Lumax

Family of Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy Defibrillators

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

Technical Manual

BIOTRONIK

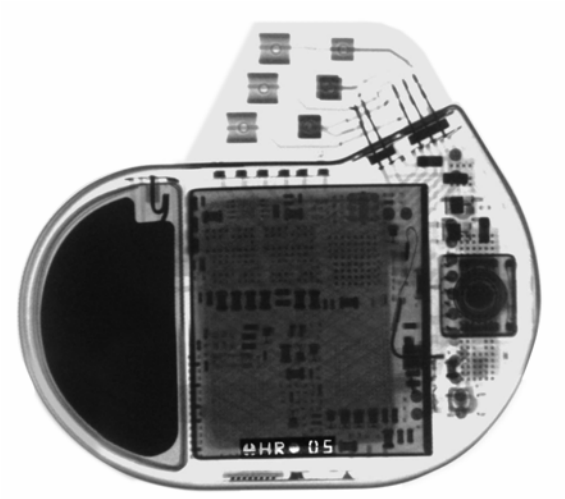
X-ray Identification

Lumax Family
Implantable Cardioverter Defibrillator and

Cardiac Resynchronization Therapy Defibrillators

Inside the housing:

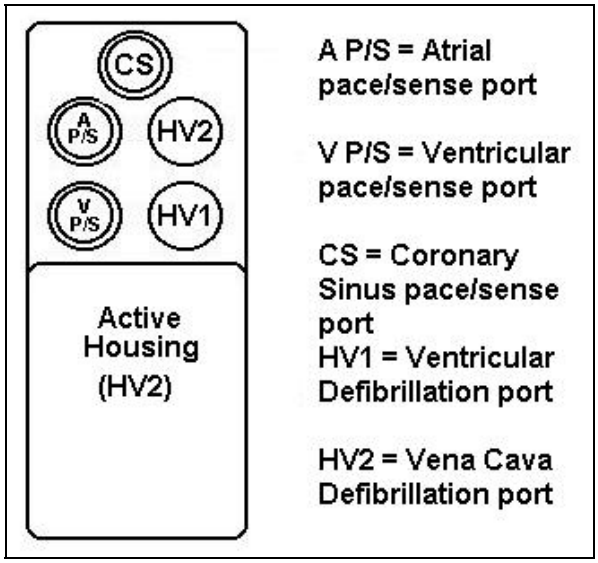
X-Ray identification	Year of manufacture
HR	nn



CAUTION

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

Contents



*Lumax VR (-T) and DR (-T) ICDs do not have coronary sinus pace/sense ports
** Lumax VR (-T) ICDs do not have atrial pace/sense ports

Lumax Specifications and Description

Battery Voltage:	3.2 Volts
300 models: Maximum Shock Energy:	30 joules programmed 26.6 joules delivered
340 models: Maximum Shock Energy:	40 joules programmed 35.7 joules Delivered
Defibrillation Lead Ports	Two DF-1 (3.2 mm)
Pacing Lead Ports	Three IS-1 (3.2 mm) (one for Lumax VR (-T) and two for Lumax DR (-T)s)
Dimensions:	See Technical Details in Section 6
Volume:	
Mass:	
Housing Material:	Titanium
Header Material:	Epoxy Resin
Sealing Plug Material:	Silicone

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 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 include 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 the added functionality of 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 the added functionality of 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 the added functionality of 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.

The 300 and 340 reference for each of the above-described models denote the maximum programmable shock energy of 30 joules and 40 joules, respectively.

All members of the Lumax device family have two DF-1 defibrillation/ cardioversion ports. In addition, the Lumax HF (-T) models have three IS-1 pacing/sensing header 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 ICS 3000 Programming and Tachyarrhythmia Monitoring System and the Implant Module System Analyzer for acute lead testing. This programmer is used to interrogate and program the ICD/CRT-D.

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 $\geq$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 bradyarrhythmias 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 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
- Guidant-Easytrak LV-1
- Guidant-Easytrak 2
- Guidant-Easytrak 3
- Medtronic-Attain
- St. Jude-Aescula
- St. Jude-Quicksite
- Biomec-Myopore Epicardial
- Medtronic-Epicardial 5071
- Medtronic-CapSure EPI
- Biotronik-ELC 54-UP

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

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

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

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

- Guidant Endotak Endurance "CPI 0125"
- Guidant Endotak Reliance 0148
- Medtronic Sprint 6932
- Medtronic Sprint 6942
- Medtronic Sprint 6943
- Medtronic Sprint 6945
- Medtronic Sprint Quattro 6944
- St. Jude Riata 1571/65
- St. Jude SPL SPO1

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 Therapy status 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.

High Output Settings – High ventricular or biventricular pacing voltage settings may significantly reduce the life expectancy of the CRT-Ds. Programming of pulse amplitudes, higher than 4.8V, in combination with long pulse widths and/or high pacing rates may lead to early activation of replacement indicators.

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 55°C (41° - 131° 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 85 days and may be reformed manually. For further information, please refer to **Section 2.9.4**, 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 30 joule shocks. After this period, all tachyarrhythmia detection and therapy is disabled. Bradycardia functions are still active at programmed values until the battery voltage drops below 3.0 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 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 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.

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.

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, 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. Damage to the device may result.

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

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 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.

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 does not immediately send the safe program to the ICD/CRT-D. Pressing the "Safe Program" key activates the emergency function screen, but an additional screen touch is required to send 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 Therapy status to DISABLED 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.

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 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

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).

Event-Triggered Report – A timely receipt of the event report cannot be guaranteed. The receipt is also dependent on whether the patient was physically situated in the required coverage range of the patient device at the time the event information was sent.

Not for Diagnosis - The data transmitted by Home Monitoring are not suitable for diagnosis, because not all information available in the implant is being transmitted.

Follow-Ups - The use of Home Monitoring does not replace regular follow-up examinations. Therefore, when using Home Monitoring, the time period between follow-up visits may not be extended.

1.5 Potential and 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
- Undersensing 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 relate 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 not 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 1** and **Table 2**, respectively.

Table 1: 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 2: 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 3** and **Table 4**. 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 3: 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**	**20.30%**	**29**	**0.28**

Table 3: 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 appropriately 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 4 summarizes by category each type of observation for the study group.

Table 4: 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 4: 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 5** provides a summary of reported patient deaths and **Table 6** provides survival percentages by follow-up interval during the first 12 months of study participation.

Table 5: 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 1 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.

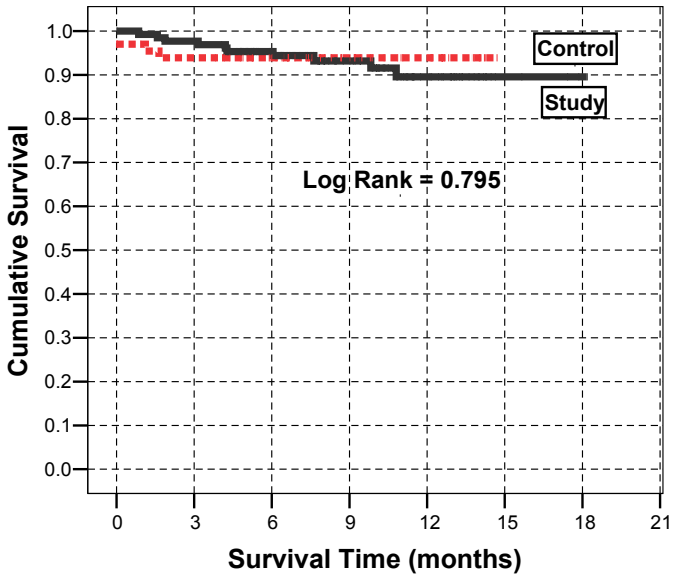


Figure 1: Kaplan-Meier Survival Curves

Table 6 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 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)

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.

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

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 2**.

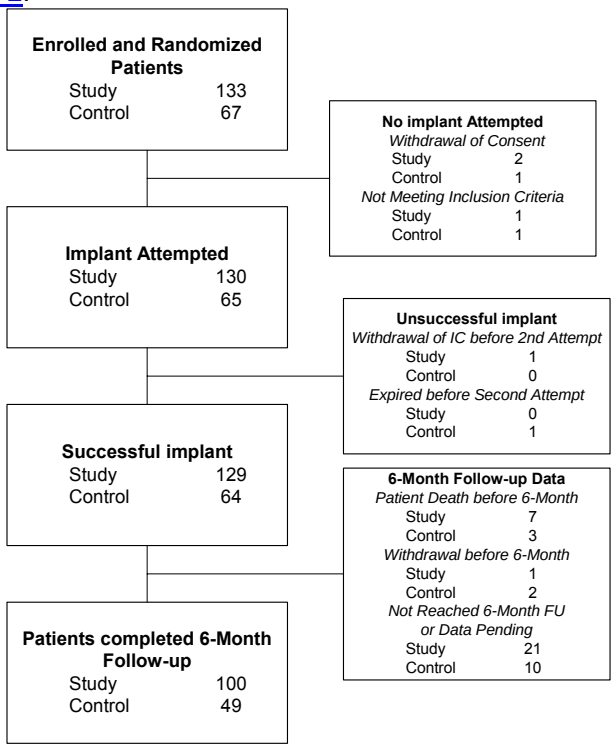


Figure 2: Patient Accountability

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.

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 7 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 7: 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.

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).

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 8 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 8: 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**

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.

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 9: 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.

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

Table 10 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.

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 11 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 11 Overall Atrial Conversion Rate

Patients	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 12 summarizes and compares the results from these two clinical studies.

Table 12: 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 13 summarizes the percentage of ventricular pacing between follow-ups as shown by device diagnostics for patients in the study group.

Table 13: 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 14 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 14: 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 15 summarizes the average improvement in NYHA from Baseline to Six-Months for 140 patients that were able to complete both NYHA classification evaluations.

Table 15: 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 16 summarizes hospitalization, ER visits and outpatient visits for enrolled patients.

Table 16: 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 17 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 17: 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

1.6.2.1 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.

1.6.2.2 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.

1.7 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 pulse generator is 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 the 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 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 the ring of the right ventricular lead (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 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 the Lumax HF devices can be programmed to sense in the left ventricle.

Potential Ventricular lead configurations are provided in **Table 18**.

Table 18. 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.
Pacing	**RV & LV Together (BiV)**	Pacing configuration is programmable between the tip and ring electrodes of the right and left ventricular leads. See Figure 3
Pacing	**RV** Only	Pacing can be programmed to occur in several combinations between the tip and ring electrodes of the right and left ventricular leads.

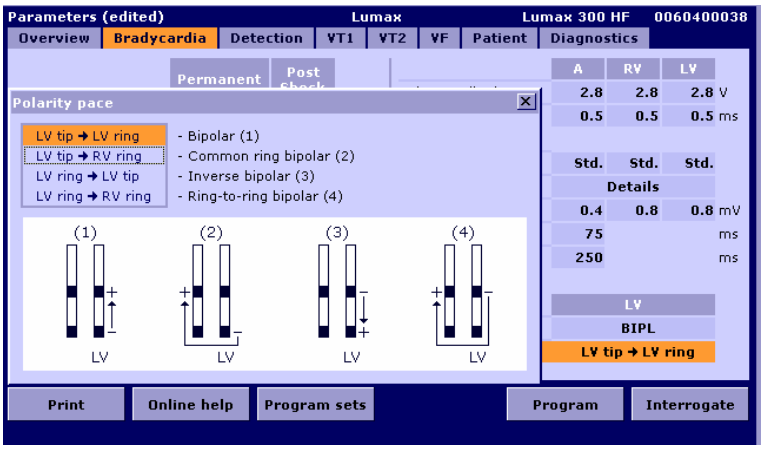


Figure 3 Programmable BiV Pacing Configurations

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 Echocardiographs.

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

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 “triggering function” was designed to ensure biventricular pacing therapy is delivered during rapidly conducted atrial arrhythmias, such as atrial fibrillation. This function triggers pacing delivery (Vp) in the ventricles after intrinsic sensing in the right ventricle. The trigger function is only available in the biventricular pacing configuration and includes a forced ventricular pace (Vp) after previous sensing (right ventricular sense event). 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 limited by the programmed UTR.

2.2 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 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.

2.2.1 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 19**.

Table 19: 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 to 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.
Individual	This parameter configuration is only accessible by a special code in the US.

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 (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 reach or until the next sensed (or paced) event.

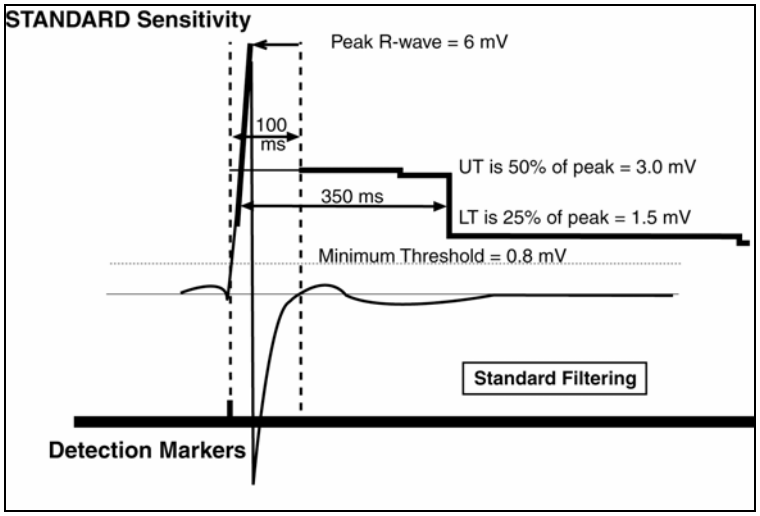


Figure 4 Automatic Sensitivity Control with Standard Stetting

Figure 4 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 is decreased to 100 ms, thus eliminating the Upper Threshold.
- The decay rate of the Lower Threshold is increased to 0.125 mV every 250 ms.

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.

2.2.2 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.

2.2.3 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 20**.

Table 20: 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.
Individual	This parameter configuration is only accessible by a special code in the US.

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.

2.2.4 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.

2.2.5 Left Ventricular Sensitivity Settings

HF versions only.

The primary option for setting the sensitivity of the left ventricular 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 20.**

Table 21: Atrial 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.
Individual	This parameter configuration is only accessible by a special code in the US.

2.2.6 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 2.5 mV.

2.2.7 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.

2.2.8 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 table titled Additional Sensing Parameters in **Section 6**.

Upper Threshold (A, RV & LV)- This feature allows the user to change the upper sensing threshold level (UT in **Figure 4**) 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 to eliminate oversensing of large T-waves.

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 4**) for the programmed time. Maximum Hold Time is programmable from 10 to 600 ms.

Lower Threshold (A, RV & LV)- This feature allows the user to change the lower sensing threshold (labeled LT in **Figure 4**) 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 feature is also used 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 Pace is programmable from 50 to 100 ms. For the left ventricle, this parameter is equal to the safety window time (100 ms). **DR and HF versions only.**

VES Discrimination after As .- This feature is used to correctly identify and classify ventricular extrasystoles (VES). With each atrial sensed event 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. **DR and HF versions only.**

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

2.3 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 Therapy status 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.

2.3.1 VF Classifications

Detection of ventricular fibrillation (VF) utilizes programmable X out of Y criterion. Both X and Y are programmable. 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.

2.3.2 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 both the rate/interval criteria and the programmed Counter / Detection criteria, in addition to any other detection enhancements to be declared a tachycardia.

2.3.3 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 tachycardias. 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 the following text.

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.

2.3.4 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 on **page 71**) 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.

2.3.5 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.

2.3.6 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%.

2.3.7 Sustained VT Timer

The Sustained VT Timer can be programmed between 30 seconds and 30 minutes (or to OFF). 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.

2.4 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.

2.4.1 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. Tachycardia redetection is declared when the programmed number of VT samples (Counter: Redetection) is satisfied.

Redetection functions identically to initial VT detection in regards to the Stability and Onset detection enhancements and it is based on individual cycle lengths (not averages).

2.4.2 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.

2.4.3 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.

2.4.4 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.

2.5 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).

2.6 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.

2.6.1 Therapy Options

The Lumax ICDs/CRT-Ds offer multiple therapy options for each tachyarrhythmia class (VT1, VT2, VF). Therapy options (up to 10 ATP sequences and 8 shocks) are available for the VT1 and VT2 zones, whereas ATPOne 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.

2.6.2 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). 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 - This mode provides a pulse train followed by one or more (up to three) 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).

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

Number S1 - This parameter defines the number of stimuli for an ATP. For Burst + PES, an extra stimulus with a separate parameter is coupled.

Add S1 - This feature can be programmed with any Burst, Ramp, or Burst + PES 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 - 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.

2.6.2.1 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.

2.6.2.2 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.).

2.6.2.3 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.

2.6.2.4 ATP One Shot

ATP One Shot offers the opportunity to treat monomorphic VTs that are detected in the VF zone with a single ATP sequence delivered during charging of the high energy capacitors. The device performs a stability check (same as VT zones) to determine if the arrhythmia might be a monomorphic VT and if the rhythm is stable, the programmed ATP sequence is delivered and the arrhythmia is confirmed prior to shock delivery. 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 is programmed ON.

2.6.3 Shock Therapy

Shock Therapy is developed by internal circuitry that stores energy across two 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, the shock will be delivered asynchronously at the end of the synchronization period.

2.6.3.1 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 the first and second shock therapies of each zone and is always OFF for remaining shock therapies.

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

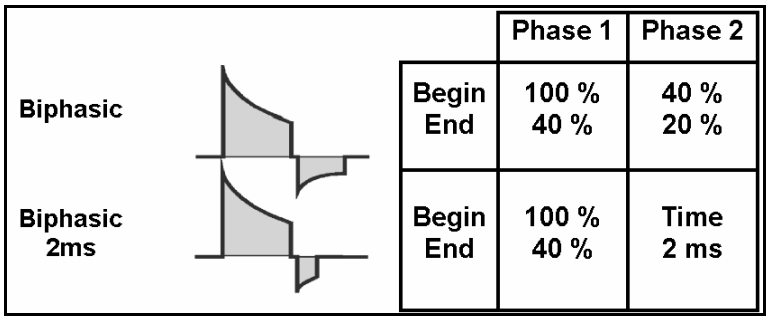
If the tachyarrhythmia spontaneously converts to bradycardia or a normal sinus rhythm during the confirmation period, shock therapy is aborted. If the device confirms the presence of the tachyarrhythmia, the device will deliver the programmed shock therapy.

2.6.3.2 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 series devices and 40 joules for 340 series devices) with Confirmation turned OFF.

2.6.3.3 Shock Waveform

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



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

Figure 5. 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 5 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.

2.6.3.4 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 and 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” in Table 22.

Table 22 Delivered Shock Energy

Programmed Energy (joules)	Approximate Delivered Energy (joules)
1	0.80
2	1.65
3	2.56
4	3.46
5	4.25
6	5.15
7	6.09
8	6.88
9	7.74
10	8.68
11	9.43
12	10.33
13	11.12
14	12.06
15	12.89
16	13.72

Programmed Energy (joules)	Approximate Delivered Energy (joules)
18	15.56
20	17.21
22	18.98
24	21.27
26	23.07
28	24.65
30	26.57
32	28.3
34	30.25
36	32.13
38	33.93
40	35.7

CAUTION

Shock Impedance - If the shock impedance is less than twenty-five ohms, 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. 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.

2.6.3.5 Shock Polarity

The polarity of the shock therapy may be programmed and changed non-invasively. The **Normal** polarity configures the HV 1 connector port as the negative electrode and the HV 2 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 delivers the first shock with normal polarity, the second shock with reversed polarity and alternates the polarity for all subsequent shocks.

2.6.4 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, 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 (30 joules).

2.7 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.

2.7.1 Bradycardia Pacing Modes

The available bradycardia pacing modes for each member of the Lumax ICD/CRT-D family are listed in Table 23.

Table 23 Lumax Pacing Modes

Mode	Lumax HF	Lumax DR	Lumax VR
DDDR	X	X	N/A
DDIR	X	X	N/A
VDDR	X	X	N/A
VDIR	X	X	N/A
AAIR	X	X	N/A
VVIR	X	X	X
DDD	X	X	N/A
DDI	X	X	N/A
VDD	X	X	N/A
VDI	X	X	N/A
AAI	X	X	N/A
VVI	X	X	X
OFF	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.

2.7.2 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.

2.7.3 Night Rate

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

At the programmed start time (Begin of Night), the rate gradually decreases 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.

2.7.4 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 -65 bpm 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.

Hysteresis is suspended 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.

2.7.4.1 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. 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). 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.

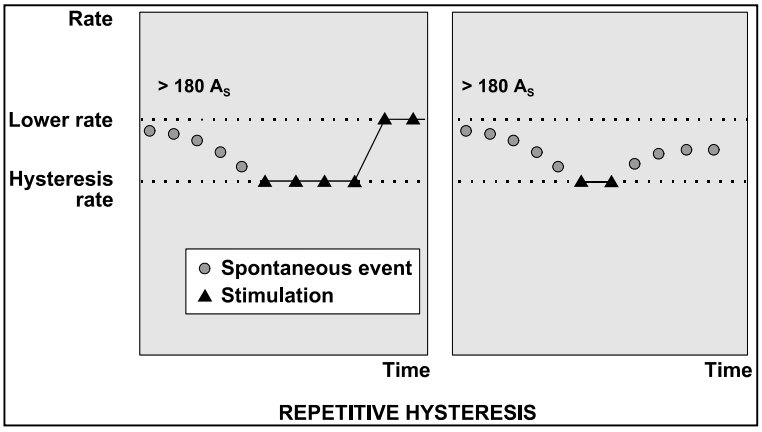


Figure 6. **Repetitive Hysteresis**

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

NOTE:

Repetitive and Scan Hysteresis are not active during the programmed Night Mode and are only available when Hysteresis is selected on.

Magnet application (closing of reed switch) suspends 180 consecutive event counter independent of synchronous or asynchronous magnet effect.

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

2.7.4.2 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. 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.

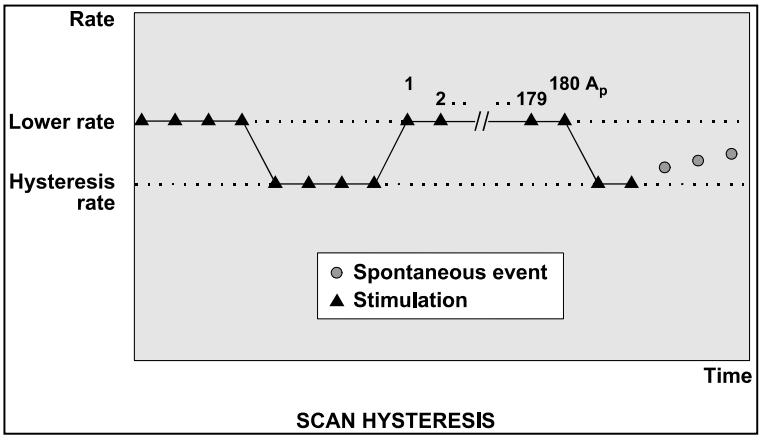


Figure 7. **Scan Hysteresis**

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

NOTE:

Magnet application (closing of reed switch) suspends 180 consecutive event counter independent of the magnet effect.

2.7.5 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 independent selection of AV Delays from five rate ranges at preset AV Delay values. In addition, the AV Delay after atrial pace events can be differentiated from the atrial sense events for dual chamber pacing modes.

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 (20 to 120 ms) 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 only available with the Lumax DR ICD.

2.7.5.1 AV Hysteresis

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 AV hysteresis enabled, the AV delay is extended by a defined time value after sensing a ventricular event (10 … (10) …150 ms). 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.

2.7.5.2 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. (1 … 6). 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.

2.7.5.3 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. (1 … 6). If an intrinsic rhythm is detected within the extended AV delay and 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.

2.7.5.4 Negative AV Delay Hysteresis

With Negative AV Delay Hysteresis, the AV delay is decreased by a defined value after a ventricular event is sensed, thereby promoting ventricular pacing. The Negative AV Delay Hysteresis value corresponds to the programmed AV delay (Table 24).

Table 24: Negative AV Delay Hysteresis Values

AV Delay (Standard)	AV Delay (Negative Hysteresis ON)
100 ms	100 ms
120 ms	100 ms
130 ms	100 ms
140 ms	100 ms
150 ms	100 ms
160 ms	120 ms
170 ms	120 ms
180 ms	130 ms
190 ms	140 ms
200 ms	150 ms
225 ms	170 ms
250 ms	180 ms
300 ms	200 ms

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

CAUTION

Negative AV Delay Hysteresis – This feature insures ventricular pacing, a technique which has been used in patients with hypertrophic obstructive cardiomyopathy (HOCM) with normal AV conduction in order to replace intrinsic ventricular activation. No clinical study was conducted to evaluate this feature, and there is 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.

2.7.6 IOPT Plus

DR versions only.

The IOPT Plus 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 25 details the settings that are preset when IOPT Plus is turned ON:

Table 25 IOPT Plus Parameters

Parameter	IOpt Plus
AV Hysteresis	400 ms
AV Scan Hysteresis	5
Repetitive AV Hysteresis	5

2.7.7 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. Furthermore, the upper tracking rate acts as a limit for the maximum tracking rate in both atrial and ventricular-tracked modes.

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

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 and Automatic Mode Conversion is OFF. 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 ms or OFF.

NOTE:

The 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.

2.7.8 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 26**. Mode switching is not available during the post-shock pacing period. Mode Switching is only available with the Lumax DR ICD.

Table 26: 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 **Activation Criteria** is also met. The activation criterion is a programmable **X out of 8** high rate intervals as programmed.

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 **Deactivation Criteria** 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.

2.7.8.1 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.

2.7.8.2 Post Mode Switch Response

Whenever Mode Switching event terminates, deactivating the mode switch pacing, the device can be programmed to react with 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.

2.7.9 PMT Protection

DR and HF versions only.

PMT protection is a combination of PMT detection and termination and is programmable ON or OFF. In cases of Pacemaker Mediated Tachycardia (PMT), the PMT protection algorithm features provide both detection and termination of PMTs. In this way, the more hemodynamically favorable AV synchronization can be quickly re-established. PMT may be suspected if 16 consecutive cycles of atrial sensing and ventricular pacing occur and these are within the range of the PVARP and the PVARP + PVARP extension and are stable. When a PMT is ongoing, there is coupling between the ventricular paced (Vp) event and the subsequent atrial sense (As). As such the **VA Criterion** is used to detect if a PMT is present.

2.7.10 VES Discrimination after Atrial Sensed Events

Stratos LV 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: OFF, 250…(5)…450 ms). 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 paced is delivered.

2.7.11 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.

2.7.11.1 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 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).

2.7.11.2 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.

2.7.11.3 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.

2.7.11.4 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, during the 24 hour period beginning at midnight, the total time recorded at maximum sensor rate exceeds 90 seconds, the sensor gain setting is reduced by one step. The sensor gain will be increased by one step after 7 consecutive days during which the time recorded at maximum sensor rate is less than 90 seconds each day.

2.7.12 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 and post-shock bradycardia pacing.

2.7.13 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 and post-shock bradycardia pacing.

2.7.14 Post Ventricular Atrial Refractory Period

DR and HF versions only.

Immediately following a each sensed or 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.

2.7.15 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.

2.7.16 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 to their programmed values.

2.7.17 Noise Response

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

2.7.18 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 DDI bradycardia therapy at the post shock pacing rate, amplitude, and pulse width for the programmed **Post-Shock Duration**.

Separate post shock programming of the following parameters is available:

- Ventricular Pacing Configuration (**RV**)
- Basic Rate
- Rate Hysteresis
- AV Delay

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

2.8 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.

2.8.1 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
- Pacing Rate
- Upper Rate (Dual Chamber modes only)
- Pulse Amplitude
- Pulse Width

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

2.8.2 Pacing Impedance Measurements

The Lumos ICDs/CRT-Ds have the ability to perform automatic and manual pacing impedance measurements. The devices can measure the pace impedance in any of the pacing configurations; RA, RV, LV or BiV. In addition, the LV pacing polarity is also programmable for impedance measurements (See Section 2.1).

The impedance is measured using a triggered mode with paces of 2.8 Volts and 0.5 ms. 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).

2.8.3 Shock Impedance Measurements

The Lumos 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 (they are done concurrently) and every four days. The results of these impedance measurements are available through the devices statistics.

2.8.4 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.

2.8.5 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.

2.8.6 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 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 S3 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.

2.8.7 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.

2.8.8 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.

2.8.9 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 2.6.2**.

2.8.10 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 (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.

2.9 Special Features

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

2.9.1 ICD Therapy Status

Interrogating the device and observing the **ICD Therapy** status section (upper right hand corner) of the main programming screen indicates the therapy status (either DISABLED or ENABLED). The status can be changed by selecting ON or OFF under the Therapy Status window.

WARNING

Unwanted Shocks – Always program Therapy status 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.

2.9.2 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 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.

WARNING

The use of Home Monitoring does not replace regular follow-up examinations. Therefore, when using Home Monitoring, the time period between follow-up visits may not be extended.

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

NOTE:

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

2.9.2.1 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 2.9.2.4**.

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

2.9.2.2 CardioMessenger

The CardioMessenger patient device (Figure 8) 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, please refer to its manual.

Figure 8: Example of CardioMessenger with Charging Stand

2.9.2.3 Cardio Report

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.

2.9.2.4 Types of Report Transmissions

When the Home Monitoring function is activated, the transmission of information from the implant can be triggered as follows:

- Periodic report – the time period (daily) initiates the transmission
- Event report – the ICD/CRT-D detects certain events, which initiate a transmission
- IEGM– 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 pre-detection IEGM.

Periodic Report

The time of the report transmission is programmable. For periodic messages, the time can be set anywhere between 0:00 and 23:59 hours. It is recommended to select a time between 0:00 and 4:00. The Lumax ICDs and CRT-Ds can be programmed to transmit IEGMs on a periodic basis with the interval selected (OFF, 2, 3, 4, or 6 months.

2.9.2.5 Home Monitoring Test Message

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.

Event Report

When certain cardiac and technical events occur, a report is automatically generated. This information is described as an "event report."

The following events initiate a report:

Table 27 Home Monitoring Report Triggers

Events that trigger event reports
Special Device Status Detected
VF Detection Inactive
Ventricular Impedance Outside Of Set Limits
Shock Impedance Outside Of Set Limits
Atrial Impedance Outside Of Set Limits
Battery Status ERI
Ineffective 30 J Shock Detected
Initial Detection In VF
Initial Detection In VT2
Initial Detection In VT1
Initial Detection In SVT
% Sensing (Ventricular) Below Set Limit
First Mode Switch During The Day (Or Since Follow-Up)
Ongoing Atrial tachyarrhythmia Episode lasting longer than the programmed time (0.5, 6, 12 or 18 hours)

WARNING

A timely receipt of the event report cannot be guaranteed. The receipt is also dependent on whether the patient was physically situated in the required coverage range of the patient device at the time the event information was sent.

2.9.2.6 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.

Table 28: Transmitted Home Monitoring parameters

Home Monitoring Parameters
Type of the last Home Monitoring Message
Time of the Transmission of the last Message
Battery Voltage
Date of the Battery Voltage Measurement
DCAC Current Counter
Charge-Time Sum
Device Status
Programmer Status
Pacemaker Mode
Last Basic Rate
% Pacing in the Atrium/24hr
% Pacing in the Ventricle/24hr
% Biventricular Pacing
% Triggered Pacing
Patient Activity/24hr (Sensor Data)
Ventricular Heart Rate (Mean) /24hr
Heart Rate at Rest (Mean) / programmable intevals
VES /24 hr
Mode Switch Counter/ 24 hr
Mode Switch Duration (cumulative) / 24 hr
Atrial Lead Status
Ventricular Lead Status
Impedance of Pacing/Sensing Lead, Atrium
Impedance of Pacing/Sensing Lead Ventricle
Date of Pacing/Sensing Impedance Measurement
Shock Impedance of the Last Saved Shock
Date of Shock Impedance Measurement
Heart Rate Variability
Number of Mode Switches
AF Burden
Date of Last VT/VF Episode

Table 28: Transmitted Home Monitoring parameters

Home Monitoring Parameters
Event Counter - Initial Detection in VT1
Event Counter- Initial Detection in VT2
Event Counter - Initial Detection in VF
Event Counter - SVT
ATP Counter – Delivered ATP
ATP Counter – Successful ATP
Shock Counter – Started Shocks
Shock Counter – Successful Shocks
Shock Counter – Canceled Shocks
Shock Counter – Ineffective 30-Joule Shocks
Date of the Last Follow-up
Interrogation Indicator

2.9.2.7 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 episodes as an additional to the current messages. In addition, the Lumax devices can be programmed to send an IEGM for each therapy episode, monitoring episodes and periodically. The transmitted data contains approximately 10 seconds of IEGM data, recorded directly before the initial detection of the episode. The data source is the Holter memory. With triple chamber configurations (RA, RV, and LV) all three channels are transmitted. For dual chamber configurations, the atrial and ventricular marker channels are transmitted. In single chamber configuration, the data from the ventricular marker channel is transmitted only. The morphology information for the RV channel is transmitted in all configurations.

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).

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 after every “Periodic message“, “Impedance trend triggered message“ and “Event triggered message“. The delay between the delivery of the counter message and the IEGM message is approximately 60 seconds.

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

2.9.3 Real-time IEGM Transmission

The pulse generators provide real time transmission of the unfiltered intracardiac electrogram (IEGM) to the programmer. During dual chamber operation, IEGMs from the atrium and ventricle can be simultaneously recorded with a bandwidth of 0.5 to 200 Hz. During single chamber operation, a far field ventricular electrogram can be simultaneously recorded. The IEGMs may be transmitted to the programmer via the programming head positioned over the implanted pulse generator. They are then displayed together with surface ECG and markers on the programmer screen and printed on the ECG recorder. Likewise, intracardiac signals and markers identifying atrial/ventricular paced and sensed events are received via the programming head, and may be displayed on the programmer screen and printed on the ECG recorder.

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

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

2.9.4 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 does not reset the automatic reformation clock (i.e., shock therapies).

An automatic or manually initiated capacitor reform fully charges the capacitors with a specific sequence 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 may be reformed manually.

2.9.5 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.

2.9.6 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

2.9.7 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.

2.9.7.1 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 equal to or above a programmed Activity Threshold.

The default value for the Activity Rate Threshold is 70 bpm independent of the pacing mode. The sensor indicated pacing rate is the sensor rate inclusive attack rate and decay. The daily value is stored in the device for a period of 120 days. After 120 days, new daily values replace the oldest daily values.

2.9.7.2 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 to 180 bpm. The daily value is stored for a period of 120 days. After 120 days, new daily values shall replace the oldest daily values. The programmer presents the daily bpm-value in a trend graph for the last 120 days.

2.9.7.3 Mean Heart Rate at Rest

On a daily basis, the Kronos LV-T 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 120 days. After 120 days, new daily values replace the oldest daily values. The programmer presents the daily bpm-value in a trend graph for the last 120 days.

2.9.7.4 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.

2.9.8 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.

2.9.8.1 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 EGM button. 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
- IEGMs

2.9.8.2 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

2.9.8.3 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

2.9.9 Real-time IEGM

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.

The sensing / impedance screen allows automatic measurement of P-waves and R-waves. The sensing / impedance screen also allows a temporary bradycardia program to be sent to the Lumax for evaluation of pacing parameters. IEGM markers are available for all sensed and paced events.

2.9.10 Timing Statistics

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

2.9.10.1 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.

2.9.10.2 Event Episodes

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

- As – Vs
- As – Vp
- Ap – Vs
- Ap – Vp
- Vx - Vx

2.9.10.3 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.

2.9.10.4 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.

2.9.10.5 Counters

The following counters are available within the Timing Statistics:

- PMTs
- Safety Window Pacings
- Mode Switching Episodes

2.9.11 Atrial Arrhythmias

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

2.9.12 Ventricular Arrhythmias

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

2.9.13 Sensor

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

2.9.14 Sensing

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

2.9.15 Impedances

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

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 55°C (41° - 131° 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 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 6932
- Medtronic Sprint 6943
- Medtronic Sprint Quattro 6944
- Medtronic Transvene RV 6936
- St. Jude (Ventritex) TVL- ADX 1559
- St. Jude SPL SP02
- Guidant Endotak DSP
- Guidant Endotak Endurance EZ, Endotak Reliance
- Guidant (Intermedics) 497-24.

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

- Guidant Endotak Endurance "CPI 0125"
- Guidant Endotak Reliance 0148
- Medtronic Sprint 6932
- Medtronic Sprint 6942
- Medtronic Sprint 6943
- Medtronic Sprint 6945
- Medtronic Sprint Quattro 6944
- St. Jude Riata 1571/65
- St. Jude SPL SPO1."

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
- Guidant-Easytrak LV-1
- Guidant-Easytrak 2
- Guidant-Easytrak 3
- Medtronic-Attain
- St. Jude-Aescula
- St. Jude-Quicksite
- Biomec-Myopore Epicardial
- Medtronic-Epicardial 5071
- Medtronic-CapSure EPI
- Biotronik-ELC 54-UP

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

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

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 must not be placed closer than 2 cm to the device (implanted or out of the box). Programming wand distance closer than 2 cm may damage the device.

CAUTION

Shock Impedance - If the shock impedance is less than twenty-five ohms, 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. 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

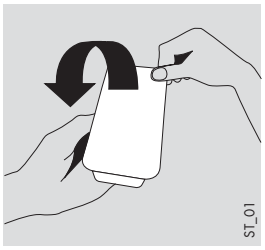
The ICD/CRT-D is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference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

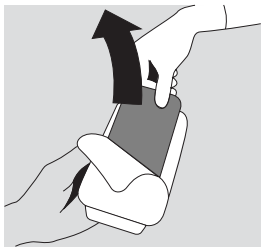
4.3 Opening the Sterile Container

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 (Lumax DR and HF only) and the CS lead for biventricular pacing (LV) is utilized by the Lumax HF. Figure 9 depicts the configuration of the header ports on the Lumax HF CRT-Ds, where HV1 and HV2 are for DF-1 connectors, and A P/S and V P/S are for IS-1 connectors. Lumax VR ICD is identical except for the absence of the Atrial and CS pace/sense ports.

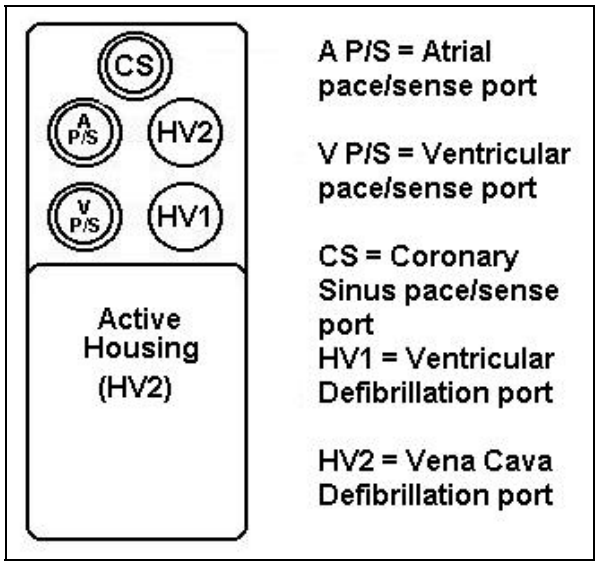


Figure 9. Header Ports

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).
1. 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.
2. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
3. After carefully retracting 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.

1. Insert the blind plug into the connector port of the ICD/CRT-D until the connector pin becomes visible behind the setscrew.
2. 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.
3. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
4. After carefully retracting 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 programmer to communicate with the device.

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.

WARNING

Unwanted Shocks – Always program ICD therapy to **Disabled** 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.

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 beside or above 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, 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. 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 at least 20 ppm 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.

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.

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 30 joules per shock.

The service times from beginning of service (BOS) to elective replacement indication (ERI) are listed in the following tables. All estimates assume pacing rate of 50 ppm with a pulse width of 0.5 ms and pulse amplitude of 2.4 volts and 500 ohm pacing impedance with all shocks at maximum energy (30 joules) 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 four tables represent the mean longevity estimates for the Lumax DR-T and Lumax HF-T and the two available batteries because they represent different potential versions and battery capacities.

The dual-chamber Lumax variants (Lumax 300 DR, Lumax 340 DR, Lumax 300 DR-T, and Lumax 340 DR-T) of ICDs are intended to operate for more than 6 years under normal use. Table 29 provides longevity estimates for the Lumax DR-T ICD with Wilson 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 29 Lumax 340 DR-T Longevity Estimates

	Pacing Support			
Shocks per year	**0%**	**15%**	**50%**	**100%**
4	8.6	8.1	7.1	6.1
5	8.2	7.7	6.8	5.9
6	7.8	7.4	6.5	5.6
7	7.4	7.0	6.3	5.5
8	7.1	6.7	6.0	5.3
9	6.8	6.5	5.8	5.1
10	6.5	6.2	5.6	4.9
11	6.2	6.0	5.4	4.8
12	6.0	5.8	5.2	4.7

The Lumax HF CRT-Ds (Lumax 300 HF, Lumax 340 HF, Lumax 300 HF-T, and Lumax 340 HF-T) are intended to operate for more than 5 years under normal use. Table 29 provides longevity estimates for the Lumax HF-T CRT-D with Wilson Greatbatch batteries. The table provides several different support scenarios. It is assumed that the shocks are equally spaced throughout the life of the CRT-D.

Table 30 Lumax 340 HF-T Longevity Estimates

Pacing Support				
Shocks per year	**0%**	**15%**	**50%**	**100%**
4	8.2	7.6	6.3	5.2
5	7.8	7.2	6.1	5.0
6	7.5	6.9	5.9	4.8
7	7.1	6.6	5.7	4.7
8	6.8	6.3	5.5	4.6
9	6.5	6.1	5.3	4.4
10	6.3	5.8	5.1	4.3
11	6.0	5.7	5.0	4.2
12	5.8	5.5	4.8	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.

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 Therapy status 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	LUMAX 340 (THICKER CAPACITORS)	LUMAX 340 HF
Dimensions (ICD/CRT-D)	66 mm x 55 mm x 12 mm	66 mm x 55 mm x 13 mm	66 mm x 59 mm x 13 mm
Volume (ICD/CRT-D)	34.6 cm^3	37.2 cm^3	39.8 cm^3
Mass (ICD/CRT-D)	81 g	92 g	94 g
Housing	Titanium		
Header	Epoxy resin		
Seal Plug	Silicone		
Lumax VR 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
Lumax DR 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, IND – Locked-out in US	STD
Minimum threshold	0.2...(0.1)...2.0 mV	0.4 mV
Far-field protection after Vp	50...(25)...225 ms	75 ms

Parameter	Range	Standard
Far-field protection after Vs	Off, 25...(25)...225 ms	75 ms
Upper threshold	50; 75; 87.5 %	50 %
Lower threshold	12.5; 25; 50 %	25 %
Right-ventricular Sensing Parameters		
Sensing RV	STD - standard, TWS - extended T-wave suppression, VFS - extended VF sensitivity, IND – Locked-out in US	STD
Minimum threshold	0.5...(0.1)...2.5 mV	0.8 mV
Blanking after atrial pacing	50...(10)...100 ms	50 ms
Upper threshold	50; 75; 87.5%	50 %
Lower threshold	12.5; 25; 50%	25 %
Hold of upper threshold	100...(20)...600 ms	360 ms
Left-ventricular Sensing Parameters		
Sensing LV	S–D - standard, A–S - inactive, IND – Locked-out in US	STD
Min. threshold	0.5...(0.1)...2.5 mV	0.8 mV
Blanking after atrial pacing	= Safety window	100 ms
Upper threshold	50; 75; 87.5%	50 %
Hold of upper threshold	100...(20)...600 ms	360 ms
Lower threshold	12.5; 25; 50%	50 %
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 sense	UNIP (LV-tip/housing), BIPL (LV-tip/LV-ring)	UNIP
Pulse Amplitudes and Pulse Widths		
Pulse amplitude	0.2...(0.1)...6.2, 7.5 V	2.8 V
Pulse width	0.5, 1.0, 1.5 ms	0.5 ms

Parameter	Range	Standard
Mode		
Mode (DR/HF)	DDD, DDDR, DDI, DDIR, VDD, VDDR, VDI, VDIR, VVI, VVIR, AAI, AAIR, OFF	DDD
Mode (VR)	VVI, VVIR, OFF	VVI
Basic Rate Day/Night		
Basic rate	30..(5)..100..(10)..160 ppm	60 ppm
Night rate	OFF, 30..(5)..100 ppm	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
Repetitive	OFF; 1..(1)..15	[OFF]
Scan	OFF; 1..(1)..15	[OFF]
AV Delay		
AV delay	Low, medium, high, fixed, individ.	Low
AV delay 1	40..(5)..350 ms	-
At rate 1	30..(10)..160 ppm	60 ppm
AV delay 2	40..(5)..350 ms	-
At rate 2	70..(10)..160 ppm	130 ppm
Sense compensation	OFF; -5..(-5)..-60 ms	-30 ms
AV-hysteresis mode	OFF, positive, negative I-Opt (only for DR devices)	OFF
AV hysteresis	10..(10)..150 ms	[50 ms]
AV repetitive (positive)	OFF; 1..(1)..10	[OFF]
AV repetitive (negative)	OFF; 1..(1)..15..(5)..100..(10)..180	[OFF]
AV scan	OFF, 1..(1)..10	[OFF]
I-Opt Plus (Only for DR Devices)		
I-Opt Plus	OFF, ON	OFF
AV hysteresis at I-Opt	400 ms	400 ms

Parameter	Range	Standard
AV repetitive at I-Opt	OFF; 1..(1)..10	[5]
AV scan at I-Opt	OFF, 1..(1)..10	[5]
AV max at I-Opt	400 ms	400ms
Post-ventricular Atrial Refractory Period (PVARP)		
PVARP	175..(25)..600 ms	250 ms
Auto PVARP	OFF, ON	OFF
VES Classification (VES Lock-in Protection)		
VES differentiation after As	250..(50)..450 ms	350 ms
Rate Adaptation (Acceleration Sensor)		
Maximum sensor rate	AUTO, 90..(5)..160ppm	120ppm
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; 8.5; 10; 11; 12; 14; 16; 18; 20; 22; 24; 28; 32; 35; 40	6.0
Auto Sensor gain	OFF, ON	OFF
Sensor threshold	Very low = 0 Low = 3 Medium = 7 High = 11 Very high = 15	Medium
Rate increase	0.5; 1..(1)..6 ppm/cycle	2 ppm/cycle
Rate drop	0.25..(0.25)..1.25 ppm/cycle	0.5 ppm/cycle
Upper Tracking Rate (UTR)		
Upper tracking rate	90..(10)..160 ppm	130 ppm
Upper tracking rate atrium	OFF, 240 ppm	240 ppm
Mode Switching		
Intervention rate	OFF, 100..(10)..250 ppm	160 ppm
Activation criterion X	3..(1)..8	5
Deactivation criterion Z	3..(1)..8	5

Parameter	Range	Standard
Mode	DDI, DDIR at permanent DDD(R) VDI, VDIR at permanent VDD(R)	DDI [VDI]
Change in basic rate	OFF, +5 ... (5) ...+30 ppm	+10 ppm
Post-Mode Switch Response (PMSR)		
Post-ModeSw rate	OFF, +5 ... (5) ...+50 ppm	+10 ppm
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	ENABLED DISABLED	ENABLED
Interval		
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
Detection Counter		
Detection counter VT1	10...(2)...60	[26]
Detection counter VT2	10...(2)...40	[16]
Detection counter VF – X	6...(1)...30	8
Detection counter VF – Y	8...(1)...31	12
Onset		
Onset in VT1/2 with SMART	20%	[20%]
Onset VT1 without SMART	OFF; 3…(4)…32%	OFF
Onset VT2 without SMART	OFF; 3…(4)…32%	OFF
Stability		
Stability in VT1/2 with SMART	12%	[12%]

Parameter	Range	Standard
Stability VT1 without SMART	OFF; 8…(4)…48 ms	OFF
Stability VT2 without SMART	OFF; 8…(4)…48 ms	OFF
SMART Detection		
SMART detection VT1	OFF, ON	[ON]
SMART detection VT2	OFF, ON	[ON]
Sustained VT (without SMART 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]
Forced Termination (with SMART Incl. SMART Redetection)		
Forced termination	OFF; 1…(1)…15 min	[1 min]
Redetection Counter		
Redetection counter VT1	10...(2)...30	[20]
Redetection counter VT2	10...(2)...30	[14]
SMART Redetection		
SMART redetection (VT1 & VT2)	OFF, ON	[ON]
Ventricular Therapy Parameters		
Energy 1st shock and 2nd shock VT1, VT2 (model 300) [1)]	OFF; 1..(1)..16..(2)..30 J	30 J
Energy 1st shock and 2nd shock VF (model 300)	1..(1)..16..(2)..30 J	30 J
Energy 1st shock and 2nd shock VT1, VT2 (model 340)	OFF; 1..(1)..16..(2)..40 J	40 J
Energy 1st shock and 2nd shock VF (model 340)	1..(1)..16..(2)..40 J	40 J

Parameter	Range	Standard
Number of shocks (VT1/VT2)	0..(1)..8	[8]
Number of shocks (VF)	6..(1)..8	8
Confirmation (per zone)	OFF, ON	ON
Shock form (per zone)	Biphasic, biphasic2	Biphasic
Polarity (per zone)	Normal, inverse, alternating	Normal
ATP Parameters		
ATP type	Burst, ramp, Burst + PES	[Burst]
ATP attempts	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 %]
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]
ATP timeout	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
S1 number	1...(1)...10	[5]
R-S1 interval	200...(10)...350 ms (absolute); 70...(5)...95 % (adaptive)	[80%]

Parameter	Range	Standard
S1 decrement	5...(5)...40 ms	[10ms]
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
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	
Basic rate	30 .. (5)..100..(10) .. 160 ppm	60 ppm
Rate hysteresis	OFF, -5 .. (-5) .. –65 bpm	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
Home Monitoring		
Home Monitoring	OFF, ON	OFF
Transmission time	Time (hh:mm)	[01:00 hh:mm]
IEGM for therapy episode	OFF, ON	[OFF]
IEGM for monitoring episode	OFF, ON	[OFF]
Periodic IEGM	OFF, 2, 3, 4, 6 months	[OFF]
Sustained atrial episode	OFF, 0,5, 6, 12, 18 h	[12 h]

FCC Statement: (FCC ID: QRILUMAXT): 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

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