(Draft)

Cardiac Airbag / Cardiac Airbag-T

Family of Implantable Cardioverter Defibrillators and Software Cartridge for TMS 1000^{PLUS} and EPR 1000^{PLUS}

Technical Manual

BIOTRONIK

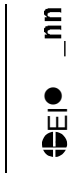
X-ray Identification

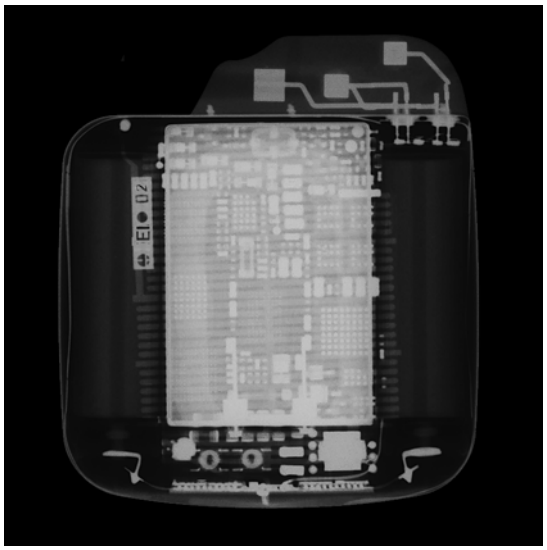
Cardiac Airbag/Cardiac Airbag-T
Implantable Cardioverter Defibrillator

Inside the housing, top left-hand side:

Year of manufacture

X-Ray identification

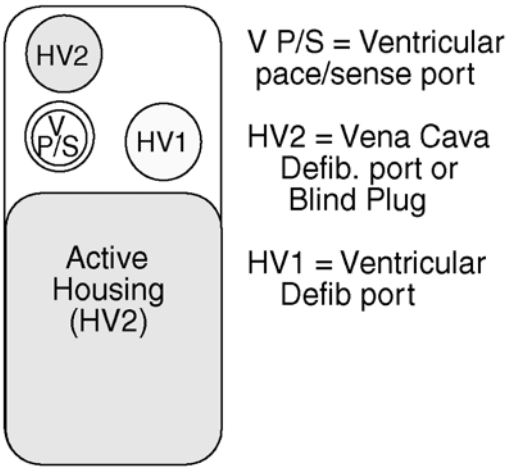




CAUTION

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

Contents



Cardiac Airbag Specifications

Battery Voltage:	6.3 Volts
Maximum Shock Energy:	30 joules
Defibrillation Lead Ports	Two DF-1 (3.2 mm)
Pacing Lead Ports	One IS-1 (3.2 mm)
Dimension:	55 x 67 x 13 mm
Volume:	39 cc
Mass:	73 g
Housing Material:	Titanium
Header Material:	Epoxy Resin
Sealing Plug Material:	Silicone
Battery Composition	Li / MnO_2

1. General

1.1 System Description

The Cardiac Airbag family of Implantable Cardioverter Defibrillators (ICDs) detects and treats ventricular tachyarrhythmias as well as provides 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 Cardiac Airbag ICDs are specifically designed to have reduced complexity for implant and follow-up, yet provide essential therapies for conversion of life threatening ventricular tachyarrhythmias.

There are 10 programmable parameters to simplify the implant procedure, and detailed diagnostic information is stored for up to 10 ventricular tachycardia (VT) episodes and 3 treated ventricular fibrillation (VF) episodes. There are 30 minutes of single-channel IEGM storage available to record spontaneous and induced ventricular tachyarrhythmias. The Cardiac Airbag is restricted to storage of diagnostic information up to and including 3 treated ventricular fibrillation episodes.

The Cardiac Airbag ICDs provide therapy for ventricular tachyarrhythmias with programmable defibrillation therapy. The ICDs provide high energy biphasic shocks with the first shock having with programmable energies of 20 or 30 joules and up to 8 shocks per VF episode. The remaining 7 shocks in the therapy progression are pre-set at 30 joules.

The Cardiac Airbag family of ICDs includes the following members:

- **Cardiac Airbag** provides therapies for ventricular tachyarrhythmias and single chamber rate adaptive bradycardia pacing support.
- **Cardiac Airbag-T** is identical to the Cardiac Airbag 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 Cardiac Airbag and Cardiac Airbag-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 ICDs. In addition, the programmer software is used to perform the interrogation and programming of the ICDs during implant and follow-up testing.

1.2 Indications and Usage

The Cardiac Airbag Implantable Cardioverter Defibrillators (ICDs) are intended to provide ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

1.3 Contraindications

Do not use the Cardiac Airbag 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 brady arrhythmia or atrial arrhythmia

1.4 Warnings and Precautions

ATP (Anti-Tachycardia Pacing) – The Cardiac Airbag ICD does not provide ATP therapy. Do not implant this ICD in patients with documented ventricular tachycardias unless high energy defibrillation is desired for treatment of the ventricular arrhythmia.

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 2.6.3**, 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, tachyarrhythmia detection and therapy will proceed until EOS is declared. 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.

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 16 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 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.

Programming Wand - Throughout the EP Test session, the programming wand must be positioned and remain directly over the device. If appropriate arrhythmia detection does not occur shortly after induction, remove the programming wand from the ICD and perform external defibrillation.

Data Transmission - Data collection and transmission may take up to 30 seconds. The ICD cannot be reprogrammed during this time even if the **[Emergency]** key is pressed. Remove the programming wand immediately to restore the permanent program.

EP Test Functions - Ensure that cardiac resuscitation equipment is available during all EP Test Function operations. Physicians should be trained and experienced in tachyarrhythmia induction, conversion protocols, and have adequate training and experience with this device prior to use.

Potential side effects include:

- Non-terminable arrhythmia's that result in death
- Complications from hypoxia due to prolonged arrhythmia's
- Arrhythmia induction that requires cardioversion or defibrillation
- Arrhythmia induction that requires pharmacologic treatment, to which the patient could have an adverse reaction

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 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.

Date and Time Values - If date and time values are incorrect, the system may, as a result, generate false system status information for the implant.

Impedance Measurement - During the impedance measurement with high stimulation amplitudes, nerve or skeletal muscles may be briefly stimulated.

Threshold Test - A minimum 2:1 voltage safety margin should be permanently programmed any time capture thresholds are assessed. Monitor the ECG display closely with pacer-dependent patients. The test should be terminated immediately upon loss of capture.

Inadvertent Programming - The programmer utilizes a touch sensitive screen for menu selections. Care must be used to avoid inadvertent menu selection by accidentally touching the screen.

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 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 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 XM involved 155 devices implanted in 154 patients with cumulative implant duration of 1286 months (mean implant duration 8.3 months). This clinical study was performed with the Phylax XM and Phylax 06 ICDs, which are earlier versions of the Cardiac Airbag ICDs. The observed adverse events are applicable because the Cardiac Airbag ICD is a downsized version of the Phylax XM with rate adaptive pacing capabilities.

NOTE:

The Phylax XM ICD is an earlier generation of BIOTRONIK devices. The Cardiac Airbag family is based upon the Phylax XM and other BIOTRONIK ICDs (i.e., Belos VR and Belos VR-T).

There were a total of five deaths during the course of the trial; none of the deaths were judged by the clinical study investigator to be device related. Heart failure was a major factor in two deaths. The other three deaths were related to renal failure, lung disease, and septic shock secondary to an ischemic bowel, respectively. All five of the deaths occurred more than one month post implant.

Two ICDs were explanted during the trial. One was secondary to the patient being unable to tolerate further testing required by the clinical protocol. The other was secondary to a systemic infection; the patient was subsequently implanted with another device.

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 is defined as a clinical event that results in invasive intervention, injury, or death. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.

Table 1: Reported Adverse Events (AEs)
Number of Patients = 154, Number of Patient-Years = 107.1

Event	# of pts with AEs	% of pts with AEs	# of AEs	AE/ pt-yrs
Complications (total)	**7**	**4.5%**	**8**	**0.07**
Lead repositioning	2	1.3%	2	0.02
Hematoma	1	0.6%	1	0.01
Systemic infection	1	0.6%	1	0.01
Explant (did not to tolerate testing)	1	0.6%	1	0.01
Insertion of separate sensing lead	1	0.6%	2	0.02
ICD/lead connection	1	0.6%	1	0.01
Observations (total)	**79**	**51.3%**	**89**	**0.83**
Inappropriate therapy (SVT)	18	11.7%	20	0.19
ICD response to magnet in wand[1]	13	8.4%	15	0.14
Software messages and errors[2]	11	7.1%	13	0.12
Increased pacing threshold	7	4.5%	9	0.08
Decreased R-wave amplitude	7	4.5%	7	0.07
Frequent VT	5	3.2%	5	0.05
Oversensing	3	1.9%	3	0.03
TMS 1000 difficulties[3]	3	1.9%	3	0.03
VT below rate cut-off	2	1.3%	3	0.03

Event	# of pts with AEs	% of pts with AEs	# of AEs	AE/ pt-yrs
High DFT's	1	0.6%	2	0.02
Minor stroke	1	0.6%	1	0.01
Renal failure	1	0.6%	1	0.01
Required additional drug therapy	1	0.6%	1	0.01
ICD/lead connection	1	0.6%	1	0.01
ICD therapy during lead connection	1	0.6%	1	0.01
Non-sustained VT	1	0.6%	1	0.01
Non-conversion of arrhythmia	1	0.6%	1	0.01
Interpretation of real-time markers	1	0.6%	1	0.01
Reconfirmation algorithm	1	0.6%	1	0.01

1. This category includes issues related to movement of the programmer wand that caused the reed switch to toggle during high voltage capacitor charging or tachyarrhythmia detection. As a result, appropriate therapy was not delivered in a timely manner. The orientation of the reed switch was optimized and is being monitored as part of the manufacturing process to prevent future occurrences of this type of event.
2. This category includes various software "anomalies" that were related to error messages or the retrieval of diagnostic information. Each of these events has been resolved through revisions made to the software.
3. This category includes any difficulties encountered while using the TMS 1000 Tachyarrhythmia Monitoring System. Each of these events has been resolved through revisions to the software and hardware of the system.

1.6 Clinical Studies

NOTE:

The Phylax XM ICD is an earlier generation of BIOTRONIK devices. The Cardiac Airbag family is based upon the Phylax XM and other BIOTRONIK ICDs (i.e., Belos VR and Belos VR-T).

This clinical study was performed on the Phylax XM and Phylax 06 ICDs, which are earlier versions of the Cardiac Airbag ICD. The clinical study data presented here is applicable because the Cardiac Airbag / Cardiac Airbag-T is a downsized version of the Phylax XM with the addition of rate adaptive pacing capabilities. The Cardiac Airbag / Cardiac Airbag-T ICDs are slightly different as compared to the Phylax XM in the following areas:

- Motion based rate adaptive pacing
- Reduced programmable feature set
- Minor adjustments to therapy delivery options including no availability of ATP
- Reduced size from 69 cc to 39 cc
- Addition of Home Monitoring functionality

The rate adaptive pacing circuitry of Cardiac Airbag / Cardiac Airbag-T ICD is based on other US distributed BIOTRONIK products. Due to the similarities between the Cardiac Airbag / Cardiac Airbag-T, Belos VR / VR-T, and Phylax XM and the limited nature of these changes, a clinical study of the Cardiac Airbag / Cardiac Airbag-T ICD was determined to be unnecessary.

1.6.1 Patients Studied

The clinical study involved 154 patients (121 male and 33 female) with a mean age of 64.9 years (range: 26 to 95 years) and a left ventricular ejection fraction of 33% (range: 10% to 80%). Most (72%) presented with coronary artery disease / ischemic cardiomyopathy; 71% presented with monomorphic ventricular tachycardia (MVT) as their primary tachyarrhythmia.

1.6.2 Methods

The multicenter clinical investigation was designed to validate the safety and effectiveness of the ICD system to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included the determination of ventricular tachyarrhythmia conversion rate, sudden cardiac death (SCD) survival rate, morbidity rate, and the appropriate sensing and pacing rate.

The primary endpoint of the study was to evaluate the ventricular tachyarrhythmia conversion rate. Patients underwent standard ICD implantation and then were evaluated at predischarge and regular follow-ups every three months. Induction and conversion of the patient's tachyarrhythmias was required at the implant procedure and predischarge follow-up.

1.6.3 Results

The mean implant duration was 8.3 ± 0.4 months with cumulative implant duration of 1286 months. There were 39 patients followed for over twelve months and 108 patients followed for over six months. The patient follow-up compliance rate was 99.6% out of 473 follow-up procedures.

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]
Tachyarrhythmia Conversion Rate[1] Induced	95.8% (496/518) [93.6%, 97.3%]
Spontaneous	99.7% (1540/1544) [99.3%, 99.9%]
Total	98.7% (2036/2062) [98.2%, 99.2%]
Sudden Cardiac Death Survival (at one year)	100.0% (39/39) [91.0%, 100.0%]
Complication Rate (per total number of patients)	5.2% (8/154) [2.3%, 10.0%]
Appropriate Sensing and Pacing Rate[2]	98.0% (703/717) [96.8%, 98.9%]

1. Conversion data were collected in the clinical study for both induced and spontaneous tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.
2. The investigator determined the appropriateness of bradycardia sensing and pacing. The rate will be determined by the number of appropriate bradycardia sensing and pacing evaluations divided by the total number of evaluations.

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.

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 XM 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 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.

2. Device Features

The Cardiac Airbag family feature set is presented under the following sub-headings: Sensing, Tachyarrhythmia Detection, Tachyarrhythmia Redetection, Tachyarrhythmia Therapy, Bradycardia Therapy, and Special Features. The features apply to all members of the Cardiac Airbag family except where specifically referenced differently.

2.1 Sensing

The Cardiac Airbag ICDs use Automatic Sensitivity Control (ASC) to adjust the sensitivity characteristics 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. The Automatic Sensitivity Control (ASC) utilizes an automatic step-down threshold for sensing ventricular signals. The ASC begins by tracking the cardiac signals (R-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 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 3**.

Table 3: 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 (UT) 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 (250 ms) after which the ventricular threshold is set to the minimum programmed value.

STANDARD - The UT is set at 50% of the measured R-wave for the Standard sensitivity setting following the 100 ms sensed refractory period. The UT 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 (LT). The LT is set to 25% of the measured peak R-wave. The LT then decreases 0.125 mV every 500 ms until the Minimum Threshold is reach or until the next sensed (or paced) event.

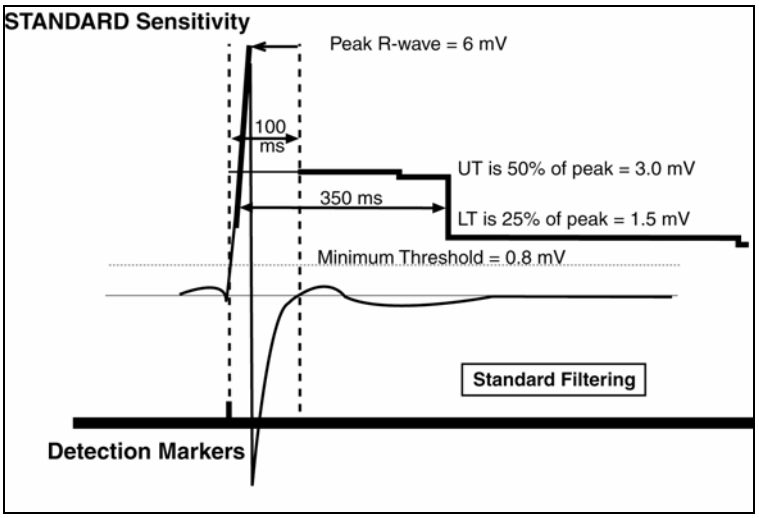


Figure 1. Automatic Sensitivity Control with Standard Setting

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 UT 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.

ENHANCED VF SENSITIVITY - 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 UT
- The decay rate of the LT is increased to 0.125 mV every 250 ms.

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

ENHANCED T-WAVE SUPPRESSION - The Enhanced T-Wave Suppression setting is specifically designed to avoid double counting of each QRS-T complex during normal sinus rhythms. Two adjustments are made to ASC with this setting:

- High pass filtering is increased to reduce low frequency signal components such as T-waves and respiratory artifacts.
- The UT is increased to 75% of the measured R-wave.
- The UT 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.

2.2 Ventricular Tachyarrhythmia Detection

The Cardiac Airbag ICDs detect and measure the rate of sensed cardiac signals to discriminate ventricular tachyarrhythmias from 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.

Classification of cardiac signals is accomplished primarily by measuring the cardiac cycle length (R-R intervals). 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 Ventricular Tachycardia Monitoring Zone
- VF Ventricular Fibrillation

Each rhythm class is set to a separate rate with the zone limit defining the lowest rate in each class. The upper rate limit of the VT zone is equal to the VF zone limit.

2.2.1 VF Classifications

Detection of ventricular fibrillation (VF) utilizes a non-programmable X out of Y criterion. If X number of intervals within the sliding window (defined by Y) are shorter than the programmed VF rate interval in ms (> in bpm), VF is detected. After fibrillation is detected, the programmed therapy sequence for VF is initiated.

Preset 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 criterion.

2.2.2 VT Interval Counters

The VT Interval Counters utilize non-programmable VT rate classifications. The Interval Counter is the number of intervals required to declare a tachyarrhythmia as VT. A tachyarrhythmia must meet both the rate/interval criteria and the preset Interval Counter, in addition to other detection enhancements (onset and stability) to be declared a tachycardia.

2.2.3 VT Classification

The VT classification zone utilizes a non-programmable detection parameter (VT interval counter) that is different from the VF zone. Classification of VT is based on the last interval average preceding declaration of tachyarrhythmia detection. If this average falls within the VT zone, an IEGM is stored since the VT zone is designed as a "**Monitoring Zone**" only and no therapies are available.

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

2.2.4 Onset and Stability

In addition to the standard tachycardia detection parameters previously described, the VT Monitoring Zone incorporates two additional detection enhancements: Onset and Stability. Both Onset and Stability are preset to standard values and are not programmable for the VT Monitoring Zone.

2.2.4.1 Onset

The Onset function provides an additional discrimination test that must be satisfied before a VT tachyarrhythmia can be declared. The purpose of this detection parameter is to discriminate between sinus tachycardia (often characterized by a gradual rate increase) and a ventricular tachycardia, which typically begins with an abrupt rate change.

Onset criterion evaluates the most recently sensed cardiac intervals and compares it to the previous four-interval sliding average. Onset will be satisfied if a change in cycle length exceeds the preset Onset value (as compared to the average) and is followed by a cycle that lies within the corresponding VT zone. Onset criterion is defined as a 20% adaptive value (expressed as a percentage of the latest cardiac cycle length). VT is not declared until Onset and any additional detection criteria are satisfied.

2.2.4.2 Stability

The purpose of Stability is to assist in the discrimination of stable ventricular tachyarrhythmias from SVTs that conduct irregularly down to the ventricles (i.e., atrial fibrillation). Stability evaluates sudden changes in the cardiac cycle length. The Stability criterion compares each interval with the three preceding cardiac cycles to determine if they remain within the Stability range (as defined by the parameter setting of ± 24 ms). A rhythm is declared stable after the number of intervals (equal to the Interval Count) is found to be stable within the range.

2.3 Tachyarrhythmia Redetection

The Cardiac Airbag ICDs incorporate 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 Count is not programmable and remains independent of the initial detection parameters:

Redetection of an ongoing tachyarrhythmia is declared when the Redetection Count is satisfied (based on individual cycles). If a sensed cardiac signal meets the VT rate criterion, following initial detection, that signal is counted and compared to the Redetection Count. Tachycardia redetection is declared when the number of VT samples (Redetection Count) is satisfied.

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

2.3.2 VF Redetection

VF redetection uses the same X out of Y algorithm as initial detection. The 8 out of 12 criterion for initial detection is used for redetection to ensure consistent classification of VF.

2.3.3 Tachyarrhythmia Termination

Termination of a ventricular tachyarrhythmia episode is declared when 12 out of 16 consecutive sensed intervals are longer than the VT-interval counter.

2.4 Tachyarrhythmia Therapy

The Cardiac Airbag ICDs offers only defibrillation therapy for the treatment of ventricular tachyarrhythmias classified as VF.

2.4.1 Shock Therapy

The Cardiac Airbag ICDs offer shock therapy only for the VF rate classifications. Up to 8 shocks are available for the VF zone for each episode detected.

The first defibrillation shock in the therapy sequence is delivered with confirmation (while the capacitors are being charged). The first shock energy is programmable to 20 or 30 joules and is delivered following confirmation of the arrhythmia. The remaining shock energies are non-programmable and predetermined to deliver 30 joules using defibrillation without confirmation. All shocks utilize a standard biphasic waveform and normal polarity.

2.4.1.1 Number of Shocks

The number of shocks defines the total number of shock attempts for each VF detection. Up to 8 shocks are available in this therapy zone. The first shock energy parameter is programmable to 20 or 30 joules, while the remaining shocks are fixed at 30 joules.

2.4.1.2 Confirmation

Confirmation 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 is always ON for the first shock therapy and is always OFF for remaining shock therapies.

Confirmation OFF - When Confirmation is 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.

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.

2.4.1.3 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 switches polarity. At that point, it discharges to 20% of the initial charge voltage before the waveform is truncated. Figure 2 provides a pictorial representation of the biphasic waveform.

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

Figure 2. Biphasic Waveform

2.4.1.4 Shock Energy

The Cardiac Airbag 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.

2.4.1.5 Shock Polarity

The polarity of the shock therapy is non-programmable and preset to **Normal**. This 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.

2.5 Bradycardia Therapy

The Cardiac Airbag ICDs have programmable bradycardia and post-shock bradycardia pacing functions. The post-shock bradycardia parameters are preset to a higher rate and output values following a delivered shock, without compromising the longevity of the ICD for patients who require chronic bradycardia pacing. The post-shock values are presented in the following subsections after the chronic bradycardia support values.

2.5.1 Bradycardia Pacing Modes

The bradycardia pacing **mode** may be programmed to VVI or VVIR for bradycardia pacing support or to OFF (OVO). The basic rate timer is initiated by a sensed or paced event. A sensed event outside of the refractory period inhibits pacing and resets the lower rate timer. In the absence of a sensed event, a pacing pulse will be delivered at the end of the lower rate interval. The OFF mode disables bradycardia pacing; however tachycardia sensing and therapy may remain active.

The mode that contains an “R” in its designation is a rate adaptive mode. This mode is functionally the same as the corresponding non-rate adaptive mode; except that the pacing rate will be automatically adjusted to take into account the current load on the patient’s heart in response to increased physical activity.

2.5.2 Basic Rate

The **basic rate** is the rate at which bradycardia pacing will occur in the absence of a patient’s intrinsic rhythm. This rate may be individually programmed for normal bradycardia pacing.

2.5.3 Rate Adaptation

Cardiac Airbag / Cardiac Airbag-T ICDs allow the selection of a rate responsive pacing mode (VVIR). This mode allows the ICDs bradycardia therapy function to adapt the pacing rate to increasing or decreasing patient activity, based on data collected from a motion sensor within the ICD. Separate criteria controls the rate of increase and decrease of pacing, as well as the sensitivity of the sensors.

2.5.4 Gain and Threshold

The Gain defines how much the sensor signal is amplified before it is used by the rate adaptive algorithm. The Gain is programmed so the maximum desired pacing rate during exercise occurs at a maximum exertion level. The Gain is preset to 4 when programmed to the VVIR mode.

The Sensor Threshold defines the lowest sensor output that initiates a change in the pacing rate and all motion below this threshold is ignored by the algorithm. The Sensor Threshold is preset to Mean when programmed to the VVIR mode.

2.5.5 Rate Increase / Decrease

The Rate Increase and Rate Decrease parameters work together with the Gain to determine how quickly pacing rate increases or decreases to occur with changes in the sensor output. A rate increase of 2 ppm per second would take 45 seconds to change from a pacing rate of 60 ppm to 150 ppm. The Rate Increase is preset to 2 ppm/sec when programmed to the VVIR mode. A rate decrease setting of 0.4 ppm per second will take 225 seconds to decrease a pacing rate of 150 ppm to 60 ppm. The Rate Decrease is preset to 0.4 ppm/sec when programmed to the VVIR mode.

2.5.6 Maximum Sensor Rate

Regardless of the sensor output, the sensor-driven pacing rate never exceeds the programmable Maximum Sensor Rate. The maximum sensor rate only limits the pacing rate during sensor-driven pacing. The Maximum Sensor Rate is programmable to either 100 or 125 ppm when programmed to the VVIR mode.

2.5.7 Pulse Amplitude

The Pulse Amplitude parameter defines the amplitude in volts of the pacing pulses. The pulse amplitude is independently set for normal and post-shock bradycardia pacing.

2.5.8 Pulse Width

The Pulse Width parameter defines the duration of the pacing pulses. The pulse width is independently set for normal and post-shock bradycardia pacing.

2.5.9 Noise Response

The Cardiac Airbag ICD's response to detected noise is to deliver asynchronous pacing in ventricular channel.

2.5.10 Post Shock Pacing

Separately, bradycardia pacing support is available with the ICD following shock therapy delivery. 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 post shock duration.

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

2.6 Special Features

2.6.1 Home Monitoring (Cardiac Airbag-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 graphs and tables. 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.

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.

2.6.1.1 Transmission of Information

The implant transmits information with a small transmitter, which has a range of about 2 meters. The transmissions are activated by the detection of an arrhythmia episode, as programmed. The types of transmissions are discussed in **Section 2.6.1.4**.

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

2.6.1.2 Patient Device

The patient device (**Figure** 3) is designed for use in the home and is comprised of the mobile device and the associated charging station. The patient can carry the mobile device with them during his or her occupational and leisure activities. The patient device is rechargeable, allowing for an approximate operational time of 24 hours. It receives information from the implant and forwards it via a GSM mobile cell phone network to a BIOTRONIK Service Center.

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

Figure 3: Example of Patient Device with Charging Stand (CardioMessenger)

2.6.1.3 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 titled depending on the type of event transmission. This Cardio Report contains current and previous implant data. The Cardio Report is sent to the attending physician via fax. All reports use the same report format.

2.6.1.4 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

- To ensure successful transmission of the patient data, the Cardiac Airbag-T is programmed to send up to 10 repetitive transmissions of identical data at an hourly time interval.

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 a message transmission:

- Special device status (errors)
- Detected VT
- Detected and terminated VF
- First ineffective shock detected
- Pace impedance < 200 Ohm or > 3 K Ohm
- Shock impedance < 25 Ohm or > 150 Ohm
- Device status - ERI

2.6.1.5 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.

Detection

- # of episodes in VT Monitoring Zone
- # of episodes in VF Zone

Therapy

- Shocks delivered
- Shocks successful
- Shocks aborted
- 1st Shock without success

Battery

- Status (i.e., OK, ERI, EOS)
- Date of voltage measurement

Leads

- Pace impedance (ventricular)
- Shock impedance
- Date of impedance measurements

Device Status Summary

- Status
- Remarks

2.6.2 Real-time IEGM Transmission

The pulse generators provide real time transmission of the unfiltered intracardiac electrogram (IEGM) to the programmer. IEGMs from the proximal shock coil (SVC) and ventricle can be simultaneously recorded with a bandwidth of 0.5 to 200 Hz. The IEGMs may be transmitted to the programmer via the programming head positioned over the ICD. They are then displayed together with the surface ECG and markers on the programmer screen and printed on the ECG recorder. Likewise, intracardiac signals and markers identifying 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. IEGM markers are available for all sensed and paced events.

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

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

2.6.3 Capacitor Reformation

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

An automatic or manually initiated capacitor reform fully charges the capacitors and then allows the capacitors to drain off through the internal circuitry of the ICD. No shock will be delivered to the patient. Throughout the reformation process the ICD will provide bradycardia pacing support and tachyarrhythmia sensing and detection as programmed. If a tachyarrhythmia is detected during capacitor reformation, the process is aborted and therapy is available if required.

2.6.4 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 retrieval if needed.

2.6.5 System Status

Various device parameters can be monitored through the Status section of the programmer screen. (**See Figure** 4) Displayed data includes ICD information, charge circuit parameters, capacitor reformation data, battery status, and lead information. The system status screen presents a large variety of information about the Cardiac Airbag ICDs including:

- Serial number (always displayed after interrogation)
- Software release
- Device status
- Battery status

– BOL (Begin of Life)
– ERI (Elective Replacement Indication)
– EOS (End of Service)

- Last charge event

– Date
– Energy
– Charge time

- Total number of charges
- Last R-wave measurements
- Last pacing lead impedance (ventricle)
- Last pacing threshold measurement with pulse width (ventricle)
- Last shock impedance measurement and date

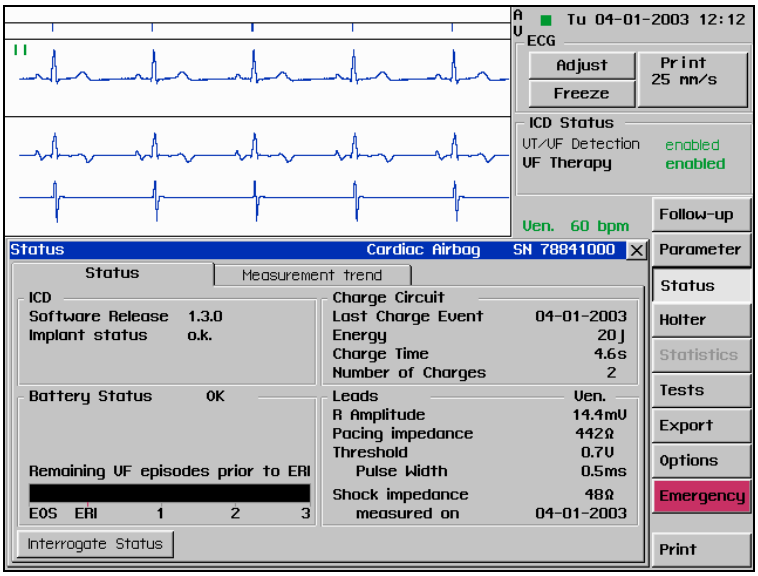


Figure 4. System Status

2.6.6 Holter Memory

Important information is available within the Holter memory. The Holter memory has a preset configuration to provide the most critical information to the physician.

2.6.6.1 Episode List

The ICD stores essential diagnostic data about tachyarrhythmia episodes that may be used to optimize tachyarrhythmia detection and therapy parameters. This diagnostic data includes a therapy history and stored intracardiac electrograms.

Episode Details - Detailed information about each individual episode is presented as a table of events with the most recent episode listed first. 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 and a closer examination of specific segments. (**See Figure** 5**)**

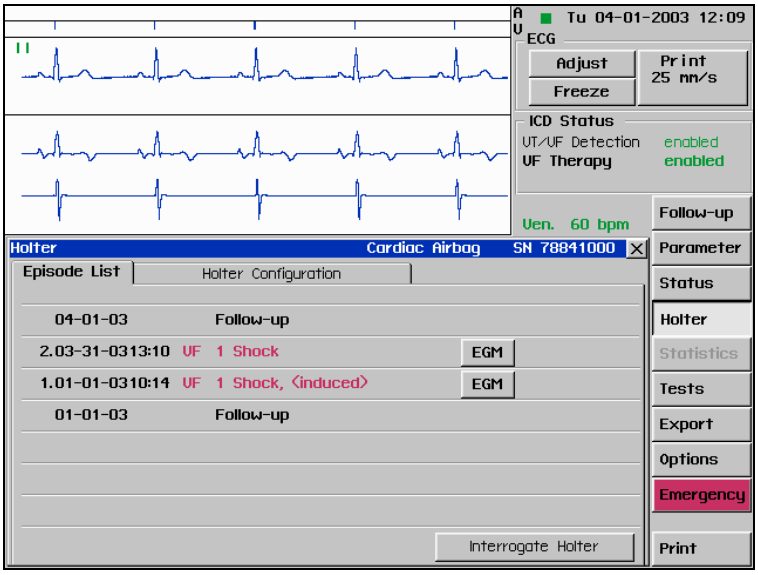


Figure 5. Episode List

Stored IEGM - The ICD can store up to 30 minutes of two channel intracardiac electrograms (IEGMs) including the history and prehistory of the following events:

- Detection
- Redetection
- Terminations
- Delivered Shocks

The ICD can store IEGMs for the following events prior to ERI:

- 3 spontaneous VF episodes treated with shock therapy
- Non-sustained VF episodes without shock therapy
- 10 VT monitoring zone episodes
- Induced episodes while the programmer wand is over the implanted ICD

Following ERI declaration, no further EGMs are stored in the ICD. However, the episode counters continue to update until EOS is declared. (**See Figure** 6)

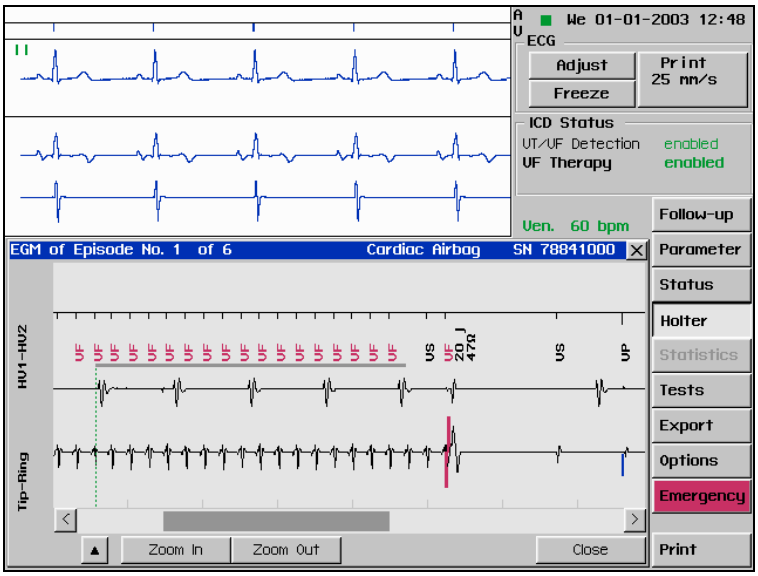


Figure 6. Stored IEGM

2.6.7 Arrhythmia Induction Features

The Cardiac Airbag ICD offers two 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.

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.

2.6.8 Manual Shock

The Cardiac Airbag 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.

2.6.9 Test Shock

The Cardiac Airbag ICD can deliver a low-energy 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.

3. Software Features

This section describes the features available with A-K00.0.U programmer software and the procedures necessary for interrogating and programming Cardiac Airbag ICDs. All references to Cardiac Airbag are also applicable to the Cardiac Airbag-T.

Please refer to the TMS 1000^{PLUS} or EPR 1000^{PLUS} technical manuals for detailed descriptions of how to operate within the specific menus and windows.

3.1 Follow-Up Assistant (FAST) Window

After interrogating the ICD, the programmer initially displays the Follow-Up Assistant window. (See **Figure 7**)

The Follow-up Assistant (FAST) is a program incorporated into the Cardiac Airbag applications for a user-defined guided follow-up. The “guided” follow-up function was developed to allow the user to be directed through the required program modules with the press of a single button.

- Interrogation of the device
- Measurement of the battery status
- Interrogation of the episode counters
- Measurement of the R-wave amplitude
- Measurement of the ventricular pacing impedance
- Measurement of pacing threshold - Threshold test screen appears and waits for the user to perform the ventricular threshold test.
- Printing of the follow-up data, which contains the results of the performed interrogations.

The routines are activated in the order displayed on the programmer screen. Functions belonging to a common topic are grouped together. Use the check boxes to control whether a specific procedure is performed or not.

When all of the functions have been completed the system opens the Follow-Up Assistant window displaying the measured values (See **Figure 7**). The Printed Follow-Up report contains the measured values listed in the completed window.

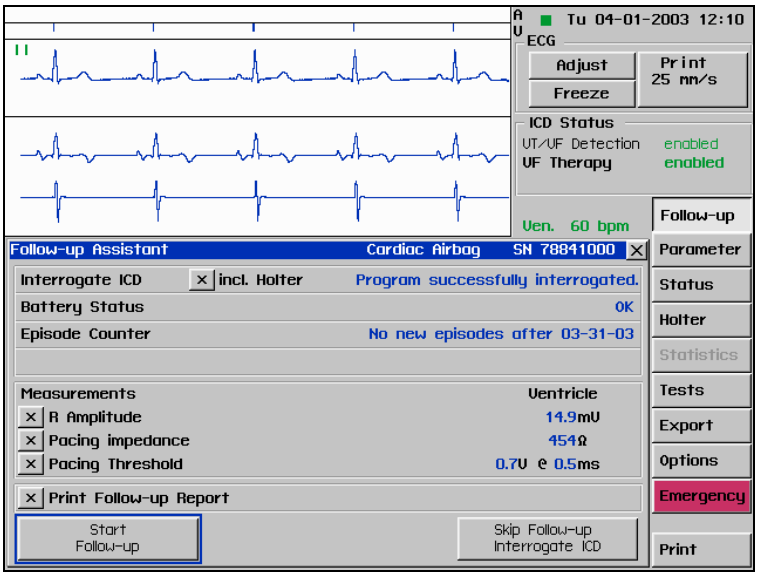


Figure 7. Follow-Up Assistant with measured values

3.1.1 Interrogate ICD without Follow-up

To perform an interrogation without using the Follow-Up Assistant, select **Skip Follow-Up Interrogate ICD.** Once interrogation is completed all current programmed parameters are listed within the **Parameter** screen.

3.2 Main Function Keys

A general description the main function keys is presented below:

[VT/VF Detection] - The VT/VF Detection key is used to activate or deactivate the programmed VF therapy in the ICD. The user may select either Enable Detection or Disable Detection from the pop-up menu. Detection is automatically enabled following selection of the Enable Detection command. The user is required to confirm before the Disable Detection is transmitted.

[Follow-Up] - The Follow-up Assistant (FAST) is incorporated into the programmer applications to provide a user-defined system guided follow-up. The “guided” follow-up function was developed to allow consistent and quick actions by the user through a single command.

[Parameter] - The [**Parameter**] window serves for programming all parameters for sensing, detection and therapies.

[Status] - The [**Status**] window displays information on the interrogated ICD and the connected lead system. The window is grouped under two tabbed sections: **Status** and **Measurement Trend**.

[Holter] - The [**Holter**] functions are grouped within the following tabs: **Episode List** and **Holter Configuration**. **Episode List** displays a list of all stored episodes. **Holter Configuration** contains Holter configuration and a function for modifying the date and time setting of the programmer. Holter Time Setting clears the date and time from the implant memory and sets the internal clock of the implant to the time of the programming device.

[Tests] - The [**Tests**] are grouped within the following tabs**: Amplitude** / **Impedance**, **Threshold**, and **DFT Test**. Each of these tabs activates windows for various tests used at implant and follow-up procedures.

[Export] - The [**Export**] selection is used to copy the complete database of the implant to a separate computer via a serial interface and BIOTRONIK’s CDM 3000 software which is not be available in the US.

[Options] - The [**Options**] window contains the following three tabs:

Options: for manually reformation of the high voltage capacitors contained within the ICD, to activate Home Monitoring, and for programmer control functions.

Patient Data: For storing information regarding the patient and their physician.

Reset: To re-initialize the ICD. This feature is locked out by code, if it is necessary to reset the ICD, please contact your BIOTRONIK representative.

[Emergency] - The [**Emergency**] function key is always present. Activating this key produces a screen display that turns ventricular tachyarrhythmia Detection ON and OFF, activates emergency bradycardia pacing parameters, or activates a programmer commanded shock.

[Print] - This function key appears in the lower right side of the screen in windows with printing options. Activation of this key immediately prints the relevant data from the open window.

3.3 Parameter Window

The [**Parameter**] window serves for programming parameters for sensing, detection and therapies. All programming of detection, therapies, pacing are completed from this Parameter screen (**see Figure** 8). Detection and Therapy parameters are displayed only if VT/VF Detection is enabled. In order to provide easily understandable parameter displays, the numeric values of the detection parameters can be shown as an Interval (ms) or as a Rate (bpm).

Two main function keys are located at the bottom of the parameter window regardless of the tab selected.

[Interrogate ICD] - This function key interrogates the ICD and loads the current programmed parameters into the programmer memory.

[Transmit] - Activation of this key transmits the displayed parameters as a permanent program to the ICD. This key also appears in the [**Options**] window as [**Transmit Settings**].

Figure 8. [Parameter] Window

4. 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 ensure sterility, the container should be checked for integrity prior to opening.

5. Implant Procedure

5.1 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.

Perform an interrogation of the ICD. Ensure programmer operation, nominal device parameters and battery status is appropriate for a new Cardiac Airbag ICD. Program Detection and Therapy to “Disabled” prior to handling the Cardiac Airbag 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.

5.2 Lead System Evaluation

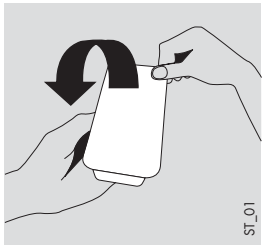
The ICD is mechanically compatible with DF-1 defibrillation lead connectors and IS-1 sensing and pacing lead connectors. IS-1, wherever stated in this manual, refers to the international standard, whereby leads and pulse generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992].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

Refer to the appropriate lead system technical manual.

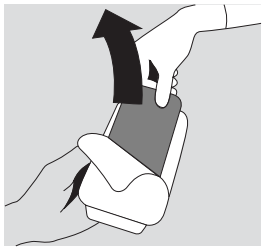
5.3 Opening the Sterile Container

The Cardiac Airbag 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.

5.4 Pocket Preparation

Using standard surgical technique, create a pocket for the device in the patient's pectoral region. 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.

5.5 Lead to Device Connection

The Cardiac Airbag 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. **Figure** 9 depicts the configuration of the header ports on the Cardiac Airbag, where HV1 and HV2 are for DF-1 connectors, and V P/S is for IS-1 connectors.

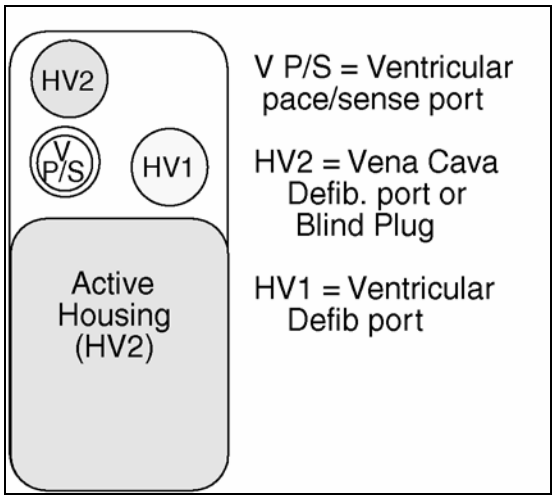


Figure 9. Header Ports

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.

5.6 Blind Plug Connection

The Cardiac Airbag 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.

5.7 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.

5.8 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.

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.

5.9 Suggested Cardiac Airbag Implant Procedure

Pre-Operative steps

1. Check paper supply TMS 1000^{PLUS} or EPR 1000^{PLUS}
2. Ensure both the programmer date and time are correct. (To change the date and time, access **More** → **Preferences** → **PC**)
3. Connect the PK-44 ECG cable and verify the signal before the patient is prepped and draped.
4. Run a baseline ECG
5. Ensure that an external defibrillator is connected to the patient.

Preparing the ICD

1. Select a **Cardiac Airbag** ICD package.
2. Place the programming wand over the ICD. A green flashing light indicates a good telemetry communication.
3. **Cardiac Airbag** is automatically interrogated with the wand over the ICD.
4. Press **Status**, (**See Figure** 10) located on the right side of the screen. The button performs a complete interrogation of the ICD.

   Verify **Implant Status OK**.
   Verify **Battery Status OK**.
   Verify **Episode Gauge** is full.

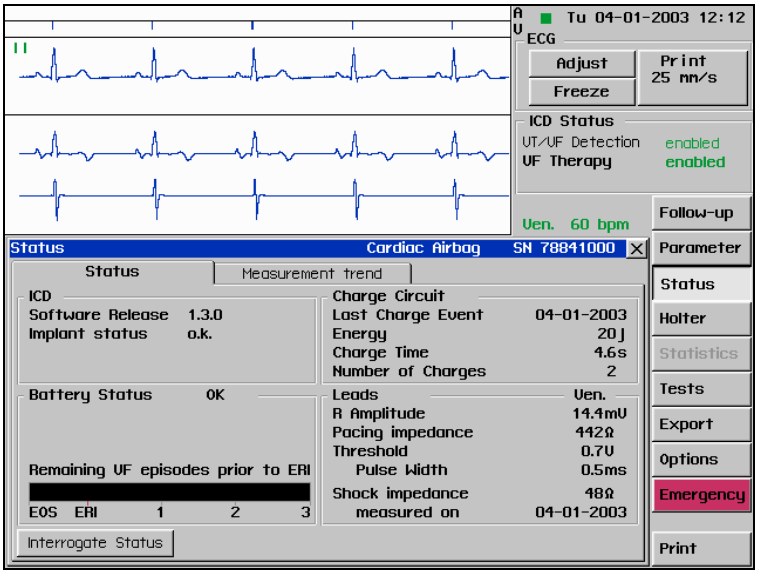


Figure 10. System Status

Performing a manual capacitor reformation

1. Press **Options** button.
2. Select **Start Formation** (See Figure 11.) and then **OK**.
3. During charging, an ICD Charging meter is displayed in the **ICD Status** box.
4. Return to **Status** screen.
5. Verify the ICD **Charge Time**.

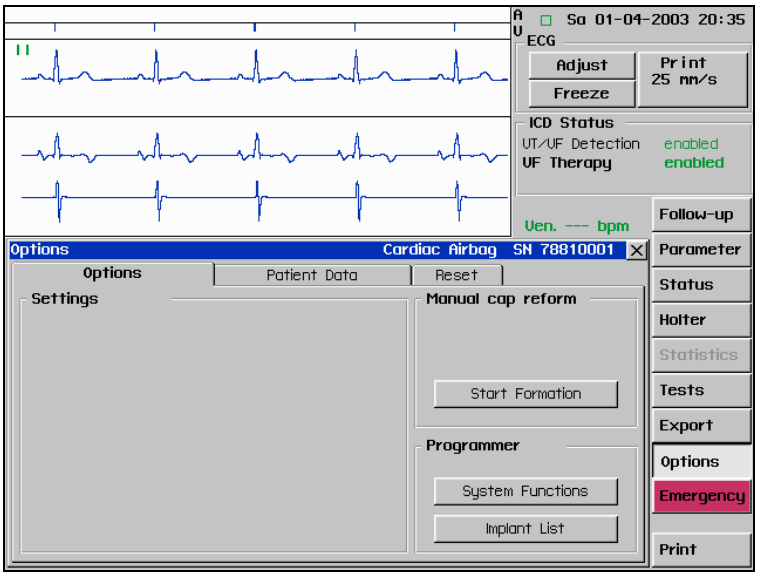


Figure 11. Manual Cap Reform

Accessing the TMS 1000^{PLUS} for lead and device-based testing

1. Press **Options** button.
2. In the Programmer area, press **Implant List** button to return to the main programmer screen.
3. Select **TMS 1000** from the Implant List.

Connecting the ventricular lead for testing

1. Connect the terminal pins of the ventricular lead to the appropriate port of the PK-44 Cable.

   Pace/Sense pin = PA-2 block

   Shock pins = PA-3 block

Measuring R-wave Amplitude

1. Select **Intracardiac Measurements**
2. Press and hold the **Record Data** (See Figure 12) button to measure the R-wave amplitude. There is an audible tone when the ICD has detected a sensed R-wave.
3. In general, R-wave amplitudes should be greater than 5 mV.
4. Press **Print** to obtain a printout of the measurement.

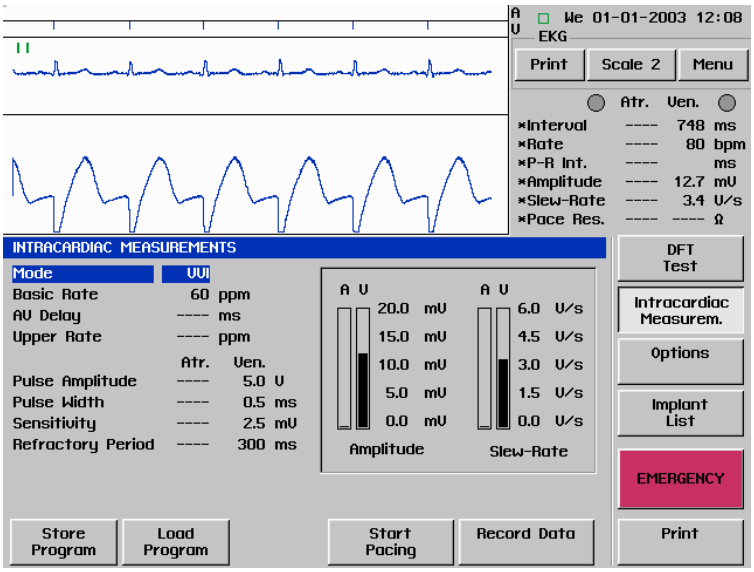


Figure 12. R-Wave Measurement

Determining ventricular capture thresholds

1. Verify **VVI** mode is highlighted.
2. Set the **Lower Rate** at 5 to 10 ppm above the patient's intrinsic rate.
3. Press **Start Pacing** to begin threshold testing at the displayed parameters.
4. Decrease **Pulse Amplitudes** (**See Figure** 13) until loss-of-capture occurs.
5. Press **Stop Pacing** to return to the patient's intrinsic rhythm.

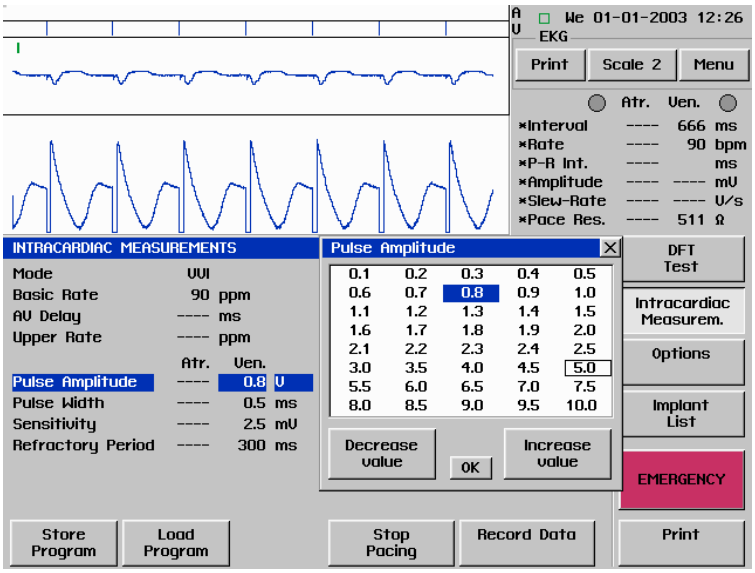


Figure 13. Pacing Threshold Test

6. In general, ventricular pacing thresholds should be less than 1.0 V.
7. Press **Print** to obtain a printout of the threshold.

Testing for diaphragmatic stimulation

1. Select **10.0 V** in the Pulse Amplitude pop-up menu to test for diaphragmatic stimulation.
2. Press **Start Pacing**.
3. Check for diaphragmatic stimulation.
4. Press **Stop Pacing** to return to the patient's intrinsic rhythm.

Connecting the ICD to the leads

5. Verify **VT/VF Detection** is **disabled**.
6. Hand off the pre-programmed ICD to the implanting physician.
7. Disconnect the ventricular lead pins from the PK-44 cable and insert each lead pin into the appropriate ICD header port.

   Pace/Sense pin = P/S V {IS-1}
   HV 1 Shock pin = HV 1 {distal coil}
   HV 2 Shock pin = HV 2 {proximal coil}
8. Tighten each set-screw using a BIOTRONIK torque wrench until a clicking sound is heard.
9. Insert the ICD into the pocket with etching facing up.

Performing device-based testing measurements

1. Press **Implant List** button.
2. Place a sterile cover over the programming wand and instruct the implanting physician to position the wand over the device.
3. A green flashing light on the wand indicates good telemetry communication
4. **Cardiac Airbag** is automatically interrogated.
5. Press **Start Follow-Up** to automatically interrogate the device. ***Battery status***, ***sensing***, ***lead impedance***, and ***episode counters*** are automatically verified.
6. Check R-wave Amplitudes (greater than 5 mV).
7. Verify pacing Impedance values are within an acceptable range (300-1000Ω).
8. Verify Battery Status is **OK**.
9. Perform a **Pacing Threshold** test.
10. Press **Resume Follow-up** to print out a summary of these baseline measurements.
11. Enable **VT/VF Detection**.
12. Verify ICD settings with implanting physician.

Performing 1 J test shock

1. Verify external defibrillation is available.
2. Verify testing sequence with implanting physician.
3. Press **Tests** button.
4. Select **DFT Test** tab.
5. Ensure wand is over the device and good telemetry communication is established.
6. Press **1 J Test Shock** and press **OK** to deliver a synchronized low-energy shock (1 Joule test shock) to confirm adequate shock coil impedance.
7. Confirm **Shock Impedance** values are within an acceptable range (30-120Ω).

DFT testing

1. Select method to induce ventricular fibrillation with the ICD: Shock on T wave or HF burst.
2. Press **Print** button to begin printing induction.
3. Press **Start VT/VF Induction** (**See Figure** 14) and **OK** to induce VF.
4. Observe the IEGM, markers, and ICD charging indicator on the programmer screen.

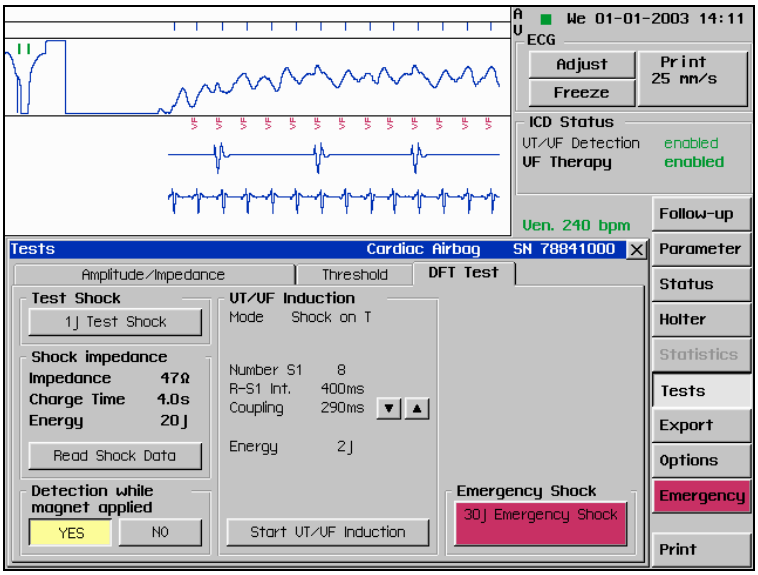


Figure 14. VF Induction Test

5. After successful delivery of therapy, press **Print** to stop printing. (**See Figure** 15)

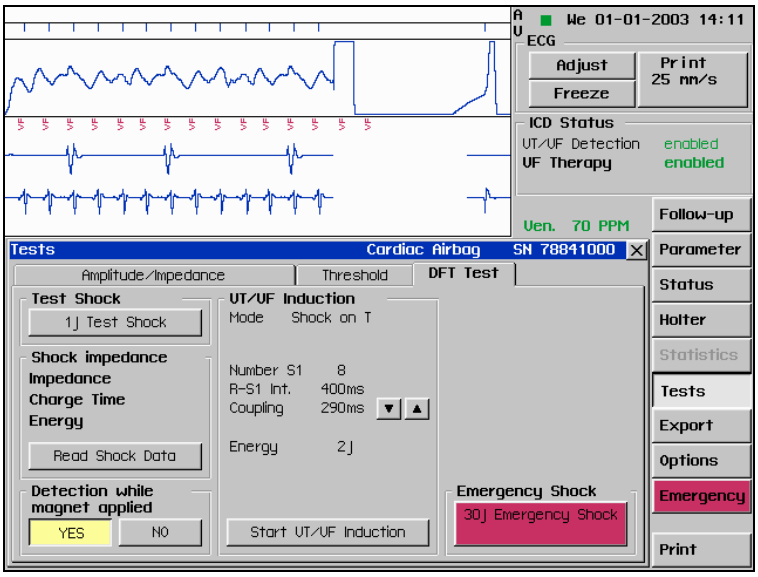


Figure 15. VF Induction Test

6. **Read Shock Data** is automatically updated with shock values.
7. Press **Print** to print out the DFT Test Screen.
8. Select **Holter** and review EGM to ensure proper sensing during VF.
9. Repeat induction process for a second therapy success or until the DFT is found.
10. After testing is complete, select **VT/VF Detection** to disable detection and prevent any inappropriate shocks during the remainder of the implantation procedure.

Final Programming

1. Verify final programming of the following parameters: **detection intervals**, **pacing**, **sensing**, and **therapy**.
2. Select **Transmit** to permanently program final parameters.
3. Verify **VT/VF Detection** is **Enabled**.
4. Select **Parameter** button and press **Interrogate** then **Print** to print out final programming and system status.

6. Follow-up Procedures

6.1 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. As the final step during the patient follow-up, the programmed parameters should be verified with the physicians and the permanent program should be retransmitted to the ICD. ACC/AHA/NASPE Guidelines recommend the physician perform a patient follow-up visit every 3 months.

6.2 Suggested Cardiac Airbag Follow-Up Procedure

Setting up the programmer

1. Turn power ON.
2. Ensure the programmer date and time are correct.
3. To change the date and time, access **More → Preferences → PC** from the implant screen
4. Connect the patient to the surface ECG cable.
5. Place the programming wand over the ICD. A green flashing light indicates a good telemetry communication.
6. The **Cardiac Airbag** is automatically interrogated with the wand over the ICD.

Starting Follow-Up Assistant

1. The software begins by displaying the **Follow-Up Assistant screen**. (**See Figure** 16) (To fully activate the Follow-Up Assistant program, ensure that all boxes are checked.)
2. Press **Start Follow-Up**, located in the lower left corner of the screen. This button begins the follow-up procedure by performing a complete interrogation of the ICD. ***Battery status***, ***sensing***, ***lead impedance***, and ***episode counters*** are automatically verified.

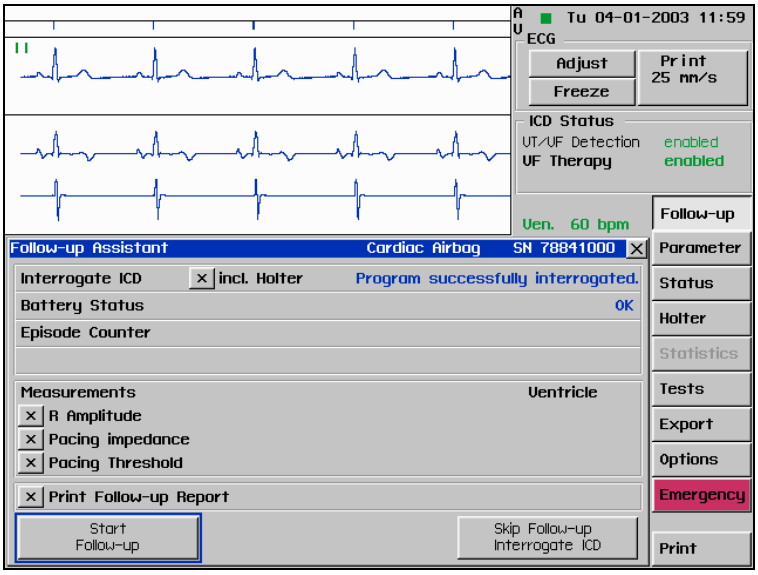


Figure 16. Follow-up Assistant

Determining the ventricular pacing threshold

1. Enter **Tests→Threshold** (See Figure 17) (automatic through Follow-up Assistant.)
2. Set **Rate** at 5 to 10 ppm above the patient's intrinsic rate.
3. If desired, turn **Print Test ON** to run paper during testing.
4. Press **Start Test** to begin threshold testing at displayed parameters.
5. Decrease **Test Amplitudes** until loss-of-capture occurs.
6. Press **Stop Test**. (Permanently programmed pacing values are immediately restored.)
7. Select the threshold value from the pop-up menu and press **OK**.
8. Select **Resume Follow-up** to return to the **Follow-up Assistant** screen.
9. A **Follow-up Report** will be printed automatically.

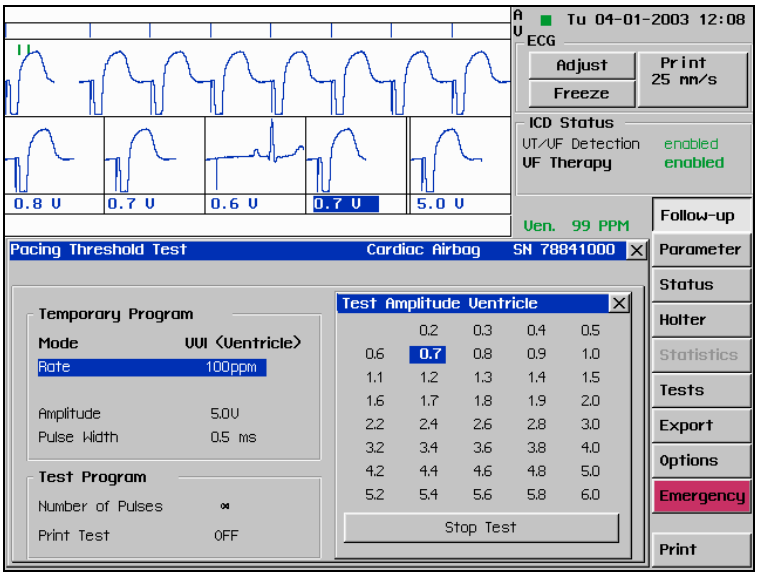


Figure 17. Pacing Threshold Test

Printing and analyzing detailed Holter data information

1. Press the **Holter** (**See Figure** 18) button to view episodes.
2. From the **Episode List**, select the episode EGM you wish to view and/or print.
3. Press **Print** to obtain a printed record of all events since implantation.

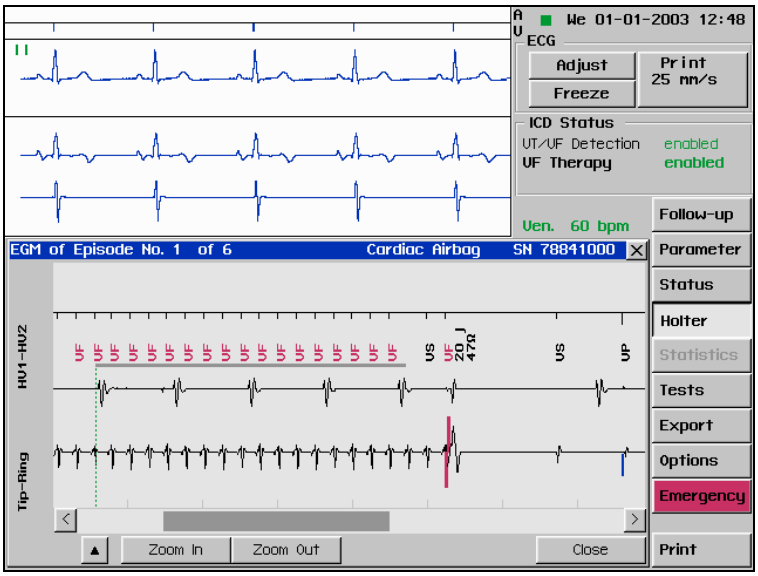


Figure 18. Holter EGM Episode

Verify system status

1. Press **Follow-up** button.
2. Check **R Amplitudes** (greater than 5 mV)
3. Verify **Pacing Impedance** values are within an acceptable range (300-1000Ω)
4. Verify **Battery Status** is **OK**.

Verifying remaining shocks to ERI

1. Press **Status** button. (**See Figure** 19)
2. Review the **date of last charge event**, **charge time**, **delivered energy**, and **shock impedance**.

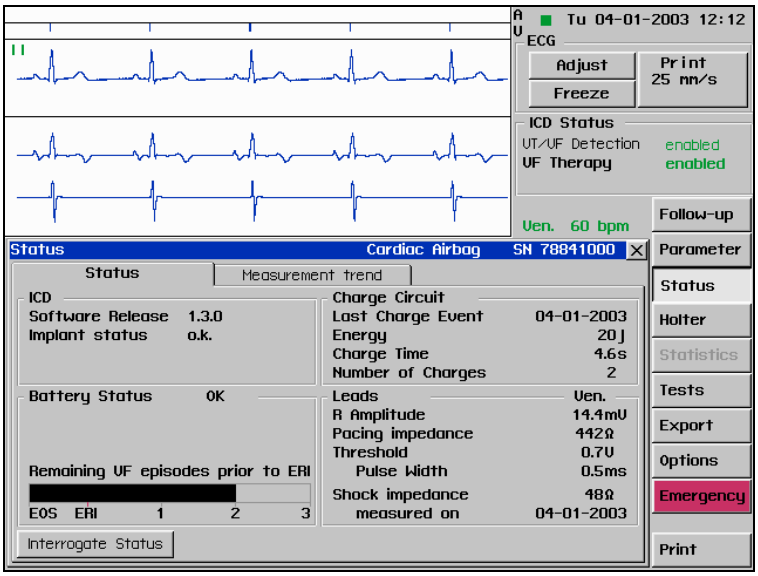


Figure 19. System Status

3. Verify remaining shocks to ERI by checking the level of the episode gauge.
4. ERI is reached when 3 treated VF episodes have occurred.
5. At ERI, contact your local BIOTRONIK representative.

Making parameter changes and obtaining final printouts

1. Touch the parameter to be changed and select the new value from the pop-up menu.
2. Permanently program any changes by pressing **Transmit**.
3. Interrogate the device and print final summary by selecting the **Print** button from the **Follow-Up** screen.

6.3 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. For the Cardiac Airbag ICD, there are two methods for reaching ERI. One method is standard battery depletion over the life of the time with no delivered therapies and the other method is based on the number of treated VF episodes. Both methods are described in detail below.

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 at least three months along with the ability to deliver a minimum of six high-energy shocks. Upon reaching end of service (EOS) all tachyarrhythmia detection and therapy is disabled.

6.3.1 Standard ERI Method

The service times from beginning of service (BOS) to elective replacement indication (ERI) are listed below in **Table 4**. 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 and all shocks at maximum energy (30 joules) at 37C. The estimates for service time are based on a 24 month shelf life, therefore, if the Cardiac Airbag ICD is implanted prior to the 24 month period, the service time may be longer than what is depicted in **Table 4**.

In this table, it is assumed that the device delivers no shocks to treat ventricular tachyarrhythmias, however, automatic capacitor reformations are equally spaced on a quarterly (every 3 months) basis throughout the life of the ICD. Therefore, the table starts at a minimum of 4 shocks per year, because capacitor reformations are equivalent to shocks. The estimates associated with 0% pacing support assume the ICD is sensing an intrinsic sinus rhythm at a rate of 70 bpm.

Table 4: Longevity Estimates

VVI Pacing Support	Shocks Per Year (includes cap reforms)	Years
100 %	12	3.5
	10	3.7
	8	3.9
	6	4.1
	4	4.4
50 %	12	3.7
	10	3.9
	8	4.1
	6	4.4
	4	4.7
15 %	12	3.8
	10	4.0
	8	4.3
	6	4.6
	4	4.9
0 %	12	3.9
	10	4.0
	8	4.4
	6	4.7
	4	5.0

After the ERI period the device is at EOS (End of Service) and requires explantation. Upon reaching EOS all tachyarrhythmia detection and therapy is disabled.

6.3.2 Treated VF Episode ERI Method

The Cardiac Airbag ICD is designed to treat a limited number (3) of spontaneous VF episodes prior to reaching ERI. Induced VF episodes via the BIOTRONIK programmer that receive shock therapy with the programmer wand in place do not increment against the 3 treated VF episode limit. Only spontaneous VF episodes that receive shock therapy increment the treated VF episode count. Any VF episode that is detected by the ICD and the resulting charge is aborted prior to receiving a shock does not count against the 3 treated VF episode limit.

The programmer screen and printouts have been designed to display the current status of the Cardiac Airbag ICD upon interrogation. **Figure** 20 displays the VF treated episode Gauge after one spontaneous therapy was delivered. **Figure** 21 displays the ERI status after the Cardiac Airbag has treated 3 VF episodes.

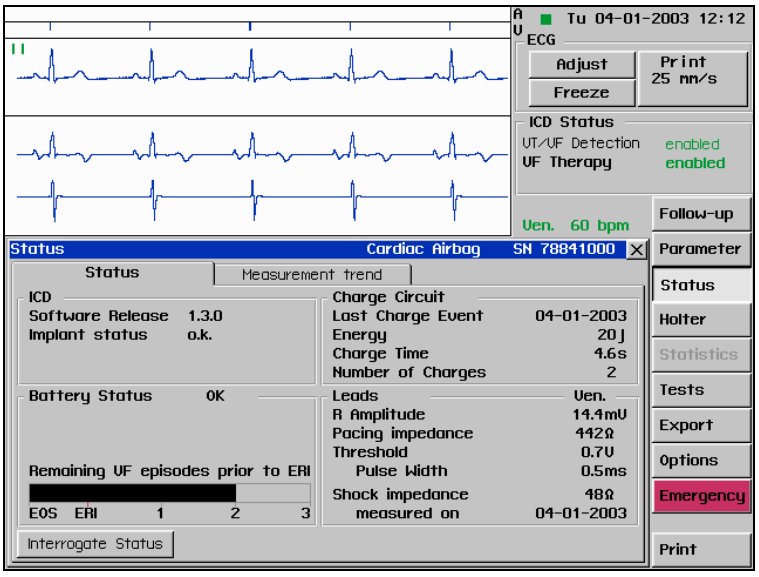


Figure 20. Status Following 1 VF Episode

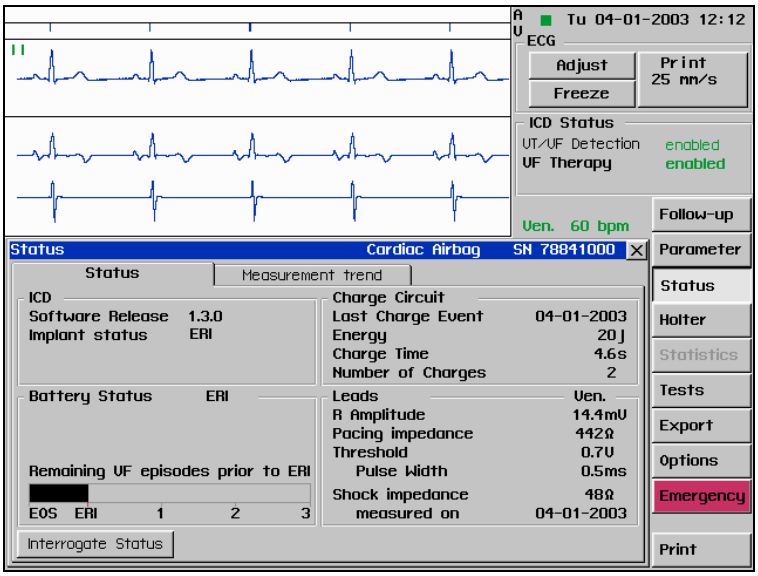


Figure 21. Status at ERI

Upon reaching ERI, the battery has enough energy left to continue monitoring for at least three months and to deliver a minimum of 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 and should be explanted. Upon reaching EOS all tachyarrhythmia detection and therapy is disabled.

6.4 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 packaged in a bio-hazard container. These may be delivered to either 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.

7. Technical Specifications

The following are the technical specifications for the Cardiac Airbag ICDs. The ranges are presented in the format:

x…(y)…z

where x = the lowest value, y = the increment, and z = the largest value.

NOTE:

Values depicted in gray are preset in the ICD and are not programmable values.

Mechanical Properties

Parameter	Value Range
Dimensions	67 x 55 x 13 mm
Conducting Surface Area	67 cm^2
Volume	39 cc
Mass	73 g
Housing Material	Titanium
Header Material	Epoxy resin
Seal Plug Material	Silicone
Cardiac Airbag and Cardiac Airbag-T Lead Ports	1 x 3.2 mm IS-1 Bipolar 2 x 3.2 mm DF-1

Parameters - Tachyarrhythmias

Parameter	Value Range
Detection Parameters for VT Monitoring Zone	
Rate (VT Monitoring)	OFF; 270…(10)…600 ms 100…222 bpm
Interval Counter: Initial Detection	16
Interval Counter: Redetection	12
Onset	20 % (adaptive)
Stability	±24 ms (absolute)
Detection and Redetection Parameters for VF Zone	
Interval / Rate	OFF; 200 …(10)…400 ms 150…300 bpm
Number of X	8
Number of Y	12
Termination Detection	12 in 16

Shock Therapy

Parameter	Value Range
Number of Shocks 1st Shock Energy Further Shocks	6...(1)...8 (VF) 20, 30 Joules 30 Joules
Shock Waveform	Biphasic
Confirmation	ON
Polarity	Normal

Sensing

Parameter	Value Range
Sensitivity	Standard Enhanced T wave suppression Enhanced VF sensitivity Free (This feature is locked-out in the US)
Minimum Threshold	0.5…(0.1)…2.5 mV

Bradycardia Therapy

Parameter	Value Range
Mode	VVI, VVIR, OVO (OFF)
Rate	30…(5)…120 ppm
Amplitude	0.2…(0.1)…6.2, 7.5 V
Pulse Width	0.5, 1.0, 1.5 ms
Maximum Sensor Rate	100, 125 ppm
Sensor Gain	4
Sensor Threshold	mean
Rate Increase	2 ppm/s
Rate Decrease	0.4 ppm/s

Post-Shock Bradycardia Therapy

Parameter	Value Range
Mode	VVI
Rate	70 ppm
Amplitude	7.5 V
Pulse Width	1.5 ms
Duration	30 seconds

Home Monitoring (Cardiac Airbag-T Only)

Parameter	Value Range
Home Monitoring	**OFF**, ON
Event Report	On
Repeated Interval	60 minutes

Federal Communications Commission Disclosure

The Belos-T ICD is equipped with an RF transmitter for wireless communications. This transmitter is authorized by rule under the Medical Implant Communications Service (47 CFR Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

The FCC ID number for this device is: PG6BELOS-T.

Appendix A

Connector Compatibility

Cardiac Airbag 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 Cardiac Airbag family of ICDs is mechanically compatible with:

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

The Cardiac Airbag and Cardiac Airbag-T ICDs have a single IS-1 header port and two DF-1 header ports.

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

Manufactured by:
BIOTRONIK GmbH & Co.
Woermannkehre 1
D-12359 Berlin
Germany

M4088-A 3/03