Lumax

Family of Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy Defibrillators

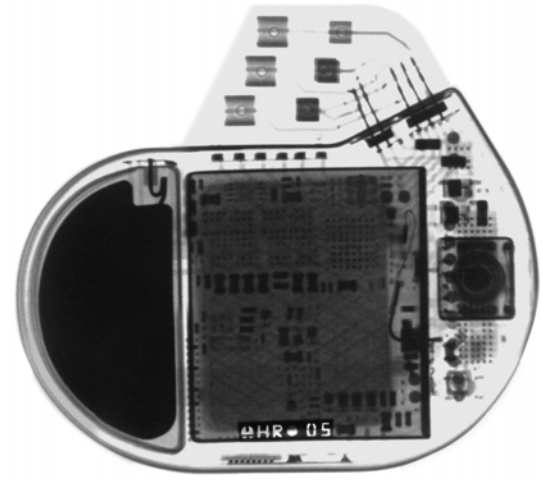
- VR ICD
- VR-T ICD
- VR-T DX ICD
- DR ICD
- DR-T ICD
- HF CRT-D
- HF-T CRT-D

Technical Manual

BIOTRONIK
excellence for life

X-ray Identification
Lumax Family
Implantable Cardioverter Defibrillator and Cardiac Resynchronization Therapy Defibrillators
Inside the housing:

Model	X-Ray Identification	Year of Manufacture
Lumax 300	HR	nn
Lumax 340	HR	nn
Lumax 500	SH	nn
Lumax 540	SH	nn
Lumax 600	RH	nn
Lumax 640	RH	nn
Lumax 700	RH	nn
Lumax 740	RH	nn

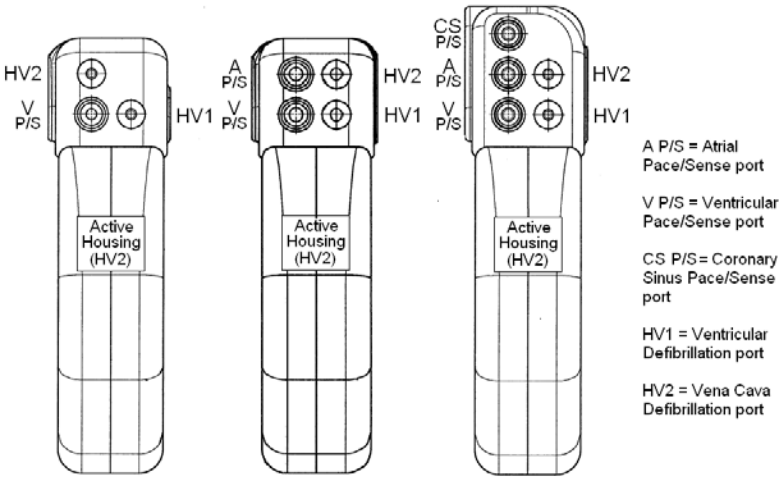


CAUTION

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

Contents

Figure 1. Lumax 300/340 ICDs and CRT-D



VR(-T) **DR(-T)/VR-T DX** **HF(-T)**

Figure 2. Lumax 500/540, 600/640 & 700/740 ICDs and CRT-D

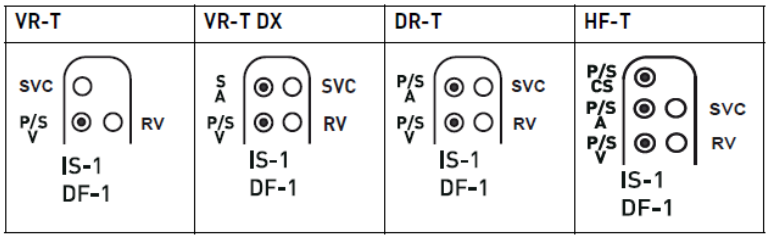


Table 1. Lumax Specifications

Battery Voltage	3.2 Volts
Maximum Shock Energy	
300/500/600/700 Models	30 Joules programmed
340/540/640/740 Models	40 Joules programmed
Defibrillation Lead Ports	Two DF1 (3.2 mm)
Pacing Lead Ports	

VR(-T) Models	One IS-1 (3.2 mm)
DR(-T)/VR-T DX Models	Two IS-1 (3.2 mm)
HF(-T) Models	Three IS-1 (3.2 mm)
Materials	
Housing	Titanium
Header	Epoxy Resin
Sealing Plug	Silicone

Detailed technical specifications are provided in **Section 6**.

1. General

1.1 System Description

The Lumax 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 and HF-T versions of Lumax provide Cardiac Resynchronization Therapy (CRT) through biventricular pacing. Both CRT-Ds and ICDs detect and treat ventricular tachyarrhythmias and provide rate adaptive bradycardia pacing support. They 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 Lumax 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 5 to 40 joules.

The Lumax family of ICDs/CRT-Ds includes the following members:

- Lumax HF - provides three chamber rate-adaptive bradycardia pacing support including biventricular pacing via a left ventricular pacing lead. The CRT-D uses right atrial and ventricular sensing/pacing leads to provide enhanced atrial and ventricular tachyarrhythmia discrimination through BIOTRONIK's SMART Detection™ algorithm.
- Lumax HF-T - In addition, to the functionality found with HF model, Lumax HF-T also has BIOTRONIK's Home Monitoring system. The Home Monitoring System enables automatic exchange of information about a patient's cardiac status from the implant to the physician remotely.
- Lumax DR - 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.

- Lumax DR-T - In addition, to the functionality found with the DR model, it also has BIOTRONIK's Home Monitoring® system. The Home Monitoring System enables automatic exchange of information about a patient's cardiac status from the implant to the physician remotely.
- Lumax VR - provides single chamber rate adaptive bradycardia pacing support as well as tachyarrhythmia detection and therapy.
- Lumax VR-T - In addition, to the functionality found with standard VR model, it also has BIOTRONIK's Home Monitoring system. The Home Monitoring System enables automatic exchange of information about a patient's cardiac status from the implant to the physician remotely.
- Lumax VR-T DX – provides ventricular rate adaptive bradycardia pacing support that can include atrial tracking with a single pass ICD lead and also has BIOTRONIK's Home Monitoring system.

The 300/500/600/700 and 340/540/640/740 designation for each of the above-described models denote the maximum programmable shock energy of 30 joules and 40 joules, respectively.

The Lumax 500/540, 600/640 and 700/740 models feature a third programmable shock path for delivery of defibrillation/cardioversion shocks. The shock path is programmable between the different shock coils (SVC/RV) and/or the device housing. **Section 2.8.3.6** provides further details on the available shock configurations. The Lumax 600/640 and 700/740 models also feature an additional left ventricular (LV) pacing polarity for HF-T devices from LV-tip to housing (unipolar).

Additionally, the Lumax 500/540 models feature Automatic Threshold Measurement (ATM) of ventricular pacing thresholds. This feature is separately programmable for the right (RV) and left (LV) ventricle. Section 2.4 provides further details.

The Lumax 700/740 and 600/640 models feature ATM with automatic adjustment of pacing amplitudes (RV & LV Capture Control). This feature functions the same as ATM for threshold search and is also separately programmable for the right (RV) and left (LV) ventricle. In addition, it automatically adjusts the permanent pacing amplitude with a programmed safety margin. Section 2.4.5 provides a detailed description of this feature.

The Lumax 600/640 and 700/740 also provides wandless telemetry to ease implantation and follow-up procedures. In addition, these devices include Thoracic Impedance monitoring and Atrial NIPS that can be used for an EP study to induce an arrhythmia or to burst pace a patient out of a stable tachyarrhythmia.

Lumax 700/740 and 600/640 will present with automatic Far-Field IEGM to provide a means to generate the surface ECG-like signal without the need for attaching the surface electrodes to the patients.

The Lumax HF (-T) models have three IS-1 pacing/sensing header ports and two DF-1 defibrillation/cardioversion ports. The Lumax DR (-T) models have two IS-1 pacing/sensing header ports. The Lumax VR (-T) models have one IS-1 pacing/sensing header ports. IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO 11318:1993].

External devices that interact with and test the implantable devices are also part of the ICD/CRT-D System. These external devices include the Programming and Tachyarrhythmia Monitoring System and the Implant Module System Analyzer or Pacing System Analyzer for acute lead testing. The ICS 3000 or Renamic programmer are used to interrogate and program the ICD/CRT-Ds.

The Lumax 600/640 and 700/740 models also feature SafeSync Telemetry (RF-Telemetry) via the Renamic programmer or the ICS 3000 programmer in combination with the SafeSync Module (an external communication module).

BIOTRONIK conducted the TRUST study to evaluate the safety and effectiveness of Home Monitoring, which is available in most models of this device. Refer to Section 1.6.4 for details regarding the study design and results. With the TRUST study, BIOTRONIK was able to show the following with regards to Home Monitoring:

- BIOTRONIK Home Monitoring information may be used as a replacement for device interrogation during in-office follow-up visits.
- A strategy of care using BIOTRONIK Home Monitoring with office visits when needed has been shown to extend the time between routine, scheduled in-office follow-ups of BIOTRONIK implantable devices in many patients. Home Monitoring data is helpful in determining the need for additional in-office follow-up.
- BIOTRONIK Home Monitoring-patients—who are followed remotely with office visits when needed—have been shown to have similar numbers of strokes, invasive procedures and deaths as patients followed with conventional in-office follow-ups.
- BIOTRONIK Home Monitoring provides early detection of arrhythmias.
- BIOTRONIK Home Monitoring provides early detection of silent, asymptomatic arrhythmias.
- Automatic early detection of arrhythmias and device system anomalies by BIOTRONIK Home Monitoring allows for earlier intervention than conventional in-office follow-ups.
- BIOTRONIK Home Monitoring allows for improved access to patient device data compared to conventional in-office follow-ups since device interrogation is automatically scheduled at regular intervals.

1.2 Indications and Usage

The Lumax 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 $\leq$ 35%); and

- Intraventricular conduction delay (QRS duration ≥130 ms)

The Lumax Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are intended to provide ventricular anti-tachycardia pacing and ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias.

1.3 Contraindications

The Lumax 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 brady arrhythmias or atrial arrhythmias

1.4 Warnings and Precautions

MRI (Magnetic Resonance Imaging) - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

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
- Active or passive fixation technology
- Insertion and withdrawal forces as specified by ISO 5841-3 (IS-1)

The following LV leads were evaluated in the OPTION CRT/ATx study with BIOTRONIK's CRT-Ds:

- Guidant-EASYTRAK® IS-1 Lead
- Guidant-EASYTRAK LV-1 Lead
- Guidant-EASYTRAK 2 Lead
- Guidant-EASYTRAK 3 Lead
- Medtronic-Attain® OTW Lead
- St. Jude-Aescula™ Lead
- St. Jude-QuickSite® Lead
- Biomec-Myopore™ Epicardial Lead
- Medtronic-Epicardial 5071 Lead
- Medtronic-CapSure® EPI Lead
- BIOTRONIK-ELC 54-UP Lead

The following LV leads were bench tested for compatibility with BIOTRONIK's CRT-Ds:

- Guidant EASYTRAK 4512 (unipolar) Lead
- Guidant EASYTRAK 4513 (bipolar) Lead
- Guidant EASYTRAK 3 4525 (bipolar) Lead
- Medtronic Attain OTW 4193 (unipolar) Lead
- Medtronic Attain OTW 4194 (bipolar) Lead
- Medtronic Attain LV 2187 (unipolar) Lead
- St. Jude Medical QuickSite 1056K (unipolar) Lead
- ELA SITUS® OTW (unipolar) Lead
- BIOTRONIK Corox OTW 75-UP Steroid #346542 (unipolar) Lead
- BIOTRONIK Corox+ LV-H 75-BP #341885 (bipolar) Lead

ICD Lead Systems – BIOTRONIK ICDs/CRT-Ds maybe 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)
- 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 30 joules

- Insertion and withdrawal forces as specified by ISO 5841-3 (IS-1) and ISO 11318:1993 (E) DF-1

The following leads were evaluated in a retrospective study with BIOTRONIK's ICDs/CRT-Ds:

- Medtronic Sprint™ Lead 6932
- Medtronic Sprint Lead 6943
- Medtronic Sprint Quattro™ Lead 6944
- Medtronic Transvene™ RV Lead 6936
- St. Jude (Ventritex) TVL™- ADX Lead 1559
- St. Jude SPL® SP02 Lead
- Guidant ENDOTAK® DSP Lead
- Guidant ENDOTAK Endurance EZ Lead, ENDOTAK Reliance Lead
- Guidant (Intermedics) Lead 497-24.

The following leads were bench tested for compatibility with BIOTRONIK's ICDs/CRT-Ds:

- Guidant ENDOTAK Endurance Lead "CPI 0125"
- Guidant ENDOTAK Reliance Lead 0148
- Medtronic Sprint Lead 6932
- Medtronic Sprint Lead 6942
- Medtronic Sprint Lead 6943
- Medtronic Sprint Lead6945
- Medtronic Sprint Quattro Lead 6944
- St. Jude Riata® Lead 1571/65
- St. Jude SPL SPO1 Lead.

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.

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

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.

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 90 days. For further information, please refer to **Section 2.11.5**, Capacitor Reforming.

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 or the programming wand over the ICD/CRT-D will suspend tachycardia detection and treatment. The minimum magnet strength required to suspend tachycardia treatment is 1.8 mT. When the magnet strength decreases to less than 1 mT, the reed contact 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.

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.

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 automatically deactivated as soon as electrophysiological tests (e.g., Impedance measurement) have been performed. To ensure delivery of programmed shock energy, make sure shipment mode is disabled prior to completion of implant procedure.

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

Shock Impedance - If the shock impedance is less than twenty-five 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 twenty-five ohms (25 Ω). Damage to the device may result.

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

1.4.3 Lead Evaluation and Connection

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.

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 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 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 perpendicular to the connector receptacle. Failure to do so may result in damage to the plug and its self-sealing properties.

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 – Within the EP Test screen, pressing the "Safe Program" key on the programmer head immediately sends the safe program to the ICD/CRT-D.

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 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 also 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 a level not higher than is 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.

MRI (Magnetic Resonance Imaging) - Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

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 during the procedure. Avoid applying ablation energy near the implanted lead system whenever possible.

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 6 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 they are placed in close proximity to the device.

1.4.11 Home Monitoring®

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

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

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

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

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

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 CRT-D:

- Air embolism
- 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 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 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.

1.5.2 Observed Adverse Events

Reported Adverse Events are classified as either observations or complications. Complications are defined as clinical events that require additional invasive intervention to resolve. Observations are defined as clinical events that do not require additional invasive intervention to resolve.

1.5.2.1 Kronos LV-T Study

NOTE:

The Kronos LV-T CRT-D is an earlier generation of BIOTRONIK devices. The Lumax CRT-Ds are based upon the Kronos LV-T and other BIOTRONIK CRT-Ds and ICDs (i.e., Tupos LV/ATx CRT-D, Lexos and Lumos families of ICDs).

The HOME-CARE Observational study, conducted outside the US on the Kronos LV-T cardiac resynchronization defibrillator (CRT-D) in patients with congestive heart failure (CHF) involved 45 devices implanted with a cumulative implant duration of 202 months (mean implant duration of 4.5 months).

Of the 31 adverse events reported, there have been 26 observations in 23 patients and 5 complications in 3 patients with a cumulative implant duration of 202 months (16.8 patient-years). 6.7% of the enrolled patients have experienced a complication with two patients experiencing 2 separate complications. The rate of complications per patient-year was 0.30. 51% of the enrolled study patients had a reported observation with 3 patients having more than 1 observation. The rate of observations per patient-year is 1.54. Complications and observations for the patient group are summarized in **Table 2** and **Table 3**, respectively.

Table 2: Summary of Complications – Kronos LV-T

Category	Number of Patients	% of Patients	Number	Per patient-year
Left Ventricular Lead Related				
Dislodgement	1	2.2%	1	0.06
No Capture	1	2.2%	1	0.06
Total	**2**	**4.4%**	**2**	**0.12**
ICD Lead Related				
Dislodgement	1	2.2%	1	0.06
Elevated Pacing Threshold	1	2.2%	1	0.06
Total	**2**	**4.4%**	**2**	**0.12**
Unrelated to CRT-D or Leads				
Hemathorax	1	2.2%	1	0.06
Total	**1**	**2.2%**	**1**	**0.06**
Overall Complication Totals	**3**	**6.7%**	**5**	**0.30**

Number of Patients = 45, Number of Patient-Years = 16.8

Table 3: Summary of Observations – Kronos LV-T				
Category	**Number of Patients**	**%of Patients**	**Number**	**per patient-year**
Unsuccessful LV lead implant	8	17.8%	8	0.48
Elevated LV pacing threshold	5	11.1%	5	0.30
Phrenic nerve stimulation	3	6.7%	3	0.18
Elevated DFT measurement	2	4.4%	2	0.12
T-wave oversensing	2	4.4%	2	0.12
Worsening CHF	2	4.4%	2	0.12
Elevated RV pacing threshold	1	2.2%	1	0.06
Hepatitis	1	2.2%	1	0.06
Arrhythmias	1	2.2%	1	0.06
Cardiac Decompensation	1	2.2%	1	0.06
All Observations	**23**	**51.1%**	**26**	**1.54**

Number of Patients = 45, Number of Patient-Years = 16

Two patient deaths were reported during the HOME-CARE Observational Study. One death resulted from worsening heart failure and the second death resulted from cardiogenic shock due to ischemic cardiomyopathy. None of the deaths were related to the implanted CRT-D system. There were no device explants during the HOME-CARE Observational Study.

1.5.2.2 Tupos LV/ATx Study

NOTE:

The clinical study information included in this section and in **Section 1.6.2** was performed with the Tupos LV/ATx CRT-D, which is an earlier version of the Lumax CRT-D/ICD families. The clinical study data presented here is applicable because the Lumax family are downsized versions of the Tupos LV/ATx CRT-D and Tachos ICD families. The Lumax family is slightly different as compared to the Tupos LV/ATx (and Tachos family) in the following areas:

- Reduced size from 50/48 cc to 40/35 cc
- Addition of Home Monitoring® functionality
- Addition of triggered pacing for biventricular pacing modes
- True three chamber pacing and sensing capabilities (CRT-Ds)

The OPTION CRT/ATx study was a prospective, randomized, multi-center study to demonstrate the safety and effectiveness of the investigational Tupos LV/ATx Cardiac Resynchronization Therapy Defibrillator (CRT-D) in patients with congestive heart failure (CHF) and atrial tachyarrhythmias. All patients enrolled into the clinical study were randomly assigned to either the study group or the control group at a 2 to 1 ratio. Patients in the study group were implanted with the Tupos LV/ATx. Patients in the control group were implanted with a legally marketed ICD that provides CRT.

Of the 278 adverse events reported in the Tupos LV/ATx study group, there have been 210 observations in 104 patients and 68 complications in 50 patients with a cumulative implant duration of 1240.4 months (101.9 patient-years). 37.6% of the enrolled study patients have experienced a complication. The rate of complications per patient-year is 0.67. 78.2% of the enrolled study patients have a reported observation. The rate of observations per patient-year is 2.06.

Complications and observations for the Tupos LV/ATx study group are summarized in **Table 4** and **Table 5**. The total number of patients may not equal the sum of the number of patients listed in each category, as an individual patient may have experienced more than one complication or observation.

Table 4: Summary of Complications – Tupos LV/ATx

Category	Number of Patients	% of Patients	Number of Complications	Complications per patient-year
Procedure Related				
Hematoma	4	3.01%	4	0.04
Pneumothorax	2	1.50%	2	0.02
Total	**6**	**4.51%**	**6**	**0.06**
Atrial Lead Related				
Dislodgement	3	2.26%	3	0.03
Total	**3**	**2.26%**	**3**	**0.03**
ICD Lead Related				
High threshold/No capture	2	1.50%	2	0.02
Diaphragmatic/Intercostal stimulation (RV)	1	0.75%	1	0.01
Total	**3**	**2.26%**	**3**	**0.03**
LV Lead Related				
High threshold/Intermittent biventricular capture/No capture	11	8.27%	12	0.12
Unable to implant lead via coronary sinus	11	8.27%	11	0.11
Dislodgement	4	3.01%	4	0.04
Diaphragmatic/Intercostal stimulation	1	0.75%	2	0.02
Total	**27**	**20.3%**	**29**	**0.28**

Table 4: Summary of Complications – Tupos LV/ATx				
Category	**Number of Patients**	**% of Patients**	**Number of Complications**	**Complications per patient-year**
Device Related				
Infection	3	2.26%	7	0.07
Device migration	4	3.01%	4	0.04
Elective replacement indicator reached	4	3.01%	4	0.04
Inductions and conversions	1	0.75%	1	0.01
Unable to interrogate device	1	0.75%	1	0.01
Total	**12**	**9.02%**	**17**	**0.17**
Total Procedure and Device Related	**43**	**32.33%**	**58**	**0.57**
Other Medical Related				
Non-CHF Cardiac Symptoms	4	3.01%	4	0.04
Ventricular arrhythmias	2	1.50%	3	0.03
Other medical	2	1.50%	2	0.02
Atrial arrhythmia	1	0.75%	1	0.01
Total	**9**	**6.77%**	**10**	**0.10**
Total – All Patients and Categories	**50**	**37.59%**	**68**	**0.67**

Number of Patients = 133, Number of Patient-Years = 101.9

* 1 Unanticipated Adverse Device Effect (UADE) occurred with a Tupos LV/ATx CRT-D during the OPTION clinical study. The device was explanted after it was unable to be interrogated with the programmer software and no pacing output was evident. The analysis showed an inappropriately depleted battery and no anomalies with the IC module. The battery depletion strongly suggests that the high voltage circuit was activated over a prolonged period due to a single-bit execution path failure. The current programmer software with Automatic Battery Management (ABM) would have prevented the battery from becoming completely depleted. There were no other instances of this failure mechanism in Tupos LV/ATx devices.

For the Tupos LV/ATx study group, there were 210 observations in 104 patients with cumulative implant duration of 1240.4 months (101.9 patient years). 78.2% of the enrolled study patients have a reported observation. The rate of observations per patient-year was 2.06. **Table 5** summarizes by category each type of observation for the study group.

Table 5: Summary of Observations – Tupos LV/ATx

Category	Number of Patients	% of Patients	Number	per patient-year
Procedure Related				
Hematoma	10	7.52%	10	0.10
Cardiac arrest	2	1.50%	2	0.02
Unable to implant system	1	0.75%	1	0.01
Total	**13**	**9.77%**	**13**	**0.13**
Atrial Lead Related				
Dislodgement	1	0.75%	1	0.01
High threshold	1	0.75%	1	0.01
Total	**2**	**1.50%**	**2**	**0.02**
ICD Lead Related				
High threshold/No capture	1	0.75%	1	0.01
Total	**1**	**0.75%**	**1**	**0.01**
LV Lead Related				
High threshold/ Intermittent biventricular capture/ No capture	24	18.05%	24	0.24
Diaphragmatic/ Intercostal stimulation	8	6.02%	8	0.08
Total	**30**	**22.56%**	**32**	**0.31**

Table 5: Summary of Observations – Tupos LV/ATx				
Category	**Number of Patients**	**% of Patients**	**Number**	**per patient-year**
Device Related				
Infection	1	0.75%	1	0.01
Inductions and conversions	6	4.51%	6	0.06
Inappropriate sensing	20	15.04%	20	0.20
Symptomatic with biventricular pacing	2	1.50%	2	0.02
Total	**25**	**18.80%**	**29**	**0.28**
Total Procedure, Lead and Device Related	**61**	**45.86%**	**77**	**0.76**
Other Medical Related				
Non-CHF Cardiac Symptoms	21	15.79%	21	0.21
Ventricular arrhythmias	11	8.27%	11	0.11
Other medical	26	19.55%	32	0.31
Atrial arrhythmia	14	10.53%	14	0.14
Dizziness	4	3.01%	4	0.04
Medication	5	3.76%	5	0.05
Worsening CHF	46	34.59%	46	0.45
Total	**82**	**61.65%**	**133**	**1.31**
Total – All Patients and Categories	**104**	**78.20%**	**210**	**2.06**

Number of Patients = 133 Number of Patient-Years = 101.9

There have been 4 patient deaths reported for the control group (out of 67 total control patients) and 10 patient deaths have been reported for the study group (out of 133 total study patients). None of the deaths were related to the implanted CRT-D system. One patient in the control group died prior to receiving a biventricular device implant. There is no significant difference between the number of deaths in the study group versus the control group (p = 0.777, Fisher's Exact Test, 2 sided). **Table 6** provides a summary of reported patient deaths and **Table 7** provides survival percentages by follow-up interval during the first 12 months of study participation.

Table 6: Summary of Patient Deaths

Category of Death	Study (N = 133)	Control (N = 67)
	Number of Patients	Number of Patients
Sudden Cardiac	1	1
Non-Sudden Cardiac	5	2
Non-Cardiac	4	1
All Causes	10	4

Figure 3 shows the associated Kaplan-Meier survival curves for the study and control group. The significance level for the difference between the two study groups based on a Log Rank test was p = 0.795.

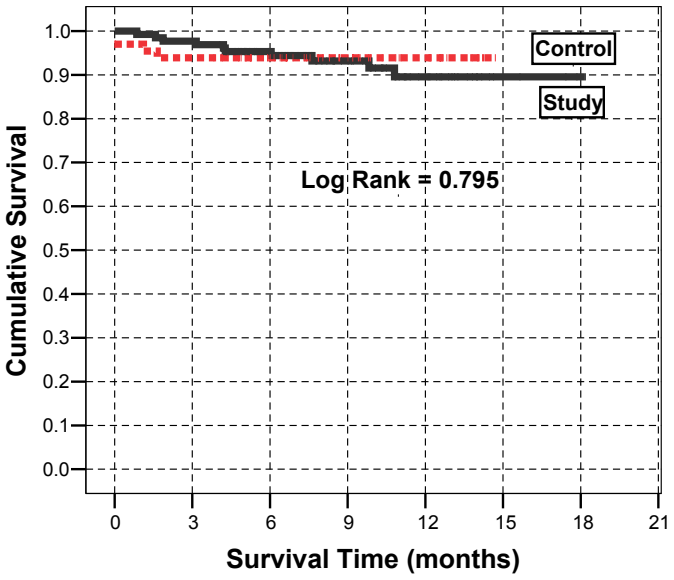


Figure 3: Kaplan-Meier Survival Curves

Table 7 Survival Table				
	Study Group (n = 133)		Control Group (n = 66)	
	Number	%	Number	%
Enrollment	133	100.00%	67	100.00%
3-month	131	98.50%	63	94.03%
6-month	127	95.49%	63	94.03%
12-month	123	92.48%	63	94.03%

1.6 Clinical Studies

The Kronos LV-T Clinical study (HOME-CARE, **Section 1.6.1**) supports the safety of the Lumax CRT-D/ICD device family. Additionally, because the Tupos LV/ATx and the Lumax CRT-D devices have identical CRT and ventricular ICD therapy, the effectiveness results from the OPTION CRT/ATx IDE Clinical study (Tupos LV/ATx, **Section 1.6.2**) support the effectiveness of the Lumax family.

1.6.1 Kronos LV-T Study

The purpose of the HOME-CARE Observational Study is to demonstrate the safety of the CE-marked Kronos LV-T cardiac resynchronization defibrillator (CRT-D) in patients with congestive heart failure (CHF).

1.6.1.1 Methods

The multi-center, non-randomized observational study was designed to evaluate the safety of the Kronos LV-T through an analysis of the complication-free rate through three months.

The HOME-CARE Observational Study Primary Endpoint was to evaluate complications (adverse events that require additional invasive intervention to resolve) related to the implanted CRT system which includes the Kronos LV-T, the right atrial lead, the right ventricular ICD lead, and the left ventricular lead

Inclusion Criteria

To support the objectives of this investigation, patients were required to meet the following inclusion criteria prior to enrollment:

- Indication for Cardiac Resynchronization Therapy
- Sufficient GSM-network coverage in the patient's area
- Age greater than or equal to 18 years

Exclusion Criteria

To support the objectives of this investigation, the exclusion criteria at the time of patient enrollment included the following:

- Permanent atrial fibrillation
- Myocardial infarction or unstable angina pectoris within the last 3 prior to enrollment
- Planned cardio-surgical intervention within 3 months after enrollment (e.g. PTCA, CABG, HTX)
- Acute myocarditis
- Life expectancy less than 6 months
- Pregnant or breast-feeding woman
- Drug or Alcohol abuse
- The patient is mentally or physically unable to take part in the observational study
- No signed declaration of consent for the patient

At the enrollment screening, the physician evaluated the patient to verify that all inclusion/exclusion criteria were met in accordance to the protocol and the patient signed the informed consent. After successful enrollment, all patients were implanted with the Kronos LV-T CRT-D. Evaluations at the One- and Three-month follow-ups included resting ECG, NYHA classification, medications, and activation of Home Monitoring.

1.6.1.2 Summary of Clinical Results

The study involved 45 patients (37 males, 82.2%, and 8 females, 17.8%), with a mean age of 64 years (range: 36-79), a left ventricular ejection fraction of 26 % (range: 15-43), NYHA Class III (NHYA Class 1 (2.3%), Class II (11.4%), Class III (79.5%), Class IV (6.8%)) and QRS duration of 154 ms (range: 84-208).

The mean implant duration was 4.5 months with a cumulative implant duration of 202 months. The patient follow-up compliance rate was 95.9% out of 221 required follow-ups.

Primary Endpoint

The safety of the Kronos LV-T was evaluated based on complications (adverse events that require additional invasive intervention to resolve) related to the implanted CRT system which includes the Kronos LV-T, the right atrial lead, the right ventricular ICD lead, and the left ventricular lead. 5 complications were seen in 3 patients with cumulative implant duration of 202 months (16.8 patient-years). 6.7% of the patients had a reported complication. The rate of complications per patient-year is 0.30.

The freedom from Kronos LV-T system-related complications is 93.3% with a two sided lower 95% confidence bound of 83.8%. The null hypothesis is rejected, and it is concluded that the complication-free rate is equivalent to 85% within 10%.

1.6.2 Tupos LV/ATx Study

NOTE:

The clinical study information included in this section was performed with the Tupos LV/ATx CRT-D, which is an earlier version of the Lumax CRT-D/ICD families. The clinical study data presented here is applicable because the Lumax family are downsized versions of the Tupos LV/ATx CRT-D and Tachos ICD families. The Lumax family is slightly different as compared to the Tupos LV/ATx (and Tachos family) in the following areas:

- Reduced size from 50/48 cc to 40/35 cc
- Addition of Home Monitoring functionality
- Addition of triggered pacing for biventricular pacing modes
- True three chamber pacing and sensing capabilities (CRT-Ds)

1.6.2.1 Study Overview

The purpose of the prospective, randomized, multi-center OPTION CRT/ATx study was to demonstrate the safety and effectiveness of the investigational Tupos LV/ATx Cardiac Resynchronization Therapy Defibrillator (CRT-D) in patients with congestive heart failure (CHF) and atrial tachyarrhythmias. Patients in the study group were implanted with a BIOTRONIK Tupos LV/ATx. Patients in the control group were implanted with any legally marketed CRT-D. Patients in both the study and control groups were implanted with a legally marketed left ventricular lead.

1.6.2.2 Methods

Primarily, the study evaluates and compares the functional benefits of CRT between the two randomized groups using a composite endpoint consisting of a six-minute walk test (meters walked) and quality of life measurement (assessed using the Minnesota Living with Heart Failure Questionnaire). Relevant measurements were completed twice for each patient: once at the Baseline evaluation (two-week post implant follow-up) and again at a six-month follow-up evaluation. The data collected during this clinical study was used to demonstrate equivalent treatment of CHF in both the study and control groups. This study also evaluated other outcomes including: the effectiveness of atrial therapy to automatically convert atrial tachyarrhythmias, the percentage of time CRT is delivered, and other measures of CHF status including NYHA classification, peak oxygen consumption during metabolic exercise testing, and the rate of hospitalization for CHF.

Inclusion Criteria

To support the objectives of this investigation, patients were required to meet the following inclusion criteria prior to enrollment:

- Stable, symptomatic CHF status
- NYHA Class III or IV congestive heart failure
- Left ventricular ejection fraction ≤ 35% (measured within Six-Months prior to enrollment)
- Intraventricular conduction delay (QRS duration greater than or equal to 130 ms)
- For patients with an existing ICD/CRT-D, optimal and stable CHF drug regimen including ACE-inhibitors and beta-blockers unless contraindicated (stable is defined as changes in dosages less than 50% during the last 30 days)
- Indicated for ICD therapy
- History or significant risk of atrial tachyarrhythmias
- Willing to receive possibly uncomfortable atrial shock therapy for the treatment of atrial tachyarrhythmias
- Able to understand the nature of the study and give informed consent
- Ability to tolerate the surgical procedure required for implantation

- Ability to complete all required testing including the six-minute walk test and cardiopulmonary exercise testing
- Available for follow-up visits on a regular basis at the investigational site
- Age greater than or equal to 18 years

Exclusion Criteria

To support the objectives of this investigation, the exclusion criteria at the time of patient enrollment included the following:

- Previously implanted CRT device
- ACC/AHA/NASPE indication for bradycardia pacing (sinus node dysfunction)
- Six-minute walk test distance greater than 450 meters
- Chronic atrial tachyarrhythmias refractory to cardioversion shock therapy
- Receiving intermittent, unstable intravenous inotropic drug therapy (patients on stable doses of positive inotropic outpatient therapy for at least One-Month are permitted)
- Enrolled in another cardiovascular or pharmacological clinical investigation
- Expected to receive a heart transplant within 6 months
- Life expectancy less than 6 months
- Presence of another life-threatening, underlying illness separate from their cardiac disorder
- Acute myocardial infarction, unstable angina or cardiac revascularization within the last 30 days prior to enrollment
- Conditions that prohibit placement of any of the lead systems

1.6.2.3 Summary of Clinical Results

A total of 200 patients were enrolled in the OPTION CRT/ATx clinical study at 25 sites:

There were 133 study patients and 67 active control patients in this prospective, multi-center, randomized clinical study. For the study group, there were 129 successful implants (91.4%) of the Tupos LV/ATx CRT-D system. For the active control group, there were 64 successful implants (92.2%) of the legally marketed CRT-D systems.

Patient Accountability

After randomization and enrollment, 7 patients (4 in the study group and 3 in the control group) did not receive an implant. The reasons for patients not receiving an implant are outlined in **Figure 4**.

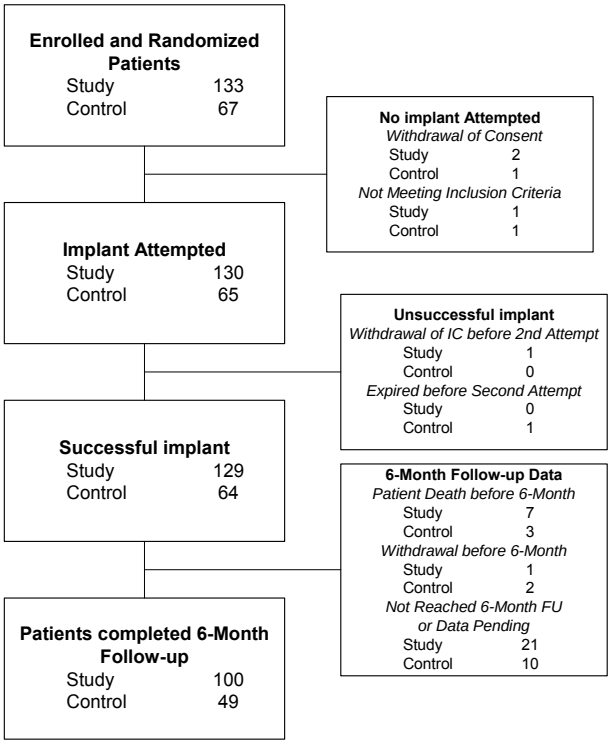


Figure 4: Patient Accountability

Overall Results

- There were 192 endocardial and 19 epicardial leads implanted in 193 patients. Investigators were allowed to choose among any legally marketed LV lead according to familiarity with the lead and patient anatomy. The Tupos LV/ATx CRT-D was implanted with 7 endocardial and 4 epicardial lead models from 6 different manufacturers. There were no adverse events reported attributable to lead-generator incompatibility.

- The cumulative implant duration was 1240.4 months with a mean duration of 9.6 months for the study group. The cumulative implant duration is 596.5 months with a mean duration of 9.3 months for the control group.
- For the study group, there have been 278 adverse events (210 observations in 104 patients and 68 complications in 50 patients). There has been one unanticipated adverse device effect reported.
- For the control group, there have been 105 adverse events (81 observations in 44 patients and 24 complications in 19 patients). There have been no unanticipated adverse device effects reported.
- There have been 10 patient deaths reported in the study group and 4 patient deaths reported in the control group. The clinical investigators have determined that no deaths were related to the study device.

1.6.2.4 Primary Endpoint 1: Six Minute Walk Test & QOL (Effectiveness)

The purpose of Primary Endpoint 1 is to evaluate the effectiveness of the Tupos LV/ATx system in providing CRT as measured by the average composite rate of improvement in six minute walk test and QOL.

Table 8 presents the average composite rate of improvement in six minute walk test distance and QOL score, the average 6-minute walk test distance and the average QOL score at Baseline and at the Six-Month follow-up, as well as the average difference in 6-minute walk test distance and QOL score between Baseline and the Six-Month follow-up for the Study and Control Groups for those patients with six minute walk test data and complete QOL data at both Baseline and the Six-Month follow-up.

Table 8: Composite of Six Minute Walk Test and QOL (Effectiveness)			
Category	**Study Group (N = 74) Mean ± SE**	**Control Group (N = 38) Mean ± SE**	**P-value***
Distance Walked at Baseline	310.51 ± 10.89	288.76 ± 15.37	0.249
Distance Walked at Six-Months	340.77 ± 12.32	301.84 ± 17.02	0.067
∆ Distance Walked	30.26 ± 10.40 17.27% ± 5.59%	13.08 ± 13.05 8.71% ± 5.26%	0.322 0.326
QOL Score at Baseline	44.39 ± 2.78	45.53 ± 4.13	0.817
QOL Score at Six-Months	28.68 ± 2.66	33.95 ± 4.35	0.279
∆ in QOL Score**	15.72± 2.83 19.08% ± 12.21%	11.58 ± 3.45 -13.42% ± 34.54%	0.376 0.281
Composite Rate***	18.18% ± 7.07%	-2.36% ± 17.73%	0.030

*The calculated p-values are associated with a Student's t-test (2-sided) of the equality of means in the two groups, except for the p-value of the composite rate, which is associated with a test of equivalence (non-inferiority).

**∆ in QOL Score is calculated as the average of the individual differences between Baseline and Six-Months for each patient. Negative values for mean ∆ QOL in percent are possible when positive mean values for absolute changes in QOL are recorded. In some cases, small, negative changes in absolute QOL scores resulted in relatively large percentage changes.

***The Composite Rate (=(∆ Distance Walked (%) + ∆ QOL Score (%))/2) is calculated for each patient and then averaged to obtain the Composite Rates. For all calculations, a positive number represents improvement from Baseline to Six-Months.

1.6.2.5 Effectiveness Endpoint Analysis and Conclusions

A composite rate of six minute walk test and QOL improvement from Baseline to the Six-Month follow-up is evaluated as a measure of CRT effectiveness. For this analysis both six minute walk test and QOL are equally weighted at 50%.

The mean difference in the composite rate between study and control group was 20.53% with an associated one-sided, 95% confidence bound is (-6.10%). The p-value for non-inferiority within 10% is 0.030. The analysis of the composite rate in six minute walk test distance and QOL score demonstrates that the study group is non-inferior to the control group and that the primary effectiveness endpoint was met (p=0.030).

1.6.2.6 Primary Endpoint 2: Complication-Free Rate (Safety)

The purpose of Primary Endpoint 2 was to evaluate complications (adverse events that require additional invasive intervention to resolve) related to the implanted CRT system which includes the Tupos LV/ATx, the right atrial lead, the right ventricular ICD lead, the left ventricular lead, and the implant procedure. The target complication-free rate at Six-Months is 85%.

Table 9 provides the categorized complication rates at 6-months for the study and the control group as well as a comparison between the study and the control group.

Table 9: Complications at 6-Month – Study and Control					
Category	**Study N = 133**	**Control N = 67**	**Study versus Control Comparison**		
			Delta	**95% CI**	**P-value**
Procedure Related	6 (4.51%)	1 (1.49%)	3.02 %	[-3.64%, 8.45%]	0.428
Atrial Lead Related	3 (2.26%)	1 (1.49%)	0.76 %	[-5.74%, 5.37%]	1.000
ICD Lead Related	3 (2.26%)	0 (0%)	2.26 %	[-3.03%, 6.53%]	0.552
LV Lead Related	26 (19.55%)	9 (13.43%)	6.12 %	[-5.50%, 16.45%]	0.329
Device Related	7 (5.26%)	5 (7.46%)	-2.20 %	[-11.42%, 4.77%]	0.541
Other Medical Related	9 (6.77%)	2 (2.99%)	3.78 %	[-3.82%, 10.13%]	0.341
Total Procedure, Lead and Device Related	39 (29.32%)	15 (22.39%)	6.94 %	[-6.46%, 19.17%]	0.317
Total	**46 (34.59%)**	**17 (25.37%)**	**9.21 %**	**[-4.96%, 21.99%]**	**0.201**

1.6.2.7 Primary Safety Enpoint Analysis and Conclusions

The observed procedure, lead and device related complication-free rate at 6 months was 70.68%. The 95% confidence interval for the complication-free rate was [62.16%, 78.25%]. The lower, one-sided 95% confidence bound for the complication-free rate was 63.50%. Therefore the procedure, lead and device related complication-free rate at 6 months did not meet the pre-specified acceptance criterion for this endpoint.

1.6.2.8 Post-hoc Safety Analysis

BIOTRONIK did not meet the pre-specified objective performance criteria of 85% within 10% for the safety endpoint. Therefore, a post-hoc safety analysis was conducted. It was noted that 79.80% (39 out of 49 events) of the complications were right atrial lead, right ventricular ICD lead, left ventricular lead and procedure related. The atrial, ICD and LV leads used during this study are legally marketed devices.

This post-hoc analysis evaluated the LV lead complications that were “related” or “possibly related” to the Tupos LV/ATx CRT-D, but excludes the complications that were “not related” to the Tupos LV/ATx device (see Table 9). There were 11 patients who had an attempt to implant the LV lead, but the physician was unsuccessful in either obtaining coronary sinus (CS) access or unable to find a stable position for the LV lead. Additionally, there were 4 patients with a documented LV lead dislodgement that has no direct relationship to the implanted Tupos LV/ATx.

Table 10: Complications at 6-Months (Excluding LV Lead Related) - Study versus Control

Category	Study N=133	Control N=67	Difference Study vs. Control
Procedure Related	6 (4.51%)	2 (2.99%)	1.53%
Atrial Lead Related	3 (2.26%)	1 (1.49%)	0.76%
ICD Lead Related	3 (2.26%)	0 (0%)	2.26%
LV Lead Related	11 (8.27%)	1 (1.49%)	6.78%
Device Related	7 (5.26%)	5 (7.46%)	-2.20%
Other Medical Related	9 (6.77%)	2 (2.99%)	3.78%
Total Procedure, Lead and Device Related	27 (20.30%)	8 (11.94%)	8.36%
Total	**35 (26.32%)**	**10 (14.93%)**	**11.39%**

The pulse generator related complication rate is higher in the control group as compared to the study group. The complication rates for procedure related, atrial lead related, ICD lead related, LV lead related and other medical related are higher in the study group as compared to the control group.

1.6.2.9 Post hoc Safety Analysis Conclusion

There are no clinically substantial differences in the total complication rate or in the rates for the different complication rate categories between the study and the control group.

Table 11 compares this post-hoc Safety Endpoint analysis to previous CRT-D clinical studies:

Table 11 Safety Endpoint Comparisons

CRT-D Study	Estimated freedom from Complications @ 6mos.	Lower 95% CI	95% lower bound criteria
BIOTRONIK OPTION (Original Analysis)	70.68%	63.5%	75%
BIOTRONIK OPTION (Post-hoc Analysis)	78.95%	72.29%	75%
Medtronic Insync ICD	81.1%	77.6%	67%
Guidant Contak CD	N/A	N/A	70%
St. Jude Medical Epic HF	93.4%	90.6%	70%

This analysis confirms that the safety profile of the Tupos LV/ATx is within a similar range determined during trials of other legally marketed CRT-D devices.

1.6.2.10 Secondary Endpoint Results

1. The purpose of Secondary Endpoint 1 is to evaluate the overall ability of the Tupos LV/ATx to appropriately convert spontaneous AT (atrial tachycardia) and AF (atrial fibrillation). The results from the OPTION study were compared to the results from BIOTRONIK's TACT study (P000009/S4, dated 09-09-2002) that demonstrated the effectiveness of these atrial therapy features in the Tachos DR - Atrial Tx ICD.

   Table 12 summarizes success rates for each individual atrial tachyarrhythmia therapy type and overall success rate from the OPTION study compared to the TACT study. The number of episodes and patients receiving any therapy is less than the total episodes of each therapy type, as episodes may have included more than one type of therapy.

Table 12 Overall Atrial Conversion Rate

	OPTION Study			
	Patients	**Success**	**Episodes**	**Conversion rate**
ATP	3	3	5	60.0%
HF Burst	17	45	111	40.5%
Shock	12	30	34	88.2%
All Therapies	**25**	**78**	**129**	**60.5%**
TACT Study				
ATP	29	62	142	43.6 %
HF Burst	49	156	408	38.2 %
Shock	42	84	108	77.8 %
All Therapies	**66**	**302**	**542**	**55.7 %**

The overall conversion rate and the conversion rates for each therapy are comparable to the conversion rates observed in the TACT study, demonstrating that the Tupos LV/ATx device has similar atrial conversion capabilities as the legally marketed Tachos DR – Atrial Tx ICD.

2. The purpose of Secondary Endpoint 2 is to evaluate VT (ventricular tachycardia) and VF (ventricular fibrillation) detection times of the Tupos LV/ATx. This is a measure of the ability of the ventricular detection algorithm to detect VT and VF in an appropriate timeframe. This endpoint was evaluated based on the review of electrograms following induced VT/VF episodes. A comparison of data from the TACT study that utilized the legally marketed Tachos DR – Atrial Tx ICD (P000009/S4, dated 09-09-2002) to data collected during the OPTION study for the Tupos LV/ATx was performed.

   Table 13 summarizes and compares the results from these two clinical studies.

Table 13: Summary of Detection Times

Detection Time	Tachos DR - Atrial Tx ICD Mean (SE)/N	Tupos LV/ATx Mean (SE)/N	Difference
Individual Readings	2.27 (0.06)/52	2.26 (0.06)/71	0.01
By Patient	2.27 (0.07)/26	2.24 (0.06)/35	0.03

   The analysis demonstrates that the average detection times of the Tupos LV/ATx are comparable to the detection times observed with the legally marketed Tachos DR - Atrial Tx ICD. Both devices utilize identical ventricular detection algorithms and only sense with the right ventricular lead. This clinical data demonstrates that the ventricular detection times are similar in both devices.

3. The purpose of Secondary Endpoint 3 is to evaluate the percentage of ventricular pacing (thus, CRT) as demonstrated by the device diagnostics at required follow-ups. This data was based on diagnostic data stored by the Tupos LV/ATx.

   Table 14 summarizes the percentage of ventricular pacing between follow-ups as shown by device diagnostics for patients in the study group.

Table 14: Percentage of Ventricular Pacing – 3-Month and 6-Month Follow-ups		
Percentage of Ventricular Pacing	**3-Months Patients (percentage)**	**6-Months Patients (percentage)**
<80%	9 (7.4%)	4 (4.0%)
81 – 85 %	4 (3.3%)	2 (2.0%)
86 – 90 %	13 (10.7%)	9 (9.1%)
91 – 95 %	19 (15.7%)	20 (20.2%)
96 – 100 %	76 (62.8%)	64 (64.7%)
Totals	**121 (100%)**	**99 (100%)**

The majority of the follow-ups (84.9%) show a percentage of ventricular pacing of 91% or more at Six-Months.

4. The purpose of secondary endpoint 4 is to evaluate improvement in functional capacity as measured by the six minute walk test. The six minute walk test is a well-accepted measure of functional capacity and exercise tolerance. Also, this test more closely mimics the patient's day-to-day activities than maximal exercise testing.

   Table 15 summarizes the six minute walk test distance at Baseline and the Six-Month follow-up for patients in the study group and the control group.

Table 15: Six Minute Walk Distance		
Distance (meters)	**Study**	**Control**
Baseline		
N	127	61
Mean ± SE	283.14 ± 9.27	269.43 ± 13.77
Range	23 to 511	29 to 507
Median	302.00	244.00
Six-Month		
N	93	44
Mean ± SE	329.73 ± 10.82	310.70 ± 15.49
Range	78 to 596	91 to 489
Median	335.00	313.00

* Student's t-test, 2-sided

There are no clinically relevant differences in the six minute walk test results between the study and the control group.

5. The purpose of Secondary Endpoint 5 is to evaluate the improvement in the patient's NYHA classification. Table 16 summarizes the average improvement in NYHA from Baseline to Six-Months for 140 patients that were able to complete both NYHA classification evaluations.

Table 16: Improvement in NYHA Classification at Six-Months from Baseline		
NYHA Change During OPTION Study		
Change in NYHA Class	**Study Patients (N=97) (percentage)**	**Control Patients (N=43) (percentage)**
Improved 2 classes	10 (10.3%)	2 (4.7%)
Improved 1 class	47 (48.5%)	20 (46.5%)
Total improved	57 (58.8%)	23 (51.2%)
No change	39 (40.2%)	20 (46.5%)
Worsened 1 class	1 (1.0%)	1 (2.3%)

The study and the control group have similar NYHA classes and similar rates of improvement in NYHA class from Baseline to the Six-Month follow-up.

6. The purpose of Secondary Endpoint 6 is to evaluate the rate of hospitalization, for CHF and for all other causes. The occurrence rate and reasons for hospitalization of the study group were compared to the control group. To be consistent with other large-scale clinical trials, clinical sites were instructed to report hospitalizations for CHF using the following definitions: 1) hospitalization for heart failure management, 2) outpatient visit in which IV inotropes or vasoactive infusion are administered continuously for at least 4 hours, or 3) emergency room (ER) visit of at least 12 hours duration in which intravenous heart failure medications including diuretics are administered.

   Table 17 summarizes hospitalization, ER visits and outpatient visits for enrolled patients.

Table 17: Hospitalization, ER Visits and Outpatient Visits		
Medical Visits	**Study (N=128)**	**Control (N=65)**
Hospital Admissions	**CHF Related:**	**CHF Related:**
Patients	20 (15.6%)	5 (7.7%)
Hospitalizations	28	9
	All causes:	All causes:
Patients	68 (53.1%)	29 (44.6%)
Hospitalizations	76	46
Emergency Room Visits	**CHF Related:**	**CHF Related:**
Patients	1 (0.8%)	0 (0.0%)
Visits	1	0
	All causes:	All causes:
Patients	13 (10.1%)	2 (3.1%)
Visits	16	2
Outpatient Visits		
Patients	**CHF Related:**	**CHF Related:**
Visits	1 (0.8%)	0 (0.0%)
	1	0
Patients	All causes:	All causes:
Visits	5 (3.9%)	2 (3.1%)
	5	2

A large percentage of All Cause hospitalizations can be attributed to pacing lead revisions, device infections, or other device-related interventions (e.g., pocket revision or device replacements for ERI or device recall). The CHF hospitalization rate for both the study and control groups is clinically acceptable considering the enrollment CHF status of the patients.

7. The purpose of Secondary Endpoint 7 is to evaluate the observation rate. Observations are defined as clinical events that do not require additional invasive intervention to resolve. For the study group, there were 210 observations in 104 patients with cumulative implant duration of 1240.4 months (101.9 patient years). 78.2% of the enrolled study patients have a reported observation. The rate of observations per patient-year is 2.06. For the control group, there were 81 observations in 44 patients with cumulative implant duration of 596.5 months (49.0 patient years). 65.7% of the enrolled control patients had a reported observation. The rate of observations per patient-year was 1.65.
8. The purpose of Secondary Endpoint 8 is to evaluate peak VO2 as a measure of effectiveness of the Tupos LV/ATx system in providing CRT. The core lab was blinded to study randomization assignments during evaluation of the results of the cardiopulmonary exercise (CPX) testing in order to minimize the potential for bias. According to the protocol, to be included in the analysis, patients were required to attain a respiratory exchange ratio (RER) of ≥ 1.

   Table 18 provides a summary of peak VO_2 results for 42 patients with CPX testing completed at Baseline and the Six-Month follow-up and with an RER of ≥ 1.

Table 18: Peak VO2 Testing Results – Patients with RER ≥ 1		
Results	**Study**	**Control**
Peak VO_2 (ml/kg/min)	**N=32** **Baseline:** Mean: 13.46 ± 0.57 Range: 6.9 to 21.1 **Six-Month:** Mean: 13.39 ± 0.53 Range: 7.6 to 20.70 **Difference:** Mean: -0.06 ± 0.42 Range: -7.9 to 4.9	**N=10** **Baseline:** Mean: 12.58 ± 0.75 Range: 8.0 to 14.8 **Six-Month:** Mean: 12.89 ± 0.94 Range: 7.0 to 17.2 **Difference:** Mean: 0.31 ± 0.67 Range: -2.7 to 4.6

1.6.2.11 Multi-site Poolability and Gender Analysis

The OPTION CRT/ATx clinical report includes data from multiple centers with centralized coordination, data processing, and reporting at BIOTRONIK. All of the clinical centers followed the requirements of an identical clinical protocol, and all of the clinical centers used the same methods to collect and report the clinical data. In order to justify pooling of the data from multiple centers, several analyses were completed. All of the centers were divided into two groups based on implant volume. Comparisons were then made between the patient populations based on the results of each of the endpoints. Additionally, analyses were performed on the data collected in the OPTION CRT/ATx clinical investigation in order to compare results between males and females. The first type of analysis compared enrollment by patient gender in each of the study and control groups. The second type of analysis compared effectiveness outcomes in each gender.

The results of these analyses demonstrate poolability of the data between sites. There were no significant differences in the second primary endpoint or any of the secondary endpoints between high and low volume implant centers.

The gender distribution in this clinical investigation is consistent within the study groups and includes a representative proportion of female participants. There were no significant differences in any of the primary or secondary endpoints between the male and female population.

1.6.2.12 Conclusions

The IDE Clinical study (OPTION LV/ATx) demonstrated that the safety and effectiveness of the Tupos LV/ATx CRT-D device is equivalent to that of similar legally marketed CRT-D devices. Although the study missed its primary safety endpoint, additional post hoc analyses were conducted to reassure that the safety profile of the device is comparable to other legally marketed CRT-D devices.

1.6.3 Lumax HF-T V-V Clinical Study

1.6.3.1 Study Overview

The Lumax HF-T V-V clinical study is a randomized, double-blinded, crossover, multi-center, prospective trial. The purpose of the study is to assess the safety and efficacy of adding programmable V-V delay biventricular pacing when used as part of echo optimization of V-V timing (OPT). The assessment consisted of comparing one-month periods of CRT with (OPT) and without (SIM) V-V programmability and optimization in the same patients to assess whether a statistically significant increase of worsened HF status occurred during V-V adjustment. The V-V delay feature is programmed to provide CRT through the selection of the first chamber paced and adjustment of the V-V delay. When V-V delay programmability is not available, CRT provides simultaneous biventricular pacing (V-V delay is 0 ms).

1.6.3.2 Methods

The study primarily evaluates and compares the functional benefits of the Lumax HF-T with OPT versus the Lumax HF-T with SIM using an endpoint that includes both a 6-minute walk (6MW) test and quality of life (QOL) measurement assessed using the Minnesota Living with Heart Failure questionnaire (MLWHFQ). As such, relevant measurements are completed 3 times for each patient: once at the baseline evaluation (up to 14 days after enrollment), once at the 1-month follow-up (30 days after baseline) and once at the 2-month follow-up (30 days after the 1-month follow-up). Baseline data is collected with the Lumax HF-T programmed to SIM.

6MW testing was chosen as a meaningful measure of CRT therapy effect on HF status because 6MW has been shown to improve during chronic CRT therapy (Olsson LG, Swedberg K, Clark AL et al. Six minute corridor walk test as an outcome measure for the assessment of treatment in randomized, blinded intervention trials of chronic heart failure: a systematic review. Eur Heart J 2005; 26:778–793.) Example improvements of 6MW include increase in the range of 20 meters.

In this trial, the intent was to detect any loss of CRT benefit by assessing the incidence of HF “worsening”, defined as reduction of 35 meters distance on 6MW during CRT with V-V programmability and optimization compared to during CRT without V-V programmability and optimization.

QOL testing was chosen as a meaningful measure of CRT therapy effect on HF status because QOL has been shown to improve during chronic CRT therapy (Albouaini K, Egred M, Rao A, et al. Cardiac resynchronisation therapy: evidence based benefits and patient selection. Eur J Intern Med. 2008 May;19(3):165-72) Example magnitude improvements of QOL include change in the range of 10 points.

In this trial, the intent was to detect any loss of CRT benefit by assessing the incidence of HF “worsening”, defined as increase of 10 points in QOL score by MLWHFQ during CRT with V-V programmability and optimization compared to during CRT without V-V programmability and optimization.

Worsening in the trial was defined as either a worsening (as defined) in 6MW or in QOL score during CRT with V-V programmability and optimization.

The primary endpoint hypothesis required that a high proportion of subjects remain “not worsened” when CRT with V-V programmability and optimization was delivered compared to when CRT without V-V programmability and optimization. A high proportion was defined according to an Objective Performance Criteria (OPC), derived from observations of how often stable subjects in the BIOTRONIK Tupos LV/ATX CRT-D trial (OPTION) experienced spontaneous worsening due to the underlying disease among other factors.

During the Lumax V-V clinical study, the V-V optimization was completed utilizing echocardiography specifically determining an optimal V-V delay using the velocity time integral (VTI) to non-invasively measure stroke volume. The assessment was performed by determining the V-V delay setting associated with the largest VTI value. The VTI of the aortic flow is measured in the apical 5 chamber view.

Prior to the V-V delay optimization procedure, each patient underwent an optimization of AV timing. Following the AV timing adjustment, this standardized procedure was followed for the optimization of V-V delay:

1. Program the Lumax HF-T “Initially Paced Chamber” parameter to either RV or LV based on preference.
2. Assess the VTI measurement at the following V-V delays (additional V-V settings may be utilized at the investigator’s discretion):
    - 100 ms
    - 80 ms
    - 60 ms
    - 40 ms
    - 20 ms
    - 0 ms

Note: Use the average VTI parameter over a 3 beat cycle and wait 10 to 15 seconds between changing V-V delay settings. Also, attempt to measure the VTI parameter within the same patient respiratory cycle.

3. Record the VTI measurement associated with each V-V delay setting

Repeat steps 1-3 for the remaining “Initially Paced Chamber” parameters

Select permanent “Initially Paced Chamber” and “V-V delay after Vp” to reflect the maximum VTI measurement for final programming.

Inclusion Criteria

To support the objectives of this investigation, the inclusion criteria at the time of patient enrollment for this investigational study included the following requirements:

- Meet the indications for therapy.
- Successfully implanted with a BIOTRONIK Lumax HF-T CRT-D system and have received SIM for a minimum of 30 days prior to enrollment.
- Treated with stable and optimal CHF medications.
- Age ≥ 18 years.
- Able to understand the nature of the study and give informed consent.
- Able to complete all testing required by the clinical protocol, including the 6-minute walk test and QOL questionnaire.
- Available for follow-up visits on a regular basis at the investigational site.

Exclusion Criteria

To support the objectives of this investigation, the exclusion criteria at the time of patient enrollment included the following requirements:

- Meet one or more of the contraindications.
- Have a life expectancy of less than 6 months.
- Expected to receive heart transplantation within 6 months.
- Have had more than 1 CHF-related hospitalization within past 30 days.
- Currently receiving IV inotropic medications.
- Chronic atrial fibrillation.
- Enrolled in another cardiovascular or pharmacological clinical investigation, except for FDA required post-market registries.
- Any condition preventing the patient from being able to perform required testing.

- Presence of another life-threatening, underlying illness separate from their cardiac disorder.

1.6.3.3 Summary of Clinical Results

The study involved 122 patients (96 males, 78.7%, and 26 females, 21.3%), with a mean age of 67.1 years (range: 35-87). The cumulative enrollment duration is 621.3 months with mean enrollment duration of 5.1 months. The patient follow-up compliance rate for all enrolled patients is 98.5% (394 of 400 required follow-ups).

1.6.3.3.1 Primary Endpoint 1: Effectiveness of the V-V Delay Feature

The primary endpoint was intended to detect whether V-V programmability and optimization contributed to significantly more patients with "worsened" HF. Worsened was defined as:

- For 6MW, reduction of 35 meters distance on 6MW during CRT with V-V programmability and optimization compared to during CRT without V-V programmability and optimization
- For QOL score, increase of 10 points in QOL score by MLWHFQ during CRT with V-V programmability and optimization compared to during CRT without V-V programmability and optimization
- For each patient, i.e. as a responder's analysis, the occurrence of either worsened 6MW or QOL score during CRT with V-V programmability and optimization.

Table 19 presents the mean 6-minute walk test distances and QOL scores for Group 1 and Group 2 patients at the baseline, 1-month and 2-month follow-ups. Table 19 reports unpaired patient data for information purposes, with the primary endpoint analysis utilizing paired data from the 1-month and 2-month follow-ups.

The analysis of the primary effectiveness endpoint is an intention-to-treat analysis based on the responder classification of changes in the MLWHFQ and 6-minute walk distance between periods of SIM and OPT, obtained at the 1-month and 2-month follow-ups. **Table 20** presents the percentage of all patients worsened and not worsened to evaluate the effectiveness of OPT vs. SIM utilizing the QOL and 6-minute walk responder classification. A total of 106 out of the 110 patients that completed the primary endpoint follow-up met the primary endpoint analysis based on paired QOL and 6-minute walk data at the 1-month and 2-month follow-up visits.

Table 19. QOL and 6-Minute Walk Test Results (Effectiveness)

Category	Group 1	Group 2
QOL score at baseline	N = 60 35.4 ± 23.0	N = 53 30.0 ± 21.6
QOL score at 1-month follow-up	N = 57 31.2 ± 24.0 OPT	N = 54 30.1 ± 22.5 SIM
QOL score at 2-month follow-up	N = 58 32.6 ± 25.5 SIM	N = 52 25.9 ± 19.8 OPT
Distance walked at baseline (m)	N = 61 328.9 ± 152.8	N = 54 309.1 ± 139.7
Distance walked at 1-month follow-up (m)	N = 58 343.9 ± 161.8 OPT	N = 54 337.6 ± 160.7 SIM
Distance walked at 2-month follow-up (m)	N = 57 341.1 ± 152.6 SIM	N = 51 334.7 ± 148.9 OPT

Table 20. QOL and 6-Minute Walk Responder Classification (Effectiveness)

QOL	Group 1 (N = 56)	Group 2 (N = 52)	Total (N = 108)
Worsened	9 (16.1%)	6 (11.5%)	15 (13.9%)
Not worsened	47 (83.9%)	46 (88.5%)	93 (86.1%)
6-Minute Walk	**(N = 56)**	**(N = 51)**	**(N = 107)**
Worsened	14 (25.0%)	15 (29.4%)	29 (27.1%)
Not worsened	42 (75.0%)	36 (70.6%)	78 (72.9%)
Composite	**(N = 55)**	**(N = 51)**	**(N = 106)**
Worsened	21 (38.2%)	18 (35.3%)	39 (36.8%)
Not worsened	34 (61.8%)	33 (64.7%)	67 (63.2%)

The estimate of the proportion of subjects who were classified as "Not Worsened" was 63.2% (67/106). The lower, exact, one-sided 95% confidence bound for this observed proportion is 54.8%. The difference between the performance goal of 63% and 54.8% is 8.2%. This is lower than the pre-specified clinically significant difference (δ) of 12%.

1.6.3.3.2 Primary Endpoint 2: Safety of the V-V Delay Feature

The purpose of Primary Endpoint 2 is to evaluate adverse events that require additional invasive intervention to resolve, specifically related to the V-V delay feature of the Lumax HF-T. These adverse events include any software issues related to V-V delay programming or any adverse event that occurs after V-V delay optimization and that can be directly attributed to the use of the V-V delay feature.

There have been 0 reported complications related to the V-V delay feature for the 122 patients enrolled into the study.

The observed complication-free rate was 100.0%. The lower, exact, one-sided 95% confidence bound for this observed rate is 97.6%. This exceeds the pre-specified rate (90% - δ) required for demonstrating non-inferiority.

1.6.3.4 Conclusions

The cumulative enrollment duration is 621.3 months with a mean duration of 5.1 months. Sixty-one (50.0%) of the patients have been enrolled for 91-180 days.

The proportion of subjects who are “Not Worsened” while their device was programmed to OPT was found to be not inferior to the performance goal of 63% within 12%. In addition, there have been 0 complications reported regarding the Lumax HF-T V-V delay feature.

The data received and analyzed demonstrates the general safety of the Lumax HF-T V-V timing feature, with 0 complications reported as caused by the feature. Also, the data received and analyzed demonstrates the effectiveness of the Lumax HF-T V-V timing feature, by providing evidence of non-inferiority to simultaneous biventricular pacing in a responder classification.

1.6.4 TRUST Clinical Study

1.6.4.1 Study Overview

The TRUST study is a multi-center, prospective and randomized trial. The purpose of the study was to demonstrate that the use of the BIOTRONIK Home Monitoring system (HM) can safely reduce the number of regularly scheduled office follow up visits, compared to the conventional method of ICD follow-up. The assessment consists of comparing the number of in-office follow-ups for patients with HM (HM group) versus patients without HM (Control group). With the use of HM, the number of in-office follow up visits per year could be reduced from an expected five scheduled office follow up visits (3, 6, 9, 12 and 15 months) to two visits (3 and 15 months). Additionally, the time from onset to evaluation of arrhythmias in both groups was compared. It was expected that evaluation of cardiac events in the HM arm would occur earlier than those in the Control group.

1.6.4.2 Methods

All enrolled patients received a BIOTRONIK ICD with Home Monitoring/IEGM-Online® technology and were randomized to either Group 1 (Home Monitoring (HM)) or Group 2 (No Home Monitoring (Control)) using a randomization ratio of 2:1.

Group 1 (HM)

Device evaluations for scheduled follow-ups, patient-initiated inquiries and event triggered notifications were performed with HM/IEGM Online. Patients were scheduled for office device interrogations only at the 3 month and 15 month follow-up points (following the HM online check). At 6, 9 and 12 months, a HM check was performed first. Investigators may then elect to perform an office device interrogation if they determine that it is necessary after reviewing the HM data.

Group 2 (Control)

Patients were evaluated using conventional, calendar-based office visits at 3, 6, 9, 12 and 15 months post-implant. Interim visits were made according to physician discretion (e.g. following any ICD discharges or symptoms). Home Monitoring was programmed OFF for the duration of the study.

HM Event Triggered Device Evaluations

Investigators with patients in Group 1 (HM) may receive HM notifications in response to pre-programmed events such as VT1 detected and SVT detected. Upon the receipt of a HM Event Notification, investigators reviewed the notification and the associated information on the HM/IEGM-Online website and recorded the type of event and what type of action, if any, was taken as a result of this notification.

Patient-Initiated Device Evaluations

Investigators may be contacted by the patient for device/arrhythmia-related care (e.g. perceived device discharge, symptoms). For patients in Group 1 (HM), investigators triaged the complaint using the Home Monitoring website. Investigators recorded if the information from Home Monitoring was sufficient. For patients in Group 2 (Control), the complaint was assessed per standard of care or normal clinic procedures.

Primary Endpoints

The purpose of primary endpoint 1 (HM efficacy) was to compare the number of in-office ICD follow-ups for patients in Group 1 (HM) to the conventional, calendar-based method of ICD follow-up as in Group 2 (Control).

The purpose of the primary endpoint 2 (safety) was to compare the Safety Event Rate (SER), which includes death, incidence of strokes and events requiring surgical interventions (e.g. device explants or lead revision) between the two groups.

Secondary Endpoints

The purpose of secondary endpoint 1 was to compare AF, VT and VF events between Group 1 and Group 2 in terms of the number, categories, and detection time relative to onset.

Inclusion Criteria

To support the objectives of this investigation, the inclusion criteria at the time of patient enrollment for this investigational study included the following requirements:

- Implanted within the last 45 days or being considered for implant with a BIOTRONIK ICD with Home Monitoring/IEGM-Online technology
- Able to utilize the HM system throughout the study
- Ability to give informed consent
- Geographically stable and able to return for regular follow-ups for fifteen (15) months
- At least 18 years old

Exclusion Criteria

To support the objectives of this investigation, the exclusion criteria at the time of patient enrollment included the following requirements:

- Patients who do not fulfill all inclusion criteria
- Patients who are pacemaker dependent
- Currently enrolled in any other cardiac clinical investigation.

Clinical Events Committee

The Clinical Events Committee (CEC) is an advisory review board comprised of three physicians that are not participating in the TRUST Study who reviewed and adjudicated all deaths, strokes, surgical interventions, and cardiac adverse events that occur during the study. The CEC also reviewed all divergent classifications of actionable vs. non-actionable office follow up visits between the physician and BIOTRONIK, and reviewed a random sampling of 1% of office follow up visits in which there is no disputed classification.

1.6.4.3 Summary of Clinical Results

The study involved 1443 patients (1038 males, 71.9%), with a mean age of 63.5 years (range: 20-95). The cumulative enrollment duration is 18,367 months with mean enrollment duration of 12.7 months. The patient follow-up compliance rate for all enrolled patients is 87.5% in Group 1 and 78.8% in Group 2.

1.6.4.3.1 Primary Endpoint 1: Home Monitoring Effectiveness

The purpose of primary endpoint 1 (HM efficacy) was to compare the number of in-office ICD follow-ups for patients in Group 1 (HM) to the conventional, calendar-based method of ICD follow-up as in Group 2 (Control).

Detailed primary endpoint 1 results are presented in **Table 21**.

Table 21: Primary Endpoint Group 1 vs. Group 2

	No. of Pts**	Office Follow-up Visits		
		Scheduled	**Unscheduled**	**Total**
Group 1 (HM)	898	*n* = 991 1.3 ± 1.0 per pt yr 13.1% actionable	*n* = 401 0.6 ± 1.7 per pt yr 29.7% actionable	**1.9 ± 1.9 per pt yr**
Group 2 (Control)	414	*n* = 1110 3.0 ± 1.1 per pt yr 10.7% actionable	*n* = 117 0.4 ± 1.4 per pt yr 29.1% actionable	**3.4 ± 1.7 per pt yr**
p value		< 0.001	0.032	**< 0.001**

* Up to and including 12 month follow-up data

** Number of patients that have contributed at least 1 follow-up

Analysis

The comparison of the number of 3, 6, 9, and 12 month and unscheduled office follow-up visits in Group 1 versus Group 2 showed that there was an average number of 1.9 office follow-up visits on a per year basis in Group 1 (HM) and an average number of 3.4 office follow-up visits on a per year basis in Group 2 (Control). Therefore, the null hypothesis (HØ) can be rejected, indicating that the average number of office visits per year is statistical significantly less in the HM group than in the Control group ($p < 0.001$). The primary effectiveness endpoint was met.

1.6.4.3.2 Primary Endpoint 2: Safety Event Rate

The purpose of the primary endpoint 2 was to compare the Safety Event Rate (SER), which includes death, incidence of strokes and events requiring surgical interventions (e.g. device explants or lead revision) between the two groups.

Table 22 summarizes the Safety Event Rate for the study patients for 12 months post-enrollment. Figure 5 shows these data in a Kaplan-Meier analysis.

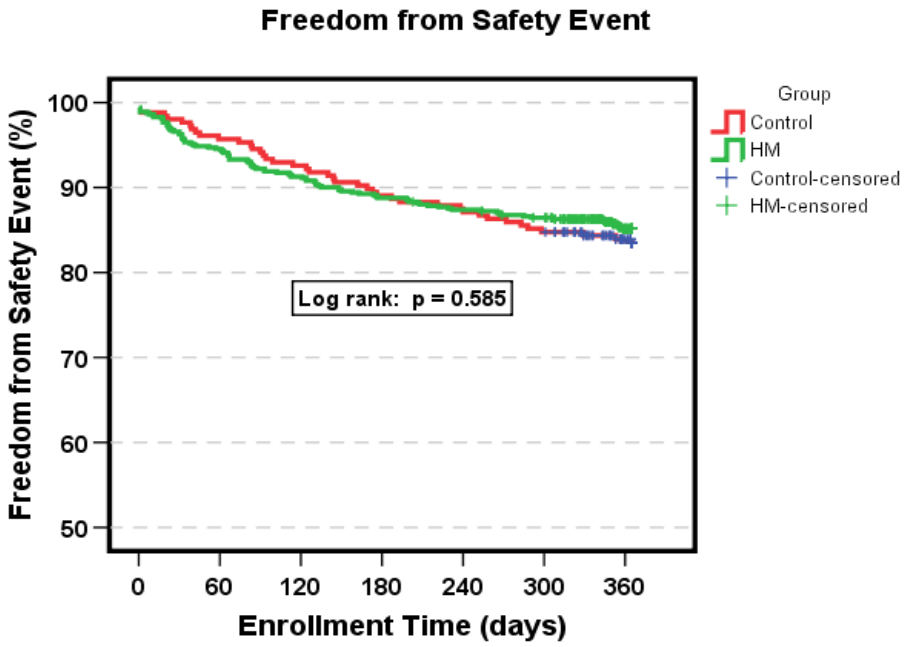
Table 22: Safety Event Rate Comparison

Safety Event Rate*	Group 1	Group 2	p value**
Type of Event			
Death	36/608 (5.9%)	18/245 (7.3%)	0.440
Stroke	2/574 (0.3%)	3/227(1.3%)	0.141
Surgical intervention	57/605 (9.4%)	22/239 (9.2%)	1.000
Any Event	95/643 (14.8%)	42/256 (16.4%)	0.539

* Only includes events occurring within 12 months of enrollment

** 2-sided Fisher Exact test

Figure 5: Safety Event Rate Kaplan Meier



Analysis

The safety event rate for a 12-month duration was 14.8% for Group 1 (HM) and 16.4% for Group 2 (Control), with a non-inferiority p-value of 0.005. Therefore, the safety event rate for HM Group was non-inferior to the safety event rate for the Control Group within 5%. The upper, one-sided 95% confidence bound for the difference was 2.7%.

A rejection of the null hypothesis indicates that the safety event rate for Group 1 (HM) is equivalent (non-inferior) to that of Group 2 (Control).

1.6.4.3.3 Secondary Endpoint 1: Early Detection of Cardiac Events (AF, VT & VF)

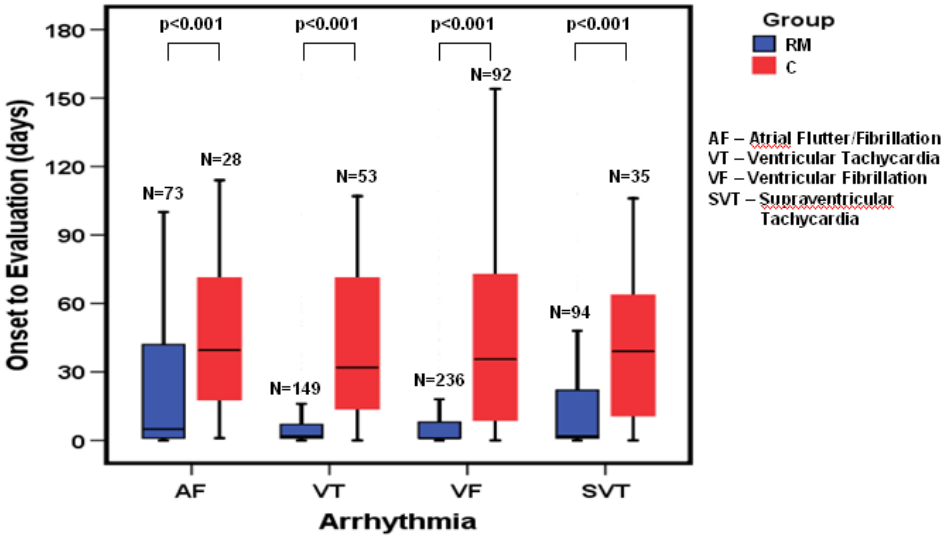
The purpose of secondary endpoint 1 was to compare AF, VT and VF events between Group 1 and Group 2 in terms of the number, categories, and detection time relative to onset.

Table 23 compares the time from onset to evaluation of the first AF, VT and VF events for each patient that have occurred in each group, as well as the first of any type of event for each patient in each group. Figure 6 illustrates the time from onset to evaluation of arrhythmic events in a box plot graph.

Table 23: Time from First Event Onset to Evaluation

Time from Event Onset to Evaluation of First Event/Patient	Group 1 N=972	Group 2 N=471	p value
AF			
Median	5.0	39.5	p < 0.001
Mean ± SD (days)	25.2 +/- 34.2	46.8 +/- 33.7	p = 0.005
Min	0	1	
Max	171	114	
# of patients with events	73 (7.5%)	28 (5.9%)	
VT1 & VT2			
Median	2.0	32.0	p < 0.001
Mean ± SD (days)	12.9 +/- 33.8	46.6 +/- 46.9	p < 0.001
Min	0	0	
Max	256	245	
# of patients with events	149 (15.3%)	53 (11.2%)	
VF			
Median	1.0	35.5	p < 0.001
Mean ± SD (days)	10.5 +/- 22.2	45.0 +/- 47.0	p < 0.001
Min	0	0	
Max	145	287	
# of patients with events	236 (24.3%)	92 (19.5%)	
SVT			
Median	2.0	39.0	p < 0.001
Mean ± SD (days)	16.6 ± 27.4	42.1 ± 35.6	p < 0.001
Min	0	0	
Max	108	157	
# of patients with events	94 (9.7%)	35 (7.4%)	

Figure 6: Median Time from Onset to Evaluation of Arrhythmic Events



Analysis

The mean time from onset to evaluation of first AF, VT, and VF events in Group 2 is greater than the mean time from onset to evaluation of first AF, VT, or VF events in Group 1. A rejection of the null hypothesis for AF, VT and VF event types indicates that the mean time from onset to evaluation of the first AF, VT and VF events in Group 1 is significantly less than the mean time from onset to evaluation of the first AF, VT and VF events in Group 2. P-values are =0.005, <0.001 and <0.001 respectively.

1.6.4.4 Conclusions

- Use of HM in Group 1 resulted in an average of 1.9 office visits per patient year in the 12 months post-implant, versus an average of 3.4 office visits per patient year in Group 2, a 44% reduction in office visits. The average number of office visits is significantly less in the HM group than in the Control group ($p < 0.001$).

- The safety event rate for a 12 month duration for Group 1 (HM) was non-inferior to the safety event rate for Group 2 (Control) within 5% (p = 0.005). The upper, one-sided 95% confidence bound for the difference was 2.7%.
- The mean time from onset to evaluation of AF, VT and VF events indicates that those events for Group 1 patients are evaluated in significantly less time when compared to Group 2 patients (AF p = 0.005, VT p < 0.001, VF p < 0.001).

1.6.5 Deikos A+

NOTE:

The clinical study information included in this section was performed with the Deikos A+ ICD and the Kainox VDD ICD lead. Due to the similarities in detection and therapy a clinical study of the Lumax 540 VR-T DX with the Kainox A+ was not performed.

The Deikos A+ was formed on the Tachos DR platform, whereas the Lumax 540 VR-T DX was formed on the Lumax DR-T platform. Both ICDs are designed to be used with a VDD lead. In this study, the Kainox VDD lead (single shock RV shock coil and dual atrial floating dipoles) was implanted. In order to enhance the intrinsic signal from the floating dipoles, both ICDs contain an atrial sensing amplifier. The signal is amplified 4 times in the Deikos A+ and 5 times in the Lumax 540 VR-T DX.

Both the Kainox VDD and the Kainox A+ ICD leads have identical floating electrodes in the atrium and identical pacing electrode tip, ring and shock electrodes designed for placement in the right ventricle. The minor differences are in the ventricular shock coil (Kainox A+ coil has a slightly larger surface area, and the surface is not coated with fractal iridium).

1.6.5.1 U.S. Clinical Study

1.6.5.1.1 Patients Studied

The Single-Lead ICD system clinical study involved 9 patients (7 males and 2 female) with a mean age of 58.8 years (range: 25 to 83 years). 66.7% presented with ventricular fibrillation/polymorphic ventricular tachycardia as their primary tachycardia. The Single-Lead ICD system was selected for the diagnostic value of the atrial EGMs in 88.9% of the patients.

1.6.5.1.2 Methods

The feasibility clinical investigation was designed to evaluate the quality of atrial signals obtained using the Single-Lead ICD. The study was also designed to evaluate the safety and effectiveness of the Single-Lead ICD system to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included UADE-free survival rate, appropriate bradycardia sensing and pacing, detection and treatment of ventricular tachyarrhythmias and appropriate atrial sensing during activities of daily living.

1.6.5.1.3 Results

The mean implant duration was 6.1 ± 9.4 months with a cumulative implant duration of 54.5 months. There were 5 patients followed for over six months and 2 patients followed for over three months. The patient follow-up compliance rate was 100%, 43 out of 43 required follow-ups.

Table 24 provides a summary of the results of the study group.

Table 24: Clinical Study Results

Description	Results
UADE-free Survival Rate	100% (9/9)

Description	Results
Complication Rate	11.1% (1/9)
Appropriate Atrial Sensing Rate[1]	97.6% (41/42)
Appropriate Atrial Sensing during 24-hour Holter Test	100% (9/9)
Appropriate Atrial Sensing during Exercise Treadmill Test	100% (6/6)
Detection and Conversion of Ventricular Tachyarrhythmias[2]	100% (68/68)

1.6.5.2 European Clinical Study

1.6.5.2.1 Patients Studied

The European Deikos A+/Kainox VDD lead clinical study involved 82 patients (66 males and 16 female) with a mean age of 61.8 years (range: 29 to 84 years). 42.7% presented with monomorphic ventricular tachycardia as their primary tachycardia.

[1] The investigator determined the appropriateness of atrial sensing. The rate is determined by the number of appropriate atrial sensing evaluations divided by the total number of evaluations.

[2] Conversion data were collected in the clinical study for both induced and spontaneous ventricular tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.

1.6.5.2.2 Study Objectives

This clinical investigation was designed to collect information on the performance and function of the Deikos A+/Kainox VDD ICD system. The specific predefined objectives of the investigation included the rate of inappropriate, i.e. unnecessary deliveries of antitachycardia therapy due to supraventricular tachycardia (SVT), the tachyarrhythmia conversion efficacy of the system with activated SMART Detection™ algorithm, the rate of appropriate atrial sensing and the morbidity rate.

1.6.5.2.3 Results

The mean implant duration was 8.9 ± 4.4 months with a cumulative implant duration of 732 months. No unanticipated adverse events were reported during the study. There were two deaths reported, which were unrelated to the implanted device. A summary of the results obtained during the evaluation is provided in **Table** 25 .

Table 25: OUS Clinical Study Results

Description	Results
UADE-free Survival Rate	100% (82/82)
Complication Rate	19.5% (16/82)
Inappropriate Therapies with SMART Detection™ algorithm ON Rate	94.8% (234/250)
Inappropriate Therapies with SMART Detection™ algorithm OFF Rate	84.7% (133/157)
Appropriate Atrial Sensing Rate[1]	92.7% (165/211)
Detection and Conversion of Ventricular Tachyarrhythmias[2]	100% (211/211)

[1] The investigator determined the appropriateness of atrial sensing. The rate is determined by the number of appropriate atrial sensing evaluations divided by the total number of evaluations.

[2] Conversion data were collected in the clinical study for both induced and spontaneous ventricular tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.

1.7 Patient Selection and Treatment

1.7.1 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 if 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 technical services 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 to do 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.

1.7.2 Specific Patient Populations

Pregnancy - If there is a need to image 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 detailed in this manual were over the age of 60 years (see Clinical Studies).

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.

1.8 Patient Counseling Information

The implanted devices are subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to sense arrhythmias, and could lead to the patient's death.

Persons administering 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.)

1.9 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:

- an evaluation of the specific tachycardia rate(s)
- the confirmation and/or evaluation of any supraventricular arrhythmias or bradyarrhythmias
- the evaluation of various ATP and cardioversion therapies
- the presence of any post-shock arrhythmias, and
- an 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 if 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.

2. Device Features

The Lumax family feature set is presented under the following sub-headings: Tachyarrhythmia Detection, Tachyarrhythmia Redetection/Acceleration, Tachyarrhythmia Therapy, Tachyarrhythmia Termination, Bradycardia Therapy, EP Test Functions and Special Features. The features apply to all members of the Lumax 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.

2.1 SafeSync Telemetry

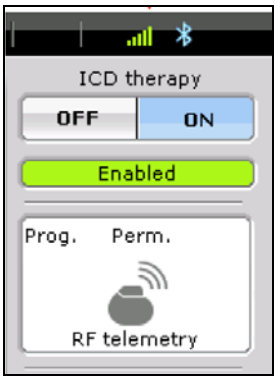
The Lumax 700/740 and 600/640 models offer "wandless" communication between the device and the programmer by using radio frequency (RF) telemetry, in addition to the currently available telemetry used by applying the programming head (PGH) over the implanted device. This function is called SafeSync Telemetry.

SafeSync Telemetry can be used with the Renamic programmer or with the ICS 3000 programmer (using the SafeSync Module, an external communication module).

To Establish SafeSync Telemetry contact:

The programmer (or the SafeSync module) must be no more than 9 feet (3 m) from the device; ideally there should be no obstacles between the patient and the programmer.

- Switch on RF telemetry on the programmer. Select: **Preferences→Connectivity→RF telemetry→ Interrogation→ON**. Or, select: **More→Lumax→ Telemetry→RF,** during the follow-up.
- Apply the programming head for about 2 seconds until successful initialization is displayed on the programmer:



The SafeSync symbol is displayed in the navigator and the signal strength is displayed in green bars on the information line. The SafeSync telemetry status is shown in five increments: 1 bar = 20% up to 5 bars = 100%. A weak contact shows only one bar in green, whereas all five bars are shown in green when there is optimal contact. The bars are shown in gray if RF telemetry is lost. The display should have at least three green bars. Otherwise, it is recommended to reposition the programmer until an adequate signal strength is achieved.

- Remove the programming head.
- To restore the SafeSync Telemetry after an interruption during follow-up or after a programmer restart: select **Speciąl→Continue RF session** on the start screen to restore the most recent active session. This SafeSync Telemetry session must not have been inactive for longer than five minutes, since the device's SafeSync Telemetry activity is automatically switched off after five minutes of inactivity.

  Note: If the SafeSync Telemetry session has been inactive for more than 5 minutes, the programming head must be reapplied to reinitialize the SafeSync Telemetry.

To End SafeSync Telemetry contact:

To end the SafeSync Telemetry session:

- End Follow-up session

To switch to telemetry via the programming head (PGH):

- Apply the programming head on the patient over the device.
- Select: **More→Lumax→ Telemetry→PGH**.

Power Consumption Consideration:

SafeSync telemetry requires somewhat more power than telemetry via the programming head. Power consumption during implantation corresponds to approximately 10 days of service time and consumption during 20-minute follow-up corresponds to approximately 3 days. As a result:

- Do not establish SafeSync Telemetry sessions unnecessarily.
- After 5 minutes without input, SafeSync Telemetry switches to the economy mode. In order to re-establish telemetry from the economy mode, select “Close” in the pop-up window with the patient’s name:

- Check the battery capacity of the device at regular intervals.

2.2 Cardiac Resynchronization Therapy (CRT)

HF versions only

For Cardiac Resynchronization Therapy (CRT), a sensing/pacing lead is placed in the right atrium, while an ICD lead is placed in the right ventricle. The third lead is positioned to pace the left ventricle. When connected together, this system provides coordinated, simultaneous stimulation of the right and left ventricles. This resynchronization therapy is designed to coordinate the contraction of both ventricles, which allows the heart to contract more efficiently. As a result, patients with CHF and intraventricular conduction delay may have a greater ability to complete physical activities thus improving their quality of life.

As a result of the device design and header configuration, ventricular pacing pulses can be delivered between the right/left ventricular lead tip electrodes simultaneously (cathode) and at programmed intervals. In some configurations the ring of the right ventricular lead works as LV anode. Ventricular sensing primarily uses the poles of the right ventricular lead tip and ring. This design avoids sensing of ventricular activity twice during a single cardiac cycle (double counting) in patients with a wide QRS complex. However, for diagnostic purposes and LV pacing protection the Lumax HF devices can be programmed to sense in the left ventricle.

Atrial Channel

The Lumax ICDs/CRT-Ds pace and sense in bipolar configuration, between the atrial lead's tip and ring electrodes. A bipolar atrial lead must be used to ensure reliable sensing of atrial activity.

Ventricular Channel

The Lumax HF devices can be programmed to pace in both the right and left ventricle (as well as RV only). The Lumax HF primarily senses in a bipolar configuration in the right ventricle. However, for diagnostic purposes and LV pacing protection the Lumax HF devices can be programmed to sense in the left ventricle.

Potential Ventricular lead configurations are provided in **Table 26**.

Table 26. Lead Configurations		
	Configuration	**Explanation**
Sensing	**RV** Only	Sensing takes place between the tip and ring electrodes of the right ventricular lead.
	LV Only	Sensing takes place between the tip and ring electrodes (bipolar) or the tip electrode of the left ventricular lead and the CRT-D housing (unipolar).
Pacing	**RV & LV Together (BiV)**	Pacing configuration is programmable between the tip and ring electrodes of the right and left ventricular leads. See **Figure 7**
Pacing	**RV** Only	Pacing takes place between the tip and ring electrodes of the right ventricular lead. See **Figure 7**

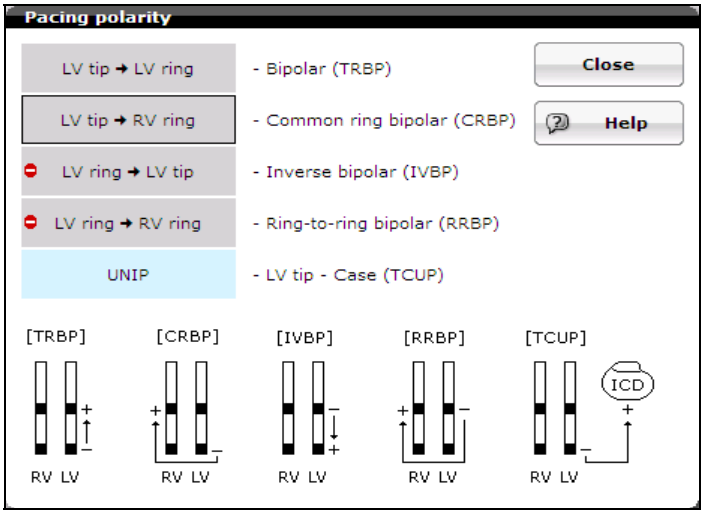


Figure 7 Programmable Pacing Configurations

For CRT to be effective, ventricular pacing must occur. Therefore, AV delays must be programmed short enough to override intrinsic ventricular contractions. Additional information to further optimize AV delays can be obtained with echocardiography.

CRT can be programmed ON or OFF via the programmer using the [**Ventricular Pacing**] parameter. Ventricular Pacing Configuration allows standard right ventricular [**RV**] (CRT = OFF) pacing or Cardiac Resynchronization Therapy [**BiV**] (CRT = ON).

The Lumax HF CRT-D can provide triggered biventricular pacing. This is a functional expansion of the basic ventricular modes (DDD(R); DDI(R); VDI(R); VDD(R); VVI(R)) used for biventricular pacing. The “RVs triggering” was designed to ensure CRT is delivered even when rapid intrinsic activation interferes with pacing, such as in the case of conducted atrial fibrillation. This function triggers LV pacing (Vp) after intrinsic sensing (RVs) in the right ventricle. Triggered pacing can be programmed to react to only normal RV sensed events or to right ventricular extrasystoles as well as normal RV sensed events. The maximum trigger rate is normally limited by the programmed UTR (+20bpm), but can also be programmed to function up to a separate and higher maximum trigger rate.

V-V Delay Programming

V-V delays should be programmed based on optimization of the echocardiographic parameter Aortic Valve Velocity Time Integral, evaluating the full range of available delays, as was performed in the clinical study demonstrating the safety and effectiveness of this feature. RV pre-excitation may cause a decline of LV function.

The V-V delay features for the Lumax HF-T devices include the ability to program the following parameters “first chamber paced,” which allows either the right or the left ventricle to be paced first, and “VV delay” for setting a delay between the left and right ventricular pacing pulses (programmable range: 0 ms … (5ms) … 100 ms).

Suggested optimization procedure:

During the V-V clinical study assessment was performed by determining the V-V delay setting associated with the largest VTI value. The VTI of the aortic flow is measured in the apical 5 chamber view.

Prior to the V-V delay optimization procedure, each patient underwent an optimization of AV timing. Following the AV timing adjustment, this standardized procedure was followed for the optimization of V-V delay:

1. Program the Lumax HF-T “Initially Paced Chamber” parameter to either RV or LV based on preference
2. Assess the VTI measurement at the following V-V delays (additional V-V settings may be utilized at the physician’s discretion):
    - •100 ms
    - • 80 ms
    - • 60 ms
    - • 40 ms
    - • 20 ms
    - • 0 ms

Note: Use the average VTI parameter over a 3 beat cycle and wait 10 to 15 seconds between changing V-V delay settings. Also, attempt to measure the VTI parameter within the same patient respiratory cycle.

3. Record the VTI measurement associated with each V-V delay setting

Repeat steps 1-3 for the remaining “Initially Paced Chamber” parameters

Select permanent “Initially Paced Chamber” and “V-V delay after Vp” to reflect the maximum VTI measurement for final programming.

2.3 Sensing (Automatic Sensitivity Control)

The Lumax ICDs/CRT-Ds use Automatic Sensitivity Control (ASC) to adjust the input stage sensitivity threshold for each channel to appropriately detect the various cardiac signals. The characteristics of the sensing circuitry have been optimized to ensure appropriate sensing during all potential cardiac rhythms.

Cardiac signals vary in amplitude; therefore detection thresholds cannot be static. With the Automatic Sensitivity Control (ASC) every paced/sensed event is measured, and the upper and lower thresholds are re-set accordingly (also known as beat-by-beat adaptation). The ASC begins by tracking the cardiac signals (R and P-waves) during the sensed refractory periods. The peak values measured during this time are used to set the sensing thresholds during the active detection periods.

2.3.1 Right Ventricular Sensitivity Settings

There are three programmable preset options for setting the sensitivity of the right ventricular input stage. The sensitivity selections are designed to adapt the parameters of the input stage to various signal conditions. The predefined parameter sets are described in **Table 27**.

Table 27: Sensitivity Settings

Setting	Definition for Use
Standard	This setting is recommended for most patients, especially for those with measured R-wave amplitude of ≥3 mV.
Enhanced T Wave Suppression	This setting offers suppression of T-wave oversensing. This mode should not be used on patients with the following conditions: • Sinus rhythms with small signal amplitudes, R-waves <4 mV • VF with highly fluctuating signal amplitudes.
Enhanced VF Sensitivity	This setting enhances VF detection, in cases of highly fluctuating signal amplitudes. It is not to be used for patients that have sinus rhythms containing large amplitude T-waves.

Typically, the upper threshold is reset with each sensed R-wave, but in order to ensure that pacing does not occur during an episode of VF, the ASC behaves differently with paced events. Each paced event is followed by a paced refractory period after which the ventricular threshold is set to the minimum programmed value.

For example, the upper threshold is set at 50% of the measured R-wave for the **Standard** sensitivity setting following the 100 ms sensed refractory period. The upper threshold decays 0.125 mV every 250 ms through the T-wave discrimination period (hold of upper threshold: 360 ms). After the T-wave discrimination period, the threshold is decreased to the lower threshold. The lower threshold is set to 25% of the measured peak R-wave. The lower threshold then decreases 0.125 mV every 500 ms until the Minimum Threshold is reached or until the next sensed (or paced) event.

For Lumax 600/640 and 700/740 devices, the decrease is controlled on a percentage basis. Every 156 ms 87.5% of the threshold reference. Initially this is the maximum amplitude. Hold of upper threshold: 400 ms.

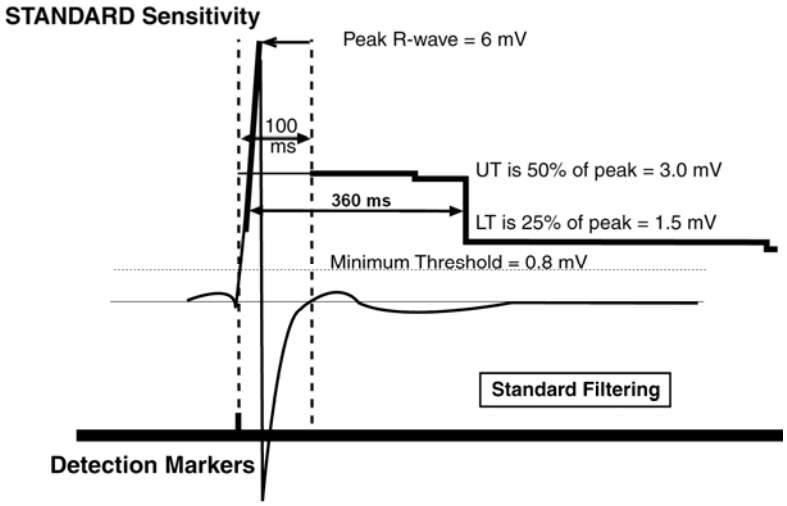


Figure 8 Automatic Sensitivity Control with Standard Setting

Figure 8 provides an illustration of Automatic Sensitivity Control with the sensitivity programmed to Standard. The tracked R – wave is measured to be 6.0 mV, following the sensed refractory period the upper threshold is set to 3.0 mV. After the T-wave discrimination period, the threshold is further reduced to 1.5 mV. Both the Upper and Lower Thresholds decay over time, but the Minimum Threshold is never violated. Nominally, the minimum threshold is set to 0.8 mV, but it can be adjusted by the user.

The Enhanced VF Sensitivity setting is specifically designed to improve VF detection when the VF signal is very small. Two adjustments are made to ASC with this setting:

- The T-wave discrimination period (hold of upper threshold) is decreased to 100 ms [110 ms for Lumax 600/640 and 700/740 models], thus eliminating the Upper Threshold.
- The decay rate of the Lower Threshold is increased to 0.125 mV every 250 ms. This is not applicable for the Lumax 600/640 and 700/740 models.

These adjustments ensure that the threshold reaches the lower values more quickly in order to assure that all VF signals are sensed appropriately.

The Enhanced T-Wave Suppression setting is specifically designed to avoid double counting of each QRS-T complexes during normal sinus rhythms. With sensitivity programmed to Enhanced T-Wave Suppression:

- High pass filtering is increased to reduce low frequency signal components such as T-waves and respiratory artifacts.
- The Upper Threshold is increased to 75% of the measured R-wave.
- The Upper Threshold may not retrigger with each sensed event, it is only triggered when the new sensed R-wave crosses the 50% point of the previous measured R-wave.

2.3.2 Minimum Right Ventricular Threshold

This parameter limits the minimum sensitivity of the ICD/CRT-D to a programmable value. Nominally, the minimum threshold is set to 0.8 mV, but it can be adjusted from 0.5 to 2.5 mV.

2.3.3 Atrial Sensitivity Settings

DR and HF versions only

The primary option for setting the sensitivity of the atrial input stage is “Standard”. When atrial sensing is active, the sensitivity is set to “Standard” for most patients, which is designed to adapt the parameters of the input stage to various signal conditions. The available settings are described in **Table 28**.

Table 28: Atrial Sensitivity Settings	
Setting	**Definition for Use**
Standard	This setting is recommended for all patients with a functioning atrial lead.
Inactive	This setting deactivates the atrial channel for sensing, EGM telemetry and Holter recording and is typically used when no atrial lead is implanted.

Typically, the upper threshold is reset with each sensed P-wave, but in order to ensure that pacing does not occur during an episode of AF/VF, the ASC behaves differently with paced events. Each paced event is followed by a paced refractory period after which the atrial threshold is set to the minimum programmed value.

2.3.4 Minimum Atrial Threshold

This parameter limits the minimum sensitivity of the ICD/CRT-D to a programmable value. Nominally, the minimum threshold is set to 0.4 mV, but it can be adjusted from 0.2 to 2.0 mV.

2.3.5 Left Ventricular Sensitivity Settings

HF versions only

The primary option for setting the sensitivity of the left ventricular input stage is “Standard”. When LV sensing is active, the sensitivity is set to “Standard” for most patients, which is designed to adapt the parameters of the input stage to various signal conditions. The available settings are described in **Table 29**.

Table 29: Left Ventricular Sensitivity Settings	
Setting	**Definition for Use**
Standard	This setting is recommended for all patients with a functioning left ventricular lead.
Inactive	This setting deactivates the left ventricular channel for sensing, EGM telemetry and Holter recording and is typically used when no LV lead is implanted.

2.3.6 Minimum Left Ventricular Threshold

This parameter limits the minimum sensitivity of the CRT-D to a programmable value. Nominally, the minimum threshold is set to 0.8 mV, but it can be adjusted from 0.5 to 5.0 mV.

2.3.7 Far Field Protection

DR and HF versions only

This parameter blanks the atrial channel of the ICD/CRT-D to the period before and after each ventricular event. This blanking period is programmable separately based on whether the ventricular event is a paced or sensed event and is designed to prevent sensing of ventricular signals with the atrial leads.

CAUTION

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.

2.3.8 Additional Sensing Parameters

The parameters of the Additional Sensing Parameters menu are to provide additional flexibility for physicians to non-invasively correct over/undersensing situations. The ranges and nominal values are located in the Technical Specifications in Section 6.

Upper Threshold (A, RV & LV) - This feature allows the user to change the upper sensing threshold level (UT in **Figure 8**) from the nominal value of 50% of the sensed R-wave/P-wave amplitude to either 75% or 87.5% of the R-wave/P-wave value. This feature is used in the ventricle for example to eliminate oversensing of large T-waves. This is not applicable to the Lumax 600/640 and 700/740 models.

Hold of Upper Threshold (RV & LV) - This parameter determines when the sensing decrement begins after an event (small step-down on the 50% threshold before LT in the figure above). This parameter "holds" the threshold at a constant value (UT in **Figure 8**) for the programmed time. Maximum Hold Time is programmable from 100 to 600 ms in Lumax 300/340 & 500/540 and 110 to 500 ms in the Lumax 600/640 & 700/740 models (T-Wave discrimination period). Additionally, the Lumax 600/640 & 700/740 models are separately programmable between the paced and sensed signals.

Lower Threshold (A, RV & LV)- This feature allows the user to change the lower sensing threshold (labeled LT in **Figure 8**) from the default value of 25% of the sensed R-wave/P-wave amplitude to either 12.5 or 50% of the measured R-wave/P-wave value. This is not applicable to the Lumax 600/640 and 700/740 models. This feature is also used in the ventricles to alleviate T-wave oversensing and/or undersensing of small amplitude events (e.g., fine VF).

Blank after atrial pacing (RV) - This feature is used to eliminate sensing of artifacts after atrial paced events. Blank Post atrial Pace in the RV is programmable from 50 to 100 ms. For the left ventricle, this parameter is equal to the safety window time (100 ms).

VES Discrimination after As - This feature is used to correctly identify and classify ventricular extrasystoles (VES). With each atrial sensed event (also with Ars falling into PVARP) a special timing interval is started for the ventricle, if the subsequent ventricular event does not fall within the AV delay or the programmed VES discrimination interval, it is classified as a VES.

LV T-wave Protection - Used to eliminate unintended pacing in the vulnerable period of the left ventricle. This feature is only used when left ventricular sensing is active. **HF versions only.**

2.4 Automatic Threshold Measurement (ATM)

Lumax 500/540 Models only

The Lumax 500/540 models have an automatic threshold measurement (ATM) feature for determining ventricular pacing thresholds. This feature is separately programmable for the right (RV) and left (LV) ventricles.

ATM is initiated once each day, typically during the nighttime while the patient is normally sleeping. It can measure the right and the left ventricular pacing thresholds and stores this information for use in trends of daily threshold values. This information is available on the programmer during in-office follow-ups and via BIOTRONIK's Home Monitoring system. The permanent pacing amplitude is not adjusted by the ATM feature.

The ATM features of Lumax 500/540 are based on the evaluation of the morphology of the ventricular evoked response (VER) to determine if the pacing pulse has captured the myocardium. In order to measure the pacing threshold, a sequence of two algorithmic steps is carried out:

- Signal Quality Check (SQC)
- Threshold Measurement

The signal quality check determines if the morphology of the evoked response of a captured beat is sufficiently different from the morphology of the evoked response of a non-captured pace. If the SQC is sufficient (i.e., if the algorithm can clearly distinguish between capture and non-capture), then the automatic threshold measurement is activated by initiating a series of pacing pulses. The amplitude of these pulses is continuously decreased until a loss of capture is detected. When loss of capture is detected a back-up pulse is delivered (right ventricle only) to avoid ventricular pauses caused by the threshold measurement.

2.4.1 Signal Quality Check

During the Signal Quality Check, five single effective pacing pulses are delivered. These pulses are followed by five double pulses. The second pulse of each double pulse is delivered into the refractory phase of the ventricle (as a non-capturing pulse). The VER morphology of the single pulses and the second pulse of the double pulses are assessed. The signal quality check is successful if the single pulses are recognized as capturing pulses and the second pulses of the double pulses are classified as non-capturing pulses. The AV delay of the 2 x 5 pulses is shortened to 50 ms after pace and by 15 ms after sense, in order to avoid ventricular fusion beats which would otherwise disturb the SQC. If the SQC is successful, then the threshold measurement is started, if not, the SQC is repeated once again after 30 minutes.

2.4.2 Threshold Measurement

The threshold measurement begins by delivering pulses at the programmed pacing amplitude. The pulse amplitude is decreased in steps of 0.6 Volts (V) each until loss of capture is detected. During the loss of RV-capture sequence, a backup pulse is issued. The back-up is set to a value of the programmed pacing amplitude plus 0.6 V with a pulse width of 1.0 ms. There are no backup paces for left ventricular ATM (LV-ATM).

The pulse amplitude is then set to the last effective value (0.6 Volts above the initial non-capture level) and then subsequent pacing pulses are reduced in 0.1 V steps until loss of capture reoccurs. The last effective pacing amplitude is then recorded as the pacing threshold.

2.4.3 Loss of Capture Detection

In order to ensure against ATM loss of capture detection due to an isolated non-capture event (i.e. as a result of VES), loss of capture is only declared if two out of three consecutive cycles show loss of capture.

2.4.4 ATM in Lumax HF-T Models

If the device is programmed to biventricular pacing (BiV), the RV ATM functions in the RV mode as described above. The LV ATM, if active, is initiated after the RV ATM is complete. For the LV ATM, the left ventricle is stimulated first with a VV delay of 50 ms and then completed in a similar manner.

Lumax 600/640 & 700/740 Models only

2.4.5 RV & LV Capture Control

RV & LV Capture Control uses the determined pacing threshold to adjust the permanent pulse amplitude. The new permanent pulse amplitude is composed of the determined pacing threshold plus a safety margin (1.0 or 1.2 V) and is automatically programmed in the ICD.

2.5 Ventricular Tachyarrhythmia Detection

The Lumax 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 appropriate 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 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:

- VT-1 Lower rate ventricular tachycardia
- VT-2 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.

2.5.1 VF Classifications

Detection of ventricular fibrillation (VF) utilizes programmable X out of Y criterion. For the Lumax 300/340 & 500/540 models, both X and Y are programmable. For the Lumax 600/640 and 700/740 models there are fixed combinations of X out of Y criterion. If X number of intervals within the sliding window (defined by Y) are shorter than the programmed VF rate interval (>bpm), VF is detected. After fibrillation is detected, the programmed therapy sequence for VF is initiated.

Nominal settings for classification of ventricular fibrillation (VF) are 8 of 12 intervals; meaning that within a sample window of 12 intervals, 8 intervals must meet or exceed the VF zone rate criteria.

2.5.2 VT Interval Counters

The VT Interval Counters are separately programmable for VT-1 and VT-2 rate classifications. The Counter: Detection is the number of intervals required to declare a tachyarrhythmia as VT. A tachyarrhythmia must meet the rate/interval criteria and the programmed Counter/Detection criteria, in addition to any other detection enhancements to be declared a tachycardia.

2.5.3 VT Classification

Both VT-1 and VT-2 classification zones utilize separately programmable detection parameters. Classification of VT-1 or VT-2 is based on the last interval average preceding declaration of tachyarrhythmia detection. If this average falls within the VT-1 zone, the programmed VT-1 therapy is delivered. If the average falls within the VT-2 limits, the programmed VT-2 therapy is delivered. If additional detection parameters are activated, each of these supplemental criteria must also be satisfied before a VT rhythm can be classified and treated.

The ICDs/CRT-Ds may be programmed to use ventricular-only information, or both atrial and ventricular information for the discrimination of ventricular tachyarrhythmias. With SMART Detection™ turned ON, the Lumax ICDs/CRT-Ds use atrial and ventricular signals for discrimination of fast heart rhythms. With SMART Detection™ turned OFF, only the ventricular rate is used to discriminate between ventricular rhythm classes. If SMART Detection™ is enabled, this algorithm evaluates all cardiac signals within the VT range and increments the VT Sample Count for all intervals that are deemed VT. A full description of SMART Detection™ is provided in **Section 2.5.4**.

In addition, when the Lumax senses the programmed number of consecutive intervals (termination count) within the sinus rate zone, all tachyarrhythmia detection criteria, including the VT sample counters are reset.

2.5.4 SMART Detection™

DR and HF versions only

This discrimination algorithm enhances VT-1 and VT-2 detection by applying a series of tests to the sensed cardiac signal. SMART Detection™ is intended to discriminate VT from a variety of supraventricular arrhythmias that are conducted to the ventricle and that would otherwise satisfy VT-1 or VT-2 rate detection criteria.

First, the average ventricular rate is compared to the average atrial rate. In the event that the measured ventricular rate is faster than the atrial rate, the device immediately declares the rhythm a VT and delivers programmed ventricular therapy for the detected VT zone.

In the event that an atrial rate is faster compared to the ventricular rate one of three tests are performed:

Ventricular rhythm stability, (see Stability in **Section 2.5.6** if the ventricular signal is unstable, then the rhythm is declared a supraventricular tachyarrhythmia, (SVT) and ventricular therapy is typically withheld.

If the ventricular signal is stable, and the atrial rate is a multiple of the ventricle rate, then the rhythm is declared a supraventricular tachyarrhythmia (SVT) and ventricular therapy is typically withheld.

If the ventricular rhythm is stable and the atrial rate is not a multiple of the ventricular rate, then the rhythm is declared a VT and ventricular tachycardia therapy is delivered.

In the event that both the atrial and ventricular signals are detected at the same rate, a series of additional discrimination tests are applied.

2.5.5 Onset

Another detection enhancement that may be used independently (VT-1 or VT-2, when SMART Detection is active) or as an adjunct to the SMART Detection™ algorithm is the Onset parameter. This parameter measures abrupt changes in ventricular cycle length to discriminate between sinus tachycardias and ventricular and atrial tachyarrhythmias, which characteristically begin with an abrupt change in cardiac rate.

This feature allows therapy to be withheld if a sinus tachycardia rate crosses into one of the VT zones.

2.5.6 Stability

In VT-1 and VT-2 zones, the purpose of STABILITY is to assist in discriminating between stable ventricular tachyarrhythmias and supraventricular tachyarrhythmias that conduct irregularly to the ventricles. STABILITY evaluates sudden changes in the regularity of cardiac events (R-R and P-P intervals) on a beat by beat basis. The STABILITY criterion compares the current measured interval with the three preceding cardiac intervals. If a difference between the current interval and each of the three preceding intervals is less than the stability range, then the current intervals are stable.

The SMART Detection™ algorithm utilizes both atrial and ventricular STABILITY as integral parts of the discrimination algorithm. Therefore, when SMART Detection™ is enabled, the STABILITY parameter must also remain enabled and set to 12%.

2.5.7 Sustained VT Timer

The Sustained VT Timer can be programmed between 30 seconds and 30 minutes (or to OFF) for the Lumax 300/340 & 500/540 models and 1 min to 30 minutes (or to OFF) in the Lumax 600/640 and 700/740 models. When the timer expires, therapy is initiated regardless of the detection enhancements.

The Sustained VT parameter is intended to force tachycardia therapy in cases where a cardiac rhythm meets the VT rate criteria but does not satisfy one or more detection enhancement criterion (Onset, SMART Detection, or Stability) for an extended duration. This “safety” timer is initiated within one of the VT zones. If the programmed Sustained VT time period expires without tachycardia detection, redetection is initiated without utilizing the detection enhancements.

A simple up/down counter is used to initiate the safety timer. The counter is incremented by one when an interval falls into a VT zone and decrements by one when an interval falls into the sinus zone. When the counter reaches a number equal to the programmed VT detection counter, the safety timer is started. The timer runs until the programmed time expires and therapy is delivered or until the timer is reset. The timer is reset with initial detection or VT termination.

The safety timer is not used in redetection. If initial detection was due to the safety timeout and SMART Redetection is programmed “ON”, then SMART Detection™ will not be used for redetection.

2.5.8 VT Monitoring Zone

The VT1 zone can be programmed to monitor for non-sustained arrhythmias not requiring therapy. The monitoring zone can be programmed with all the standard detection enhancements including SMART Detection™ to monitor for non-sustained ventricular tachycardia or atrial tachyarrhythmias. Any tachyarrhythmia meeting the Monitor Zone criteria will store an IEGM.

2.5.9 Atrial Monitoring Zone

This feature allows the device to store an IEGM for atrial tachyarrhythmias such as Atrial Fibrillation or Atrial Flutter. The zone is programmed by rate with a range of 100 bpm to 250 bpm. Any atrial tachyarrhythmia meeting the Atrial Arrhythmia Monitor Zone criteria will store an IEGM.

2.6 Tachyarrhythmia Redetection

The Lumax ICDs/CRT-Ds offer independently programmable settings for determining if tachyarrhythmias remain after therapy has been delivered. The redetection routine allows the ICDs/CRT-Ds to determine whether further therapy is required when the initial therapy was unsuccessful in terminating the arrhythmia.

Tachyarrhythmia redetection criteria are based on cardiac cycle length and number of intervals. The number of intervals is distinct and independent of the initial detection criteria.

2.6.1 VT Redetection

The Counter: Redetection parameter may be programmed separately for each arrhythmia class, independent of the initial detection parameters:

Redetection of an ongoing tachyarrhythmia is declared when the Counter: Redetection is satisfied (based on individual cycles). If a sensed cardiac signal meets any VT rate criteria, following therapy, that signal is counted and compared to the programmed Counter: Redetection setting.

Redetection functions are based exclusively on the VT criterion.

2.6.2 SMART Redetection

DR and HF versions only

With SMART Redetection programmed ON, both atrial and ventricular signals are used for redetection after initial detection and therapy for a VT. SMART Detection™ will function identically as in initial VT detection. SMART Redetection is autotmatically programmed ON in the Lumax 600/640 and 700/740 models.

2.6.3 Forced Termination

DR and HF versions only

With SMART Redetection programmed ON, this programmed parameter sets a time after which the SMART Redetection will be terminated even if the SVT is still ongoing. This forces the device to terminate the episode and allow detection of a new VT or VF episode.

2.6.4 VF Redetection

VF redetection uses the same X in Y algorithm as initial detection. The X and Y values for initial detection are also used for redetection to ensure consistent classification of VF.

2.7 Tachyarrhythmia Termination

Termination of a ventricular tachyarrhythmia episode is declared when 12 out of 16 consecutive sensed intervals are longer than the VT-interval parameter of the lowest VT class (sinus or bradycardia rhythm).

2.8 Tachyarrhythmia Therapy

The Lumax ICDs/CRT-Ds offer a variety of therapy options that can be tailored to meet a patient's specific anti-tachycardia or defibrillation therapy requirements. Anti-tachycardia pacing (ATP) therapies can be combined with defibrillation therapies to provide a broad spectrum of tachyarrhythmia treatment options.

2.8.1 Therapy Options

The Lumax ICDs/CRT-Ds offer multiple therapy options for each tachyarrhythmia class (VT1, VT2, VF). Therapy options (up to 20 ATP sequences and 8 shocks) are available for the VT1 and VT2 zones, whereas ATP One Shot and up to 8 shock therapies are available for the VF class. The specific characteristics of an ATP and shock therapy are independently programmed for each VT/VF zone.

The ATP and shock therapy options are discussed in detail in the following sections.

2.8.2 Anti-Tachycardia Pacing (ATP)

Anti-tachycardia pacing therapy (ATP) is available in both VT detection zones. Available modes of ATP include **Burst**, **Ramp**, and **Burst + PES** (Programmed Extra Stimuli). However, in the Lumax 600/640 and 700/740 models, **Burst + PES** is only available at DFT test for EP examinations. In addition, the Burst and Ramp modes allow interval scanning of the **R-S1 Interval**, the **S1 Decrement**, or both. The **Attempts** parameter determines the number of burst schemes to be delivered before the scan parameter is incremented.

Burst – This mode will deliver a series of pacing stimuli with user defined duration of the burst (**Number S1**), coupling cycle length (**R-S1**) and burst rate (**S1-S1**). The coupling interval and the start interval are calculated from the intrinsic R-R average.

Ramp - This mode will deliver a series of pacing stimuli with the above options including a parameter which decrements each successive stimuli interval in the burst.

Burst + PES – In the Lumax 300/340 & 500/540 models, this mode provides a pulse train followed by one additional timed stimuli. The coupling cycle length of the burst and each extra stimulus (**S1-S2 Interval**) is individually programmed either as an adaptive value (as a percentage) or as an absolute value (expressed in milliseconds). In the Lumax 600/640 & 700/740 models, **Burst + PES** is only available at DFT test for EP examinations.

Ventricular Pacing - This parameter defines the type of ventricular pacing performed during delivery of ATP sequences in CRT-Ds and is programmable to biventricular (VV delay = 0 ms) or right ventricular only.

Number S1 - This parameter defines the number of stimuli for an ATP. For Burst + PES, a single extra stimulus with a separate parameter setting is coupled. In the Lumax 600/640 & 700/740 models, **Burst + PES** is only available at DFT test for EP examinations.

Add S1 - This feature can be programmed with any Burst, Ramp, or Burst + PES (Lumax 300/340 & 500/540 models only) scheme. When “Add S1” is “ON,” the number of S1 intervals is incremented by one on each successive ATP therapy. The next S1-S1 interval is dependent on the initial start interval (S1 decrement) and the programmed Scan Decrement (if activated).

R-S1 Interval - The R-S1 programmable coupling interval occurs at the beginning of each ATP. It defines the interval between the last R-wave signal and the first stimulus (S1). The second stimulus always follows the first one with the same interval.

S1 Decrement - The S1 decrement continuously reduces the pulse intervals of the ATP from the second pulse onward.

S1-S2 Interval - The S1-S2 programmable coupling interval occurs between the Burst sequence and the extra stimuli (PES). It defines the interval between the first stimulus (S1) and the extra stimuli (S2).

Scan Decrement - The Scan decrement continuously reduces the starting pulse intervals of each Burst or Scan.

Minimum ATP Interval – For the Lumax 300/340 & 500/540 models, the programmed minimum interval prevents ATPs from being given with stimulation values less than the minimum interval. When the ATP interval reaches the value of the minimum interval with the S1 decrement or scan decrement, it then assumes this value and remains constant. For the Lumax 600/640 & 700/740 models, the minimum ATP interval is 200 ms fixed.

2.8.2.1 ATP Help

ATP help is a useful tool to assist the physician in choosing and confirming appropriate ATP programming. The “ATP Help” button is displayed in each ATP therapy option. When the ATP help button is pressed, a histogram of the chosen therapy scheme is shown. The histogram displays the intervals for the programmed ATP scheme. When rate adaptive intervals are programmed, the displayed intervals are based on the programmed R-R average.

2.8.2.2 ATP Optimization

In order to optimize future therapies, the ICD will store the parameter configuration of the last successful ATP attempt in each the VT1 and VT2 classes. The last successful stored ATP attempt is then used as the starting point for the next detected episode of the same arrhythmia class. If the stored parameter configuration is not successful, it is deleted from the ATP optimization memory of the respective arrhythmia class and subsequent therapy sequences will begin with ATP1 for the next detected episode.

ATP Optimization is programmable ON or OFF for all ATP therapies and VT zones with one parameter.

NOTE:

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.).

2.8.2.3 ATP Timeout

ATP Timeout is a timer that decrements after the initial ventricular ATP is delivered (VT-1 zone) and limits the additional ATP therapies that may be delivered. Once the timer expires, all further ATP therapies in the sequence are blocked. If further therapy is required after the timer has expired, the system advances to the first programmed shock therapy for the applicable VT zone. Therapy continues until arrhythmia termination or all programmed therapy (in the applicable zone) has been delivered. The ATP Timeout is reset each time an arrhythmia is terminated.

Note: ATP Timeout is not applicable in the Lumax 600/640 & 700/740 models since the Progressive Course of Therapy is automatically programmed in these devices.

2.8.2.4 ATP One Shot

ATP One Shot offers the opportunity to treat fast VTs that are detected in the VF zone with a single ATP sequence delivered immediately before charging of the high energy capacitors. The device performs a stability check (same as VT zones, criterion 12% fixed) to determine if the arrhythmia might be a fast VT and if the rhythm is stable, the programmed ATP sequence is delivered prior to charging. Charging starts without redetection and the successful treatment of the arrhythmia will be confirmed prior to shock delivery during shock charging. If the arrhythmia is converted by the ATP, the shock is aborted. All ATP therapy parameters are available for programming ATP One Shot and it can only be used with Shock Therapy programmed ON.

2.8.3 Shock Therapy

Shock Therapy is developed by internal circuitry that stores energy across high energy capacitors. The voltage level for the charging cycle is based on the programmed energy level. The energy is then delivered over the connected ICD lead and through the ICD/CRT-D housing utilizing a biphasic waveform. The first and second shock energies in each shock module have independently programmable Shock Energy.

A synchronization window is started at the end of the charging period. During this window, the device will attempt to synchronize the shock therapy to an R-wave. If no R-wave is detected and Confirmation is programmed to OFF, the shock will be delivered asynchronously at the end of the synchronization period (DF). If no R-wave is detected and Confirmation is programmed to ON, the shock will be aborted at the end of the synchronization period (DFc = Cardio Version).

2.8.3.1 Confirmation

The Confirmation parameter is used to verify the presence of a tachyarrhythmia during charging of the shock capacitors. This function is designed to avoid delivery of shock therapy if a tachyarrhythmia has spontaneously terminated. The programmed shock will be delivered unless bradycardia or a normal sinus rhythm is detected during the Confirmation period. Confirmation may be programmed ON or OFF for each zone (VT-1, VT-2 or VF). Although if a shock is aborted and redetection occurs (even in a zone with confirmation programmed ON) the subsequent shock will be delivered without confirmation (see confirmation OFF).

Confirmation OFF

When Confirmation is programmed OFF, shock therapy will be delivered to the patient during the synchronization period regardless of the detected cardiac signal.

Confirmation ON

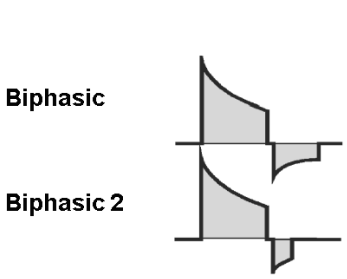
If the tachyarrhythmia spontaneously converts to bradycardia or a normal sinus rhythm during the confirmation period, shock therapy is aborted. If the device confirms the presence of the tachyarrhythmia, the device will deliver the programmed shock therapy synchronized to the R-wave.

2.8.3.2 Number of Shocks

The number of shocks defines the total number of shock attempts per therapy zone (VT-1, VT-2 or VF). Up to 8 shocks are available in each therapy zone. The first and second shock energies are independently programmable, while the remaining shocks are fixed at maximum energy (30 joules for 300/500/600/700 series devices and 40 joules for 340/540/640/740 series devices).

2.8.3.3 Shock Waveform

Two waveforms of shock therapy are available with the Lumax ICDs/CRT-Ds, Biphasic and Biphasic 2 (ms). The following diagram describes each of the shock waveforms.



	Phase 1	Phase 2
Begin End	100 % 40 %	40 % 20 %
Begin End	100 % 40 %	Time 2 ms

Figure 9. Biphasic Waveforms

Both waveforms start at the calculated voltage, based on the programmed energy level. After an exponential discharge through the lead system to 40% of the initial charge voltage, both shock waveforms switch polarity. At the second phase the:

- Biphasic waveform discharges to 20% of the initial charge voltage before the waveform is truncated
- Biphasic 2ms waveform discharges the remaining energy for two milliseconds before the waveform is truncated

Figure 9 provides a pictorial representation of both biphasic waveforms.

BIOTRONIK recommends use of the standard Biphasic shock waveform for initial defibrillation threshold testing. If testing demonstrates high defibrillation thresholds, testing with the Biphasic 2ms waveform is offered as a therapeutic alternative to the standard Biphasic shock.

2.8.3.4 Shock Energy

The Lumax 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 1 joules for Lumax 300/340 & 500/540 models and 2 joules for Lumax 600/640 & 700/740 models and the maximum energy for the device type. 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 Lumax 340/540/640/740 variants in **Table 30**, and for the Lumax 300/500/600/700 in **Table 31**

Table 30 Delivered Shock Energy (340/540/640/740 Variants)	
Programmed Energy (joules)	**Approximate Delivered Energy (joules)**
1	0.8
2	1.7
3	2.6
4	3.5
5	4.3
6	5.2
7	6.1
8	6.9
9	7.8
10	8.7
11	9.6
12	10.5
13	11.3
14	12.2
15	13.1
16	13.9
18	15.7
20	17.3
22	19.1
24	21.1
26	22.8
28	24.4
30	26.3
32	27.9
34	29.7
36	31.5
38	33.3
40	35.0

Table 31 Delivered Shock Energy (300/500/600/700 Variants)	
Programmed Energy (joules)	**Approximate Delivered Energy (joules)**
1	0.8
2	1.7
3	2.5
4	3.3
5	4.3
6	5.1
7	6.0
8	7.0
9	7.8
10	8.6
11	9.6
12	10.6
13	11.4
14	12.3
15	13.1
16	14.2
18	16.0
20	17.7
22	19.5
24	21.4
26	23.2
28	24.9
30	27.0

CAUTION

Shock Impedance - If the shock impedance is less than twenty-five 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 twenty-five ohms (25 Ω). 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.

2.8.3.5 Shock Polarity

The polarity of the shock therapy may be programmed and changed non-invasively. The **Normal** polarity configures the HV 1 or RV connector port as the negative electrode and the HV 2 or SVC connector port and the outer housing of the ICD/CRT-D as the positive electrode for the first phase of the shock. **Reversed** polarity will switch the electrical polarity of the connector ports and housing. The shock polarity is separately programmable for each arrhythmia zone.

Alternating polarity is automatically employed when a maximum energy shock with normal polarity fails to cardiovert. The next shock will have reversed polarity and alternates the polarity for all subsequent shocks.

2.8.3.6 Third Programmable Shock Pathway

Lumax 500/540, 600/640 & 700/740 Models only

The Lumax 500/540, 600/640 and 700/740 models offer three programmable shock delivery configurations. The defibrillation shock pathways include a “non-active housing” shock path and a shock paths between the ICD/CRT-D housing and either or both shock coils when connected to a dual coil shock lead.

The Shock Configuration parameter operates independently of Shock Polarity. So each of the pathways described below can be reversed for delivered defibrillation/cardioversion shocks.

Table 32 outlines the current shock pathways that are available with Lumax 500/540, 600/640 and 700/740 models.

Table 32 Lumax 500/540, 600/640 & 700/740 Programmable Shock Pathways

#	Electrical Pathway
1)	RV➔ SVC and Housing (can)*
2)	RV ➔ SVC
3)	RV ➔ Housing (can)

* 300/340 Models are limited to this configuration.

2.8.4 Progressive Course of Therapy

By design, the Lumax ICDs/CRT-Ds will deliver more aggressive therapy for each successive attempt within a single detected episode. Therefore, the device will not deliver ATP1 therapy following ATP2 therapy, and will not deliver ATP therapy following a high voltage defibrillation shock.

When Progressive Course of Therapy is turned ON (this is automatically programmed ON in the Lumax 600/640 & 700/740 models), the ICD/CRT-D will always deliver a maximum energy shock after re-detecting in an arrhythmia class with programmed shock energy less than or equal to the previously delivered therapy. In addition, the ICD/CRT-D blocks all ATP therapy during the current episode if a shock has already been delivered during the episode.

Furthermore, the ICD/CRT-D prevents therapies of different arrhythmia classes from permanently retarding or accelerating a VT in such a way that the cardiac rhythm fluctuates between the different arrhythmia classes without achieving termination of the arrhythmia, regardless of the Progressive Course of Therapy setting.

For example, a 10-joule defibrillation shock is delivered for an arrhythmia detected in the VT-2 zone and results in a deceleration of the VT so that it is subsequently redetected in the VT-1 zone. At that point, the Lumax ICDs/CRT-Ds would continue with shock therapy, but all shocks programmed at less than 10 joules would be delivered at 10 joules.

If a defibrillation shock is delivered but does not terminate the arrhythmia, the next shock will always have the same or higher energy than the last delivered shock. Beginning with the third shock, all shocks are delivered at maximum energy.

2.9 Bradycardia Therapy

The Lumax 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 a separate subsection from the normal bradycardia pacing support values.

2.9.1 Bradycardia Pacing Modes

The available bradycardia pacing modes for each member of the Lumax ICD/CRT-D family are listed in **Table 33**.

Table 33 Lumax Pacing Modes

Mode	Lumax HF(-T)	Lumax DR(-T)	Lumax VR(-T)	Lumax VR-T DX
DDDR	X	X	N/A	N/A
DDIR	X	X	N/A	N/A
VDDR	X	X	N/A	X
VDIR	X	X	N/A	X
AAIR	X	X	N/A	N/A

Table 33 Lumax Pacing Modes				
Mode	**Lumax HF(-T)**	**Lumax DR(-T)**	**Lumax VR(-T)**	**Lumax VR-T DX**
VVIR	X	X	X	X
DDD	X	X	N/A	N/A
DDI	X	X	N/A	N/A
VDD	X	X	N/A	X
VDI	X	X	N/A	X
AAI	X	X	N/A	N/A
VVI	X	X	X	X
V00	X	X	X	X
D00	X	X	N/A	N/A
OFF	X	X	X	X

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.

2.9.2 Basic Rate

The basic rate is the pacing rate in the absence of a patient’s intrinsic rhythm. This rate may be independently programmed for normal and post-shock bradycardia pacing.

2.9.3 Night Rate

The night rate is the effective basic rate during the programmed “sleep” period for the patient. This parameter provides a different pacing rate during the patient’s normal sleep time in an attempt to match, for example, the decreased metabolic needs during sleep. When Night Mode is active, the basic rate automatically changes to the programmed NIGHT RATE during the nighttime hours.

At the programmed start time (Begin of Night), the rate gradually adapts to the night rate. When the internal clock reaches the programmed end time (End of Night), the pacing rate gradually changes to the programmed basic rate. The rate changes at the same rate as the Sensor Gain decrease and increase parameters.

NOTE:

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.

2.9.4 Rate Hysteresis

The ability to decrease the effective lower rate through **Hysteresis** is intended to preserve a spontaneous rhythm. The pulse generator operates by waiting for a sensed event throughout the effective lower rate interval (Hysteresis interval). If no sensed event occurs, a pacing pulse is emitted following the Hysteresis interval.

Hysteresis can be programmed OFF or to values as low as -90 bpm in Lumax 300/340 & 500/540 models (-65 bpm in the Lumax 600/640 & 700/740 models) of the basic rate. Hysteresis is initiated by a sensed event. The resulting Hysteresis rate is always less than the lower rate. The Hysteresis rate can only be programmed to provide a basic rate that is 30 bpm or greater.

NOTES:

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

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 ppm. 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.

2.9.4.1 Repetitive Hysteresis

Repetitive hysteresis is expanded programmability of the Hysteresis feature. Repetitive hysteresis searches for an intrinsic cardiac rhythm, which may exist below the programmed lower rate (or sensor-indicated rate) of the patient (see **Figure 10**). Following 180 consecutive sensed events, this feature allows the intrinsic rhythm to drop to or below the hysteresis rate. During the time when the intrinsic rate is at or below the hysteresis rate, pacing occurs at the hysteresis rate for the programmed number of beats (up to 10) in the Lumax 300/340 & 500/540 models and at 10 beats with scan hysteresis in the Lumax 600/640 & 700/740 models. Should the number of programmed beats be exceeded, the stimulation rate returns to the lower rate (or sensor-indicated rate).

If an intrinsic cardiac rhythm is detected within the programmed number of beats between the hysteresis rate and the lower rate, the intrinsic rhythm is allowed and inhibits the pulse generator.

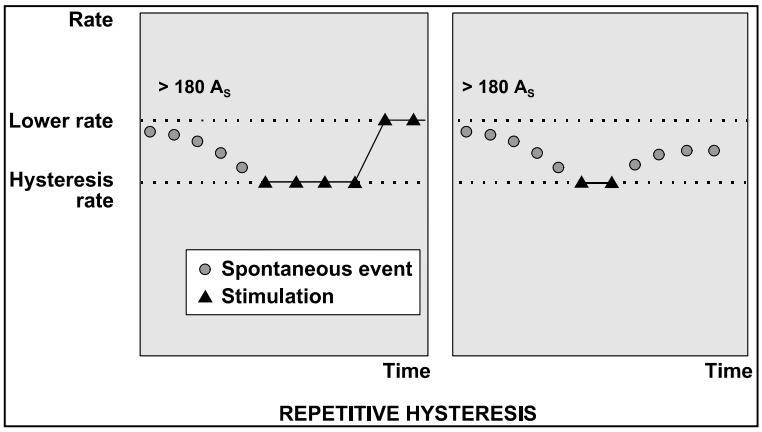


Figure 10. **Repetitive Hysteresis**

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

NOTE:

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.

2.9.4.2 Scan Hysteresis

Scan hysteresis is expanded programmability of the Hysteresis feature. Scan hysteresis searches for an intrinsic cardiac rhythm, which may exist just below the programmed lower rate (or sensor-indicated rate). Following 180 consecutive paced events, the stimulation rate is temporarily decreased to the hysteresis rate for a programmed number of beats (see **Figure 11**) in the Lumax 300/340 & 500/540 models and at 10 beats with scan hysteresis in the Lumax 600/640 & 700/740 models. If a cardiac rhythm is not detected within the programmed number of beats at the hysteresis rate, the stimulation rate returns back to the original lower rate (or sensor-indicated rate). Several programmable beat intervals are available to allow a greater probability of detecting a spontaneous rhythm.

If an intrinsic cardiac rhythm is detected within the programmed number of beats between the hysteresis rate and the lower rate, the intrinsic rhythm is allowed and the pulse generator inhibits.

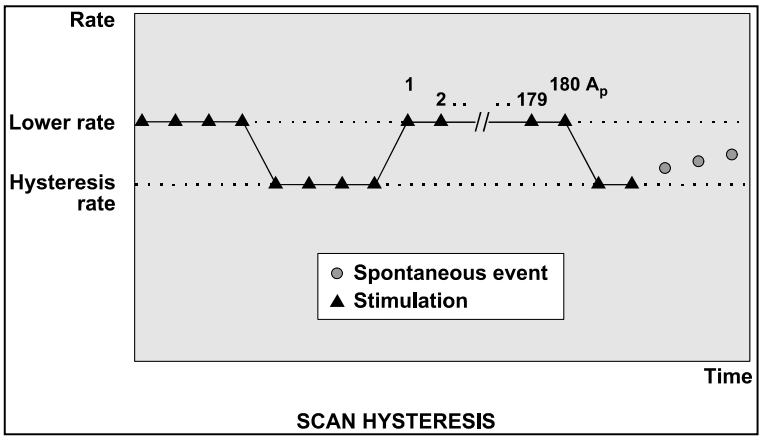


Figure 11. **Scan Hysteresis**

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

2.9.5 Dynamic AV Delay

DR and HF versions only

The AV Delay defines the interval between an atrial paced or sensed event and the ventricular pacing pulse. If the pulse generator is programmed to a dual chamber sensing mode, an intrinsic ventricular event falling within the AV Delay will inhibit the ventricular pacing pulse. If not contraindicated, a longer AV Delay can be selected to preserve intrinsic AV conduction.

Dynamic AV Delay is where the AV Delay is varied depending on the spontaneous atrial rate. Dynamic AV Delay provides a linear change of AV Delays depending on current rate at preset lower and upper AV Delay values.

In addition to selecting the preset values (**Low, Medium, and High**) with the Dynamic AV Delay window, the Dynamic AV Delays may be programmed individually (**Individual**) for each rate zone or to a fixed AV Delay (**Fixed**).

The AV Delay feature includes an AV Delay shortening option (**Sense Compensation**) for dual chamber pacing modes. When enabled, the AV Delay is shortened by the programmed value (-5 to -60 ms in Lumax 300/340 & 500/540 models and up to -120 ms in Lumax 600/640 & 700/740 models) from the programmed AV Delay after an intrinsic atrial sensed event.

The Dynamic AV Delay is intended to mimic physiologic-shortening of the AV Delay with increasing heart rate. It also serves for automatic prevention and termination of “circus movement” pacemaker mediated tachycardia and for prevention of reentrant supraventricular tachycardias. Dynamic AV Delay is available with the Lumax DR-T and HF-T ICDs/CRT-Ds.

2.9.5.1 Positive AV Hysteresis

Positive AV Hysteresis allows a user-programmable change in AV delay that is designed to encourage normal conduction of intrinsic signals from the atrium into the ventricles. With Positive AV hysteresis enabled, the AV delay is extended by a defined time value after sensing a ventricular event (10 … (10) …150 ms) in the Lumax 300/340 & 500/540 models and (70, 110, 150, 200 ms) in the Lumax 600/640 & 700/740 models. The long AV interval is used as long as intrinsic ventricular activity is detected. The programmed short AV delay interval resumes after a ventricular paced event.

2.9.5.2 AV Repetitive Hysteresis

With AV Repetitive Hysteresis, the AV delay is extended by a defined hysteresis value after sensing an intrinsic ventricular event. When a ventricular paced event occurs, a long AV delay is used for the programmed number of cycles. (OFF, 1 … 10) in Lumax 300/340 & 500/540 models and 5 fixed cycles with scan AV hysteresis in the Lumax 600/640 & 700/740 models. If an intrinsic rhythm occurs during one of the repetitive cycles, the long duration AV delay interval remains in effect. If an intrinsic rhythm does not occur during the repetitive cycles, the original AV delay interval resumes.

2.9.5.3 AV Scan Hysteresis

With AV Scan Hysteresis enabled, after 180 consecutive pacing cycles, the AV delay is extended for the programmed number of pacing cycles. (OFF, 1 … 10) in Lumax 300/340 & 500/540 models and 5 fixed cycles with scan AV hysteresis in the Lumax 600/640 & 700/740 models. If an intrinsic rhythm is detected within the extended AV delay, the longer AV delay remains in effect. If an intrinsic rhythm is not detected within the number of scan cycles, the original AV delay value resumes.

2.9.5.4 Negative AV Hysteresis

With Negative AV Hysteresis, the AV delay is decreased by a programmable value (10 … (10) …150 ms) after a ventricular event is sensed, thereby promoting ventricular pacing. The shortened AV interval is used for one time.

2.9.5.5 Negative AV Repetitive Hysteresis

With AV Repetitive Hysteresis and negative AV Hysteresis, the AV delay is shortened by a defined hysteresis value after sensing an intrinsic ventricular event as described above. The short AV Delay will remain until the programmed number of cycles has elapsed. (OFF,1 … 180) in Lumax 300/340 & 500/540 models and 180 fixed cycles in the Lumax 600/640 & 700/740 models. The normal AV delay resumes after the programmed number of consecutive ventricular paced events (Repetitive Negative AV Hysteresis) elapses.

CAUTION

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

2.9.6 IOPT

DR versions only

The IOPT function serves to support the patient's intrinsic rhythm and avoid excessive ventricular pacing. This feature simply activates all of the AV hysteresis parameters with a single selection. **Table 34** details the settings that are preset when IOPT is turned ON:

Table 34 IOPT Parameters

Parameter	IOPT
AV Hysteresis (max AV Delay)	400 ms
AV Scan Hysteresis	5
Repetitive AV Hysteresis	5

2.9.7 Upper Tracking Rate

DR and HF versions only

In the atrial tracking modes (DDDR, VDDR, DDD, and VDD) ventricular pacing tracks atrial pace/sense events. The maximum tracking rate (ventricular pacing rate) is limited by the **Upper Rate** parameter.

The UTR response will automatically toggle between 2:1 and WKB (Wenckebach) depending on the relative programmed values for upper rate and atrial refractory period (AV Delay + PVARP).

If the UTR is less than the maximum sensed atrial rate, defined by the atrial refractory period (60,000/ARP), the WKB response is utilized. Atrial rates exceeding the selected upper rate will result in a Wenckebach-type pacing pattern. This is accomplished by progressively lengthening the AV delay to keep the ventricular pacing rate at the upper rate. Lengthening of the AV interval is interrupted as soon as: 1) a P-wave falls within the atrial blanking period and is not detected; or 2) a succeeding P-wave is detected before the end of the AV delay previously started. In the second case, the corresponding ventricular pacing pulse is suppressed. If the atrial rate is just above the upper rate, a low degree (i.e. 6:5) block results. Higher atrial rates result in higher degrees of AV block until the intrinsic atrial cycle length violates the programmed atrial refractory period causing a 2:1 or greater block.

The 2:1 response is utilized when the rate defined by the atrial refractory period is less than the upper rate. In such a case, the maximum pacing rate is regulated by the inability to respond to P-waves falling within the atrial refractory period.

If the resulting length of the spontaneous atrial cycle is shorter than the atrial refractory period in a rate-adaptive mode, the resulting pacing rate will depend on whether the 2:1 rate has been exceeded. If this is the case, the pulse generator will use the sensor rate as the pacing rate. If the 2:1 rate is not exceeded, the pulse generator will use a rate that lies between the sensor rate and the rate determined by the atrial refractory period.

Atrial Upper Rate is designed to prevent pacing in the vulnerable period after an atrial sensed event during PVARP. It ensures that the next atrial pace is emitted outside of the patient's normal sinus atrial refractory period. Atrial Upper Rate is limited to 240 ppm or OFF in Lumax 300/340 & 500/540 models and OFF, 175, 200 or 240 ppm in the Lumax 600/640 & 700/740 models.

NOTE:

Lumax DR ICDs and Lumax HF CRT-Ds allow the UTR to be programmed within the VT-1 zone. This feature is for patients that are active and have exercise and VT rates that overlap. This may be desirable in young active patients. Also, with RVsense Triggering programming the UTR in the VT-1 zone is blocked.

2.9.8 Mode Switching

DR and HF versions only

Mode switching is designed to avoid tracking of atrial arrhythmias. In the presence of a high atrial rate, the bradycardia pacing mode is automatically reprogrammed to a non-atrial tracking mode. The modes available during mode switching are as shown in **Table 35**. Mode switching is not available during the post-shock pacing period. Mode Switching is only available with the Lumax DR and Lumax HF ICDs/CRT-Ds.

Table 35: Mode Switching Modes	
Programmed Mode	**Converted Mode**
DDDR	DDIR DDI
DDD	DDIR DDI
VDDR	VDIR VDI
VDD	VDIR VDI

Mode switching is initiated in atrial tracking modes when the atrial rate, defined by the programmable mode switch **Intervention Rate** is achieved. However, mode switching will not occur until the Mode Switch **Onset Criterion** is also met. The activation criterion is a programmable **X out of 8** high rate intervals as programmed. RVsense Triggering can be programmed separately during mode switching.

After switching to a non-atrial tracking mode, the ICD/CRT-D activates a **Y out of 8** counter that deactivates mode switching when Y number of cardiac cycles out of the last 8 are below the Intervention Rate. When this **Resolution Criterion** parameter is fulfilled, the ICD/CRT-D returns to the normal programmed pacing mode.

In addition, the ventricular pacing configuration (RV or BiV) and biventricular pacing parameters (LV T-wave protection and Triggering) are programmable separately for mode switching events.

2.9.8.1 Mode Switch Basic Rate

Whenever Mode Switching occurs, the device switches to a non-tracking mode and will provide bradycardia pacing support at the Mode Switch Basic Rate, which is displayed as the **Change of Basic Rate** parameter. Once Mode Switching is terminated, the permanently programmed pacing mode and programmed pacing rate are restored.

2.9.8.2 Post Mode Switch Response

Whenever Mode Switching event terminates, deactivating the mode switch pacing, the device can be programmed to react with a different basic rate for a specified amount of time. Two parameters are used to set the Post Mode Switch Response. **Post ModeSw Rate** sets the rate difference (from permanent program) in pacing rate during the programmed **Post ModeSw Duration** time period. After the **Post ModeSw Duration** expires, the pacing rate is ramped down to the programmed basic rate.

2.9.9 PMT Management

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

2.9.9.1 Protection

PMT protection is accomplished by the following mechanisms (see **Figure 12**):

- Upon detection of a ventricular extrasystole (VES), the lower rate interval and the atrial refractory period (ARP) are reset. Additionally, in VDD mode, the atrial refractory period is initiated with a ventricular pacing pulse that has not been triggered by atrial detection. This prevents a retrograde P-wave with a VA conduction time shorter than the ARP from being sensed and thus from triggering a ventricular pacing pulse. This provides an automatic PMT protection.
- A programmable atrial refractory period extension (ARPE) is available in the DDD and VDD modes. To prevent the initiation of a pacemaker mediated tachycardia (PMT) by a ventricular depolarization not preceded by an atrial depolarization, the ARP will be extended by the ARPE if the ARP was:
  - started by a ventricular sense event outside of the AV delay (e.g., PVC) in DDD and VDD or
  - reset by a ventricular pulse not triggered by an atrial sense event in VDD.

In these instances, the ARP will usually be long enough to prevent sensing of retrograde P-waves. Programming to an ARPE other than 0 ms may rarely be required but could provide additional protection if the ARP is limited or the retrograde conduction time extended.

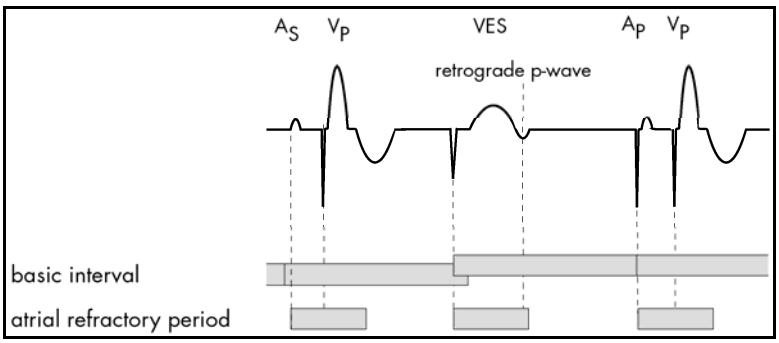


Figure 12. Prevention of PMT by VES starting ARP (DDD).

2.9.9.2 Termination

PMT termination can be accomplished by the following mechanism:

The programmable dynamic AV delay in combination with a fixed TARP (i.e. modulated PVARP) can act as a 'passive' termination of a PMT. Because a PMT is generally at higher rates, the AV delay will be relatively short. This causes the PVARP to be prolonged, which then increases the chance that a retrograde conducted atrial depolarization falls in the PVARP and thus will be inhibited, terminating the PMT (see **Figure 13**).

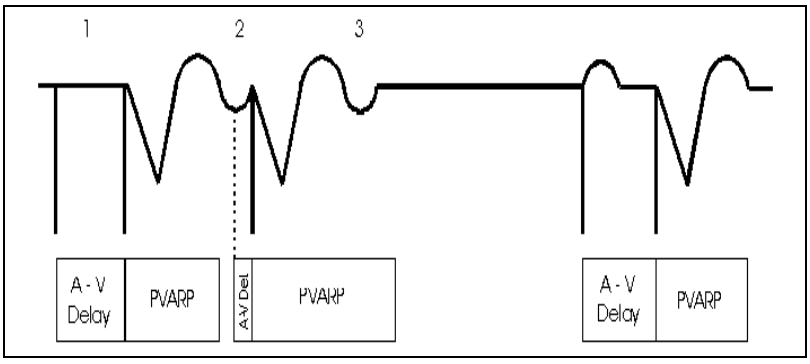


Figure 13. Dynamic AV delay for PMT termination

2.9.9.3 PMT Detection and Termination

In addition to PMT prevention, Lumax contains a programmable PMT detection and termination algorithm. The termination feature will take action in case the prevention was not effective and a PMT is detected. The PMT detection constantly monitors for the presence of a PMT.

The Lumax PMT detection/termination algorithm consists of suspicion, confirmation and termination components and is described as follows.

Suspicion

A PMT is suspected when two criteria are met:

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

Confirmation

When the suspicion criterion has been met, the Lumax slightly modifies the AV delay interval (+ or - 50 ms) or the upper tracking rate (+50ms) for one cardiac cycle. If the Vp-As interval remains stable, a PMT is confirmed. Otherwise, a PMT is not confirmed and the algorithm restarts. Once the PMT algorithm has confirmed a PMT, the cycle is broken as follows:

Termination

Lumax extends TARP (Total Atrial Refractory Period) for one cycle to equal the V-V interval + 50 ms. The Lumax 600/640 & 700/740 models extend the AV delay and the PVARP+ Ext.

2.9.10 VES Discrimination after Atrial Sensed Events

Lumax ICD/CRT-D has a special timing interval (VES/As) – VES discrimination after atrial sense events to identify ventricular extrasystoles.

With each As and As (PVARP), a VES discrimination interval is started in the ventricle. If a ventricular sensed event occurs within the discrimination interval, this event is interpreted as a Vs (ventricular sensed event), and no PVARP after VES protection interval is started.

In the factory setting, the VES discrimination after As is set to 350 ms (programmable: 250…(50)…450 ms in Lumax 300/340 & 500/540 models and up to 500 ms in the Lumax 600/640 & 700/740 models). The VES/As terminates with each ventricular event.

If a ventricular event does not fall within the AV delay or the VES discrimination interval, it is classified as a VES. A ventricular event that is sensed within the VES discrimination interval, but outside the AV delay, starts a VA delay after which an atrial pace is delivered.

2.9.11 Rate-Adaptive Pacing

WARNING

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

Lumax ICD/CRT-D allows the selection of rate-responsive pacing modes. These modes allow the ICD/CRT-D's bradycardia therapy function to adapt the pacing rate to increasing or decreasing patient physical activity, based on data collected from a motion based sensor within the ICD/CRT-D. Separately programmable criteria allow the clinician to control the rate of increase and decrease of pacing, as well as the sensitivity of the sensors in response to motion.

2.9.11.1 Sensor Gain and Threshold

The Sensor Gain defines how much the sensor signal is amplified before it is transformed to a rate change. When the **Sensor Gain** is low (e.g., 2), a great deal of exertion is needed to cause a significant change in sensor output (and an equal change in the pacing rate). When the **Sensor Gain** is high (e.g., 18), little exertion is needed to increase the sensor output. Ideally, the gain is programmed so the maximum desired pacing rate during exercise occurs at a maximum exertion level. The Lumax 600/640 & 700/740 models use **AUTO, VERY LOW, LOW, MEDIUM, HIGH, and VERY HIGH** values to program the Sensor Gain.

The device ignores all activity that occurs below the **Sensor Threshold** because the **Sensor Threshold** defines the lowest sensor output that initiates a change in the pacing rate. Five different threshold settings are available including; **VERY LOW, LOW, MEAN, HIGH, and VERY HIGH**. When the threshold is programmed optimally, the basic rate is the effective rate while the patient is not moving (at rest).

2.9.11.2 Rate Increase/Decrease

The **Rate Increase** and **Decrease** parameters work with the Sensor Gain to determine how quickly the pacing rate will increase or decrease during changes in the sensor output.

2.9.11.3 Maximum Sensor Rate

Regardless of the sensor output, the sensor-driven pacing rate never exceeds the programmable **Max. Sensor Rate**. The maximum sensor rate only limits the pacing rate during sensor-driven pacing.

2.9.11.4 Auto Sensor Gain

The Lumax ICDs/CRT-Ds offer Automatic Sensor Gain **Auto Gain** settings, which allows the Auto Gain parameter to be adjusted automatically.

When the Automatic Sensor Gain is activated, the pulse generator samples the sensor-indicated rate.

- If 90% of the maximum sensor rate is not reached for the duration of 1 hour within a week (7 days), gain is incremented by one step.

- If 90% of the maximum sensor rate is reached for 1 hour within 24 hours, gain is reduced by one step.

2.9.12 Pulse Amplitude

The Pulse Amplitude parameters, are separately programmable for atrial and both ventricular channels and they, define the amplitude in volts of the pacing pulses. The pulse amplitude is also independently programmable for normal bradycardia pacing and fixed to 7.5V for post-shock pacing in RA and RV and as permanent programmed in LV.

2.9.13 Pulse Width

The Pulse Width parameters are separately programmable for atrial and both ventricular channels and they define the duration of the pacing pulses. The pulse widths are also independently programmable for normal bradycardia pacing and fixed to 1.5 ms for post-shock pacing in RA and RV and as permanent programmed in LV.

2.9.14 Post Ventricular Atrial Refractory Period

DR and HF versions only

Immediately following each paced ventricular event, an atrial refractory period is started; this period is called Post Ventricular Atrial Refractory Period or PVARP. Atrial signals are ignored during this time for bradycardia timing purposes to prevent the ICD/CRT-D from sensing inappropriate signals.

2.9.15 PVARP after VES

DR and HF versions only

This parameter extends the Post Ventricular Atrial Refractory Period by the programmed interval, if the ventricular event is not followed by an atrial sensed event (VES).

2.9.16 Auto PVARP

DR and HF versions only

This parameter automatically adjusts the Post Ventricular Atrial Refractory Period (PVARP) and PVARP after VES, if a pacemaker mediated tachycardia (PMT) has been detected and terminated to avoid additional PMT events. After seven days, PVARP and PVARP after VES are reduced as short as possible until a new PMT occurs or the shortest value of these parameters is reached. This helps to keep the PVARP and PVARP after VES as short as possible to protect the patient from PMT.

2.9.17 Noise Response

The Lumax ICD/CRT-D's response to detected noise is to deliver asynchronous pacing in the affected channel.

2.9.18 Post Shock Pacing

Separately programmable bradycardia pacing support is available with the ICD/CRT-D following shock therapy delivery. Because a delay in bradycardia pacing may avoid re-initiation of a tachyarrhythmia, after a short blanking period (1 second), the ICD/CRT-D will begin in standard program (DDI in DR & HF type devices and VVI in VR & DX type devices) bradycardia therapy at the post shock pacing rate, amplitude (fixed to 7.5 V for RV and as permanent programmed for LV), and pulse width (fixed to 1.5 ms) for the programmed **Post-Shock Duration**.

Separate post shock programming of the following parameters is available:

- Ventricular Pacing Configuration (RV, BiV)
- Basic Rate
- Rate Hysteresis
- Fixed AV Delay
- Post Shock Duration

If bradycardia pacing is still required after the post shock duration expires, standard bradycardia pacing parameters are active.

2.10 EP Test Functions

Several EP test functions are available with the Lumax family of ICD/CRT-Ds including; P and R-wave amplitude, pacing and shock impedances, retrograde conduction and pacing threshold measurements. Extensive testing of defibrillation thresholds as well as the ability to verify the effectiveness of anti-tachycardia pacing and defibrillation shocks are also available.

2.10.1 P and R-wave Amplitude Measurements

The Lumax ICDs/CRT-Ds provide a P-/R-wave test for measuring the amplitude of intrinsic events during follow-up examination. The test determines the amplitudes with a predetermined temporary pacing mode.

To permit evaluation of the sensing function, the pacing rate must be lower than the patient's intrinsic rate. In demand pacing, the proper sensing function can be recognized if the interval between intrinsic events and the following pacing pulse equals the basic interval (if no Hysteresis is programmed). The following parameters are programmable when performing the measurements:

- Pacing Mode
- Ventricular Pacing (HF(-T) only)
- Pacing Rate
- Upper Rate (Dual Chamber modes only, not in Lumax 600/640 & 700/740 models)
- Pulse Amplitude (Not applicable to Lumax 600/640 & 700/740 models)
- Pulse Width (Not applicable to Lumax 600/640 & 700/740 models)

For evaluation of the sensing function, the pulse generator features an intracardiac electrogram (IEGM) with marker signals to indicate sensed and paced events.

2.10.2 Pacing Impedance Measurements

The Lumax ICDs/CRT-Ds have the ability to perform automatic and manual pacing impedance measurements. The devices can measure the pace impedance in all leads; RA, RV and LV. In Lumax 300/340 and 500/540 models, the measurement can be performed in any the of the pacing configurations; RA, RV, LV or BiV. In Lumax 600/640 and 700/740 models, it uses a sub-threshold measurement in all channels connected to leads automatically. In all Lumax devices, the LV pacing polarity is also programmable for impedance measurements additionally. (See **Section 2.1**).

The impedance in Lumax 300/340 and 500/540 models is measured using a triggered mode with paces of 2.4 Volts and 0.5 ms, or programmed value (whichever is higher). During automatic measurements both atrial (only with an atrial pacing mode) and ventricular (RV, LV or BiV) impedances are measured. However, they will not be measured if the normal pacing output is programmed to a value greater than the impedance test output (2.8 V).

2.10.3 Shock Impedance Measurements

The Lumax ICDs/CRT-Ds have the ability to perform automatic and manual painless shock impedance measurements. The devices can measure the shock impedance by delivering an undetectable 3 nJ shock by applying 1 mA of current. The device then measures the resulting voltage drop and calculates the resulting shock impedance. This impedance measurement is tied to the pacing impedance measurement, meaning that the pacing impedance measurement is done daily, and shock impedance is done (concurrently with pacing impedance measurement) every fourth day. The results of these impedance measurements are available through the device's statistics function.

2.10.4 Testing for Retrograde Conduction

Retrograde conduction from the ventricles to the atrium can be assumed when a 1:1 relationship between the ventricular stimulation and atrial depolarization has been obtained with a constant coupling interval during ventricular stimulation. The ICD/CRT-D features a test for measuring retrograde conduction time. During operation of this test, the patient is paced (in VDI mode) at an increased ventricular rate over several cycles while the retrograde conduction time is measured. Therefore, the pacing **Rate** must be programmed at a rate higher than the patient's intrinsic rhythm.

This measurement can be made for both the right and left ventricles, but only one at a time. The ventricle being tested, pacing rate, voltage and pulse width are all programmable. In addition, the pacing polarity of the left ventricle is also programmable as described in **Section 2.1**. Both the programmer display and printout provide measured retrograde conduction times. The duration of time that the test is conducted is based on how long the Measure button is depressed. The paper speed for the test printout is also programmable for this test.

To prevent retrograde P-waves from triggering ventricular pulses, thereby mediating a "re-entry" tachycardia (pacemaker mediated tachycardia, PMT), it is recommended that the programmed post-ventricular atrial refractory period be programmed longer than the retrograde conduction time.

2.10.5 Pacing Threshold

The test is activated as a temporary program with specific operation. Removal of the programmer head immediately stops the test and reactivates the permanent program.

The following parameters are programmable during the pacing threshold test: Appropriate chamber and pacing mode, pacing rate, AV Delay (if appropriate), upper rate, pulse amplitude and pulse width, and number of pulses for each test voltage. In addition, the preferred automatic printing capabilities are adjustable. The pacing modes available for the threshold test are AAI (atrial only), VVI (LV and RV only), DDI, and DDD. The pulse amplitude is easily adjustable during the threshold testing by selecting the desired value from the table.

2.10.6 Arrhythmia Induction Features

The ICD/CRT-D offers three arrhythmia induction methods for non-invasive EP testing. These include the following:

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

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.

HF Burst Induction consists of a large number of pulses delivered in rapid succession over a period of several seconds. The frequency of the pulses and the duration of the burst are defined by the user.

Burst + PES (Lumax 300/340 & 500/540 models only) Induction delivers a programmed number of pacing stimuli followed by a programmable number (**Number S1**) of timed extra stimuli. The burst rate (intervals) is independently programmable, as is the chamber being stimulated (RV, LV or BiV). The interval between S1s and the remaining programmed extra stimuli (PES: S1 through S4 possible) are also programmable.

Shock on T induction mode allows tachyarrhythmia induction by means of a timed T wave shock delivered after a series of paced stimuli. **Energy** of the T wave shock, number of pulses (**Number S1**) in the pulse train, synchronization interval (**R-S1**) and the shock **Coupling** interval are all programmable.

2.10.7 Manual Shock

The ICD/CRT-D can deliver a manual shock on demand through a programmer command in the EP test menu. For manual shocks, the **energy**, **polarity** and **waveform** are programmable by the user. To deliver a shock, place the wand over the device and select the **Start Shock** button. A confirmation menu will appear and the shock command will be delivered upon selecting the **OK** button in this screen. After each manual shock, the EP test screen will display the shock energy, lead impedance and charge time.

2.10.8 Test Shock

The ICD/CRT-D can deliver a 1 Joule (R-wave synchronous) test shock on demand through a programmer command in the EP test menu. This shock is designed to measure the shock impedance and test the integrity of the shock electrodes of an implanted ICD lead.

NOTE:

When the test shock is administered, VF detection is automatically enabled.

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

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.

2.10.9 Manual ATP

The ICD/CRT-D can deliver a manual ATP on demand through a programmer command in the EP test menu. To deliver an ATP sequence, place the wand over the device and select the **Start ATP** button. A confirmation menu will appear and the programmed pacing sequence command will be delivered upon selecting the **OK** button in this screen. Programming of the manual ATP is similar to the programming available for automatic ATP therapy as described in **Section 2.8.2**.

2.10.10 Emergency Shock

The ICD/CRT-D can deliver an emergency maximum energy shock on demand through a programmer command in the EP test menu. For emergency shocks, the energy (maximum 30 or 40 J), polarity (Standard) and waveform (Biphasic) are pre-defined. To deliver a shock, place the wand over the device and select the **Emergency Shock** button. A confirmation menu will appear and the shock will be delivered.

2.11 Special Features

The Lumax includes several special features to improve ease of use and provide additional information to the user.

2.11.1 ICD Therapy Status

Interrogate the device to observe the ICD Therapy window (upper right hand corner) of the main programming screen which indicates the ICD Therapy status (either ON or OFF). The overall ICD therapy can be controlled by selecting ON (enabled) or OFF (disabled). If the device has not been interrogated, the programmer displays “Unknown” highlighted in red in the ICD therapy window.

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 the person handling the device during the implant procedure.

2.11.2 Thoracic Impedance

The thoracic impedance is measured between the distal shock-coil of the RV lead and the ICD housing. Up to 1,024 measurements are done every hour and these measurements are then averaged. The 24 measurements per day are stored in the device and transmitted via Home Monitoring. The Home Monitoring website then displays a trend of the daily average. The same trend of daily TI averages is displayed on the programmer upon interrogation of the 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 a revision.

2.11.3 Home Monitoring®

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

BIOTRONIK conducted the TRUST study to evaluate the safety and effectiveness of Home Monitoring. Refer to Section 1.6.4 for details regarding the study design and results. With the TRUST study, BIOTRONIK was able to show the following with regards to Home Monitoring:

- BIOTRONIK Home Monitoring information may be used as a replacement for device interrogation during in-office follow-up visits.

- A strategy of care using BIOTRONIK Home Monitoring with office visits when needed has been shown to extend the time between routine, scheduled in-office follow-ups of BIOTRONIK implantable devices in many patients. Home Monitoring data is helpful in determining the need for additional in-office follow-up.
- BIOTRONIK Home Monitoring-patients—who are followed remotely with office visits when needed—have been shown to have similar numbers of strokes, invasive procedures and deaths as patients followed with conventional in-office follow-ups.
- BIOTRONIK Home Monitoring provides early detection of arrhythmias.
- BIOTRONIK Home Monitoring provides early detection of silent, asymptomatic arrhythmias.
- Automatic early detection of arrhythmias and device system anomalies by BIOTRONIK Home Monitoring allows for earlier intervention than conventional in-office follow-ups.
- BIOTRONIK Home Monitoring allows for improved access to patient device data compared to conventional in-office follow-ups since device interrogation is automatically scheduled at regular intervals.

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

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.

2.11.3.1 Transmission of Information

The implant transmits information with a small transmitter, which has a range of about 2 meters. The patient's implant data are sent to the corresponding patient device in configurable periodic intervals. The transmissions may also be activated by the detection of a cardiac event, as programmed. The types of transmissions are discussed in **Section 2.11.3.3**.

The minimal distance between the implant and the patient device must be maintained at 15 cm.

2.11.3.2 CardioMessenger II

The CardioMessenger II patient device (**Figure 14**) is designed for use in the home and is comprised of the mobile device and the associated charging station. The patient can carry the mobile device with them during his or her occupational and leisure activities. The patient device is rechargeable, allowing for an approximate operational time of approximately 24 hours. It receives information from the implant and forwards it via telephone networks (cellular or traditional) to the BIOTRONIK Service Center.

For additional information about the CardioMessenger II, please refer to its manual.

Figure 14: Example of CardioMessenger II with Charging Stand

2.10.2.3 Transmitting Data

The implant's information is digitally formatted by the BIOTRONIK Service Center and processed into a concise report called a Cardio Report. The Cardio Report is available in two formats; via fax or via BIOTRONIK's secure Internet connection. Reports are available depending on the type of report transmission—periodic or event triggered. This Cardio Report, which is adjusted to the individual needs of the patient, contains current and previous implant data. An Intracardiac Electrogram (IEGM) is included for each tachycardia episode (VT/VF). The Internet site allows the physician to "program" the Service Center on how the Cardio Report information is supplied; either by fax, SMS message or on the Internet. All reports use a similar report format.

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 36 Additionally, Table 36 provides system specifications that are recommended for optimizing usage of the Internet.

Table 36: System Requirements/Recommendations

	System Requirements	System Recommendations (for Optimal Usage)
Screen Resolution	1024 x 768	≥ 1280 x 1024
Internet Bandwidth	56 kB/sec	≥ 128 kB/sec (DSL, cable modem)
PC	800 MHz Pentium processor, 128 MB RAM	N/A
Internet Browser	MS Internet Explorer 5.5	≥ MS Internet Explorer 5.5 - or - ≥ Mozilla 1.8 (Firefox ≥ 2.0)
Acrobat Reader	Version 6.1	Version 6.1 or higher

Table 36: System Requirements/Recommendations		
	System Requirements	**System Recommendations (for Optimal Usage)**
Communication Channel	Fax (G3) or e-mail	Fax (G3), e-mail or mobile phone

2.11.3.3 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 – the ICD/CRT-D detects certain events, which initiate a transmission (IEGM included if not yet sent)
- Periodic IEGM report – certain event reports can be programmed to have an IEGM included each time that they are transmitted. The IEGM includes comprehensive event details with up to 10 seconds of IEGM (8 seconds pre-detection and 2 seconds pre-termination).
- Programmer triggered report – a test message transmitted upon request of the physician in the clinic.

Daily Report

The time of daily Home Monitoring Report transmission is programmable. For periodic messages, the time can be set anywhere between 0:00 and 23:59 hours. It is recommended to select a time between 0:00 and 4:00.

Periodic Report with IEGM

The Lumax ICDs and CRT-Ds can be programmed to transmit IEGMs with the daily Home Monitoring report on a periodic basis with the interval selected; OFF, 2, 3, 4, or 6 months.

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 Detection while Magnet applied (DTM) episode)
- Ongoing Atrial Monitoring Episode lasting longer than the programmed time (0.5, 6, 12 or 18 hours)
- Impedance out-of-range for A, RV, LV, shock lead (painless)
- Special Device Status
- First ineffective 30 J shock detected
- Initial detection SVT
- Percent of ventricular sensing below set limit
- Device status – ERI/EOS/ROM-Mode

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.

NOTE:

Battery voltage and pace/sense lead impedance are measured before the first transmission of the day. Therefore, the first transmission may occur 2 minutes after the programmed transmission time.

2.11.3.4 Description of Transmitted Data

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

Device Status & Home Monitoring Settings
Containing device and message identifying values that pertain to the implant and Home Monitoring:

- Implantation Date
- Battery voltage & Date of Measurement
- Device Status
  - Master-switch (e.g., ICD Therapy ON or OFF)
  - Standard error flags
- Current Consumption for ERI calculation (done by the Service Center)
- Date and time of Last Follow-up and Program Counter
- Message Creation Date/Time
- Device Serial Number
- Current ROM/RAM Version Information

Leads

- Automatic Threshold Monitoring
  - Measured RV pacing threshold
  - Measured LV pacing threshold
  - RV enabled/disabled
  - LV enabled/disabled
  - Date/time of ATM measurement
- Pacing Impedance (RA, RV, LV/BiV)
  - Mean of 4 daily measurements
- Sensing Amplitude (RA, RV, LV(BiV)
  - Mean of 4 daily measurements
  - Minimum of 4 daily measurements
- Painless Shock Impedance
  - Mean of 4 daily measurements
- Thoracic Impedance
  - Hourly mean of up to 1024 measurements/hour
- Data of last Shock
  - Impedance & Date of last Shock delivered
  - Complete Shock Holter Entry

Pacing Counters (Brady)

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

The above parameters are transmitted as 3 byte counter.

Pacing Counters (CRT)

- LV-RV-Sequences
  - BiVp (RVp-LVp or LVp-RVp
  - RVs-LVp
  - RVp-noLVp, RVs-noLVp (LV T-wave protection ON)
  - LVp, noLVp (LV pacing only)
- VES-Triggered Resynchronization
  - VES-LVp (Triggering: RVs+RVES)
  - VES-noLVp (LV T-wave protection ON)
  - VES per hour

  The above parameters are transmitted as 3 byte counter.

Atrial Arrhythmia

- Atrial Tachy Episodes (36 out of 48 criteria)
  - Life-Time Counter on AT/AF detections
  - Atrial Burden per Day°
  - Ongoing Atrial Episode Time (programmable for 30min, 6, 12 or 18 hrs)
- Mode Switching
  - Number of Mode Switches per Day°
- SVT (Discrimination within VT zones)
  - Lifetime Counter of Detections in SVT
  - Number of SVT by SMART
  - Number of SVT without SMART
  - Ongoing SVT episode (current episode open)

Ventricular Arrhythmia

- Lifetime Counters
  - Detections in VT1, VT2, VF,

  - Initial Detections during Detection while Magnet applied (DTM) (induction)
  - Started + successful ATP in VT
  - Started + successful ATP-One-Shot in VF
  - Started + cancelled + successful Shocks
  - Shock Path
  - Ineffective maximum energy shocks
- Date, Time and Number of last Episode (number as in episode listing in Holter)
- Other Ventricular Arrhythmia
  - 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 ventricular heart rate
  - Minimal ventricular heart rate at rest
  - Max/mean ventricular heart rate during atrial episodes
- Heart Rate Variability
  - Atrial SDANN per day (5 min periods of As-As)
- Patient Activity
  - Duration per day (from Sensor)

Transmitted Device Settings

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

- Leads – (e.g., Pacing Output, Configuration)
- Brady - (e.g., Basic Rate, UTR, AV-Delays, RV Sensitivity)
- CRT - (e.g., Configuration, VES Triggering, VV delay)
- IOPT - (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 energies)
- HM Settings - (e.g., ON/OFF, transmission time (daily), IEGM transmissions ON/OFF, periodic IEGM, ongoing atrial episode, statistics, holter)

System Information
Information is also added by the CardioMessenger II to the message from the implant. This information contains the following data:

- Timing delay between reception in the CardioMessenger II and Delivery to a provider
- Cardio Messenger II Serial Number
- Technical Parameters for Troubleshooting

2.11.3.5 IEGM Online HDs

The Lumax ICDs/CRT-Ds provide the ability to transmit IEGM Online HD (IEGM and marker data) from the most recent SVT/VT/VF/AF episodes as an additional to the current messages.

An IEGM with up to 3 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 up to 8s of pre-detection IEGM and up to 2s of pre-termination IEGM

If the episode is not terminated each IEGM Frame shall contain up to 10s 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 (8s + 2s), because HM is triggered after termination detection.
- If AF, SVT, or VT monitoring episodes are terminated, both pre-detection and post-detection parts are sent (8s + 2s), if this episode is the most actual episode at the time of the next periodic message, because termination of the monitoring episodes does not trigger a message. If it is not terminated only pre-detection is sent.

- If an ongoing atrial episode fulfills a programmed time duration criteria, a message is triggered to provide the physician with the information early on.
- For the periodic IEGM only a pre-detection-part is available, recording of this episode is performed right before a periodic message, as often as configured.

The Lumax ICD/CRT-D transmits 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 setting (VT zones activated)
- SMART path (for SVT)
- Duration of episode

The following markers are also transmitted: A_S (including A_{rs}), A_P, V_S (including V_{rs}), V_P, VT1, VT2, VF, SVT (atrial and refractory sensed events included with sensed events), and AF.

The IEGM Online HD from the most recent episode is 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 Lumax ICD/CRT-D includes a programmable parameter to disable or enable the IEGM transmission. The default value is “enabled.”

2.11.3.6 Scheduling Remote Follow-up

The Lumax 700/740 and 600/640 ICDs/CRT-Ds provide the ability to automatically schedule remote follow-ups using the programmer. This feature has the following two options:

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

Periodic IEGM for follow-up					
Cycle duration [days]	90				
	1st date	2nd date	3rd date	4th date	5th date
Transmission date(s)	08/19/2011				

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

Periodic IEGM for follow-up					
Cycle duration [days]	Date				
	1st date	2nd date	3rd date	4th date	5th date
Transmission date(s)	08/19/2011	10/19/2011	01/19/2012	05/18/2012	08/20/2012

*If the 5 dates have been expired the standard period for periodic IEGM (30 days) will be enabled.

2.11.4 Real-time IEGM Transmission

The pulse generators provide real time transmission of the unfiltered intracardiac electrogram (IEGM) to the programmer. IEGMs from the atrium and ventricles can be simultaneously recorded with a bandwidth of 0.5 to 200 Hz. Depending on the device, the following channels are simultaneously recorded:

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

The IEGMs may be transmitted to the programmer via the programming wand positioned over the implanted pulse generator. 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, and may be displayed on the programmer screen and printed on the ECG recorder.

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

Please refer to the appropriate software technical manual for a description of marker signal operation.

2.11.5 Capacitor Reforming

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 Lumax devices automatically re-form the capacitors after every 3 months. 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 into an internal resistor. 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.

2.11.6 Patient and Implant Data

The Patient and Implant data screens allow input of data regarding the patient name, demographics, implanting physician, date, devices implanted, location of the implant, and various conditions related to the patient. This information is transmitted to the ICD/CRT-D and resides in the device memory for later recall if needed.

2.11.7 System Status

Various device parameters can be monitored through the Status section of the programmer screen. Displayed data includes ICD/CRT-D information, charge circuit parameters, capacitor reform information, battery status and voltage, and lead information. The system status screen presents a large variety of information about the Lumax ICDs/CRT-Ds including:

- Serial number (always displayed after interrogation)
- Software Release
- ICD status
- PID Number
- Battery status
- Battery voltage
- Last charge event and Last event with a maximum energy charge:
  - Energy
  - Charge time
  - Date
  - Time
- Total number of charges
- Last Home Monitoring message
  - Type of message
  - Time and date

2.11.8 HF Monitor Statistics

The ICD/CRT-D stores a variety of useful diagnostic data related to heart failure status as described in the following sections.

2.11.8.1 Patient Activity

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

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

2.11.8.2 Mean Heart Rate

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

2.11.8.3 Mean Heart Rate at Rest

On a daily basis, the Lumax CRT-D measures and stores the patient's resting heart rate (MHRR). Average values are calculated over a defined period. The daily value is based on the smallest mean value in any evaluation window over the resting period. The mean heart rate is calculated based on both ventricular sensed and paced events. All types of events, including VES (PVC) shall be included in the calculation of the mean value.

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

2.11.8.4 Heart Rate Variability

Heart Rate Variability, which is the standard deviation of the 5-minute mean normal to normal interval over the recorded time is available in the statistics of the Lumax devices. This is based on the atrial rate (P-P).

2.11.9 Holter Memory

Various device information is available within the Holter memory. The Holter memory can be configured a number of different ways depending on the physician's preference.

2.11.9.1 Episode List

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.

Episode Details

Detailed information about each individual episode 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.

Stored IEGM

The ICD/CRT-D can store up to 32 minutes of triple chamber intracardiac electrograms (IEGMs) including the history and prehistory of the following events regarding AT/AF, VT/VF and SVTs:

- Time
- Zone
- Descriptions
- PP and RR intervals (before detection and termination, displayed only in the episode list)
- IEGMs

2.11.9.2 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
- Shock Pathway

2.11.9.3 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.
- SVT
- VT1
- VT2
- VF

SVT Details

- AFlut
- AFib
- 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

2.11.10 Timing Statistics

The ICD/CRT-D stores a variety of useful diagnostic data of the bradycardia history as described in the following sections.

2.11.10.1 Event Counters

The total percentages of atrial sensed (PVARP and atrial refractory period), atrial paced, right ventricular sense (VES and refractory period) and ventricular paced events since the statistics package was initiated are available. The total percentage of time for each of the above listed events is also available. The total numbers of atrial and ventricular events are also recorded.

2.11.10.2 Event Episodes

The total percentages of several timing events are displayed under the Event Episode heading. These include:

Pacing Counters (Brady)

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

Pacing Counters (CRT)

- LV-RV-Sequences

  - BiVp (RVp-LVp or LVp-RVp
  - RVs-LVp
  - RVp-noLVp, RVs-noLVp (LV T-wave protection ON)
  - LVp, noLVp (LV pacing only)
- VES-Triggered Resynchronization
  - VES-LVp (Triggering: RVs+RVES)
  - VES-noLVp (LV T-wave protection ON)
  - VES per hour

2.11.10.3 Rate Trends

The device counts the number of paced and sensed events and displays them in two different graphs (rate and paced). These trends are available for 24 hour periods and as long-term durations.

2.11.10.4 Rate Histogram

The rate histogram shows the percentage of time the rate lies within given heart rate bins regardless if the sensor is used or not. The heart rate range is divided into sixteen segments ranging from less than 40 to greater than 380 ppm.

2.11.10.5 Counters

The following counters are available within the Timing Statistics:

- PMTs
- Mode Switching Episodes
- Safety Window Pacings

2.11.11 Atrial Arrhythmias

The activity report provides information that can assist the physician in determining the patient's susceptibility to atrial arrhythmias including Atrial Burden (length of episodes), Number of Episodes and Stress Duration (minutes/day). This screen also includes graphing of the ventricular reaction to atrial arrhythmias including the rates of paced and sensed ventricular events.

2.11.12 Ventricular Arrhythmias

The activity report provides information in graphic form that details number of PVCs/hour.

2.11.13 Sensor

This report contains individual rate bins for the sensor indicated rate percentages. The activity report provides information that can assist the physician in optimizing pacing and/or sensor parameters.

2.11.14 Sensing

The activity report provides trend information on atrial and right ventricular sensing measurements.

2.11.15 Impedances

The activity report provides trend information on atrial and right ventricular pacing impedance as well as shock impedance measurements.

2.11.16 Automatic Threshold

The activity report provides trend information on right and left ventricular pacing thresholds, if active.

2.11.17 Asynchronous Pacing Modes

The Lumax 700/740 and 600/640 models offer the following asynchronous pacing modes for use during medical procedures:

- V00 – asynchronous pacing in the ventricle
- D00 – asynchronous pacing in the atrium and ventricle with a fixed AV delay for conduction between chambers

Tachyarrhythmia detection is deactivated when using these asynchronous modes in the Lumax 700/740 and 600/640 devices.

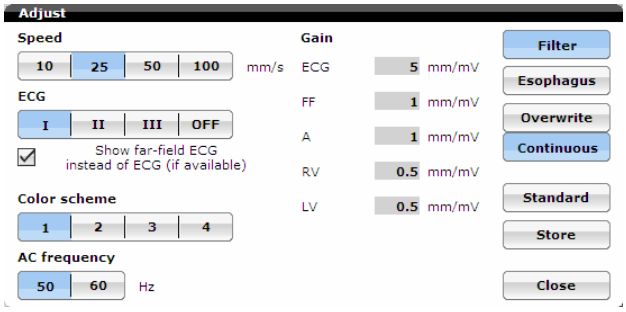
The asynchronous modes are intended for use during medical procedures, such as cautery. In patients with inadequate intrinsic rhythm, the pacemaker should be reprogrammed to an asynchronous mode during the procedure in order to prevent inhibition by electromagnetic interference. Thus, the asynchronous modes V00 and D00 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 V00 and D00 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.

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

The Lumax 700/740 and 600/640 models offer a new feature, leadless ECG, which 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 (near-field) IEGM, conventional surface ECG signals (I, II, or III) or leadless ECG (FF IEGM) as display options automatically. The figure below shows FF option:



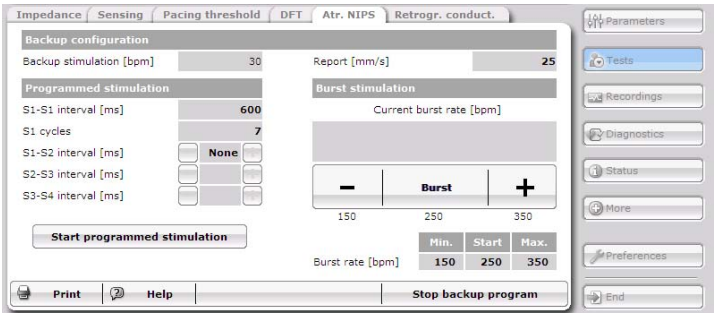
2.11.19 Advanced AT/AF Diagnostics (Lumax 700/740 only)

The Lumax 700/740 models offer the ability to record longer pre-history of atrial episodes (AT/AF events). This feature has been doubled from 30 seconds to > 1 minute. This feature is important in terms of genesis evaluation of atrial tachyarrhythmias.

2.11.20 Atrial NIPS (Lumax 700/740 & 600/640 only)

The Lumax 700/740 models offer Atrial Non-Invasive Programmable Stimulation (NIPS), which allows manual stimulation in the atrium via the programmer. With Atrial NIPS manual stimulation in the atrium can be programmed to the following (shown in the figure below):

- Programmed stimulation from 80 to 2000 ms
- Burst Stimulation from 30 to 800 bpm
- Backup stimulation in VVI mode



3. 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.

4. Implant Procedure

4.1 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 ICS 3000 and Implant Module based DFT testing, the following cabling and accessories are available:

PK44 - used to connect the Implant Module to implanted lead systems for complete testing of the lead systems during the implant procedure. 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-44 cable. The PA-3 adapter is used to connect DF-1 compatible leads to the PK-44 cable.
- Adapter PA-4 - used to connect the PK-44 cable to sensing and pacing leads while the stylet is still inserted.

The ICD/CRT-D System also has the following accessory available (at the discretion of the physician) for the implant procedure:

- Test housing that allows acute testing of the lead system prior to opening the sterile package.

Perform an interrogation of the ICD/CRT-D. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Lumax ICD/CRT-D. Note that the battery status may appear lower than its true value when the ICD/CRT-D is not at body temperature. Program detection and therapy to “Disabled” prior to handling the Lumax 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)
- 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 30 joules
- Insertion and withdrawal forces as specified by ISO 5841-3 (IS-1) and ISO 11318:1993 (E) DF-1

The following leads were evaluated in a retrospective study with BIOTRONIK's ICDs/CRT-Ds:

- Medtronic Sprint™ Lead 6932
- Medtronic Sprint Lead 6943
- Medtronic Sprint Quattro™ Lead 6944
- Medtronic Transvene™ RV Lead 6936
- St. Jude (Ventritex) TVL™- ADX Lead 1559
- St. Jude SPL® SP02 Lead
- Guidant ENDOTAK® DSP Lead
- Guidant ENDOTAK Endurance EZ Lead, ENDOTAK Reliance Lead
- Guidant (Intermedics) Lead 497-24.

The following leads were bench tested for compatibility with BIOTRONIK's ICDs/CRT-Ds:

- Guidant ENDOTAK Endurance Lead "CPI 0125"
- Guidant ENDOTAK Reliance Lead 0148
- Medtronic Sprint Lead 6932
- Medtronic Sprint Lead 6942
- Medtronic Sprint Lead 6943
- Medtronic Sprint Lead6945
- Medtronic Sprint Quattro Lead 6944
- St. Jude Riata® Lead 1571/65

- St. Jude SPL SPO1 Lead

WARNING

Left Ventricular Lead Systems – BIOTRONIK CRT-Ds maybe 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)

The following LV leads were evaluated in the OPTION CRT/ATx study with BIOTRONIK's CRT-Ds:

- Guidant-EASYTRAK® IS-1 Lead
- Guidant-EASYTRAK LV-1 Lead
- Guidant-EASYTRAK 2 Lead
- Guidant-EASYTRAK 3 Lead
- Medtronic-Attain® OTW Lead
- St. Jude-Aescula™ Lead
- St. Jude-QuickSite® Lead
- Biomec-Myopore™ Epicardial Lead
- Medtronic-Epicardial 5071 Lead
- Medtronic-CapSure® EPI Lead
- BIOTRONIK-ELC 54-UP Lead

The following LV leads were bench tested for compatibility with BIOTRONIK's CRT-Ds:

- Guidant EASYTRAK 4512 (unipolar) Lead
- Guidant EASYTRAK 4513 (bipolar) Lead
- Guidant EASYTRAK 3 4525 (bipolar) Lead
- Medtronic Attain OTW 4193 (unipolar) Lead
- Medtronic Attain OTW 4194 (bipolar) Lead
- Medtronic Attain LV 2187 (unipolar) Lead
- St. Jude Medical QuickSite 1056K (unipolar) Lead
- ELA SITUS® OTW (unipolar) Lead
- BIOTRONIK Corox+ LV-H 75-BP #346542
- BIOTRONIK Corox OTW 75-UP Steroid #346542 (unipolar)

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 (25 Ω), 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 (25 Ω). 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.

4.2 Lead System Evaluation

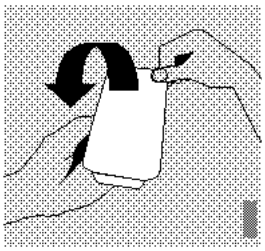
The ICD/CRT-D is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1, wherever stated in this manual, refers to the international standard [Reference ISO 11318:1993].

Refer to the appropriate lead system technical manual.

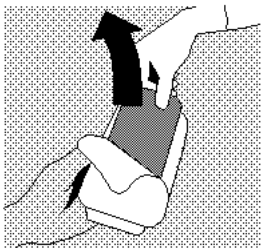
4.3 Opening the Sterile Container

The Lumax 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.

4.4 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 ICD/CRT-D should be implanted with the etched side facing up. 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 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)).

4.5 Lead to Device Connection

The Lumax ICD/CRT-Ds have been designed and are recommended for use with a defibrillation lead systems having one IS-1 connector for ventricular sensing and pacing and up to two DF-1 connectors for 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 15 depicts the configuration of the header ports on the Lumax 300/340 ICD/CRT-Ds, where HV1/RV and HV2/SVC are for DF-1 connectors, and A P/S and V P/S are for IS-1 connectors. Figure 16 depicts the configuration of the header ports on the Lumax 500/540, 600/640 and 700/740 ICD/CRT-D devices.

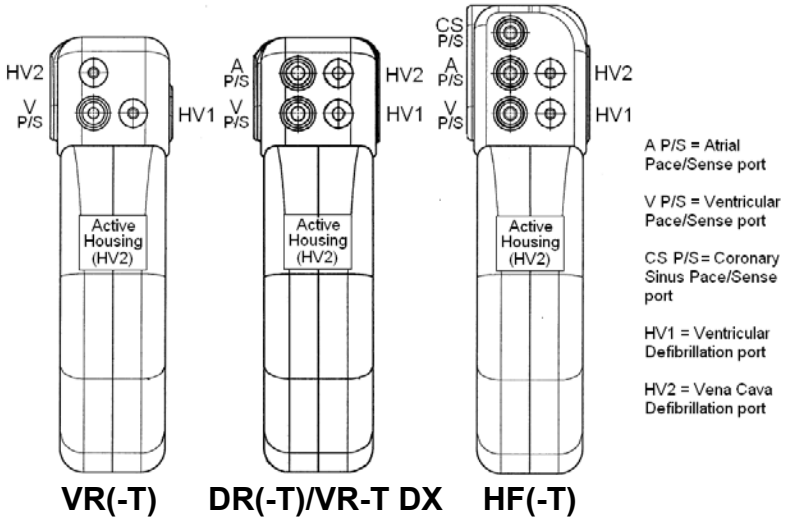


Figure 15. Lumax 300/340 ICD and CRT-D Header Ports

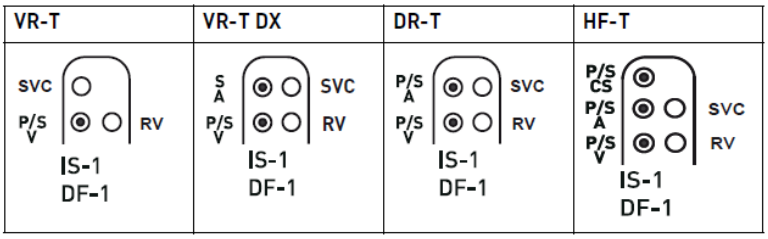


Figure 16. Lumax 500/540, 600/640 & 700/740 ICDs and CRT-D Header Ports

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 overtighten the setscrew(s). Use only the BIOTRONIK supplied torque wrench.

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

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. If necessary, apply silicone oil only to the o-rings on the connector (not the connector pin).
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.

4.6 Blind Plug Connection

The Lumax DR ICD and HF CRT-D are 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.

4.7 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 and interrogated.

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 the person handling the device during the implant procedure.

4.8 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 (25 Ω), 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. Shipment mode is automatically deactivated when electrophysiological tests (e.g., Impedance Measurement) are initiated by the programmer. 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 Form provided with the ICD/CRT-D and return it to BIOTRONIK.

5. Follow-up Procedures

5.1 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 and interrogated. 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.

5.2 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. After this period, 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 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 ppm with a pulse width of 0.4 ms and pulse amplitude of 2.8 volts and 500 ohm pacing impedance with all shocks at maximum programmable energy at 37C. It is assumed that the shocks are equally spaced throughout the life of the ICD/CRT-D. 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. If there are multiple available batteries for a particular device, the worst case longevity option is presented.

5.2.1 Lumax 300/340 Devices

The single chamber Lumax (Lumax 300 VR, Lumax 340 VR, Lumax 300 VR-T, and Lumax 340 VR-T) ICDs are intended to operate for more than 4 years under normal use. Table 37 provides longevity estimates for the Lumax 340 VR-T ICD, which has the worst case longevity estimates of the devices listed above. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 37 Lumax 340 VR-T Longevity Estimates

	Pacing Support			
Shocks per year (max energy)	**0%**	**15%**	**50%**	**100%**
4	6.0	5.8	5.4	4.9
5	5.7	5.5	5.2	4.7
6	5.4	5.3	4.9	4.5
7	5.2	5.0	4.7	4.4
8	5.0	4.8	4.5	4.2
9	4.8	4.6	4.4	4.0
10	4.6	4.4	4.2	3.9
11	4.4	4.3	4.1	3.8
12	4.2	4.1	3.9	3.7

The dual chamber Lumax (Lumax 300 DR, Lumax 340 DR, Lumax 300 DR-T, and Lumax 340 DR-T) ICDs are intended to operate for more than 5 years under normal use. **Table 38** provides longevity estimates for the Lumax 340 DR-T ICD (order number 355267), which has the worst case longevity estimates of the devices listed above. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 38 Lumax 340 DR-T Longevity Estimates				
	Pacing Support			
Shocks per year (max energy)	0%	15%	50%	100%
4	5.7	5.4	4.8	4.1
5	5.4	5.1	4.6	3.9
6	5.2	4.9	4.4	3.8
7	5.0	4.7	4.2	3.7
8	4.8	4.5	4.1	3.6
9	4.6	4.4	3.9	3.4
10	4.4	4.2	3.8	3.3
11	4.2	4.0	3.7	3.2
12	4.1	3.9	3.6	3.2

Table 39 and Table 40 provide longevity estimates for the Lumax 300 & 340 HF-T CRT-D with Greatbatch batteries. The tables are limited to 100% ventricular pacing because that is the goal for each CRT-D device. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 39 Lumax 300 HF-T Longevity Estimates	
Shocks per year	100% Pacing Support (in years)
4	5.4
5	5.3
6	5.2
7	5.1
8	4.9
9	4.8
10	4.7
11	4.6
12	4.5

Table 40 Lumax 340 HF-T Longevity Estimates	
Shocks per year	**100% Pacing Support (in years)**
4	5.2
5	5.0
6	4.8
7	4.7
8	4.6
9	4.4
10	4.3
11	4.2
12	4.1

The Lumax 300/340 HF CRT-Ds (Lumax 300 HF-T, and Lumax 340 HF-T) are intended to operate for more than 5 years under normal use.

5.2.2 Lumax 500/540 Devices

The single chamber Lumax 500/540 ICD variants (Lumax 500 VR-T and Lumax 540 VR-T) of are intended to operate for more than 6 years under normal use. **Table 41** provides longevity estimates for these devices. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 41 Lumax VR-T Longevity Estimates					
		Pacing Support			
Device	**Shocks per year**	**0%**	**15%**	**50%**	**100%**
500 VR-T	4	8.3	8.1	7.6	7.0
	8	7.0	6.9	6.5	6.1
	12	6.1	6.0	5.7	5.4
540 VR-T	4	8.7	8.5	8.0	7.4
	8	7.1	6.9	6.6	6.2
	12	6.0	5.9	5.6	5.3

The dual-chamber Lumax 500/540 variants (Lumax 500 DR-T, and Lumax 540 DR-T) of ICDs are intended to operate for more than 6 years under normal use. Table 42 provides longevity estimates for these devices. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 42 Lumax DR-T Longevity Estimates					
		Pacing Support			
Device	**Shocks per year**	**0%**	**15%**	**50%**	**100%**
500 DR-T	4	7.9	7.5	6.7	5.8
	8	6.7	6.4	5.8	5.2
	12	5.9	5.6	5.2	4.6
540 DR-T	4	8.3	7.9	7.1	6.2
	8	6.8	6.5	6.0	5.4
	12	5.8	5.6	5.2	4.7

The Lumax 540 VR-T DX ICDs are intended to operate for more than 6 years under normal use. Table 43 provides longevity estimates for these devices. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 43 Lumax VR-T DX Longevity Estimates					
		Pacing Support			
Device	**Shocks per year**	**0%**	**15%**	**50%**	**100%**
540 VR-T DX	4	8.3	8.1	7.6	7.1
	8	6.8	6.6	6.4	6.0
	12	5.8	5.7	5.4	5.2

The Lumax 500/540 HF-T variants of ICDs are intended to operate for more than 6 years under normal use. Table 44 provides longevity estimates for these devices with Greatbatch batteries. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 44 Lumax 500/540 HF-T Longevity Estimates		
Pacing Support		
Device	**Shocks per year**	**100%**
500 HF-T	4	5.6
	5	5.5
	6	5.4
	7	5.2
	8	5.1
	9	5.0
	10	4.9
	11	4.7
	12	4.6
540 HF-T	4	5.3
	5	5.1
	6	5.0
	7	4.8
	8	4.6
	9	4.5
	10	4.4
	11	4.3
	12	4.1

Upon reaching ERI, the battery has enough energy left to continue monitoring for three months and to deliver 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. After this period the device is at EOS (End of Service) and requires explantation. Once at EOS, all tachyarrhythmia detection and therapy is disabled. The ERI and EOS voltages are listed in the **Table 45**.

Table 45 ERI and EOS Voltages	
Operating Mode	**Voltage**
Elective Replacement Indicator (ERI)	2.50 Volts
End of Service (EOS)	1.75 Volts

5.2.3 Lumax 600/640 & 700/740 Devices

Table 41 provides longevity estimates for the single chamber Lumax 600/640 & 700/740 ICD variants (Lumax 600/700 VR-T and Lumax 640/740 VR-T). The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 46 Lumax VR-T Longevity Estimates					
		Pacing Support			
Device	Shocks per year	0%	15%	50%	100%
600 VR-T 700 VR-T	4	9.91	9.60	8.95	8.17
	8	8.32	8.10	7.64	7.06
	12	7.17	7.01	6.66	6.21
640 VR-T 740 VR-T	4	10.21	9.92	9.31	8.55
	8	8.20	8.01	7.60	7.09
	12	6.84	6.71	6.42	6.05

Table 42 provides longevity estimates for the dual-chamber Lumax 600/640 and 700/740 ICD variants (Lumax 600/700 DR-T, and Lumax 640/740 DR-T). The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 47 Lumax DR-T Longevity Estimates					
		Pacing Support			
Device	Shocks per year	0%	15%	50%	100%
600 DR-T 700 DR-T	4	8.95	8.42	7.40	6.31
	8	7.62	7.24	6.47	5.61
	12	6.64	6.34	5.74	5.06
640 DR-T 740 DR-T	4	9.31	8.80	7.80	6.71
	8	7.59	7.25	6.55	5.77
	12	6.40	6.16	5.65	5.05

Table 43 provides longevity estimates for the Lumax 640/740 VR-T DX ICDs. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the ICD.

Table 48 Lumax VR-T DX Longevity Estimates					
	Pacing Support				
Device	Shocks per year	0%	15%	50%	100%
640 VR-T DX 740 VR-T DX	4	9.31	9.07	8.54	7.89
	8	7.59	7.43	7.07	6.62
	12	6.40	6.29	6.03	5.70

Table 44 provides longevity estimates for the Lumax 600/640 and 700/740 HF-T variants of CRT-Ds. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the CRT-D.

Table 49 Lumax 600/640 & 700/740 HF-T Longevity Estimates		
	Pacing Support	
Device	Shocks per year	100%
600 HF-T 700 HF-T	4	6.09
	5	5.93
	6	5.77
	7	5.63
	8	5.49
	9	5.36
	10	5.23
	11	5.11
	12	5.00
640 HF-T 740 HF-T	4	5.72
	5	5.53
	6	5.34
	7	5.17
	8	5.01
	9	4.86
	10	4.72
	11	4.59
	12	4.46

Upon reaching ERI, the battery has enough energy left to continue monitoring for three months and to deliver 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. After this period the device is at EOS (End of Service) and requires explantation. Once at EOS, all tachyarrhythmia detection and therapy is disabled. The ERI voltages are listed in the **Table 45**.

Table 50 ERI and EOS Voltages	
Operating Mode	**Voltage**
Elective Replacement Indicator (ERI)	2.50 & 2.85 Volts

5.3 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 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.

6. Technical Specifications

The following are the technical specifications for the Lumax 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				
	Lumax 300/500 600/700	**Lumax 340/540 640/740**	**Lumax 500 600/700 HF-T**	**Lumax 340/540 640/740 HF-T**
Dimensions	66 mm x 55 mm x 12 mm	66 mm x 55 mm x 13 mm	66 mm x 59 mm x 12 mm	66 mm x 59 mm x 13 mm
Volume	34.6 cm^3	37.2 cm^3	37.1 cm^3	39.8 cm^3
Mass	81 g	92 g	83 g	94 g
Housing	Titanium			
Header	Epoxy resin			
Seal Plug	Silicone			
VR-T Lead Ports	1 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1		3 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1	
DR-T Lead Ports	2 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1			

Parameter	Range	Standard
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, 25...(25)...225 ms	75 ms
Upper threshold	50; 75; 87.5 %	50 %

Parameter	Range	Standard
Upper threshold (Lumax 700/740 & 600/640 only)	25, 50; 75 %	50 %
Lower threshold	12.5; 25; 50 %	25 %
Lower threshold (Lumax 700/740 & 600/640 only)	25	25 %
Hold of upper threshold after As (Lumax 700/740 & 600/640 only)	350 ms	350 ms
Hold of upper threshold after Ap (Lumax 700/740 & 600/640 only)	350 ms	350 ms
Initial Noise Interval (Lumax 700/740 & 600/640 only)	110 ms	110 ms
High pass (Lumax 700/740 & 600/640 only)	18 Hz	18 Hz
Right-ventricular Sensing Parameters		
Sensing RV	STD - standard, TWS - extended T-wave suppression, VFS - extended VF sensitivity	STD
Minimum threshold	0.5...(0.1)...2.5 mV	0.8 mV
Blanking after atrial pacing	50...(10)...100 ms	50 ms (N/A VR-T DX)
Upper threshold	50; 75; 87.5 %	50 %
Upper threshold (Lumax 700/740 & 600/640 only)	50; 75 %	50 %
Lower threshold	12.5; 25; 50%	25 %
Lower threshold (Lumax 700/740 & 600/640 only)	25; 50%	25 %

Parameter	Range	Standard
Hold of upper threshold	100...(20)...600 ms	360 ms
Hold of upper threshold after Vs (Lumax 700/740 & 600/640 only)	110, 150...(50)...500 ms 110 ms (VFS)	350 ms
Hold of upper threshold after Vp (Lumax 700/740 & 600/640 only)	110, 150...(50)...500 ms 110 ms (VFS)	400 ms
Initial Noise Interval (Lumax 700/740 & 600/640 only)	110 …(10) … 200 ms	110 ms
High pass (Lumax 700/740 & 600/640 only)	24, 32 Hz 32 Hz (TWS, VFS)	24 Hz
Low pass (Lumax 700/740 & 600/640 only)	100 Hz	100 Hz
Left-ventricular Sensing Parameters		
Sensing LV	STD - standard, OFF - inactive	STD
Min. threshold	0.5...(0.1)...2.5 mV	1.6 mV
Min. threshold (Lumax 700/740 & 600/640 only)	0.5…(0.1)…2.5….(0.5)…. 5.0 mV	1.6 mV
Blanking after atrial pacing	= Safety window	100 ms (N/A VR-T DX)
Upper threshold	50; 75; 87.5%	50 %
Upper threshold (Lumax 700/740 & 600/640 only)	50; 75 %	50 %
Hold of upper threshold	100...(20)...600 ms	360 ms
Hold of upper threshold after Vs (Lumax 700/740 & 600/640 only)	110, 150...(50)...500 ms	350 ms

Parameter	Range	Standard
Hold of upper threshold after Vp (Lumax 700/740 & 600/640 only)	110, 150...(50)...500 ms	400 ms
Lower threshold	12.5; 25; 50 %	50 %
Lower threshold (Lumax 700/740 & 600/640 only)	50 %	50 %
In channel/Cross channel Blanking		
In-channel blank after RV pace	Auto, 100...(10)...350 ms	Auto
RV Blanking after RV pacing (Lumax 700/740 & 600/640 only)	100...(10)...350 ms	120 ms
In-channel blank after LV pace	Auto, 100...(10)...350ms	Auto
LV Blanking after LV pacing (Lumax 700/740 & 600/640 only)	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
Polarity Pace/Sense		
LV polarity pace	LV-tip -> LV-ring (bipolar (1)), LV-tip -> RV-ring (common ring bipolar (2)), LV-ring -> LV-tip (inverse bipolar (3)), LV-ring -> RV-ring (ring ring bipolar (4))	LV-tip -> RV-ring
LV polarity pace (Lumax 700/740 & 600/640 models only)	LV-tip -> housing (unipolar (5)),	
LV polarity sense	UNIP (LV-tip/housing), BIPL (LV-tip/LV-ring)	UNIP

Parameter	Range	Standard
Shock Path (Valid for all shocks including the pain-free shock impedance)	RV -> SVC + ICD (Housing) RV -> ICD (500/540 only) RV -> SVC (500/540 only)	RV -> SVC + ICD
Pulse Amplitudes and Pulse Widths		
Pulse amplitude	0.2...(0.1)...6.2, 7.5 V	2.8 V
Pulse amplitude (Lumax 700/740 & 600/640 models only)	0.5…(0.25)…4.0…(0.5)…..6.0, 7.5 V	2.5 V
Pulse width	0.4, 0.5, 0.7, 1.0, 1.2, 1.5 ms	0.4 ms
Pulse width (Lumax 700/740 & 600/640 models only)	0.4, 0.5…(0.25)…1.5 ms	0.4 ms
Automatic Threshold Measurement (ATM) For Lumax 500/540 Models Only		
RV	ON; OFF	ON[1]
LV (HF-T Only)	ON; OFF	ON
Active Threshold Tracking (ATT) For Lumax 700/740 & 600/640 Models Only		
RV	ON; OFF	ON[2]
LV (HF-T Only)	ON; OFF	ON
Thoracic Impedance Measurement (TI) For Lumax 700/740 & 600/640 Models Only		
TI	ON; OFF	ON
Mode		
Modes	DDD, DDDR, DDI, DDIR, VDD, VDDR, VDI, VDIR, VVI, VVIR, AAI, AAIR, OFF	DDD

[1] The Standard Program for the ATM feature is ON only for the Lumax 500/540 VR-T

[2] The Standard Program for the ATT feature is ON only for the Lumax 700/740 & 600/640 VR-T

Parameter	Range	Standard
Modes (Lumax 700/740 & 600/640 models only)	DDD, DDDR, DDI, DDIR, D00, VDD, VDDR, VDI, VDIR, VVI, VVIR, V00, AAI, AAIR, OFF	
Modes (VR-T DX Only)	VDD, VDDR, VDI, VDIR, VVI, VVIR, OFF	VVI
Modes (Lumax 740/640 VR-T DX Only)	VDD, VDDR, VDI, VDIR, VVI, VVIR, V00, OFF	
Basic Rate Day/Night		
Basic rate	30..(5)..100..(10)..160 bpm	60 bpm
Night rate	OFF, 30..(5)..100 bpm	OFF
Night beginning	00:00..(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)..-90 ppm	OFF
Rate hysteresis (Lumax 740/640 VR-T DX Only)	OFF, -5…(-5)… -25… (-20)…-65 bpm	OFF
Repetitive	OFF; 1..(1)..15	[OFF]
Scan	OFF; 1..(1)..15	[OFF]
Scan / Repetitive (Lumax 740/640 VR-T DX Only)	OFF; ON (10)	[ON(10)]
AV Delay		
AV delay	Low, medium, high, fixed, individ.	Low
AV delay 1	40..(5)..350 ms	150 ms
AV delay 1 after pace (Lumax 740/640 VR-T DX Only)	15, 40..(5)..350 ms	-
AV delay 1 after sense (Lumax 740/640 VR-T DX Only)	=AV delay 1 after pace + Sense compensation	-
AV rate 1	30..(10)..120 bpm	60 bpm

Parameter	Range	Standard
AV rate 1 (Lumax 740/640 VR-T DX Only)	50..(10)..130 bpm	60 bpm
AV delay 2	40..(5)..350 ms	120 ms
AV delay 2 (Lumax 740/640 VR-T DX Only)	15, 40..(5)..350 ms	-
AV rate 2	70..(10)..160 bpm	130 bpm
AV rate 2 (Lumax 740/640 VR-T DX Only)	60..(10)..140 bpm	130 bpm
Sense compensation	OFF; -5..(-5)..-60 ms	-30 ms (N/A VR-T DX)
Sense compensation (Lumax 740/640 VR-T DX Only)	OFF; -5..(-5)..-120 ms	-40 ms (N/A VR-T DX)
AV-hysteresis mode	OFF, positive, negative	OFF
AV hysteresis	10..(10)..150 ms	[50 ms]
AV hysteresis (positive) (Lumax 740/640 VR-T DX Only)	70, 110, 150, 200 ms	[70 ms]
AV hysteresis (negative) (Lumax 740/640 VR-T DX Only)	10..(10)..150 ms	[50 ms]
AV repetitive (positive)	OFF; 1..(1)..10	[5]
AV repetitive (negative)	OFF; 1..(1)..15..(5)..100..(10)..180	[180]
AV scan / repetitive (positive) (Lumax 740/640 VR-T DX Only)	OFF; ON (5)	[ON (5)]

Parameter	Range	Standard
AV repetitive (negative) (Lumax 740/640 VR-T DX Only)	ON (180)	ON (180)
AV scan	OFF, 1..(1)..10	[5]
I-Opt		
I-Opt	OFF, ON	OFF
AV hysteresis at I-Opt	400 ms	400 ms
AV repetitive at I-Opt	OFF; 1..(1)..10	[5]
AV scan at I-Opt	OFF, 1..(1)..10	[5]
AV scan / repetitive at I-Opt (Lumax 740/640 VR-T DX Only)	ON (5)	[ON(5)]
AV max at I-Opt	400 ms	400ms
Post-ventricular Atrial Refractory Period (PVARP)		
PVARP	175..(25)..600 ms, Auto	250 ms
PVARP (Lumax 740/640 VR-T DX Only)	175..(25)..600 ms, Auto	225 ms
Auto PVARP	OFF, ON	OFF
VES Classification (VES Lock-in Protection)		
VES discrimination after As	250..(50)..450 ms	350 ms
VES discrimination after As (Lumax 740/640 VR-T DX Only)	250..(50)..500 ms	350 ms
Rate Adaptation (Acceleration Sensor)		
Maximum sensor rate	90..(5)..160 bpm	120 bpm
Maximum sensor rate (Lumax 740/640 VR-T DX Only)	80..(10)..160 bpm	120 bpm

Parameter	Range	Standard
Sensor gain	1.0; 1.1; 1.3; 1.4; 1.6; 1.8; 2.0; 2.2; 2.6; 3.0; 3.3; 3.7; 4.0; 4.5; 5.0; 6.0; 7.0; 8.0; 9.0; 10; 11; 12; 14; 16; 18; 20; 22; 24; 28; 32; 35; 40	6.0
Sensor gain (Lumax 700/740 & 600/640 only)	AUTO, Very low (1.3), Low (3), Medium (6), High (12), Very high (26)	Medium (6)
Auto Sensor gain	OFF, ON	OFF
Sensor threshold (numbers are not displayed on screen)	Very low = 0 Low = 3 Medium = 7 High = 11 Very high = 15	Medium
Rate increase	0.5; 1..(1)..6 ppm/cycle	2 bpm/cycle
Rate increase (Lumax 700/740 & 600/640 only)	1, 2, 4, 8 bpm/cycle	2 bpm/cycle
Rate drop	0.25..(0.25)..1.25 ppm/cycle	0.5 ppm/cycle
Rate decrease (Lumax 700/740 & 600/640 only)	0.1, 0.2, 0.5, 1.0 bpm/cycle	0.5 ppm/cycle
Upper Tracking Rate (UTR)		
Upper tracking rate	90..(10)..160 bpm	130 bpm
Upper tracking rate atrium	OFF, 240 bpm	240 bpm (N/A VR-T DX)
Upper tracking rate atrium (Lumax 700/740 & 600/640 only)	OFF, 175, 200. 240 bpm	200 ppm (N/A VR-T DX)
Mode Switching		
Intervention rate	OFF, 100..(10)..250 bpm	160 bpm
Intervention rate (Lumax 700/740 & 600/640 only)	OFF, 120..(10)..200 bpm	160 bpm
Activation criterion X	3..(1)..8	5

Parameter	Range	Standard
Deactivation criterion Z	3..(1)..8	5
Mode	DDI, DDIR at permanent DDD(R) VDI, VDIR at permanent VDD(R)	DDI [VDI]
Modes (VR-T DX Only)	VDI, VDIR at permanent VDD(R)	VDI
Change in basic rate	OFF, +5 ... (5) ...+30 bpm	+10 bpm
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 AT/AF	100….(10)…250 bpm (240…..600 ms)	200 bpm
Interval VT1	OFF, 270...(10)...600 ms	OFF
Interval VT2	OFF, 270...(10)...500 ms	OFF
Interval VF	OFF, 200...(10)...400 ms	300 ms
Interval VF (Lumax 700/740 & 600/640 only)	OFF, 240...(10)...400 ms	300 ms
Detection Counter		
Detection counter VT1	10...(2)...60	[16]
Detection counter VT2	10...(2)...40	[14]
Detection counter VF – X	6...(1)...30	8
Detection counter VF – Y	8...(1)...31	12

Parameter	Range	Standard
Detection counter VF – X out of Y (Lumax 700/740 & 600/640 only)	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	20%	[20%]
Onset VT1 without SMART	OFF; 4…(4)…32%	20%
Onset VT2 without SMART	OFF; 4…(4)…32%	20%
Stability		
Stability in VT1/2 with SMART	12%	[12%]
Stability VT1 without SMART	OFF; 8…(4)…48 ms	24 ms
Stability VT2 without SMART	OFF; 8…(4)…48 ms	24 ms
SMART Detection		
SMART detection VT1	OFF, ON	[ON]
SMART detection VT2	OFF, ON	[ON]
Sustained VT (without SMART Detection and without SMART Redetection)		
Sustained VT	OFF, 00:30, 01:00, 02:00, 03:00, 05:00, 10:00, 15:00, 20:00, 25:00, 30:00 [mm:ss]	[OFF]
Sustained VT (Lumax 700/740 & 600/640 only)	OFF, 01:00, 02:00, 03:00, 05:00, 10:00, 20:00, 30:00 [mm:ss]	[OFF]
Forced Termination (with SMART Detection Including SMART Redetection)		
Forced termination	OFF; 1…(1)…15 min	[1 min]

Parameter	Range	Standard
Forced termination (Lumax 700/740 & 600/640 only)	OFF; 1…(1)…10 min	[1 min]
Redetection Counter		
Redetection counter VT1	10...(2)...30	[12]
Redetection counter VT2	10...(2)...30	[10]
SMART Redetection		
SMART redetection (VT1 & VT2)	OFF, ON	[ON]
Ventricular Therapy Parameters		
Energy 1st shock and 2nd shock VT1, VT2 (model 300/500)[1]	OFF; 1..(1)..16..(2)..30 J	30 J
Energy 1st shock of VT1, VT2 (Lumax 700/600 only)	OFF; 2..(2)..20..(5)..30 J	30 J
Energy 2nd shock of VT1, VT2 (Lumax 700/600 only)	OFF; 4..(2)..20..(5)..30 J	30 J
Energy 1st shock and 2nd shock VF (model 300/500) [1]	1..(1)..16..(2)..30 J	30 J
Energy 1st shock of VF (Lumax 700/600 only)	2..(2)..20..(5)..30 J	30 J
Energy 2nd shock of VF (Lumax 700/600 only)	4..(2)..20..(5)..30 J	30 J

[1] Programmed values are stored energies.

Parameter	Range	Standard
Energy 1st shock and 2nd shock VT1, VT2 (model 340/540) [1]	OFF; 1..(1)..16..(2)..40 J	40 J
Energy 1st shock of VT1, VT2 (Lumax 740/640 only)	OFF; 2..(2)..20..(5)..40 J	40 J
Energy 2nd shock of VT1, VT2 (Lumax 740/640 only)	OFF; 4..(2)..20..(5)..40 J	40 J
Energy 1st shock and 2nd shock VF (model 340/540) [1]	1..(1)..16..(2)..40 J	40 J
Energy 1st shock of VF (Lumax 740/640 only)	2..(2)..20..(5)..40 J	40 J
Energy 2nd shock of VF (Lumax 740/640 only)	4..(2)..20..(5)..40 J	40 J
Number of shocks (VT1/VT2)	0..(1)..8	[8]
Number of shocks (VT1/VT2) (Lumax 700/740 & 600/640 only)	0, 1, 2, 6, 8	[8]
Number of shocks (VF)	2; 6..(1)..8	8
Number of shocks (VF) (Lumax 700/740 & 600/640 only)	6, 8	8
Confirmation (per zone)	OFF, ON	ON
Shock form (per zone)	Biphasic, Biphasic2	Biphasic

Parameter	Range	Standard
Polarity (per zone)	Normal, Reverse, Alternating	Normal
ATP Parameters		
ATP type	Burst, Ramp, Burst + PES	[Burst]
ATP type (Lumax 700/740 & 600/640 only)	Burst, Ramp	[Burst]
ATP attempts	OFF, 1…(1)...10	3
ATP attempts (Lumax 700/740 & 600/640 only)	OFF, 1…(1)...10	[OFF]
S1 number	1...(1)...10	[5]
Add. S1	OFF, ON	[ON]
R1-S1 interval	200...(10)...500 ms (absolute); 70...(5)...95 % (adaptive)	[80 %]
R1-S1 interval (Lumax 700/740 & 600/640 only)	70...(5)...95 % (adaptive)	[80 %]
S1 (RAMP) decrement	5...(5)...40 ms	[10 ms]
Scan decrement	OFF, 5...(5)...40 ms	[OFF]
S1-S2 interval	200...(10)...500 ms (absolute); 70...(5)...95 % (adaptive)	[70 %]
Minimal ATP interval	200...(5)...300 ms	[200 ms]
Minimal ATP interval (Lumax 700/740 & 600/640 only)	200 ms	-
ATP timeout (not applicable in Lumax 700/740 & 600/640)	OFF, 00:15...(00:15)...05:00 mm:ss	OFF
ATP optimization	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 + PES	OFF

Parameter	Range	Standard
ATP type (Lumax 700/740 & 600/640 only)	OFF, Burst, Ramp	Burst
S1 number	1...(1)...10	[5]
S1 number (Lumax 700/740 & 600/640 only)	1...(1)...10	[8]
R-S1 interval	200...(10)...350 ms (absolute); 70...(5)...95 % (adaptive)	[80%]
R-S1 interval (Lumax 700/740 & 600/640 only)	70...(5)...95 % (adaptive)	[85%]
S1 decrement	5...(5)...40 ms	[10 ms]
S1-S2 interval	200...(10)...350 ms (absolute); 70...(5)...95 % (adaptive)	[70%]
Stability	12%	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 Lumax 700/740 & 600/640 Only		
ATP type	Burst, Ramp, Burst + PES	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)...95 % (adaptive)	[80%]
S1 decrement	5...(5)...40 ms	[10 ms]
S1-S2 interval	200...(10)...600 ms simply alterable via [+ / -] buttons	290
S2-S3 interval	OFF, 200...(10)...600 ms simply alterable via [+ / -] buttons	OFF

Parameter	Range	Standard
S3-S4 interval	OFF, 200...(10)...600 ms simply alterable via [+ / -] buttons	OFF
Minimum ATP interval	200 ms	
Atrial NIPS Lumax 700/740 & 600/640 Only		
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.	30…(10)…800 bpm	350 bpm
Post-Shock Pacing		
Mode	DDI at permanent DDD(R), DDI (R), AAI(R) VDI at permanent VDD(R), VDI(R), VVI at permanent VVI(R), OFF	
Modes (VR-T DX Only)	AAI VDI at permanent VDD(R), VDI(R), VVI at permanent VVI(R), OFF	
Basic rate	30 .. (5)..100..(10) .. 160 bpm	60 bpm
Rate hysteresis	OFF, -5 .. (-5) .. –65 bpm	OFF

Parameter	Range	Standard
Rate hysteresis (Lumax 700/740 & 600/640 only)	OFF	-
AV delay	50..(10)..350 ms (fixed AV delay)	140 ms
Post-shock duration	OFF, 00:10 .. (00:10) .. 00:50, 01:00 .. (01:00) .. 10:00 mm:ss	00:10 mm:ss
Post-shock duration (Lumax 700/740 & 600/640 only)	OFF, 00:10, 00:30, 01:00, 02:00, 05:00, 10:00 mm:ss	00:10 mm:ss
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	Time (hh:mm)	[01:00 hh:mm]
Transmission time (Lumax 700/740 & 600/640 only)	Std., 00:00 ..(01:00) .. 23:00 (hh:mm)	[Std.]
IEGM for therapy episode	OFF, ON	[OFF]
IEGM for therapy episode (Lumax 700/740 & 600/640 only)	OFF, ON	[ON]
IEGM for monitoring episode	OFF, ON	[OFF]
IEGM for monitoring episode (Lumax 700/740 & 600/640 only)	OFF, ON	[ON]
Periodic IEGM	OFF, 2, 3, 4, 6 months	[OFF]
Periodic IEGM (Lumax 700/740 & 600/640 only)	OFF, Date, 30, 60, 90, 120, 180 days	[90]
Sustained atrial episode	OFF, 0,5, 6, 12, 18 h	[12 h]

Parameter	Range	Standard
Sustained atrial episode (Lumax 700/740 & 600/640 only)	OFF, 6, 12, 18 h (5 min, 30 min)	[12 h]
Diagnostics		
Periodic Recordings (Lumax 700/740 & 600/640 only)	if Home Monitoring ON: = Cycle duration	[90]
	If Home Monitoring OFF: OFF, 30 .. (30) .. 180	[90]

FCC Statement: (FCC ID: QRILUMAXT, QIRLUMAXT50): 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 A

Connector Compatibility

Lumax ICDs/CRT-Ds are indicated for use only with commercially available BIOTRONIK bipolar ICD lead systems or other lead systems with which it has been tested. The separate atrial pacing/sensing lead may be any commercially available pacing lead. The Lumax family of ICDs/CRT-Ds are mechanically compatible with:

- IS-1 sensing/pacing lead connectors
- DF-1 defibrillation lead connectors.

The Lumax DR ICD has two IS-1 header ports and two DF-1 header ports while the Lumax VR ICD has a single IS-1 header port and two DF-1 header ports. The Lumax HF CRT-Ds have three IS-1 header ports and two DF-1 header ports

Appendix B – Known Anomalies

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
RF communication session may be unexpectedly interrupted when a long episode is printed with high paper feed. ID# 424185	Limited effect on patient. Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior): may cause follow-up prolongation. Acceptable residual risk resulting from low severity and low probability of occurrence.	Product safety and performance are only marginally affected.
Caption annotation missing in printout for Lumax 740 VR-T DX and several statistics (Rate Histogram, AV Histogran, Paced Trend), ID# 422748	Limited effect on patient. Layout Issue (Screen Display, Printout): User confusion unlikely. Acceptable residual risk resulting from low severity and low probability of occurrence.	Lumax 740 VR-T DX only: Product safety and performance are only marginally affected.

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
The Far Field channel display may disappear when the ECG window is minimized after having been maximized immediately before. ID# 421905	Limited effect on patient. Diagnostic Data Issue (Interrogation, Display, Printout): Display/printout of missing diagnostic information may cause user confusion. Acceptable residual risk resulting from low severity and low probability of occurrence.	Product safety and performance are only marginally affected.
Missing parameter "AF Intervall/Rate" in printout. ID# 421245	Limited effect on patient. Program Parameter Issue (Interrogation, Display, Selection, Transmission): Display/Printout of missing program data without risk of incorrect diagnosis. Acceptable residual risk resulting from low severity and low probability of occurrence.	Product safety and performance are only marginally affected.

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
The transmission date for Periodic IEGM messages for Remote Follow-Up (Home Monitoring) may be off by one day. ID# 412325	No effect on patient. Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior): Unexpected/Unspecified behavior without clinical relevance or negative therapeutical/diagnostic implication. No message is lost, no data is altered. Accepted due to low probability of occurrence and very low severity	N/A
Event Counter Statistics may be slightly off by single counts of Vx events dependent on internal statistics state transitions. This is a rare event. ID# 410925	Limited effect on patient. Diagnostic Data Issue (Interrogation, Display, Printout): Display/printout of incorrect diagnostic information without risk of incorrect diagnosis. Acceptable residual risk resulting from low severity and low probability of occurrence.	Product safety and performance are only marginally affected.

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
Inconsistent behavior for "Alert" navigation. Clicking the alert icon on the TrendView time axis and on the Information Details the expectedly the navigation leads to the corresponfing trend. This is omitted if the alert icons are clicked from the Diagnostics Details. ID# 406945	No effect on patient. Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior): without clinical relevance or negative therapeutical/diagnostic implication. Acceptable residual risk resulting from low severity and low probability of occurrence.	N/A

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
For long patient names involving umlauts the transmission of patient data may suppress the patient name (empty field). ID# 393925	No effect on patient. Functional/Usability Issue (missing, insufficient user guidance, unexpected behavior): Unexpected/Unspecified behavior without clinical relevance or negative therapeutical/diagnostic implication. Acceptable residual risk resulting from low severity and low probability of occurrence.	N/A
Dual Chamber devices only: When programmed to DDDR mode and with sensor activity it is possible for a sudden rate drop at start of a capacitor reformation procedure. After the reformation the pacing rate again sensor indicated rate. ID# 19607	Limited effect on patient, temporary rate drop to programmed post-shock pacing rate ensures sufficient support.	N/A

Anomaly	Possible Effect on Patient or Implant Procedure	Impact on Lumax 700/740 & 600/640
Lumax Application (Programmer Software)		
An ineffective pacing program may continue during the threshold test at programming distances close to the loss of communication . Lifting the wand corrects the problem. ID# 17903	Limited potential effect on patient, non-capture is quickly recognized and removal of programming wand is typical response. This anomaly can only occur during manual threshold testing (in physician's office).	N/A

Distributed by:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369
(800) 547-0394 (24-hour)
(503) 635-9936 (FAX)

Manufactured by:
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
Germany

M4117-H 10/11