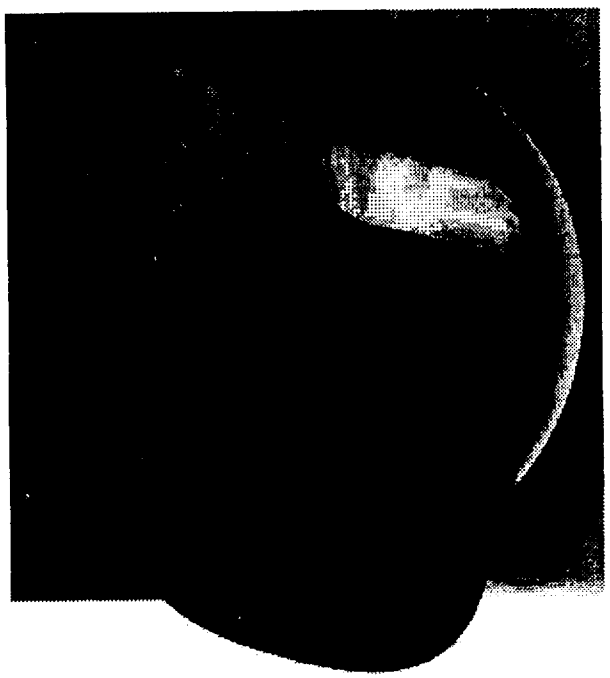
DUAL CHAMBER DEFIBRILLATOR

Defender II

9201 - VVED

USER'S MANUAL



Implantable cardioverter-Defibrillator
Dual chamber arrhythmia detection
Ventricular antitachycardia pacing
Dual chamber antitachycardia pacing

ela

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE OR ON THE ORDER OF A PHYSICIAN

The Defender models described in this manual are covered by the following US patents:
5 339 820, 5 350 406, 5 325 856, 4 462 060, 5 818 703, 5 591 218, 5 558 097, 5 545 181, 5 564 430, 5 513 645.

Defender II 9201
is manufactured by ELA Medical,
98, rue Maurice Arnoux,
92120 Montrouge Cedex, France.

TABLE OF CONTENTS

TABLE OF CONTENTS

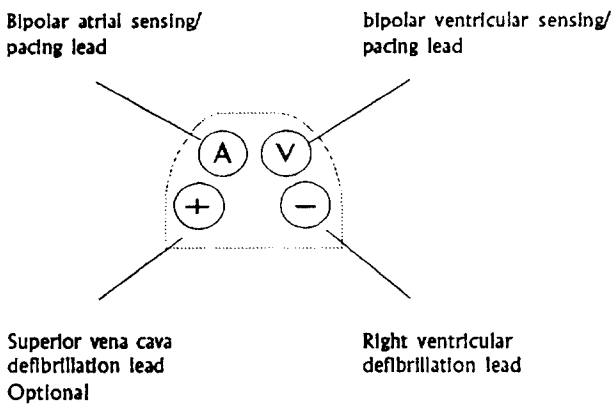
1 - DEVICE SPECIFICATIONS

Maximum Energy	Defibrillating Lead Connection	Pacing Lead Connection	Dimensions W x H x D	Volume	Weight
33 J	Two DF-1 (3.2mm)	Two IS-1 bipolar (3.2mm)	60 x 84.9 x 17.9mm	75cc	140g

Case Material Titanium
Header Materials Silicone elastomer (medical grade)
Power Supply Two silver vanadium oxide batteries (each 3.2 V nominal)

Lead Connections Diagram

CONNECTORS:



Lead Compatibility
The following high voltage and defibrillation leads were used during the clinical study (N = number of patients) and are compatible with the Defender II Model 9201 ICD.

Manufacturer	Model (n)	Placement	Fixation
Biotronik	SL-ICD (56)	RV and SVC coils	Tines
	SPS (13)	RV	Tines
Guidant	Endotak 0048 (1)	RV and SVC coils	Tines
	Endotak 0072 (3)	RV and SVC coils	Tines
	Endotak 0095 (9)	RV and SVC coils	Tines
	Endotak 0125 (3)	RV and SVC coils	Tines
	Endotak (Model Unk. 4)	RV and SVC coils	Tines
Medtronic	Sprint 6932 (1)	RV	Tines
	Sprint 6942 (36)	RV and SVC coils	Tines
	Sprint 6943 (4)	RV	Extendable Screw
	Sprint 6945 (1)	RV and SVC coils	Extendable Screw

2 - DEVICE DESCRIPTION

The Defender™ II Model 9201 (Defender II) is a multiprogrammable, implantable cardioverter defibrillator (ICD) that monitors and regulates a patient's heart rate by providing ventricular arrhythmia therapy and single and/or dual chamber pacing.

Defender II 9201, along with compatible commercially available pace/sense leads and cardioversion/defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems for the Defender II generator are implanted using either transvenous or transthoracic techniques. Defender II can be programmed and interrogated via bi-directional telemetry using an ELA Medical programmer. This, along with programming software 9201 Version 1.00 or higher, and a CPR1D programming head, constitutes the external portion of the ICD system.

3 - INDICATIONS AND USAGE

Defender II is indicated for use in patients who are at risk of sudden death due to ventricular arrhythmias and have experienced one of the following situations:

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

NOTE : The clinical outcome for hemodynamically stable VT patients is not fully known. Safety and effectiveness studies have not been conducted.

4 - CONTRAINDICATIONS

Do not use the Defender II in:

- Patients whose ventricular tachyarrhythmias may have transient or reversible causes such as:
  - acute myocardial infarction
  - digitalis intoxication
  - drowning
  - electrocution
  - electrolyte imbalance
  - hypoxia
  - sepsis
- Patients with incessant VT or VF,
- Patients who have a unipolar pacemaker,
- Patients whose primary disorder is bradyarrhythmias or atrial tachyarrhythmias,
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction,
- Dual-chamber and single-chamber atrial pacing is contraindicated in patients with chronic refractory atrial tachyarrhythmias,
- Asynchronous pacing (VOO/AOO) is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

5 - WARNINGS AND PRECAUTIONS

Resuscitation Availability: Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

Electrical Isolation: Do not permit the patient to contact grounded equipment that could produce hazardous leakage current. Ensuing arrhythmia induction could result in the patient's death.

Avoiding Shock During Handling: Program **Shock Therapy** to OFF during surgical implant and explant or post mortem procedures because the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.

5.1. STERILIZATION, STORAGE AND HANDLING

Resterilization: Do not resterilize and re-implant explanted ICDs.

"Use Before" Date: Do not implant the device after the "Use Before" date because the battery may have reduced longevity.

If Package Is Damaged: Do not use the device or accessories if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to the manufacturer.

Device Storage: Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage. Store the device between 0 - 50°C (32 - 122°F) because temperatures outside this range may damage the device.

Equilibration: Allow the device to reach room temperature before programming or implanting the device because rapid temperature changes may affect initial device function.

5.2. IMPLANTATION AND DEVICE PROGRAMMING

In frequent charging of the high voltage capacitors may extend the ICD charge time. Every 6 months, the device automatically reforms the shock capacitors by charging them to the maximum voltage and maintaining this voltage for 100 seconds.

Use only an ELA Medical programmer to communicate with the device.

Do not position any magnet over the ICD; this suspends tachyarrhythmia detection and treatment.

Replace the device when the programmer displays an EOL and a battery voltage of 4.9 ± 0.12V or a magnet rate ≤ 80 min^{-1}.

Program device parameters such as sensitivity threshold and VT and VF detection intervals as specified in the device manuals.

Lead System: Do not use a lead system other than those with demonstrated compatibility (see page 5) because undersensing cardiac activity and failure to deliver necessary therapy may result.

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 should be explanted if previously implanted).

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.

A safety margin of at least 10 J in the defibrillation threshold (DFT) is strongly recommended. Carefully confirm that true ventricular fibrillation has been induced because the DFT for ventricular tachycardia or flutter may be lower.

Defender II should be implanted with the engraved side facing outwards in order to facilitate telemetric communication with the programming head and to display the radiographic identification correctly.

5.3. LEAD EVALUATION AND LEAD CONNECTION

Defender II has two DF-1 and two IS-1 connector ports. IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit (ISO 5841-1:1992). DF-1 refers to the international standard for defibrillation lead connectors (ISO 11318:1993).

Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this may damage the lead.

Do not immerse leads in mineral oil, silicone oil, or any other liquid.

Do not grip the lead with surgical instruments.

Do not use excessive force or surgical instruments to insert a stylet into a lead.

Use the same polarity evaluated during testing when connecting the leads to the generator to ensure defibrillation effectiveness.

If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.

Do not place the patch lead over nerve tissue as this may cause nerve damage.

Place the patch lead with the conducting coil side facing the heart to ensure delivery of energy to the heart.

Place the sutures well outside the coil of the patch lead or in the area between the coils to avoid possible coil fracture.

If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior-posterior) and be sure that the external paddle is not positioned over the patch.

Do not fold, alter, or remove any portion of the patch as it may compromise electrode function or longevity.

Use ventricular transvenous leads with caution in patients with either a mechanical or bioprosthetic tricuspid valvular prosthesis.

Use the correct suture sleeve (when needed) for each lead to immobilize the lead and protect it against damage from ligatures.

5- WARNINGS AND PRECAUTIONS

Never implant the system with a lead system that has a measured shock impedance of less than 30 ohms. A protection circuit in the defibrillator prevents shock delivery when impedance is too low. If the shock impedance is less than 30 ohms, reposition the lead system to allow a greater distance between the electrodes.

Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

Do not insert a lead connector pin into the connector block without first visually verifying that the set screws are sufficiently retracted. Do not tighten the set screws unless a lead connector pin is inserted because it could damage the connector block.

Do not suture directly over the lead body as this may cause structural damage. Use the lead stabilizer to secure the lead lateral to the venous entry site.

Lead electrodes in contact during a cardioversion or defibrillation therapy will cause current to bypass the heart, possibly damaging the ICD and leads. While the ICD is connected to the leads, make sure that the metal portions of any electrodes do not touch each other.

If a pacing 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.

If a header port is unused on the generator, the port must be plugged to protect the generator.

5.4. FOLLOW-UP TESTING

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.

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 nonconversion 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.

5.5. GENERATOR EXPLANT AND DISPOSAL

Interrogate the device, and program shock therapy off prior to explanting, cleaning or shipping the device to prevent unwanted shocks.

Return all explanted generators and leads to the manufacturer.

Never incinerate the device due to the potential for explosion. The device must be explanted before cremation.

5.6. ENVIRONMENTAL AND MEDICAL THERAPY HAZARDS

Patients should be directed to avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the generator to return to its normal mode of operation.

5.6.1. HOSPITAL AND MEDICAL ENVIRONMENTS

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 device and leads as possible (a minimum of 15 cm [six inches]). In addition, VT and VF therapies should be disabled prior to any electrocautery and proper function of the device should be checked afterwards.

External defibrillation may damage the generator or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporary or permanent elevated pacing thresholds. Minimize current flowing through the generator and lead system by following these precautions when using external defibrillation on a patient with a generator:

- Position defibrillation paddles as far from the generator as possible (minimum of 13 cm (5 inches)). Minimize current flowing through the generator and leads by positioning the defibrillation paddles perpendicular to the implanted generator/lead system.
- Use the lowest clinically-appropriate energy output (joules).
- Confirm generator function following any defibrillation.

High radiation sources such as cobalt 60 or gamma radiation should not be directed at the device. If a patient requires radiation therapy in the vicinity of the device, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Lithotripsy may permanently damage the device if this one is at the focal point of the lithotripsy beam. If lithotripsy must be used, keep the defibrillator at least 2.5 to 5 cm (1-2 inches) away from the focal point of the lithotripsy beam.

Magnetic resonance imaging (MRI) may cause device malfunction or damage. If MRI must be used, patients should be closely monitored and programmed parameters should be verified upon cessation of MRI.

A radio frequency ablation procedure in a patient with a generator may cause device malfunction or damage. RF ablation risks may be minimized by:

- Programming **Shock Therapy** and ATP to OFF,
- Avoiding direct contact between the ablation catheter and the implanted lead or generator,
- Positioning the ground, placing it so that the current pathway does not pass through or near the device, i.e. place the ground plate under the patient's buttocks or legs,
- Having external defibrillation equipment available.

5- WARNINGS AND PRECAUTIONS

5.7. HOME AND OCCUPATIONAL ENVIRONMENTS

High voltage power transmission lines may generate enough EMI to interfere with defibrillator operation if approached too closely.

Communication equipment such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with defibrillator operation if approached too closely.

Commercial electrical equipment such as arc welders, induction furnaces, or resistance welders may generate enough EMI to interfere with generator operation if approached too closely.

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with defibrillator operation. There are reports of device disturbances caused by electric hand tools or electric razors used directly over the device implant site.

Body fat monitor and electronic muscle stimulation (TENS device) : A patient implanted with a Defender II should not use these devices.

5.7.1. ELECTRONIC ARTICLE SURVEILLANCE (EAS)

EAS equipment such as retail theft prevention systems may interact with the device. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.

5.7.2. CELLULAR PHONES

Testing has indicated there may be a potential interaction between cellular phones and some ICDs. 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 device is within 30 cm (12 inches) of the ICD.

Patients with a Defender II ICD who operate a cellular telephone should:
- Maintain a minimum separation of 30 cm (12 inches) between a hand-held personal cellular telephone and the implanted device,
- Set the telephone to the lowest available power setting, if possible,
- Hold the phone to the ear opposite the site of the implanted device. Patients should not carry the telephone in a breast pocket or on a belt over or within 12 inches (30 cm) of the implanted device as some telephones emit signals when they are turned ON but are not in use (e.g., in the "Listen" or "Stand-by" mode). Store the telephone in a location opposite the site of the implant.

Based on results to date, adverse effects resulting from interactions between cellular telephones and implanted ICDs have been transitory. If EMI emitted from a telephone does adversely affect an implanted ICD, moving the telephone away from the immediate vicinity of the ICD should restore normal operation.

6 - ADVERSE EVENTS

Clinical study of Defender 9001 and Defender II 9201 included 167 devices implanted in 167 patients worldwide.[1] Implant duration ranged from 0 to 40.6 months with an average of 13.6 months. Total device exposure was 2,277 device months.

No deaths, serious adverse experiences or complications were judged to be device-related, as determined by an independent physician advisory committee.

There were a total of 15 deaths in the study, two of which were classified as sudden cardiac death; all were reviewed by an independent physician advisory committee. Thirteen of these deaths occurred more than one month post-implant. Causes of death are presented in Table 6-1.

Table 6-1. Causes of Death During Study
All deaths (15 of 167 patients)

Cause of Death (n = 15)	# of Patients	Time After Implant (Months)
Heart Failure/Pulmonary Edema	8	0, 39, 14, 7.5, 5.5, 5, 3, 0.5
Sudden Cardiac Death	2	2.5, 31
Acute Myocardial Infarction	1	7
Electromechanical Dissociation	2	9, 6
Non Cardiac: Gastric Bleeding, Intestinal Infarction	2	17.5, 7.5

Twelve (7.2%) of the devices were explanted (Table 6-2).

Table 6-2. Causes of Explants During Study
All explants, 12 of 167 patients

Cause of Explant (n = 12)	# of Patients	Time After Implant (Months)
Heart Transplant	3	7.5, 12.5, 10.5
Device Migration/Exteriorization/Tissue Erosion	3	20, 13, 10
Device Reset	1	15.5
Endocarditis	1	4.5
Infection/Pocket Infection/Device Migration	2	13.25, 13
Lead Malfunction, Ventricular	1	19
Worsening Rhythm Disorder	1	23

[1] Ninety-five patients were implanted with Defender; 72 patients received Defender II. Both devices operated identically, however, Defender was intended for abdominal implant only and Defender II was implanted pectorally.

6 - ADVERSE EVENTS

6.1. OBSERVED ADVERSE EVENTS

Table 6-3 presents an overview of complications/observations attributed to the ICD system and/or implant procedure for Defender 9001 and Defender II 9201, respectively.

Thirty of the 95 Defender 9001 patients (abdominal implant) experienced a total of 50 complications, including device failures and replacements. Fifty-five of the 95 Defender 9001 patients experienced a total of 104 observations. Some have already been reported in Tables 6-1 and 6-2.

Table 6-3. Overview of Complications/Observations During Study
All patients (n=167)

Event	Device	Patients with Events	% of Patients	95% Exact C.I.	# of Events	Events/100 Device Years
Complications	Defender I	30/95	31.6	22 - 42	50	34
Observations	Defender I	55/95	57.9	47 - 68	104	70
Complications	Defender II	4/72	5.6	1.5 - 14	4	9.5
Observations	Defender II	19/72	26.4	17 - 38	23	55

Four of the 72 Defender II patients experienced a total of 4 complications, including device failures and replacements.

Table 6-4. Complications, Including Device Failures and Replacements
All complications, 4 of 72 Defender II patients

Event	# of Patients	% of Patients	# of Events	Events/100 Device-Years*
Any complication[2]	4	5.6	4	9.508
Absence of therapy for VT below VT rate zone	1	1.4	1	2.377
Incomplete ventricular lead connection	1	1.4	1	2.377
Ventricular lead blood infiltration	1	1.4	1	2.377
Ventricular lead replacement due to VF undersensing at implant	1	1.4	1	2.377
*Event rate per 100 device-years is calculated as the number of events multiplied by a factor, 2.377. This factor is equal to 100/total device-years. In these data, 72 patients had a total of 42.067 device-years.				

Nineteen of the 72 Defender II patients experienced a total of 23 observations.

[2] Complications are adverse events requiring invasive measures to correct, e.g. surgical revision.

Table 6-5. Observations, Including Patient Complaints, for the Defender II Patients in this Study.
All observations, 19 of 72 patients

Event	# of Patients*	% of Patients	# of Events	Events/100 Device-Years**
Any observation[3]	19	26.4	23	54.671
Absence of therapy on slow non-sustained VT	1	1.4	1	2.377
Absence of VT therapy	2	2.8	2	4.754
Atrial undersensing	2	2.8	2	4.754
Atypical chest pain	1	1.4	1	2.377
Elevated ventricular threshold, decreased ventricular amplitude	1	1.4	1	2.377
EMI, suspected	1	1.4	1	2.377
Hematoma	1	1.4	1	2.377
Inappropriate ATP	2	2.8	2	4.754
Inappropriate shock	4	5.6	4	9.508
Ineffective ATP therapy	1	1.4	1	2.377
Multiple painful ICD shocks	1	1.4	1	2.377
Pneumothorax	1	1.4	1	2.377
Programmer software malfunction	1	1.4	1	2.377
Thrombus	1	1.4	1	2.377
VF therapy for ST in VF rate zone	1	1.4	1	2.377
Wound dehiscence	1	1.4	1	2.377
Wound infection	1	1.4	1	2.377

*Some patients experienced more than one type of observation.
**Event rate per 100 device-years is calculated as the number of events multiplied by a factor, 2.377. This factor is equal to 100/total device-years. In these data, 72 patients had a total of 42.067 device-years.

[3] Observations are adverse events which are correctable by noninvasive measure, e.g., reprogramming.

6- ADVERSE EVENTS

6.2. POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order), including those reported in the previous tables, associated with ICD systems include:

- Acceleration of arrhythmias (caused by device),
- Air embolism,
- Bleeding,
- Chronic nerve damage,
- Erosion,
- Excessive fibrotic tissue growth,
- Extrusion,
- Fluid accumulation,
- Formation of hematomas or cysts,
- Inappropriate shocks,
- Infection,
- Keloid formation,
- Lead abrasion and discontinuity,
- Lead migration/dislodgment,
- Myocardial damage,
- Pneumothorax,
- 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).

7 - CLINICAL STUDIES

One hundred twenty-eight patients were enrolled at 35 institutions in Europe and 43 patients were enrolled at seven institutions in the U.S. in this non-randomized, prospective study. Clinical data are here presented for 167 of those patients; data from four of the U.S. patients have not been analyzed due to their recent implant dates. Ninety-five patients were implanted with Defender 9001; 72 patients received Defender II 9201. Both devices operated identically, however, Defender 9001 was intended for abdominal implant only and Defender II was implanted pectorally.

Patients studied: The patients (147 M / 20 F) had a mean age of 61.4 (range 18 to 87) years and a left ventricular ejection fraction of 35.0% (10% to 75%) (n = 141). The primary indication for implant was ventricular tachycardia in 107 (64.0%), ventricular fibrillation in 50 (30.0%), ventricular tachycardia and ventricular fibrillation in 8 (4.8%), syncope in 1 (0.6%) and 1 (0.6%) other. Cardiovascular history included cardiomyopathy (29.3%), other coronary disease (91.6%), hypertension (23.4%), heart failure (37.3%), and valvular disease (17.4%) (non-exclusive categories).

Methods: The primary objectives of this study were to determine ventricular arrhythmia termination success rates and specificity of the PARAD™ (P- and R-arrhythmia detection) algorithm in differentiating VT from rhythms of supraventricular origin, such as supraventricular tachycardia (SVT) and sinus tachycardia (ST).

The sponsor sought to demonstrate, at 95% confidence:
- $\geq$ 98% VF termination success,
- $\geq$ 95% of spontaneous VT termination success and
- $\geq$ 85% specificity in rejecting spontaneous SVT/ST.

Patients underwent standard ICD implantation and were evaluated at predischarge, and at 1, 3, and 6 months post implant and every 3 months thereafter.

Results: Mean defibrillation threshold was 9.5 J. Table 7.1 demonstrates that all three objectives of this study were successfully met. Overall cumulative survival rate at one year was 92.01%.

Table 7.1. ICD Clinical Study Results
(n = 167)

Parameter	Sample	Observed successes	Observed success rate %	95% Exact CI
VF Termination	Patients	136/136	100	97.8 -100
	Spontaneous Episodes	31/31	100	90.8 - 100
VT Termination	Patients	55/58	94.8	85.6 - 98.9
	Episodes	410/416	98.6	96.9 - 99.5[4]
SVT Untreated	Patients	151/167	90.4	84.9 - 94.4
	Episodes	475/526	90.3	87.8 - 92.7

[4] 96.7 - 100% after adjustment for statistical dependence of episodes in the same patient.

8 - PATIENT SELECTION AND TREATMENT

8.1. INDIVIDUALIZATION OF TREATMENT

Pectoral or abdominal implant site: Evaluate the prospective patient's size and activity level to determine whether a pectoral or abdominal implant is suitable.

Exercise stress testing: If the patient's condition permits, use exercise stress testing to:
- Determine the maximum rate of the patient's normal rhythm,
- Identify any supraventricular tachyarrhythmias,
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

Electrophysiologic (EP) testing: It is strongly recommended that candidates for the ICD therapy have a complete cardiac evaluation including EP testing. EP testing should identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or during EP testing.

Drug resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

Antiarrhythmic drug therapy: If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of ICD implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify ICD detection and conversion. The ICD also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affects the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

Direct any questions regarding the individualization of patient therapy to ELA Medical's representative.

8.2. SPECIFIC PATIENT POPULATIONS

Pregnancy: If there is a need to image the device, care should be taken to minimize radiation exposure to the fetus and the mother.

Nursing Mothers: Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

Pediatric Patients: This device has not been studied in patients younger than 18 years of age.

Geriatric Patients: Most (62%) of the patients receiving this device in clinical studies were over the age of 60 years.

Handicapped and Disabled Patients: Special care is needed in using this device for patients using an electrical wheel chair or other electrical (external or implanted) devices.

9 - PATIENT COUNSELING INFORMATION

The physician should consider the following points in counseling the patient about this device:
- 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.
- Advise patients to use ID cards (issued by ELA Medical) and/or ID bracelets documenting their ICD system.

Discuss the information in the Patient Manual with patients before and after generator implantation so they are fully familiar with operation of the device. Advise patients on how to obtain additional copies of the patient manual from ELA Medical.

10 - CONFORMANCE TO STANDARDS

This device was developed in conformance with all or parts of the following standards:
- Pr EN 45502-1: Active Implantable Medical Devices, General requirements for safety, marking and for information to be provided by the manufacturer, November 1995 (Draft standard),
- ISO 5841-3:1992, IS-1 Pacemaker Lead Connector Standard,
- ISO 11318: 1993(E), DF-1: Defibrillator Connector Standard,
- AAMI Pacemaker Standard – Labeling Requirements, Performance Requirements and Terminology for Implantable Artificial Cardiac Pacemakers. FDA Contract No. 223-74-5083. August, 1975.

This information should not be used as a basis of comparison among devices since different parts of the standards mentioned may have been used.

11 - CLINICIAN USE INFORMATION

11.1. PHYSICIAN TRAINING

Physicians should be familiar with sterile generator implant procedure and familiar with follow-up evaluation and management of patients with an implantable defibrillator (or referral to such a physician).

11.2. DIRECTIONS FOR USE

ICD operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the *Patient Registration Form* and return it to ELA Medical, as it provides necessary information for warranty purposes and patient tracking.

The *Programmer's Manual* is a separate document supplied with each programmer. This User's Manual is supplied with each generator. Copies can be obtained by contacting the ELA Medical representative. This manual was last updated in April 1999.

11.3. MAINTAINING DEVICE EFFECTIVENESS

11.3.1. DEVICE STORAGE

This device is **FOR SINGLE USE ONLY.** Do not resterilize and reimplant explanted ICDs.

ELA Medical has sterilized the ICD with ethylene oxide prior to shipment. Resterilizing the generator is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use Before" date because this date is based on battery life and sterility.

Do not implant the device when:
- It has been dropped on a hard surface because this could have damaged generator components.
- Its sterility indicator within the inner package is not green, because it might not have been sterilized.
- Its storage package has been pierced or altered, because this could have rendered it non-sterile.
- It has been stored or transported outside the environmental temperature limits: 32° F (0°C) to 122°F (50°C) as an electrical reset condition may occur.
- Its "Use Before" date has expired, because this can adversely affect generator longevity or sterility.

11.3.2. STERILIZATION INSTRUCTIONS

Do not resterilize the device or the torque wrench using an autoclave, gamma radiation, organic cleaning agents, e.g., alcohol, acetone, etc., or ultrasonic cleaners.

12 - PATIENT INFORMATION

Information for the patient is available in a separate booklet, *An ICD: like a life jacket for my heart,* available from ELA Medical. Copies can be obtained by contacting the ELA Medical representative. This information should be given to each patient with their first ICD and offered to the patient on each return visit or as deemed appropriate.

13 - HOW SUPPLIED

Defender II is packaged one per package in a sterile package.

14 - DEFIBRILLATOR FUNCTIONS

In this chapter programmable parameters are indicated by **bold underlined** typeface.

14.1. ANTIBRADYCARDIA FUNCTION

PACING MODES

Defender II paces both chambers with programmable **pulse width** and **amplitude**. Pacing and sensing lead configurations are bipolar.
Defender II has three antibradycardia pacing **modes**: DDD, DDI and VVI.

In DDD mode, atrial sensing outside atrial refractory periods starts an atrial escape interval corresponding to the basic rate. If no atrial sensing occurs during that interval, Defender II paces the atrium at the basic rate. Atrial sensing or pacing outside the refractory periods starts the **AV delay**. If no ventricular sensing occurs during the AV delay, Defender II paces the ventricle at the end of the AV delay. Defender II adds an **AV extension** to the AV delay following atrial pacing. If ventricular sensing occurs outside the AV delay, Defender II starts an atrial escape interval VA equivalent to the basic rate minus the AV delay.

In DDI mode, Defender II paces the atrium and ventricle at the basic rate in the absence of any spontaneous activity. Defender II adds an AV extension to the AV delay following atrial pacing. Ventricular sensing outside the AV delay triggers an atrial escape interval VA equal to the basic rate minus the AV delay. A sensed beat in either chamber inhibits pacing in that chamber. Unlike DDD mode, a sensed beat in the atrium does not start an AV delay, but simply inhibits atrial pacing in that cycle.

In VVI mode, ventricular sensing outside ventricular refractory periods starts an escape interval corresponding to the **basic rate**. If no ventricular sensing occurs during that interval, Defender II paces the ventricle at the basic rate. In this mode, atrial sensing has no effect and the atrium is not paced.

After sensing a heartbeat in any pacing mode, Defender II lengthens the escape interval corresponding to the programmed basic rate by the programmed **rate hysteresis**. The purpose of hysteresis is to allow the patient's sinus rhythm to fall below the programmed basic rate.

SENSITIVITY

The P-wave sensing threshold is determined by the **atrial sensitivity**.
In the ventricle, Defender II provides an automatic sensitivity control. When sensing a spontaneous ventricular event, the amplitude is measured and the ventricular sensitivity is automatically set according to this measurement until next ventricular event. The sensing threshold is set as follows:
- If it measures a signal of 1.6 mV or less, it sets sensitivity to 0.4 mV,
- If it measures a signal of 6 mV or more, it sets sensitivity to 3 mV,
- between these two values it sets sensitivity to increase linearly from 1/4 to 1/2 over the measured range of amplitudes,
- 156 ms after ventricular detection, it sets sensitivity to 1/4 of the measured amplitude,
- 500 ms after ventricular detection, it sets sensitivity to the programmed value (minimum 0.4 mV).

Whatever the calculated value, the sensitivity can never fall below the programmed **ventricular sensitivity** since this determines the minimum R-wave sensing threshold.
Following ventricular pacing, ventricular sensitivity is set for the first 500 milliseconds to the programmed value increased by a **post-pacing margin** before returning to the programmed value.

44

Response to noise

If Defender II senses continuous ventricular noise with a period shorter than 63 ms (i.e., a frequency above 16 Hz) the ventricular sensitivity is decreased until noise is no longer detected. It becomes less sensitive until it stops detecting the noise. During the presence of noise, ventricular pacing is inhibited if the **Inhibit ventricular pacing** parameter is programmed to Yes, otherwise Defender II continues pacing according to the programmed mode as long as the noise persists.

Refractory periods

PVARP, the post-ventricular atrial refractory period, is a relative refractory period. Any P-waves detected during PVARP are considered for the arrhythmia detection, but they do not trigger an AV delay. In DDD mode, the maximum ventricular pacing rate is determined by PVARP + AV delay (2:1 point).

In DDD mode, to prevent pacemaker-mediated tachycardias (PMT), Defender II automatically sets the PVARP to 500 ms in all cases of potential atrioventricular dissociation, i.e., where the previous cycle presents atrial or ventricular noise or is a non-conducted ventricular beat (asynchronous ventricle or PVC).

Defender II does not sense in the atrium during the AV delay following atrial pacing, or during the following programmable atrial absolute refractory periods:
- Atrial absolute refractory period **post ventricular sensing**
- Atrial absolute refractory period **post ventricular pacing**
- Atrial absolute refractory period **post atrial sensing**

Defender II does not sense in the ventricle during the following ventricular absolute refractory periods:
- Ventricular absolute refractory period **post ventricular sensing**, not programmable (94 ms)
- Ventricular absolute refractory period **post ventricular pacing**
- Ventricular absolute refractory period post atrial pacing (blanking period). This period is not programmable (= 47 ms) and is terminated at the end of the AV delay if the latter is below 47 ms.

The safety window is a ventricular relative refractory period post atrial pacing. Ventricular sensing after the blanking period but within the safety window will cause Defender II to pace the ventricle at the end of the safety window, to avoid inhibiting ventricular pacing by late sensing of atrial pacing artefacts in the ventricle. This period is not programmable (= 94 ms) and is terminated at the end of the AV delay if the latter is below 94 ms.

Conducted ventricular beat

Any R-wave preceded by a sensed or paced atrial event within the range from programmed **Min PR** to **Max PR** is considered conducted.

NOTE : The antibradycardia pacing mode is independent of the selected tachyarrhythmia detection mode. It is possible to program VVI mode simultaneously with an algorithm for tachyarrhythmia detection using atrial and ventricular signals. In this case, the parameters for atrial detection are used (sensitivity and refractory periods) but the atrium is not paced. The PVARP lasts throughout the cycle and the sensed P-waves are therefore taken into account only for arrhythmia detection, but never for recycling pacing intervals.

PACEMAKER FUNCTION PARAMETERS	PROGRAMMABLE VALUES	TOLERANCES
(Underlined values are nominal values)		
BASIC		
Atrial sensitivity (mV)	From 0.4 to 4 by steps of 0.2, nominal 0.4	50% max
Ventricular sensitivity (mV)	From 0.4 to 4 by steps of 0.2, nominal 0.4	50% max
Atrial pulse width (ms)	0.12, 0.24, 0.37, 0.49, 0.61, 0.73, 0.85, 0.98	0.02 ms
Ventricular pulse width (ms)	0.12, 0.24, 0.37, 0.49, 0.61, 0.73, 0.85, 0.98	0.02 ms
Ventricular amplitude (V)	2.4, 4.8, 7.2	10%
Atrial amplitude (V)	2.4, 4.8, 7.2	10%
INTERVALS		
Mode	DDD, DDI, VVI	
Basic rate (min^{-1}) [1]	From 30 to 90 by steps of 5, nominal 60	4%
Rate hysteresis (%)	0, 6, 13, 19, 25, 31	18 ms
AV delay (ms)	31, 47, 62, 78, 94, 109, 125, 141, 156, 172, 188, 203, 219, 234, 250	19 ms
AV extension (ms)	0, 16, 31, 47, 63, 78, 94, 109, 125	1 ms
PVARP (ms)	281, 297, 313, 328, 344, 359, 375, 391, 406, 422, 438, 453, 469, 484, 500, 516, 531, 547, 563	16 ms
Committed period: 94 ms	Not programmable	
ABSOLUTE ATRIAL REFRACTORY PERIODS		
Post ventricular sensing (ms)	47, 63, 78, 94, 109, 125, 141, 156	16 ms
Post ventricular pacing (ms)	78, 94, 109, 125, 141, 156	4 ms
Post atrial sensing (ms)	47, 63, 78, 94	16 ms
ABSOLUTE VENTRICULAR REFRACTORY PERIODS		
Post ventricular sensing: 94 ms	Not programmable	16 ms
Post ventricular pacing (ms)	172, 188, 203, 219	4 ms
Post atrial pacing (blanking): 47 ms	Not programmable	3 ms
CONDUCTED BEAT		
Max PR (ms)	250, 266, 281, 297, 313, 328, 344, 359, 375, 391, 406	16 ms
Min PR (ms)	31, 47, 63, 78, 94	16 ms
VENTRICULAR SENSITIVITY		
Post-pacing margin (mV)	from 0 to 2 by steps of 0.2, nominal 0	
RESPONSE TO VENTRICULAR NOISE		
Inhibit ventricular pacing	Yes, no	

NOTE: Ventricular sensitivity is measured using a triangular symmetrical positive and negative signal with a width of 10 ms. Atrial sensitivity is measured using a triangular symmetrical negative signal with a width of 10 ms.

The corresponding sensitivity for a triangle of 2/13 ms is obtained by dividing the programmed sensitivity by the appropriate conversion constant:
V+ = 0.93, respectively V- = 0.93, for a positive triangle, respectively negative, for the ventricle,
A+ = 0.54, respectively A- = 1.09, for a positive triangle, respectively negative, for the atrium.

[1] The corresponding intervals are 2000, 1714, 1500, 1333, 1200, 1091, 1000, 923, 857, 800, 750, 706, 667.

14.2. TACHYARRHYTHMIA DETECTION

Defender II senses and analyses atrial and ventricular signals in order to classify tachyarrhythmias. Defender II first classifies each ventricular cycle by cycle length, and then determines the majority rhythm as either VF (ventricular fibrillation), VT (ventricular tachycardia), SR (slow rhythm) or No majority. If the rhythm is a tachycardia, three further criteria (RR stability, PR association and acceleration at onset) are used to determine the origin: VT or SVT/ST (supraventricular tachycardia / sinus tachycardia). In case of VT or VF, and if the rhythm persists, Defender II delivers the programmed therapy.

14.2.1. VF/TACHYCARDIA DETECTION

CLASSIFICATION OF VENTRICULAR CYCLES

Defender II first classifies each ventricular cycle according to programmable **Tachy** and **VF cycle length** criteria.
- If the cycle length is shorter than the programmed VF cycle length, it is classified as a VF cycle.
- If it is between the programmed VF cycle length and the programmed Tachy cycle length, it is classified as a Tachy cycle.
- If it is longer than the programmed Tachy cycle length, or if it is a paced cycle, it is classified as a SR cycle.

MAJORITY RHYTHM

Defender II applies the **majority (X% of Y cycles)** to determine the predominant rhythm:

X% of the Y last RR are classified as VF cycles	VF majority
X% of the Y last RR are classified as Tachy or VF cycles	Tachy majority
X% of the Y last RR are classified as SR cycles	SR majority
No RR majority	No majority

Defender II uses the Tachycardia sorting template to reclassify rhythms with Tachy majority. This sorting depends on RR stability (stable or unstable), PR association (N:1, 1:1, or none), and acceleration at the tachycardia onset (atrial origin, ventricular origin or none). Tachycardia sorting template and Tachycardia criteria are discussed in sections 14.2.2. and 14.2.3. of this chapter.

PERSISTENCE OF MAJORITY RHYTHM AND THERAPIES

The **Tachy** and **VF persistence** criteria requires the same arrhythmia to remain in the majority for a programmed number of cycles. Defender II then applies the programmed therapy:

VF	Defender II provides medium energy shocks, then high energy shocks (Shock 2 and Shock 3 programs).
VT	Defender II provides ATP programs 1 and 2, followed by low energy shocks (Shock 1 cardioversion program), then medium and high energy shocks.
SVT/ST	Defender II provides no therapy.
Unsure	Once Tachy persistence is reached, Defender II initiates a new **deferment** cycle count, after which it provides VT therapy if the arrhythmia still persists. This delayed therapy allows treatment of sustained tachycardia.

An episode of tachyarrhythmia is terminated when SR majority is detected. The sequential therapies are then reinitialised. Defender II only resets the persistence cycle counter when it finds some other majority rhythm, not when applying therapy. Defender II only applies therapy for a given category (VF, VT, or Unsure) when it finds the latest ventricular cycle in that category. This avoids applying inappropriate therapy for a rhythm that just changed. Defender II does not apply therapy for VT when it finds VF majority, in case VT degenerated to VF instead it waits for VF persistence, then applies VF therapy.

14- DEFRIBRILLATOR FUNCTIONS

Defender II provides reversion cycles after applying therapy, but before beginning redetection of tachycardias, in order to allow time for transient post-therapy rhythm to revert. It provides one cycle (not programmable) for reversion after antitachycardia pacing, or a programmable number of cycles after a shock (**post-shock reversion**). During reversion Defender II still continues analyzing VF and SR cycles.

14.2.2. TACHYCARDIA SORTING

Defender II uses the combinations of three criteria to analyze arrhythmias: RR stability, PR association and acceleration.

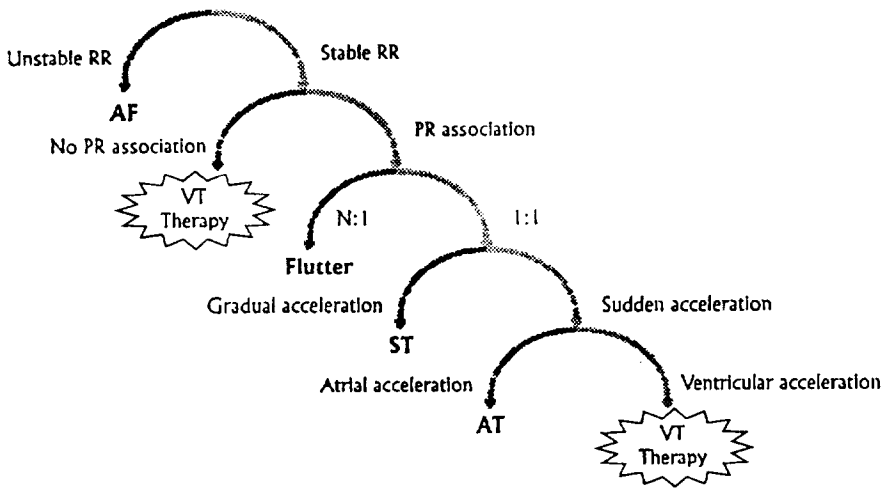
Depending on the diagnosis, therapy is applied or not:

VT	VT therapy
SVT/ST	No treatment
Unsure	Deferred treatment

Defender II provides three predefined tachycardia sorting **templates:**

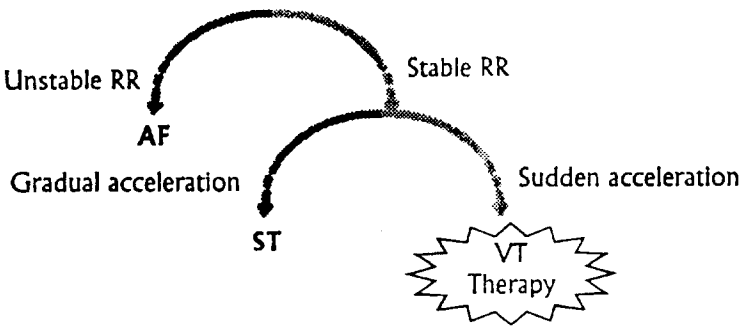
Std AV	uses atrial and ventricular sensing together (takes into account all three criteria)
Std V	uses ventricular sensing alone (does not take into account PR association nor the chamber in which acceleration occurs). This sorting template has been designed for patients with permanent AF or lead dislodgment.
Rate only	uses ventricular rate only

STD AV:



48

STD V:



Programs other than the standard templates may be used; for example, **Unsure** rhythm can be used for one or more combinations. In this case, the tachycardia sorting is said to be "custom".

When neither the antibradycardia function nor the arrhythmia detection uses the atrial sensing information (when programmed to VVI and the tachycardia sorting template does not use atrial sensing) **atrial monitoring always on** must be programmed to Yes in order to see and record atrial markers.

14.2.3. TACHYCARDIA CRITERIA

Defender II keeps a continuous histogram of the RR intervals in the last Y ventricular cycles shorter than the programmed Tachy or VF cycle lengths. It also makes a histogram of all the PR intervals in the corresponding cycles.

Defender II excludes the post-ATP cycle or post-shock reversion cycles in the histograms. Defender II can also exclude a few **unretained initial fast cycles** from the histograms to avoid including in stability calculations the first few cycles before an arrhythmia stabilizes.

RR Stability

Defender II scans its RR interval histogram with a window set to the programmed **RR stability window width**, looking for the window position which contains the maximum number of RR intervals stored in the histogram. The stability criterion is fulfilled when the number of RR intervals contained in the window is equivalent to at least X% of the cycles stored in the histogram.

PR Association

If the RR stability criterion is met, Defender II scans its PR interval histogram with a window set to the programmed **PR association, window width**, looking for the window position which contains the maximum number of PR intervals. It finds PR association when this number is at least X% of the number of stable RR intervals. In addition, if the number of PR intervals within this window represents at least X% of the cycles stored in the histogram, Defender II considers this as 1:1 PR association. Otherwise, if X% of the number of stored PR intervals is not within the window, it considers this as N:1 association.

ACCELERATION

This criterion attempts to distinguish pathological tachycardias from physiological ones by examining the onset of acceleration. Defender II defines an accelerated cycle when its cycle length is shorter than the reference cycle decreased by the programmed **acceleration prematurity** percentage, and when its cycle length is shorter than the programmed Tachy cycle length.
The reference cycle is the preceding ventricular interval except in some cases: asynchronous beats and pause. In these cases the reference cycle is the mean of the last four non-accelerated cycles.

There is atrial acceleration when the first accelerated cycle and the preceding one are conducted; that is preceded by an atrial event within the range from programmed Min PR to Max PR. If one or two of these two beats is not conducted, the acceleration is defined as ventricular.
Defender II defines acceleration as ended as soon as it detects two consecutive cycles which fail to meet either the acceleration or cycle length criteria.
After therapy, Defender II always considers acceleration as ventricular (since sensing is suspended during therapy application).

TACHYCARDIA/VF DETECTION PARAMETERS **(Underlined values are nominal values)**	PROGRAMMABLE VALUES	TOLERANCES
TACHYCARDIA/VF DETECTION		
VF cycle length (ms)	250, 266, 281, 297, 313, 328, 344, 391, 406, 422, 438, 453, 469, 484, 500, 516, 531, 547, 563, 578, 594	16 ms
Tachy cycle length (ms)	250, 266, 281, 297, 313, 328, 344, 359, 375, 391, 406, 422, 438, 453, 469, 484, 500, 516, 531, 547, 563, 578, 594	16 ms
VF persistence (cycles)	from 4 to 20 by steps of 1, nominal 6	
Tachy persistence (cycles)	4, 6, 8, 12, 16, 20, 30, 50, 100, 200 [12 at delivery]	
Majority (X,Y): X%	63, 69, 75, 81, 88, 94, 100	
Majority (X,Y): Y (cycles)	from 8 to 16 by steps of 1, nominal 8	
TACHYCARDIA SORTING		
Template	Std AV, Std V, Rate Only, Custom	
Deferment (cycles, 1K = 1024)	16, 32, 128, 256, 512, 1K, 2K, 3K, 5K, 10K, 20K, 30K, 50K	
Atrial monitoring always on	Yes, No	
TACHYCARDIA CRITERIA		
RR stability, window width (ms)	16, 31, 47, 63, 78, 94, 109, 125	1 ms
PR association, window width (ms)	16, 31, 47, 63, 78, 94, 109, 125	1 ms
Unretained initial fast cycles (cycles)	from 0 to 8 by steps of 1, nominal 0	
Post-shock reversion (cycles)	from 0 to 30 by steps of 1, nominal 2	
Acceleration prematurity (%)	6, 13, 19, 25, 31, 38, 44, 50	8 ms

14.3. ANTITACHYCARDIA PACING (ATP)

Defender II provides two antitachycardia pacing programs, called ATP 1 and ATP 2, if **Enable ATP therapy** is programmed to Yes. Each of these two programs contains a programmable **number of sequences**. A sequence is a series of rapid pacing cycles with a **first cycle prematurity** which is a percentage of the average length of the last four VT cycles. The number of cycles in each sequence depends on the number of **cycles in the first sequence** and the number of **cycles added per sequence**.

Each program can contain a number of bursts, ramps, scanned bursts, or scanned ramps. A burst is a sequence of fixed-length cycles. A ramp is a sequence with cycles of decreasing length (**decrement cycle by cycle**). Scanned bursts or scanned ramps are simply bursts or ramps in which the first cycle of each sequence is shorter than the previous one (**decrement sequence by sequence**).

If the calculated pacing cycle length is shorter than the **minimum cycle length** during an ATP sequence, Defender II paces until the end of the sequence at the programmed minimum cycle length. When all cycles in a sequence are delivered at the programmed minimum cycle length, the current program is terminated at the end of the sequence.

The current program terminates if the programmed **time limit** is reached at the end of the sequence.

The device resumes tachycardia detection after each sequence in order to determine its efficacy. If the tachycardia persists, the next programmed sequence is applied. If the first ATP program applied fails to stop the tachycardia, the second program is delivered. Defender II can be programmed to deliver the last successful ATP program. (**Do program first if successful.**)

If these two programs fail, shock therapy is delivered.

During ATP, the device functions in VOO mode. Pacing is delivered at the maximum pulse width and amplitude (7.2 V and 0.98 ms).

ANTITACHYCARDIA PACING PARAMETERS (ATP) (2 independent programs) **(Underlined values are nominal)**	PROGRAMMABLE VALUES	TOLERANCES
Enable ATP therapy	Yes, <u>No</u>	
Number of sequences	from 0 to 15 by steps of 1, nominal <u>0</u>	
Time limit (minutes)	from 0.5 to 4 by steps of 0.5, nominal <u>0.5</u>	1 cycle
Minimum cycle length (ms)	94, 109, 125, 141, 156, 172, 188, 203, 219, 234, 250, 266, 281, 297, <u>313</u>	3 ms
Do program first if successful	Yes, <u>No</u>	
Cycles in first sequence	from 1 to 15 by steps of 1, nominal <u>1</u>	
Cycles added per sequence	from 0 to 15 by steps of 1, nominal <u>0</u>	
First cycle prematurity (%)	<u>13</u>, 19, 25, 31, 38, 44, 50	8 ms
Decrement cycle by cycle (ms)	<u>0</u>, 4, 8, 12, 16, 20, 23, 27, 31, 35, 39, 43, 47, 51, 55, 59, 63	
Decrement seq by seq (ms)	<u>0</u>, 4, 8, 12, 16, 20, 23, 27, 31, 35, 39, 43, 47, 51, 55, 59, 63	

14.4. SHOCKS

When **enable shock therapy** is programmed to Yes, Defender II provides three biphasic shock programs:

Shock 1 Low energy shocks (cardioversion) for VT therapy only.

Shock 2 and Shock 3 Medium and high energy shocks for VT or VF therapy.

The **number of shocks** and the **stored energy** can be individually programmed for each shock program.

The **waveform** of the biphasic shock can be programmed as either constant tilt or constant width.

Tilt means the fraction the shock pulse amplitude decays. Constant tilt means that Defender II adjusts the pulse width to maintain the same tilt and thus deliver a constant energy for all load resistances. Defender II's constant tilt shocks have 50% tilt in each phase thus delivering 94% of stored energy. Each phase is limited to 15 ms duration.

Constant width shocks have 5 ms width in each phase. Tilt decreases with increasing load resistance, as does the fraction of delivered energy.

Normal **polarity** makes Defender II's ⊕ shock terminal and active case positive for the first phase of the shock. Inverted polarity changes this to negative.

When the programmer selects **committed shocks**, Defender II no longer operates arrhythmia detection while charging; when charged, it shocks. When the committed shock option is disabled, Defender II continues to detect cardiac activity during capacitor charging; the shock is only delivered if the arrhythmia persists when the programmed energy has been attained.

After shock delivery, Defender II provides no pacing, arrhythmia detection, nor therapy during the **post-shock recovery** period. This period is followed by a post-shock reversion period (temporary Tachycardia detection pause).

NOTE : The capacitor charging time cannot be longer than 40 seconds. After this period, Defender II stops charging whatever the energy stored. However, its functioning remains the same: if applicable, it delivers the shock with the energy stored. In such a case, the device should be checked by your ELA Representative.

SHOCK PARAMETERS **(Underlined values are nominal)**	PROGRAMMABLE VALUES	TOLERANCES
ALL SHOCKS		
Enable shock therapy	Yes, No (No at delivery)	
Waveform	Width, tilt	
Polarity	Normal, inverted	
Committed shock	Yes, No	
Post-shock recovery (seconds)	from 1 to 10 by steps of 1, nominal 1	16 ms
SHOCK 1 PROGRAM [VT]		
Number of shocks	0, 1, 2, 3, 4	
Stored energy (J)	0.8, 1.2, 1.6, 2.1, 2.8, 3.4, 4.2, 5, 5.9, 6.9, 8, 9.1, 10, 12, 13, 14, 16, 17, 19, 21, 23, 25, 26, 28, 31, 33	30% max
SHOCK 2 PROGRAM [VT/VF]		
Number of shocks	0, 1, 2, 3, 4	
Stored energy (J)	0.8, 1.2, 1.6, 2.1, 2.8, 3.4, 4.2, 5, 5.9, 6.9, 8, 9.1, 10, 12, 13, 14, 16, 17, 19, 21, 23, 25, 26, 28, 31, 33	30% max
SHOCK 3 PROGRAM [VT/VF]		
Number of shocks	1, 2, 3, 4	
Stored energy (J)	0.8, 1.2, 1.6, 2.1, 2.8, 3.4, 4.2, 5, 5.9, 6.9, 8, 9.1, 10, 12, 13, 14, 16, 17, 19, 21, 23, 25, 26, 28, 31, 33	30% max

14.5. STUDIES, TEST AND STORED INFORMATION

14.5.1. ELECTROPHYSIOLOGICAL STUDIES

With the programmer, Defender II can perform non-invasive electrophysiological studies to check inducibility of arrhythmias and efficacy of programmed therapies.

VT INDUCTION

Defender II delivers a sequence of N pulses of coupling interval s1 followed by a sequence of extra-stimuli (s2, s3, s4) of adjustable cycle length. All pulses occur at maximum amplitude and pulse width (7.2 V and 0.98 ms).

ANTITACHYCARDIA PACING (ATP)

Defender II delivers an ATP sequence with adjustable parameters that do not affect the automatic ATP program.

VF INDUCTION

Defender II can induce VF either by providing burst pacing or by delivering a T-wave shock.
The pacing burst is delivered in VOO mode at a frequency of 30 Hz at the maximum amplitude and pulse width for an adjustable period of 1 to 30 seconds.
T wave shocks are delivered following a programmable pacing sequence in VVI mode.

SHOCK

Defender II delivers a single shock, the adjustable parameters of which do not affect permanent programming.

NOTE : Defender II's automatic Tachycardia/VF detection is disabled during the induction of tachyarrhythmias. This detection is restored if the action is cancelled, on completion of the induction or on interruption of telemetry.

14.5.2. TESTS

Using the programmer, Defender II can perform an atrial or ventricular pacing threshold, lead impedance tests, defibrillation electrode continuity tests, or a capacitor charge-time test.

14.5.3. STATISTICS

Defender II stores statistical information concerning bradycardia and tachycardia therapies.
These statistics are established by incrementing various counters and help confirm that the pacing and detection functions as well as the efficacy of therapies delivered by the device are functioning optimally. These counters can be reset by the programmer.

In addition, Defender II stores the characteristics of the last shock delivered and last capacitor charging.

BATTERY STATUS

Defender II maintains a graph of battery voltage as a function of time (in months) since manufacture and displays the elective replacement indicator (ERI) and the end of life indicator (EOL) voltages.

14.5.4. HOLTER FUNCTION

The Holter records four tachyarrhythmias episodes as well as the therapy history.

HOLTER EPISODES

Defender II stores the most recent episodes, and retains at least four episodes of each of three types (VF, VT and SVT/ST/Unsure) while giving priority to episodes of VF and VT. For each type, Defender II always retains the oldest treated episode.

Defender II records endocardial EGM over several cycles as well as a marker chain for the start and end of each recorded episode and a list of events (up to 31) characterizing the episode.

THERAPY HISTORY

At the start of each arrhythmia, for every therapy delivered (either automatically or during an electrophysiological study) and at the end of an arrhythmia, Defender II records the type of majority rhythm, the number of sequences delivered in the event of ATP, the energy of the shock and the number of shocks delivered in the case of a shock therapy.

15 - INSTRUCTIONS FOR USE OF THE DEFIBRILLATOR

15.1. FOREWORD

15.1.1. PACKAGING

CONTENTS

The Defender II and its accessories are sterilized and hermetically sealed in two-ply clear packaging meeting international requirements.

The sterile packaging contains a defibrillator, two set screw wrenches, an insulating plug for the IS-1 pacing/sensing connector and an insulating plug for the DF-1 defibrillation connector.

The non-sterile items contained in the outer storage package are the user's manual, the warranty card and 12 identification labels.

NOTE : Defender II is shipped programmed to nominal values, except shock therapies which are disabled.

15.2. IMPLANTATION

15.2.1. NECESSARY EQUIPMENT

Implantation of Defender II requires the following equipment:

- ELA Medical's 9201 programmer,
- A pacing system analyzer, as well as its sterile connecting cables, to perform pacing/sensing and defibrillation testing,
- One set of leads with adequate introducers,
- A physiological signal monitor capable of displaying simultaneously the surface ECG and arterial pressure,
- An external defibrillator with external paddles.

15.2.2. COMPATIBLE LEADS AND CONFIGURATIONS

To function properly, Defender II must be connected to:

- one bipolar atrial sensing/pacing lead,
- one ventricular lead with sensing/pacing bipolar electrodes, and:
  . 1 defibrillation electrode
  . or 2 defibrillation electrodes, optional

The defibrillator case serves as an electrode. Its area is 52 cm^2 each side.

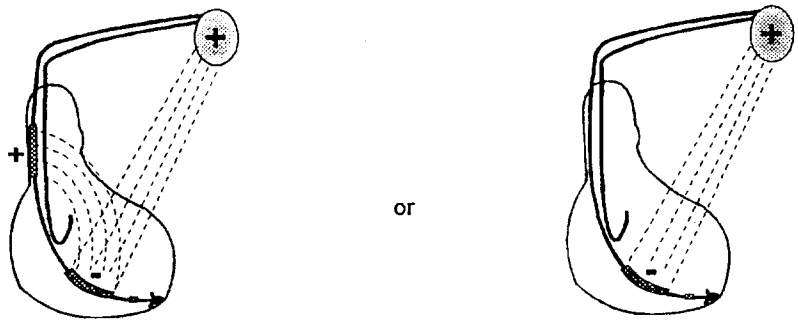
The choice of the leads and their configuration is left to the implanting physician's judgement. The physician must refer to the Leads' technical manuals to learn about their use.

15 - INSTRUCTIONS FOR USE OF THE DEFIBRILLATOR

The two bipolar pacing/sensing connectors are compatible with the IS-1 standard: seal diameter of 3.2 mm, terminal pin of 5 mm in length and of 1.6 mm in diameter.
The two defibrillation connectors are compatible with the DF-1 standard: seal diameter of 3.2 mm, terminal pin of 5 mm in length and of 1.25 mm in diameter.

NOTE : With respect to IS-1 and DF-1 standards, Defender II is equipped with an additional sealing ring.

LEAD CONFIGURATION:



15.2.3. IMPLANT PROCEDURE

CHECKING THE EQUIPMENT

Check that the "use before" dates of the device and accessories are not exceeded. Use the programmer to verify all shock therapies are disabled in order to avoid accidental discharge during implantation.

IMPLANTATION OF LEADS AND PACING/SENSING TESTS

Implant the ventricular lead, then the atrial lead. Use the pacing system analyzer to carry out the following tests:

Pacing threshold
The pacing threshold is the lowest amplitude capable of capturing the heart. Acute thresholds should be lower than 1 V (or 2 mA) for a 0.37 ms pulse width, both in the ventricle and in the atrium.

Measurement of R and P-wave amplitudes
For proper ventricular sensitivity, the amplitude of the R-wave should be greater than 5 mV. For proper atrial sensitivity, the amplitude of the P-wave should be greater than 2 mV.

Impedance measurements
Ventricular and atrial pacing impedances should range from 300 to 1500 ohms (refer to the lead characteristics, especially if a high impedance lead is used). If not, check lead connections and electrode position.

PREPARING THE POCKET

The pocket should preferably be prepared in the left pectoral position, either subcutaneously or submuscularly.

OPENING THE DEFIBRILLATOR PACKAGE

Remove the defibrillator from the package by peeling back the outer tray cover using the thread provided for that purpose, and slide the inner tray to reach the sterile package.

15- INSTRUCTIONS FOR USE OF THE DEFIBRILLATOR

CONNECTING LEADS TO THE DEFIBRILLATOR

Defender II should be implanted with the engraved side facing outwards for optimal communication with the programming head and radiographic identification.
The IS-1 insulating plug seals the atrial pacing/sensing connector if no atrial lead is implanted. When connecting two defibrillation electrodes, remove the DF-1 insulating plug from the ⊕ terminal, by loosening the set screw.

The lead terminal pins should be thoroughly cleaned before leads are connected to the defibrillator. (See paragraph 15.2.2. for the connection configuration.) The set screws and plugs for affixing the leads are located on top of the connection header. Two set screws serve for each pacing/sensing lead and a single set screw for each defibrillation electrodes. To avoid errors, particular attention should be paid to the connection of the two pacing/sensing leads: before tightening the set screws, check that all leads are fully inserted into the distal header, then screw down the proximal lead first and test the connection before screwing down the distal lead. The wrench should be dipped in the lubricant to allow easier access in the silicone connection header. To avoid over tightening the set screws, the wrenches delivered with the device stop screwing as soon as excessive torque is applied and an audible click is heard.

Place the device in the pocket. In its final position, the defibrillator should be no more than 4 cm below the skin surface.

NOTE: To optimize cardioversion/defibrillation shocks, electrodes must be positioned so that the electric field between anode (s) and cathode covers the largest myocardial mass. In normal conditions, the anode and cathode are adequately separated. In case of a short-circuit, the shock may be aborted to prevent damaging the defibrillator. In addition, if the leads are to be replaced, it is strongly advisable to remove unused leads.

NOTE: In the case of an external defibrillation shock delivered to the patient, verify that the device functions correctly

DEFIBRILLATION EFFICACY

It is recommended to obtain a defibrillation threshold at least 10 J lower than the maximum programmable energy. ELA Medical recommends obtaining two successful consecutive defibrillation shocks at 23 J or less. It is advisable to wait 4 to 5 minutes between each shock.

FINAL CHECK AND PROGRAMMING

Check the pacing threshold, impedance and defibrillation lead continuity with the programmer. Verify the efficacy of a defibrillation shock and test the defibrillation lead impedance.
The defibrillator can be sutured to tissues using the hole at the rear of the header, and the pocket may then be closed.
Enable shock therapies, then program the device to the desired values. Save the patient's file on the programmer's hard disk and a diskette.

FILLING IN THE IMPLANT FORM

Once the procedure has been completed, do not forget to complete the registration form EURID/IAPM. One copy must be handed over to the patient before he/she is discharged from hospital and will serve as a follow-up and identification card. Another copy must be sent to ELA Medical within the 30 days following implant for warranty conditions to apply. The two other copies are for the hospital and for the national registration center.

15 - INSTRUCTIONS FOR USE OF THE DEFIBRILLATOR

15.3. PATIENT FOLLOW-UP

NOTE : Before any surgical operation, it is essential to disable shock therapies to avoid accidental discharges.

15.3.1. RECOMMENDATIONS

Before the patient's discharge, and at each follow-up visit, it is recommended to:
- Read the statistics and the Holter episodes and history,
- Perform tests to assess the battery status and the integrity of the pacing and defibrillating leads,
- Check for proper sensing (sensitivity, crosstalk) and pacing. Set the pacing amplitude to twice the pacing threshold to increase device longevity,
- Assess the efficacy of the programmed therapies before the patient's discharge and during subsequent routine follow-up if parameters have been reprogrammed or the patient's drug regimen has been changed (that can lead to changes in the electric characteristics of cardiac cells),
- Print out programmed parameters, lead test results, statistics and Holter data,
- Save the patient's file onto the programmer's hard disk and a diskette after completion of interrogation,
- Reset the Holter episodes and statistics data after saving the patient's file.

Any procedure to check the efficacy of therapies should be performed by the medical staff with resuscitation equipment at hand. It is recommended to conduct a routine examination one month after the patient's discharge, then every three months until the device nears the elective replacement time, thereafter every two months.

Contact ELA Medical should any "reset" or "charging aborted" indication be identified in the statistics.

15.3.2. MAGNET TEST

Applying the magnet over the defibrillator case:
- Inhibits antiarrhythmic functions (therapies and arrhythmia detection),
- Causes no changes to the pacing mode or AV delay,
- Reprograms the device as follows:
  . Rate hysteresis and AV extension set to 0,
  . Pacing amplitude and pulse width set to their maximum values,
  . Pacing rate set to the magnet rate.

All programmed parameters are restored upon magnet withdrawal.

NOTE : The magnet mode is not active during telemetry.

Magnet rates

Magnet rate (min^{-1})	96	93.6	91.4	89.3	87.3	85.3	83.6	81.7	80	78.3	77
magnet period (ms)	625	641	656	672	687	703	718	734	750	766	780

Tolerance for magnet period is 8 ms.

15.3.3. BATTERY REPLACEMENT INDICATORS

Elective replacement indicator (ERI) corresponds to a battery voltage lower than or equal to 4.9 +/- 0.12 V and is identified by the programmer.

The magnet rate can be used to determine ERI. The magnet rate is 96 min^{-1} at beginning of life, 80 min^{-1} at ERI and 77 min^{-1} at end of service (EOL).

Defender II must thus be replaced as soon as:
- The magnet rate is ≤ 80 min^{-1},
- The programmer displays an ERI warning.

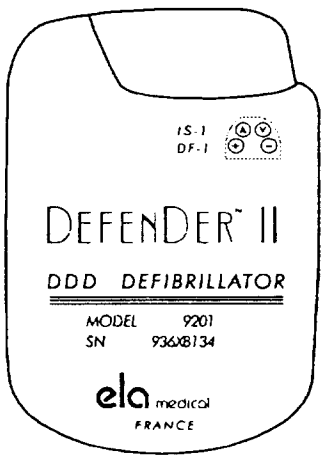
In the case of abnormal charging time, further investigations must be carried out to determine if an explantation is needed.

16 - DEFENDER II CHARACTERISTICS

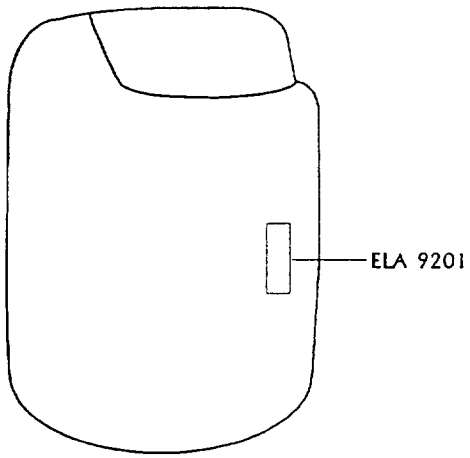
16.1. PHYSICAL CHARACTERISTICS

Interrogating Defender II through the programmer enables identification of the serial number: the first figure corresponds to the manufacturing year in the decade (e.g., 9 for 1999) and the two following figures correspond to the manufacturing week in the year.
The model and manufacturer's name appear inside the defibrillator case. They are radiopaque and can therefore be seen by X-ray.

Photographic identification



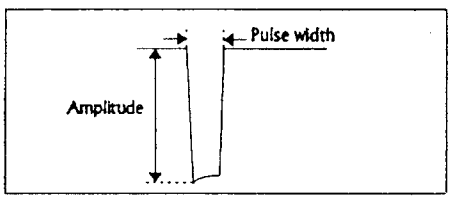
X-ray identification



16.2. ELECTRICAL CHARACTERISTICS

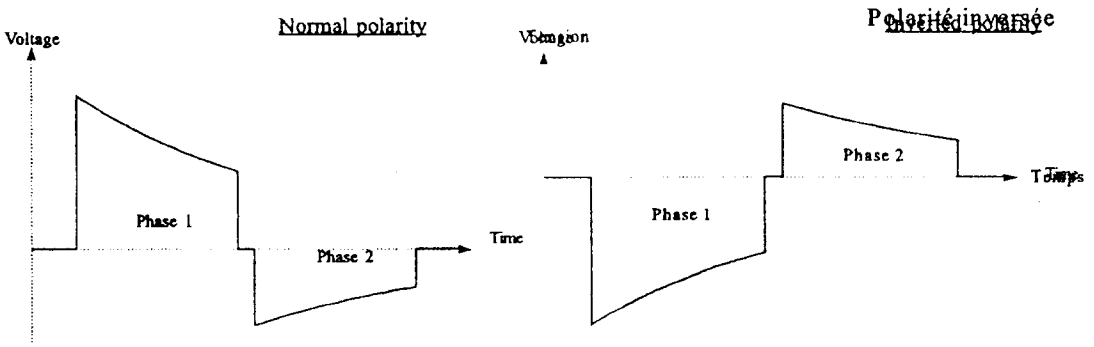
16.2.1. WAVEFORMS OF ELECTRICAL PULSES

Pacing waveform:



The pulse amplitude varies with lead impedance; the programmed values correspond to a 500 ohm lead impedance. There are no changes to pulse amplitude or width due to battery depletion during the life-span of the device.

Shock waveform: Defender II delivers a biphasic shock, the polarity of which (normal or inverted) depends on programming.



16.2.2. RELATIONSHIP: SHOCK ENERGY / VOLTAGE

The relationship between the shock voltages of the two phases (V1 and V2), total stored energy and total delivered energy (at 37 °C, 50 ohm load) for the minimum, mean and maximum programmed energy values:

	Constant tilt waveform			Constant duration waveform		
Stored energy (J)	0.8	17	33	0.8	17	33
V1 (Volts)	114	539	739	114	539	739
V2 (Volts)	64	264	364	50	234	321
E delivered : Phase 1 (J)	0.53	13.2	24.8	0.63	14.1	26.4
E delivered : Phase 2 (J)	0.15	3.0	5.8	0.12	2.7	5.1

Tolerances are 12% for voltage and 30% for energy.

16.2.3. CAPACITOR AND BATTERY REFORMATION

Capacitor maintenance: every 6 months, the device automatically reforms the shock capacitors by charging them to the maximum voltage and maintaining this voltage for 100 seconds. At the end of this period, the charge slowly dissipates into the device's internal load. If during reformation a shock therapy is initiated, the device charges to the programmed shock energy and delivers therapy.

Battery maintenance: if over the previous two months Defender II has not charged its capacitors to maximum energy, it immediately performs battery reformation by charging its capacitors to maximum energy.

16 - DEFENDER II CHARACTERISTICS

16.2.4. CAPACITOR CHARGE TIME

The battery status affects the charge time of the shock capacitors. This time increases when the battery becomes depleted. It is below 16 seconds at ERI for a maximum stored energy of 33 J (depending on the date of the last capacitor reforming).

The charge time cannot be longer than 40 seconds. If the device has not reached the energy level required after a 40 second charge time, the shock is delivered with the energy stored in the capacitors. The "charging aborted" statistics counter is then incremented.

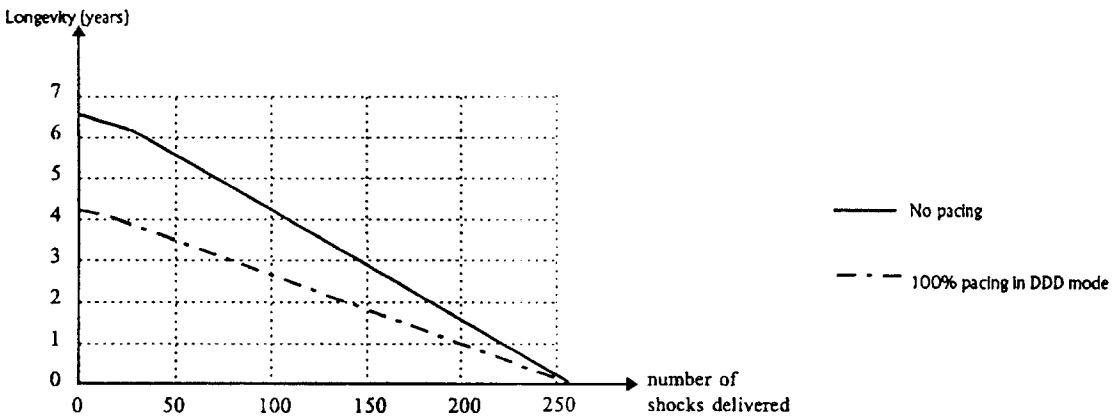
16.2.5. LONGEVITY

The longevity of the device, i.e. the duration of functioning between the beginning of life of the device and elective replacement indicator (ERI), depends mainly on the patient's requirements in terms of antibradycardia pacing and shocks delivered.

The longevity of DEFENDER III is:

- 5.7 years under the following conditions:
  15% of pacing in DDD* mode
  one shock at maximum energy (33 J) every three months

- 4.0 years under the following conditions:
  100% of pacing in DDD* mode
  one shock at maximum energy (33 J) every three months



Mean longevity as a function of shocks delivered at maximum energy, with and without pacing*

Between the ERI voltage and EOL voltage, Defender II can function for four months delivering one shock every two weeks (15% pacing in DDD mode with nominal settings), or deliver 18 shocks.

* nominal settings, with a load of 500 ohms at 37°C.

16.2.6. POWER SUPPLY

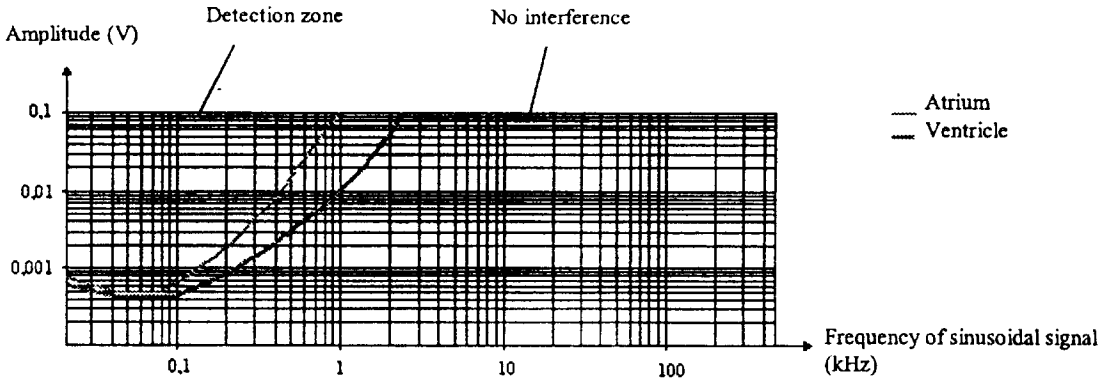
Type	Two WGL9531 batteries (silver vanadium oxide), 3.2 V
ERI voltage	4.90 +/- 0.12 V
ERI capacity	900 mAh
EOL voltage	4.47 +/- 0.16 V
EOL capacity	1.0 Ah

16.2.7 OTHER CHARACTERISTICS

Atrial input impedance: 18.5 kΩ
Ventricular input impedance: 17.5 kΩ
Shock capacitance: 120 µF

Rate limitation: 192 +/- 10 min^{-1}

Detection performance in the presence of electromagnetic interference in differential mode



16.3. TABLE OF NOMINAL SETTINGS

Caution : Defender II's nominal programming enables high energy shocks.

ANTI-BRADYCARDIA FUNCTION	
Ventricular pulse width	0.37 ms
Ventricular amplitude	4.8 V
Ventricular sensitivity	0.4 mV
Mode	VVI
Basic rate	60 min^{-1}
Rate hysteresis	0%
Absolute ventricular refractory period post ventricular sensing	94 ms
Absolute ventricular refractory period post ventricular pacing	219 ms
Ventricular sensitivity post pacing safety margin	0 mV
Inhibition of ventricular pacing by noise	Yes
Atrial sensitivity	0.4 mV
Absolute atrial refractory period post ventricular sensing	47 ms
Absolute atrial refractory period post ventricular pacing	78 ms
Absolute atrial refractory period post atrial sensing	47 ms
Max PR	313 ms
Min PR	31 ms
TACHYCARDIA/VF DETECTION	
Tachy cycle length	297 ms [202 min^{-1}]
VF cycle length	297 ms [202 min^{-1}]
Majority X% of Y	75% of 8 cycles
Tachy persistence	8 cycles
VF persistence	6 cycles
Tachycardia sorting	Standard AV
RR stability, window width	63 ms
PR association, window width	63 ms
Unretained initial fast cycles	0 cycle
Post-shock reversion	2 cycles
Acceleration, prematurity %	25%
THERAPIES	
Enable ATP therapy	No
Enable shock therapy	Yes
Cardioversion shocks [Shock1 program]	0
Medium-energy shocks [Shock2 program]	0
High-energy shocks [Shock3 program]	4 shocks of 33 J
Shock waveform	Constant tilt
Shock polarity	Normal
Committed shock	No
Post-shock recovery	1 second

Nominal programming

HIGH VOLTAGE

STERILISED WITH ETHYLENE OXIDE

DATE OF MANUFACTURE

USE BEFORE

SERIAL NUMBER

BATCH NUMBER

ela

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ela medical

User Assistance Information

(Ask your doctor or nurse to complete the information on this page before you leave the hospital.)

Emergency Medical Assistance: .....

Ela Medical Customer Assistance:

.....

Name/Address/Phone Number of your Cardiologist:

.....

.....

.....

ICD:

Type/Model Number .....

Date Implanted .....

Atrial Lead:

Type/Model Number .....

Date Implanted .....

Ventricular Lead:

Type/Model Number .....

Date Implanted .....

Name/Address/Phone Number of Hospital:

.....

.....

.....

Current Medications:

.....

.....

.....

.....

Name/Phone Number of Relatives:

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.....

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Table of contents

Warnings and Precautions

Tell your doctor immediately if there is redness, swelling, fever, or drainage from your incisions. This may indicate an infection. If untreated, you could become very ill. Contact your doctor if your arm becomes swollen.

If pain persists after the initial healing of your incision, check with your doctor. Pain can sometimes indicate the presence of an infection. If an infection is not treated, you could become very ill.

Your ICD functions like a pacemaker and you should follow the posted warning for pacemaker patients in airports, near high voltage sources, and near extremely strong magnets. Really strong interference can affect your ICD. The circuits of your ICD can be permanently damaged or the programmed setting changed.(see section 5)

Always walk briskly through security gates in stores, libraries, and airports. The gates contain magnets which may cause interference with your ICD.

Magnetic resonance imaging (MRI) is not recommended for any patient with an ICD. Because the equipment uses such powerful magnets, avoid entering any room with MRI equipment. The circuits of your ICD can be permanently damaged or the programmed setting changed.

Always tell all medical and dental personnel that you have an ICD. Some medical and dental equipment can interfere with your ICD. Also, you may need extra antibiotics before and after any dental work (even teeth cleaning) or surgery. This is an extra precaution against infection.

Make sure others know that they should :

* Dial the emergency number immediatly if you remain unconscious for more than one minute

*Call your doctor after a shock treatment, or if you don't feel well If you do not receive this care, further damage to your health may occur.

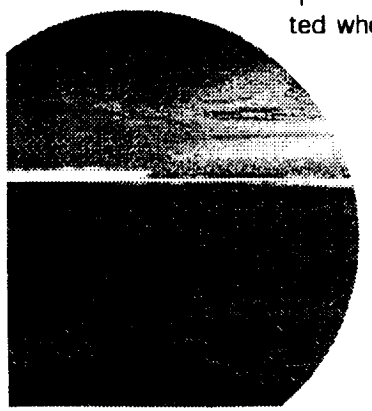
1 Introduction

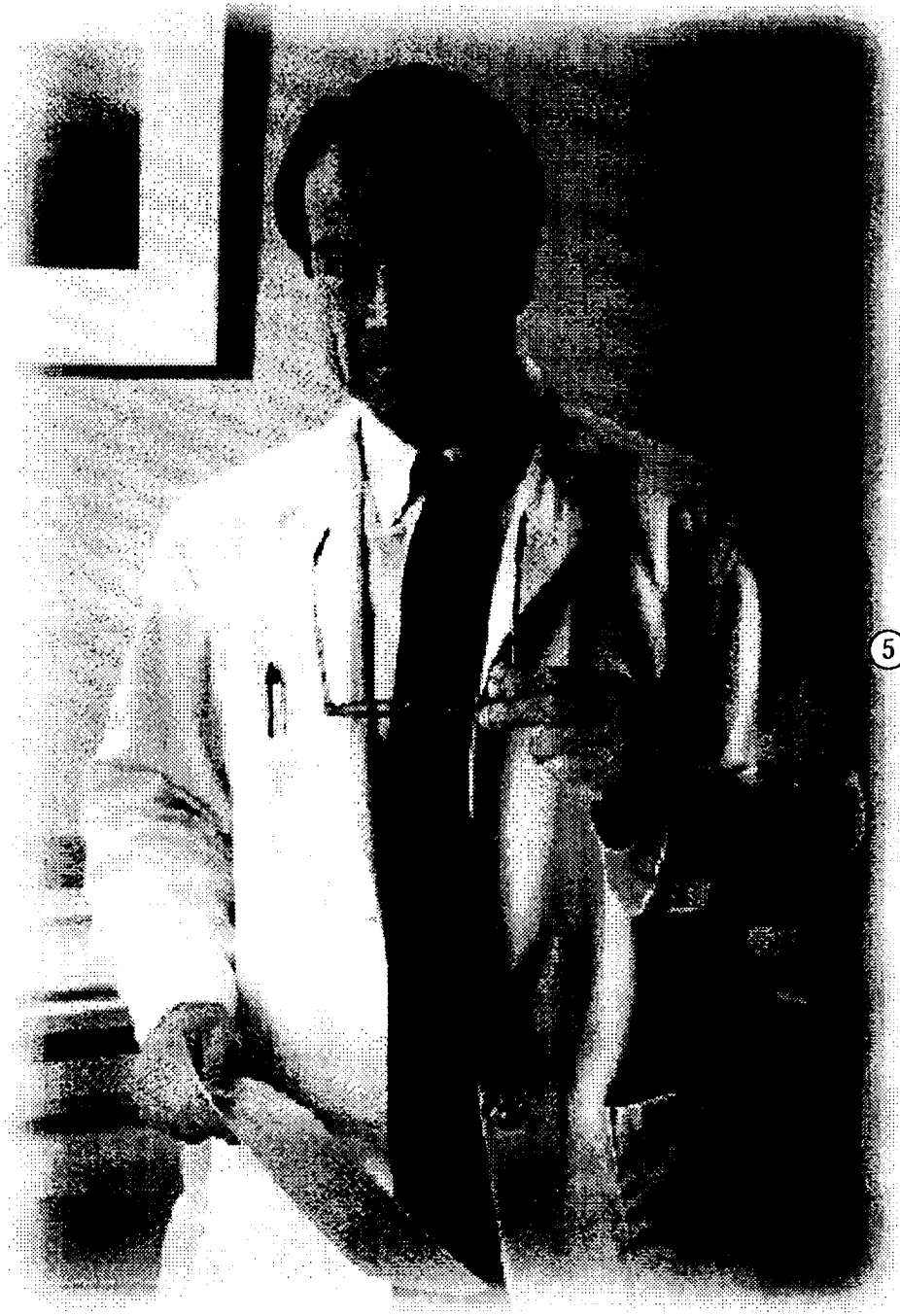
1.1 What is an ICD?

An implantable cardioverter defibrillator (ICD) is a life-saving device that is implanted in a patient. It will automatically detect when the heart's rhythm becomes dangerously fast, and give an electric shock to restore the normal rhythm.

1.2 Why did my doctor recommend that I receive an ICD?

Your doctor has recommended that you have an ICD implanted. This is because your doctor believes you are at risk of developing a dangerous heart rhythm (arrhythmia) which can be treated with an ICD. You may have already experienced a cardiac arrest, requiring the help of doctors or emergency medical personnel to give a shock to restore your heart's normal rhythm. If you are implanted with an ICD, that ICD can take the place of those other people, so that if you have another episode of arrhythmia, it will be automatically treated wherever you are.





1.3 Are there alternative treatments?

A number of conditions, such as a previous heart attack, can put people at risk of life-threatening arrhythmias. In some patients, these conditions can be completely cured. In others, the risk of arrhythmias is significantly reduced when the cause is treated, for example, by surgery or medication. However, for many patients the risk remains unacceptably high despite these treatments, and an ICD is the best "insurance policy" against the risk of a cardiac arrest.

1.4 Who should not receive an ICD?

Some patients should not be treated with an ICD. This may be because their arrhythmia is only temporary or because an ICD cannot treat their problem. These include:

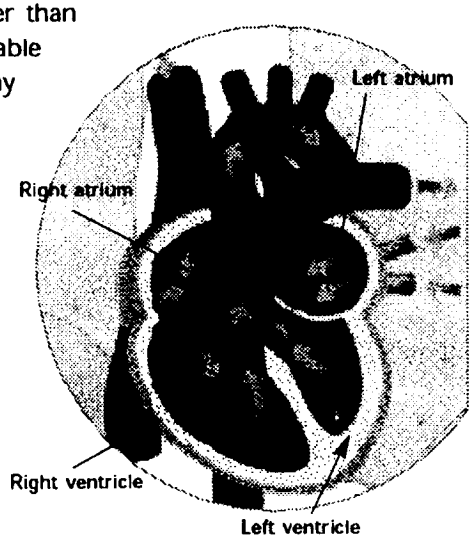
- Patients whose tachyarrhythmias are due to a reversible cause, such as drug treatment, electrolyte imbalance, etc.
- Patients with tachyarrhythmias due to a recent heart attack or unstable ischemic episodes.
- Patients with incessant ventricular tachyarrhythmias.
- Patients whose tachyarrhythmia was due to electrocution.

2 The heart and its rhythms

2.1 Parts of the heart

The heart is a pump that consists of four chambers separated by a wall and four valves. The two top chambers are called atria. They act like reservoirs. They collect and hold the blood until it can be moved to the main pumping chambers, the ventricles. The right atrium collects "used" blood from all over your body. The left atrium collects the newly oxygenated blood from your lungs. Between heartbeats, the atria pump blood into the lower chambers, the ventricles. The right ventricle pumps the "used" blood to both lungs. The left ventricle pumps the oxygen-rich blood back to feed the heart muscle itself and to the rest of your body.

Your heart is normally slightly larger than your clenched fist. Your heart is capable of beating over 100,000 times a day (at a rate of about 70 beats per minute). In one day it pumps more than 1,760 gallons (8,000 liters) of blood through approximately 11,800 miles (19,000 km) of circulatory system.



2.2 Normal rhythm

The normal rhythm is called sinus rhythm. Your own natural pacemaker, the sinoatrial (SA) node, is located in the right atrium. Every second or less, this pacemaker fires, and an electrical signal spreads through the right and left atria. This causes them to contract and empty their blood into the relaxed ventricles. The electrical signal then continues on through a special junction, the atrioventricular (AV) node, down to the ventricles. The atria relax and the ventricles contract, pumping the blood to the lungs and throughout the body.

2.3 Abnormal rhythms (arrhythmias)

The normal rhythm of your heart can be disturbed in a number of ways.

Bradycardia
Your heart normally beats between 60 and 80 times a minute. A rate lower than 60 beats per minute is normal only if you are resting, asleep, or very physically fit. A heart rate below 60 beats per minute is called bradycardia.
There are two causes for an abnormally slow heart rate:

- the SA node may fire too slowly, or
- the electrical signal cannot get through the AV node from the atria to the ventricles.

An abnormally slow heart rate or a very long pause between beats can cause tiredness, dizziness, and blackouts. This condition is treated with a pacemaker.

Tachyarrhythmias (abnormal tachycardias)
Exercise, mental or emotional stress, and some illnesses can cause your heart rate to rise. If your heart rate is over 100 this is called tachycardia. Tachycardia is a normal response under these conditions. When your heart rate is too fast, however, or occurs without cause, or is too fast and irregular, it is called a tachyarrhythmia.

The different types of tachyarrhythmia include:

Atrial fibrillation (AF): In AF the electrical activity becomes very rapid and irregular, and the pumping action of the atria is lost. Fortunately, this is not usually very important. However, in some cases, the rapid beating of the atria can also cause the ventricles to contract very rapidly, too. This rapid beating of the ventricles can cause dizziness, blackouts, shortness of breath, or angina.
AF is usually treated with medications that maintain the normal rhythm,

or that prevent the ventricles from beating too fast. Blood-thinning medicines are also usually given to help prevent blood clots that can cause strokes and heart attacks.

Ventricular tachycardia (VT): In VT, regular heart rate starts in the ventricles instead of the SA node. The heart pumps less blood with each beat. There isn't enough time for the chambers to refill with blood between beats. Less blood reaches your brain and other organs. Occasionally this causes few symptoms, but usually patients feel quite ill, get dizzy, faint, experience blackouts, or even pass out. For most patients, VT is dangerous if not properly treated. This is because it leads to unconsciousness or even VF.

Ventricular fibrillation (VF): In VF, the electrical activity of the ventricles is very rapid and irregular. Little or no blood is pumped. Your brain, heart and the rest of your body are quickly starved of oxygen. Patients usually pass out within a few seconds.

VF almost never stops on its own, and is therefore fatal unless the normal rhythm is restored with an electric shock to "reset" the heart (**defibrillation**). This can be given by doctors or emergency medical personnel using paddles held to the chest (external defibrillation), or automatically by an ICD.

VT and VF have a number of causes, the most common of which is scarring of the heart due to a previous heart attack.
Cardiac arrest rarely gives any warning. Sadly, emergency medical personnel and their external ICDs are usually not present or immediately available when one occurs.

In a patient who has suffered cardiac arrest due to VT or VF, doctors will first attempt to treat the condition which caused it. If, despite treatment, the doctor believes that the patient is at an unacceptably high risk of another cardiac arrest or if VT keeps occurring, is poorly tolerated, and cannot be stopped, he or she may recommend an ICD. At the first sign of VF or VT, your ICD will pace or shock your heart out of its abnormal rhythm.

3 Description of the ICD

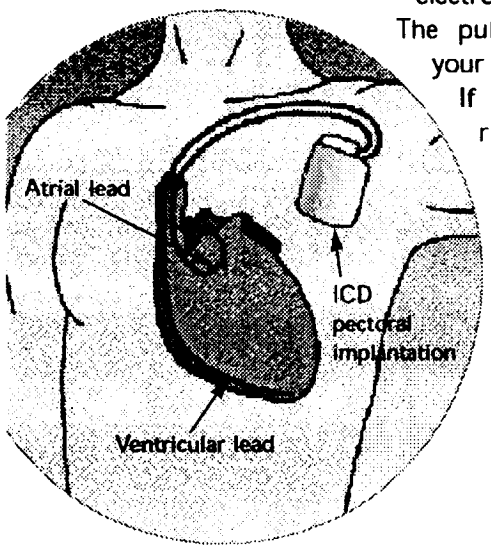
Your ICD is a device that can automatically recognize and treat heart rhythm problems, including VF and VT.

3.1 Parts of the device

Pulse Generator

The pulse generator is a sealed titanium metal container that contains:

- a battery, which powers the ICD,
- the capacitors (parts that store the electric charge needed to shock the heart),
- a microprocessor (a small computer), and
- electronic circuits.



The pulse generator constantly checks your heart's natural electrical signals. If it detects an abnormal heart rhythm, it delivers electrical energy (treatment). This causes your heart to return to a more normal rhythm.

Your pulse generator's computer memory stores:

- treatment settings your doctor has programmed
- the number and kinds of treatments your heart has received between each office visit,
- how successful each treatment was,
- ECGs
- the status of the pulse generator's battery (how much energy it still contains at each follow-up visit).

Lead

The pulse generator is connected to the heart by two leads (insulated wires). These leads allow the ICD to:

- check on your heart's rhythm,
- act as a pacemaker if the heartbeat is too slow, and
- give a shock, if necessary.

The leads are threaded into the heart through veins, making their implantation a simple procedure.

Programmer

The programmer is a kind of computer, kept in the hospital or your doctor's office. It can communicate with the pulse generator by means of a wand that is held over the skin covering your pulse generator. It is used to:

- test your ICD after it is implanted,
- program the treatments that your doctor wishes the ICD to use, and
- "read" information stored in the pulse generator's memory between office visits.

3.2 How an ICD works

Your ICD constantly checks your heart's electrical activity. It can tell whether the heart rhythm is normal, too slow, or too fast. If the rhythm is abnormal, an electrical treatment will automatically be given to your heart. The kind of treatment will depend on the settings your doctor chooses. Your doctor will tell you which therapy he or she has programmed into your ICD.
The most important function of an ICD is to give a shock to restore the heart's normal rhythm in the case of VF. This is called defibrillation. But, your ICD can deliver other types of therapy, too: antitachycardia pacing, cardioversion, and bradycardia pacing.

Antitachycardia pacing
When VT is detected, the ICD checks if the rhythm should be treated. If the doctor has programmed this treatment, the ICD gives a short burst of small, rapid electrical pulses to interrupt the arrhythmia. This is called antitachycardia pacing. These pulses are usually not even felt by the patient.

Cardioversion
Your ICD can be programmed to give low-and medium-energy shock treatments to your heart if your heart rhythm is very fast. This is called cardioversion. This can cause a small amount of discomfort.
Most ICDs can be programmed to treat VT with antitachycardia pacing and/or cardioversion. If these treatments fail, then a full strength defibrillation shock is given.

Defibrillation
If your ICD detects VF, it delivers a high-energy shock. This is called defibrillation. Because the shock is given directly to the heart, the strength required is only about 1/10th of that given when doctors or emergency medical personnel place paddles on the chest. The total time from the start of VF to the shock itself is usually around 10 seconds. This is the amount of time it takes for the ICD to charge the capacitors in the pulse generator so that a big shock can be given. During the time it is charging, it is not uncommon for the patient to faint from the VF.

Bradycardia pacing
Your ICD can also act as a pacemaker, to prevent your heart from beating too slowly. ICDs can sense and pace one or two chambers of your heart, atrium and/or ventricle. This is called single- (VVI) or dual-chamber (DDD) pacing.

3.3 Implantation procedure

The operation to implant an ICD is usually carried out with a general anaesthetic, though a heavy sedative is sometimes enough. Your doctor will discuss this with you.
The pulse generator may be implanted in either your chest or in your abdomen, depending on the model chosen. Your doctor will base his or her decision on:

- your size and shape
- your age and heart size
- whether you've already had chest surgery
- your activities and lifestyle
- which method is safest for you

Whether your pulse generator is placed in your chest or your abdomen, your doctor will first make an incision in the skin. Some doctors prefer to place the pulse generator right below the skin. Others prefer to make a further incision in the muscle, too. Your doctor will then make a "pocket", either under the skin or under the muscle, in which to place the pulse generator.

The two leads are then passed through a vein under the collar bone and positioned in chambers of your heart. The position is checked by x-ray, and the leads are tested to ensure that they are in good contact with the heart.The leads are connected to the pulse generator, which is then placed in the pocket. Before the incision is closed, your doctor will perform a defibrillation test. This important test involves deliberately making the heart go into VF, and ensuring that the ICD is able to defibrillate the heart with a shock. You will not be aware of this test. You will still be anesthetised or heavily sedated.) When your doctor has made sure that the results of all the tests are satisfactory, the pocket and skin incision are closed with stitches.

3.4 At hospital discharge

Your doctor will tell you whether you have skin stitches which dissolve in time, or whether the stitches will need to be removed later in an office visit. Always follow your doctor's directions while you recover and begin to resume normal activities. Some suggestions that will help in your recovery:

- Bathe, exercise, and walk according to your doctor's instructions.
- Don't lift anything heavy (more than 10 or 15 pounds) until your doctor gives the OK.
- Limit arm movements that could affect the leads, if your doctor has instructed you to.

Tell your doctor immediately if there is any redness, swelling, fever, or drainage from your incisions. Contact your doctor if your arm becomes swollen.

- Don't wear tight clothing that may irritate the skin over the pulse generator.
- Avoid any activity or contact sport that could result in a blow to your implant. These include, but are not limited to, karate, football, or placing a shotgun or rifle against the side of the chest your device is implanted.

Be sure to tell all your doctors, dentists or any emergency personnel that you have an implant. You may need extra antibiotics before and after any dental work (even teeth cleaning!) or surgery. This is an extra precaution against infection.The wound and the pocket under the skin will be rather sore for a few days. The wound should be kept dry.

3.5 Follow-up visits

Every few months, you will be seen in your doctor's office for a checkup. Your doctor will use the programmer to "talk" with the ICD. He/she will:

- check that the leads are working well,
- check the battery to see how much energy is left, and
- find out if the ICD has treated any arrhythmias.

Your doctor will also ask you which drugs you are taking and check if there are any interactions with your ICD. He or she will also check to see if your heart condition has changed since your last visit. Depending upon your condition and the information retrieved from the ICD, your doctor may wish to "fine-tune" some of the ICD's settings. Your doctor will use the programmer to make any of these changes. Your doctor will give you a schedule to follow for these follow-up visits.

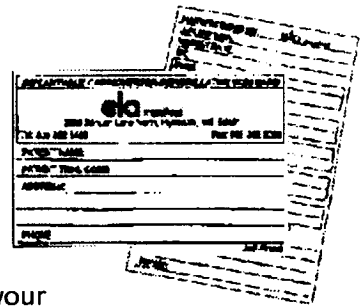
3.6 Unit replacement

The batteries in your ICD should last for a number of years. They wear down very gradually and predictably.

Several months before the batteries are expected to run down, your doctor will tell you that your pulse generator must be replaced. In an operation much like the original implant, your scar will be opened and the old pulse generator removed (it is a sealed unit, so the batteries cannot be replaced separately). The leads will also be tested. They are then connected to a new pulse generator and then the pocket is closed. Occasionally, leads need to be replaced.

4.1 Your ICD identification card

Always carry your ICD identification card with you when you go out, even for a quick errand. You will be given a card when you leave the hospital.



Your card has important information about your ICD and leads, and your doctor's name and phone number. It also has important information for emergency medical personnel, if treatment is necessary.

If you move, change your phone number, or change doctors, tell your doctor you need a new ICD identification card. Or, you can contact Ela Medical customer service directly. (See the table of content)

4.2 Activities and exercise

Your doctor may advise you to avoid activities where a few seconds of dizziness or unconsciousness could be dangerous to you or others. These activities might include:

- driving a car,
- swimming or boating alone, or
- climbing a ladder.

Your doctor will tell you if you can start driving again. This will be determined by the laws in your state and by your medical condition. Any dizziness, blackouts, or loss of consciousness caused by your condition is the cause of concern, not your ICD.

Patients with an ICD automatically lose their right to pilot an airplane because of their underlying heart condition.
Always follow your doctor's recommendations about resuming your normal daily activities. Such activities may include:

- returning to your job,
- resuming sexual activity,
- travel, and
- exercise, recreation, or other hobbies.

[redacted]

Your ICD should not affect your ability to work, except under special circumstances. Because jobs and workplaces vary, there is no single answer. Be sure to tell your doctor if you use or must come near:

- high voltage electrical equipment,
- strong magnets, like those used in the steel or auto scrap industry,
- radar, or
- other sources of strong electromagnetic interference.

Tell people at work that you have an ICD and what they should do if you receive a shock (see Section 4.4).

If you have any questions about your work or workplace, ask your doctor. He or she can arrange an evaluation to see if your job may affect your ICD's function.

[redacted]

Your ICD will not interfere with sexual intimacy. If you receive a shock treatment while someone is in contact with you, they feel no more than a tingle through their skin.

[redacted]

First, check with your doctor before planning a trip. Remember to:

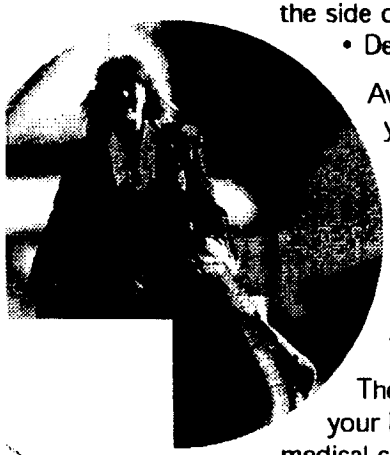
- take along this manual, if you or emergency medical personnel have any questions.

- ask your doctor for the name of a doctor or heart clinic in the city, state, or country you will be visiting. If an emergency occurs, you will be prepared to seek help.
- always show your ICD identification card at security checkpoints, such as airports. Ask for a hand search without a hand-held screening wand. Security detectors are unlikely to cause problems if you walk through the "gate" without lingering.
- ask your doctor to arrange a follow-up visit with a doctor in the area you will be visiting if you will be away for more than six months.

Exercise is good for the heart, and you are encouraged to lead an active life. You should discuss with your doctor what kind of exercise program is best for you.

A small number of sports should be avoided:

- Contact sports (such as karate or football) may cause a blow to the skin over the ICD. This would not normally damage the device, but could injure the tissues lying over it.
- The barrel of a shotgun or rifle should not be held against the side of your chest where the ICD is implanted.
- Deep sea diving should be avoided.



Avoid direct sun exposure to the skin over your implant. Be sure to wear at least a T. shirt or other clothing to shield this area.

You should discuss possible heart risks with your doctor regarding:

- snorkeling, and
- shallow scuba-diving.

These activities will not cause problems to your ICD but may be of concern because of your medical condition.

4.3 When to call your doctor

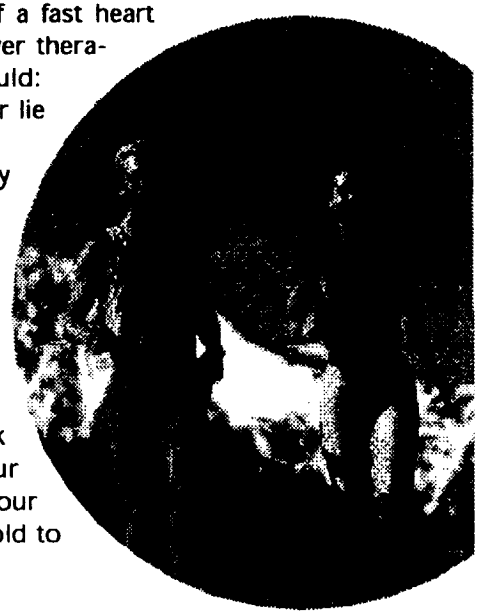
Your doctor will give you instructions about when you should call him or her. In general, call your doctor if you:

- receive a shock or any other therapy from your ICD and have been told to call.
- have symptoms of an abnormal heart rhythm and have been told to call.
- notice any swelling, redness, warmth, or drainage from any incision.
- develop a fever that does not go away in two or three days.
- have any questions about your ICD, heart rhythm, or medications.
- plan to travel or move.
- notice anything unusual, such as new, unexplained symptoms or symptoms like those you had before you received your ICD.

4.4 What to do if you receive a shock treatment

If you begin to feel symptoms of a fast heart rate, your ICD will probably deliver therapy within a few seconds. You should:

1. Stay calm. Find a place to sit or lie down.
2. If possible, ask someone stay with you throughout the event.
3. Have a friend or family member phone the emergency number if you remain unconscious for more than one minute.
4. If you are conscious but do not feel well after shock therapy, have someone call your doctor immediately. Follow your doctor's orders. You may be told to come to the emergency room.



5. If you feel fine after therapy and symptoms do not reappear, you may not need to seek medical help immediately. Follow your doctor's instructions on when to call after receiving a shock. When you do call, your doctor or a nurse may ask you the following questions:
   - What were you doing right before shock therapy?
   - What symptoms did you notice before shock therapy?
   - How did you feel right after shock therapy?

It is important to plan ahead with your family and friends for contacting emergency medical personnel and your doctor. Pages 1 and 2 of this manual have space for your local emergency phone numbers and information about your current medications. Keep a copy of this information next to your phone, too, so anyone can see it easily if an emergency occurs.

If someone is touching you when the ICD delivers a shock, they might feel a tingle. This is because energy passes through your skin to the other person. It will not harm anyone touching you. They might also feel your muscles become tense or see you "jump" slightly, as if startled.

5 Electromagnetic interference

Anything that uses electricity, is powered by batteries, or contains magnets has an electromagnetic field around it. For most household appliances, these fields do not cause any problem to your ICD. This is because the field is very weak to begin with. It is also because the strength of an electromagnetic field decreases very rapidly, even with a small distance.

However, a very strong electromagnetic field could interfere with your ICD; this is called electromagnetic interference (EMI).

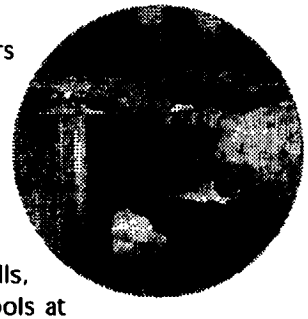
WARNING: **Follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets.**

Strong EMI can keep your ICD from delivering the right treatment to your heart when you need it. It can even cause your ICD to give you an inappropriate shock. The effect usually lasts only while you are near the source of strong EMI. Move away and the normal function of your ICD will usually return once the EMI stops. In rare cases, really strong EMI can permanently damage your ICD's circuits or change the programmed settings.

■ 5.1 Safe household appliances, tools, and other equipment

Your ICD has been built to protect it from interference by most electrical appliances. The following are safe to operate if they are in good repair and properly grounded (if required):

- microwave ovens
- televisions, AM/FM radios, video cameras, VCRs, and their remote controls
- garage door openers
- countertop appliances, such as toasters, blenders, food processors, electric knives, electric can openers, etc.
- hand-held appliances, such as hair dryers, shavers, curling irons, etc.
- major appliances, such as washers, dryers, electric stoves, refrigerators and freezers, dishwashers, etc.
- electric blankets and heating pads
- remote-controlled transmitters for toy cars and airplanes



Other equipment you may safely operate if it is good repair and properly grounded:

- personal computers and printers
- electric typewriters, fax machines, and copy machines
- machine shop tools, such as electric drills, circular saws, table saws, etc. (Keep all tools at least 12 inches from your implant site, whether in chest or abdomen.)
- low-power radio transmitters, such as cordless telephones or walkie-talkies

Also safe to use are:

- spark-ignited internal combustion engines, such as those in lawn mowers, leaf-blowers, and automobiles (if your doctor has not restricted your right to drive)
- battery-operated conveyances, such as golf carts or electric wheelchairs.

■ 5.2 Equipment that may not be safe to use

Cellular phones

Digital cellular phones can cause EMI if they are very close (within 6 to 12 inches) to the ICD. The effect is temporary. To avoid interference:

- Don't carry a cellular phone in a breast pocket on the same side as the pulse generator, if it is implanted in your chest.
- Do not carry a cellular phone from your belt if the pulse generator is implanted in your abdomen.
- Hold the cellular phone to the ear on the opposite side of your body from the pulse generator.

Security detectors

CAUTION: **Security detectors may cause temporary interference with your ICD.**

Security detectors used in stores and libraries are unlikely to cause problems if you walk through the "gate" without lingering. And, do not stand close to the outside of the detection equipment, either. If you have any concern, show your ICD identification card and ask that the detector be turned off while you walk through.

The security detectors (both walk-through and hand-held wands) used in airports and government buildings may cause temporary interference with your ICD.

The metal case of your pulse generator may set off security alarms. Present your ICD identification card to security personnel and ask for a hand search. It is important that security personnel understand that a search with a hand-held wand should be avoided.

Other equipment

The following may be sources of strong EMI. Keep them at least 24 inches away from your ICD:

- stereo speakers in large stereo systems, large radios
- strong magnets
- industrial equipment such as power generators and arc-resistance welders
- battery-powered cordless tools, such as drills, screwdrivers, etc.
- antennas used for medium power radio transmitters, such as ham or CB radio, long-distance radio, or satellite telephones
- high-power loudspeakers (such as those found in public buildings)

Because of sparks or other EMI, stay at least 12 inches (30 cm) away from:

- a running car engine (sparks can cause EMI and some alternators contain strong magnets)
- electric motors, if running
- furnaces
- hot water heaters

Do not use body-fat monitors designed for home use.

Keep away from:

- any radar equipment
- large TV or radio transmission towers
- power lines carrying more than 100,000 volts

■ 5.3 Medical and Dental Procedures

CAUTION: **Always tell all medical personnel that you have an ICD.**

Most medical and dental procedures will not interfere with your ICD. These procedures include:

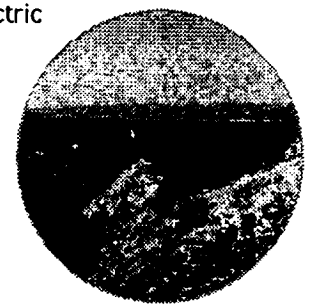
- diagnostic x-rays, such as chest, dental, CT scans, and mammography
- dental procedures to clean or repair teeth

Some procedures can be carried out with proper precautions (the equipment should not be placed directly over the pulse generator):

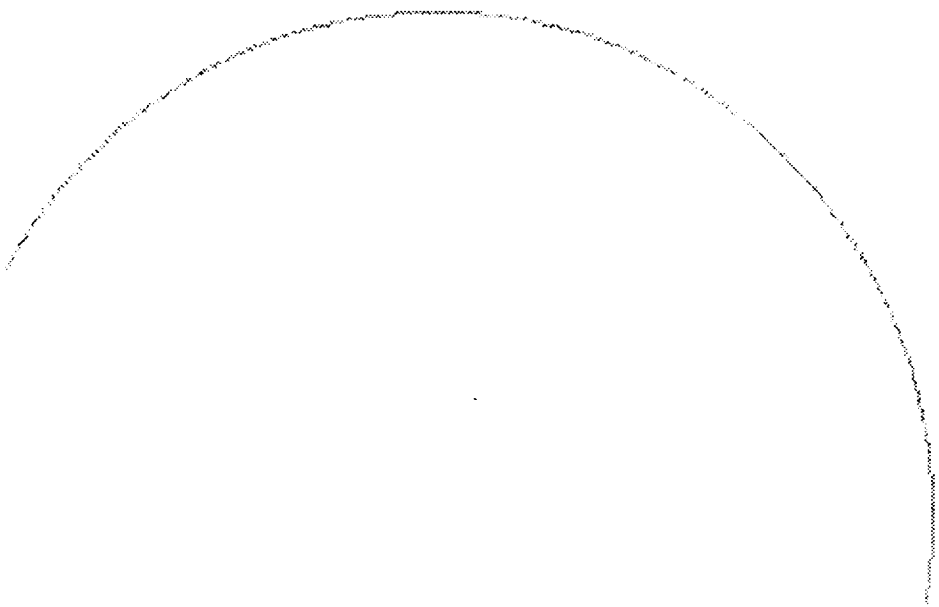
- transcutaneous electrical nerve stimulation (TENS)

Other medical procedures or devices produce a high level of interference that could seriously affect the function of your ICD. Be sure to discuss their risks and benefits with your doctor. These include:

- lithotripsy (the use of shock waves to break up kidney and gall stones inside your body)
- electrocautery (this is an electronic device used to stop bleeding during surgery)
- diathermy (this equipment uses an electric field to apply heat to tissues, such as muscle)
- radiation therapy
- therapeutic ultrasound



WARNING: **Magnetic resonance imaging (MRI) is not recommended for any patient with an ICD UNDER ANY CONDITIONS. Because the equipment uses such powerful magnets, avoid even entering any room with MRI equipment - no matter what the reason.**



6 Some questions you may have about your ICD

■ 6.1 Should I be worried about my ICD?

An ICD is meant as an aid to live a normal life, without the constant fear of cardiac arrest. For some patients, the ICD itself can become a focus of worry at first. It is best to remember that it was given to you as a sort of insurance policy, so that you can put worries behind you. ICDs are extremely reliable -- they save lives every day. It is best to bring your worries into the open by discussing them with your doctor, your family, or possibly a support group.

■ 6.2 Will I experience pain, or a big lump under the skin?

WARNING: **If pain persists after the initial healing of your incision, check with your doctor.**

After the initial healing of the wound, the area around your ICD should be painless. However, it is quite common for patients to remain "aware" of its presence under the skin.

In the same way, once the incision has healed, all that should be visible is a bulge under the skin, and this cannot be seen when a shirt or blouse is worn.

■ 6.3 Will the ICD cure my heart disease?

Unfortunately not. The ICD can only treat rhythm disturbances caused by your heart disease. You may still need treatment for the condition that caused the arrhythmias.

■ 6.4 Will I need to take medication?

Most patients with ICDs are also taking regular medication.

This may be for angina, a weak heart, or a number of other reasons. The ICD does not affect the need for these medications, but it does not interfere with them either. Even though the ICD can stop ventricular arrhythmias very successfully, it cannot prevent them from occurring. Some patients, therefore, take medication to reduce the frequency of arrhythmias and prevent the ICD from firing too often.

6.5 What will happen when the ICD "fires"?

The ICD can give a number of different treatments. Bradycardia pacing is not felt at all. Brief awareness of a rapid heart beat may occur right before antitachycardia pacing.

Some people report a defibrillation shock as feeling like a small jolt, others like a kick in the chest. Either way, the discomfort is momentary and there are no after-effects. Of course, the arrhythmia that triggers the device may make you feel a very rapid heart beat, dizziness or even fainting.

VF causes most people to black out or faint within a few seconds, so that they are not aware of the shock when it occurs.

6.6 What should I tell my family and friends?

You should tell your family, friends, and co-workers about your ICD. They should know that if the device fires, they do not need to do anything other than to make you comfortable while you recover. If someone is touching you when the ICD gives a shock, they should feel little more than a tingle, as the device is designed to focus its current on your heart, not elsewhere.

Some friends and family members may want to learn cardiopulmonary resuscitation (CPR). This can be arranged through your local Red Cross chapter.

WARNING: **Make sure others know that they should dial the emergency number immediately if you remain unconscious for more than one minute after a shock treatment. Give them your doctor's phone number ahead of time. Make sure they know they should call your doctor if you don't feel well after shock treatment, even if you regain consciousness.**

7 Summary

This is not meant to replace the complete instructions found in this manual summary.

Your doctor may have recommended that you have a cardiac defibrillator (ICD) implanted. This is because your doctor believes you are at risk of developing a dangerous heart rhythm that can be treated with this device.

If you are implanted with an ICD, follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets.

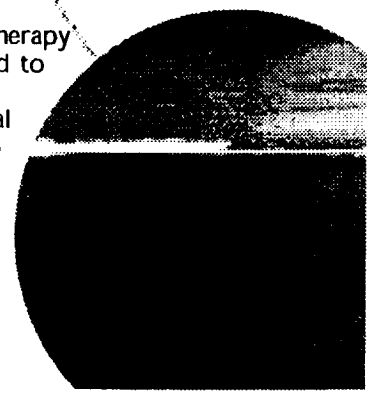
Your doctor has already discussed with you any precautions you need to take to protect your implant from damage. Follow these instructions very carefully.

Always follow your doctor's recommendations about resuming your normal daily activities. These may include:

- returning to your job,
- returning to sexual activity,
- travel, and
- exercise, recreation, or other active hobbies.

Your doctor will give you instructions about when you should call him or her. In general, call your doctor if you:

- receive a shock or any other therapy from your ICD and have been told to call
- have symptoms of an abnormal heart rhythm and have been told to call
- notice any swelling, redness, warmth, or drainage from any incision



8 Glossary

AF (see **Atrial fibrillation**)

Antitachycardia pacing:

Some tachycardias can be interrupted by rapid pacing of the heart. Modern ICDs can be programmed to use antitachycardia pacing to stop an episode of ventricular tachycardia, avoiding the need for a high-energy shock.

Arrhythmia:

An abnormal heart rhythm.

Atrial fibrillation (AF):

Abnormally fast and irregular electrical activity of the atria. This common arrhythmia can make the ventricles beat irregularly, and sometimes rapidly. Atrial fibrillation is not acutely dangerous, and is often not even noticed by patients. However, a rapid heart rate can sometimes cause palpitations, dizziness, and shortness of breath.

Atrioventricular (AV) node:

A specialized part of the heart that is normally the only electrical connection between the atria and the ventricles. If the AV node does not function properly, your ICD can take over by pacing the ventricle in the right rhythm with the atrium.

Atrium:

The left and right atria are the upper chambers of the heart. The right atrium pumps blood into the right ventricle. The left atrium pumps blood into the left ventricle.

AV node (see **Atrioventricular node**)

Bradycardia:

A heart rate less than 60 beats per minute. This can be quite normal in especially physically fit people, particularly at rest and while sleeping. It may also be caused by the sinoatrial node working too slow or blockage of the electrical pathways in the heart. (See **sinoatrial node**)

Cardiac arrest:

During cardiac arrest the heart stops completely.

Cardiomyopathy:

A disease of the heart muscle. Most heart disease is due to coronary artery disease, high blood pressure, or abnormal heart valves. Less frequently, the heart muscle becomes abnormal without an obvious cause.

Cardioversion:

Stopping a cardiac arrhythmia. In patients with an ICD, this term is used to describe the use of a low energy shock (perhaps 1/10th of the maximum strength of the device) to treat ventricular tachycardia.

Defibrillation:

Stopping ventricular fibrillation with an electric shock. This can be achieved by medical personnel at the scene of a cardiac arrest, using paddles placed on the chest, or automatically by a device implanted in the patient (an ICD).

Defibrillator:

An external or implanted device that can deliver a shock to the heart. It is used to treat abnormally fast and irregular heart rhythms.

ECG/EKG:

Electrocardiogram. A printout of the electrical activity of the heart.

Electrocautery:

A procedure that uses electricity to stop bleeding during surgery.

Electromagnetic field:

This is an invisible area of energy. It is found around magnets. It also occurs when electricity is used, both around devices plugged into an outlet and those that are battery-powered.

Electromagnetic interference:

If an electromagnetic field is very strong, it can interfere with your ICD. It can prevent your ICD from giving you the right treatments or it can even cause your ICD to give you an inappropriate shock.

Fibrillation:

Rapid, irregular beating of the atrium or ventricle. (See **Atrial fibrillation, Ventricular fibrillation).**

Heart attack:

If an artery that carries blood to the heart muscle becomes blocked, the muscle is starved of oxygen. Some of your heart tissues die as a result. A previous heart attack is one of the more common causes for ventricular arrhythmias that require treatment with an ICD. The medical term for a heart attack is a myocardial infarction.

Heart failure:

Weakness of the heart muscle. This can cause many symptoms, including breathlessness, dizziness, tiredness, and the accumulation of fluid in the lungs, abdomen, and legs.

ICD:

An implantable cardioverter defibrillator. An ICD is used to treat abnormally fast heart rhythms. It is usually implanted in the chest or abdomen.

Implantable cardioverter defibrillator (see **ICD**)

Myocardial infarction (see **Heart attack**)

Pacing:

Stimulation of the heart by small electrical impulses. Pacemakers are used to treat slow heart rates. ICDs use pacing to treat slow heart rates (**bradycardia**).

Programmer:

Equipment kept in your doctor's office that communicates with your ICD when you come for a checkup. The programmer can "read" a great deal of information stored in the ICD's memory. It reports the status of the battery and leads, the rhythms and rates of your heart since your last visit, and any therapies your ICD has given. The programmer can then be used to program your ICD, setting the therapies that your doctor has selected for the treatment of slow and fast heart rates.

Pulse generator:

The main part of an ICD. It is a sealed unit containing a battery, microprocessor (minicomputer), and electronic components. When an ICD's battery is running down, the entire pulse generator is replaced.

SA node (see **Sinoatrial node**)

Sinoatrial (SA) node:

This is a small group of cells in the right atrium that sends electrical signals that make the heart beat.

Sinus tachycardia:

A normal increase in the heart rate, usually due to exercise, stress, or illness.

Sudden cardiac death:

Death due to an electrical problem in the heart. It is usually caused by ventricular fibrillation or ventricular tachycardia. An ICD can greatly lower the risk of sudden cardiac death.

Tachycardia:

A heart rate usually greater than 100 beats per minute. If this is a normal response to exercise, stress, or illness, it is called sinus tachycardia.

Tachyarrhythmia:

Any disturbance of the heart's rhythm, regular or irregular, resulting in a rate over 100 beats per minute. Causes of tachyarrhythmias include heart attack, coronary artery disease, and cardiomyopathy.

Ventricles:

The left and right ventricles are the main pumping chambers of the heart. They receive blood from the left and right atria, and pump it to the body and the lungs.

Ventricular fibrillation (VF):

An arrhythmia causing an abnormally rapid and irregular beating of the ventricles. Because the heart pumps little or no blood, this arrhythmia is fatal unless a shock is given (**defibrillation**) to restore normal rhythm.

Ventricular tachycardia (VT):

An arrhythmia causing an abnormally rapid but regular beating of the ventricles. This can cause anything from mild symptoms of dizziness to fainting. If untreated ventricular tachycardia can lead to **ventricular fibrillation**.