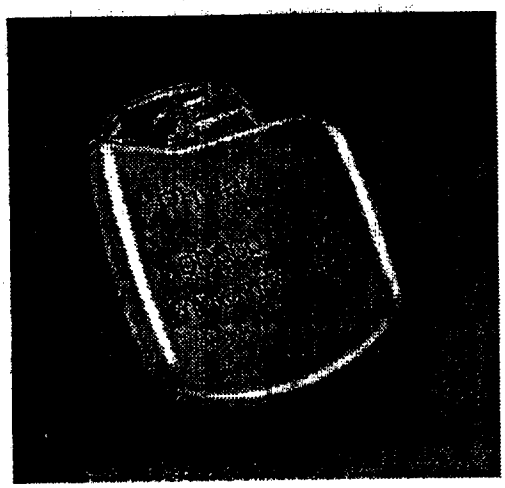
Phylax AV

Implantable Cardioverter Defibrillator



Technical Manual

BIOTRONIK

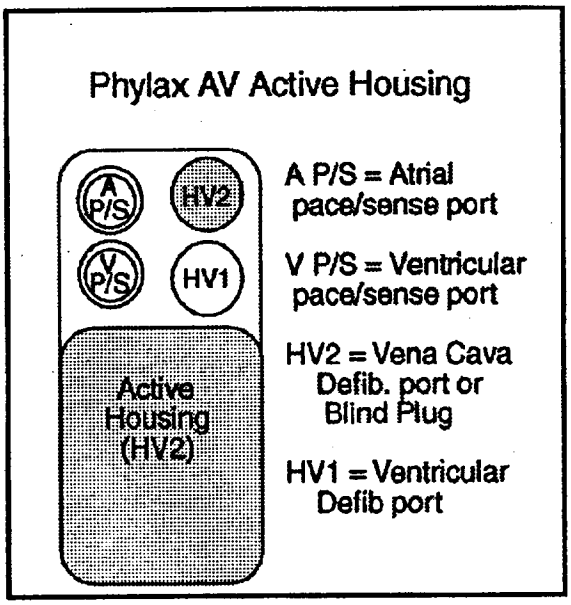
Phylax AV
Implantable Cardioverter Defibrillator

x-ray identification
Inside the housing, top right-hand side:

CAUTION

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

Contents



Phylax AV Specifications

Model:	122382
Battery Voltage:	6.2 volts
Maximum Energy:	30 Joules
Defibrillation Lead Ports	Two DF-1 (3.2 mm)
Pacing Lead Ports	Two IS-1 (3.2 mm)
Dimension:	76 X 63 X 17 mm
Volume:	69 cc
Mass:	109 g

Phylax AV Description

Housing Material:	Titanium
Header Material:	Epoxy Resin
Sealing Plug Material:	Silicone
Battery Material	Anode: Lithium (Li) Cathode: Manganese Dioxide (MnO_2) and Lead Chromate ($PbCrO_4$)

1. General

1.1 System Description

The Phylax AV is a dual chamber implantable cardioverter defibrillator (ICD) that detects and treats ventricular tachyarrhythmias and provides dual chamber bradycardia pacing support. The ICD uses dedicated bipolar atrial and ventricular sensing/pacing leads to provide enhanced discrimination of atrial and ventricular tachyarrhythmias. In response to a detected ventricular tachyarrhythmia, the ICD is capable of delivering antitachycardia pacing (ATP) as well as cardioversion and defibrillation shock therapy. The ICD is designed to collect diagnostic data to aid the physician's assessment of a patient's condition and the performance of the implanted device.

The Phylax AV has two DF-1 defibrillation/cardioversion and two 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

Use the Phylax AV in patients who are at high risk of sudden death due to ventricular arrhythmias and have experienced one or more of the following situations:

- survival of at least one episode of cardiac arrest (manifested by a loss of consciousness) due to a ventricular tachyarrhythmia
- recurrent, poorly tolerated sustained ventricular tachycardia (VT)

NOTE:

The clinical outcome for hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies for this indication have not been conducted.

1.3 Contraindications

Do not use the Phylax AV in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as:
  - acute myocardial infarction
  - digitalis intoxication
  - drowning
  - electrocution
  - electrolyte imbalance
  - hypoxia
  - sepsis
- Patients with incessant VT or VF
- Patients who have a unipolar pacemaker
- Patients whose only disorder is bradyarrhythmias or atrial arrhythmias
- Patients with chronic refractory atrial tachyarrhythmias who require dual chamber pacing

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** - Do not use integrated bipolar leads with the Phylax AV as ICD damage may occur. 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.
- **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 detection status to OFF prior to handling the device to prevent the delivery of serious shocks to the patient or the person handling the device during the implant procedure,.

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 2.7.2 Capacitor Reforming.
- **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 mT.
- **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}).
- **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.
- **Sealing System** - Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.
- **Defibrillation Threshold** - Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.
- **Manual Shocks** – User-commanded shocks may be withheld if the ICD is already busy processing a manual command or the Battery Status is low.
- **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.

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.
- **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 Bioprothesis** - Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

1.4.4 Follow-up Testing

- **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.
- **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 detection status to OFF prior to handling the device during the implant procedure to prevent the delivery of serious shocks to the patient or the person handling the device.

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 be checked after any of the following medical procedures:

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

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs 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 Observed Adverse Events

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

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
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 vent. 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 TMS1000 PLUS. Tachyarrhythmia Monitoring System, which is a commercially available device that was used during the clinical investigation.

1.6 Potential Adverse Effects

In addition to the adverse events reported in the clinical study, other possible adverse events may occur with this type of device including:

- Acceleration of arrhythmias (caused by device)
- 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
- Potential mortality due to inability to defibrillate or pace
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- 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)

1.7 Clinical Studies

1.7.1 Patients Studied

The 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.

1.7.2 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.

1.7.3 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 2 provides a summary of the results of the study group for the predefined endpoints.

Table 2: Clinical Study Results

Description	Study Group [95% CI]
UADE-free Survival Rate (for 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%]

1.7.4 SMART Detection Algorithm

The SMART Detection algorithm is an integral portion of the Phylax AV ICD 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 Phylax AV 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 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.

Note that the Phylax AV provides a feature called the Safety Timer, which allows the physician to program the device to override the SMART Detection algorithm after a certain period of time. This timer is nominally active in order to provide a more conservative approach to arrhythmia discrimination. However, this timer may be extended or turned off altogether once the physician becomes more familiar with the response of the SMART Detection algorithm in each of their individual patients.

1.8 Patient Selection and Treatment

1.8.1 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.

1.8.2 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 this device in clinical studies 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 electrical wheel chair or other electrical (external or implanted devices).

1.9 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.)

1.10 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 Phylax AV feature set is presented under the following sub-headings: Tachyarrhythmia Detection, Tachyarrhythmia Redetection, Tachyarrhythmia Therapy, Tachyarrhythmia Termination, Bradycardia Therapy, EP Test Functions and Special Features.

2.1 Tachyarrhythmia Detection

The ICD detects and measures the rate of sensed cardiac signals to discriminate ventricular tachyarrhythmias from sinus rhythm or sinus bradycardia. If a tachyarrhythmia is detected, the ICD classifies the arrhythmia and delivers the appropriate therapy. If a tachyarrhythmia persists following the first therapy attempt, then the ICD will re-detect the tachyarrhythmia and deliver subsequent therapies as programmed.

Classification of the cardiac rhythm is primarily accomplished by measuring the cardiac cycle length. In addition the ICD can also utilize abrupt changes in rate, or irregularity of the cardiac signal to further discriminate ventricular tachycardias (VT) from supraventricular tachyarrhythmias (SVT).

2.1.1 VF Classification

Classification of ventricular fibrillation (VF) is accomplished when the cardiac rate meets or exceeds the VF Zone Limit criteria and when the X out of Y Interval Ratio criteria are satisfied. Nominal settings for the X/Y criteria 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. The test window (Y criteria) is updated on a beat-to-beat basis.

2.1.2 VT Classification

Both VT-1 and VT-2 classification zones in the Phylax AV utilize identical 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.

In addition to cardiac rate, VT Sample Count must be satisfied before a VT is classified. The VT Sample Count is the programmed number of VT intervals that are required to fulfill the associated VT rate and other supplemental criteria before a VT is declared. 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 deemed VT. A full description of SMART Detection is provided in the following text.

In addition, when the Phylax AV senses six consecutive intervals within the sinus rate zone, all tachyarrhythmia detection criteria, including the VT sample counter are reset.

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 therapy appropriate to the detected VT zone.

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

- Ventricular rhythm stability (see Stability on page 21), if the ventricular signal is unstable then the rhythm is declared a supraventricular tachyarrhythmia (SVT) and 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 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 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.

Specific data was collected during the clinical investigation of the Phylax AV to demonstrate the function of the SMART Detection algorithm. Please refer to Section 1.7.4 for a summary of the clinical data collected.

Onset Delta

Another detection enhancement that may be used independently or as an adjunct to the SMART Detection algorithm is the Onset Delta parameter. This parameter measures abrupt changes in ventricular cycle length to discriminate between supraventricular rhythms (including sinus tachycardia) and tachyarrhythmias originating in the ventricle, which characteristically begin with an abrupt change in cardiac rate.

When **ONSET Delta** is enabled, VT is not declared until **ONSET Delta** and any additional detection criteria are satisfied. This feature allows therapy to be withheld if a sinus tachycardia rate crosses into one of the VT zones.

Stability

The purpose of STABILITY is to assist in discriminating between stable ventricular tachyarrhythmias and supraventricular tachyarrhythmias that conduct irregularly to the ventricles (i.e., atrial fibrillation). 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 interval is 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.

Safety Timer

The safety timer is a countdown timer that is activated when the programmed VT sample count has been reached. At the end of the safety timer countdown, if no tachyarrhythmia has been classified (no therapy delivered) and the cardiac rate remains within the VT-1 or VT-2 zone limits, a classification will be mandated and programmed therapy will begin.

2.1.3 Monitoring Zone

By programming the Monitoring Only parameter ON within the VT-1 Therapy window, a monitoring zone (no programmed therapy) is implemented in order to store electrograms when VT-1 detection criteria are met. However, activation of the monitoring zone disables all VT-1 therapy. This feature allows the device to be programmed with a zone of VT that inhibits all VT therapy, while monitoring and storing the patients cardiac rhythm.

2.2 Tachyarrhythmia Redetection / Acceleration

The Phylax AV offers independently programmable settings for influential tachyarrhythmia redetection.

Tachyarrhythmia redetection and episode termination criteria are based on cardiac cycle length and number of intervals. Following delivery of any VT or VF therapy, the resulting cardiac rhythm is evaluated. Either the VT or VF redetection counter or the episode termination counter is incremented for each detected post-therapy ventricular cardiac event. The cycle length of the cardiac rhythm determines which counter is incremented.

The Phylax AV is also able to redetect an arrhythmia if it has accelerated (from VT to VF) using the programmed Redetection Count. The interval and stability ranges are identical to the initial detection parameter values for each arrhythmia class.

2.2.1 VT Redetection / Acceleration

With each cycle length that is shorter than the VF Zone limit (monitoring OFF) the VT redetection counter is incremented.

The arrhythmia will be redetected once the counter reaches the programmed Redetection Count (shared setting for both VT and VF Redetection). If the arrhythmia accelerates (after therapy) to the VF zone (or within the VF Redetect Limit, if programmed), VF therapy will be delivered when the redetection counter has incremented to the programmed Redetection Count.

2.2.2 VT Redetection with Smart Detection

If SMART Detection is activated for initial detection, it may also be programmed ON for VT redetection as well.

2.2.3 VF Redetection

With each cycle length that is shorter than the VT-1 Zone limit (or than the VF Redetect Limit, if programmed) and monitoring OFF the redetection counter is incremented. The arrhythmia will be redetected once the counter reaches the programmed Redetection Count, then VF therapy will continue.

2.2.4 VF Redetection with Smart Detection

The SMART Detection Redetect for VF parameter provides SMART Detection discrimination during redetection of an arrhythmia initially detected in the VF Zone. This feature is designed to avoid unnecessary therapy when a VF shock induces an atrial fibrillation that conducts to the ventricle at a rate that meets the VT rate criterion.

2.2.5 VF Redetection Limit

VF Redetect limit allows an on-going ventricular arrhythmia to be redetected at a lower rate than initial detection. This may be useful if a previous VF therapy attempt results in slowing the ventricular rate below the initial VF cutoff limit. VF Redetect limit effectively lowers the zone limit for all VF redetection within a single episode.

2.3 Tachyarrhythmia Therapy

The Phylax AV offers a wide choice of therapy options that can be tailored to meet each specific patient's needs. Multiple

therapies can be combined to provide a broad spectrum of treatment options.

2.3.1 Therapy Options

The Phylax AV offers independent programming of two ATP sequences and up to six cardioversion shock therapies for each VT class. In a two-zone configuration, VT-1 is always the slowest programmed VT rate and VT-2 is the faster VT rate. The therapies for the VT-1 class are defined as ATP1 and ATP2. Therapies for VT-2 are defined as ATP3 and ATP4.

2.3.2 Therapy Progression

By design, the Phylax AV will deliver successively aggressive therapy for each attempt within a single detection episode. Therefore, the device will not deliver antitachycardia pacing (ATP) therapy following a cardioversion shock, and will not deliver a low energy cardioversion shock following a high energy defibrillation shock.

ATP will be aborted if the device is unable to couple the initial ATP pace to a ventricular sensed event. This behavior could be caused by a spontaneous conversion of the arrhythmia to sinus rhythm immediately following the event that established the arrhythmia classification.

2.3.3 Antitachycardia Pacing Schemes

ATP therapy may be programmed with a wide range of pacing schemes.

2.3.4 ATP Pacing Parameters

ATP Therapy may be programmed differently for treated arrhythmias designated VT-1 and VT-2 with parameters as defined below:

- **Number of Bursts** - defines the number of sequences of ATP pulses.
- **Number of Pulses** - defines the number of ATP pulses in each sequence.

- **ATP Coupling** - duration from sensed ventricular event to the first pacing pulse of ATP attempt, used for ATP synchronization.
- **Scan Decrement** - intervals will decrease by the programmed value between subsequent ATP attempts after the first attempt.
- **Burst Decrement** - subsequent intervals will decrease within each ATP attempt by the programmed value.
- **Add 1** - Additional pacing pulses may be added between ATP attempts.

NOTE:

All intervals may be programmed as absolute values or adaptive values (based on a percentage of the last detected interval average).

Universal ATP Therapy

The following ATP Therapy parameters are applicable for treated arrhythmias designated VT-1 and VT-2 and are not separately programmable for each arrhythmia classification:

- **Minimum ATP Interval** - defines the minimum interval between ATP pulses.
- **ATP Amplitude** - defines the voltage amplitude for each ATP pulse.
- **ATP Pulse Width** - defines the pulse width for each ATP pulse.
- **ATP Time-out** – A timer that begins to decrement after ATP is delivered. If further therapy is required after the timer has expired, the system advances to the programmed shock therapy for the applicable VT zone. Therapy continues until arrhythmia termination or all programmed therapy (in the applicable zone) has been delivered. Arrhythmia acceleration to VT-2 or VF will then allow additional therapy to be delivered.

2.3.5 Shock Therapy

Shock Therapy can be delivered with or without reconfirmation after the high energy capacitors have been charged. The first two shock energies in each shock sequence have independently programmable Shock Energy. The remaining shock therapies are non-programmable and predetermined to deliver 30 joules.

2.3.6 Shock Therapy Parameters

The following parameters are separately programmable for the shock therapy of each arrhythmia classification including VT1, VT2 and VF therapies. The shock polarity parameter is used for all programmed shocks to assure consistent shock delivery.

Number of Shocks

The Number of Shocks parameter defines the total number of shock attempts per zone (VT-1, VT-2 or VF). For each VT zone, up to 6 shocks may be delivered, if necessary. For the VF zone up to 10 shocks may be delivered.

Reconfirmation

In the nominal setting (Reconfirmation = YES), the device will reconfirm the presence of an arrhythmia after completion of charging and prior to delivering shock therapy. If Reconfirmation is turned OFF, a shock therapy will be delivered upon completion of charging If any programmed shock is aborted, then the second attempt of the shock will be committed (delivered without confirmation). Therefore, two successive shocks cannot be aborted.

The reconfirmation algorithm will deliver a shock if two out of three intervals with a rate faster than the lowest programmed tachyarrhythmia zone are detected within the reconfirmation window after charging is completed. Alternatively, the shock will also be delivered if no sensed events are detected. In all other cases, the shock will be aborted.

If reconfirmation is programmed to NO, then the shock will be delivered without reconfirming the presence of the tachyarrhythmia.

Shock Waveform

All shocks utilize a standard biphasic waveform. 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, the shock changes polarity and discharges to 20% of the initial charge voltage. Figure 1 provides a pictorial representation of the biphasic waveform.

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

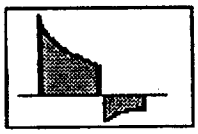


Figure 1. Biphasic Waveform

Shock Energy

The Shock Energy is programmable in 1-joule steps from 1.0 to 30 joules. The energy delivered is equal to the programmed energy. The first two shocks in each shock therapy sequence have programmable Shock Energies. After the first two shocks, all remaining shocks in each therapy sequence are fixed at maximum energy (30 joules).

Shock Polarity

The polarity of the shock therapy may be programmed and changed non-invasively. The Standard polarity configures the HV 1 port as the negative electrode and the HV 2 port and the outer housing as the positive electrode for the first phase of the shock. Reversed polarity will reverse the electrical polarity of both of the connector ports and the housing. As a shared parameter, polarity applies to all programmed shocks.

2.4 Tachyarrhythmia Termination

Termination of a tachyarrhythmia episode is declared when the number of consecutive ventricular events below the lowest programmed arrhythmia zone limit equals the programmed Termination Count.

2.5 Bradycardia Therapy

The Phylax AV has 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.

2.5.1 Bradycardia Mode

The Bradycardia Pacing Mode may be programmed to DDD, DDI, VDD or VVI.

2.5.2 Rate

The rate is the pacing rate in the absence of a patient's intrinsic rhythm.

2.5.3 Hysteresis Rate

The Hysteresis Rate parameter can be disabled (programmed OFF) or set to a rate lower than the bradycardia Basic Rate. The Hysteresis function is designed to promote the patient's intrinsic rhythm and increase the longevity of the ICD by reducing unnecessary bradycardia pacing. If the rate of the patient's sinus rhythm drops below the hysteresis rate, bradycardia pacing will be initiated at the programmed basic rate. The patient's intrinsic rate must then be sensed faster than the programmed basic rate to inhibit pacing again.

2.5.4 Upper Tracking Rate

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

2.5.5 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 or to a fixed AV delay.

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 30 ms from the programmed value 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.

2.5.6 Pulse Amplitude

The Pulse Amplitude parameters, both atrial and ventricular, define the amplitude in volts of the pacing pulses.

2.5.7 Pulse Width

The Pulse Width parameters, both atrial and ventricular, define the duration of the pacing pulses.

2.5.8 Block Mode

The Block Mode parameter controls whether a ventricular pacing pulse, based on tracking of a fast atrial event, will be suppressed (2:1) or delivered after an extended AV delay (WRL).

2.5.9 Post Ventricular Atrial Refractory Period

Immediately following a ventricular event, an atrial refractory period is started. Atrial signals are ignored during this time for bradycardia timing purposes to prevent the ICD from sensing inappropriate signals.

2.5.10 Post PVC Atrial Refractory Period

Immediately following a premature ventricular contraction (PVC), an atrial refractory period is started. Atrial signals are ignored during this time to prevent the ICD from sensing inappropriate signals.

2.5.11 Mode Switch Limit

Automatic Mode Switching is available in atrial tracking modes (DDD and VDD) and is initiated by detection of a non-physiologic high atrial rate, as specified by the parameter, Mode Switch Limit. If the criterion is met, the device will automatically switch to a pacing mode without atrial tracking (DDD switches to DDI and VDD switches to VVI). The Mode Switch Limit determines the atrial rate limit at which the Phylax AV automatically switches from an atrial tracking to a non-atrial tracking mode. Once the atrial rate falls below the Mode Switch Limit, the device will switch back to the permanently programmed pacing mode.

2.5.12 Mode Switch Pacing Rate

Whenever Mode Switching occurs, the device switches to a non-tracking mode and will provide bradycardia pacing support at the Mode Switch Pacing Rate. Once Mode Switching is terminated, the permanently programmed pacing mode and programmed pacing rate are restored.

2.5.13 Maximum Atrial Sensitivity

This parameter limits the maximum sensitivity of the atrial channel. It may be modified in the event that atrial oversensing is observed

2.5.14 Maximum Ventricular Sensitivity

This parameter limits the maximum sensitivity of the ventricular channel. It may be modified in the event that ventricular oversensing is observed

2.5.15 T-wave Extension

T-wave Extension lengthens the threshold step duration (2nd hold off) to avoid sensing large T-waves. BIOTRONIK recommends use of the extended T-wave parameter only in cases where large T-waves are detected by the device resulting in "double counting." Figure 2 provides a pictorial representation of the Extended T-wave parameter.

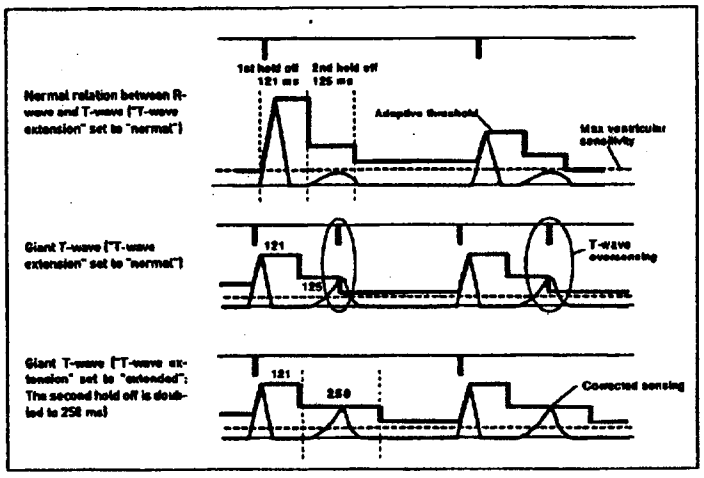


Figure 2. T-wave Extension

2.5.16 Noise Response

The Phylax AV response to detected noise is programmable to either deliver asynchronous pacing or to inhibit pacing in the ventricular channel.

2.5.17 Atrial Paced Refractory Period

Immediately following a paced atrial event, a refractory period is started. Intracardiac signals are ignored during this time to prevent the ICD from sensing inappropriately.

2.5.18 Ventricular Paced Refractory Period

Immediately following a paced ventricular event, a refractory period is started. Intracardiac signals are ignored during this time to prevent the ICD from sensing inappropriately.

2.5.19 Post Shock Pacing

Bradycardia pacing support is available in the ICD following shock therapy delivery. Because a delay in bradycardia pacing has shown to be clinically useful in avoiding re-initiation of a tachyarrhythmia, after a short blanking period and post shock pause period, the ICD will begin bradycardia therapy at the post shock pacing rate, amplitude, and pulse width. Separate post-shock programming of the following parameters is available:

- Upper Tracking Rate,
- Dynamic AV Delay
- Pacing Mode
- Basic Rate
- Pulse Width
- Pacing Amplitude

The duration of post shock pacing can be modified by the Post-Shock Duration parameter. If bradycardia pacing is still required, standard bradycardia pacing parameters will be used at the completion of post-shock pacing. The mode conversion feature is not available during Post-Shock Pacing.

2.6 EP Test Functions

When the EP test screen is active, the Phylax AV is able to automatically detect and treat ventricular tachyarrhythmias.

PRECAUTION

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.

2.6.1 Arrhythmia Induction Features

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

Burst Induction delivers a programmable number of high frequency pacing stimuli. The burst duration (defined by the number of S1s) and rate are both independently programmable. The burst rate

PES Induction delivers a burst of pacing stimuli followed by a programmable number of timed extra stimuli. The burst rate is independently programmable, as is the number of S1's. The interval between S1s and the remaining programmed extra stimuli (PES: S1 through S5 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, rate of the pulse train, and the shock coupling interval are all user programmable.

2.6.2 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 Manual Shock button. A confirmation menu will appear and the shock command will be delivered upon selecting the Deliver Manual Shock button in this screen. After each manual shock, the EP test screen will display the shock lead impedance and shock charge time.

NOTE:

The shock lead impedance may not be automatically displayed on the EP Test Screen but is available from either the Episode History or System Status / Counters screens.

2.6.3 Test Shock

The ICD can deliver a 2 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.

PRECAUTION

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

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.

2.7 Special Features

2.7.1 Detection Status

Interrogating the device and observing the Detection section of the Main programming screen displays the ICD detection status (either ON or OFF). The detection status can be changed from the Detection screen.

2.7.2 Capacitor Reforming

Shock charge times may be extended 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, 6, 9 or 12 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. BIOTRONIK recommends reforming the capacitors every 12 months.

An automatic or manually initiated capacitor reform fully charges the capacitors and then dumps the charge to 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 re-form process is aborted and therapy is available if required.

2.7.3 Pacing Threshold /Impedance

The test is activated as a temporary program with specific operation. Removal of the programmer head immediately stops the test and reactivates the permanent program. When using this function, the pacing rate should be set at least 20 bpm higher than the patient's spontaneous rate to ensure pacing. The following parameters are programmable during the pacing threshold test: Appropriate chamber and pacing mode, pacing rate, AV delay (if appropriate), pulse amplitudes and pulse widths, number of pulses and automatic printing capabilities. The pacing modes available for the threshold test are AOO or AAI, VVI, DVI, or DDD. The pulse amplitude is easily adjustable during the threshold testing by selecting the desired value from the table. Pacing impedance can also be measured directly from the threshold test screen.

NOTE:

The impedance measurement has a tolerance of ± 20%.

2.7.4 Patient Data

The Patient Data screen allows input of data regarding the patient name, demographics, implanting physician, date, devices implanted, location of the implant, and various physiologic measurements related to the implanted system. This information is transmitted to the ICD and resides in the device memory for later recall if needed.

2.7.5 System Status/Counters

Various device parameters can be monitored through this 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 Phylax AV including:

- Battery status
- Last shock charge time
- Last shock impedance
- Date of last capacitor reforming
- Number of total capacitor reforms
- Event counter information
  - ATP Therapies
  - VF Shocks
  - VT Shocks
  - Aborted VF Shocks
  - Aborted VT Shocks
  - Manual Shocks
  - Discrimination Successes
  - Mode Conversions
- Percent atrial paced
- Percent ventricular paced

See Section 5.2 Longevity, for a more complete description of the anticipated battery depletion, longevity estimates, and the elective replacement indicator.

2.7.6 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 test and real-time IEGM screens.

The real-time IEGM programming screen allows automatic measurement of P-waves and R-waves. The real-time IEGM programming 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.

2.7.7 Episode History

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, stored intracardiac electrograms, and stored R-R and P-P intervals.

2.7.7.1 Episode Details

Detailed information about each individual episode presented as a table of events ordered from most recently delivered to first delivered.

2.7.7.2 Stored IEGM

The ICD can store up to 16 minutes of single chamber (8 minutes of dual chamber) intracardiac electrograms (IEGMs) including the history and prehistory of the following events:

- Detection
- Redetection
- Terminations
- Manual Shocks
- AV Discrimination Success (optional)

2.7.8 Stored P-P and R-R Intervals

The ICD stores P-P and R-R intervals preceding and after the tachyarrhythmia episodes to provide additional information for episodes that do not have an associated stored IEGM.

2.7.8.1 View IEGM

Each IEGM segment can be viewed from the episode detail sub-menu by selecting the View IEGM button. From this screen, an IEGM can be expanded, scaled and scrolled to assist in a more accurate IEGM interpretation by enabling a closer examination of specific segments.

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 sterilization and storage information.

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.

PRECAUTION

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

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

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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. The available cabling and accessories are as follows:

- PK44 - used to connect the TMS 1000 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 PA-4 adapter has alligator clips to connect to the sensing and pacing portion of the lead system.

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 Phylax AV. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Phylax AV ICD. Note that the battery status may appear lower than its true value when the ICD is not at body temperature. Program detection "OFF" prior to handling the Phylax AV ICD.

Sufficient training on the device and its associated components is required prior to implanting the Phylax AV. 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. Do not use integrated bipolar leads with the Phylax AV as ICD damage may occur.

PRECAUTION

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.

Shock Impedance - 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. If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes.

4.2 Lead System Evaluation

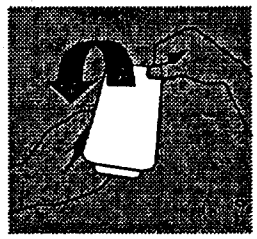
The ICD is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992].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

Refer to the appropriate lead system technical manual.

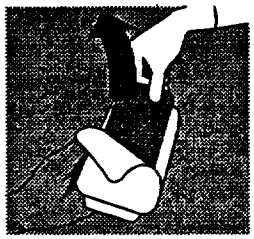
4.3 Opening the Sterile Container

The Phylax AV is packaged in two plastic containers, one within the other. Each is individually sealed and then sterilized with ethylene oxide.

Due to the double packing, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed on the sterile field.



Peel off the sealing paper of the outer container as indicated by the arrow. 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.

PRECAUTION

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.

PRECAUTION

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.

4.5 Lead to Device Connection

The Phylax AV has been designed and is recommended for use with a defibrillation lead system 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. Figure 3 depicts the configuration of the header ports on the Phylax AV, where HV1 and HV2 are for DF-1 connectors, and A P/S and V P/S are for IS-1 connectors.

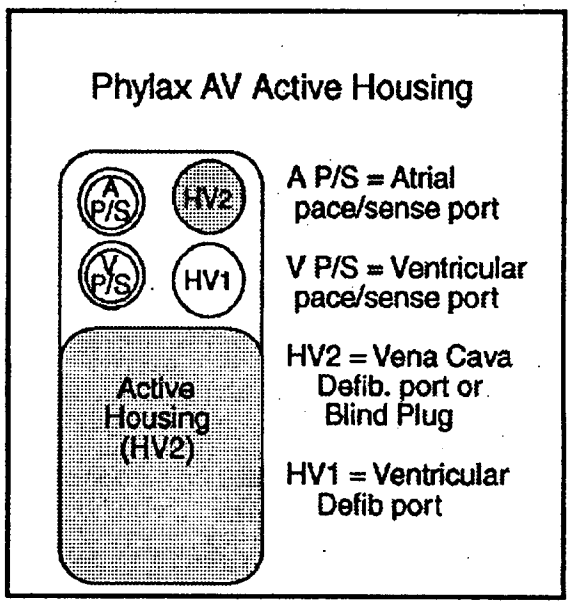


Figure 3. Header Ports

PRECAUTION

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.

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.

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 ICD comes with a blind plug for insertion into 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.

PRECAUTION

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 antitachyarrhythmia 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 "OFF".
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 "ON".
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 places 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.

PRECAUTION

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 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.

PRECAUTION

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.

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.

WARNING

Unwanted Shocks - Prior to handling the device during the implant procedure, program the detection status of the device to OFF to prevent the delivery of unwanted shocks to the patient or the person handling the device.

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.

NOTE:

During the clinical study of the Phylax AV, see Section 1.7, defibrillation threshold testing was required to result in two consecutive successful defibrillation shocks at an energy of 20 joules or less. This assured a 10 joule safety margin for all implants.

PRECAUTION

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 - 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. If the shock impedance is less than twenty-five ohms, reposition the lead system to allow a greater distance between the electrodes.

WARNING

Pacing Threshold - Testing of the pacing threshold by the ICD system shall 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.

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.

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.

Ensure the ICD detection status has been deactivated prior to using electrocautery.

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

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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.

PRECAUTION

Program Transmission – Be aware that if a communication error occurs during transmission of a new program to the ICD, that there may be a conflict between the parameters contained within the new program.

5.2 Longevity

The service time of an ICD can vary based on several factors, including the number of charge sequences, programmed parameters, 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 enough energy left to continue monitoring for three months along with the ability to deliver at least six high-energy shocks. After this period, all

tachyarrhythmia detection and tachyarrhythmia therapy is disabled.

PRECAUTION

Charge Time - When preparing a high energy shock the Phylax 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 3. 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 37°C. 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 3: Longevity Estimates

DDD Pacing Support	Shocks Per Year	[illegible]
100 %	12	38
	4	47
	1	52
	0	53
50 %	12	39
	4	48
	1	53
	0	55
15 %	12	40
	4	49
	1	54
	0	56
0 %	12	40
	4	50
	1	55
	0	57

Each maximum energy (30 joule), high voltage charging sequence reduces the longevity of the device by approximately 15 days.

Upon reaching ERI, the battery has enough energy left to continue monitoring for three months and to deliver six high energy shocks. 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.

PRECAUTION

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 - Prior to explanting the ICD, program the detection status of the device to OFF to prevent unwanted shocks.

6. Technical Specifications

The following are the technical specifications for the Phylax AV. 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	76 x 63 x 17 mm
Conducting Surface Area	92 cm^2
Volume	69 cc
Mass	109 g
Housing Material	Titanium
Header Material	Epoxy resin
Seal Plug Material	Silicone
Phylax AV Lead Ports	2 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1

Electrical Properties - Tachycardia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Detection Parameters for VT Arrhythmia Classes			
Detection	ON, OFF	OFF	ON
VT-1 Zone Limit	OFF,300...(10)...600 ms 100 ... 200 bpm	OFF	OFF
VT-2 Zone Limit	OFF, 300...(10)...590 ms 101 ... 200 bpm	N/A	N/A
Tachyarrhythmia	Onset Delta Stability SMART Detection	Stability	Stability
VT Sample Count	12...(1)... 20	N/A	N/A

Electrical Properties - Tachycardia Therapy (continued)

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Safety Timer	OFF, 0:30...(0:15)...10:00... (0:30) ... 30:00 min	1	1
Onset Delta	OFF, Absolute:30...(10)..500ms Adaptive: 10... (5) ...90 %	N/A	N/A
Stability	Absolute: 0...(5)...100...(10)...180 ms Adaptive: 5... (1) ...30 %	12	12
Detection Parameters for VF Class			
VF Zone Limit	OFF, 250...(10)...400ms 150 ... 240 bpm	400	400
Number of X	5 ... (1) ... 25	8	8
Number of Y	8 ... (1) ... 32	12	12
Atrial Detection Refractory Period	102 ms	102 ms	102 ms
Ventricular Detection Refractory Period	121 ms	121 ms	121 ms
Redetection			
Redetection Count	12...(1)...31	12	12
VF Redetect Limit	OFF,250...(10)...600 ms 100...240 bpm	DFLT	DFLT
SMART Redetect for VT	ON, OFF	N/A	N/A
SMART Redetect for VF	ON, OFF	N/A	N/A

Bradycardia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Mode	DDD, DDI, VDD, VVI	VVI	VVI
Basic Rate	31...(1)...88...(2)... 110 ppm	50	70
Hysteresis Rate	OFF,31...(1)...88...(2)... 110 ppm	OFF	OFF
Amplitude	0.1...(0.1)...4.8...(0.2)... 7.2 V	2.4	7.2
Pulse Width	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	0.50	1.00
Upper Tracking Rate	80, 100...(10)...140, 160, 185 ppm	N/A	N/A
Block Mode	Wenckebach, 2:1	N/A	N/A
Mode Switch Limit	OFF,200 (10)...600 ms 100 ... 300 bpm	N/A	N/A
Mode Switch Pacing Rate	31...(1)...80 ppm	N/A	N/A
PVARP	75 ...(5)...800 ms	N/A	N/A
Post PVC ARP	75 ...(5)...800 ms	N/A	N/A
Dynamic AV Delay	low, medium, high, fixed	N/A	N/A

Additional Sensing Parameters

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Atrial Max Sensitivity	0.250 ... (.125) ... 3.000	0.375	0.375
Ventricular Max Sensitivity	0.250 ... (.125) ... 3.000	0.500	0.500
T-wave Extension	NORMAL, EXTENDED	NORM	NORM
Noise Response - Ventricle	ASYNCHRONOUS, INHIBIT	ASYNC	ASYNC

Additional Sensing Parameters (continued)

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Noise Response - Atrial	ASYNCHRONOUS	ASYNC	ASYNC
Atrial Paced Refractory Period	150 ... (5) ... 400 ms	N/A	N/A
Ventricular Paced Refractory Period	150 ... (5) ... 400 ms	240	240

Post-Shock Bradycardia Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Mode	DDD, DDI, VDD, VVI	DDD	DDD
Basic Rate	31..(1)...8...(2)...110 ppm	60	60
Dynamic AV Delay	low, medium, high, fixed	N/A	N/A
Amplitude	0.1 ... (0.1) ... 4.8...(0.2) ... 7.2 V	7.2	7.2
Pulse Width	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	1.03	1.03
Upper Tracking Rate	80, 100 ... (10) ... 140, 160, 185 ppm	120	120
Post –Shock Duration	0:30... (0:15) ... 30.00 min	0:30	0:30

Basic ATP Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Amplitude	0.1 ... (0.1) ... 4.8...(0.2)... 7.2 V	7.2	7.2
Pulse Width	0.20, 0.30, 0.40, 0.50, 0.80, 1.00, 1.50 ms	1.00	1.00
Number of Bursts	0 ... (1) ... 10	N/A	N/A
Number of Pulses	1 ... (1) ... 25	N/A	N/A
ATP Coupling	Absolute: 200...(10)...600 ms Adaptive: 70... (1) ...98 %	N/A	N/A
Minimum ATP Interval	200 ... (10) ... 300 ms	200	200
Burst Decrement	0 ... (-5) ... -40 ms	N/A	N/A
Scan Decrement	0 ... (-5) ... -40 ms	N/A	N/A
Add 1	ON, OFF	N/A	N/A
ATP Time-out	OFF, 0:30 ... (:15)... 2:00 ... (:30) ... 5:00 ...(1:00) ... 20:00	1:00	1:00

Shock Therapy

PARAMETER	VALUE RANGE	STD PROGRAM	SAFE PROGRAM
Number of VT Shocks	0...(1)...6	N/A	N/A
Number of VF Shocks	6...(1)...10	6	6
Shock Waveform	Biphasic	Biphasic	Biphasic
Reconfirmation	YES, NO	YES	NO
1st and 2nd Shock Energy	1.0...(1)...16...(2)...30 Joules	30	30
Shock Polarity	STANDARD REVERSED	STD	N/A

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Appendix A

Connector Compatibility

Phylax AV ICDs are indicated for use only with commercially available BIOTRONIK ICD dedicated 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 Phylax AV is mechanically compatible with:

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

The ICD has two IS-1 header ports and two DF-1 header ports.

Inside back cover

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