SQ-RX™ PULSE GENERATOR
A COMPONENT OF THE S-ICD® SYSTEM
USER'S MANUAL
MODEL 1010

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Table of Contents

Table of Contents (Continued)

SQ-RX PULSE GENERATOR GENERAL DESCRIPTION

Description

The SQ-RX Pulse Generator (the "device") is a component of the Cameron Health S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. Implanted with the Q-TRAK Subcutaneous Electrode (the "electrode"), the device detects cardiac activity and provides defibrillation therapy.

Indications for Use

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias.

Contraindications

The S-ICD System is contraindicated for patients with symptomatic bradycardia, incessant ventricular tachycardia and patients with documented spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Unipolar pacemakers are contraindicated for use with the S-ICD System.

Warnings and Cautions

Before using the S-ICD System, read and follow all warnings and cautions provided in this manual.

The S-ICD System contains sterile products for single use only. Do not resterilize.
Handle the S-ICD System with care at all times and maintain proper sterile technique.

All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver life saving defibrillation therapy.

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response. Refer to the S-ICD System Magnet Model 4520 section.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.

SQ-RX PULSE GENERATOR GENERAL DESCRIPTION

SQ-RX Pulse Generator Packaging

The device has been sterilized with ethylene oxide gas and is packaged in a sterile container that is suitable for use in the operating field. Store in a clean, dry area. Each package contains the following:

- One SQ-RX Pulse Generator Model 1010
- One Bi-Directional Torque Wrench
- SQ-RX Pulse Generator Model 1010 User's Manual

Before opening any package, visually inspect the sterile packaging to ensure the contents are not contaminated or been previously used. Do not use if any of the following conditions exist:

- Tears or punctures in the packaging
- "Use By" date has expired
- Evidence of damage exists
- Sterile package is dropped from a height of 24 in/61 cm or greater

Return the product to Cameron Health if any of these conditions exist. Contact your local Cameron Health representative or Customer Service Department for instructions and return packaging.

Storage and Handling

- Store the S-ICD System components in a clean, dry area away from magnets or any other electromagnetic interference source that could cause damage to the device.
- Do not expose the S-ICD System to temperatures outside the recommended storage temperatures indicated on the device package.
- Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Impairment to the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.

Implant and Programming

- Use only the electrode insertion tool to tunnel.
- Suture only those areas indicated in the implant procedure.
- Do not place a suture directly on the electrode body.
- Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- Use only the Q-TECH Programmer (the "programmer") and appropriate software for communicating with and programming the device.

- Verify the device is in Shelf mode or Therapy Off to prevent the delivery of unwanted shocks to the patient or the person handling the device during the implant procedure.

Explanting the System

- To avoid inadvertent shock discharges, program the device to Therapy Off during device explantation or postmortem procedures.
- Remove the device from a deceased patient prior to cremation. The device battery may explode when exposed to extreme temperatures.

Use of Other Medical Therapies/Diagnostic Procedures

- External defibrillation or cardioversion may damage the implanted SQ-RX Pulse Generator. Current flow through the SQ-RX Pulse Generator may be minimized by avoiding the placement of defibrillation paddles directly over the device.
- Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted SQ-RX Pulse Generator can damage the SQ-RX Pulse Generator and cause patient injury.
- Do not expose the patient to MRI scanning. MRI scanning can damage the SQ-RX Pulse Generator and cause patient injury.
- Electrical interference or "noise" from sources such as electrosurgical and monitoring equipment can interfere with the communication between the programmer and the SQ-RX Pulse Generator or cause inappropriate therapy. If interference occurs, move the programmer away from the source of the interference.
- Ionizing radiation therapy, such as radioactive cobalt, linear accelerators, and betatrons, may adversely affect the S-ICD System operation. Therapeutic ionizing radiation may not be immediately detected; however, it can damage the electronic components of the SQ-RX Pulse Generator. Follow these conditions to minimize the risks of ionizing radiation:
  - Shield the SQ-RX Pulse Generator with a radiation-resistant material, regardless of the distance between the SQ-RX Pulse Generator and the radiation beam.
  - Do not project the radiation port directly at the SQ-RX Pulse Generator.
  - Always evaluate the S-ICD System operation following each radiation treatment.
- Lithotripsy and other therapeutic forms of ultrasound may damage the SQ-RX Pulse Generator. If required, avoid direct flow of the pulse waves near the site of the implanted device.
- Use caution during ablation procedures. Program the S-ICD System to Therapy Off. Keep the current path (electrode tip to ground) as far away as possible from the implanted SQ-RX Pulse Generator and electrode.

SQ-RX PULSE GENERATOR GENERAL DESCRIPTION

Electromagnetic Interference (EMI) Outside of the Hospital Environment

Exposure to Electromagnetic Interference (EMI) or Static Magnetic Field sources may suspend tachyarrhythmia detection and cause temporary inhibition of therapy delivery. EMI may also trigger delivery of a shock in the absence of a tachyarrhythmia. Automatic sensing and detection of tachyarrhythmias will resume when the patient moves away from the EMI or static magnetic field source.

To minimize the risk, advise patients to avoid sources of EMI or static magnetic fields having strengths >10 gauss or 1 mTesla.

- Sources of EMI include, but are not limited to:
  - High-voltage power lines
  - Arc welding equipment
  - Electrical smelting furnaces
  - Large radio-frequency transmitters (such as radar)
  - Alternators on running engines in automobiles
  - Communications equipment (such as high-power radio transmitters)
- Sources of strong static magnetic fields may include the following:
  - Industrial transformers and motors
  - Large stereo speakers
  - Magnetic wands, such as those used for airport security

Patients should seek medical guidance from their physician before entering an area where a posted sign prohibits patients with an implantable cardioverter defibrillator or pacemaker.

Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following:

- Acceleration of arrhythmia
- Allergic reaction
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Electrode dislodgement
- Electrode insulation failure
- Electrode deformation and/or breakage
- Erosion/extrusion
- Improper electrode connection to the device
- Inappropriate shock delivery

- Infection
- Hematoma
- Hemothorax
- Keloid formation
- Migration or dislodgement
- Muscle stimulation
- Nerve damage
- Pneumothorax
- Postoperative discomfort
- Potential mortality due to inability to defibrillate or pace
- Premature battery depletion
- Random component failures
- Tissue necrosis
- Ventricular arrhythmia

If any adverse events occur, invasive corrective action and/or S-ICD System modification or removal may be required.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following:

- Depression
- Fear of shocks
- Phantom shocks

Clinical Studies

Results

Results

Observed Adverse Events

SQ-RX PULSE GENERATOR GENERAL DESCRIPTION

Patient Screening

The patient screening tool (Figure 1) is a customized measurement tool made of transparent plastic printed with colored profiles. The profiles are designed to ensure appropriate device performance by identifying signal characteristics that may lead to unsatisfactory detection outcomes for a patient before implant.

The patient screening tool can be obtained from any Cameron Health representative or by calling the Customer Service Department.

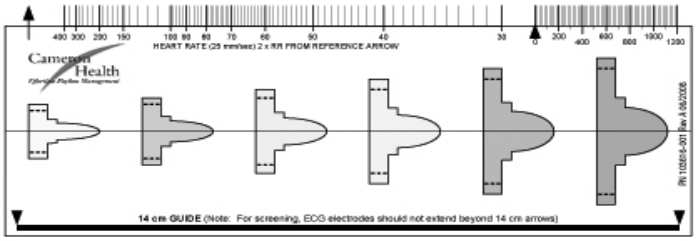

Figure 1: *Patient Screening Tool*

Instructions for using the screening tool:

1. Place standard ECG skin electrodes according to Figure 2. This will simulate the three sensing vectors used by the device.
   - Electrode LL should be placed in a lateral location, at the 5th intercostal space along the mid-axillary line.
   - Electrode LA should be placed 1 cm to the left of the patient's xiphoid.
   - Electrode RA should be placed 14 cm superior to the LA electrode, 1 cm left lateral of the sternal margin.

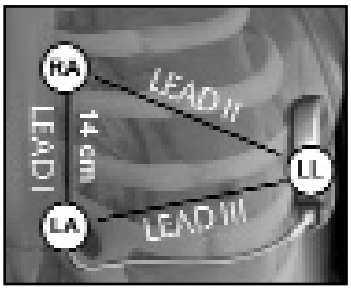

Figure 2: *Placement of ECG Leads*

2. Record 10 - 20 seconds of ECG using a sweep speed of 25 mm/sec and ECG gain between 5 - 20 mm/mV (use the largest ECG gain that does not result in clipping).
3. Record ECG signals in at least two postures: (1) Supine and (2) Standing.
4. Select a representative QRS complex from the first sense vector.

   Note: *If multiple morphologies are noted (e.g., bigeminy, pacing, etc.), all morphologies should be tested as described below before the vector is deemed acceptable.*
5. Select the colored profile from the Patient Screening Tool that best matches the amplitude of the QRS from Step 4. The QRS peak must fall within the window bounded by the dotted line and the peak of the colored profile (Figure 3). For biphasic signals, the larger peak should be used to determine the appropriate colored profile.

   Note: *ECG gains > 20 mm/mV are not permitted. If when printed at the maximum 20 mm/mV gain the QRS peak does not reach the minimum boundary (dotted line) of the smallest colored profile, the vector should be deemed unacceptable.*

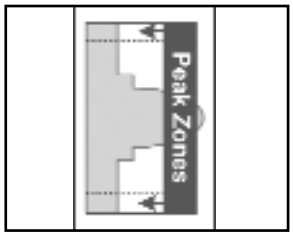

Figure 3: *Determine colored profile for QRS amplitude*

6. Align the left edge of the selected colored profile with the onset of the QRS complex and the horizontal line with the complex's isoelectric baseline.
7. If the entire QRS complex and trailing T-wave are contained within the colored profile, the vector/posture combination is deemed acceptable. If any portion of the QRS complex or trailing T-wave extends above or below the colored profile, the sense vector is deemed unacceptable (Figure 4).

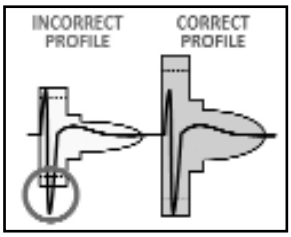

Figure 4: *QRS profile selection*

8. Test all vectors in each posture.
9. A patient should be considered suitable for implant if at least one sense vector is deemed acceptable for all tested postures (Figure 5).

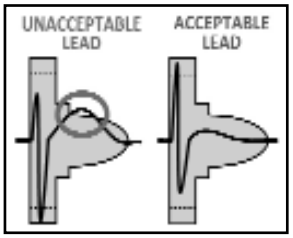

Figure 5: *Acceptance of one sense vector*

SQ-RX PULSE GENERATOR OPERATION

General

The S-ICD System is designed for ease of use and simplicity of patient management. The arrhythmia detection system employs up to two rate zones, and the device has a single automatic response to a detected ventricular tachyarrhythmia – a nonprogrammable, maximum-energy, biphasic shock of 80 J. The device has a number of automatic functions designed to reduce the amount of time required for implantation, initial programming and patient follow-up.

Modes of Operation

The device has three modes of operation:

- Shelf
- Therapy On
- Therapy Off

Shelf Mode

The Shelf mode is a low power consumption state intended for storage only. When communication is initiated between the device and the programmer, a full-energy capacitor reformation is performed and the device is prepared for set-up. Once the device is taken out of Shelf mode, it cannot be reprogrammed back into Shelf mode.

Therapy On Mode

The Therapy On mode is the primary operating mode of the device, allowing automatic detection of and response to ventricular tachyarrhythmias. All device features are active.

> ***Note:*** *The device must be programmed out of Shelf mode before being programmed to Therapy On.*

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Therapy Off Mode

The Therapy Off mode disables automatic therapy delivery and enables manual control of shock delivery. Programmable parameters may be viewed and adjusted via the programmer. Also, the subcutaneous electrogram (S-ECG) may be displayed or printed.

The device automatically defaults to Therapy Off when taken out of Shelf mode.

> ***Note:*** *Manual and rescue shock therapy are available only after the initial Setup process is complete. Refer to the Q-TECH Programmer User's Manual for details.*

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Sensing Configuration and Gain Selection

During the Automatic Setup process, the device automatically selects an optimal sensing vector based on an analysis of cardiac signal amplitude and signal-to-noise ratio. This analysis is performed on the three available vectors:

- Primary: Sensing from the proximal electrode ring on the electrode to the active surface of the device.
- Secondary: Sensing from the distal sensing electrode ring on the electrode to the active surface of the device.
- Alternate: Sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the electrode.

The sensing vector can also be selected manually. The Q-TECH Programmer User's Manual provides instructions for sensing vector selection.

The device automatically selects an appropriate gain setting during the Automatic Setup process. The gain can also be manually selected, as further explained in the Q-TECH Programmer User's Manual. There are two gain settings:

- 1x Gain (±4 mV): Selected when the signal amplitude is clipped at the 2x gain setting.
- 2x Gain (±2 mV): Selected when the signal amplitude is not clipped at this setting.

Sensing and Tachyarrhythmia Detection

The device is designed to prevent inappropriate therapy delivery as a result of noise sensing or multiple counting of individual cardiac cycles. This is accomplished by an automatic analysis of sensed signals, which includes event detection, certification and decision phases.

Detection Phase

During the Detection Phase, the device uses a detection threshold to identify sensed events. The detection threshold is automatically adjusted continuously using amplitudes of recently detected electrical events. In addition, detection parameters are modified to increase sensitivity when rapid rates are detected. Events detected during the Detection Phase are passed on to the Certification Phase.

Certification Phase

The Certification Phase examines the detections and classifies them as certified cardiac events or as suspect events. Certified events are used to ensure that an accurate heart rate is passed to the Decision Phase. A suspect event can be one whose pattern and/or timing indicates the signal is caused by noise, such as a muscle artifact or some other extraneous signal. Events are also marked as suspect if they appear to derive from double or triple detections of single cardiac events. The device is designed to identify and correct multiple detections of wide QRS complexes and/or erroneous detections of a T-wave.

Decision Phase

The Decision Phase examines all certified events and continuously calculates a running four R-to-R interval average (4 RR average). The 4 RR average is used throughout the analysis as an indicator of the heart rate.

Therapy Zones

The device allows the selection of rate thresholds that define a Shock Zone and an optional Conditional Shock Zone. In the Shock Zone, rate is the only criterion used to determine if a rhythm will be treated with a shock. The Conditional Shock Zone has additional discriminators used to determine if a shock is warranted to treat an arrhythmia.

The Shock Zone is programmable from 170 - 250 bpm in increments of 10 bpm. The Conditional Shock Zone must be lower than the Shock Zone, with a range of 170 - 240 bpm in increments of 10 bpm.

Graphically, the use of a Shock Zone and Conditional Shock Zone is shown in Figure 6.

Figure 6: Shock Zone Rate Detection Diagram

The device declares a Tachycardia when the 4RR average enters either therapy zone.

Once a Tachycardia is declared, the 4RR average must become longer (in ms) than the lowest rate zone, plus 40 ms for 24 cycles for the device to consider the episode to have ended. In the Shock Zone, treatable arrhythmias are determined by rate alone.

Analysis in the Conditional Shock Zone

In contrast, rate and morphology are analyzed in the Conditional Shock Zone. The Conditional Shock Zone is designed to discriminate between treatable and other high-rate events such as atrial fibrillation, sinus tachycardia and other supraventricular tachycardias.

A normal sinus rhythm template (NSR Template) is formed during device initialization. This NSR template is used during analysis in the Conditional Shock Zone to identify treatable arrhythmias. In addition to morphology comparison with the NSR template, other morphologic analysis is used to identify polymorphic rhythms. Morphology and QRS width are used to identify monomorphic arrhythmias such as ventricular tachycardia. If the Conditional Shock Zone is enabled, then an arrhythmia is found to be treatable according to the decision tree shown in Figure 7.

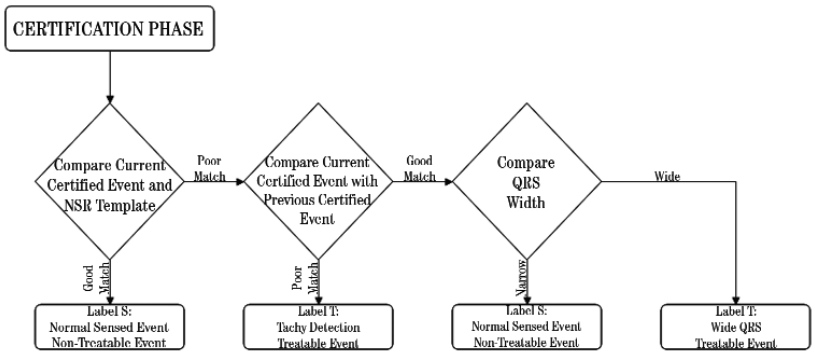

Figure 7: Decision tree for determining treatable arrhythmias in the Conditional Shock Zone

For some patients, a NSR Template may not be formed during device initialization as a result of variability in their cardiac signal at resting heart rates. For such patients, the device uses beat-to-beat morphology and QRS width analysis for arrhythmia discrimination.

Charge Confirmation

The device must charge the internal capacitors before shock delivery. Confirmation of the ongoing presence of a tachyarrhythmia requires monitoring a moving widow of the 24 most recent intervals defined by certified events. Charge confirmation employs an X (treatable interval) out of Y (total intervals in the window) strategy to accomplish this. If 18 of the 24 most recent intervals are found to be treatable, the device begins to analyze rhythm persistence. Persistence analysis requires the X out of Y condition be maintained or exceeded for at least two consecutive intervals; however, this value may be increased as a result of Smart Charge, as explained below.

Capacitor charging is initiated when the following three conditions are met:

1. X of Y criterion met
2. Persistence requirement is met
3. The last two certified intervals are in the treatable zone.

Therapy Delivery

Rhythm analysis continues throughout the capacitor charging process. Capacitor charging is aborted if the 4 RR average interval becomes longer (in ms) than the lowest rate zone, plus 40 ms for 24 intervals. When this occurs, an untreated episode is declared and a Smart Charge extension is incremented, as explained below.

Capacitor charging continues until the capacitor has reached its target voltage, at which time reconfirmation is performed. Reconfirmation requires the last three consecutive detected intervals (regardless of whether the intervals are certified or suspect) to be faster than the lowest therapy zone.

Reconfirmation is always performed and shock delivery is non-committed until reconfirmation is complete. Once the criteria for reconfirmation is met, the shock is delivered.

Smart Charge

Smart Charge is a feature that automatically increases the Persistence requirement by three intervals each time an untreated episode is declared, up to a maximum of five extensions. Thus, after an untreated episode, the requirement to start capacitor charging becomes more stringent. The Smart Charge extension value can be reset to its nominal value (zero extensions) using the programmer. The Smart Charge feature cannot be disabled, though it is not used for the second and later shocks that occur during any given episode.

Redetection

A blanking period is enabled following delivery of a high-voltage shock. After delivery of the first shock, up to four additional shocks will be delivered if the episode does not terminate. Rhythm analysis for delivering shocks 2 - 5 generally follows the detection steps described above, with the following exceptions:

1. Following the first shock delivery, the X/Y criterion is modified to require 14 treatable intervals in the last 24 (14/24), rather than 18.
2. The Persistence Factor is always set to two intervals (i.e., not modified by the Smart Charge feature).

Shock Waveform and Polarity

The shock waveform is biphasic, with a fixed tilt of 50%. The shock is delivered synchronously unless a 1000 ms time out expires without an event being detected for synchronization, at which time the shock is delivered in an asynchronous manner.

The device is designed to automatically select the appropriate polarity for therapy. Both

standard and reversed polarity shocks are available. If a shock fails to convert the arrhythmia and subsequent shocks are required, polarity is automatically reversed for each successive shock. The polarity of the successful shock is then retained as the starting polarity for future episodes. Polarity can also be selected during the Induction and Manual Shock process to facilitate device-based testing.

Post-Shock Bradycardia Pacing Therapy

The device provides optional post-shock, on-demand bradycardia pacing therapy. When enabled via the programmer, bradycardia pacing occurs at a non-programmable rate of 50 bpm for up to 30 seconds. The pacing output is fixed at 200 mA, and uses a 15-ms biphasic waveform.

Pacing is inhibited if the intrinsic rate is greater than 50 bpm. In addition, post-shock pacing is terminated if a tachyarrhythmia is detected or a magnet is placed over the device during the post-shock pacing period.

Manual and Rescue Shock Delivery

Upon programmer command, the device can deliver manual and rescue shocks. Manual shocks are programmable from 10 to 80 J delivered energy in 5 J steps. Rescue shocks are non-programmable, delivering the maximum output of 80 J.

Note: *The Rescue Shock will NOT be inhibited with magnet application.*

Additional Features of the S-ICD System

This section presents descriptions of several additional features available in the S-ICD System.

Magnet Application

Application of the S-ICD System Magnet over the device will:

- Suspend arrhythmia detection
- Inhibit shock therapy delivery except for a programmer-commanded Rescue Shock
- Terminate post-shock pacing therapy
- Prohibit arrhythmia induction testing
- Activate the device's beeper with each detected QRS complex for 60 seconds

Note: *Magnet application does not affect wireless communication between the device and the programmer.*

Auto Capacitor Reformation

The device automatically performs a full-energy (80 J) capacitor reformation when taken out of Shelf mode and every four months until the device reaches End of Life (EOL). The energy

output and reformation time interval are non-programmable.

The Auto Capacitor Reformation interval is reset after any 80 J capacitor charge is delivered or aborted.

Internal Warning System – Beeper Control

The device has an internal warning system (beeper) that emits an audible tone to alert the patient to certain device conditions that require prompt consultation with the physician. These conditions include:

- Elective Replacement Indicator (ERI)
- Electrode impedance out of range
- Prolonged charge times
- Failed Device Integrity Check

This internal warning system is automatically activated at time of implant. Once triggered, the beeper sounds for 16 seconds every nine hours until the trigger condition has been resolved. If the triggering condition reoccurs, then the tones will once again alert the patient to consult the physician. The beeper can be disabled via the programmer once ERI is reached.

> ***Note:*** *The beeper also sounds with each certified QRS complex when a magnet is positioned over the device.*

Arrhythmia Induction

The device facilitates testing by providing the capability to induce a ventricular tachyarrhythmia. Via the programmer, the implanted system can deliver a 200 mA output at a frequency of 50 Hz. The maximum length of stimulation is 10 seconds.

> ***Note:*** *Induction requires that the device be programmed to Therapy On.*

System Diagnostics

The S-ICD System automatically performs a diagnostic check at scheduled intervals.

Electrode Impedance

Electrode impedance is measured each time a shock is delivered. In addition, a lead electrode integrity test is performed once a week. The shock impedance values are stored and displayed in the episode data and summary report.

> ***Note:*** *If the device is taken out of Shelf mode, but not implanted, the internal warning system will be activated due to the weekly automatic measurements of impedance. Device beeping due to this mechanism is normal behavior.*

Device Integrity Check

The Device Integrity Check is automatically performed daily by the implanted system, and

also each time the programmer links to an implanted device. This test scans for any unusual conditions in the device, and if any are detected, the system provides a notification either via the device's internal warning system or on the programmer screen.

Battery Monitoring

The device automatically monitors battery status to provide notice of impending battery depletion. Two indicators are provided via messages on the programmer, each activated by declining battery voltage. ERI is also signaled by activation of the device's beeper.

- Elective Replacement Indicator (ERI): When the ERI is detected, the device will provide therapy for at least three months, if no more than five maximum energy charges/shocks occur. The patient should be scheduled for replacement of the device.
- End of Life (EOL): When the EOL indicator is detected, the device should be replaced immediately. Therapy may not be available when EOL is declared.

Storing and Analyzing Data

The device stores S-ECGs for up to 24 treated and 20 untreated tachyarrhythmia episodes. The number of treated episodes, untreated episodes, and the therapy shocks delivered since the last follow-up procedure and initial implant are recorded and stored. Through wireless communication with the programmer, the stored data is retrieved for analysis and report printouts.

> ***Note:*** *Episodes that occur during communication with the programmer will not be stored.*

Treated Episodes

Up to 128 seconds of S-ECG data is stored for each treated episode:

- First Shock: 44 seconds of pre-episode, up to 24 seconds of pre-shock, up to 12 seconds of postshock S-ECG.
- Subsequent Shocks: A minimum of 6 seconds of pre-shock and up to 6 seconds post-shock S-ECG.

Untreated Episodes

For untreated episodes, 44 seconds of pre-episode and up to 24 seconds of episode S-ECG are stored. A return to normal sinus rhythm during an untreated episode halts S-ECG storage.

Captured S-ECG

The S-ECG can be captured in real time on rhythm strips when the device is actively linked via wireless telemetry to the programmer. Up to five 12-second recordings of S-ECG can be stored.

S-ECG Rhythm Strip Markers

The system provides S-ECG annotations to identify specific events during a recorded episode. These markers are shown in Table 1; sample annotations are shown for the programmer display (Figure 8) and the printed reports (Figure 9).

Table 1: S-ECG Rhythm Strip Markers

Description	Marker	Display Screen	Printed Reports
Charging	C	X	✓
Sensed Beat	S	✓	✓
Noisy Beat	N	✓	✓
Paced Beat	P	✓	✓
Tachy Detection	T	✓	✓
Discard Beat	•	✓	✓
Shock		✓	✓
Return to NSR		X	✓

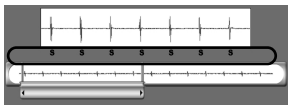

Figure 8: *Display Screen Markers*

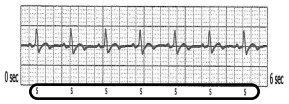

Figure 9: *Printed Report Markers*

Patient Data

The device can store the following patient data, which can be retrieved and updated through the programmer:

- Patient's name
- Physician's name and contact information
- Device and electrode identification information (model and serial numbers) and implant date
- Notes up to 50 characters

S-ICD System Magnet Model 4520

The Cameron Health magnet is a nonsterile accessory used to inhibit the delivery of therapy from the device. Placing the magnet against the skin directly over the implanted device (Figure 10) will temporarily inhibit rhythm detection, abort high-voltage capacitor charging and post-shock pacing. Removal of the magnet will return the device to normal operation. If the magnet is applied during an episode, the episode will not be stored in the device memory.

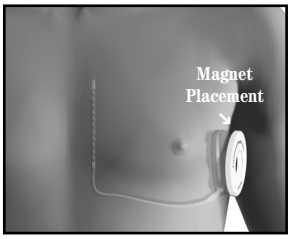

Figure 10: *Magnet Model 4520*

SQ-RX PULSE GENERATOR USING THE SQ-RX GENERATOR

This section presents the information necessary for implanting and testing the S-ICD System, including:

- Implanting the SQ-RX Pulse Generator (the "device")
- Implanting the Q-TRAK Subcutaneous Electrode (the "electrode") using the Q-GUIDE Subcutaneous Electrode Insertion Tool (the "EIT")
- Setting up and testing the device using the Q-TECH Programmer (the "programmer"). Refer to the Q-TECH Programmer User's Manual for additional information.

Implanting the S-ICD System

The device and electrode are implanted subcutaneously in the left thoracic region (Figure 11). The EIT is used to create the subcutaneous tunnel in which the the electrode is inserted.

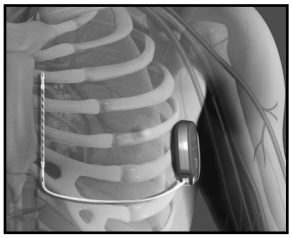

Figure 11: *Placement of the S-ICD System*

Creating the Device Pocket

The device is implanted in the left lateral thoracic region. To create the device pocket, make an incision such that the device can be placed in the vicinity of the left 5th and 6th intercostal spaces and near the mid-axillary line (Figure 12). This can be accomplished by making an incision along the inframammary crease.

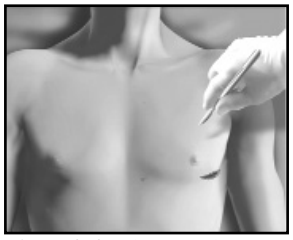

Figure 12: *Creating the device pocket*

Implanting the Q-TRAK Subcutaneous Electrode

There are two methods for implanting the electrode, referred to as the "Pull/Pull" and the "Pull/Push" techniques. The electrode tunneling is facilitated by the use of the Q-GUIDE model 4010 and/or 4020 Subcutaneous Electrode Insertion Tool.

Pull/Pull Implant

1. Make a small (approximately 1 cm) lateral incision 1 - 2 cm to the left and 1 cm superior to the xiphoid
2. Insert the distal tip of the EIT at the xiphoid incision and tunnel laterally until the distal tip emerges at the device pocket (Tunnel 1).
   Note: *The EIT is malleable and can be curved to match the patient's anatomical profile.*
3. Using conventional suture material, tie the distal end of the electrode to the EIT creating a loop knot that allows for free motion of both tips (Figure 13).

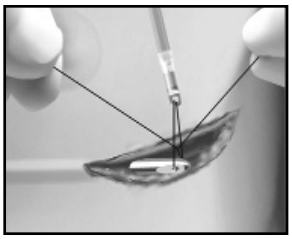

Figure 13: *Connecting distal end of electrode to the EIT*

4. With the electrode attached, carefully pull the EIT back through the tunnel to the xiphoid incision until the electrode emerges (Figure 14).
   Note: *Do not use surgical instructions to advance the electrode.*

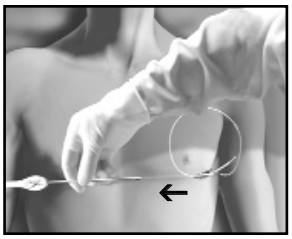

Figure 14: *Tunneling the electrode to the xiphoid incision*

5. Once the distal tip of the electrode is pulled through the tunnel, cut and discard the suture loop that connects the electrode to the EIT.
6. Make a second incision approximately 14 cm superior to the xiphoid incision and approximately 2 cm to the left of the sternal midline.
7. Insert the distal tip of the EIT into the new incision and tunnel subcutaneously in the caudad direction to the lower xiphoid incision (Tunnel 2, Figure 15).

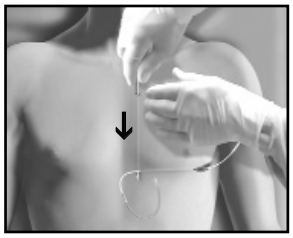

Figure 15: *Tunneling in the caudad direction*

8. Using conventional suture material, tie the distal end of the electrode to the EIT, creating a loop knot that allows for free motion of both tips.
9. With the electrode attached, carefully pull the EIT back through the tunnel until the electrode's distal tip emerges at the upper sternal incision. The electrode should be parallel to the sternum, approximately 2 cm to the left of the sternal midline.
10. Cut and discard the suture material.
11. Using conventional suture material, anchor the electrode through the anchor hole at the distal tip to the subcutaneous tissue to prevent possible device migration (Figure 16).

    Note: *If there is excess electrode body at the xiphoid incision, pull it through the tunnel to the device pocket.*

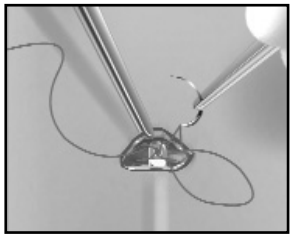

Figure 16: *Anchoring the distal electrode tip*

12. Optional: Secure a suture sleeve to the electrode at least 1 cm away from the proximal sensing electrode using the pre-formed grooves. Verify that the suture sleeve is stable with no slippage by grasping the suture sleeve with the fingers and trying to move the electrode in either direction. Anchor the electrode by suturing the suture sleeve to the subcutaneous tissue at the xiphoid incision (Figure 17).

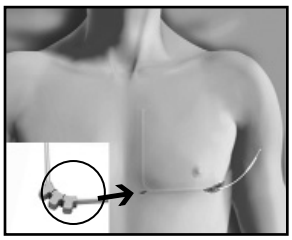

Figure 17: *Secure the electrode with a suture sleeve at the xiphoid incision*

13. To dispose of the EIT, return the used product to the original package, then dispose in a biohazard container.

Pull/Push Implant

1. Make a small (approximately 1 cm) lateral incision 1 - 2 cm to the left and 1 cm superior to the xiphoid.
2. Insert the distal tip of the EIT at the xiphoid incision and tunnel laterally until the distal tip emerges at the device pocket (Tunnel 1).

   Note: *The EIT is malleable and can be curved to match the patient's anatomical profile.*
3. Using conventional suture material, tie the distal end of the electrode to the EIT, creating a loop knot that allows for free motion of both tips (Figure 13).
4. With the electrode attached, carefully pull the EIT back through the tunnel to the xiphoid incision until the electrode emerges (Figure 14).

   Note: *Do not use surgical instruments to advance the electrode.*
5. Once the distal tip of the electrode is pulled through the tunnel, cut and discard the suture loop that connects the electrode to the EIT.
6. Place a 12 French peel-away introducer sheath over the Model 4020 EIT's shaft and secure to the luer-lock ring.

7. Starting at the xiphoid incision, create a cephalad tunnel (Tunnel 2) approximately 2 cm to the left of the sternal midline (Figure 18).

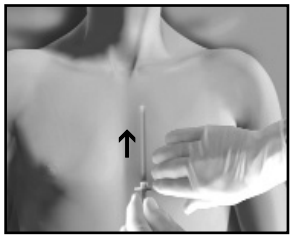

Figure 18: *Creating a cephalad tunnel parallel to the sternal line using the EIT & 12 Fr sheath*

8. Once the EIT is fully inserted in Tunnel 2, unlock the sheath from the luer-lock hub. Carefully withdraw the EIT while leaving the sheath in place.
9. Insert the distal tip of the electrode into the sheath and push through until the electrode's distal tip is in the desired location, approximately 14 cm superior to the xiphoid incision.
10. Stabilize the electrode's position during sheath removal by applying manual pressure over the electrode's distal tip. Grasp the tabs of the sheath and split while maintaining the implanted electrode position.
11. Secure a suture sleeve to the electrode at least 1 cm away from the proximal sensing electrode. Verify that the suture sleeve is stable with no slippage by grasping the suture sleeve with the fingers and trying to move the electrode in either direction. Anchor the electrode by suturing the suture sleeve to the subcutaneous tissue at the xiphoid incision (Figure 17).
12. Optional: Make a second incision at the point where the electrode distal tip anchor hole resides. Using conventional suture material, anchor the distal tip of the electrode through the anchor hole to the subcutaneous tissue to prevent possible device migration (Figure 16).
13. To dispose of the EIT, return the used product to the original package, then dispose in a biohazard container.

Connecting the Electrode to the Device

Note: *Avoid allowing blood or other body fluids to enter the connector port in the device header. If blood or other body fluids inadvertently enter the connector port, flush with sterile water.*

Note: *Do not implant the device if the set screw seal plug appears to be damaged.*

1. Insert the proximal end of the electrode into the connector port until it will no longer advance.

   Note: *Do not use surgical instruments to advance the electrode.*
2. Ensure that the electrode pin is protruding past the innermost connector ring in the connector cavity (Figure 19).

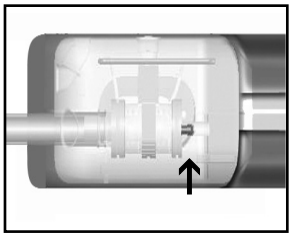

Figure 19: *Proper position for inserted electrode pin*

3. Use the torque wrench to tighten the set screw in a clockwise motion (Figure 20). The torque wrench is designed to apply the proper amount of force to the set screw. Tighten the set screw until the wrench ratchet clicks.

   Note: *When connecting the electrode to the device, use only the tools provided in the device tray. Failure to use the supplied tools may result in damage to the set screw. Retain the tools until all testing procedures are complete and the device is implanted.*

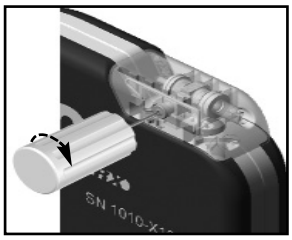

Figure 20: *Using torque wrench to tighten set screw*

4. Gently tug on the electrode body to confirm a secure connection.
5. Insert the device into the subcutaneous pocket, with any excess electrode placed underneath the device.

6. Anchor the device to subcutaneous tissue to prevent possible migration using conventional suture material. A suture hole is provided in the header for this purpose (Figure 21).

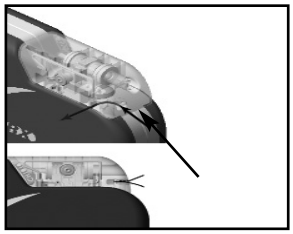

Figure 21: *Anchoring the device using header suture holes*

7. Refer to the Q-TECH Programmer User's Manual for set-up instructions and/or induction testing.
   Note: *Initial set-up is recommended at implant.*
8. After device set-up, close all incisions using standard suture protocol (Figure 22).

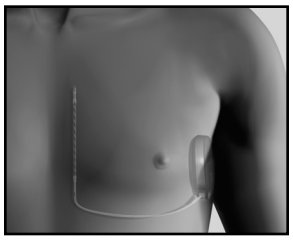

Figure 22: *System placement after closure of all incisions*

Setting Up the SQ-RX Pulse Generator

A brief Setup process must be completed before the device can deliver manual or automatic therapy. This process can be performed automatically or manually during the implant procedure, although Automatic Setup is recommended.

During Setup, the system automatically:

- Confirms entry of the subcutaneous electrode model and serial numbers
- Measures the shock electrode impedance
- Optimizes the sense electrode configuration
- Optimizes the gain selection
- Provides an option to acquire a reference NSR template

Instructions for completing this process can be found in the Q-TECH Programmer User's Manual.

Post Implant Follow-Up Procedures

During a follow-up procedure, it is recommended that the location of the electrode be periodically verified by palpation and or X-ray. When device communication with the programmer is established, the programmer automatically notifies the physician of any unusual conditions. Refer to the Q-TECH Programmer User's Manual for more information.

Patient management and follow-up are at the discretion of the patient's physician, but are recommended at least once a year and should be more frequent when the device is approaching end-of-life.

Explanting the S-ICD System

If a device explant is required, observe the following guidelines:

1. Use the programmer to ensure the device is programmed to Therapy Off.
2. Use a sterile no. 2 wrench to disconnect the electrode from the device.
3. Return the explanted device to Cameron Health, Inc. along with a completed Explant/Complication Reporting Form. Contact your local Cameron Health representative or Customer Service Department for instructions and return packaging.

SQ-RX PULSE GENERATOR COMPLIANCE

Federal Communications Commission (FCC) Compliance

This transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 - 406.00 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.

FCC ID SDYCHI1010

1999/5/EC Compliance (R&TTE Directive)

The S-ICD System contains radio equipment in the frequency range 402 MHz to 405 MHz for ultra low power active medical implants. The radio equipment in the S-ICD System complies with the applicable harmonized standards and essential requirements of the R&TTE Directive.

Specifications

Specifications provided at 37° C ± 3° C, and assume a 75W (± 1%) load unless noted otherwise.

Table 2: Physical Characteristics

Dimensions: Height x Width x Depth	78.2 mm x 65.5 mm x 15.7 mm
Mass	145 gm
Volume	69.9 cc
Longevity	Normal Use*: 5 years
ERI to EOL	3 months therapy if no more than 5 maximum-energy charges/shocks occur.
Radiopaque ID in Device Header	CH1010
SQ-RX Pulse Generator Storage and Shipping Range	Temp: 0° F or -18° C / +131° F or +55° C
Defibrillation/Pace/ Sense Ports	Cameron Health Proprietary Tripolar Connector
Pulse Generator Casing Material	Hermetically Sealed Titanium, Coated With Titanium Nitride
Connector Block Header	Implantation Grade Polymer
Battery	Lithium Manganese Dioxide

*Normal use is defined as three full-energy capacitor charges per year.

SQ-RX PULSE GENERATOR ADDITIONAL INFORMATION

Table 3: Programmable Parameters

Parameter	Programmable Values	Nominal (as shipped)
Shock Zone	170 bpm - 250 bpm (steps of 10 bpm)	200 bpm
Conditional Shock Zone	Off, 170 bpm - 240 bpm If On, at least 10 bpm less than Shock Zone	Off
S-ICD System Therapy	Off, Manual, Auto Therapy	Off
Post-shock Pacing	On, Off	Off
Sensing Configuration	Primary: Proximal electrode ring to device. Secondary: Distal electrode ring to device. Alternate: Distal electrode ring to proximal electrode ring.	Primary
Max Sensing Range	x1 (± 4 mV) x2 (± 2 mV)	x1
Manual Shock	10 - 80 J (in steps of 5 J)	80 J
Smart Charge	Resets to nominal	
Polarity	Standard: Phase 1 Coil (+) Reverse: Phase 1 Coil (-)	

Table 4: Non-Programmable Parameters (Shock Therapy)

Parameter	Value
Shock Therapy	
Delivered Energy	80 J
Shock Tilt (%)	50%
Waveform Type	Biphasic
Maximum Number of Shocks per episode	5 shocks
Sync Time Out	1 sec
Shock Sync Delay	60 ms
Post-Shock Blanking Period	1600 ms

SQ-RX PULSE GENERATOR ADDITIONAL INFORMATION

Table 5: Non-Programmable Parameters (Post-Shock Pacing)

Parameter	Value
Post-Shock Pacing	
Rate	50 ppm
Pacing Output	200 mA
Pulse Width	7.6 ms phase 1, 7.6 ms phase 2
Waveform	Biphasic
Polarity (of the first phase)	Standard Phase 1 Coil (+)
Mode	Inhibited Pacing
Duration	30 s
Post-Pace Blanking Period/Refractory Period	550 ms (precedes refractory period)
Runaway Protection	120 ppm

Table 6: Non-Programmable Parameters (Detection/Rhythm Discrimination, Fibrillation Induction, Shock Electrode, Capacitor Reform Schedule)

Parameter	Value
Detection/Rhythm Discrimination	
X/Y for Initial Detection	18/24 intervals
X/Y for Redetection	14/24 intervals
Confirmation Before Shock	3 consecutive tachy intervals
Refractory Period	Fast 160 ms, Slow 200 ms
Fibrillation Induction	
Frequency	50 Hz
Output	200 mA
Time out After Activation	10 sec

Table 6: Continued

Capacitor Reform Schedule	
Automatic Capacitor Reformation Interval	Approximately 4 months*
Internal Warning System	
High Impedance	> 400 Ohms
Maximum Charge Time out	44 seconds

* Reform can be delayed if capacitor was charged due to sustained/nonsustained arrhythmia in past 4 months

Table 7: Episode Data Parameters

Parameter	Value
Episode Data Parameters	
Treated Episodes	24 stored
Untreated Episodes	20 stored
Maximum Length per S-ECG Episode	128 seconds
Captured S-ECG Report	5 Captured S-ECG at 12 seconds each

Table 8: Magnet Response

Parameter	Value
Shelf Mode	No Response
Therapy On	Arrhythmia detection and response are suspended. Beeper sounds for 60 seconds to indicate sensing is occurring.*
Therapy Off	Beeper sounds for 60 seconds to indicate sensing is occurring.*

* Beeper Sounds – Beeper will sound for 60 seconds to indicate sensing is occurring or until the magnet is removed, whichever occurs first.

SQ-RX PULSE GENERATOR ADDITIONAL INFORMATION

Table 9: Stored Patient Information

Patient Information (Stored Data)
Patient Name
Physician Name
Physician Contact Information
Device Model Number
Device Serial Number
Electrode Model Number
Electrode Serial Number
Notes up to 50 characters

Table 10: Model 4520 S-ICD System Magnet Specifications

Specifications	Description
Shape	Circular
Size	Approximate Diameter 2.7 in/7.0 cm Thickness 0.5 in/1.3 cm
Content	Ferrous Alloys coated with epoxy
Field Strength	90 gauss minimum when measured at a distance of 1.5 in/3.8 cm from magnet surface.

Definitions of Package Label Symbols

Table 11: Packaging Symbols

Symbol	Definition	Symbol	Definition
STERILE EO	**Sterilized by Ethylene Oxide Gas -** Product is sterilized using ethylene oxide gas.		**Date of Manufacture -** Date on which the device was manufactured. Date shown as YYYY/MM/DD.
EC REP	**Limitation European Community Represented -** Authorized Representative in the EU community.		**Use By -** Use by the indicated date. Date shown as YYYY/MM/DD.
PART	**Part Number -** Component number.		**Storage Temperature -** Product is stored with temperature limitations.
LOT	**Lot Number -** Batch code.		**Hazardous Voltage -** Caution - dangerous voltage.
REF	**Reference Number -** Finished goods stock number.		**Radio -** Radio frequency.
SN	**Serial Number -** Serial number of the device.		**Instructions -** Consult instructions before use.
Rx	**Intended Use Symbol -** In the USA Federal Law restricts the device to sale by or on the order of a physician.		**Open Here -** Symbol showing how to open the package.
2	**Non-reusable -** Single use only.		**Fragile: Handle with Care -** Transport and store with care.
	Manufacturer - Place at which the device is manufactured.		**Keep Dry -** Ship and store in a dry place.
	Magnetic Field - To warn of a magnetic field.	CE	**Reserved for CE mark**
FCC ID SDYCHI1010 - Federal Communications Commission - Identifier serial number.			

S-ICD System And Pacemaker Interaction

Interaction between the S-ICD System and a temporary or permanent pacemaker is possible and can interfere with the identification of tachyarrhythmias in several ways.

- If the pacing pulse is detected, the S-ICD System may not adjust sensitivity appropriately, fail to sense a tachyarrhythmia episode and/or not deliver therapy.
- Pacemaker sensing failure, lead dislodgment or failure to capture could result in the sensing of two asynchronous sets of signals by the S-ICD System, causing the rate measurement to be faster, and may result in delivery of unnecessary shock therapy.
- Conduction delay may cause the device to oversense the evoked QRS and T-wave resulting in unnecessary shock therapy.

Pacemakers that employ impedance checks like MV sensors and unipolar pacemakers are contraindicated for use with the S-ICD System. This includes pacemakers that revert or reset to the unipolar pacing mode.

The following test procedure aids in determining S-ICD System and pacemaker interaction.

Note: *External defibrillation equipment should be available for immediate use during the implantation procedure as well as during testing and follow-up.*

Note: *If implanting a pacemaker with an existing S-ICD System, program the S-ICD System to Therapy Off.*

During the testing procedure, program the pacemaker output to maximum and asynchronously pace in the pacing mode to which the pacemaker will be permanently programmed (e.g., DOO for most dual-chamber modes and VOO for single-chamber modes).

1. Follow the patient screening tool procedure to assure that the patient's paced S-ECG signal passes the criteria.
2. Program the S-ICD System to Therapy On and complete the set-up procedure.
3. Observe the S-ECG for any pacing artifacts. If any pacing artifacts are present and larger in amplitude than the R-wave, use of the S-ICD System is not recommended.
4. Induce the tachyarrhythmia and observe the S-ECG markers to determine appropriate detection and delivery of therapy.
5. If inappropriate sensing is observed as a result of the device sensing the pacing artifact, reduce the pacemaker's pacing output and retest.

In addition, pacemaker operation may be affected by the S-ICD System therapy delivery. This could alter the pacemaker's programmed settings or damage the pacemaker. In this situation,

most pacemakers will conduct a memory check to determine if the parameters for safe operation were affected. Further interrogation will determine if programmed pacemaker parameters are altered. Refer to the manufacturer's pacemaker manual for implantation and explantation considerations.

Limited Warranty

Cameron Health, Inc. warrants to Purchaser, that for a period of five (5) years or sixty (60) months commencing with the date of implantation of the SQ-RX Pulse Generator ("the Product"), that should the Product fail to function in accordance with Cameron Health, Inc.'s published specifications, due to a defect in materials or workmanship, Cameron Health, Inc. will as Purchaser's sole remedy and Cameron Health, Inc.'s sole liability:

1. If within the three (3) year period, or 36 months, commencing with the date of implantation, Cameron Health, Inc. will provide a functionally comparable replacement defibrillator at no charge.
2. If after the three (3) year period from month 37 and until five (5) years or 60 months from the date of implant, Cameron Health, Inc. will provide a credit to the Purchaser for a replacement product in an amount equal to 50% of the original purchase price reduced on a pro rata basis over this two year period. The prorated credit amount will be calculated on a monthly basis over this twenty-four month period.

In no event will any warranty credit issued hereunder exceed the original purchase price of the Product or the purchase price of the replacement Product.

The Product is designed as a single use device and must not be resterilized. Any resterilization voids the warranty.

OTHER LIMITATIONS ON THE TERM OF THIS LIMITED WARRANTY ARE PROVIDED WITH THE SALES DOCUMENTS AND ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY, AS ARE THE WARNINGS CONTAINED IN THE PRODUCT LABELING. CONTACT YOUR LOCAL CAMERON HEALTH, INC. REPRESENTATIVE OR THE CAMERON HEALTH, INC. CUSTOMER SERVICE DEPARTMENT TO OBTAIN THIS INFORMATION AND TO OBTAIN INFORMATION ON HOW TO PROCESS A CLAIM UNDER THIS LIMITED WARRANTY.

To qualify for this limited warranty, the following conditions must be met:

- The Product must be implanted prior to the "USE BEFORE DATE" in conjunction with a Cameron Health, Inc. electrode.
- The replaced Product must be returned to Cameron Health, Inc. within thirty (30) days after explant and shall be the property of Cameron Health, Inc.
- The device must be clean and free from any bodily residue before returning.

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