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Medtronic

XXXXXX™GENII

Implantable Cardioverter Defibrillator

Implant Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician or properly licensed practitioner.

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1 Description

The Mode lXXXX Marquis II DR Implantable Cardioverter Defibrillator (ICD) System is a multiprogrammable, implantable cardioverter defibrillator that monitors and regulates a patient's heart rate by providing ventricular arrhythmia therapy, and single or dual chamber rate responsive bradycardia pacing.

The Model XXXX Marquis II DR ICD, along with commercially available pace/sense leads and cardioversion/ defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems for the Marquis II DR system are implanted using standard transvenous placement techniques.

The Model 9790C programmer, Model 9966 software, Model 9466 patient magnet, Model 9322 SmartMagnet and Model 9767 (or Model 9767L) programming head constitute one external portion of the ICD system. The Model 2090 programmer is compatible. Programmers from other manufacturers are not compatible.

Contents of sterile package – The sterile package contains one implantable cardioverter defibrillator, one torque wrench, and one DF–1 pin plug.

About this manual – This document is intended primarily as an implant manual. Regular patient follow-up sessions should be scheduled after implant. Follow-up procedures such as monitoring battery measurements and confirming therapy parameters are described in the manual included with the software supporting the Model XXXX Marquis II DR ICD. (To obtain additional copies of this manual, contact your Medtronic representative.)

2 Indications and usage

The implantable cardioverter defibrillator is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias.

3 Contraindications

The Marquis II DR system is contraindicated for

- patients whose tachyarrhythmias may have transient or reversible causes, such as: acute myocardial infarction, digitalis intoxication, drowning, electrocution, electrolyte imbalance, hypoxia, or sepsis.
- patients with incessant VT or VF
- patients who have a unipolar pacemaker
- patients whose primary disorder is bradyarrhythmias or atrial arrhythmias

4 Warnings and precautions

Avoiding shock during handling – Program tachyarrhythmia detection Off during surgical implant and explant or post-mortem procedures because the ICD can deliver a serious shock if you touch the defibrillation terminals while the ICD is charged.

Electrical isolation during implantation – Do not permit the patient to contact grounded equipment, which could produce hazardous leakage current during implantation. Resulting arrhythmia induction could result in the patient's death.

Lead system – Do not use another manufacturer's lead system without demonstrated compatibility, as undersensing of cardiac activity and failure to deliver necessary therapy could result.

Resuscitation availability – Do not perform ICD testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

4.1 Storage and handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of its contents. Return damaged packages to the manufacturer. For instructions on opening the sterile package, see the diagram inside the lid of the shelf box.

Device storage – Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm (12 in) or more after removal from its packaging.

Equilibration – Allow the device to reach room temperature before programming or implanting, because rapid temperature changes could affect initial device function.

Temperature limits – Store and transport the package between -18 °C (0 °F) and +55 °C (+131 °F).

"Use By" Date – Do not implant the device after the "Use By" date because the battery longevity could be reduced.

4.2 Resterilization

Medtronic has sterilized the device package contents with ethylene oxide prior to shipment. Resterilization is necessary only if the seal on the sterile package is broken. (Resterilization does not affect the "Use By" date.) If necessary, resterilize with ethylene oxide using a validated sterilization process, observing the following precautions:

- Do not resterilize the device using an autoclave, gamma radiation, organic cleaning agents (such as alcohol, acetone, etc.), or ultrasonic cleaners.
- Do not resterilize the device more than twice.
- Do not exceed 55 °C (131 °F) or 103 kPa (15 psi) when sterilizing.

4.3 Device operation

Accessories – The device may be used only with accessories, parts subject to wear and disposable items, of which the completely safe use on safety and technical grounds has been demonstrated by a testing agency approved for the testing of the device.

Battery depletion – Battery depletion will eventually cause the device to cease functioning and should be carefully monitored. Cardioversion and defibrillation are high energy therapies and may quickly deplete the battery and shorten the device longevity. An excessive number of charging cycles will also shorten the longevity.

Charge Circuit Timeout or Charge Circuit Inactive – Replace the device immediately if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message.

Concurrent pacemaker use – If a pacemaker is used concurrently with the ICD, verify that the ICD will not sense the pacemaker output pulses. Program the pacemaker so that pacing pulses are delivered at intervals longer than the ICD tachyarrhythmia detection intervals.

End of Life (EOL) indicator – Replace the device immediately if the programmer displays an End of Life (EOL) symbol.

Higher energy on the output capacitor – A higher than programmed energy can be delivered to the patient when the device has been previously charged to a higher energy and the energy is still present on the output capacitors.

Lead compatibility – Do not use another manufacturer's lead system without demonstrated compatibility as undersensing of cardiac activity and failure to deliver necessary therapy could result.

Medical treatment influencing device operation – The electrophysiological characteristics of a patient's heart can alter over time and the programmed therapies may become ineffective and even dangerous to the patient. This is especially to be considered when the patient's drug treatment has changed.

Pacemaker dependent patients – Always program Ventricular Safety Pacing (VSP) On for pacemaker dependent patients.

Programmers – Use only Medtronic programmers, application software, and accessories to communicate with the device.

Use of a magnet – Positioning a magnet over the device suspends detection and treatment but does not alter bradycardia therapy. The programming head contains a magnet that can suspend detection, but if telemetry between the device and programmer is established, detection is not suspended.

4.4 Lead evaluation and lead connection

- Use only ethylene oxide for lead resterilization. Do not resterilize more than one time.
- 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 can 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 ICD to ensure defibrillation effectiveness.
- Do not fold, alter, or remove any portion of the patch because doing so could compromise electrode function or longevity.
- Do not use ventricular transvenous leads in patients with tricuspid valve disease or a mechanical prosthetic tricuspid valve. Use with caution in patients with a bioprosthetic valve.
- Use the correct suture sleeve (when needed) for each lead to immobilize the lead and protect it against damage from ligatures.
- Ensure that the defibrillation lead impedance is greater than 20 Ω. An impedance below 20 Ω could damage the ICD.
- Do not kink the leads. Kinking leads can cause additional stress on the leads, possibly resulting in lead fracture.
- Do not suture directly over the lead body as this may cause structural damage. Use the lead anchoring sleeve to secure the lead lateral to the venous entry site.
- Lead or Active Can electrodes in electrical contact during a high voltage therapy could cause current to bypass the heart, possibly damaging the ICD and leads. While the ICD is connected to the leads, make sure that no therapeutic electrodes, stylets, or guidewires are touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (e.g., an implanted guidewire) well away from all electrodes before a high voltage shock is delivered.
- Make sure to cap any pacing lead that is abandoned rather than removed to ensure that the lead does not become a pathway for currents to or from the heart.
- Make sure to plug any unused lead port in the device to protect the ICD.
- Refer to the lead technical manuals for specific instructions and precautions about lead handling.

4.5 Follow-up testing

- Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant ICD testing should the patient require external rescue.
- Be aware that 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 testing is no assurance that conversion will occur post-operatively.

4.6 Explant and disposal

- Interrogate the ICD, program VF and VT Detection Off, and disable ICD functions prior to explanting, cleaning, or shipping the ICD to prevent unwanted shocks.
- Explant the ICD postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check your local regulations. In addition, if subjected to incineration or cremation temperatures, the device could explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and re-implant explanted devices.
- Please return explanted devices to Medtronic for analysis and disposal. See the back cover for mailing addresses.

4.7 Medical therapy hazards

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause implanted device malfunction or damage. If electrocautery cannot be avoided, observe the following precautions to minimize complications:

- Have temporary pacing and defibrillation equipment available.
- Program the implanted device to the DOO mode.
- Suspend tachyarrhythmia detection using a magnet, or turn detection Off using the programmer.
- Avoid direct contact with the implanted device or leads. If unipolar cautery is used, position the ground plate so that the current pathway does not pass through or near the implanted device system (minimum of 15 cm [6 in]).
- Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
- Use a bipolar electrocautery system, where possible.

External defibrillation – External defibrillation may damage the implanted device or may result in temporary and/or permanent myocardial damage at the electrode tissue interface as well as temporary or permanent elevated pacing thresholds. Attempt to minimize the voltage potential across the device and leads by following these precautions:

- Use the lowest clinically appropriate energy output.
- Position defibrillation patches or paddles as far from the device as possible (minimum of 15 cm [6 in]), and perpendicular to the implanted device-lead system.

  If an external defibrillation was delivered within 15 cm (6 in) of the device, contact your Medtronic representative.

High-energy radiation – Diagnostic X-ray and fluoroscopic radiation should not affect the device; however, high-energy 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 implant site as a precaution against radiation damage.

Lithotripsy – Lithotripsy may permanently damage the implanted device if it is at the focal point of the lithotripsy beam. If lithotripsy must be used, temporarily turn off ICD therapies during the lithotripsy procedure and keep the focal point of the lithotripsy beam at least 2.5 to 5 cm (1 to 2 in) from the implanted device.

Magnetic resonance imaging (MRI) – Magnetic resonance imaging (MRI) should not be used on patients who have an implanted cardiac device because of the potential damage to the implanted device.

Radio frequency (RF) ablation – Radio frequency ablation procedure in a patient with an implanted cardiac device could cause implanted device malfunction or damage. To minimize the risks from radio frequency ablation,

- Have temporary pacing and defibrillation equipment available.
- Program the implanted device to the DOO mode.
- Suspend tachyarrhythmia detection using a magnet, or turn detection Off using the programmer.
- Avoid direct contact between the ablation catheter and the implanted lead or device.
- Position the ground plate so that the current pathway does not pass through or near the implanted device system (minimum of 15 cm [6 in]).

Therapeutic ultrasound – Exposure of the device to therapeutic ultrasound is not recommended as it may permanently damage the device. Damage to the device may affect therapy.

4.8 Home and occupational environments

Cellular phones – Marquis II DR ICDs contain a filter that prevents most cellular phone transmissions from interacting with device operation. To further minimize the possibility of interaction, observe the following cautions:

- Maintain a minimum separation of 15 cm (6 in) between the device and the hand-held telephone handset.
- Maintain a minimum separation of 30 cm (12 in) between the device and any antenna transmitting above 3 watts.
- Hold the handset to the ear furthest from the implanted device.
- Do not carry the handset within 15 cm (6 in) of the implanted device (even if the handset is not on).

The ICD has been tested using the ANSI/AAMI PC-69 standard to ensure compatibility with hand-held wireless and PCS phones and other similar power hand-held transmitters. These transmission technologies represent the majority of the cellular telephones in use worldwide. The circuitry of this device, when operating under nominal conditions, has been designed to eliminate any significant effects from the cellular telephones.

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

Communication equipment – Communication equipment such as microwave transmitters, line power amplifiers, or high-power amateur transmitters could generate enough EMI to interfere with device operation if approached too closely.

Electric or magnetic interference (EMI) – Patients should be directed to avoid devices that generate strong electric or magnetic interference (EMI). EMI could cause malfunction or damage resulting in prevention of proper programming, or confirmation, non-detection or delivery of unneeded therapy. Moving away from the interference source, or turning it off, usually allows the device to return to its normal mode of operation.

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

High voltage lines – High voltage power transmission lines could generate enough EMI to interfere with device operation if approached too closely.

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

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields (greater than 10 gauss or 1 millitesla) since it could suspend detection. Examples of magnetic sources that could interfere with normal device operation include: stereo speakers, bingo wand, extractor wand, magnetic badges, or magnetic therapy products.

5 Adverse events

5.1 Observed adverse events

Clinical studies were not performed on the Marquis II DR. Because of the similarity between the Marquis II DR and the GEM DR, clinical data generated by the GEM DR implant study was used to support the Marquis II DR.

The Clinical study of the GEM DR system (approved October 1998) included 300 ICDs implanted in 300 patients worldwide, and 297 Model 6940 CapSure Fix leads implanted in 295 patients worldwide. Total ICD exposure was 828 device months. Individual patient exposure averaged 2.8 months (ranging from 0 to 5.3 months).

Each adverse event was reviewed by an independent clinical events committee to determine whether it was related to the ICD system and/or the implantation procedure. There were a total of 15 deaths in the 300 patient clinical study; all were judged to be non-ICD related by the clinical events committee. Table 1 reports the causes of patient death during the clinical study in descending order of frequency. Except where noted, all deaths were non-sudden cardiac deaths.

Table 1. Patient deaths during the clinical study performed on GEM DR (approved Oct. 1998) (N=300)

Cause of Deaths (15 deaths total)	# of Patients	When occurred (days after implant)
Congestive heart failure	5	21, 50, 68, 77, 89
Cardiac and/or respiratory arrest or failure	5 [a]	1, 4, 20, 21, 64
Cardiogenic shock	2	12, 45
Electromechanical dissociation	1 [a]	118
Ischemic cardiomyopathy	1	28
Pneumonia	1	64

[a] One sudden cardiac death.

In the 300 patient clinical study one (1) device was explanted due to inappropriate VT detections.

The following adverse events were observed during the implant procedure (prior to skin closure): helix extension failure (4 patients); cut in ventricular lead (1 patient); ST elevation (1 patient); electromechanical dissociation (1 patient).

Table 2 and Table 3 report the adverse events attributed to the ICD system and/or implant procedure, on a per patient and per patient-year basis in descending order of frequency. The tables list complications and observations that occurred more than once. Complications and observations that occurred only once are listed following Table 2 and following Table 3.

Table 2. Complications related to ICD system and/or implant procedure (all patients, N=300): multiple complications. Data from GEM DR clinical study (approved Oct. 1998).

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Complications [a] (total, including single complications)	24	8.0%	31	0.45
Atrial lead dislodgement	13	4.3%	13	0.19
Pneumothorax	5	1.7%	5	0.07
Ventricular lead dislodgement	3	1.0%	3	0.04
Hematoma	2	0.7%	2	0.03
Respiratory failure	2	0.7%	2	0.03

[a] Complications are adverse events that required invasive intervention. Complications that occurred in only one patient are listed following the table. Some patients had more than one type of adverse event.

Single complications – Each of the following was observed once in one patient in the 300 patient clinical study: Atrial oversensing/undersensing; Failure to capture ventricle; Inappropriate ventricular detection; Increased pulse width threshold (atrium); Infection; and Protrusion under skin.

Table 3. Observations related to ICD system and/or implant procedure (all patients, N=300): multiple observations. Data from GEM DR clinical study (approved Oct. 1998).

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Observations [a] (total, including single observations)	134	44.7%	189	2.74
Incisional pain	66	22.0%	67	0.97
Inappropriate ventricular detection	23	7.7%	29	0.42
Patient Alert tone triggered	11	3.7%	14	0.20
Atrial oversensing/undersensing	10	3.3%	11	0.16
Hematoma	7	2.3%	7	0.10
Atrial fibrillation/flutter	6	2.0%	6	0.09
Incessant ventricular tachyarrhythmia	6	2.0%	6	0.09
Ecchymosis	4	1.3%	4	0.06
CHF/CHF exacerbation	3	1.0%	4	0.06
Increased DFT	3	1.0%	3	0.04
Ventricular oversensing	3	1.0%	3	0.04
Inadequate pace/sense measurements (atrium)	2	0.7%	2	0.03
Increased pacing threshold	2	0.7%	4	0.06
Infection	2	0.7%	2	0.03

Table 3. Observations related to ICD system and/or implant procedure (all patients, N=300): multiple observations. Data from GEM DR clinical study (approved Oct. 1998). (continued)

	# of Patients	% of Patients	# of Events	Events per Patient-Year
Pacemaker mediated tachycardia	2	0.7%	2	0.03
Palpitations	2	0.7%	2	0.03

[a] Observations are adverse events that did not require invasive intervention. Observations that occurred in only one patient are listed following the table. Some patients had more than one type of adverse event.

Single observations – Each of the following was observed once in one patient in the 300 patient clinical study: Awareness of ventricular pacing; Bronchitis; Cardiogenic shock; Cellulitis; Cut in outer lead insulation of 6940 lead during repositioning; Delayed wound healing; Dizziness; Failure to defibrillate/cardiovert; Fatigue; Fever; Frequent spontaneous SVTs; Generator migration; Inadequate pace/sense measurements (ventricle); Insomnia; Lethargy; Multisystem failure; Near syncope; Pericardial effusion; Pneumothorax; Pulmonary edema; Respiratory failure; Subclavian vein thrombosis; and VF therapy delivered despite spontaneous episode termination.

5.2 Potential adverse events

Adverse events in alphabetical order, including those reported in Table 2 and Table 3, associated with ICD systems include:

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

Patients susceptible to frequent shocks despite antiarrhythmic medical management could develop psychological intolerance to an ICD system that might 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).

6 Clinical studies

Clinical studies were not performed on the Marquis II DR. Because of the similarity between the Marquis II DR and the GEM DR, the GEM DR implant study was used to support the Marquis II DR. Clinical study of the GEM DR system (approved October 1998) involved an acute study and an implant study.

6.1 Acute study

The study was conducted in 62 patients undergoing ICD implantation or cardiac electrophysiology (EP) study using an external device that contained the GEM DR ICD dual and single chamber tachyarrhythmia detection algorithms.

Patients studied – The patients (44 M / 18 F) had a mean age of 65.7 (range 33 – 87) years, and a mean left ventricular ejection fraction of 36.8% (range 10 – 70%) (n=37). Arrhythmia histories included non-sustained VT (24%), atrial fibrillation (19%), VT (18%) (non-exclusive).

Methods – The study evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias. Arrhythmias (VT, VF, or SVT) were induced in 48 patients and the episode records evaluated for relative sensitivity and incremental specificity.

Results – In the acute study, the GEM DR dual chamber detection algorithm (PR Logic Criteria for SVT discrimination) demonstrated relative sensitivity (Table 5) of 98.5% [95% confidence interval of 89.9 – 99.8%] and incremental specificity (Table 6) of 77.4% [63.7 – 87.0%], compared to the GEM DR single chamber detection algorithm. No adverse interactions between sensing, pacing and detection were observed. No adverse events occurred during the study.

6.2 Implant study

This was a non-randomized, prospective study of 300 patients implanted with the GEM DR in the U.S., Europe, Canada and Australia. Most (295 patients) also received a Model 6940 CapSure Fix lead. The mean implant duration was 2.8 months (range 0 to 5.3 months), with a cumulative implant duration of 828 device months.

Patients studied – The patients (238 M / 62 F) had a mean age of 63.5 (range 13 to 90) years and a left heart ventricular ejection fraction of 37.5% (10% to 82%). The primary indications for implant included ventricular arrhythmias (47%), ventricular arrhythmias and sudden cardiac death (34%) and sudden cardiac death (17%). Cardiovascular history included coronary artery disease and myocardial infarction (59%), dilated cardiomyopathy (30%), congestive heart failure (26%) and hypertension (26%) (non-exclusive).

Methods – The primary objective was to demonstrate unanticipated device related effect [1] (UADRE) -free survival greater than 90% (lower confidence interval) at three months post-implant. Patients underwent standard ICD implantation and were evaluated at one month and three months post-implant. The implant criterion was DFT ≤ 22 J by the binary search method or 2 out of 2 successful defibrillations at ≤ 24 J. Pacing and sensing were evaluated via ambulatory monitoring of 51 patients. Activity sensor-driven pacing was evaluated in 20 patients who completed an exercise test. The heart rates at rest and during exercise were measured, and the physician reported whether or not the exertional rate [2] was acceptable for the patient's level of exercise (Table 8). Spontaneous VT/VF episodes were evaluated for therapy effectiveness (Table 7), relative sensitivity (Table 5), and incremental specificity (Table 6), using the ICD stored episode records. Patient Alert tone identifiability was evaluated via telephone monitoring at two months post-implant. Subthreshold (painless) lead impedance testing was performed at each visit.

[1] Any "serious [incapacitating, life threatening, or fatal] unanticipated clinical event related to the ICD," excluding random component failure and device misuse.

[2] At the end of stage 3 of the CAEP treadmill exercise challenge.

Results – The implant study results are detailed in Table 4 through Table 8. Patient Alert tones were correctly identified by the patient and clinician in 115 of the 119 patients tested (96.6% success [95% confidence interval of 91.6 – 99.2%]). No unanticipated device-related effects (UADRE) were identified by the clinical events committee. All pacing and sensing functions evaluated via ambulatory monitoring performed as intended.

Table 4. Implant study results from GEM DR clinical study (approved Oct. 1998).

Measure	Results	Successes (#)	Patients (#)
Results at Implant			
% of patients meeting implant criterion of DFT ≤ 22 J with initial lead system using binary search protocol [95% confidence interval [b]]	91.9% [88.0 – 95.8%]	171	186
% of patients meeting implant criterion of 2/2 inductions at ≤ 24 J with initial lead system [95% confidence interval [b]]	88.0% [81.8 – 94.1%]	95	108
Chronic Results			
Overall survival at 3 months [95% confidence interval [a]]	94.7% [89.5 – 97.3%]	285	300
Complication-free survival at 3 months [95% confidence interval [a]]	92.0% [88.3 – 94.6%]	276	300
UADRE-free survival at 3 months [95% confidence interval [b]]	100.0% [95.5 – 100.0%]	117	117

[a] Estimated by the Kaplan-Meier method.
[b] Estimated by the exact binomial method.

Table 5. Relative detection sensitivity, per VT/VF episode: dual chamber algorithm relative to single chamber algorithm, based on data from GEM DR clinical study (approved Oct. 1998).

	Relative Sensitivity [a] (%)	Detections of VT/VF (#) by dual chamber algorithm [b]
Acute Study, n = 30 [c] [95% c.i.]	98.5% [89.9 – 99.8%]	67 / 68 [e] (98.5%)
Implant Study, n = 66 [d] [95% c.i.]	99.8% [99.2 – 99.9%]	795 / 797 [e] (99.7%)

[a] As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.
[b] Episode data recorded by the external device (acute study) or ICD memory (implant study), using the GEM DR dual and single chamber detection algorithms.
[c] 30 patients with one or more induced VT/VF episodes.
[d] 66 patients with one or more spontaneous VT/VF episodes.
[e] Detections of VT/VF episodes by the single chamber algorithm are stated as the denominator.

Table 6. Incremental detection specificity, per VT/VF episode: dual chamber algorithm relative to single chamber algorithm based on data from GEM DR clinical study (approved Oct. 1998).

	Incremental Specificity [a] (%)	Discrimination of non-VT/VF (#) by dual chamber algorithm [b]
Acute Study, n = 32 [c] [95% c.i.]	77.4% [63.7 – 87.0%]	43 / 60 [e] (71.7%)
Implant Study, n = 42 [d] [95% c.i.]	63.0% [49.0 – 75.1%]	212 / 295 [e] (71.9%)

[a] As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation.

[b] Episode data recorded by the external device (acute study) or ICD memory (implant study), using the GEM DR dual and single chamber detection algorithms.

[c] 32 patients with one or more induced SVT episodes.

[d] 42 patients with one or more spontaneous SVT episodes.

[e] Detections of non-VT/VF episodes by the single chamber algorithm are stated as the denominator.

Table 7. Spontaneous episode termination effectiveness, per episode based on data from GEM DR clinical study (approved Oct. 1998).

	Effectiveness [a] (%)	VT/VF Episodes (#)	Episodes Successfully Terminated (#)
Implant Study, n = 64 [b] [95% c.i.]	99.1% [96.8 – 99.8%]	1153	1147

[a] As adjusted for multiple episodes within a patient, based on the Generalized Estimating Equations Model with exchangeable correlation. The unadjusted results are essentially the same.

[b] 64 patients with one or more spontaneous VT/VF episodes.

6.2.1 Rate response

Methods – Clinical studies were not performed on the Marquis II DR. Because the same accelerometer-based rate reponse feature is used by both the Marquis II DR and Sigma 300 DR, the Sigma 300 DR clinical study (approved August 1999) was used to support the Marquis II DR. This study, conducted at 17 investigational centers worldwide, was a prospective evaluation of the rate response feature of the Sigma 300 DR pacemaker. Patient data were collected at implant, pre-discharge, one month, three months, and six months post-implant.

Objective – Rate response operation was evaluated to demonstrate that increases in pacing rates are concurrent with increases in workload. Patients were evaluated utilizing a modified version of the Minnesota Pacemaker Response Exercise Protocol (M-PREP) [3] at their one month visit. Evaluation of rate response performance was conducted using the Metabolic Chronotropic Response model described by Wilkoff as applied by Kay [4] . Valid data collected from patients that performed the exercise per protocol for at least three minutes were included in the analysis.

Description of Patients – A total of 67 patients were enrolled and received an implanted pacemaker. The mean age was 67.2 years (range: 19.5 to 85.2 years). Patients met the indications for dual chamber pacing: atrial fibrillation/flutter in 23 patients and normal AV conduction in 13 patients (patients could have more than one indication). Mean duration of implant was 3.8 months with a range of 0 to 6.9 months and a total experience of 257 patient months.

[3] Benditt, David G.M., Editor, Rate Adaptive Pacing, Blackwell Scientific Publications, Boston. 1993:63-65.

[4] Kay, Neal G., *Quantitation of Chronotropic Response: Comparison of Methods for Rate-Modulating Permanent Pacemakers*. JACC. Dec 92;20(7):1533-41.

Results of the Study – The rate response clinical study was not performed on the Marquis II DR. Because the same accelerometer-based rate reponse feature is used by both the Marquis II DR and Sigma 300 DR, the Sigma 300 DR clinical study (approved August 1999) was used to support the Marquis II DR.

Table 8 provides the results of the clinical study. The performance of the rate response feature was found to meet the study objective. Each of the 31 patients included in the analysis individually met the minimum 0.65 slope requirement.

Table 8. Effectiveness Analysis based on Sigma 300 DR clinical study (approved Aug. 1999) [a]

Mean Slope of M-PREP Rate Response at 1 Month (n=31 patients)	Observed 95% CI (Confidence Interval)	Performance Objective Criterion: 95% CI (Confidence Interval)
1.02	[0.97, 1.06]	[0.65, 1.35]

[a] All patients implanted (n=68 devices in 67 patients totaling 257 device-months).

Figure 1 shows the sensor-indicated rate (SIR) versus the Wilkoff-predicted heart rate achieved during the M-PREP test at one month.

Figure 1. Rate Response Exercise Data based on Sigma 300 DR clinical study (approved Aug. 1999)

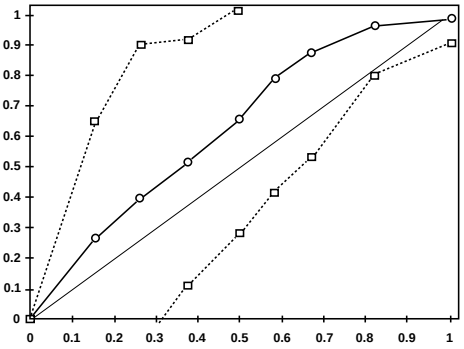


Table 9. Heart rate during activity sensor-driven [a] pacing, based on GEM DR clinical study (approved Oct. 1998). This table does not apply to Marquis II DR.

	Rate at Rest n = 20 [b]	**Rate During Exercise n = 20** [b]
Heart Rate (Mean ± s.d.)	69.9 bpm ± 14.2 bpm	104 bpm ± 15.9 bpm

[a] The type of sensor used by the GEM DR is a piezoelectric crystal. Because the Marquis II DR and GEM DR do not use the same type of rate response sensor, the GEM DR clinical study for rate response was not used to support the Marquis II DR.

[b] 20 patients with activity sensor-driven pacing during an exercise test. All 20 were judged by the physician to have attained an adequate heart rate during exercise.

7 Patient selection and treatment

7.1 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 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 induced 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 device implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify detection and conversion. The device 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 effectiveness of therapy.

Direct any questions regarding the individualization of patient therapy to a Medtronic representative at 1-800-PCD-INFO (1-800-723-4636).

7.2 Specific patient populations

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

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

Pediatric patients – This device has not been studied in patients younger than 13 years of age.

Geriatric patients – Most (67%) of the patients receiving the GEM DR ICD in clinical studies were over the age of 60 years (see Section 6, "Clinical studies", page 11).

Handicapped and disabled patients – Special care is needed in using this device for patients using electrical wheelchairs or other electrical (external or implanted) devices.

8 Patient counseling information

Physicians 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 device delivers a shock.
- Advise patients to contact their physician immediately if they hear tones coming from their device.
- Encourage patients to use identification cards (issued by Medtronic) and/or identification bracelets documenting their device.

Discuss information in the Patient Manual (*Restoring the Rhythms of Life* and *Model 9466 Patient Magnet Instructions For Use*) with patients before and after device implantation so they are fully familiar with operation of the device. Advise patients how to obtain additional copies of the patient manuals.

9 Conformance to standards

This ICD was developed in conformance with all or parts of the following standards:

- ISO 5841-3:1992(E), IS-1 IPG Connector Standard.
- ISO 11318:1993(E), DF-1 Defibrillator Connector Standard.
- EN45502 - Active Implantable Medical Devices, Part 1: General Requirements for Safety, Marking and Information to be provided by the Manufacturer, August 1997.
- prEN45502 - Active Implantable Medical Devices; Part 2-2: Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia (Includes Implantable Defibrillators), March 1998.
- IEC 601-1, Medical Electrical Equipment: General Requirements for Safety.

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

10 How supplied

The Model 7274 Marquis II DR device is packaged one per package in a sterile package.

11 Clinician use information

11.1 Physician training

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

11.2 Directions for use

Device operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Device Registration Form and return it to Medtronic as it provides necessary information for warranty purposes and patient tracking.

The Marquis II DR Reference Manual, supplied with the XXXX software, provides complete programming instructions and recommendations. Copies can be obtained by contacting the Medtronic representative, or by calling 1-800-PCD-INFO (1-800-723-4636). The Reference Manual was last updated in xxxxxxxxxxx.

This Implant Manual was last updated xx-xxxx.

11.3 Maintaining device effectiveness

11.3.1 Device storage

FOR SINGLE USE ONLY. Do not resterilize and reimplant an explanted device. Medtronic has sterilized the device with ethylene oxide prior to shipment. Resterilizing the device is necessary if the seal on the sterile package is broken. Resterilization does not affect the "Use By" 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 from a height of 30 cm (12 in) or more because this could have damaged ICD components;
- 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 of –18 to +55 ^{O}C (0 to 131 ^{O}F), as the device circuitry may have been damaged; or
- Its "Use By" date has expired, because this can adversely affect device 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.

Should sterilization be required:

- Repackage all items in a gas permeable container;
- Use a validated ethylene oxide gas process;
- Follow the manufacturer's operation instructions so long as the maximum temperature does not exceed 55 ^{O}C (131 ^{O}F), nor pressures of 15 psi;
- Store the resterilized components for an appropriate period to permit aeration of ethylene oxide gas.

12 Patient information

Information for the patient is available in a separate booklet, *Restoring the Rhythms of Life*, from Medtronic (supplied with the device). To obtain additional copies, contact the Medtronic representative or call 1-800-PCD-INFO (1-800-723-4636). This information should be given to each patient with their device, and offered to the patient on each return visit or as deemed appropriate.

Restoring the Rhythms of Life was developed using patient and clinician input to ensure that it is understandable. *Restoring the Rhythms of Life* was last updated December 2001.

13 Implant procedure

Warnings:

- Do not permit the patient to contact grounded equipment that could produce hazardous leakage current during implantation. Resulting arrhythmia induction could result in the patient's death.
- The device is intended for implantation with Medtronic transvenous or epicardial defibrillation leads. Transvenous (Endotak® series) or epicardial defibrillation leads manufactured by Guidant Corporation can also be used. No claims of safety and efficacy can be made with regard to other non-Medtronic acutely or chronically implanted lead systems.
- Lead or Active Can electrodes in electrical contact during a high voltage therapy could cause current to bypass the heart, possibly damaging the device and leads. While the device is connected to the leads, make sure that no therapeutic electrodes, stylets, or guidewires are touching or connected by an accessory low impedance conductive pathway. Move objects made from conductive materials (for example, an implanted guidewire) well away from all electrodes before a high voltage shock is delivered.

13.1 Pre-operative programming

Check the "Use By" date printed on the package. Do not implant the device after the "Use By" date, because the battery's longevity could be reduced.

Before opening the sterile package, prepare the ICD for implant as follows:

1. Interrogate the ICD and print a full summary report.
2. Confirm that the battery voltage is at least 3.0 V at room temperature.[5]

   If the device has been exposed to lower temperatures or has delivered a recent high voltage charge, the battery voltage will be temporarily lower.
3. Set the ICD internal clock.
4. Perform a manual capacitor formation as follows:
   - Dump any charge on the capacitors.
   - Perform a test charge to full energy.
   - Retrieve the charge data.
   - Do not dump the stored charge. Allow it to dissipate, thus reforming the capacitors.
   - If the reported charge time is clinically unacceptable, contact a Medtronic representative.
5. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that all tachyarrhythmia detection is **programmed off**.

13.2 Testing lead operation

1. Implant endocardial leads according to the supplied instructions, unless suitable chronic leads[6] are already in place. Do not use any lead with this device without first verifying connector compatibility. A bipolar atrial lead with closely spaced pacing and sensing electrodes is recommended.
2. Verify appropriate sensing and an adequate pacing threshold margin (Table 10) using an implant support instrument (PSA), according to its supplied instructions.

Table 10. Acceptable Implant Values[a]

Measurements required	Acute transvenous leads	Chronic leads[b]
R-wave amplitude	≥ 5 mV	≥ 3 mV
P-wave amplitude	≥ 2 mV	≥ 1 mV
Slew rate	≥ 0.5 V/s (atrial)	≥ 0.3 V/s (atrial)
	≥ 0.75 V/s (ventricular)	≥ 0.5 V/s (ventricular)
Capture threshold (0.5 ms pulse width)	≤ 1.5 V (atrial)	≤ 3.0 V (atrial)
	≤ 1.0 V (ventricular)	≤ 3.0 V (ventricular)
V. Defib. impedance	20 - 200 Ω	

[5] Use the Quick Look screen to verify the voltage.

[6] Chronic leads are leads implanted for 30 days or more.

Table 10. Acceptable Implant Values [a] (continued)

Measurements required	Acute transvenous leads	Chronic leads [b]
SVC (HVX) Defib. impedance [c]	20 - 200 Ω	
Defibrillation threshold [d]	≤ 20 J (two consecutive) or ≤ 18 J (binary search)	

[a] The measured pacing lead impedance is a reflection of measuring equipment and lead technology. Refer to the lead technical manual for acceptable impedance values.

[b] Chronic leads are leads implanted for 30 days or more.

[c] This measurement only applies if a supplementary electrode is connected to the SVC (HVX) port.

[d] If a two-electrode system fails to meet the implant criterion, a third electrode can be added using the SVC port.

13.3 Connecting leads to the implanted device

Warning: Loose lead connections may result in inappropriate sensing and failure to deliver necessary arrhythmia therapy.

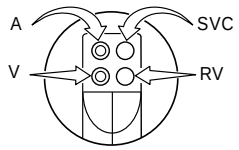
Caution: Use only the torque wrench supplied with the device. It is designed to prevent damage to the device from overtightening a setscrew.

For easier lead insertion, insert the ventricular IS-1 leg before the other legs.

Table 11. Lead Connections

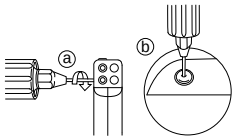
Device Port	Connector Type	Software Name
SVC	DF-1	HVX
RV	DF-1	HVB
Can	n/a	HVA, Can
V	IS-1 bipolar	
A	IS-1 bipolar	

Figure 2. Lead connections



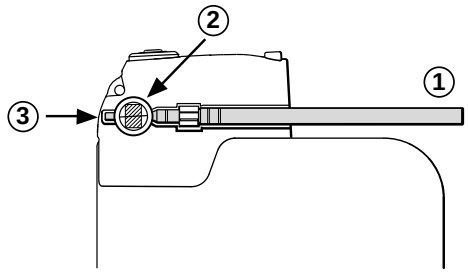
13.3.1 Lead connection procedure

1. Insert the torque wrench into the appropriate setscrew.
   a. If the port is obstructed, retract the setscrew to clear it. Take care not to disengage the setscrew from the connector block.
   b. Leave the torque wrench in the setscrew until the lead is secure. This allows a pathway for venting trapped air when the lead is inserted.



2. Push the lead or plug into the connector port until the lead pin is clearly visible in the pin viewing area. No sealant is required, but sterile water may be used as a lubricant.
3. Tighten the setscrew by turning clockwise until the torque wrench clicks.
4. Tug gently on the lead to confirm a secure fit. Do not pull on the lead until all setscrews have been tightened.
5. Repeat these steps for each lead.

Figure 3. Inserting a lead into the device



1 Lead
2 Setscrew block is located behind grommet
3 Tip of lead extends past setscrew block

13.4 Defibrillation threshold testing

Warning: Ensure that an external defibrillator is charged for a rescue shock.

1. Place the programming head over the ICD, start a patient session, and interrogate the device, if you have not already done so.
2. Observe the Marker Channel annotations to verify that the ICD is sensing properly.
3. Conduct a manual Lead Impedance Test to verify the defibrillation lead connections. Perform this test with the ICD in the surgical pocket and keep the pocket very moist. If the impedance is out of range, perform one or more of the following tasks:
   - Recheck lead connections and electrode placement.
   - Repeat the measurement.
   - Inspect the bipolar EGM for abnormalities.
   - Measure the defibrillation impedance with a manual test shock.
4. Program the ICD or support instrument to properly detect VF with an adequate safety margin (1.2 mV sensitivity).

5. Program the defibrillation parameters to the desired settings to be tested.
6. Induce and terminate VF using the ICD or support instrument and the implanted lead system (Table 10). Proper post-shock sensing must be observed.

13.5 Placing the device

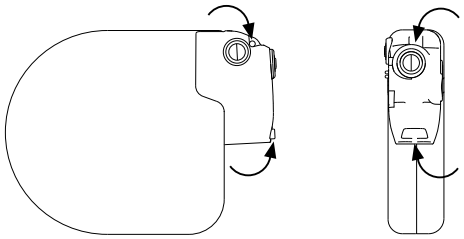
Cautions:

- If no SVC electrode is implanted, the pin plug provided with the device must be secured in the SVC port.
- Program tachyarrhythmia detection Off before closing.

13.5.1 Placing the device procedure

1. Ensure that each lead pin or plug is fully inserted into the connector block and that all setscrews are tight.
2. Coil any excess lead length beneath the device. Avoid kinks in the lead conductors.
3. Implant the device within 5 cm of the skin. This position optimizes the ambulatory monitoring operations.
4. Suture the device securely within the pocket to minimize post-implant rotation and migration of the device. Use a normal surgical needle to penetrate the suture holes.

Figure 4. Suture holes



13.6 Programming

1. After closing the pocket, program detection On. Program ventricular tachyarrhythmia therapies On as desired.
2. Do not enable the Other 1:1 SVTs PR Logic detection criterion until the atrial lead has matured (approximately one month post implant).
3. If external equipment was used to conduct the defibrillation efficacy tests, perform a final VF induction and allow the implanted system to detect and treat the arrhythmia.

13.7 Replacing an old ICD

1. Program all tachyarrhythmia detection Off.
2. Dissect the leads and the device free from the pocket. Be careful not to nick or breach the lead insulation.
3. Loosen each setscrew, and gently retract the lead from the connector block.
4. Remove the ICD from the surgical pocket.
5. If the connector pin of any implanted lead shows signs of pitting or corrosion, replace the implanted lead with a new lead. The damaged lead should be discarded and replaced to assure the integrity of the device system.

6. Measure sensing, pacing, and defibrillation efficacy using the replacement ICD or an implant support instrument.
7. Evaluate the defibrillation efficacy of the replacement system.

You may need an adaptor that will enable connection of the device to the implanted leads (Table 13, page 23).

14 Feature summary

See the “Shipped” column of the tables in Section 15.5, page 26, for a list of which features are enabled at shipping.

14.1 Tachyarrhythmia operations

Anti-tachycardia pacing therapies – Deliver rapid pacing pulses to overdrive and terminate the detected arrhythmia.

Auto-adjusting sensitivity – Automatically adjusts the sensitivity thresholds following certain paced and sensed events to reduce the incidence of T-wave sensing and cross-chamber sensing.

Committed defibrillation therapy – Up to six automatic defibrillation shocks to treat VF. Therapy is delivered asynchronously if synchronization fails. Tilt is fixed at 50%.

High rate timeout – Disables supplementary SVT detection criteria when a ventricular episode exceeds a programmed duration.

PR Logic SVT discrimination – Withholds inappropriate ventricular detection during episodes of rapidly conducted supraventricular tachycardia (SVTs), using pattern and rate analysis to identify different SVTs.

Reconfirm VF – Aborts the first defibrillation therapy if synchronization fails.

Stability criterion – Withholds VT detection for rapid rhythms (in the VT detection zone) with irregular intervals.

Synchronized cardioversion therapy – Up to six shocks to treat VT or FVT. Tilt is fixed at 50% for all ventricular cardioversion.

14.2 Pacing operations

Mode Switch – Prevents tracking of paroxysmal atrial tachycardias by switching from a tracking mode to a non-tracking mode.

Non-Competitive Atrial Pacing (NCAP) – Delays an atrial pace from falling within the atrium’s relative refractory period.

Pacemaker-Mediated Tachycardia (PMT) Intervention – Provides automatic detection and interruption of pacemaker-defined PMTs.

Premature Ventricular Contraction (PVC) response – Extends the atrial refractory period following a PVC to promote dual chamber synchrony and cycle length regularity.

Rate Adaptive AV (RAAV) – Varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases during dual chamber operation.

Rate Responsive Pacing – Varies the pacing rate in response to the patient’s physical motion as detected by an activity sensor.

Ventricular Rate Stabilization – Adjusts the ventricular escape interval dynamically to eliminate abrupt variations in the cycle length.

Ventricular Safety Pacing – Prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

14.3 Monitoring operations

Cardiac Compass trends – Plots long term trends in heart rhythm and device status for up to 14 months.

Episode data and EGM storage – Records diagnostic quality electrogram during every detected arrhythmia episode.

Flashback memory – Stores dual chamber intervals for several minutes prior to recent detected arrhythmia episodes, and prior to interrogation.

Holter telemetry – Allows the implanted device to continuously transmit an EGM with marker telemetry, with or without applying the programming head, for up to 46 hours.

Patient Alert – Notifies the patient with an audible tone if the device identifies any of the programmed or automatic alert conditions.

15 Product specifications

15.1 Physical specifications (nominal)

Table 12. ICD physical characteristics [a]

Volume	36 cc
Mass	75 g
H x W x D [b]	68.3 mm x 50.8 mm x 13.9 mm
Surface area of device can	66 cm^2
Radiopaque ID [c]	PKC

[a] Measurements are nominal values based on CAD (computer aided design) model measurements, and are rounded to the nearest unit.

[b] Grommets may protrude slightly beyond the can surface.

[c] Engineering series number follows the radiopaque code.

15.1.1 Materials

The device presents the following materials into contact with human tissue: titanium; polyurethane; silicone rubber. These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue.

15.1.2 Lead compatibility

Table 13. Compatible adaptors

Port	Primary Lead	Lead Adaptor
RV, SVC	DF-1 [a]	6707 for 6.5 mm cardioversion/defibrillation lead
A, V	IS-1 [a] bipolar	5866-24M for 5 mm paired unipolar
		5866-24M for 5 mm bifurcated
		5866-38M for IS-1 unipolar
		5866-40M for Medtronic 3.2 mm low-profile

[a] DF-1 refers to the international standard ISO 11318:1993. IS-1 refers to ISO 5841-3:1992(E).

15.2 Replacement indicators

Battery voltage and messages about replacement status appear on the programmer display and on printed reports. Table 14 lists the Elective Replacement Indicator (ERI) and the End of Life (EOL) conditions.

Table 14. Replacement indicators

Elective Replacement (ERI)	≤ 2.62 V
End of Life (EOL)	3 months after ERI

EOL indication – If the programmer indicates that the device is at EOL, replace the device immediately.

ERI date – The programmer displays the date when the battery reached ERI on the Quick Look and Battery and Lead Measurements screens.

Post-ERI conditions – EOL device status is defined as three months following an ERI indication assuming the following post-ERI conditions: 100% DDD pacing at 60 ppm, 3 V, 0.4 ms; 500 Ω pacing load; and six 30 J charges. EOL may be indicated before the end of three months if the device exceeds these conditions.

Temporary voltage decrease – The battery voltage temporarily decreases following a high voltage charge. If a battery measurement is taken immediately after a high voltage charge, ERI or EOL indicator may be displayed. However, this is a temporary status which will return to normal when the battery has recovered from the charge.

15.3 Projected longevity

Longevity estimates are based on accelerated battery discharge data and device modeling at 60 ppm pacing rate, with:

- 2.5 V pacing pulse amplitude, 0.4 ms pacing pulse width, and 30 J delivered therapy energy (see Table 15)
- 3 V pacing pulse amplitude, 0.4 ms pacing pulse width, and 30 J delivered therapy energy (see Table 16)

This model assumes default automatic capacitor formation setting, as described in the Marquis II DR Reference manual. As a guideline, each full energy charge decreases device longevity by approximately 24 days.

Device longevity is affected by how certain features are programmed, such as EGM pre-storage. For more information, see the Optimizing longevity chapter of the Marquis II DR Reference manual.

Considerations for using EGM pre-storage – When the EGM pre-storage feature is programmed off, the device starts to store EGM following the third tachyarrhythmia event and also provides up to 20 seconds of information before the onset of the tachyarrhythmia, including:

- AA and VV intervals
- Marker Channel
- interval plot Flashback

When the EGM pre-storage feature is programmed on, the device also collects up to 20 seconds of EGM information before the onset of the arrhythmia.

In a patient who uniformly repeats the same onset mechanisms, the greatest clinical benefit of pre-onset EGM storage is achieved after a few episodes are captured. To maximize the effectiveness of the EGM pre-storage feature and optimize device longevity, consider these programming options:

- Turn pre-storage on to capture possible changes in the onset mechanism following significant clinical adjustments, for example, device implant, medication changes, and surgical procedures.
- Turn pre-storage off once you have successfully captured the information of interest.

Table 15. Projected longevity in years with 2.5 V pacing amplitude and 0.4 ms pulse width

Percent pacing	Maximum energy charging frequency [a]	EGM pre-storage [b]	500 Ω pacing impedance		900 Ω pacing impedance	
			DDD	VVI	DDD	VVI
0%	Semi-Annual	Off	8.6	8.6	8.6	8.6
		On	8.5	8.5	8.5	8.5
	Quarterly	Off	7.5	7.5	7.5	7.5
		On	7.3	7.3	7.3	7.3
15%	Semi-Annual	Off	8.3	8.5	8.5	8.6
		On	8.1	8.4	8.3	8.5
	Quarterly	Off	7.2	7.4	7.3	7.5
		On	7.0	7.3	7.1	7.3
50%	Semi-Annual	Off	7.5	8.2	8.0	8.5
		On	7.4	8.0	7.9	8.2
	Quarterly	Off	6.6	7.1	7.0	7.3
		On	6.5	7.0	6.8	7.1
100%	Semi-Annual	Off	6.7	7.7	7.5	8.1
		On	6.5	7.5	7.3	8.0
	Quarterly	Off	6.0	6.8	6.6	7.1
		On	5.8	6.5	6.4	6.9

[a] Maximum energy charging frequency may include full energy therapy shocks or capacitor formations.

[b] The data provided for programming EGM pre-storage on is based on a 6 month period (two 3-month follow-up intervals) over the life of the device. Additional use of EGM pre-storage reduces longevity by approximately 25% or 3 months per year.

Table 16. Projected longevity in years with 3 V pacing amplitude and 0.4 ms pulse width

Percent pacing	Maximum energy charging frequency [a]	EGM pre-storage [b]	500 Ω pacing impedance		900 Ω pacing impedance	
			DDD	VVI	DDD	VVI
0%	Semi-Annual	Off	8.6	8.6	8.6	8.6
		On	8.5	8.5	8.5	8.5
	Quarterly	Off	7.5	7.5	7.5	7.5
		On	7.3	7.3	7.3	7.3
15%	Semi-Annual	Off	8.1	8.5	8.4	8.6
		On	8.0	8.3	8.2	8.4
	Quarterly	Off	7.1	7.3	7.3	7.5
		On	6.9	7.2	7.1	7.3
50%	Semi-Annual	Off	7.2	8.0	7.8	8.3
		On	7.0	7.8	7.6	8.1
	Quarterly	Off	6.4	7.0	6.8	7.2

Table 16. Projected longevity in years with 3 V pacing amplitude and 0.4 ms pulse width (continued)

Percent pacing	Maximum energy charging frequency [a]	EGM pre-storage [b]	500 Ω pacing impedance		900 Ω pacing impedance	
			DDD	VVI	DDD	VVI
100%	Semi-Annual	On	6.2	6.8	6.7	7.0
		Off	6.2	7.3	7.1	8.0
	Quarterly	On	6.0	7.1	7.0	7.7
		Off	5.5	6.5	6.3	6.9
		On	5.4	6.3	6.1	6.8

[a] Maximum energy charging frequency may include full energy therapy shocks or capacitor formations.

[b] The data provided for programming EGM pre-storage on is based on a 6 month period (two 3-month follow-up intervals) over the life of the device. Additional use of EGM pre-storage reduces longevity by approximately 25% or 3 months per year.

15.4 Magnet behavior

Pacing mode	as programmed
Pacing rate and interval	as programmed [a]
VF, VT, and FVT detection	suspended [b]
Patient Alert audible tones	with programmable alerts enabled: • continuous tone (Test) [c] • on/off intermittent tone (seek follow-up) • high/low dual tone (urgent follow-up) with programmable alerts disabled: • no tone • high/low dual tone (urgent follow-up)

[a] Rate response adjustments are suspended while a Patient Alert tone sounds.

[b] Detection resumes if telemetry is established and the application software is running or it resumes after the application software has started.

[c] The Test tone does not sound if VF Detection/Therapy Off is the only alert enabled.

15.5 Functional parameters

Programmable parameters are determined by the software used in the programmer. Functional parameters are measured at body temperature and 500 Ω load (brady parameters) and 75 Ω load (tachy parameters). Parameter values are “typical” where no tolerance is stated.

If the programmer displays a message that an electrical reset has occurred, contact your Medtronic representative.

15.5.1 Emergency settings

Table 17. Emergency parameters

Parameter	Selectable values	Default
Defibrillation		
Energy	10, 11, …, 16, 18, 20, …, 30 J	30 J
Pathway [a]	AX>B	—
Cardioversion		
Energy	0.4, 0.6, …, 2, 3, 4, …, 16, 18, 20, …, 30 J	30 J
Pathway	AX>B	—
Fixed burst		
Pacing Interval	100, 110, …, 600 ms	350 ms
V. Pulse Amplitude [b]	8 V	—
V. Pulse Width	1.6 ms	—
VVI pacing		
Pacing Mode	VVI	—
Lower Rate	70 ppm	—
V. Sensitivity / A. Sensitivity	as programmed	—
V. Pulse Amplitude [b]	6 V	—
V. Pulse Width	1.6 ms	—
V. Pace Blanking	240 ms	—
Hysteresis	Off	—
V. Rate Stabilization	Off	—

[a] If Active Can is Off, the HVA (Can) electrode is not used as part of the high voltage delivery pathway.

[b] Peak pacing amplitude. When tested per CENELEC standard 45502-2-1, the measured amplitude A depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$.

15.5.2 Detection parameters

Table 18. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Nominal	Reset
VF Detection Enable	On, Off	Off	On	On
VF Interval [a]	240, 250, …, 400 ms	320 ms	320 ms	320 ms
VF Initial NID	12/16, 18/24, 24/32, 30/40, 45/60, 60/80, 75/100, 90/120, 105/140, 120/160	18/24	18/24	18/24
VF Redetect NID	6/8, 9/12, 12/16, 18/24, 21/28, 24/32, 27/36, 30/40	12/16	12/16	12/16
FVT Detection Enable	Off, via VF, via VT	Off	Off	Off
FVT Interval [a]	200, 210, …, 600 ms	—	—	—

Table 18. Tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
VT Detection Enable	On, Off, Monitor	Off	Off	Off
VT Interval [a]	280, 290, …, 600 ms	400 ms	400 ms	400 ms
VT Initial NID	12, 16, …, 52, 76, 100	16	16	16
VT Redetect NID	4, 8, 12, …, 52	12	12	12
Stability [a]	Off, 30, 40, …, 100 ms	Off	Off	Off
AFib / AFlutter [b, c]	On, Off	Off	Off	Off
Sinus Tach [b, c]	On, Off	Off	Off	Off
1:1 VT-ST Boundary	35, 50, 66, 75, 85%	50%	50%	50%
Other 1:1 SVTs [b]	On, Off	Off	Off	Off
SVT Limit [a]	240, 250, …, 600 ms	320 ms	320 ms	320 ms
High Rate Timeout	Off, 0.75, 1, 1.25, 1.5, 2, 2.5, …, 5, 6, 7, …, 20, 22, 24, …, 30 min	Off	Off	Off
High Rate Timeout Therapy	Zone Appropriate, Skip to VF Therapy	Zone Appropriate	Zone Appro-priate	Zone Appropriate
A. Sensitivity [d, e]	0.15, 0.3, 0.45, 0.6, 0.9, 1.2, 1.5, 2.1 mV	0.3 mV	0.3 mV	0.3 mV
V. Sensitivity [d, e]	0.15, 0.3, 0.45, 0.6, 0.9, 1.2 mV	0.3 mV	0.3 mV	0.3 mV

[a] The measured intervals are truncated to a 10 ms multiple (e.g., 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

[b] Double tachycardia (i.e. "VF/FVT/VT plus SVT") detection is automatically enabled when any Dual Chamber SVT criterion is enabled.

[c] The device is shipped with the Sinus Tach and A.Fib / A.Flutter criteria off. However, when VT Detection is set to On or Monitor, these parameters are set to On.

[d] With a 40 ms sine^2 waveform (ventricular sensitivity) or a 20 ms sine^2 waveform (atrial sensitivity). When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times (ventricular) or 1.4 times (atrial) the rated sine^2 sensing threshold.

[e] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

15.5.3 Therapy parameters

Table 19. Tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Nominal	Reset
VF Therapy Status [a]	On, Off	On	On	On
VT Therapy Status [a]	On, Off	None	On	None
VT Therapy Type [a]	CV, Burst, Ramp, Ramp+	—	—	—
FVT Therapy Status [a]	On, Off	None	On	None
FVT Therapy Type [a]	CV, Burst, Ramp, Ramp+	—	—	—

Table 19. Tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
VF therapy (defibrillation) parameters				
Energy [b, c]	0.4, 0.6, …, 1.8, 2, 3, …, 16, 18, 20, …, 30 J	30 J	30 J	30 J
Pathway	AX>B, B>AX	AX>B	AX>B	AX>B
Confirm VF after initial detection? [a, d]	Yes, No	Yes	Yes	Yes
Cardioversion parameters				
Energy [c]	0.4, 0.6, …, 1.8, 2, 3, …, 16, 18, 20, …, 30 J	—	30 J	—
Pathway	AX>B, B>AX	—	AX>B	—
Burst therapy parameters				
Initial # Pulses	1, 2, …, 15	—	6 [e]	—
R-S1 Interval (% R-R)	50, 53, 56, 59, 63, 66, …, 84, 88, 91, 94, 97	—	84 [e]	—
Interval Decrement [a]	0, 10, …, 40 ms	—	10 ms	—
# Sequences [a]	1, 2, 3, …, 10	—	3 [e]	—
Smart Mode [a, f]	On, Off	—	Off	—
Ramp therapy parameters				
Initial # Pulses	1, 2, …, 15	—	8 [g]	—
R-S1 Interval (% R-R)	50, 53, 56, 59, 63, 66, …, 84, 88, 91, 94, 97	—	91 [h]	—
Interval Decrement	0, 10, …, 40 ms	—	10 ms	—
# Sequences [a]	1, 2, …, 10	—	3	—
Smart Mode [a, f]	On, Off	—	Off	—
Ramp+ therapy parameters				
Initial # Pulses	1, 2, …, 15	—	3	—
R-S1 Interval (% R-R)	50, 53, 56, 59, 63, 66, …, 84, 88, 91, 94, 97	—	75	—
S1-S2 Interval (% R-R)	50, 53, 56, 59, 63, 66, …, 84, 88, 91, 94, 97	—	69	—
S2-SN Interval (% R-R)	50, 53, 56, 59, 63, 66, …, 84, 88, 91, 94, 97	—	66	—
# Sequences [a]	1, 2, …, 10	—	5	—
Smart Mode [a, f]	On, Off	—	Off	—
Shared therapy parameters				
Progressive Episode Therapies [a]	On, Off	Off	Off	Off
Active Can	On, Off	On	On	On

Table 19. Tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
V. Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	1.6 ms	1.6 ms	1.6 ms
V. Amplitude [i]	0.5, 1, …, 4, 5, 6, 8 V	8.0 V	8.0 V	8.0 V
V. Pace Blanking	150, 160, …, 440 ms	240 ms	240 ms	240 ms
ATP Minimum Interval	150, 160, …, 400 ms	200 ms	200 ms	200 ms

[a] This parameter does not apply to manual therapies.
[b] For automatic therapy 3, 4, 5, or 6, energy must be at least 10 J.
[c] Delivered energy based on a biphasic pulse into a 75 Ω load. For energy less than 1 J, tolerance is ±0.25 J.
[d] Applies only to the first VF therapy that is programmed On.
[e] FVT Burst therapies have the following Medtronic nominal values: Initial # Pulses is 8, R-S1 Interval is 88%, and # Sequences is 1.
[f] Smart Mode is only available for Therapies 1, 2, 3, and 4.
[g] The nominal Initial # of Pulses for manual ramp therapy is 6.
[h] The nominal R-S1 Interval for manual ramp therapy is 97%.
[i] Peak pacing amplitude. When tested per CENELEC standard 45502-2-1, the measured amplitude A depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$.

15.5.4 Bradycardia pacing parameters

Table 20. Bradycardia pacing parameters

Parameter	Programmable values	Shipped	Nominal	Reset
Pacing Mode	DDDR, DDD, DDIR, DDI, AAIR, AAI, VVIR, VVI, DOO, VOO, ODO	DDD	DDDR	VVI
Lower Rate	30, 35, 40, …, 60, 70, 75, …, 150 ppm	60 ppm	60 ppm	65 ppm
Upper Tracking Rate	80, 85, …, 150 ppm	120 ppm	120 ppm	120 ppm
Upper Sensor Rate	80, 85, …, 150 ppm	120 ppm	120 ppm	120 ppm
Paced AV	30, 40, …, 350 ms	180 ms	180 ms	180 ms
Sensed AV	30, 40, …, 350 ms	150 ms	150 ms	150 ms
PVARP	Varied, 150, 160, …, 500 ms	310 ms	310 ms	310 ms
A. Refractory	150, 160, …, 500 ms	310 ms	310 ms	310 ms
PVAB [a]	100, 110, …, 310 ms	150 ms	150 ms	150 ms
A. Amplitude [b]	0.5, 1, ..., 3, 3.5, 4, 5, 6 V	3 V	3 V	4 V
A. Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	0.4 ms	0.4 ms	0.4 ms
A. Sensitivity [c, d]	0.15, 0.3, 0.45, 0.6, 0.9, 1.2, 1.5, 2 mV	0.3 mV	0.3 mV	0.3 mV
A. Pace Blanking	150, 160, …, 250 ms	200 ms	200 ms	240 ms

Table 20. Bradycardia pacing parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
V. Amplitude [b]	0.5, 1, ..., 3, 3.5, 4, 5, 6 V	3 V	3 V	6 V
V. Pulse Width	0.03, 0.06, 0.1, 0.2, ..., 1.6 ms	0.4 ms	0.4 ms	1.6 ms
V. Sensitivity [c, d]	0.15, 0.3, 0.45, 0.6, 0.9, 1.2 mV	0.3 mV	0.3 mV	0.3 mV
V. Pace Blanking	150, 160, ..., 440 ms	200 ms	200 ms	240 ms
Post-Shock Pacing Parameters				
A. Amplitude [b]	0.5, 1, 1.5, ..., 4, 5, 6, 8 V	4 V	4 V	4 V
A. Pulse Width	0.03, 0.06, 0.1, 0.2, ..., 1.6 ms	1.6 ms	1.6 ms	1.6 ms
V. Amplitude [b]	0.5, 1, 1.5, ..., 4, 5, 6, 8 V	6 V	6 V	6 V
V. Pulse Width	0.03, 0.06, 0.1, 0.2, ..., 1.6 ms	1.6 ms	1.6 ms	1.6 ms
Mode Switch Parameters				
Enable	On, Off	Off	On	Off
A. Detect Rate	120, 125, ..., 175 bpm	175 bpm	175 bpm	175 bpm
Rate Response Pacing Parameters				
Rate Response	1, 2, ..., 10	7	7	7
Activity Threshold	Low, Medium Low, Medium High, High	Medium Low	Medium Low	Medium Low
Activity Acceleration	15, 30, 60 s	30 s	30 s	30 s
Activity Deceleration	Exercise, 2.5, 5, 10 min	5 min	5 min	5 min
Rate Adaptive AV Parameters				
Enable	On, Off	On	On	On
Start Rate	50, 55, ..., 145 bpm	60 bpm	60 bpm	60 bpm
Stop Rate	55, 60, ..., 150 bpm	120 bpm	120 bpm	120 bpm
Minimum PAV	30, 40, ..., 350 ms	140 ms	140 ms	140 ms
Minimum SAV	30, 40, ..., 350 ms	110 ms	110 ms	110 ms
Additional Pacing Features				
Non-Comp Atrial Pacing				
Enable	On, Off	On	On	On
Interval	200, 250, ..., 400 ms	300 ms	300 ms	300 ms
Single Chamber Hysteresis	Off, 30, 40, ..., 80 bpm	Off	Off	Off
V. Rate Stabilization				
V. Rate Stabilization	On, Off	Off	Off	Off
V. Rate Stabilization Minimum Interval	500, 550, ..., 900 ms	500 ms	500 ms	500 ms

Table 20. Bradycardia pacing parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
V. Rate Stabilization Interval Increment	50, 60, …, 400 ms	150 ms	150 ms	150 ms
PMT Intervention	On, Off	Off	Off	Off
PVC Response	On, Off	On	On	On
V. Safety Pacing	On, Off	On	On	On

[a] PVAB is the minimum value that PVARP is shortened to, under sensor-varied PVARP operation. Atrial events that fall within the PVAB are ignored by the Mode Switch, NCAP, PVC Response, and PMT Intervention features.

[b] Peak pacing amplitude. When tested per CENELEC standard 45502-2-1, the measured amplitude A depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$.

[c] With a 40 ms sine^2 waveform (ventricular sensitivity) or a 20 ms sine^2 waveform (atrial sensitivity). When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times (ventricular) or 1.4 times (atrial) the rated sine^2 sensing threshold.

[d] This setting applies to all sensing in this chamber, for both tachyarrhythmia detection and bradycardia pacing operations.

15.5.5 System maintenance parameters

Table 21. System maintenance parameters

Parameter	Programmable values	Shipped	Nominal	Reset
Automatic Capacitor Formation Interval	Auto, 1, 2, …, 6 months	Auto[a]	Auto	Auto
Patient Alert time	enter time in hours and minutes	8:00 am	—	8:00 am
Impedance patient alerts				
A. Pacing lead	On, Off	Off	On	Off
Minimum Threshold	200, 300, 400, 500 Ω	200 Ω	200 Ω	200 Ω
Maximum Threshold	1000, 1500, 2000, 3000 Ω	3000 Ω	3000 Ω	3000 Ω
V. Pacing lead	On, Off	Off	On	Off
Minimum Threshold	200, 300, 400, 500 Ω	200 Ω	200 Ω	200 Ω
Maximum Threshold	1000, 1500, 2000, 3000 Ω	3000 Ω	3000 Ω	3000 Ω
V. Defibrillation lead	On, Off	Off	On	Off
Minimum Threshold	20, 30, 40, 50 Ω	20 Ω	20 Ω	20 Ω
Maximum Threshold	100, 130, 160, 200 Ω	200 Ω	200 Ω	200 Ω
SVC (HVX) Defibrillation lead	On, Off	Off	On	Off
Minimum Threshold	20, 30, 40, 50 Ω	20 Ω	20 Ω	20 Ω
Maximum Threshold	100, 130, 160, 200 Ω	200 Ω	200 Ω	200 Ω
Lead impedance alert urgency	Low, High	—	Low	—

Table 21. System maintenance parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
Low Battery Voltage ERI patient alert	Off, On-Low, On-High	Off	On-Low	Off
Excessive Charge Time ERI patient alert	Off, On-Low, On-High	Off	On-Low	Off
Number of Shocks Delivered in an Episode patient alert	Off, On-Low, On-High	Off	On-Low	Off
Number of Shocks threshold	1, 2, …, 6	3	3	3
All Therapies in a Zone Exhausted for an Episode patient alert	Off, On-Low, On-High	Off	On-Low	Off
VF Detection/Therapy Off [b]	Off, On-High	On-High	On-High	On-High

[a] Automatic Capacitor Formation is disabled until VF Detection is set to On for the first time.

[b] When this alert is turned on, it does not sound when a magnet is applied unless VF detection or more than two VF therapies are turned off.

15.5.6 Data collection parameters

Table 22. Data collection parameters

Parameter	Programmable values	Shipped	Nominal	Reset
EGM Channel 1 Source	Can to HVB, Can to Vring, Can to Aring, Vtip to HVB, Vtip to Vring, Atip to Vring, Atip to Aring, Can to HVX, [a] HVB to HVX [a]	Atip to Aring	Atip to Aring	Atip to Aring
EGM Channel 1 Range	±2, ±4, ±8, ±16 mV	±8 mV	±8 mV	±8 mV
EGM Channel 2 Source	Can to HVB, Can to Vring, Vtip to HVB, Vtip to Vring, Can to HVX, [a] HVB to HVX [a]	Vtip to Vring	Vtip to Vring	Vtip to Vring
EGM Channel 2 Range	±2, ±4, ±8, ±16 mV	±8 mV	±8 mV	±8 mV
Store EGM Channel 1? [b]	Yes, No	Yes	Yes	Yes
Store EGM Channel 2	Yes (fixed)	—	—	—
Store EGM during charging?	Yes, No	Yes	Yes	Yes
Store EGM before tachycardia starts?	Yes, No	No	No	No
Device Date/Time [c]	(enter time and date)	—	—	—

Table 22. Data collection parameters (continued)

Parameter	Programmable values	Shipped	Nominal	Reset
Premature Event Threshold	56, 59, 62, 66, 69, …, 84, 88, 91, 94, 97%	69%	69%	69%
Holter Telemetry Duration	Off, 0.5, 1, 2, 4, 8, 16, 24, 36, 46 hours	Off	Off	Off

[a] An SVC lead must be present for this configuration.
[b] Both channels are available as real-time telemetered signals, regardless of this setting.
[c] The time stamp on episode records and other stored data is determined by the device's date/time clock.

15.5.7 System test and EP study parameters

Table 23. System test and EP study parameters

Parameter	Selectable values	Default
Pacing threshold test parameters		
Test Type	Pulse Width - Auto Dec, Manual	Pulse Width - Auto Dec
Chamber	Atrium, Ventricle	Ventricle
Mode (atrial test) [a]	AAI, DDI, DDD	DDD [b]
Mode (ventricular test) [a]	VVI, DDI, DDD	VVI [b]
Lower Rate	30, 35, …, 60, 70, 75, …, 150 ppm [c]	90 ppm
AV Delay	30, 40, …, 350 ms	150 ms [b]
V. Amplitude [d]	0.5, 1, …, 4, 5, 6 V	3 V [b]
V. Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	0.4 ms [b]
V. Pace Blanking	150, 160, …, 440 ms	200 ms [b]
A. Amplitude [d]	0.5, 1, …, 4, 5, 6 V	3 ms [b]
A. Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	0.4 ms [b]
A. Pace Blanking	150, 160, …, 250 ms	200 ms [b]
PVARP	150, 160, …, 500 ms	310 ms [b]
EGM Amplitude test parameters		
Mode [e]	ODO, AAI, VVI, DDI, DDD	—
AV Delay	30, 40, …, 350 ms	250 ms
Lower Rate	30, 35, …, 60, 70, 75, …, 120 ppm [b]	—
T-Shock induction parameters		
#S1	2, 3, …, 8	8
S1S1	300, 310, …, 2000 ms	400 ms
Delay	50, 60, …, 600 ms	310 ms
Energy	0.4, 0.6, …, 1.8, 2, 3, …, 16, 18, 20, …, 30 J	0.6 J
Pathway	AX>B, B>AX	AX>B
Waveform	Monophasic, Biphasic	Monophasic
Pulse Amplitude [d]	8 V (fixed)	—

Table 23. System test and EP study parameters (continued)

Parameter	Selectable values	Default
Pulse Width	1.6 ms (fixed)	—
Enable	Enabled, Disabled	Disabled
Resume at Deliver	Enabled, Disabled	Enabled
50 Hz Burst Induction Parameters		
Interval	20 ms (fixed)	—
Pulse Amplitude [d]	0.5, 1, …, 4, 5, 6, 8 V	8 V
Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	1.6 ms
Resume at Burst	Enabled, Disabled	Enabled
Manual Burst Induction Parameters		
Chamber	Ventricle, Atrium	Ventricle
Interval	100, 110, …, 600 ms	600 ms
Pulse Amplitude [d]	0.5, 1, …, 4, 5, 6, 8 V	4 V
Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	0.5 ms
Resume at Burst	Enabled, Disabled	Enabled
VVI Backup	On, Off	Off
VVI Backup Pacing Rate	30, 35, …, 120 ppm	60 ppm
VVI Backup Amplitude [d]	0.5, 1, …, 4, 5, 6 V	4 V [b]
VVI Backup Pulse Width	0.03, 0.06, 0.1, 0.2, …,1.6 ms	0.5 ms [b]
PES Induction Parameters		
Chamber	Ventricle, Atrium	Ventricle
#S1	1, 2, …, 15	8
S1S1	100, 110, …, 2000 ms	600 ms
S1S2	Off, 100, 110, …, 600 ms	400 ms
S2S3	Off, 100, 110, …, 600 ms	Off
S3S4	Off, 100, 110, …, 600 ms	Off
Pulse Amplitude [d]	0.5, 1, …, 4, 5, 6, 8 V	4 V
Pulse Width	0.03, 0.06, 0.1, 0.2, …, 1.6 ms	0.5 ms
Resume at Deliver	Enabled, Disabled	Enabled
VVI Backup	On, Off	Off
VVI Backup Pacing Rate	30, 35, …, 120 ppm	60 ppm
VVI Backup Amplitude [d]	0.5, 1, …, 4, 5, 6 V	4 V [b]
VVI Backup Pulse Width	0.03, 0.06, 0.1, 0.2, …,1.6 ms	0.5 ms [b]

Table 23. System test and EP study parameters (continued)

Parameter	Selectable values	Default
Manual therapy parameters		
In general, each manual therapy provides the same parameter values as the automatic therapy. See Table 19.		

[a] The selectable values for this parameter depend on the programmed pacing mode.

[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing if the device has been interrogated. Otherwise it defaults to the indicated nominal value.

[c] The maximum range value is dependant on the programmed pacing mode.

[d] Peak pacing amplitude. When tested per CENELEC standard 45502-2-1, the measured amplitude A depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$.

[e] Delivered energy based on a biphasic pulse into a 75 Ω load. For energy less than 1 J, tolerance is ±0.25 J.

15.5.8 Fixed parameters

Table 24. Fixed parameters

Parameter	Fixed value
Fixed blanking periods	
Atrial blanking after a sensed atrial event	100 ms
Atrial blanking after a paced ventricular event	30 ms
Atrial blanking after high voltage therapy	520 ms
Ventricular blanking after a sensed ventricular event	120 ms
Ventricular blanking after a paced atrial event	30 ms
Ventricular blanking on a high voltage pulse delivery	520 ms
Fixed bradycardia pacing parameters	
Ventricular Safety Pacing intervals	110 ms, 70 ms [a]
PVC Response (PVARP extension)	Extended to 400 ms [b]
PMT Intervention (PVARP extension)	Extended to 400 ms [b]
Fixed high voltage therapy parameters	
Maximum charging period	30 s
Waveform	Biphasic
Tilt	50%
Refractory period after V-sense during cardioversion synchronization	200 ms
Refractory period after charge end	100 ms
Refractory period after paced event during charging or synchronization [c]	400 ms
Refractory period after charge begins [c]	400 ms
Atrial Vulnerable Period	250 ms
Escape interval after high voltage therapy	1200 ms

Table 24. Fixed parameters (continued)

Parameter	Fixed value
Suspension of VT detection after defibrillation therapy	17 V. events
Fixed EP Study parameters	
T-Shock pacing amplitude [d]	8 V
T-Shock pacing pulse width	1.6 ms
50 Hz burst pacing interval	20 ms
Hardware parameters	
Atrial rate limit (protective feature)	171 ppm [e]
Ventricular rate limit (protective feature)	171 ppm [e]
Input impedance	100 kΩ minimum

[a] The shorter VSP interval takes effect when the pacing rate exceeds the results of the following formula: 60000 / 2 x (Ventricular Pace Blanking + 110) per min.

[b] PVARP is only extended to 400 ms if the current PVARP (either the programmed PVARP value or the current Sensor-Varied PVARP value) is less than 400 ms.

[c] Does not affect event classification during charging.

[d] Peak pacing amplitude. When tested per CENELEC standard 45502-2-1, the measured amplitude A depends upon the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times [0.9 – (W_p \times 0.145\ ms^{-1})]$.

[e] Does not apply during therapies, programmed high rates, or ventricular safety pacing.

REGULATORY LABELING REQUIREMENTS

The transmitter covered by this manual has been certified under FCC ID:LF5MICSIMPLANT2 and IC:3408D-MIMPLANT2.

CE

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

This device may not interfere with stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

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Printing instructions: doc#xxxxxx; refer to 'Implant manuals' row in the applicable table.

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