate in the absence of intrinsic ventricular activity

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 upper-right portion of the screen. When the Step Up or Step Down key (+ or -) is touched, NIPS is invoked starting at the nominal burst rate and then steps up or down, respectively, in 10 bpm steps. The current value is shown on the screen (Figure 214). As soon as the step-up or step-down key is released, NIPS terminates. Subsequent inductions resume at the initially programmed burst rate.

Burst may be used to induce or terminate atrial tachycardias. In the case of attempting to terminate atrial fibrillation, one may consider burst pacing for several seconds to increase the odds of success.

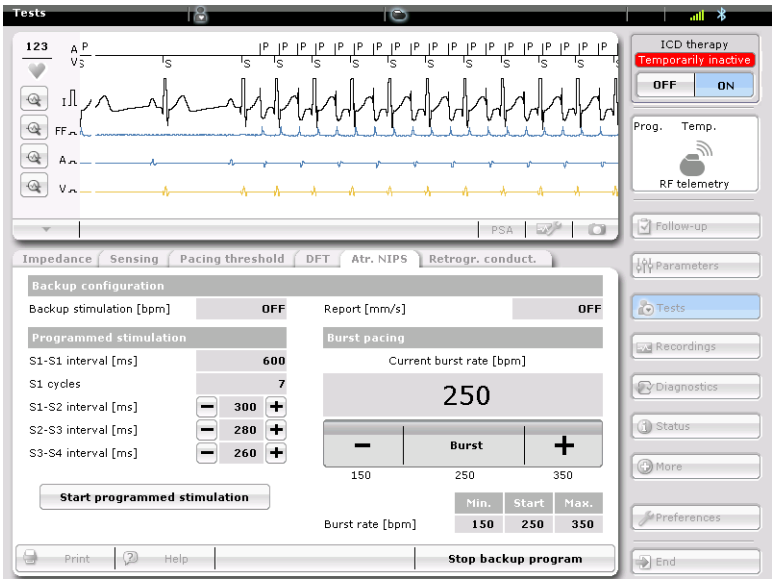

Figure 214: Atrial Burst

10.7.6.2 Programmed Stimulation

Programmed Stimulation offers burst pacing at specifically defined intervals that are user defined. Programmed stimulation offers S1-S1, S1-S2, S2-S3 and S3-S4 individual intervals.

Parameter	Range	Default Setting
S1-S1 (ms)	80 ... (10) ... 2000 ms	600 ms
S1 Cycles	0 ... (1) ... 10	7
S1-S2	None, 80 ... (10) ... 1000 ms	None
S2-S3	None, 80 ... (10) ... 1000 ms	None
S3-S4	None, 80 ... (10) ... 1000 ms	None

Table 26: Programmed Stimulation

S1-S1: This is the pacing drive train for Programmed Stimulation therapy. The drive train is used to stabilize the rhythm.

S1 Cycles: This is the number of S1 paced events in the drive train. The number used for the drive train is physician dependent.

S1-S2: This represents the coupling interval for the first extrasystole delivered. Sometimes simply referred to as "S2".

S2-S3: This represents the coupling interval for the second extrasystole delivered. Sometimes simply referred to as "S3".

S3-S4: This represents the coupling interval for the third extrasystole delivered. Sometimes simply referred to as "S4".

Plus and minus button make it easy to adjust the Sx-Sy intervals for programmed stimulation.

Figure 215: Atrial Programmed stimulation

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.

10.7.6.3 NIPS Additional

Additional information about using NIPS:

- When the battery voltage has reached the Elective Replacement Indicator (ERI) point, the NIPS feature is still available.
- NIPS can only be programmed temporarily.

NOTE:

High pacing rates and pulse amplitudes, together with long 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 pulse generator to enable continuous telemetry or a wandless telemetry session initiated.

10.7.7 Emergency Shocks

A maximum energy emergency shock can be delivered at any time using the Deliver Emergency Shock button at the bottom of the DFT test screen. The maximum energy shock is delivered as a committed shock (i.e., Confirmation = OFF) using a biphasic waveform with Normal polarity.

Chapter 11: Sterilization and Storage

The ICD/CRT-D is shipped in a storage box equipped with a quality control seal and product information label. The label contains the model specifications, technical data, serial number, use before date, as well as sterilization and storage information.

The ICD/CRT-D 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.

CAUTION

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

Re-sterilization - Do not re-sterilize and re-implant explanted devices.

Storage (temperature) - Store the device between 5° to 45°C (41° - 113°F) because temperatures outside this range could damage the device.

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

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

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

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Chapter 12: Implant, Follow-up and Explantation Procedures

12.1 Implant Procedure

12.1.1 Implant Preparation

Prior to beginning the ICD/CRT-D implant procedure, ensure that all necessary equipment is available. The implant procedure requires the selected lead system (including sterile back-ups), the programmer with appropriate software, and the necessary cabling and accessories.

For Implant Module based DFT testing, the following cabling and accessories are available for complete lead system testing:

PK-67-S/-L used to connect the Renamic PSA to implanted lead systems.

PK-144 used to connect the ICS 3000 Implant Module to implanted lead systems. The following adapters may be necessary:

- Adapters PA-2/PA-3 The PA-2 adapter is used to connect IS-1 compatible leads to the
- PK-144 cable. The PA-3 adapter is used to connect DF-1 compatible leads to the PK-144 cable.
- The BIOTRONIK adapters, PA 11 or IS4/DF4 Adapter, are used to connect a lead with DF4 connector to the alligator clips on one of the following legally marketed BIOTRONIK patient cables or patient adaptors:
- PK-141
- PK-155 in combination with PK-67-S/-L
- PA-4 in combination with PK-67-S/-L
- Adapter PA-4 used to connect the PK-144 cable to sensing and pacing leads while the stylet is still inserted.

Perform an interrogation of the ICD/CRT-D. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Rivacor ProMRI® ICD/CRT-D. Program detection and therapy to "Disabled" prior to handling the Rivacor ProMRI® ICD/CRT-D.

Sufficient training on the device and its associated components is required prior to implanting the ICD/ CRT-D. For additional information, training and training materials contact your BIOTRONIK representative.

WARNING

ICD Lead Systems - BIOTRONIK ICDs/CRT-Ds may be implanted with any legally marketed, compatible ICD lead. Compatibility is defined as:

- IS-1 pacing and sensing connector(s)
- DF-1 shock coil connector(s) or DF4 pace/sense/shock coil connector
- Integrated or dedicated bipolar pacing and sensing configuration
- Active or passive fixation technology
- Single or dual defibrillation shock coil (s)
- High energy shock accommodation of at least 40 joules
- Insertion and withdrawal forces as specified by ISO 5841 3 (IS-1) and ISO 11318:1993 (E) DF-1 or ISO 27186:2010 (DF4)

WARNING

Left Ventricular Lead Systems – BIOTRONIK CRT-Ds may be implanted with any legally marketed, compatible LV lead. Compatibility is defined as:

- IS-1 pacing connector
- Active or passive fixation technology
- Insertion and withdrawal forces as specified by ISO 5841 3 (IS-1)

CAUTION

Blind Plug - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.

Connector Compatibility - ICD/CRT-D and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD/CRT-D system. For further information, please refer to Appendix A.

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Programming Wand Separation Distance – The wand (with magnet) must not be placed closer than 2 cm to the device (implanted, in the box, or out of the box). Programming wand (with magnet) distance closer than 2 cm may damage the device.

CAUTION

Shock Impedance - If the shock impedance is less than twenty-five ohms (25Ω), reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has a measured shock impedance of less than twenty-five ohms (25Ω). Damage to the device may result.

Far-field sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/sensing parameters, and maximum sensitivity settings. If it is necessary to modify the Far-Field Blanking parameter, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending the parameter unnecessarily may cause undersensing of actual atrial or ventricular events.

12.1.2 Lead System Evaluation

The Rivacor ProMRI® IS-1/DF-1 compatible ICD/CRT-D is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1, wherever stated in this manual, refers to the international standard [Reference ISO 11318:1993].

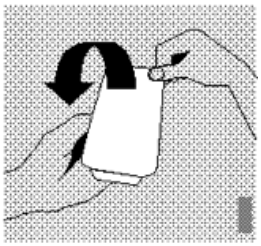
The Rivacor ProMRI® IS-1/DF4 compatible ICD/CRT-D is mechanically compatible with DF4 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF4, wherever stated in this manual, refers to the international standard [Reference ISO 27186].

Refer to the appropriate lead system technical manual.

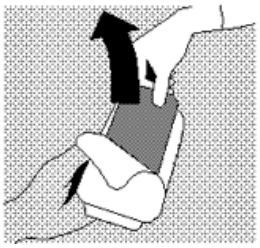
12.1.3 Opening the Sterile Container

The Rivacor ProMRI® ICD/CRT-Ds are 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. Do not contaminate the inner tray.



Take out the inner sterile tray by gripping the tab. Open the inner tray by peeling the sealing paper as indicated by the arrow.

CAUTION

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

12.1.4 Pocket Preparation

Using standard surgical technique, create a pocket for the device either in the patient's pectoral or abdominal region, dependent on patient anatomy. The device may be implanted either below the subcutaneous tissue or in the muscle tissue. The leads should be tunneled or surgically brought into the device pocket. If lead tunneling is performed, re-evaluation of the baseline lead signals, after tunneling, is recommended.

CAUTION

The ICD/CRT-D system should have detection and therapy disabled prior to performing medical procedures. In addition, the ICD/CRT-D should be checked after the procedure to assure proper programming:

Electrocautery - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible (at least 6 inches (15 cm)).

12.1.5 Lead to Device Connection

The Rivacor ProMRI® ICD/CRT-Ds have been designed and are recommended for use a DF4 RV lead connector for ventricular sensing, pacing and delivery of shock therapy. A separate bipolar atrial lead with IS-1 connector is required for atrial sensing and pacing functions and the CS lead for biventricular pacing (LV). Figure 216 depicts the configuration of the header ports on the Rivacor ProMRI® ICD/CRT-Ds.

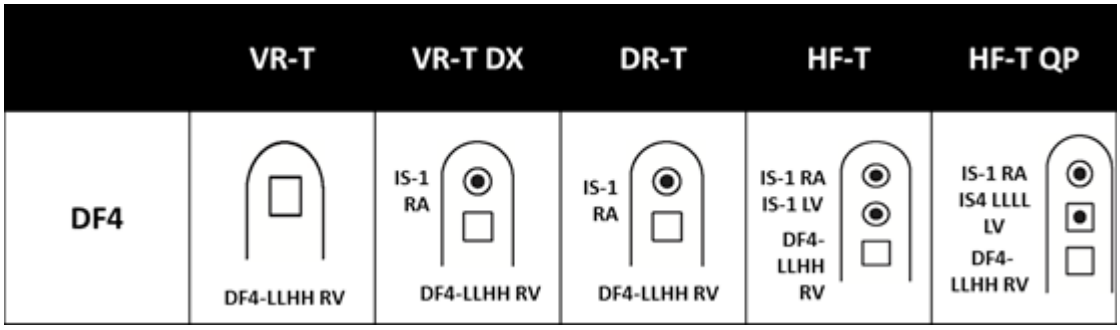


Figure 216: Rivacor ProMRI® ICDs and CRT-D Header Ports

CAUTION

Connector Compatibility - ICD/CRT-D and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD/CRT-D system. For further information, please refer to Appendix A.

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 over tighten 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.

Far-Field Sensing of signals from the atrium in the ventricular channel or ventricular signals in the atrial channel should be avoided by appropriate lead placement, programming of pacing/sensing parameters, and maximum sensitivity settings. If it is necessary to modify the Far-field Blanking parameter, the parameter should be lengthened only long enough to eliminate far-field sensing as evidenced on the IEGMs. Extending the parameter unnecessarily may cause undersensing of actual atrial or ventricular events.

Refer to the following steps when connecting the leads to the device.

1. Confirm that the setscrews are not protruding into the connector receptacles. 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. Rotate the wrench counterclockwise until the receptacle is clear of obstruction.
2. Insert the lead connector into the connector port of the ICD/CRT-D without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position.
3. 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.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. Carefully retract the torque wrench. The perforation will self-seal.

12.1.6 Blind Plug Connection

The Rivacor ProMRI® DR-T and HF-T QP may be shipped with a blind plug (pre-inserted) in an unused header port. Refer to the following steps when connecting blind plugs to the device.

1. Confirm that the setscrews are not protruding into the connector receptacles. 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. Rotate the wrench counterclockwise until the receptacle is clear of obstruction.
2. Insert the blind plug into the connector port of the ICD/CRT-D until the connector pin becomes visible behind the setscrew.
3. Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the connector until it is firmly placed in the setscrew.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. Carefully retract the torque wrench. The perforation will self-seal.

CAUTION

Blind Plug - A blind plug must be inserted and firmly connected into any unused header port to prevent chronic fluid influx and possible shunting of high energy therapy.

12.1.7 Program the ICD/CRT-D

Program the ICD/CRT-D to appropriately treat the patient's arrhythmias and other therapy needs. The information obtained during the lead system evaluation should be helpful in tailoring the various parameters of the ICD/CRT-D to treat each individual patient. The detection and therapy status of the ICD/CRT-D may be activated for testing purposes once all of the lead connectors have been securely

fastened in the device header ports. The physician shall be made aware of the program that is in effect after the patient leaves the office, by viewing the parameters displayed on the programmer screen after the device has been programmed.

CAUTION

Programmed Parameters – Program the device parameters to appropriate values based on the patient's specific arrhythmias and condition.

Programmers - Use only BIOTRONIK's ICS 3000 or Renamic programmers to communicate with the device.

Defibrillation Threshold - Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

WARNING

Unwanted Shocks – Always program ICD therapy to OFF prior to handling the device to prevent the delivery of shocks to the patient or to the person handling the device during the implant procedure.

12.1.8 Implant the ICD/CRT-D

The ICD/CRT-D may be placed in the pocket at this time. Place the device into the pocket with either side facing up (it can be interrogated and programmed from either side). Carefully coil any excess lead length behind the ICD/CRT-D.

The pacing and sensing functions of the device should be evaluated. It is also recommended that at least one induction and device conversion be done prior to closing the pocket. This will ensure that the lead system has been securely connected to the device and has not changed position.

CAUTION

Connector Compatibility - ICD/CRT-D and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD/CRT-D system. For further information, please refer to Appendix A.

Shock Impedance – If the shock impedance is less than twenty-five ohms (25Ω), reposition the lead system to allow a greater distance between the electrodes. Never implant the device with a lead system that has a measured shock impedance of less than twenty-five ohms (25Ω). Damage to the device may result.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Pacing Threshold - Testing of the pacing threshold by the ICD/ CRT-D system should be performed with the pacing rate programmed to a value higher than the patient's intrinsic rate.

Defibrillation Threshold - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Electromagnetic interference (EMI) signals present in hospital and medical environments may affect the function of any ICD/CRT-D or pacemaker. The ICD/CRT-D is designed to selectively filter out EMI noise. However, due to the variety of EMI signals, absolute protection from EMI is not possible with this or any other ICD/CRT-D.

The ICD/CRT-D system should have detection and therapy disabled prior to performing any of the following medical procedures. In addition, the ICD/CRT-D should be checked after the procedures to assure proper programming:

Electrocautery - Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible (at least 6 inches (15 cm)).

Prior to surgically closing the pocket, the telemetry contact should be evaluated to help ensure chronic programmer communication. Close the device pocket using standard surgical technique. As the final step at device implant and each patient follow-up, the permanent program should be retransmitted to the ICD/CRT-D.

Typically, each device that you receive is in the "Shipment Mode". This mode includes factory settings that control the charge current of automatic capacitor reformations to avoid the possibility of temporary low battery readings. Sensing is turned off during Shipment Mode; IEGMs will be disabled until Shipment mode is deactivated. Shipment mode is automatically deactivated by selecting the Program button and sending a permanent program to the device. The following can be used to verify status of the shipment mode:

- The shipment mode is ON if the device displays "Shipment Mode Active" in the event list
- The Shipment Mode is OFF if the device does not display "Shipment Mode Active" in the event list Complete the Medical Device Registration for the patient.

12.2 Follow-up Procedures

12.2.1 General Considerations

An ICD/CRT-D follow-up serves to verify appropriate function of the ICD/CRT-D system and to optimize the programmable parameter settings.

In addition to evaluating the patient's stored therapy history and electrograms, acute testing of sensing and pacing is recommended. The physician shall be made aware of the program that is in effect after the patient leaves the office after each follow-up, by viewing the parameters displayed on the programmer screen after the device has been programmed. As the final step at device implant and each patient follow-up, the permanent program should be retransmitted to the ICD/CRT-D. Due to longevity concerns, it is recommended the physician schedule a patient follow-up visit every 3 months.

WARNING

Resuscitation Availability - Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available. In order to implant the ICD/CRT-D system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Programming Wand Separation Distance – The wand (with magnet) must not be placed closer than 2 cm to the device (implanted or out of the box). Programming wand (with magnet) distance closer than 2 cm may damage the device.

Most patients require a routine follow-up exam every three months. Interim follow-ups may be necessary if there has been a change in a patient's anti-arrhythmic medication or if ATP and/or shock therapy have been delivered between routine follow-ups.

During the follow-up, all tachyarrhythmia episodes should be examined and printed. Sensing and pacing characteristics should be evaluated. Necessary changes should also be made to the programmed parameters.

12.2.2 Programmer Setup

Before initiating a follow-up, the surface ECG cable (i.e., PK-222) may be connected to the patient. The Rivacor ProMRI® ICD does have a far-field option, as well. At this time, the surface ECG display may be modified via the Preference/ECG buttons located via the Adjust button at the ECG display. Displayed on the main programmer screen is the current time and date. Because the programmer time and date are transmitted to the device upon interrogation, these values should always be checked for accuracy. Changes in the time and date are made under the More/Preferences/System/Set Date (Set Time).

Examples of those screens are shown below in Figure 217. Changing the device time will not affect time stamps on episodes already recorded.

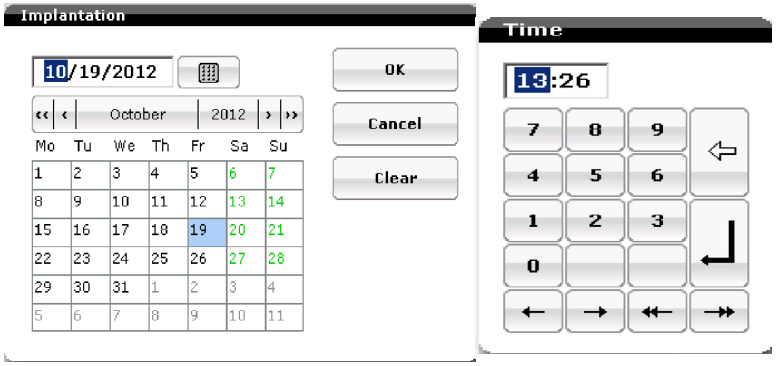


Figure 217: Programmer time and date setup

12.2.3 Follow-up Assistant

When the Rivacor ProMRI® ICD is first interrogated, the Follow-up Assistant screen is shown. It can be accessed at any time by selecting the "Follow-up" button at the right side of the programmer screen.

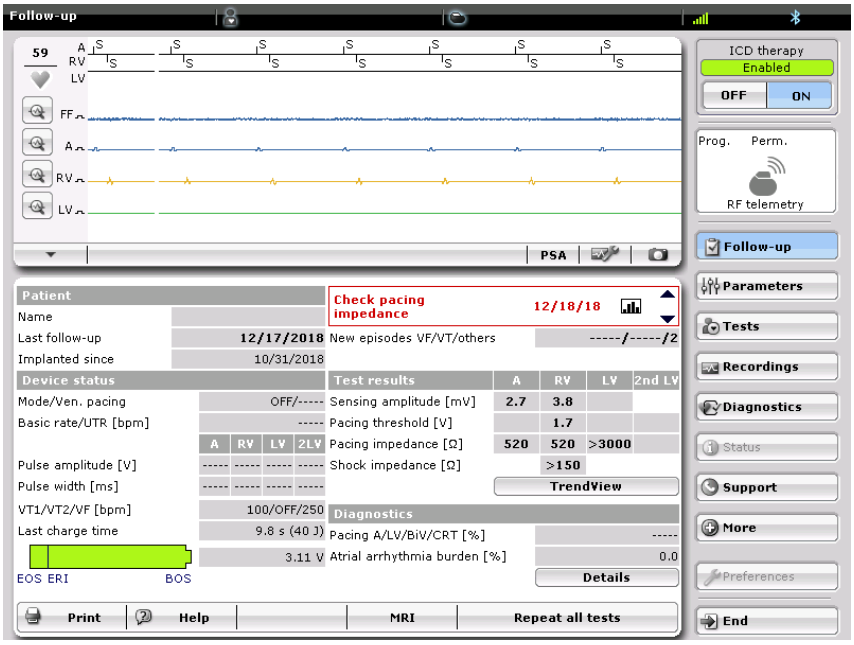


Figure 218: The Follow-Up screen after interrogation

The Follow-up page is divided into five sections; Patient, Device status, New episodes/event messages, Test results and Diagnostics.

12.2.3.1 Patient

The Patient section provides information including patient name, last follow-up and implant date. The patient name and last follow-up are bolded. Selecting the patient name takes the user to the patient data page, where the user can change or update patient information. The Last follow-up link takes the user to the Follow-up History page.

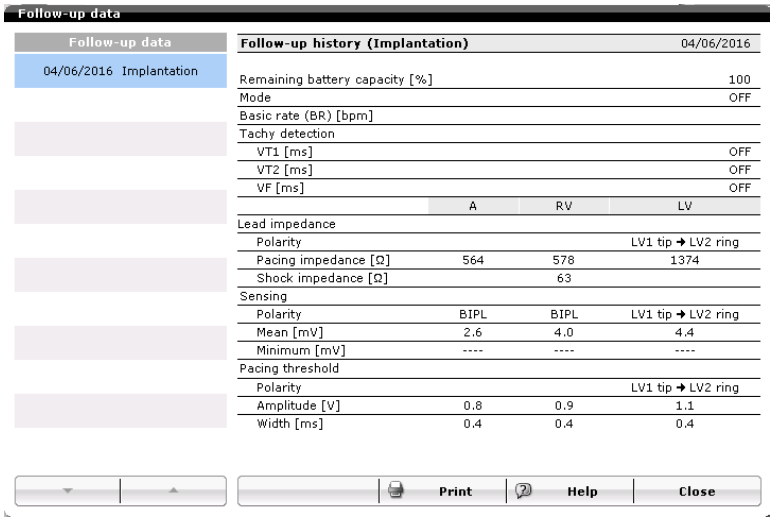


Figure 219: Follow-up History page

The History page automatically tracks the entire test data measured at implant and follow-up. The data may reveal gradual or abrupt changes that suggest further lead assessment. Follow-up data is entered into the Measurement Trend table at device interrogation and is only entered once per 24-hour period (day). The most recent data point for each day is maintained in this page. The Rivacor ProMRI® will store data from the last 11 follow-ups, as well as the implant procedure.

12.2.3.2 Device Status

The Device status provides information related to the current mode and pacing selection as well as information related to the basic and upper rate values, pulse amplitude and pulse width, tachycardia zone programming as well as battery information. This section shows the battery status along with the battery voltage and last charge time. A battery status gauge is also provided.

Figure 218 shows the Follow-Up screen after interrogation. The device type and the serial number appear across the top of the programming screen. Next, the battery status is defined by one of five codes: 1) BOS = beginning of service; 2) ERI = elective replacement indication; or 3) EOS = end of service.

The five levels related to battery status:

1. Beginning of Service (BOS) = 90%-100% of battery life remaining
2. Elective Replacement Indicator (ERI) - Pacing function and 6 maximum energy shocks remaining for DR-T and HF-T devices. For single-chamber devices, no pacing and six maximum energy charges are assumed.
3. End of Service (EOS) - Bradycardia therapy remains but tachycardia therapy is disabled.

12.2.3.3 New Episodes/Event Messages

The device provides information related to new episodes that have occurred since the last follow-up. It provides the number of new episodes and the detection zone in which the arrhythmia was detected.

Event messages are also provided in the section. Other messages include out of range values such as shock or pacing impedances. Touching the message takes the user to the appropriate diagnostic or recordings page for more detailed information. If multiple messages are present, up/down arrows will appear on the right hand side of the messages to allow the viewer to review them.

12.2.3.4 Test Results

The Follow-up page displays any automatically measured data that has been recorded within the last 24 hours. The user can automatically update the values by pressing the Repeat all tests button.

The arrows next to the pacing impedance and shock impedance numbers indicate that these are measured values derived from automatic tests and will appear when the device is initially interrogated. These are measured four times daily.

12.2.3.4.1 Trends

Trends provides information related to pacing thresholds, sensing measurements, pacing and shock impedances. The arrow keys on the bottom of the screen allows the user to go back and forth to view data for specific dates. The current date of the data displayed above each section is shown in an orange box at the bottom of the screen. Critical information can be quickly viewed by pressing the buttons with exclamation points on them.

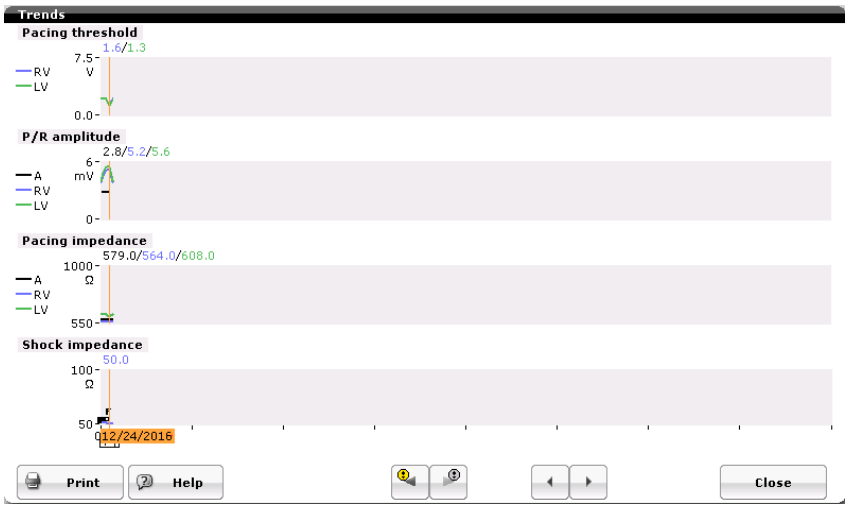


Figure 220: Trends screen

12.2.3.5 Diagnostics

The section provides the percentage of pacing in each chamber since the last follow-up. The atrial burden since last follow-up is provided. Pressing the Details button takes the user to a snapshot of diagnostic data.

Information provided includes Rate histogram data, Event episodes, Longest atrial episode duration, and Long-term trend information since the last follow-up. The buttons along the bottom of the page function in the same manner as discussed in the Trends section.

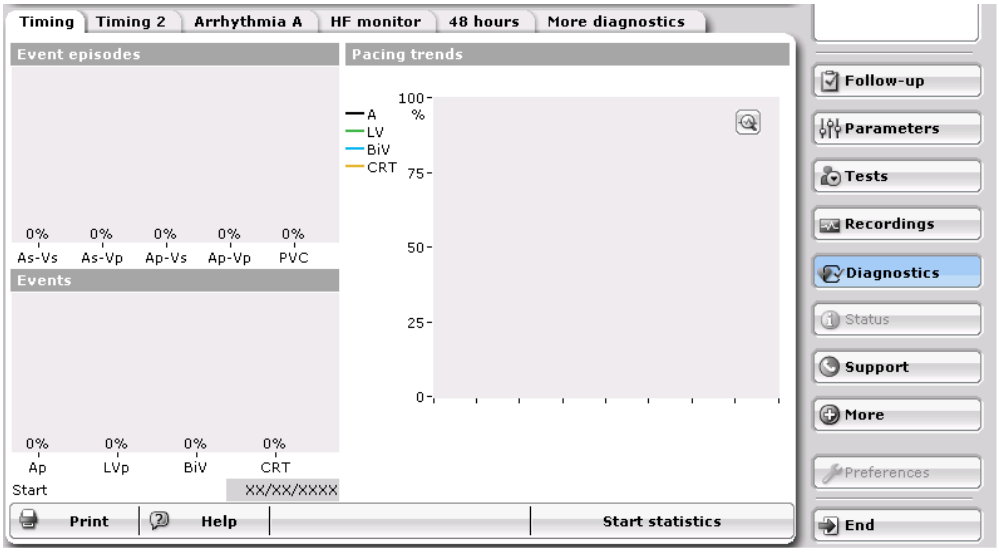


Figure 221 Diagnostics

12.2.4 Data Retrieval

Once the Follow-up Assistant is complete, all therapy data that has accumulated between follow-up exams should be printed. This includes stored IEGMs, shock data, and counter information.

Tachyarrhythmia data is retrieved via the Recordings button at the right of the screen. When Recordings is chosen, the Episode List appears. Each episode is listed with the episode number (most current on top), date and time of detection, the zone of initial detection, atrial and ventricular intervals at the time of detection, and the type of therapy delivered, atrial and ventricular intervals at termination, as well as links to the IEGM and Detail data, as illustrated in Figure 222.

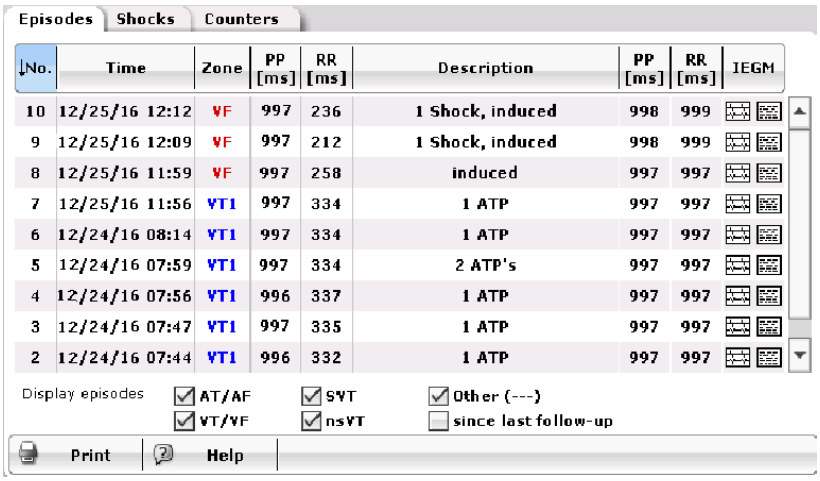


Figure 222: The Episode List chronologically displays tachyarrhythmia episodes

The IEGM records and details for each episode and can be viewed by selecting the buttons beside each episode number in the Episode List. Each IEGM record should be printed during follow-up. The selection of an IEGM for viewing will also store the IEGM in the Print manager.

The header of each category on the Episode List is a sort tab allowing the user to sort data to view in order data by groups or time.

The display episodes check boxes at the bottom of the page allow the user to sort episodes by type or since last follow-up. Simply check the desired episode box(es) to view that data only.

In addition to episode data, therapy data should be printed at follow-up. The shock data can be found in the Shocks tab. This table lists shocks in chronological order, with the most recent at the top. The time and date of charging, the delivered energy, charge time, and impedance values are given. A remarks field is provided to denote special conditions, such as manual shock delivery, aborted shocks and automatic capacitor reforms. Additional therapy data is located under the Counters tab. Detection counters show the total number of episodes declared in each tachyarrhythmia zone (i.e., SVT, VT1, VT2 and VF) since the last follow-up and over the life of the device. SVT details display the SVT episode number for each of the four SVT sub-classifications (i.e., AFlut for atrial flutter, AFib for atrial fibrillation, SinusT for sinus tachycardia, and 1:1 for atrial tachycardias). The therapy counters list the total number of successful and unsuccessful ATP and shock therapies since the last follow-up and throughout the life of the device.

12.2.5 IEGM Storage

Device memory can store IEGM data for three chambers. Far- field IEGMs are included with single- and dual-chamber IEGM storage. Far-field may be programmed by the user for Rivacor ProMRI® HF-T. However only three channels can be stored by the device. The programming options can be found under the IEGM configuration parameter on the Diagnostics page for the Rivacor ProMRI® HF-T.

The total number of episodes is dependent on the length of recordings. The duration of each IEGM episode can be in excess of four minutes with a pre-detection length of 30 seconds without Onset criterion being met and five seconds of pre-Onset when the Onset criterion is met. AT/AF IEGMs have the option to program the pre-detection duration to greater than 60 seconds by programming Advanced ON in the Diagnostics section of the parameter page (not applicable in Rivacor 5). SVT recordings may be triggered with detection and termination only if SVT IEGM is turned ON (Figure 223).

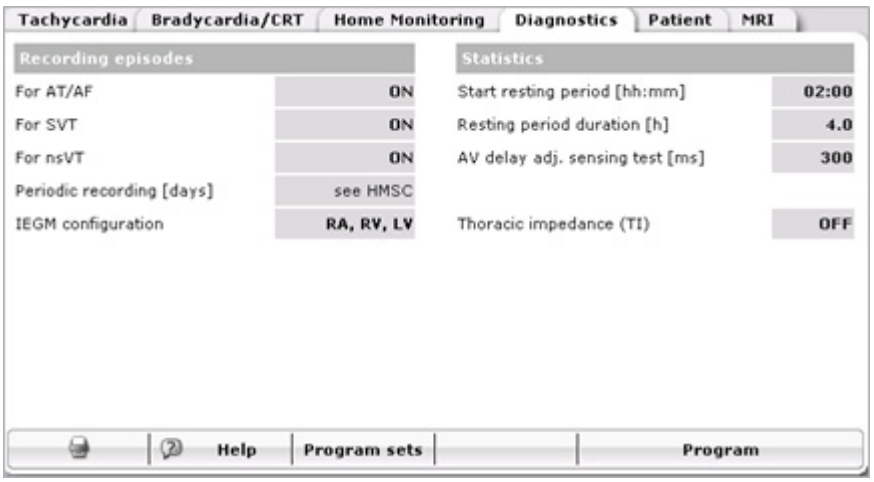


Figure 223: The Diagnostics section to set up storage of SVT and AT/Aflut IEGM

An AT/AF is determined when the device reaches a fixed criterion of 36 of 48 atrial events at the user programmed rate cut-off.

NOTE:

An SVT recording is triggered when the detection criterion for an SVT has been met. The detection criterion for an SVT recording is two times the VT zone detection count. For example, in the VT1 zone with a nominal default setting of 16 events, an SVT event will be triggered when 32 individual SVT events are counted by the device. Termination of an SVT occurs when 5 consecutive sinus events occur.

12.2.6 Reprogramming

After the Follow-up Assistant is complete and all IEGM data retrieved, it may be necessary to reprogram the device to optimize the pacing, sensing, and/or detection parameters. Appropriate changes should be made and new parameters transmitted at the end of each follow-up. New parameters should be printed and a printout kept with the patient's records for future reference.

NOTE:

Unlike previous generations of BIOTRONIK ICDs, reprogramming the Rivacor ProMRI® device will NOT automatically enable detection and therapy.

12.2.7 Manual Follow-Up

If desired, all tests in the Follow-up Assistant can be performed separately. Below is a brief description of each test.

12.2.7.1 Impedance Test

The impedance test provides information about the continuity of the lead(s), as well as shock pathway impedance information. The pacing impedances range is 200 – 3000 ohms for the device and the shock impedance is typically between 25 – 100 ohms (the device minimum reading is 25 ohms and the maximum is 150 ohms).

From the impedance screen, the painless shock impedance is performed first and then the pacing impedances. The test is performed in the programmed mode and will generally take around five seconds to perform. The test will use subthreshold pacing pulses. The painless shock impedance is measured between the RV coil and the can.

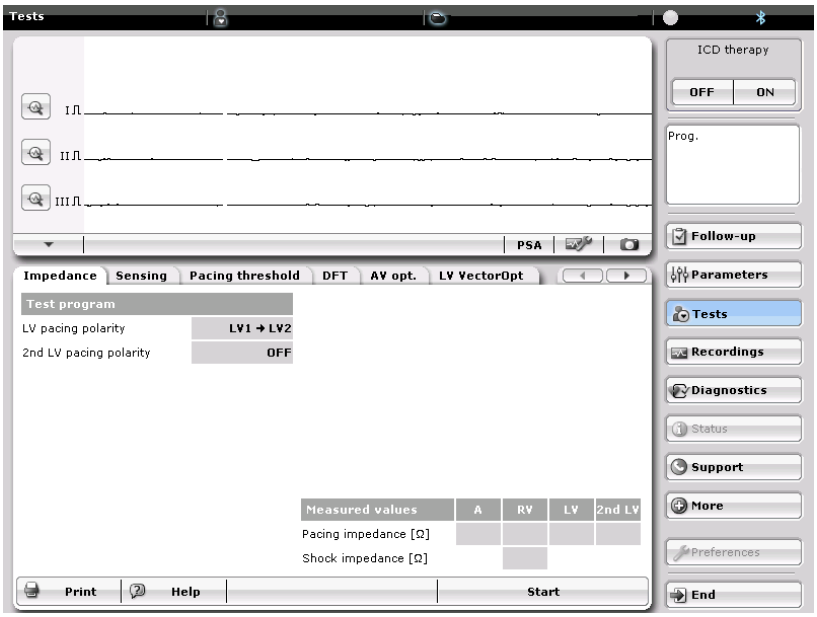


Figure 224: Impedance Test

One can expect a slightly higher reading with a single-coil lead, as opposed to a dual-coil lead. It is also important to note that at implant testing with a single-coil lead, the can must be in the device pocket in order to get a reading. Otherwise, an erroneous value will be displayed.

The user has the option to select only the LV pacing polarity, which may be different than the permanent choice.

12.2.7.2 Sensing Test

The Sensing test can be performed with or without back-up pacing. When the Start button is pressed, the test will be performed in a VDI mode with VVI back-up pacing support in the ventricle. The back-up pacing rate is programmable by the user. When Intrinsic rhythm is selected, the test is performed with no back-up pacing (ODO mode). The test is only active as long as the user has the Intrinsic rhythm button pressed.

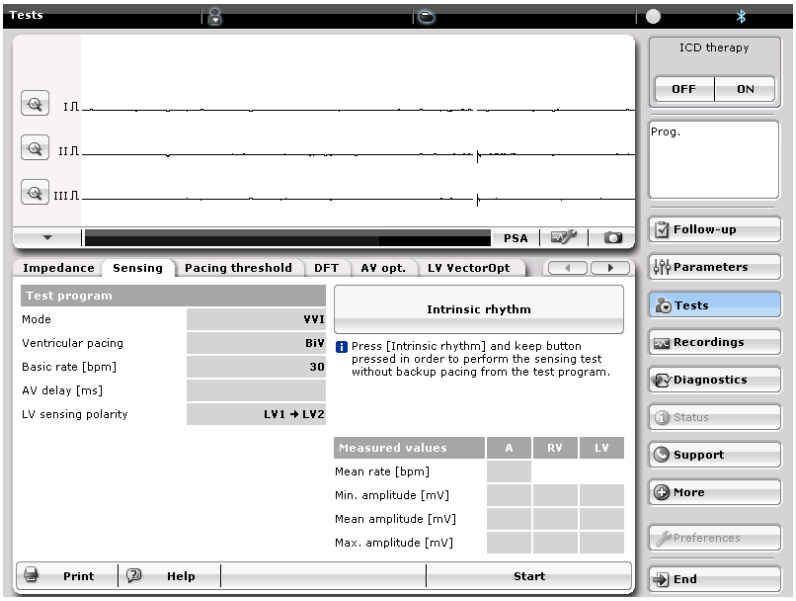


Figure 225: Sensing Test

12.2.7.3 Threshold Test

The Threshold test can be done with a surface ECG, far-field signal or by viewing the IEGM. The user can select the pacing mode and chamber to be tested. Changes can be made "on the fly" at any time while an active test is ongoing. Any value that is in bold on the screen can be changed.

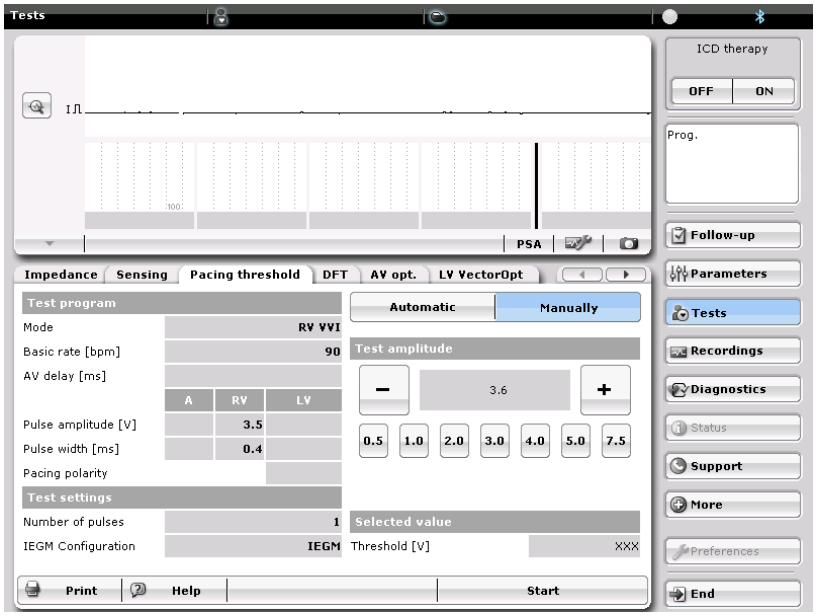


Figure 226: Threshold Test with ECG display

The Pulse amplitude and Pulse width values that are displayed will match the Mode of the Test program. For example, in Figure 226, the threshold test is being performed in the RV chamber in a VVI mode. The RV amplitude and RV pulse values are displayed. If the user changes the Mode to DDD in LV, the atrial and LV outputs would be displayed. In addition, the pacing polarity will also be present for the LV lead.

As the Rivacor ProMRI® ICD family utilizes ventricular capture control, the user will have the option to use RV and LV auto threshold tests in single-, dual- and triple-chamber devices. These tests will use the same algorithm as the VCC algorithm to determine pacing thresholds. The Rivacor ProMRI® DR-T and HF-T ICDs also provide an automatic option for the atrial threshold test.

12.2.7.4 Auto LV VectorOpt

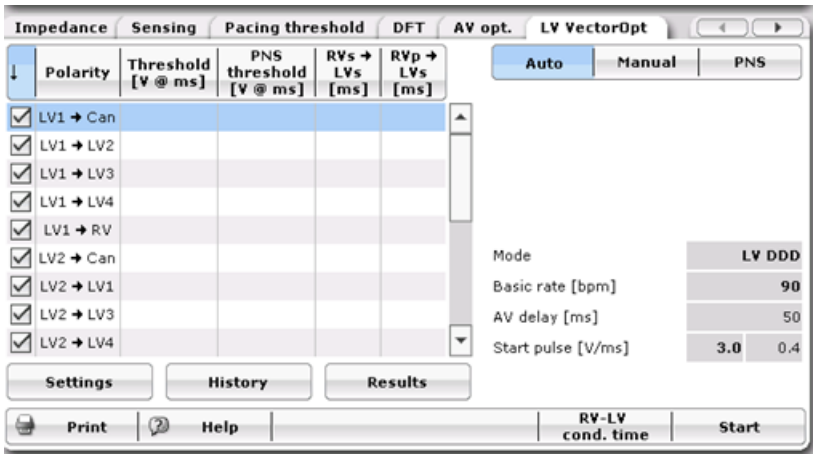


Figure 227: Auto LV VectorOpt

Auto LV VectorOpt is used to measure LV thresholds in various pacing configurations to determine the pacing thresholds and phrenic nerve stimulation (PNS) thresholds in each configuration. The results are displayed for each pacing configuration measured to allow comparisons to determine the best pacing vector for the patient.

The user selects the pacing vector to be tested and performs the threshold test. The value is placed into the threshold column. Then the phrenic nerve test is performed to determine when diaphragmatic pacing occurs. The value is placed in the PNS column. A graphic range is found by selecting the Results button.

The user can then program the best LV pacing options for the patient.

12.2.7.5 Retrograde Conduction Test

The Retrograde conduction test is performed in the VDI mode. With the Rivacor ProMRI® HF-T, the user can select either RV or LV for pacing. If LV is selected, LV pacing polarity options are made available. The pacing rate is also programmable from 30-160 bpm.

It is recommended that the pacing rate be programmed 10-15 bpm above the intrinsic ventricular rate.

As retrograde conduction may be rate dependent in some patients, consider testing at different rates if retrograde conduction is suspected.

The programmer displays the results as the maximum, minimum, and average retrograde conduction time, and the measured V-A times are displayed on the marker channel. Generally, if the min, mean, and max times are within 25 ms, retrograde conduction is suspected.

Figure 228 shows an example of a negative test result as there is no 1:1 correlation between ventricular pacing and an atrial response.

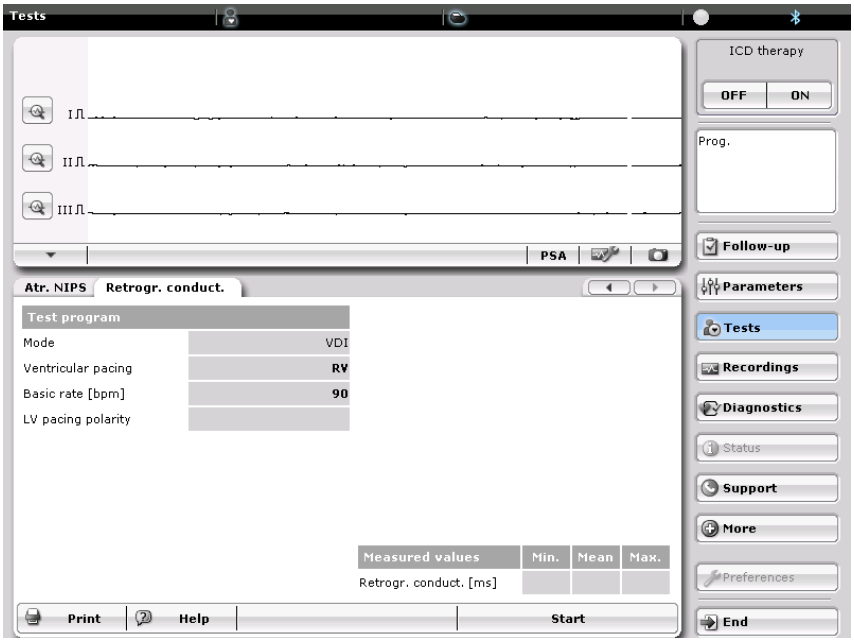


Figure 228: Retrograde Conduction Test

12.3 Explantation

Explanted ICDs/CRT-Ds, lead systems, and accessories may not be reused. Please complete the appropriate out of service (OOS) form and return it to BIOTRONIK with the explanted devices. All explanted devices should be sent either to the local BIOTRONIK representative or the BIOTRONIK home office for expert disposal. Contact BIOTRONIK if you need assistance with returning explanted devices. If possible, the explanted devices should be cleaned with a sodium-hyperchlorine solution of at least 1% chlorine and then washed with water prior to shipping.

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

WARNING

Unwanted Shocks – Always program ICD Therapy to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or to the person handling the device during the implant procedure.

CAUTION

Device Incineration – Never incinerate the ICDs/CRT-Ds due to the potential for explosion. The ICD/CRT-D must be explanted prior to cremation.

Explanted Devices – Return all explanted devices to BIOTRONIK.

Chapter 13: Longevity

The service time of an ICD/CRT-D can vary based on several factors, including the number of charge sequences, programmed parameters, number of tachyarrhythmias detected, relative amount of bradycardia pacing required, pacing lead impedance, storage time, battery properties, and circuit operating characteristics. Service time is the time from beginning of service (BOS) to the elective replacement indication (ERI). To assist the physician in determining the optimum time for ICD/CRT-D replacement, a replacement indicator is provided that notifies the user that replacement within a certain period of time is required. Upon reaching ERI, the battery has at least enough energy left to continue monitoring for three months, along with the ability to deliver six high-energy shocks. When the End of Service (EOS) indication is met, all tachyarrhythmia detection and tachyarrhythmia therapy is disabled.

CAUTION

Charge Time - When preparing a high energy shock the charge circuit stops charging the capacitors after 20 seconds, and delivers the stored energy as shock therapy. After the device reaches ERI due to a longer charge time, the stored energy may be less than the maximum programmable energy for each shock.

The projected service times from beginning of service (BOS) to elective replacement indication (ERI) are listed in the following tables. All estimates were calculated assuming a pacing rate of 60 bpm with a pulse width of 0.4 ms and pulse amplitude of 2.5 volts and 500 ohm pacing impedance with all shocks at maximum programmable energy at 37 °C with TI OFF and Home Monitoring features ON. Programming MultiPole Pacing ON reduces the estimated device longevity by approximately 13% (depending on the scenario). It is assumed that the shocks are equally spaced throughout the life of the ICD/CRT-D. The estimates include Home Monitoring: ON, 1 device message each day and 24 IEGM-Online HD transmissions per year, and four remote follow-ups per year, eight event messages per year. The estimates associated with 0% pacing support assume the ICD/CRT-D is sensing an intrinsic sinus rhythm at a rate of 70 bpm. The tables represent the mean longevity estimates for the specified devices.

13.1 Rivacor ProMRI® Devices

Tables 27 and 28 provide longevity estimates for the Rivacor VR-T ProMRI® ICD. The tables provide several different support scenarios.

Rivacor ProMRI® VR-T Longevity Estimates with UBD of 6 months

% Pacing	Maximum energy charging frequency	500 ohms pacing impedance		700 ohms pacing impedance	
		RV: 2V	RV: 2.5V	RV: 2V	RV: 2.5V
0% VVI	Semiannual	15.08	15.08	15.08	15.08
15% VVI	Semiannual	14.81	14.58	14.87	14.70
50% VVI	Semiannual	14.21	13.52	14.41	13.87
100% VVI	Semiannual	13.42	12.24	13.79	12.83

Table 27: Rivacor ProMRI® VR-T Longevity Estimates - UBD 6 months

Rivacor ProMRI® VR-T Longevity Estimates with UBD of 25 months

% Pacing	Maximum energy charging frequency	500 ohms pacing impedance		700 ohms pacing impedance	
		RV: 2V	RV: 2.5V	RV: 2V	RV: 2.5V
0% VVI	Semiannual	14.04	14.04	14.04	14.04
15% VVI	Semiannual	13.78	13.56	13.84	13.68
50% VVI	Semiannual	13.21	12.56	13.40	12.89
100% VVI	Semiannual	12.48	11.37	12.82	11.92

Table 28: Rivacor ProMRI® VR-T Longevity Estimates - UBD 25 months

Tables 29 and 30 provide longevity estimates for the Rivacor ProMRI® DR-T ICDs. The tables provide several different support scenarios.

Rivacor ProMRI® DR-T Longevity Estimates with UBD of 6 months

% Pacing	Maximum energy charging frequency	RA/RV 500 ohms Pacing impedance		RA: 500 ohms RV: 700 ohms Pacing impedance	
		RA/RV: 2V	RA/RV: 2.5V	RA/RV: 2V	RA/RV: 2.5V
15% Atrial, 15% Ventricular, DDD	Semiannual	13.40	13.06	13.45	13.14
15% Atrial, 50% Ventricular, DDD	Semiannual	12.95	12.24	13.10	12.53
50% Atrial, 50% Ventricular, DDD	Semiannual	12.52	11.48	12.67	11.73

Table 29: Rivacor ProMRI® DR-T Longevity Estimates - UBD 6 months

Rivacor ProMRI® DR-T Longevity Estimates with UBD of 25 months

% Pacing	Maximum energy charging frequency	RA/RV 500 ohms Pacing impedance		RA: 500 ohms RV: 700 ohms Pacing impedance	
		RA/RV: 2V	RA/RV: 2.5V	RA/RV: 2V	RA/RV: 2.5V
15% Atrial, 15% Ventricular, DDD	Semiannual	12.53	12.17	12.58	12.26
15% Atrial, 50% Ventricular, DDD	Semiannual	12.05	11.35	12.21	11.63
50% Atrial, 50% Ventricular, DDD	Semiannual	11.61	10.64	11.76	10.88

Table 29: Rivacor ProMRI® DR-T Longevity Estimates - UBD 25 months

Tables 30 and 31 provide longevity estimates for the Rivacor ProMRI® HF-T QP ICDs. The tables provide several different support scenarios.

Rivacor ProMRI® HF-T QP Longevity Estimates with UBD of 6 months

% Pacing	CRT Auto Adapt	Maximum energy charging frequency	RA/RV/LV 500 ohms Pacing impedance			RA/RV/LV 700 ohms Pacing impedance		
			A,RV, LV: 2.0V	A,RV: 2.5V LV: 2.5V	A,RV: 2.5V LV: 2.5V A,RV: 2.5V LV: 3.0V	A,RV, LV: 2V	A,RV: 2.5V LV: 2.5V	A,RV: 2.5V LV: 3.0V
0% Atrial, 100% DDD-BiV	OFF	Semiannual	10.60	9.19	8.94	11.07	9.88	9.65
	ON	Semiannual	11.55	10.72	10.37	11.80	11.15	10.89
15% Atrial, 100% DDD-BiV	OFF	Semiannual	10.46	9.00	8.76	10.96	9.71	9.49
	ON	Semiannual	11.41	10.46	10.13	11.68	10.96	10.68
25% Atrial, 100% DDD-BiV	OFF	Semiannual	10.37	8.88	8.64	10.89	9.6	9.39
	ON	Semiannual	11.31	10.29	9.97	11.61	10.82	10.55

Table 30: Rivacor ProMRI® HF-T QP Longevity Estimates - UBD 6 months

Rivacor ProMRI® HF-T QP Longevity Estimates with UBD of 25 months

% Pacing	CRT Auto Adapt	Maximum energy charging frequency	RA/RV/LV 500 ohms Pacing impedance			RA/RV/LV 700 ohms Pacing impedance		
			A,RV, LV: 2.0V	A,RV: 2.5V LV: 2.5V	A,RV: 2.5V LV: 2.5V A,RV: 2.5V LV: 3.0V	A,RV, LV: 2V	A,RV: 2.5V LV: 2.5V	A,RV: 2.5V LV: 3.0V
0% Atrial, 100% DDD-BiV	OFF	Semiannual	9.82	8.50	8.26	10.26	9.14	8.93
	ON	Semiannual	10.77	9.93	9.60	11.03	10.35	10.08
15% Atrial, 100% DDD-BiV	OFF	Semiannual	9.69	8.32	8.10	10.15	8.98	8.78
	ON	Semiannual	10.61	9.68	9.38	10.90	10.15	9.89
25% Atrial, 100% DDD-BiV	OFF	Semiannual	9.60	8.21	7.99	10.08	8.88	8.69
	ON	Semiannual	10.51	9.53	9.23	10.82	10.02	9.77

Table 31: Rivacor ProMRI® HF-T QP Longevity Estimates - UBD 25 months

Upon reaching ERI, the battery has enough energy left to continue monitoring / pacing for at least three months and to deliver at least six high energy shocks. The estimates associated with duration of ERI assume the ICD/CRT-D is sensing an intrinsic sinus rhythm at a rate of 70 bpm. When the EOS (End of Service) indication is met, all tachyarrhythmia detection and therapy is disabled, and explantation is required. The ERI and EOS voltages are listed in Table 32.

ERI and EOS Voltages for Rivacor ProMRI® ICDs

Operating Mode	Voltage
Elective Replacement Indicator (ERI)	2.50 Volts - Greatbatch 2.85 Volts - Litronik
End of Service (EOS)	1.75 Volts

Table 32: ERI and EOS voltages for ICDs

Chapter 14: Technical Specifications

The following are the technical specifications for the Rivacor ProMRI® ICDs/CRT-Ds. The ranges are presented in the format:

x ... (y) ... z

where x = the lowest value, y = the increment, and z = the largest value.

Mechanical Properties

Rivacor ProMRI® DF4 models			
	Rivacor ProMRI® VR-T	Rivacor ProMRI® DR-T	Rivacor ProMRI® HF-T QP
Dimensions	60 mm x 61.5 mm x 10 mm	60 mm x 66.5 mm x 10 mm	60 mm x 75 mm x 10 mm
Volume	30 cm^3	32 cm^3	35 cm^3
Mass	75 g	77 g	82 g
Lead Ports	1 x 3.2 mm DF4	1 x 3.2 mm IS-1 Bipolar 1 x 3.2 mm DF4	1 x 3.2 mm IS-1 Bipolar 1 x IS4 1 x 3.2 mm DF4
All Rivacor ProMRI® devices			
Housing	Titanium		
Header	Epoxy resin		
Seal Plug	Silicone		

Table 33: Rivacor ProMRI® Mechanical Properties

Parameter	Range	Default Setting
Bradycardia		
Atrial Sensing Parameters		
Sensing	STD - standard, OFF - inactive	STD
Minimum threshold	0.2 ... (0.1) ... 2.0 mV	0.4 mV
Far-field protection after Vp	50 ... (25) ... 225 ms	75 ms
Far-field protection after Vs	Off, AUTO, 25 ... (25) ... 225 ms	AUTO
Upper threshold	25, 50, 75%	50%
Right-ventricular Sensing Parameters		
Sensing RV	STD - standard, TWS - Enhanced T-wave suppression, VFS - Enhanced VF sensitivity	STD
Minimum threshold	0.5 ... (0.1) ... 2.5 mV	0.8 mV
Blanking after atrial pacing	40 ... (10) ... 100 ms	50 ms
Upper threshold	50; 75%	50%
Lower threshold	25; 50%	25%
Hold of upper threshold after sense	110, 150 ... (50) ... 500 ms	350 ms
Hold of upper threshold after pace	110, 150 ... (50) ... 500 ms	400 ms
Left-ventricular Sensing Parameters		
Sensing LV	STD - standard, OFF - inactive	STD
Min. threshold	0.5 ... (0.1) ... 2.5 ... (0.5) ... 5.0 mV	1.6 mV
Blanking after atrial pacing	100 ms (fixed)	100 ms
Upper threshold	50; 75%	50%
Hold of upper threshold after sense	110, 150 ... (50) ... 500 ms	350 ms
Hold of upper threshold after pace	110, 150 ... (50) ... 500 ms	400 ms
Lower threshold	25%	25%
In channel /Cross channel Blanking		
In-channel blank after RV pace	100 ... (10) ... 350 ms	120 ms
In-channel blank after LV pace	100 ... (10) ... 350 ms	120 ms
LV cross-blank after RV pace	50 ... (10) ... 100 ms	80 ms
RV cross-blank after LV pace	50 ... (10) ... 100 ms	80 ms

Parameter	Range	Default Setting
Polarity Pace / Sense		
LV polarity pace - QP	LV1 → LV2 LV1 → LV4 LV1 → RV LV1 → ICD LV2 → LV1 LV2 → LV4 LV2 → RV LV3 → LV2 LV3 → LV4 LV3 → RV LV4 → LV2 LV4 → RV LV1 →LV3 LV2 →LV3 LV2 → ICD LV3 → LV1 LV3 →ICD LV4 → LV2 LV4 → LV3 LV4 → ICD	LV1 → LV2
LV polarity sense - QP	LV1 → LV2 LV1→ICD LV2 → LV3 LV2 → ICD LV3 → LV4 LV3 →ICD LV4 → ICD	
Shock Path (Valid for all shocks including the pain-free shock impedance)	RV → SVC + Can (Housing) RV → Can (Housing) RV→ SVC	RV → SVC + Can
Pulse Amplitudes and Pulse Widths		
Pulse amplitude	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0, 7.5 V	AUTO (3.5 V)
Pulse width	0.4, 0.5, 0.75, 1.0, 1.25, 1.5 ms	0.4 ms

Parameter	Range	Default Setting
Capture Control (ATM)		
RA (DR/HF-T only)	OFF, ATM, ON	ON
RV	OFF, ATM, ON	ON
LV (HF-T Only)	OFF, ATM, ON	ON
Mode		
Modes (DR-T, HF-T)	DDD-CLS*, VVI-CLS*, DDDR-ADIR, DDD-ADI, DDD, DOO, DDDR, DDI, DDIR, VDD, VDDR, VDI, VDIR, VVI, VVIR, AAI, AAIR, DOO, VOO, OFF	DDD
Modes	VVI-CLS*, VDD, VDDR, VDI, VDI R, VVI, VVIR, VOO, OFF	VVI
Basic Rate Day/Night		
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm
Night rate	OFF, 30 ... (5) ... 100 bpm	OFF
Night beginning	0:00 ... (1 min) ... 23:59 h:m	[22:00 h:m]
Night ending	00:00 ... (1 min) ... 23:59 h:m	[06:00 h:m]
Rate Hysteresis		
Rate hysteresis	OFF, -5 ... (-5) ... -25, -45, -65 bpm	OFF
Repetitive/Scan	OFF; ON	[ON (10)]
AV Delay		
AV delay	Low, Medium, High, Fixed, Individual	Low
AV delay 1	40 ... (5) ... 350 ms	150 ms (HF-T) 180 ms (DR-T)
AV rate 1	50 ... (10) ... 120 bpm	60 bpm
AV delay 2	40 ... (5) ... 350 ms	120 ms (HF-T) 140 ms (DR-T)
AV rate 2	70 ... (10) ... 140 bpm	130 bpm
Sense compensation	OFF; -5 ... (-5) ... -120 ms	-40 ms
AV-hysteresis mode	OFF, Positive, Negative, I-Opt (DR-T only)	OFF
AV hysteresis	70, 110, 150, 200 ms	[70 ms]
AV scan/repetitive (positive)	OFF; ON	[ON]
AV repetitive (negative)	ON (180)	ON (180)
I-Opt (Rivacor ProMRI® DR-T)		
I-Opt	OFF, ON	OFF
AV hysteresis at I-Opt	400 ms	400 ms
AV scan/repetitive at I-Opt	ON (5)	[ON(5)]

Parameter	Range	Default Setting
Vp Suppression		
Vp Suppression	ON: OFF	OFF
Pacing Suppression	1 ... (1) ... 8	6
Pacing Support	1,2,3,4	3
Post-ventricular Atrial Refractory Period (PVARP)		
PVARP	175 ... (25) ... 600 ms, AUTO	225 ms
VES Classification		
Discrimination after As	250 ... (50) ... 800 ms	350 ms
Rate Adaptation (Acceleration Sensor)		
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm
Sensor gain	AUTO, Very low, Low, Medium, High, Very high	Medium
Sensor threshold (numbers are not displayed on screen)	Very low, Low, Medium, High, Very high	Medium
Rate increase	1, 2, 4 or 8 bpm/cycle	2 bpm/cycle
Rate drop	0.1, 0.2, 0.5 or 1.0 bpm/cycle	0.5 bpm/cycle
Rate Adaptation (CLS*)		
Maximum sensor rate	80 ... (10) ... 160 bpm	120 bpm
CLS Response	Very low, Low, Medium, High, Very high	Medium
CLS Resting Rate Control	OFF, +10, +20, +30, +40, +50 bpm	+20 bpm
Vp Required	Yes, No	No (Yes if BiV)
Upper Tracking Rate (UTR)		
Upper tracking rate	90 ... (10) ... 170 bpm	130 bpm
Atrial upper rate	OFF, 175, 200, 240 bpm	200 bpm
Mode Switching		
Intervention rate	OFF, 120 ... (10) ... 200 bpm	160 bpm
Onset criterion	3 ... (1) ... 8	5
Resolution criterion	3 ... (1) ... 8	5
Mode	DDI, DDIR at permanent DDD(R) VDI, VDIR at permanent VDD(R)	DDIR VDIR
Change in basic rate	OFF, +5 ... (5) ...+30 bpm	+10 bpm
Rate stabilization during mode switching	OFF, ON	OFF

Parameter	Range	Default Setting
Post-Mode Switch Response (PMSR)		
Post-ModeSw rate	OFF, +5 ... (5) ...+50 bpm	+10 bpm
Post-ModeSw duration	1 ... (1) ... 30 min	1 min
PMT Protection		
PMT detection / termination	OFF, ON	ON
VA criterion	250 ... (10) ... 500 ms	350 ms
Detection		
Detection / Therapy	ON, OFF	ON
Interval		
Interval VT1	OFF, 270 ... (10) ... 600 ms	OFF
Interval VT2	OFF, 270 ... (10) ... 500 ms	OFF
Interval VF	OFF, 240 ... (10) ... 400 ms	300 ms
Detection/Redetection Counters		
Detection counter VT1	10 ... (2) ... 100	28
Redetection counter VT1	10 ... (2) ... 50	20
Detection counter VT2	10 ... (2) ... 80	20
Detection counter VT2	10 ... (2) ... 40	14
Detection counter VF	6 out of 8, 8 out of 12, 10 out of 14, 12 out of 16, 16 out of 20, 18 out of 24, 20 out of 26, 22 out of 30, 24 out of 30, 30 out of 40	18 out of 24
Redetection counter VF	6 out of 8, 8 out of 12, 10 out of 14, 12 out of 16, 16 out of 20, 18 out of 24, 20 out of 26, 22 out of 30, 24 out of 30	8 out of 12
Onset		
Onset in VT1/2 with SMART	4 ... (4) ... 32%	20%
Onset VT1/2 without SMART	OFF; 4 ... (4)... 32%	20%
Stability		
Stability in VT1/2 with SMART	8 ... (4) ... 48%	12%
Stability VT1/2 without SMART	OFF; 8 ... (4) ... 48% OFF, 8 ... (4) ... 48 ms	12%, 24 ms
MorphMatch Detection		
MorphMatch	OFF, ON, Monitoring	OFF
MorphMatch Threshold	Low, Standard, High	Standard
SMART Detection		
SMART detection VT1	OFF, ON	ON
SMART detection VT2	OFF, ON	ON

Parameter	Range	Default Setting
Sustained VT (without SMART Detection and without SMART Redetection)		
Sustained VT	OFF, 1, 2, 3, 5, 10, 20 or 30 min	OFF
Forced Termination (with SMART Detection Including SMART Redetection)		
Forced termination	1 min	1 min
Atrial Therapy Parameters*		
AT stable	OFF, Burst, Ramp	OFF
AT unstable	HF Burst	OFF
Back-up pacing support	OFF, 70, 90 bpm	OFF
Ventricular Therapy Parameters		
Energy 1st shock of VT1, VT2	OFF; 2 ... (2) ... 20 ... (5) ... 40 J	40 J
Energy 2nd shock VT1, VT2	OFF; 4 ... (2) ... 20 ... (5) ... 40 J	40 J
Number of shocks (VT1/VT2)	0, 1, 2, 6, 8	[8]
Energy 1st shock of VF Zone	OFF; 2 ... (2) ... 20 ... (5) ... 40 J	40 J
Energy 2nd shock VF Zone	OFF; 4 ... (2) ... 20 ... (5) ... 40 J	40 J
Number of shocks (VF)	6, 8	8
Confirmation (per zone)	OFF, ON	ON
Shock form (per zone)	Biphasic, Biphasic 2, Biphasic > alternating, Biphasic 2 alternating	Biphasic
Polarity (per zone)	Normal, Reverse, Normal > alternating, Reverse > alternating	Normal
ATP Parameters		
ATP type	Burst, Ramp	Burst
ATP attempts	OFF, 1 ... (1) ... 10	OFF
S1 number	1 ... (1) ... 15	5
Add. S1	OFF, ON	ON
R1-S1 interval	70 ... (5) ... 85, 88, 90, 95% (adaptive)	80%
S1 (RAMP) decrement	5 ... (5) ... 40 ms	10 ms
Scan decrement	OFF, 5 ... (5) ... 40 ms	OFF
Minimal ATP interval	200 ms	200 ms
ATP optimization 2.0	OFF, ON	OFF
ATP pulse amplitude	7.5 V	7.5 V
ATP pulse width	1.5 ms	1.5 ms
ATP One-Shot Parameter (ATP in VF)		
ATP type	OFF, Burst, Ramp	Burst
S1 number	1 ... (1) ... 15	8
R-S1 interval	70 ... (5) ... 85, 88, 90, 95% (adaptive)	88%
S1 decrement	5 ... (5) ... 40 ms	10 ms

Parameter	Range	Default Setting
Stability	12% (fixed)	12%
ATP attempts	1	1
ATP pulse amplitude	7.5 V	7.5 V
ATP pulse width	1.5 ms	1.5 ms
Ventricular NIPS		
ATP type	Burst, Ramp, Burst + PES, Rapid pacing	Ramp
Attempts	1	1
Ventricular Pacing	BiV, LV, RV	RV
S1 number	1 ... (1) ... 25	5
R-S1 interval	200 ... (10) ... 600 ms (absolute); 70 ... (5) ... 85, 88, 90, 95% (adaptive)	80%
S1 decrement	5 ... (5) ... 40 ms	10 ms
S1-S2 interval	200 ... (10) ... 600 ms alterable via [+ / -] buttons 70 ... (5) ...9 5% (adaptive)	290
S2-S3 interval	OFF, 200 ... (10) ... 600 ms alterable via [+ / -] buttons 70 ... (5) ... 95% (adaptive)	OFF
S3-S4 interval	OFF, 200 ... (10) ... 600 ms simply alterable via [+ / -] buttons 70 ... (5) ... 95% (adaptive)	OFF
Minimum ATP interval	200 ms (fixed)	200 ms
Rapid pacing rate	150 ... (10) ... 180 ... (10) ... 300 bpm	180 bpm
Max rapid pacing duration	10 ... 5 ... (30) ... 5 ... 50 seconds	30 seconds
Atrial NIPS		
Backup Stimulation (VVI-Rate)	OFF, 30 ... (10) ... 120 bpm	OFF
Report	OFF, 5, 10, 25, 50 mm/s	Preference
S1-S1 interval	80 ... (10) ... 2000 ms	600 ms
S1 cycles	0 ... (1) ... 10	7
S1-S2 interval	None, 80 ... (10) ... 1000 ms simply alterable via [+ / -] buttons	None
S2-S3 interval	None, 80 ... (10) ... 1000 ms simply alterable via [+ / -] buttons	None
S3-S4 interval	None, 80 ... (10) ... 1000 ms simply alterable via [+ / -] buttons	None
Burst rate Min.	30 ... (10) ... 250 bpm	150 bpm
Burst rate Start	30 ... (10) ... 800 bpm	250 bpm
Burst rate Max.	250 ... (10) ... 800 bpm	350 bpm

Parameter	Range	Default Setting
Post-Shock Pacing		
Mode	DDI at permanent DDD(R), DDI (R), AAI(R), DDD-CLS, DDD(R)-ADI(R) VDI at permanent VDD(R), VDI(R), VVI at permanent VVI(R), OFF	Mode dependent
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm	60 bpm
AV delay	50 ...(10) ... 350 ms (fixed AV delay)	140 ms
Post-shock duration	OFF, 10 s, 30 s, 1 min, 2 min, 5 min, 10 min	10 s
CRT Therapy Parameters		
Initially paced chamber	LV, RV	LV
VV delay after Vp	0 ... (5) ... 100 ms	0 ms
Home Monitoring		
Home Monitoring	OFF, ON	OFF
Transmission time	Std., 00:00 ... (01:00) ... 23:00	Std.
IEGM for therapy episode	OFF, ON	ON
IEGM for monitoring episode	OFF, ON	ON
Ongoing atrial episode	OFF, 6, 12, 18 h	12 h
Diagnostics		
For AT/AF	ON, OFF, Advanced ON*	ON
For SVT	ON, OFF	ON
For nsT	ON, OFF, FastOnly	ON
Periodic Recordings	If Home Monitoring ON: = Cycle duration (days) Programmed through the remote scheduler in HMSC	

**Not applicable in Rivacor 5*

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Appendix A: Connector Compatibility

The Rivacor ProMRI® DF4 family of ICDs/CRT-Ds are mechanically compatible with:

- IS-1 sensing/pacing lead connectors
- IS4 sensing/pacing lead connectors
- DF4 sensing/pacing/defibrillation lead connector.

The Rivacor ProMRI® VR-T has one DF4 header port. The Rivacor ProMRI® DR-T has one DF4 and one IS-1 header port. The Rivacor ProMRI® HF-T QP has one DF4, one IS-1, and one IS-4 header ports.

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Appendix B: Wireless Technology

The wireless technology incorporated into the Rivacor product family 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[1]. Additionally, the device fulfills Part 15 of the FCC rules and regulations.

Wireless Communication in the Rivacor Devices

Technology	Wireless Inductive Communication	Wandless RF Communication	Home Monitoring[2]
Uses	Follow-up, programming	Wandless device interrogation and programming via programmer device during follow-up	Remote Follow-Up from patient's home via Patient Device
Operating Range	0 – 5 cm	0 – 3 meters	0 – 3 meters
Carrier Frequency	32.768 kHz	403 MHz MedRadio (MICS)	403 MHz MedRadio (MICS)
Modulation	Pulse distance coding, OOK	Binary FSK	Binary FSK
Uplink Data Rate	2978 bps	Noise level dependent 32 [kbit/s] 82 [kbit/s]	16 [kbit/s]
Downlink Data Rate	2978 bps	Noise level dependent 16 [kbit/s] 32 [kbit/s] 82 [kbit/s]	4 [kbit/s]
Effective RF Radiated Output Power	-64.09 dBm EIRP	Less than 25µW EIRP	Less than 25µW EIRP
Field Strength	Less than -50 dBuV/m	Less than 18.2 mV/m	Less than 18.2 mV/m
Bandwidth	4.71 kHz	Less than 300 kHz	Less than 300 kHz
FCC Regulation	47 CFR 15.209(a)	47 CFR Part 95	47 CFR Part 95

1. If programmed to unipolar sensing, the device complies with ISO 14708-6:2010 Sec. 27.5.1 and ISO 14117:2012 Sec. 4.5.2.2 for disturbance voltages ≤0.3mVpp
2. 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.

FCC Statement: (FCC ID: QRITACHNT2: This implant is equipped with an RF transmitter for wireless communications. This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

Appendix C: Glossary

A

active housing When the housing of the ICD is used as an electrode for shock delivery.

anode The positive pole of a circuit.

ATP (Anti-Tachycardia Pacing) Rapid pacing therapy used to terminate tachyarrhythmias.

ASC (Auto Sensitivity Control) The sensing algorithm used in ICDs to sense the cardiac signal over a wide range of intrinsic amplitudes.

B

biphasic waveform A waveform type with two phases, one positive and one negative.

blanking period A period of time in which the device does not sense. A blanking period follows shock delivery or a programmable time period after a paced event.

BOS (Beginning of Service) A term used to describe battery status.

burst A train of pacing pulses delivered at either fixed or decreasing cycle lengths used to treat or induce tachyarrhythmias.

C

capacitance The energy stored in a capacitor is proportional to the capacitance times the square of the voltage across the capacitor.

capacitor A circuit element consisting of two conducting surfaces separated by a nonconducting surface. A capacitor temporarily stores an electric charge for defibrillation in an ICD.

capacitor reformation The process in which the capacitors are fully charged and discharged. In an ICD, no energy is delivered to the patient. The process may improve charge times when the charging circuit is used infrequently.

cardioversion A shock, usually low in energy, used to terminate a tachyarrhythmia.

cathode The negative pole of a circuit.

committed shock A shock that is delivered without reconfirmation of an ongoing tachyarrhythmia.

confirmation type With respect to shocks, confirmation can be programmed to YES (i.e., a uncommitted shock) or NO (i.e., a committed shock).

coupling interval The time period between an intrinsic event and an electrical stimulus or between two consecutive programmed electrical stimuli.

current The flow rate of a charge, measured in amperes or milliamperes.

cycle length The time period between one event and the next in a repetitive signal (e.g., pacing pulse), measured in milliseconds.

D

device-based testing A process using the ICD and a programming system to perform DFT (induction) testing.

DFT (defibrillation threshold) The minimum energy or voltage required to successfully terminate a tachyarrhythmia.

E

EOS A term used to describe battery status. EOS indicates End Of Service.

ERI A term used to describe battery status. ERI indicates Elective Replacement Indicator.

H

HV1 A high-voltage port on the header of an ICD. The HV1 port connects to the electrode placed in the ventricular apex.

HV2 A high-voltage port on the header of an ICD. The HV2 port connects to the electrode placed in the vena cava. HV2 is also internally connected to the housing of ICD to act as a common electrode.

I

impedance The ratio of voltage to current, measured in ohms. Also, the total opposition (i.e., resistance and reactance) to the flow of current in an electrical circuit.

J

joule A unit of work or energy. The work done in one second by current of one ampere against a resistance of one ohm.

M

monomorphic VT A ventricular tachycardia that occurs from a single focus. The ECG pattern usually shows a regular waveform.

N

non-committed shock Shocks that are delivered only after a tachyarrhythmia is verified by the device. If a tachyarrhythmia terminates during the reconfirmation period, the device does not deliver energy to the patient.

O

onset A detection enhancement used to discriminate VTs (which occur suddenly) from sinus tachyarrhythmias (whose rate increases slowly over time).

P

PES (Programmed Electrical Stimulus or Premature Extra Stimulus) A series of pacing pulses delivered at fixed or decreasing cycle lengths used to induce arrhythmias.

polarity The condition of being positive or negative relative to a given reference. In BIOTRONIK ICDs, normal polarity refers to the configuration with the distal shock coil as the cathode and the can as the anode.

polymorphic VT A ventricular tachycardia that may have more than one focus

post-shock pacing Pacing, typically high in amplitude, that occurs after shock therapy.

R

ramp A burst of pacing pulses delivered in decreasing cycle lengths within a stimulation scheme.

reconfirmation The process of verifying an ongoing tachyarrhythmia after detection, but prior to therapy delivery.

S

scan A programmable parameter that defines the amount by which an interval decreases between successive ATP attempts.

stability Detection enhancement used to discriminate between VT and atrial fibrillation.

SVT A fast rhythm originating from the atria.

T

tilt A measurement describing the voltage drop across phases in a shock waveform.

V

ventricular fibrillation (VF) A rapid irregular cardiac rhythm resulting from many foci resulting in death if left untreated.

ventricular tachyarrhythmia (VT) A series of rapid beats (greater than 100 bpm) arising from the ventricles.

VT1 The lowest (i.e., slowest) programmable VT zone.

VT2 A programmable VT zone defined by a VT limit. The VT2 zone lies between VT1 and VF.

X

X out of Y An algorithm requiring "X number of intervals out of a window of Y intervals" to satisfy a given criterion.

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