References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each pulse generator confirmed malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, software updates, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

[1]**Capacitor** - *May 12, 2006 Voluntary Physician Advisory.* Premature battery depletion, significantly shortened duration between elective replacement indicator (ERI) and end of life (EOL). Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.

[2]**Integrated Circuit** - *May 12, 2006 Voluntary Physician Advisory.* Beeping tones and programmer warning screen upon interrogation, loss of telemetry communications, loss of pacing (intermittent or permanent) and/or loss of shock therapy. Repetitive mechanical stress-induced component damage, only when implanted sub-pectorally with the serial number facing the ribs.

[3]**Timing crystal – Failure Mode 1** – *September 22, 2005 Voluntary Physician Advisory.* Intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode or appearance of a reset warning message upon interrogation. Foreign material within a crystal timing component. Improvement implemented.

[4]**Timing crystal – Failure Mode 2** – *September 22, 2005 Voluntary Physician Advisory.* At implant procedure or during pre-implant testing: intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, reversion to VVI mode, or appearance of a reset warning message upon interrogation. Microscopic particle within a timing crystal component. No failures have been reported following confirmation of successful implantation, and all currently distributed devices are not subject to this peri-implant failure mode. Improvement implemented.

[5]**Memory latching** – *June 17 and July 22, 2005 Voluntary Physician Advisories.* Limited therapy availability. Functional "latching." Original June 17 advisory recommendations revised because new information indicated programming Atrial Tachy Episode Data Storage to 0% caused latching in subset of devices with previously stored atrial episode data. Reference July 22, 2005 advisory for more details.

[6]**Hermetic sealing component – Original Population** – *July 18, 2005 and January 21, 2006 Voluntary Physician Advisories.* Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.

[7]**Hermetic sealing component – Second Population** – *January 21, 2006 Voluntary Physician Advisory.* Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning, appearance of a reset warning message upon interrogation, inappropriate early display of replacement indicators, inappropriate accelerometer function resulting in sustained pacing at the programmed maximum sensor rate, or lack of appropriate accelerometer rate response during activity. Gradual degradation of hermetic sealing component with higher than normal moisture content in pacemaker case late in device service life. Improvement implemented.

[8]**Magnetic switch** – *June 23, 2005 Voluntary Physician Advisory.* Inhibition of tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. Magnetic switch stuck in closed position. Improvement implemented.

[9]**Short circuit (RENEWAL 1 and 2)** – *June 17, 2005 Voluntary Physician Advisory.* Permanent loss of shock and pacing therapy. Deterioration of wire insulator (in conjunction with other factors), electrical short. Improvement implemented.

[10]**Short circuit (pre-April 2002 PRIZM 2 DR)** – *June 17, 2005 Voluntary Physician Advisory.* Permanent loss of shock and pacing therapy. Deterioration of wire insulator (in conjunction with other factors), electrical short. Improvement implemented.

[11]**Overestimation of battery status** – *May 6, 2003 Voluntary Physician Advisory.* Improvement in battery status between follow-up visits and/or overestimation of remaining longevity. Very specific conditions involving the use of an atrial tachycardia response feature. Software upgrade distributed late November 2003 eliminated the possibility of battery status overestimation. Improvement implemented.

[12]**Safety mode** – *April 23, 2001 Voluntary Physician Advisory.* Switch to Safety Mode due to rare interaction between device and specific memory component; beeping tones emitted to alert patient. Affected devices still provide full output shock delivery in Safety Mode. Improvement implemented.

[13]**High current drain** – *March 29, 1999 Voluntary Physician Advisory.* Loss of pacing, premature replacement indicators, backup mode operation, disruption of diagnostic measurements. High current drain resulting from a short circuit between two integrated circuit chips. Improvement implemented.

[14]**Setscrew.** Inability to tighten or loosen setscrews during implant or replacement procedure.

[15]**Seal plug.** Non-cardiac signals on electrograms leading to inhibition of pacing and/or inappropriate shock delivery. Damaged seal plug. Improvement implemented.

[16]**Seal plug.** Lifted or missing seal plugs. Inadequate medical adhesive bond. Improvement implemented.

[17]**Capacitor.** No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.

[18]**Header.** Loosened header at pulse generator replacement or lead revision. Improvement implemented.

[19]**Integrated circuit.** No telemetry, premature battery depletion. Integrated circuit issue within high-voltage transistor. Improvement implemented.

[20]**Resistor.** Various fault codes upon interrogation. Damaged resistor. Improvement implemented.

[21]**Circuit connection.** Loss of telemetry, no magnet tones. Damaged internal circuit connection. Improvement implemented.

[22]**Device tones.** Inappropriately sustained device tone. Magnet removal or initialization of programming event during specific timing window. Device fully capable of therapy delivery as programmed. Improvement implemented.

[23]**Transformer.** Charge time fault code and/or end-of-life (EOL) indicator displayed. Damaged transformer. Improvement implemented.

[24]**Integrated circuit.** Premature battery depletion, loss of pacing output, inability to interrogate, loss of sensing, high-rate pacing. Damage to integrated circuit. Improvement implemented.

[25]**Software download.** Safety Mode operation at predetermined brady and tachy parameters. Incomplete software download. Restoration tool available; improvement implemented.

[26]**Power on Reset.** Power on Reset state for which tachy and brady therapy available at preset parameters.

[27]**Impedance measurements.** High impedance value (generally >3000 ohms) recorded and displayed as weekly average impedance. Low daily impedance recordings cause error in calculating weekly average impedance due to memory storage limitations. Device fully capable of therapy delivery as programmed.

[28]**Battery depletion.** Premature, gradual depletion of battery; in rare instances, rapid depletion with no therapy available.

[29]**Battery voltage at implant.** Premature battery depletion. Exposure to magnetic field during device shipping or storage prior to implant. Improvement implemented.

[30]**Integrated circuit.** Lack of ventricular markers and reversion to Safety Mode. Improvement implemented.

[31]**A/D Module.** Inability to obtain telemetry, Safety Mode, device beeping. Failure within Analog to Digital (A/D) module.

[32]**Battery depletion.** Rapid, premature battery depletion. Failed battery.

[33]**Hybrid circuit.** Fault codes or loss of output. Failed solder joints on device hybrid circuit. Improvement implemented.

[34]**Reset during charge.** Power on Reset state during therapeutic shock charging attempt. Improvement implemented.

[35]**Early ERI declaration.** Early appearance of elective replacement indicator (ERI). Increased battery impedance extends charge time and prompts ERI declaration. Therapy availability unaffected, end of life indicators operate as designed. Longevity estimation relabeled for certain models, improvement implemented. Please reference the January 2004 ICD Longevity *Product Update* for more details.

[36]**Oscillator circuit.** Beeping and/or display of Fault Code during interrogation shortly after implant. Oscillator circuit operates at higher frequency due to increase in temperature. Improvement implemented.

[37]**Feedthrough filter capacitor.** Inability to interrogate device following shock delivery. High voltage build-up between feedthrough leads on capacitor surface. Improvement implemented.

[38]**Capacitor array.** Loss of device output, loss of capture; inability to accurately measure charge times causing elective replacement indicator declaration. Damage to capacitor array. Improvement implemented.

[39]**Battery depletion.** Premature battery depletion and loss of capture.

[40]**Header.** High impedance, compromised header bonding identified during lead revision procedures. Insufficient medical adhesive bonding between header and case. Improvement implemented.

[41]**Interrogation at EOL.** No interrogation at EOL.

[42]**Internal device connection.** Intermittent or no telemetry. Telemetry coil connection. Improvement implemented.

[43]**Feedthrough wires.** High impedance and/or loss of pacing therapy. Broken wire connecting header to internal circuitry. Improvement implemented.

[44]**Battery depletion.** Loss of therapy, inability to interrogate, no magnet response, premature battery depletion.

[45]**Telemetry or atrial noise.** Noise during telemetry and/or atrial sensing. Inappropriate contact between telemetry coil and device case. Improvement implemented.

[46]**Memory address.** Inability to interrogate. Memory address error. Improvement implemented.

[47]**Impedance.** Atrial and/or ventricular pacing impedances >2500 ohms in unipolar and bipolar modes.

[48]**Memory location.** Inappropriate early display of elective replacement indicators. Incorrect data within a specific memory location.

[49]**Memory error.** Device resets (including pacing at reset parameters) and inability to interrogate. Errors in device memory.

[50]**Telemetry coil.** No pacing output and/or an inability to interrogate. Short circuit between pulse generator feedthrough wires and telemetry coil. Improvement implemented.

[51]**Battery weld.** No pacing output and/or inability to interrogate. Battery weld. Improvement implemented.

[52]**Sensing.** Undersensing of cardiac signals.

[53]**Sensing.** Oversensing and/or delivery of inappropriate shocks. Physiologic and/or mechanical signals. Improvement implemented.

[54]**Memory location.** Inability to perform diagnostic testing, loss of shock therapy. Incorrect data within a specific memory location.

[55]**Solder bond.** Inability to interrogate, no magnet response, no pacing output. Broken solder bond between wire mounting surface and internal circuitry. Improvement implemented.

[56]**High current drain.** Battery depletion, inability to interrogate, no telemetry. High current drain on electronic circuit.

[57]**High current drain.** Loss of pacing, premature replacement indicators, backup mode operation, disruption of diagnostic measurements. High current drain resulting from a short circuit between two integrated circuit chips. Improvement implemented.

[58]**Short circuit.** Permanent loss of shock and pacing therapy. Deterioration of wire insulator (in conjunction with other factors), electric short. Improvement implemented.

[59]**Capacitor.** No telemetry, no pacing, premature battery depletion. Gradual, premature battery depletion most common; in rare instances, rapid depletion occurred with no therapy available. Failed low-voltage capacitor.

[60]**Battery depletion.** Premature battery depletion.

[61]**Battery depletion.** Premature battery depletion.

[62]**Early replacement indicator.** Extended charge time resulting in early appearance of ERI or EOL, or shortened ERI to EOL time.

[63]**Interrupted telemetry.** Early appearance of elective replacement time (ERT) indicator, unexpected impedance measurements (>2500 ohms). Interruption in telemetry sequence during software upgrade.

[64]**Battery depletion.** Premature battery depletion.

[65]**Induced shock energy delivery.** Shock energy delivery lower than specified during induced shock.

[66]**Capacitor.** Premature battery depletion, no telemetry. Damage to capacitor.

[67]**Short circuit.** Permanent loss of shock and pacing therapy, electrical short. Insulation degradation due to incorrect wire routing.

[68]**Early ERI declaration.** Early appearance of ERI. Increased battery impedance extends charge time and prompts ERI declaration. Therapy availability unaffected, end of life indicators operate as designed.

[69]**Diagnostic data error.** No ventricular sense (VS) markers displayed on real-time EGMs when hysteresis is on. Improvement implemented.

[70]**Underestimation of battery status.** Underestimation of remaining longevity due to invalid charge time measurement.

[71]**Diagnostic data error.** Inability to view daily measurements due to rate fault reset.

[72]**Magnet response.** No magnet response.

[73]**Memory error.** Pacing not as expected. Memory map error.

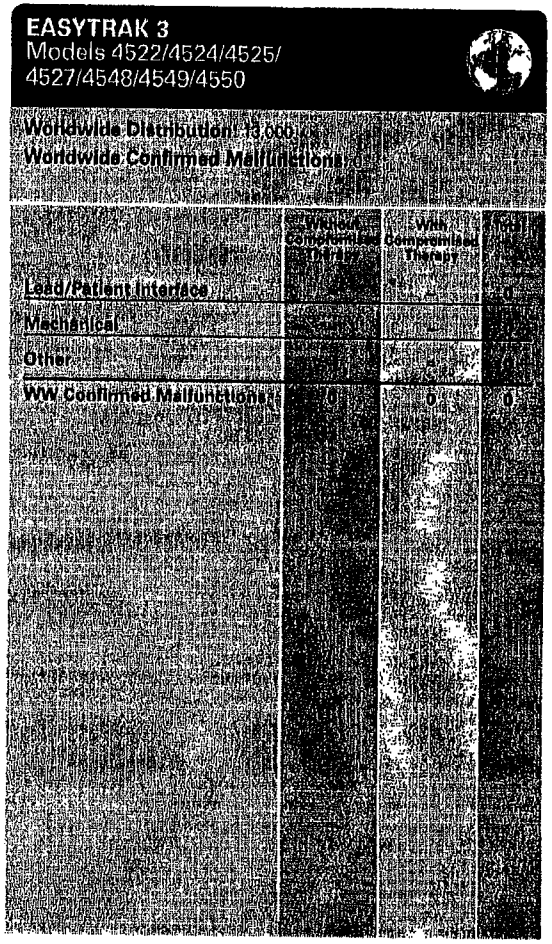
[74]**Rate fault declaration.** Inappropriate pacing due to timing interaction when Automatic Capture is programmed on.

[75]**Battery terminal.** No output, inability to interrogate. Battery wire routing.

[76]**Pacing rate limit.** Inability to interrogate. Inappropriate pacing due to feature interaction.

[77]**Setscrew block.** No pacing or pauses in pacing, intermittent or lack of setscrew contact with lead. Incorrect setscrew block. Improvement implemented.

CRT Leads


EASYTRAK 3
Models 4522/4524/4525/
4527/4548/4549/4550
Worldwide Distribution:
Worldwide Confirmed Malfunctions:
Lead/Patient Interface
Mechanical
Other
WW Confirmed Malfunctions:
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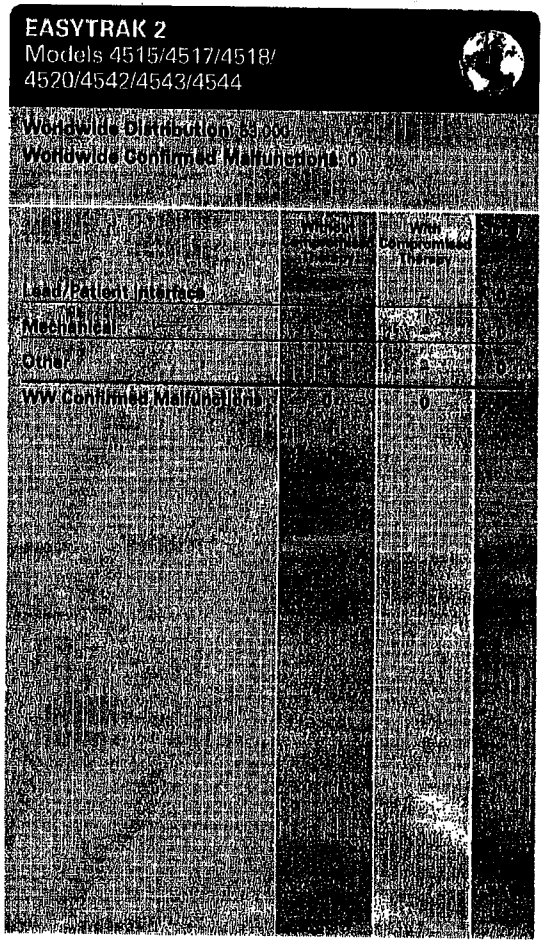
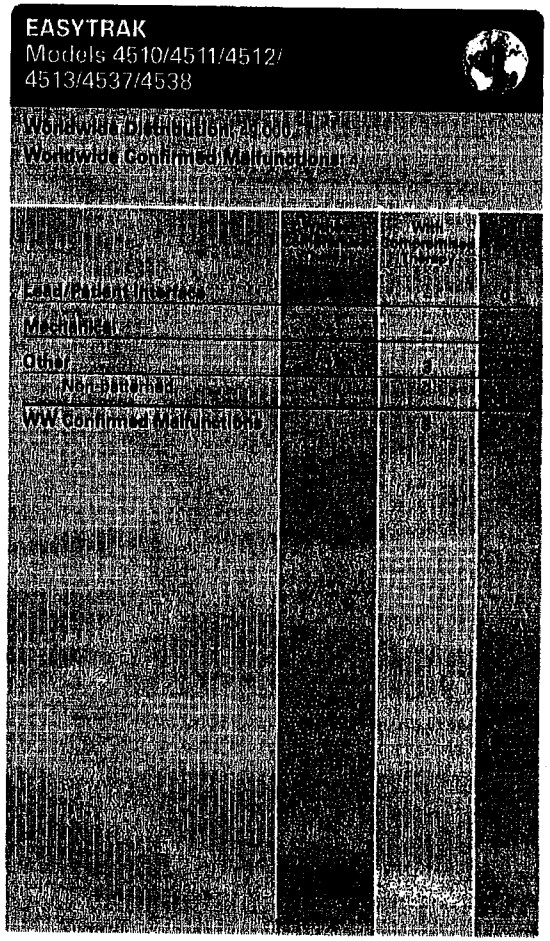
0
0


EASYTRAK 2
Models 4515/4517/4518/
4520/4542/4543/4544
Worldwide Distribution:
Worldwide Confirmed Malfunctions: 0
Lead/Patient Interface
Mechanical
Other
WW Confirmed Malfunctions:
0


EASYTRAK
Models 4510/4511/4512/
4513/4537/4538
Worldwide Distribution:
Worldwide Confirmed Malfunctions:
Lead/Patient Interface
Mechanical
Other
Non-Lead/Pac
WW Confirmed Malfunctions:

Defibrillation Leads

ENDOTAK RELIANCE G Dual Coil, Active Fixation
Models 0184/0185/0186/0187

Worldwide Distribution: 57,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	–	–	0
Other	–	–	0
WW Confirmed Malfunctions	0	0	0

ENDOTAK RELIANCE G Dual Coil, Passive Fixation
Models 0174/0175/0176/0177

Worldwide Distribution: 13,000
Worldwide Confirmed Malfunctions: 2

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical		1	1
Conductor connection		1	1
Other		1	1
Non-patterned		1	1
WW Confirmed Malfunctions	0	2	2

ENDOTAK RELIANCE SG Single Coil, Active Fixation
Models 0180/0181/0182

Worldwide Distribution: 2,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	–	–	0
Other	–	–	0
WW Confirmed Malfunctions	0	0	0