Lexos

Family of Implantable Cardioverter Defibrillators

Technical Manual

BIOTRONIK

X-ray Identification

Lexos DR, DR-T, VR and VR-T
Implantable Cardioverter Defibrillator

Inside the housing, right-hand side:

X-Ray identification	KV
Year of manufacture	nn

CAUTION

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

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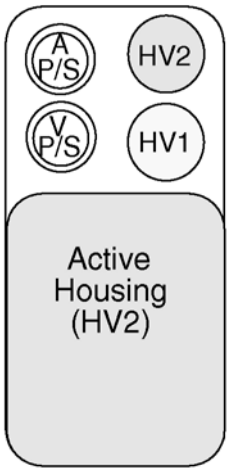


A P/S = Atrial pace/sense port

V P/S = Ventricular pace/sense port

HV2 = Vena Cava Defib. port or Blind Plug

HV1 = Ventricular Defib port

*Lexos VR and VR-T ICDs do not have an atrial pace/sense port

Lexos Specifications and Description

Battery Voltage:	6.3 Volts
Maximum Shock Energy:	30 joules
Defibrillation Lead Ports	Two DF-1 (3.2 mm)
Pacing Lead Ports	Two IS-1 (3.2 mm) (one for Lexos VR and VR-T)
Dimension:	67 x 55 x 12 mm
Volume:	32 cc
Mass:	80 g
Housing Material:	Titanium
Header Material:	Epoxy Resin
Sealing Plug Material:	Silicone
Battery Composition	Li / MnO_2

1. General

1.1 System Description

The Lexos family of Implantable Cardioverter Defibrillators (ICDs) detect and treat ventricular tachyarrhythmias and provide rate adaptive bradycardia pacing support. The ICDs are designed to collect diagnostic data to aid the physician's assessment of a patient's condition and the performance of the implanted device.

The Lexos ICDs provide therapy for ventricular tachyarrhythmias with a sophisticated range of programmable anti-tachycardia pacing (ATP), and/or defibrillation therapy. The shock polarity and energy may be programmed to tailor the therapy to appropriately treat each patient's tachyarrhythmias. The ICDs provide shock therapies with programmable energies from 5 to 30 joules.

The Lexos family of ICDs includes the following members:

- **Lexos 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.
- **Lexos DR-T** is identical to the Lexos DR with 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.
- **Lexos VR** provides single chamber rate adaptive bradycardia pacing support.
- **Lexos VR-T** is identical to the Lexos VR with 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 Lexos DR and DR-T have two DF-1 defibrillation/ cardioversion and two IS-1 pacing/sensing header ports. The Lexos VR and VR-T have two DF-1 defibrillation/ cardioversion and 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 System. These external devices include the TMS 1000 PLUS Tachyarrhythmia Monitoring System and the EPR 1000 PLUS Programming and Monitoring System. These programmers are used to interrogate and program the ICD.

1.2 Indications and Usage

The Lexos Implantable Cardioverter Defibrillators (ICDs) are intended to provide ventricular anti-tachycardia pacing and ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias.

1.3 Contraindications

Do not use the Lexos Implantable Cardioverter Defibrillators (ICDs) in patients:

- Whose ventricular tachyarrhythmias may have transient or reversible causes including:
  - acute myocardial infarction
  - digitalis intoxication
  - drowning
  - electrocution
  - electrolyte imbalance
  - sepsis
  - hypoxia
- Patients with incessant VT of VF
- Patients with unipolar pacemaker
- Patients whose only disorder is bradyarrhythmia or atrial arrhythmia

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.

Lead Systems - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as under sensing of cardiac activity and failure to deliver necessary therapy.

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 system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

Unwanted Shocks – Always program the VT/VF Detection and 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.

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

1.4.1 Sterilization, Storage, and Handling

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

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

Storage (temperature) - Store the device between 5° to 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. The capacitors may be reformed manually, or the ICD may be programmed to reform the capacitors automatically. For further information, please refer to **Section 2.8.4**, Capacitor Reformation.

Connector Compatibility - ICD 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 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 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.

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

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

Programmers - Use only BIOTRONIK programmers to communicate with the device (TMS 1000 ^{PLUS} or EPR 1000 ^{PLUS}).

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.

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.

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 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 30 joules per shock.

Shock Therapy Confirmation – Programming CONFIRMATION to OFF may increase the incidence of the ICD 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.

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 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. 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.

1.4.5 Pulse Generator Explant and Disposal

Device Incineration – Never incinerate the ICD due to the potential for explosion. The ICD must be explanted prior to cremation.

Explanted Devices – Return all explanted devices to BIOTRONIK.

Unwanted Shocks – Always program the 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 or pacemaker. The ICD 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.

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

Diathermy - Diathermy therapy is not recommended for ICD 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 to confirm device status and proper function.

Lithotripsy - Lithotripsy may damage the ICD. If lithotripsy must be used, avoid focusing near the ICD 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 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 to return to its normal mode of operation.

The following equipment (and similar devices) may affect normal ICD 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 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 cm) of the ICD, when the ICD is programmed to standard sensitivity.

Patients having an implanted BIOTRONIK ICD who operate a cellular telephone should:

- Maintain a minimum separation of 6 inches (15 cm) 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 cm) 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 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, moving the telephone away from the immediate vicinity of the ICD should restore normal operation. A recommendation to address every specific interaction of EMI with implanted ICDs 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 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 when they are placed in close proximity to the device.

1.5 Adverse Events

1.5.1 Potential Adverse Events

The following is a list of the potential risks that may occur with this device:

- Acceleration of arrhythmias
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration / dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression

- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

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

1.5.2 Observed Adverse Events

A clinical study of the Phylax AV involved 128 devices implanted in 126 patients with a cumulative implant duration of 795.5 months (mean implant duration 6.3 months).

NOTE:

The Phylax AV ICD is an earlier generation of BIOTRONIK devices. The Lexos family is based upon the Phylax AV and other BIOTRONIK ICDs (i.e., Phylax, Tachos, and Belos families of ICDs).

There were a total of two deaths during the course of the trial; neither of which was judged by the clinical study investigator to be device related. The two deaths were related to heart failure and pneumonia. Both of the deaths occurred more than three months post implant.

Three devices were explanted during the trial. One device was explanted secondary to the patient reporting pain at the implant site; the patient was subsequently implanted with another device. One device was explanted due to a random component failure, and the other device was explanted after reaching ERI, which was anticipated based on the number of shocks delivered. These two patients were subsequently implanted with other Phylax AV ICDs.

Table 1 provides a summary of the adverse events that were reported during the clinical study regardless of whether or not the event was related to the ICD system. A complication was defined as a clinical event that resulted in additional invasive intervention, injury, or death. An observation was defined as a clinical event that did not result in additional invasive intervention, injury, or death.

Table 1: Reported Adverse Events

	# of Patients with AEs	% of Patients with AEs	# of AEs	AE / pt-yrs
Complications Total	**14**	**11.1%**	**18**	**0.27**
Lead Repositioning	10	7.9%	12	0.18
Discomfort at Implant Site	1	0.8%	1	0.02
Infection	1	0.8%	1	0.02
Thrombus	1	0.8%	1	0.02
Pneumothorax	1	0.8%	1	0.02
ERI	1	0.8%	1	0.02
Random Component Failure	1	0.8%	1	0.02
Observations Total	**47**	**37.3%**	**74**	**1.12**
T-wave Oversensing	7	5.6%	7	0.11
Increased Pacing Threshold	7	5.6%	7	0.11
Required antiarrhythmic drug therapy	7	5.6%	7	0.11
SVT Therapy-Unrelated to SMART	6	4.8%	8	0.12
Software version I-GAV.1.U[1]	6	4.8%	6	0.09
Detection	5	4.0%	5	0.08
Lead revision at implant	5	4.0%	5	0.08
TMS 1000[2]	4	3.2%	4	0.06
Lead difficulties at Implant	3	2.4%	3	0.05
Difficulties with Telemetry	3	2.4%	3	0.05
Atrial Lead Dislodgment	2	1.6%	2	0.03

	# of Patients with AEs	% of Patients with AEs	# of AEs	AE / pt-yrs
SVT Therapy-Related to SMART	2	1.6%	4	0.06
Initial therapy did not convert VT/VF	2	1.6%	2	0.03
Low P/R-Wave Amplitude	2	1.6%	2	0.03
Intermittent Under / Oversensing	2	1.6%	2	0.03
Lead Repositioning at implant	2	1.6%	2	0.03
Asynchronous Pacing	2	1.6%	2	0.03
Atrial Arrhythmias	2	1.6%	2	0.03
Atrial arrhythmia with ventrical tracking	1	0.8%	1	0.02
External cardioversion due to AT	1	0.8%	1	0.02
P-wave changes with position	1	0.8%	1	0.02
Patient Symptomatic at Upper Tracking Rate	1	0.8%	1	0.02
Diaphragmatic Pacing	1	0.8%	1	0.02
Myocardial Infarction	1	0.8%	1	0.02
Cautery caused Shock Delivery	1	0.8%	1	0.02
Phantom programming	1	0.8%	1	0.02

Number of Patients = 126, Number of Patient-Years = 66.3,
see next page for notes on table.

1. This category includes various anomalies that were related to the programmer software used in the clinical study, I-GAV.1.U. Each of these events has been resolved through revisions to the programmer software resulting in version I-GAV.2.U.
2. This category includes any difficulties encountered while using the TMS 1000^{PLUS} Tachyarrhythmia Monitoring System, which is a commercially available device that was used during the clinical investigation.

1.6 Clinical Studies

1.6.1 Tachos DR

The Tachos DR clinical evaluation involved 57 patients implanted with a Tachos DR outside of the United States.

NOTE:

The clinical study information included in this technical manual was performed with the Phylax AV and Tachos DR ICDs. The Lexos DR is a downsized version of the Belos DR, which was also based on and approved with this data. The clinical study data presented here is applicable because the Lexos ICDs are downsized versions of the Belos and Tachos families of ICDs. The Lexos ICDs are slightly different as compared to the Belos ICDs in the following areas:

- Reduced size from 39 cc to 32 cc
- Additional shock waveform - Biphasic 2ms (see **Section 2.5.3.3**)
- Upper Tracking Rate (UTR) programmable in the VT-1 therapy zone
- Minimum shock energy is 5 Joules

Due to the similarities between the Lexos family and Phylax, Tachos, and Belos families of ICDs and the limited nature of these changes, a clinical study of the Lexos DR/DR-T ICD was determined to be unnecessary.

1.6.1.1 Study Objectives

The objective of the clinical evaluation was to gather basic information about the function and performance of the Tachos DR ICD in patients with standard ICD indications.

1.6.1.2 Results

The mean implant duration was 5.7 months with cumulative implant duration of 323 patient months. No unanticipated events were reported during the evaluation. A summary of the results obtained during the evaluation is provided in the following table.

1.6.1.3 Survival

During the initial experience outside of the United States with the Tachos DR, there have been no sudden cardiac deaths reported. There was one death reported, which was unrelated to the implanted device.

Table 2: Tachos DR Study Results

Evaluation	Results
Appropriate Atrial Sensing and Pacing	99% (126/127)
Appropriate Ventricular Sensing and Pacing	99% (122/123)
Appropriate Ventricular Tachyarrhythmia Detection and Conversion	96% (116/121)
Complication Rate (per patient)	3.5%
Complication Rate (per patient-year)	0.074
Sudden Cardiac Death Survival Rate	100%
Overall Survival Rate	98%

1.6.2 Phylax AV

The Phylax AV clinical study involved 126 patients (111 males (88.1%) and 15 females (11.9%) with a mean age of 66 years (range: 22-87 years) and a left ventricular ejection fraction of 31% (range: 10-60%). Most patients (80.2%) presented with coronary artery disease / ischemic cardiomyopathy; 65.1% presented with monomorphic ventricular tachycardia (MVT) as their primary tachyarrhythmia.

NOTE:

The Phylax AV ICD is an earlier generation of BIOTRONIK devices. The Lexos family is based upon the Phylax AV and other BIOTRONIK ICDs (i.e., Phylax, Tachos, and Belos families of ICDs). Therefore, the clinical data from the Phylax AV was used to support the safety and effectiveness of the Lexos DR.

1.6.2.1 Methods

The multi-center, non-randomized clinical investigation was designed to validate the safety and effectiveness of the Phylax AV through an analysis of the unanticipated adverse device effect (UADE) rate. The specific predefined objectives of the investigation included UADE-free survival rate, morbidity rate, sudden cardiac death (SCD) survival rate, the appropriate sensing and pacing rate, detection and conversion of ventricular tachyarrhythmias, and the appropriate rejection of atrial tachyarrhythmias.

1.6.2.2 Results

The mean implant duration was 6.3 ± 0.4 months with cumulative implant duration of 795.5 months. There were 20 patients followed for over twelve months and 62 patients followed for over six months during the study period from February 5, 1999 to April 15, 2000. The patient follow-up compliance rate was 98.4% out of 319 required follow-ups. **Table 3** provides a summary of the results of the study group for the predefined endpoints.

Table 3: Clinical Study Results

Description	Study Group [95% CI]
UADE-free Survival Rate (patients with at least 3 months follow-up)	100% (85/85) [96.5%, 100%]
Complication Rate	11.1% (14/126) [0%, 16.8%]
Sudden Cardiac Death Survival Rate	100% (124/124) [97.6% 100%]
Appropriate Bradycardia Sensing and Pacing Rate	96.2%(1141/1186) [95.2%, 100%]
Detection and Conversion of Ventricular Tachyarrhythmias	98.2% (650/662) [97.1%, 100%]
Appropriate Rejection of Atrial Tachyarrhythmias	94% (138/147) [89.6%, 100%]

1.6.2.3 SMART Detection Algorithm

The SMART Detection algorithm is an integral function of BIOTRONIK's dual chamber ICD product line (i.e., Phylax AV, Tachos DR, and Belos DR) and is designed to discriminate life-threatening ventricular tachycardias from relatively harmless atrial tachyarrhythmias. This algorithm uses information about the signals from the atrial and ventricular lead systems and is designed to reduce the amount of inappropriate therapy that might be delivered as a result of a supraventricular tachycardia (SVT). Neither the SMART Detection algorithm nor the ICDs are designed to detect or deliver therapy to terminate atrial arrhythmias, and therefore this is not the purpose of the algorithm or the device.

During the Phylax AV clinical study, specific data was collected to demonstrate the ability of the SMART Detection algorithm to discriminate between SVT and VT. The Phylax AV demonstrated the ability to withhold inappropriate therapy in approximately 94% of the SVT episodes that were reported during the study. In addition, the SMART Detection algorithm appropriately delivered therapy in 100% of the ventricular episodes in which the feature was activated. At routine follow-ups, the algorithm was activated in 80% of patients enrolled into the study, which further supports the overall ability of the algorithm to appropriately discriminate between SVT and VT. In addition, during the clinical study, the investigators indicated that the primary reason for selecting a dual-chamber ICD was SVT discrimination for 70% of the patients enrolled.

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 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 (72%) of the patients receiving an ICD in the Phylax AV clinical study 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 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 ICD Patients

The prospective ICD 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 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 ICDs, additional ICD experience, and individual medical judgment will aid in determining the need for additional testing and follow-up.

2. Device Features

The Lexos 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 Lexos 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 Sensing (Automatic Sensitivity Control)

The Lexos ICDs use Automatic Sensitivity Control (ASC) to adjust the input stage sensitivity threshold 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.

2.1.1 Ventricular Sensitivity Settings

There are three programmable preset options for setting the sensitivity of the 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 4**.

Table 4: 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.
Free	This parameter configuration is only accessed by code and is not available 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.

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 (350 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.

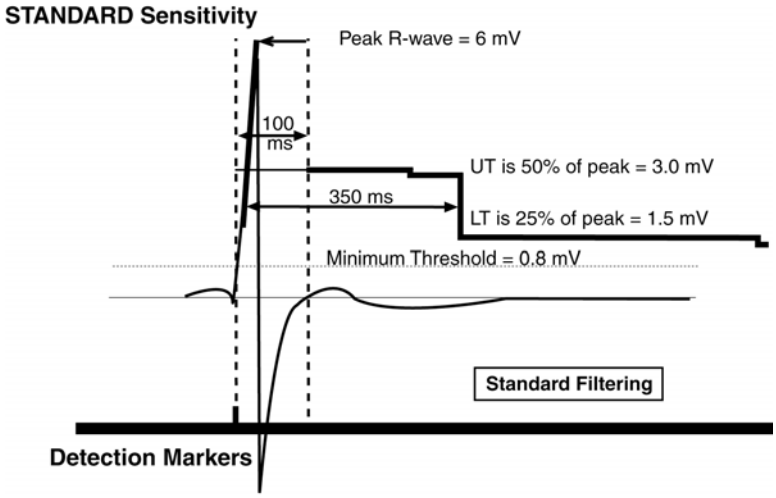


Figure 1 Automatic Sensitivity Control with Standard Setting

Figure 1 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.

2.1.2 Minimum Ventricular Threshold

This parameter limits the minimum sensitivity of the ICD 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.

2.1.3 Atrial Sensitivity Settings

There is only one option for setting the sensitivity of the atrial input stage. When atrial sensing is active, the sensitivity is set to "Standard" which is designed to adapt the parameters of the input stage to various signal conditions. The available settings are described in Table 5**.**

Table 5: 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.
Free	This parameter configuration is only accessed by code and is not available 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.

2.1.4 Minimum Atrial Threshold

This parameter limits the minimum sensitivity of the ICD to a programmable value. Nominally, the minimum threshold is set to 0.4 mV, but it can be adjusted from 0.2 to 2.5 mV.

2.1.5 Far Field Blanking

This parameter blanks the atrial channel of the ICD to the period before and after each ventricular sensed event. The first number is the pre-event blanking period and the second number is the post-event blanking period.

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 Ventricular Tachyarrhythmia Detection

The Lexos ICDs 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 classifies the arrhythmia and delivers the appropriate therapy. If a tachyarrhythmia continues following the first therapy attempt, then the ICD will redetect the tachyarrhythmia and deliver subsequent therapies as necessary.

WARNING

Unwanted Shocks – Always program the VT/VF Detection and 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.

Classification of cardiac signals is accomplished primarily by measuring the cardiac cycle length (R-R, P-R and P-P). In addition, the ICD 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.

2.2.1 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.

2.2.2 VT Interval Counters

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

2.2.3 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, 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.

The ICDs 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 Lexos ICDs 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 termination criteria are met, all tachyarrhythmia detection criteria, including the VT sample counters are reset. (See section 2.4).

2.2.4 SMART Detection™

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 33) 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.

2.2.5 Onset

Another detection enhancement is ONSET, which may be used Independently in the VT-1, VT-2, and with SMART Detection™ (deactivated),. In the VT-1 and VT-2 zones, the purpose of ONSET is to 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 appropriately withheld if a sinus tachycardia rate crosses into one of the VT zones.

The SMART Detection™ algorithm utilizes ONSET as an integral part of the discrimination algorithm, therefore when SMART Detection™ is enabled the ONSET parameter must also remain enabled and set to 20 %.

2.2.6 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%.

2.2.7 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. A “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 the 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 starts. 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.

2.3 Tachyarrhythmia Redetection

The Lexos ICDs offer independently programmable settings for determining if tachyarrhythmias remain after therapy has been delivered. The redetection routine allows the ICDs 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.

2.3.1 VT Redetection

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

Redetection of an ongoing tachyarrhythmia is declared when the Redetection Counter 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 Redetection Counter setting. Tachycardia redetection is declared when the programmed number of VT samples (Redetection Counter) 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).

2.3.2 SMART Redetection

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.

2.3.3 VF Redetection

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

2.4 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).

2.5 Tachyarrhythmia Therapy

The Lexos ICDs 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.

2.5.1 Therapy Options

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

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

2.5.2 Anti-Tachycardia Pacing (ATP)

Anti-tachycardia pacing (ATP) therapy 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-S1 interval, 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 of 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 is individually programmed either as an adaptive value (as a percentage) or as an absolute value (expressed in milliseconds).

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 new S1-S1 interval is dependent on the initial start interval (S1 decrement) and the programmed scan decrement (if activated).

S1 Count - The S1 count parameter defines the number of stimuli of an ATP. For Burst + PES, an extra stimulus with a separate parameter is coupled.

R-S1 - 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 onwards.

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.

2.5.2.1 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.

2.5.2.2 ATP Therapy 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 stores successful ATP therapies only. The stored information includes not only the number of the ATP therapy (e.g., ATP 2), but also the successful configuration in detail (for example: Burst; R-S1 Interval: 320 ms, S1-S1 Interval: 320 ms; etc.).

2.5.2.3 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.

2.5.3 Shock Therapy

Shock Therapy can be delivered as defibrillation shocks with or without confirmation (while the capacitors are being charged). The first shock energy in each shock module has independently programmable Shock Energy, and confirmation programmable ON/OFF. The remaining shock therapies are non-programmable and predetermined to deliver 30 joules using defibrillation without confirmation. All shock therapies may be programmed to normal or reversed polarity.

2.5.3.1 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 shock energy and confirmation parameters are independently programmable, while the remaining shocks are fixed at 30 joules with Confirmation turned OFF.

2.5.3.2 Confirmation

The Confirmation parameter is used to verify the presence of a tachyarrhythmia during the charging of the capacitors. This function is designed to avoid delivery of inappropriate 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 shock therapy 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. However if the device confirms the presence of the tachyarrhythmia, the device will deliver the programmed shock therapy.

CAUTION

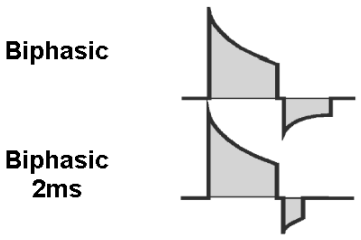
Shock Therapy Confirmation – Programming CONFIRMATION to OFF may increase the incidence of the ICD delivering inappropriate shocks.

SYNCHRONIZATION

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.

2.5.3.3 Shock Waveform

Two waveforms of shock therapy are available with the Lexos ICDs, Biphasic and Biphasic 2ms. The following diagram describes each of the shock waveforms.



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

Figure 2. Biphasic Waveforms

The waveform starts 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.

Figure 2 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.

2.5.3.4 Shock Energy

The Lexos ICDs are designed to ensure that the energy programmed for therapy is the same as what is actually delivered to the patient regardless of the lead impedance. The first shock energy in each therapy class is programmable between 5 and 30 joules. The remaining shock energies will be delivered at 30 joules.

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 delivering inappropriate shocks.

2.5.3.5 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 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.

2.5.4 Progressive Course of Therapy

By design, the Lexos ICDs 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 will always deliver a maximum energy shock upon re-detecting in an arrhythmia class with a programmed therapy with energy less than or equal to the previously delivered therapy. In addition, the ICD blocks all ATP therapy during the current episode if a shock has already been delivered during the episode.

Furthermore, the ICD 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 Lexos ICDs would continue with shock therapy, but all shocks programmed at less than 10 joules would be delivered at an energy of 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, the shocks are delivered at maximum energy (30 joules).

2.6 Bradycardia Therapy

The Lexos ICDs have independently programmable dual chamber bradycardia and post-shock bradycardia pacing functions. The post-shock bradycardia parameters may be programmed to higher rates or output values for the period following a delivered shock, without compromising the longevity of the ICD for patients who require chronic bradycardia pacing. The post-shock programmable values are presented in a separate subsection from the normal bradycardia support values.

2.6.1 Bradycardia Pacing Modes

The available bradycardia pacing modes for each member of the Lexos ICD family are listed in **Table 6**.

Table 6 Lexos Pacing Modes

Mode	Lexos DR and DR-T	Lexos VR and VR-T
DDDR	X	N/A
DDIR	X	N/A
VDDR	X	N/A
VDIR	X	N/A
AAIR	X	N/A
VVIR	X	X
DDD	X	N/A
DDI	X	N/A
VDD	X	N/A
VDI	X	N/A
AAI	X	N/A
VVI	X	X
OFF	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.

2.6.2 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.

2.6.3 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 Rate is active, the basic rate automatically decreases to the programmed pacing 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 Rate 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 Rate time may require adjustment.

2.6.4 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 is limited to only providing a basic rate that is 30 bpm or greater. Therefore, if the basic rate is 80 bpm and the hysteresis value is programmed to –65 bpm, the ICD paces at a rate of 30 bpm because this is the minimum at which it can function.

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 during the programmed pacing Night Rate. Programming conflicts arise when the total decrease in rate is below 30 ppm. Care should be exercised to avoid programming a Night Rate and hysteresis that is below what is appropriate and may be tolerated by the individual patient.

2.6.4.1 Repetitive Hysteresis

Repetitive hysteresis is expanded programmability of the Hysteresis feature. Repetitive hysteresis searches for an underlying intrinsic cardiac rhythm, which may exist slightly below the programmed lower rate (or sensor-indicated rate). 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.

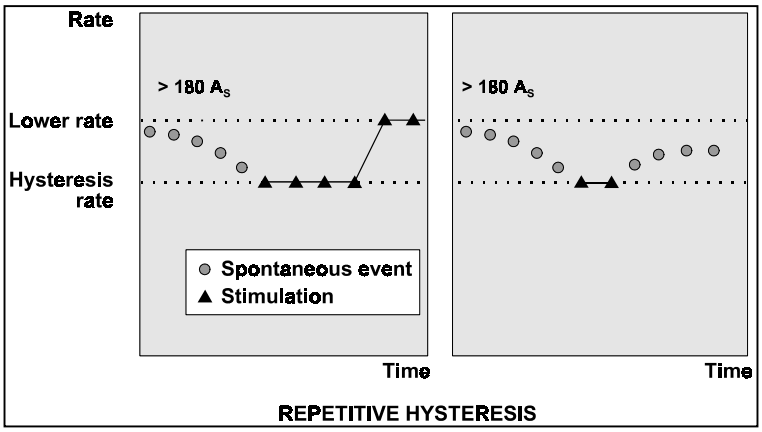


Figure 3. **Repetitive Hysteresis**

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 Rate 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.

2.6.4.2 Scan Hysteresis

Scan hysteresis is expanded programmability of the Hysteresis feature. Scan hysteresis searches for an underlying intrinsic cardiac rhythm, which may exist slightly below the programmed lower rate (or sensor-indicated rate) of the pulse generator. 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.

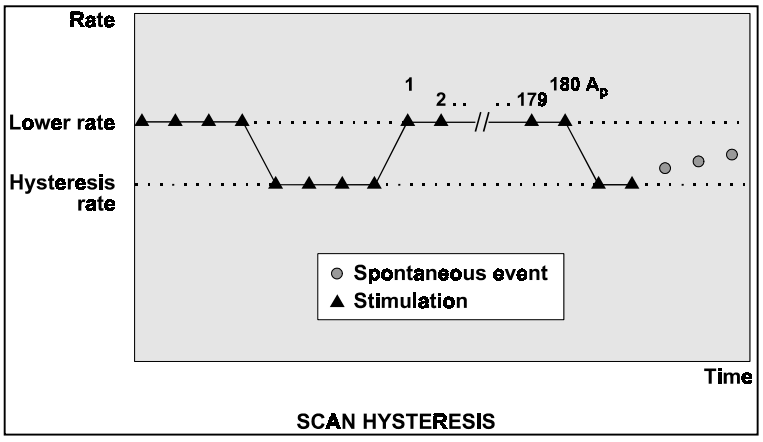


Figure 4. **Scan Hysteresis**

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.

2.6.5 Dynamic AV Delay

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 (**Dynamic**).

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 Lexos DR and DR-T ICDs.

2.6.6 Upper Tracking Rate

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

The UTR response will automatically toggle between 2:1 and WKB (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.

NOTE:

The Lexos DR and Lexos DR-T ICDs the UTR is programmable 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.

2.6.7 Mode Switching

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 7. Mode switching is not available during the post-shock pacing period. Mode Switching is only available with the Lexos DR and DR-T ICDs.

Table 7: 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 **Criteria for Activation** is also met. The criteria for activation is a programmable X

After switching to a non-atrial tracking mode, the ICD 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 **Criteria for Deactivation** parameter is fulfilled, the ICD returns to the normal programmed pacing mode.

2.6.8 PMT Management

The following features provide prevention, detection, and termination of pacemaker-mediated tachycardias (PMT):

- PMT prevention by extending PVARP
- PMT protection (PMT detection and termination)

PMT Prevention - To prevent PMT, the pacemaker restarts the basic rate and PVARP when there is ventricular sensing but no atrial event preceding it. If PVARP extension has been programmed, the PVARP is additionally prolonged after a VES. A retrograde P wave with a VA conduction time that is shorter than the PVARP is not able to trigger a ventricular pace, and thus no PMT.

PMT Termination - Pacemaker-mediated tachycardias can also be caused by artifacts and atrial extrasystoles. In such cases, 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. **PMT Protection** can be programmed ON or OFF. PMT Termination features are only available with the Lexos DR and DR-T ICDs.

2.6.9 Rate Adaptive Pacing

WARNING

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

Lexos ICDs allow the selection of rate-responsive pacing modes. These modes allow the ICD'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. 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.

2.6.9.1 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).

2.6.9.2 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.

2.6.9.3 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.

2.6.9.4 Auto Sensor Gain

The Lexos ICDs offer Automatic Sensor Gain settings, which allow 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.

2.6.10 Pulse Amplitude

The Pulse Amplitude parameters, both atrial and ventricular, define the amplitude in volts of the pacing pulses. The pulse amplitude is independently programmed for normal and post-shock bradycardia pacing.

In addition, if the time received at maximum sensor rate is more than 90 seconds, the sensor gain is decreased by 1 step.

2.6.11 Pulse Width

The Pulse Width parameters, both atrial and ventricular, define the duration of the pacing pulses. The pulse width is independently programmed for normal and post-shock bradycardia pacing.

2.6.12 Post Ventricular Atrial Refractory Period

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 from sensing inappropriate signals. PVARP is only available with the Lexos DR and DR-T ICDs.

2.6.13 PVARP Extension

Extends the Post Ventricular Atrial Refractory Period by the programmed interval. PVARP Extension is only available with the Lexos DR and DR-T ICDs.

2.6.14 Noise Response

The Lexos ICD's response to detected noise is to deliver asynchronous pacing in the affected channel.

2.6.15 Post Shock Pacing

Separately programmable bradycardia pacing support is available with the ICD 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 will begin 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:

- Basic Rate
- Hysteresis
- AV Delay

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

2.7 EP Test Functions

Several EP test functions are available with the Lexos family of ICDs including; P and R-wave amplitude, pacing and shock impedance, 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.

2.7.1 P and R-wave Amplitude Measurments

The Lexos ICDs 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
- AV Delay
- Automatic Printing Function

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

2.7.2 Testing for Retrograde Conduction

Retrograde conduction from the ventricle 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 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.

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.

2.7.3 Pacing Threshold

The test is activated as a temporary program, and 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), pulse amplitude and pulse width, number of pulses for each test voltage and automatic printing capabilities. The pacing modes available for the threshold test are AAI, VVI, DDI, and DDD. The pulse amplitude is easily adjustable during the threshold testing by selecting the desired value from the table.

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 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 is already busy processing a manual command or the Battery Status is low.

2.7.4 Arrhythmia Induction Features

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

HF Burst Induction This feature 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 burst of pacing stimuli followed by a programmable number of timed extra stimuli. The burst rate is independently programmable, as is the Number S1. The interval between S1s and the remaining programmed extra stimuli (PES: S1 through S4 possible) is 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 user programmable.

2.7.5 Manual Shock

The ICD can deliver a manual shock on demand through a programmer command in the EP test menu. 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.

2.7.6 Manual ATP

The ICD 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 2.5.2**.

2.7.7 Test Shock

The ICD 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.

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 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 Special Features

WARNING

Unwanted Shocks – Always program the VT/VF Detection and 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.

2.8.1 Detection and Therapy Status

Interrogating the device and observing the detection and therapy section (upper right hand corner) of the main programming screen indicates the detection and therapy status (either ENABLED or DISABLED). The status can be changed by selecting the Detection section of the main programming screen and selecting the desired setting from the resulting pop-up screen.

2.8.2 Home Monitoring (Lexos DR-T and VR-T Only)

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.

NOTE:

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

2.8.2.1 Transmission of Information

The implant transmits information with a small transmitter, which has a range of about 6 feet (2 meters). The patient's implant data are sent to the corresponding patient device upon the detection of an arrhythmia episode, as programmed. The types of transmissions are discussed in Section 4.

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

2.8.2.2 Patient Device

The patient device (Figure 5) is designed for use in or away from the home and is comprised of the mobile unit and the associated charging station. The patient can carry the mobile unit with them during his or her occupational and leisure activities. The patient device is rechargeable, allowing for an approximate operational time of 24 hours. It receives information from the implant and forwards it via the mobile network to a BIOTRONIK Service Center.

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

Figure 5: Example of Patient Device with Charging Stand

2.8.2.3 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, which are titled depending on the type of report transmission – trend and event. This Cardio Report, which is adjusted to the individual needs of the patient, contains current and previous implant data. The Cardio Report is sent to the attending physician via fax. All reports use the same report format.

2.8.2.4 Types of Report Transmissions

When the Home Monitoring function is activated, the transmission of a report (Cardio Report) from the implant can be triggered as follows:

• Event report – the ICD detects certain events, which initiate a report immediately

• Trend Event report – the ICD detects certain events, which initiate a report at the programmed time of trend transmission.

To assure successful transmission of the patient data, the Lexos VR-T and Lexos DR-T send 4 repetitive transmissions of identical data at a 60 minute time interval.

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 are detected by the implant, a report transmission is automatically triggered. This is described as an "event message".

The following cardiac and technical events initiate an immediate message transmission:

- Special Device Status
- Detected and terminated VT-1
- Detected and terminated VT-2
- Detected and terminated VF
- First ineffective 30 J shock detected
- Pace impedance < 300 Ohm or > 1 K Ohm
- Shock impedance < 30 Ohm or > 110 Ohm
- Device status – ERI

Trend Event Report

When certain cardiac and technical events are detected by the implant, a report transmission is triggered at the time of trend transmission. This is described as a “trend event message”.

The following cardiac and technical events initiate an immediate message transmission:

- Change of lead impedance (delta limits are programmable by the physician)

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.

2.8.2.5 Description of Transmitted Data

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

The Monitoring Interval

The monitoring interval is considered the time period since the last trend information was sampled. In the absence of an event report, the monitoring interval would be 24 hours. For an event report, the monitoring interval would be less than 24 hours, since these reports are sent after the programmed time of trend transmission.

Detection

- # of Episodes in VT1 Zone
- # of Episodes in VT2 Zone
- # of Episodes in VF Zone
- # of SVT events*

Therapy

- ATPs delivered
- ATPs successful
- Shocks delivered
- Shocks successful
- Shocks aborted
- 30J Shock without Success

Intrinsic Rhythm*

- Percentage of Atrial Senses (A_s/A_x)
- Percentage of Ventricular Senses (V_s/V_x)

Battery

- Status (i.e., BOL, MOL1, MOL2, ERI, EOS)
- Battery Voltage
- Date of voltage measurement

Leads

- Pace Impedance (atrial*, ventricular)
- Shock Impedance
- Date of impedance measurements

Device Status Summary

- Status
- Remarks

*Available only with dual chamber ICDs.

2.8.3 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.

2.8.4 Capacitor Reformation

Shock charge times may be prolonged if the high voltage capacitors remain uncharged for an extended period of time. Conditioning (or re-forming) the capacitors by periodically charging them will help assure shorter charge times in those patients that do not regularly receive shock therapy. The ICD may be programmed to automatically re-form the capacitors after every 3, or 6 months or not at all (OFF). The capacitor reformation clock is reset following an automatic or manual capacitor re-form, or any device initiated maximum charging of the high voltage capacitors.

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 will provide bradycardia pacing support and tachyarrhythmia sensing and detection as programmed. If a tachyarrhythmia is detected during capacitor re-formation, 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. The capacitors may be reformed manually, or the ICD may be programmed to reform the capacitors automatically.

NOTE:

Biotronik recommends automatic reforming capacitors, because disabling this function may reduce the benefits associated with frequent capacitor charging (e.g., short charge times in patients who have infrequent shock therapy).

2.8.5 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 and resides in the device memory for later recall if needed.

2.8.6 System Status

Various device parameters can be monitored through the Status section of the programmer screen. Displayed data includes ICD 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 Lexos ICDs including:

- Serial number (always displayed after interrogation)
- Software Release
- Device status
- Battery voltage
- Battery status
- Last charge event
  - Date
  - Energy
  - Charge time
- Total number of charges
- Last P and R-wave measurements
- Last pacing lead impedance (atrial and ventricle)
- Last pacing threshold measurement with pulse width (atrial and ventricle)
- Last shock impedance measurement and date

2.8.7 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.

2.8.7.1 Episode List

The ICD 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 can store up to 30 minutes of dual chamber intracardiac electrograms (IEGMs) including the history and prehistory of the following events:

- Detection
- Redetection
- Terminations
- Manual Shocks
- SVT Success and/or Termination

STORED INTERVALS

The ICD can store a large number of cardiac intervals including the history and prehistory of events. The graphic display of these intervals includes significant events to provide a base timeline (e.g., shocks, detections, terminations). The following intervals are available:

- R-R
- P-P
- P-R
- R-P

2.8.7.2 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

2.8.7.3 Counters

The device history regarding several therapy and detection parameters is presented in the “Counters” screen. This screen contains both the number of events since the last ICD follow-up and totals since the device was implanted. The available parameters include:

DETECTION EPISODES

- SVT
- VT-1
- VT-2
- VF

THERAPIES

- Successful ATP Therapies
- Unsuccessful ATP Therapies
- Successful ATP Therapies
- Unsuccessful ATP Therapies

SVT DETAILS

- AFlut
- AFib
- Sinus T
- 1:1

2.8.8 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 ICD for evaluation of pacing parameters. IEGM markers are available for all sensed and paced events.

2.8.9 Brady Diagnostics

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

2.8.9.1 Event Counters

The total number of atrial sensed, atrial paced, ventricular sense 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.

2.8.9.2 Activity Report

The activity report provides information that can assist the physician in optimizing pacing and/or sensor parameters. This report contains the maximum sensor rate attained and the mean sensor rate.

2.8.9.3 Ventricular Rate Histogram

The ventricular rate histogram shows the percentage of time the ventricular 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 179 bpm.

2.8.9.4 Sensor Rate Histogram

The sensor rate histogram shows the percentage of time the sensor 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 179 bpm.

3. Sterilization and Storage

The ICD 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, and information on sterilization and storage.

The ICD 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 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 TMS 1000^{PLUS} based testing, the following cabling and accessories are available:

PK44 - used to connect the TMS 1000^{PLUS} 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 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. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Lexos ICD. Note that the battery status may appear lower than its true value when the ICD is not at body temperature. Program detection and therapy to “Disabled” prior to handling the Lexos ICD.

Sufficient training on the device and its associated components is required prior to implanting the ICD. For additional information, training and training materials contact your BIOTRONIK representative.

WARNING

Lead Systems - The use of another manufacturer's ICD lead system may cause potential adverse consequences such as undersensing of cardiac activity and failure to deliver necessary therapy.

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 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 system. For further information, please refer to **Appendix A**.

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

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

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

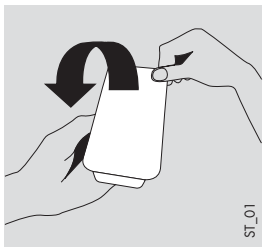
The ICD is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992].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

Refer to the appropriate lead system technical manual.

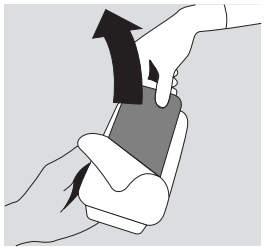
4.3 Opening the Sterile Container

The Lexos ICDs 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 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 system should have detection and therapy disabled prior to performing medical procedures. In addition, the ICD 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 Lexos ICDs 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 (Lexos DR and DR-T only). **Figure 6** depicts the configuration of the header ports on the Lexos DR , where HV1 and HV2 are for DF-1 connectors, and A P/S and V P/S are for IS-1 connectors. Lexos VR and VR-T ICDs are identical except for the absence of the Atrial pace/sense port.

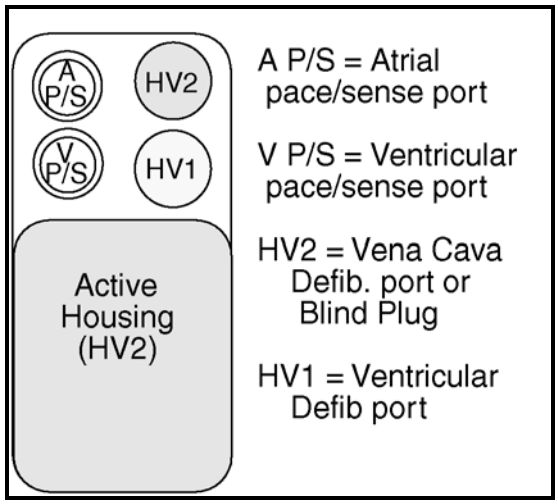


Figure 6. Header Ports

CAUTION

Connector Compatibility - ICD 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 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 without bending the lead until the connector pin becomes visible behind the setscrew. Hold the connector in this position. If necessary, apply silicone oil only to the o-rings on the connector (not the connector pin).
3. Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. After carefully retracting the torque wrench, the perforation will self-seal.

4.6 Blind Plug Connection

The Lexos DR and DR-T ICDs come with a blind plug (pre inserted) in an unused header port. Refer to the following steps when connecting blind plugs to the device.

1. Confirm that the setscrews are not protruding into the connector receptacles. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the lead connector until it is firmly placed in the setscrew. Rotate the wrench counterclockwise until the receptacle is clear of obstruction.
2. Insert the blind plug into the connector port of the ICD until the connector pin becomes visible behind the setscrew.
3. Insert the enclosed torque wrench through the perforation in the self-sealing plug at an angle perpendicular to the connector until it is firmly placed in the setscrew.
4. Securely tighten the setscrew of the connector clockwise with the torque wrench until torque transmission is limited by the wrench.
5. 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 Pacemaker Interaction Testing

There are three situations in which pacemaker/ICD interaction testing is appropriate when:

- a pacemaker and an ICD are implanted at the same procedure
- an ICD is implanted in a patient with a chronic pacemaker
- a pacemaker is implanted in a patient with a chronic ICD

In each of these cases, the pacemaker and ICD may interact in such a way that the pacemaker could interfere with the classification of tachyarrhythmias by the ICD. The three possible mechanisms of interaction are listed below:

- During a tachyarrhythmia episode, the pacemaker may not detect the patient's tachyarrhythmia. In addition, the amplitude of the pacemaker pacing pulses may be large enough to cause the ICD to detect only the pacing pulses and not sense the underlying tachyarrhythmia. Therefore, the ICD would not provide appropriate anti-tachyarrhythmia therapy.
- The ICD may detect both the pacing pulses and the resulting ventricular response as separate signals (doubled count). The ICD might then classify the normal paced rhythm as a tachyarrhythmia and subsequently deliver therapy inappropriately.
- If the pacemaker experiences a sensing failure, a lead dislodgment, or lack of capture the ICD could sense the asynchronous pacing pulses along with the patient's normal sinus rhythm. The ICD may then classify the rhythm as a tachyarrhythmia and deliver inappropriate therapy.

The following test procedures should be performed during implantation of the ICD with a concomitant pacemaker. There are two separate procedures that must be completed.

Part 1

Verify that inappropriate therapy will not be initiated by oversensing of pacemaker pulses.

1. Program the detection status and magnet mode of the ICD to “DISABLED”.
2. Keep the programming wand in place over the ICD to observe the intracardiac electrograms and markers when the pacemaker is inhibited.
3. Program the pacemaker’s lower rate and AV Delay, if applicable, to values that ensure consistent pacing. Program the pacemaker to unipolar (or bipolar) pacing with the pacing amplitude and pulse width parameters at maximum values.
4. Observe the intracardiac electrograms and markers again. If either signal shows events that are oversensed, the ICD or pacemaker leads should be repositioned in order to minimize the amplitude of the pacing artifacts.
5. It may be necessary to reduce the pacing amplitude and pulse width settings of the pacemaker during testing to eliminate interaction with the ICD. If testing indicates a set of maximum allowable programmable parameters, it should be recorded in the patient’s record for future reference, in the event that reprogramming is required.

Part 2

Verify that oversensing of pacemaker pulses during a tachyarrhythmia episode will not inhibit tachyarrhythmia therapy.

1. Program the pacemaker to a unipolar asynchronous pacing mode (V00 or D00) at maximum pacing amplitude and pulse width settings.
2. Program the detection status of the ICD to “ENABLED”.
3. Induce ventricular fibrillation from the EP Test screen
4. Observe the intracardiac electrograms and the markers. BE PREPARED TO DELIVER AN EMERGENCY SHOCK IF THE TACHYARRHYTHMIA IS NOT DETECTED AND TERMINATED BY THE ICD.

5. If the ICD did not detect the tachyarrhythmia, reduce the pacemaker's output settings and repeat step 4 until maximum allowable pacemaker output settings are defined. The maximum allowable programming set should be recorded in the patient's records for future reference, should reprogramming be required.
6. After conversion testing is complete, interrogate the pacemaker to ensure that its programmed parameters have not been changed and that no damage was caused by delivery of therapy by the ICD.
7. Program the pacemaker to the appropriate pacing parameters based on the completed testing.

To reduce the possibilities of pacemaker/ICD interaction, it is recommended that:

- the ICD and pacemaker leads be placed as far away as possible from one another
- the pacemaker leads with a short inter-electrode spacing be used
- the pacemaker be programmed to the lowest allowable amplitude and pulse width to ensure consistent, chronic capture
- the pacemaker must be programmed to the maximum sensitivity (without oversensing during a normal rhythm) to ensure pacing is inhibited during tachyarrhythmia episodes.
- the pacemaker be programmed to the minimum lower rate sufficient for the patient.

CAUTION

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

4.8 Program the ICD

Program the ICD 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 to treat each individual patient. The detection and therapy status of the ICD 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 programmers to communicate with the device (TMS 1000 PLUS, or EPR 1000 PLUS).

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 the VT/VF Detection and 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.

4.9 Implant the ICD

The ICD may be placed in the pocket at this time. Place the device into the pocket with the etched side facing up. Carefully coil any excess lead length beside or above the ICD.

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 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 system. For further information, please refer to **Appendix A.**

Pacemaker/ICD Interaction - In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted).

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 system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

CAUTION

Pacing Threshold - Testing of the pacing threshold by the ICD 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 or pacemaker. The ICD 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.

The ICD system should have detection and therapy disabled prior to performing any of the following medical procedures. In addition, the ICD 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.

Complete the Medical Device Registration Form provided with the ICD and return it to BIOTRONIK.

5. Follow-up Procedures

5.1 General Considerations

An ICD follow-up serves to verify appropriate function of the ICD 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. 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 system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias.

5.2 Longevity

The service time of an ICD 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 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 below in **Table 8**. 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. The estimates associated with 0% pacing support assume the ICD is sensing an intrinsic sinus rhythm at a rate of 70 bpm.

Table 8: Longevity Estimates

DDD Pacing Support	Shocks Per Year	Years
100 %	12	3.5
	4	4.3
	1	4.6
	0	4.8
50 %	12	4.0
	4	5.0
	1	5.5
	0	5.7
15 %	12	4.4
	4	5.6
	1	6.3
	0	6.6
0 %	12	4.6
	4	6.0
	1	6.8
	0	7.1

Each maximum energy (30 joule), high voltage charging sequence reduces the longevity of the device by approximately 21 days.

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 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, 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 the VT/VF Detection and 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.

CAUTION

Device Incineration – Never incinerate the ICD due to the potential for explosion. The ICD 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 Lexos ICDs. 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

Parameter	Value Range
Dimensions	67 x 55 x 12 mm
Conducting Surface Area	61.5 cm^2
Volume	32 cc
Mass	80 g
Housing Material	Titanium
Header Material	Epoxy resin
Seal Plug Material	Silicone
Lexos VR and VR-T Lead Ports	1 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1
Lexos DR and DR-T Lead Ports	2 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1

Parameters – Tachyarrhythmias

Parameter	Value Range	Std Program	Safe Program
Detection Parameters for VT Arrhythmia Classes			
Detection	ENABLED, DISABLED	EN	EN
Therapy	ENABLED, DISABLED	EN	EN
VT-1 Zone Limit	OFF,270…(10)… 600 ms 100 … 222 bpm	OFF	OFF
VT-2 Zone Limit	OFF,270…(10)… 500 ms 120 … 222 bpm	OFF	OFF

Parameters – Tachyarrhythmias continued…

Parameter	Value Range	Std Program/ Safe Program
Detection Parameters for VT Arrhythmia Classes (Cont.…)		
Number of Intervals – Detection	10…(2)… 30	16 14 (VT-2)
Number of Intervals – Redetection	10…(2)… 30	12 10 (VT-2)
SMART Detection	ON, OFF	OFF
Onset	OFF, Absolute: 8…(4)…48 ms Adaptive: 4… (4) … 32%	OFF
Stability	OFF, Absolute: 8…(4)…48 ms Adaptive: 4… (4) … 40%	OFF
Sustained VT	OFF, 0.5, 1, 2, 3.0, 4.0, 5.0…(5)… 30:00 min	OFF
Detection and Redetection Parameters for VF Class		
VF Zone Limit	OFF, 200…(10)…400 ms 150 … 300 bpm	300 ms
Number of X	6 … (1) … 30	8
Number of Y	8 … (1) … 31	12
Termination		
Number of X	12	12
Number of Y	16	16

Bradycardia Therapy

Lexos Pacing Modes		
Mode	**Lexos DR and DR-T**	**Lexos VR and VR-T**
DDDR	X	N/A
DDIR	X	N/A
VDDR	X	N/A
VDIR	X	N/A
AAIR	X	N/A
VVIR	X	X
DDD	X	N/A
DDI	X	N/A
VDD	X	N/A
VDI	X	N/A
AAI	X	N/A
VVI	X	X
OFF	X	X

Parameter	Value Range	Std Program	Safe Program
Mode	Lexos VR and VR-T Lexos DR and DR-T	VVI DDD	VVI DDD
Basic Rate	30…(5)…160 ppm	60	70
Night Rate	OFF, 30…(5)…150 ppm	OFF	OFF
Night Begin	00:00…(00:15)…23:45	N/A	N/A
Night End	00:00…(00:15)…23:45	N/A	N/A
V Amplitude	0.2…(0.1)…6.2, 7.5 V	2.8	7.5
V Pulse Width	0.50, 1.00, 1.50 ms	0.50	1.50
A Amplitude	0.2…(0.1)…6.2, 7.5 V	2.8	N/A
A Pulse Width	0.50, 1.00, 1.50 ms	0.50	N/A
Upper Tracking Rate	90…(10)…160 ppm	130	N/A

Parameter	Value Range	Std Program	Safe Program
Hysteresis	OFF, -5…(-5)…-65 ppm	OFF	OFF
Repetitive Hysteresis	OFF, 1…(1)…10	OFF	OFF
Scan Hysteresis	OFF, 1…(1)…10	OFF	OFF
Sense Compensation	OFF, -20…(-20)…-120 ppm	-30	OFF
Safety Window	70, 85, 100 ms	100	OFF
Mode Switch mode	DDI, DDIR, VDI, VDIR	DDI	OFF
Intervention Rate	OFF, 100…(10)…250 bpm	OFF	N/A
Mode Switch Activation Criteria	3 of 8…(1)…8 of 8	5 of 8	N/A
Mode Switch Deactivation Criteria	3 of 8…(1)…8 of 8	5 of 8	N/A
PVARP	200…(50)…500 ms	300	300
PVARP Extension	0 …(25)…275 ms	100	100
Dynamic AV Delay	Low, Medium, High, Fixed, Dynamic	Low	N/A
Sensor Gain	1.0…40.0	6	N/A
Maximum Sensor Rate	80 …(5)…160 ppm	120	N/A
Sensor Threshold	Very Low, Low, Medium, High, Very High	Medium	N/A
Auto Sensor Gain	ON, OFF	ON	N/A
Rate Increase	1, 2, 4, 8 ppm/sec	2	N/A
Rate Decrease	0.1, 0.2, 0.4, 0.8 ppm/sec	0.4	N/A

Additional Sensing Parameters

Parameter	Value Range	Std Program/ Safe Program
Sensitivity – Atrium	Standard OFF Free (Locked-out in US)	STD
Sensitivity – Ventricle	Standard Enhanced T wave suppression Enhanced VF sensitivity Free (Locked-out in US)	STD
Atrial Minimum Threshold	0.1…(0.1)…2.0 mV	0.4
Ventricular Minimum Threshold	0.5…(0.1)…2.5 mV	0.8
Blank after V Pace	100…300 ms	250
Blank after A Pace	100…300 ms	140
Blank after V Sense	4 … (4) …48 ms	8
Blank after A Sense	4 … (4) …48 ms	OFF
Far Field Blanking	8/OFF, 8/20, 16/20, 16/40, 16/60, 16/80, 16/100, 16/120, 16/140 ms	8/OFF
Ventricular Sensed Refractory Period	180 … (10) … 400 ms	200
Atrial Sensed Refractory Period	Automatic equal to AV Delay plus 20 ms	200

Parameters – Bradyarrhythmias continued…

Atrial Paced Refractory Period	180 … (10) … 400 ms	240
Ventricular Paced Refractory Period	250 … (10) … 400 ms	340
Cross Blanking	4 … (4) …96 ms	52

Post-Shock Bradycardia Therapy

Parameter	Value Range	Std Program	Safe Program
Mode	DDI, VDI and VVI Lexos DR and DR-T Lexos VR and VR-T	 DDI VVI	 VVI VVI
Basic Rate	30…(5)…160 ppm	60	70
AV Delay	15, 50…(10)…350 ms	140	N/A
Amplitude (A and V)	7.5 V	7.5	7.5
Pulse Width (A and V)	1.50 ms	1.50	1.50
Post –Shock Duration	0…(10)…50 seconds 1:00... (1:00) ... 10:00 min	10 sec	10 sec
Post –Shock Blank	1 second	1	1

Basic ATP Therapy

Parameter	Value Range	Std Program/ Safe Program
Pacing Mode	VOO	VOO
ATP Type	OFF, BURST, RAMP, BURST + PES	BURST
Amplitude	7.5 V	7.5
Pulse Width	1.50 ms	1.50
Attempts	OFF, 1 ... (1) ... 10	3
S1 Count	1 ... (1) ... 10	5
R1-S1 Interval	Absolute: 200...(10)...500 ms Adaptive: 70... (5) ...95 %	80%
S1-S2	Absolute: 200...(10)...500 ms Adaptive: 70... (5) ...95 %	70%
Minimum ATP Interval	200 … (5) … 300 ms	200
RAMP Decrement	0 ... (5) ... 40 ms	10
Scan Decrement	OFF, 0 ... (5) ...40 ms	OFF
Add S1	ON, OFF	ON

Shock Therapy

Parameter	Value Range	Std Program	Safe Program
Number of VT Shocks	Off, 1...(1)...8	8	8
Number of VF Shocks	6...(1)...8	8	8
Shock Waveform	Biphasic, Biphasic 2ms	Biphasic	Biphasic
Confirmation	ON, OFF	ON	ON
1st Shock Energy (Joules)	5 …(1) … 11, 13, 14, 15, 17, 18, 20, 21, 23, 25, 26, 28, 30	30	30
Maximum Charge Time	20 seconds	20	20
Shock Polarity	NORMAL REVERSED	NORM	NORM

Home Monitoring (Lexos VR-T and DR-T Only)

Parameter	Value Range
Home Monitoring	OFF, ON
Monitoring Interval	1 day
Time of the Trend Event Report Transmission	0:00...(10)...23:59 hours
Repeated Interval	60 minutes
Number of Event Transmissions	4

Appendix A

Connector Compatibility

Lexos ICDs 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 Lexos family of ICDs is mechanically compatible with:

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

The Lexos DR and DR-T ICDs have two IS-1 header ports and two DF-1 header ports while the Lexos VR and VR-T ICDs have a single IS-1 header port and two DF-1 header ports.

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