

A view from the trenches - building implantable Class III medical devices

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Boston Scientific – Cardiac Rhythm
Management

- Overview of implantable devices for heart disease treatment
- Classes of medical device failures
- Techniques that have been applied to increase device assurance
- Medical device security

Overview of implantable devices for heart disease treatment

Cardiac Device Therapies

Three classes of therapies currently treated

- Bradycardia
 - Slow heart rhythms treated with cardiac pacing
 - Called “Pacemakers”
- Tachycardia – Ventricular and Atrial
 - Potentially fatal fast rhythms treated with high rate pacing and/or high energy shocks
 - Called “Implantable Cardioverter Defibrillators” - ICDs
- Cardiac Resynchronization Therapy (CRT)
 - Improve diseased heart pumping function by synchronizing the timing of the left and right ventricles
 - Called “CRT devices” or “Bi-Ventricular Pacemakers”



Modern devices tend to be cumulative

- Most ICDs contain full-featured pacemakers to treat Bradycardia
- CRT devices often contain Defibrillators
 - Called “CRT-D” for CRT-Defibrillators

Impact of device failure on the patient (1 of 2)

Worst case harm is unintended direct delivery of energy to the heart

- Devices are designed to fail to no-output when the output may not be certain

Bradycardia Pacing¹

- In most cases, loss of pacing leads to patient symptoms with little short or long term harm
 - Difficulty in exertion, lethargy, dizziness
 - Small fraction (~3%) of patients are ‘pacer dependent’ – without pacing, they may pass out, due to non-functioning SA or AV nodes
- High rate pacing
 - Harm level depends on rate, duration and patient’s condition
 - Hardware monitors limit rates and duration of pacing output

¹ – Clinical Cardiac Pacing and Defibrillation – Ellenbogen, Kay & Wilkoff, 2nd Ed. 2000
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Impact of device failure on the patient (2 of 2)

Bi-Ventricular Pacing²

- Short term harm of loss of Bi-V pacing is low – beneficial effects are gradual
 - Many patients will be symptomatic and self-report

Defibrillation³

- Loss of therapy can be life-threatening
 - But conditioned on therapy being needed
 - Therapy needs vary widely by population
 - Secondary prevention patients with diseased substrate – 2-4 shocks per year
 - Primary prevention patients may not get a shock for the life of their device
- Design to diagnose and communicate as many loss-of-therapy failure modes as possible

² –Cardiac-Resynchronization Therapy with or without an Implantable Defibrillator in Advanced Chronic Heart Failure – Bristow, et al. N Engl J Med 2004; 350:2140-2150

³ – Clinical Cardiac Pacing and Defibrillation – Ellenbogen, Kay & Wilkoff, 2nd Ed. 2000

Device Follow-up

After implant patient is followed regularly to

- Optimize the therapy settings
- Monitor patient progress/disease progression
- Check lead and/or battery status

Traditionally, these have been done with clinic visits

- Recommended every 3 months

← Defines a typical exposure window for detecting device failure



In-home remote monitoring systems have emerged

- Daily monitoring of device diagnostics
- May replace some in-clinic follow-ups with remote review



**Latitude Remote
Patient Monitoring**

Device evolution



1960's
Non-programmable
Hardware



1970-80's
Programmable
Hardware



1990's
Growing use of
Software controlled
processors



2000's
Software control
100's of parameters
System of Systems

Pulse Generator Mechanical Design (Defibrillator)

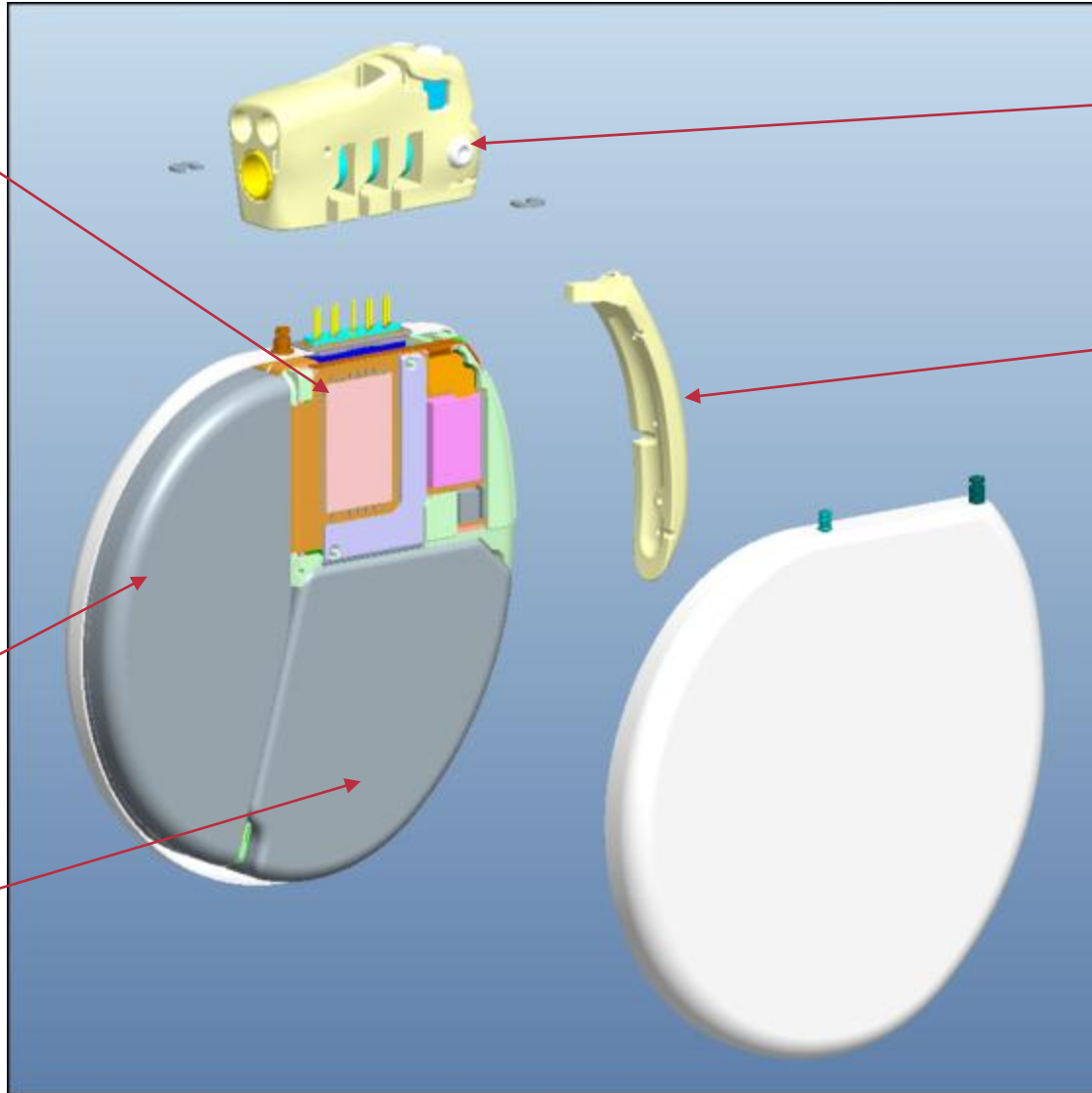
Hybrid and Integrated Circuits for Sensing, Pacing, and Defibrillation

Header for Leads Connection

Antenna for RF Telemetry to Programmer

Capacitor

Battery



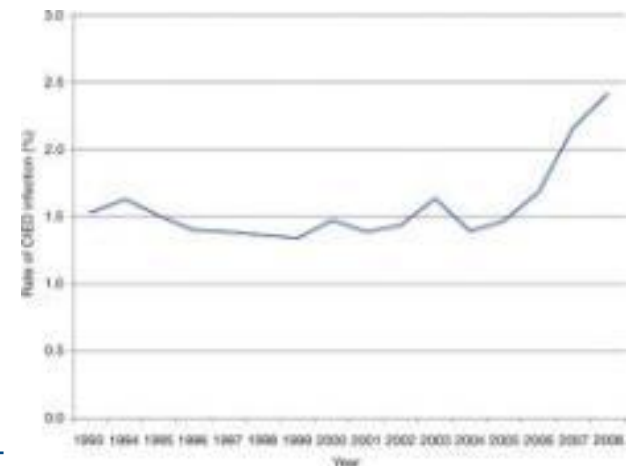
Longevity, device size and power usage

Constant drive to make devices smaller and last longer

- Patient satisfaction with smaller device
- Patient's are living longer and benefit from less frequent replacements
 - There is an infection risk in the 1-3²% range each time they have surgery to replace a depleted device

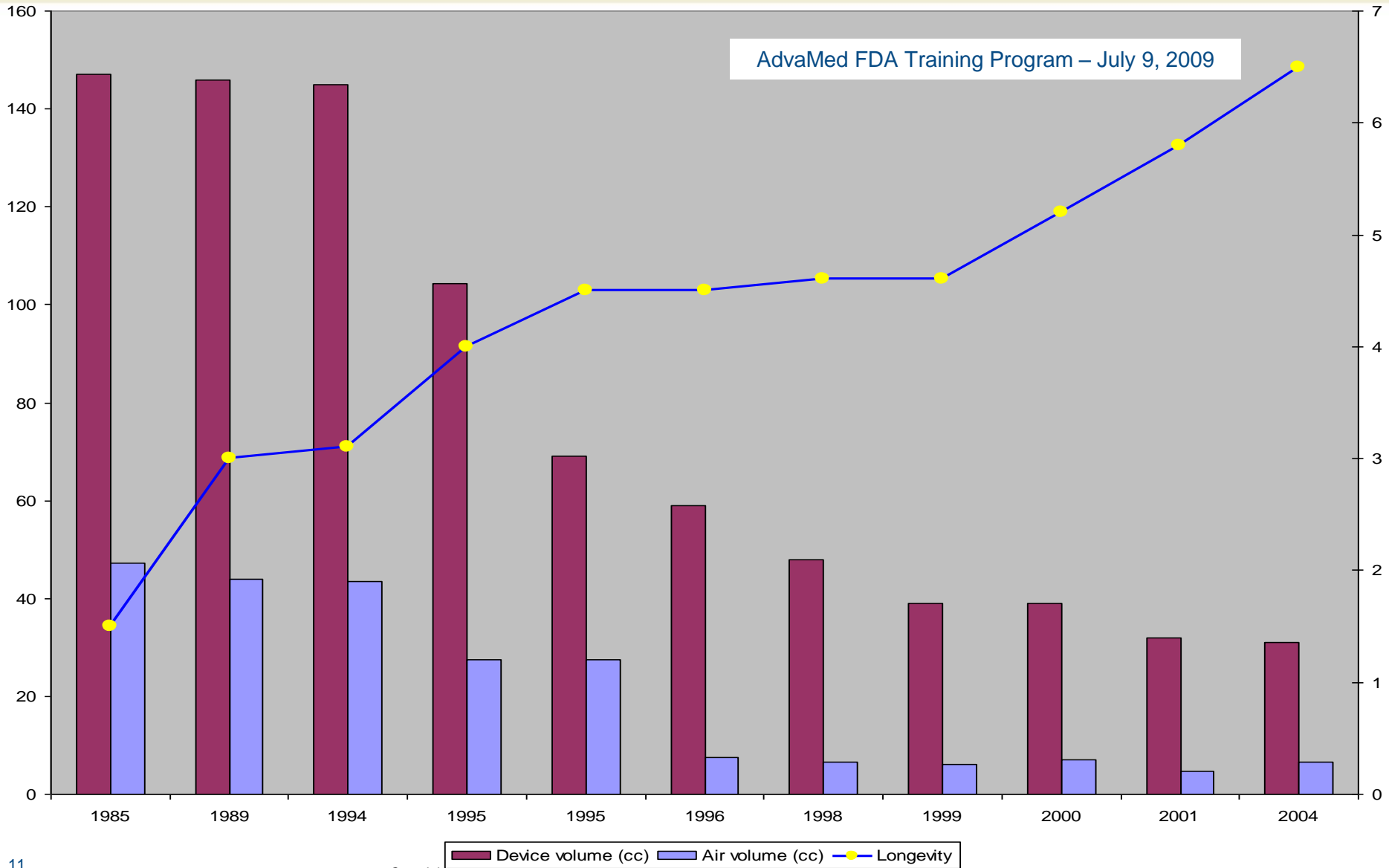
Functions that consume power must be managed carefully

- External telemetry
- Functions that require calculations every heart beat
- Redundant circuits that consume power



² - 16-Year Trends in the Infection Burden for Pacemakers and Implantable Cardioverter-Defibrillators... Greenspon et al. *J Am Coll Cardiol.*2011; 58: 1001-1006

Implantable Cardiac Defibrillators Decreased Size - Increased Longevity



Redundancy in implanted devices

Our devices have several key single-string components

- Battery and Defibrillation Capacitor
 - Redundancy not appropriate due to size impact and reliability history
- Leads
 - Redundancy would increase lead diameter, which is limited by anatomy and deliverability

Some redundancy forms are in common use

- ECC on memories to manage SEUs
- Dual oscillators to detect critical function failure
- Graceful degradation (safety core, lead safety switch)

Must balance safety/availability improvement against longevity reduction

- Improving a highly reliably device at a large impact to longevity may not help overall patient population (↑infection)

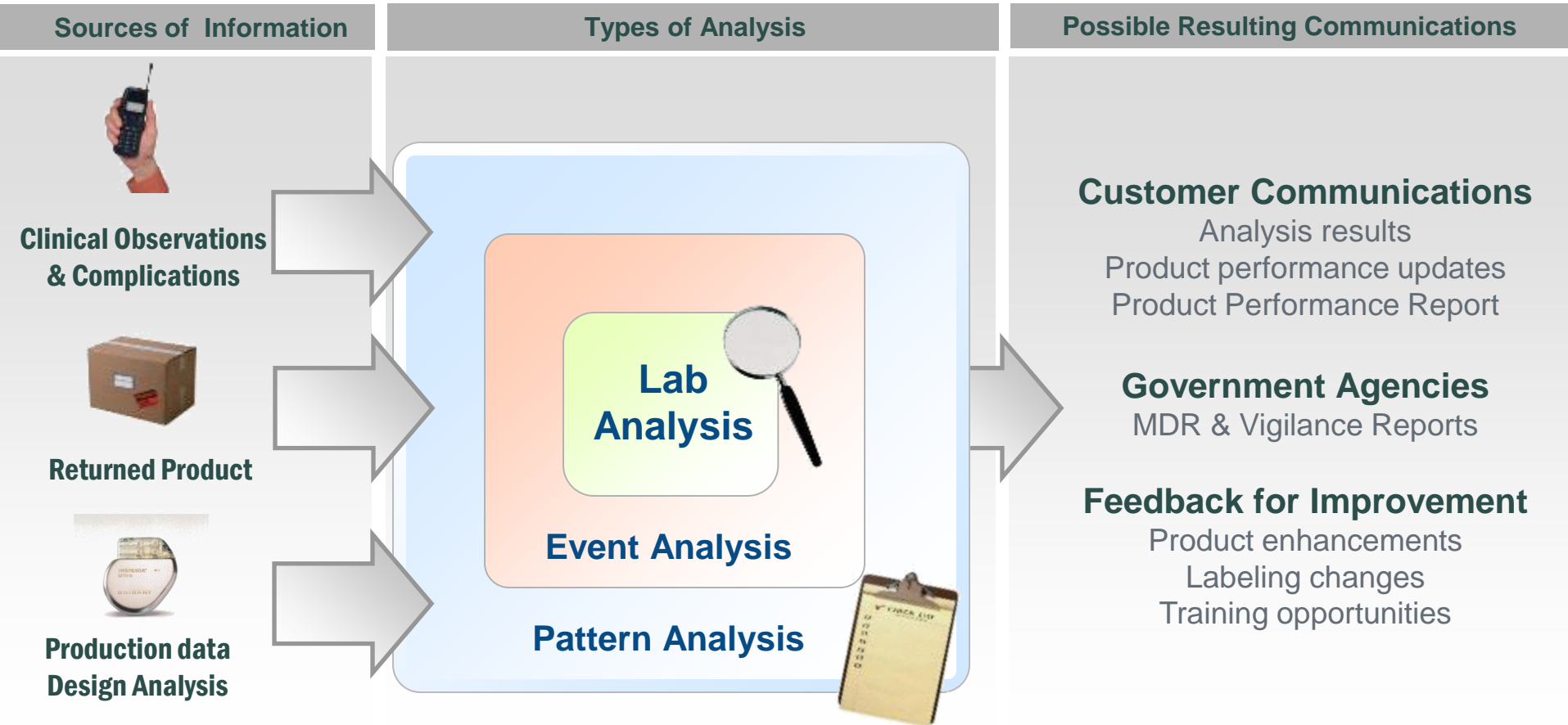
Implantable cardiac devices are control systems with a biological “physical plant”

Challenges include

- Wide variations in patient pathophysiology
 - With a dozen or so biological control systems in the body that are all interacting – we (science) don’t fully understand how yet
- We have a large database of “N-sigma” data cases
 - Augmented each time we have an incidence that identifies a patient class outside of our past experience
- Physicians are trained to behave differently from other “control systems operators”
 - Wide variation in how implants are programmed and their data is used

Post-Market Surveillance Product Performance Monitoring

BSC CRM Product Performance Monitoring System



Based on reported explants, we currently receive over 60% of explanted defibrillators, and about 55% of explanted pacemakers back for analysis*

**Information based on product returns through Sept 30, 2011 – as reported in Boston Scientific Product Performance Report – Q1 2012*

Classes of medical device failures

Device failure rate experiences

Typical industry survival rates³ (malfunction only)

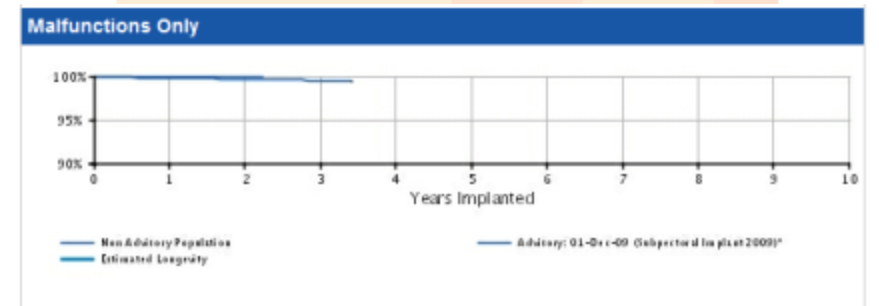
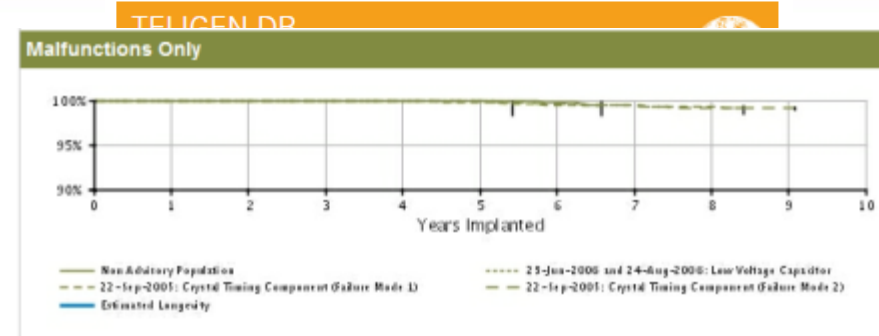
- PGs - >99.5% at 5 years (ICDs), and 8-10 years (Pacemakers)
- Leads - ~98% at 10 years with much higher variability

Detailed reporting breaks down the basic source of known failure

- For those products that are returned for analysis

When a single source of failure impacts risk predictions, an advisory may be issued

- May recommend programming changes, monitoring changes or in some cases, replacement
- Physicians need to balance the risk of replacement (e.g. infection) versus patient's specific medical condition



U.S. Survival Probability		Year	1	2	3	4	5	6	7	8
Non Advisory Population	Depletions and Malfunctions(%)		99.92	99.87	99.87	-	-	-	-	-
	(Confidence Interval)		(+0.0+0.0)	(+0.1+0.0)	(+0.1+0.0)					
Registered Implants: 42000										
	Malfunctions Only(%)		99.93	99.90	99.90	-	-	-	-	-
	(Confidence Interval)		(+0.0+0.0)	(+0.0+0.0)	(+0.0+0.0)					
	Effective Sample Size		22623	2636	307	-	-	-	-	-

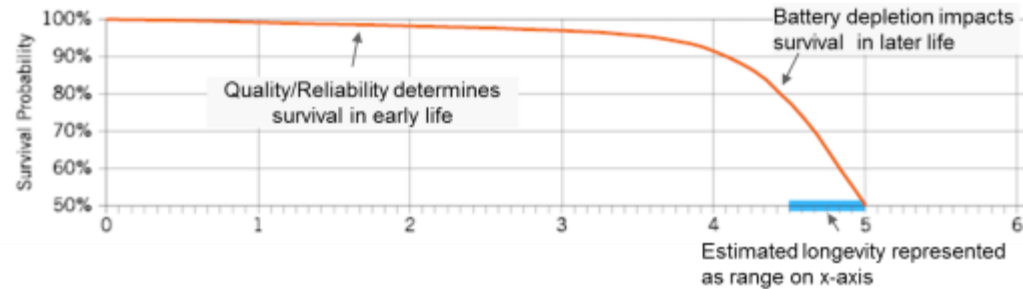
ENDOTAK RELIANCE Dual Coil, Active Fixation Models 0157/0158/0159											
U.S. Registered Implants: 96,000			U.S. Chronic Lead Complications: 295			U.S. Malfunctions: 199			99.79% No Confirmed Malfunction		
U.S. Approval Date: July 2002						Without Compromised Therapy: 30			0.21% Confirmed Malfunction		
U.S. Estimated Active Implants: 50,000						With Compromised Therapy: 169					
						U.S. Average Device Age: 53.9 mo.					
	Registered U.S. Implants	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
Non Advisory Population	96,000	99.84 (+0.0+0.0)	99.78 (+0.0+0.0)	99.68 (+0.0+0.0)	99.58 (+0.1+0.0)	99.48 (+0.1+0.1)	99.35 (+0.1+0.1)	99.15 (+0.0+0.1)	98.98 (+0.1+0.1)	98.80 (+0.2+0.1)	98.80 @ 112 mo. (+0.3+0.1)

³ – Based on an analysis of 1Q 2012

Battery Depletion

Fielded devices will consume battery energy at widely varying rates

- Due to patient physiology
 - Need for pacing
 - Needed energy to capture the heart
 - Need for defibrillation shocks
- Due to device programming
 - Excess pacing voltage
 - Turning on monitor features



Constant challenge is filtering reports of early depletion

- Is it physiological, programming, or indication of a component problem?

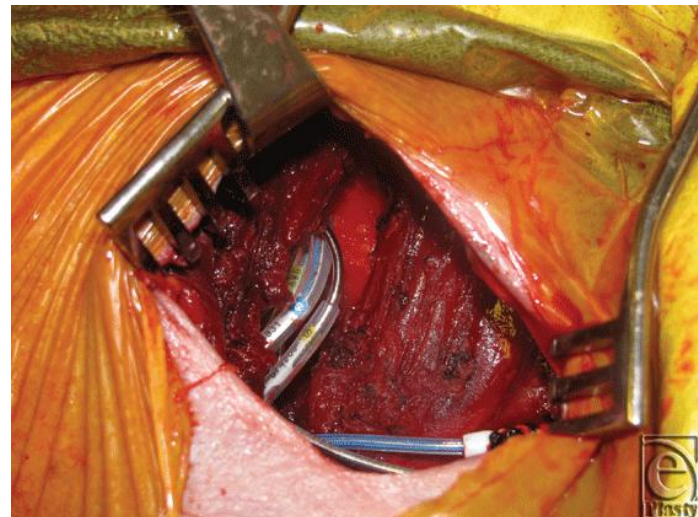
Balanced against underreporting of explanted devices

Every manufacture has an active advisory for early depletion due to leaky low-voltage capacitors

- Challenge is to determine at the time of manufacture if a component will have an unacceptable increasing failure rate

Historically⁴, across the industry, mechanical issues dominate device failure statistics

- The body is a harsh environment
- Surgical placement decisions can impact forces/cycles
 - E.g. Sub-pectoral implants exert great torsional forces
- Challenge of modeling/testing new designs under a wide range of actual conditions
 - 6-10 years for PG
 - 10-15 years for a lead

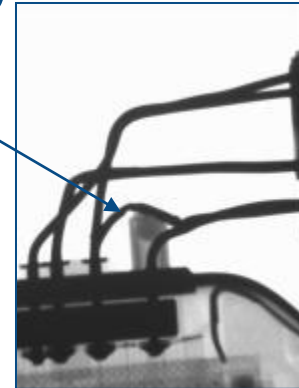


⁴ – Based on an analysis of 1Q 2012 Manufacturer's Product Performance Reports

Mechanical Examples

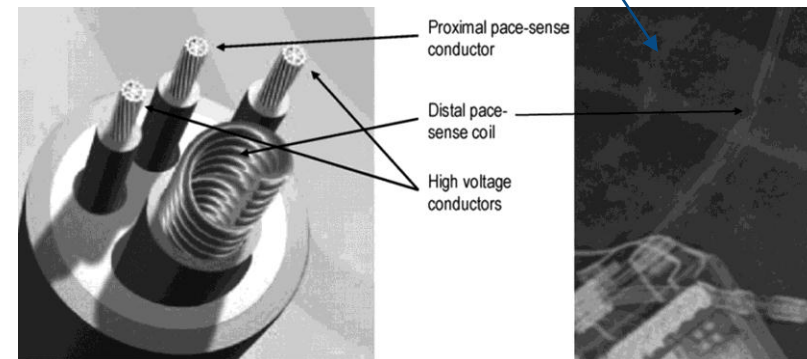
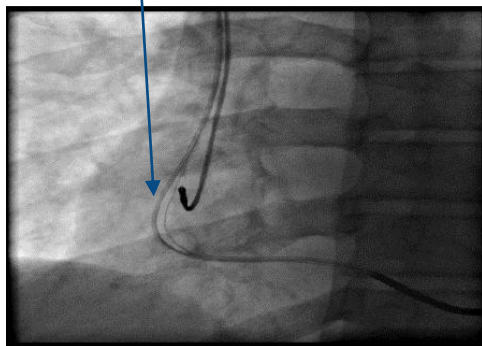
Header example – Prizm 2 DR Shorting in Header (BSC - 2005)

- Insulator break down
- 40 malfunctions in ~27,000 implants (PPR⁵ estimates 0.10-0.24%)



Leads

- Sprint Fidelis Potential Wire Fracture (MDT - 2007)
 - 5355 confirmed malfunctions/206,000 implants – MDT PPR⁶ estimates 11.4% failure @ 69 months – other studies have shown higher failure rates⁷
- Riata Externalized Conductor (STJ – 2011)
 - Current STJ PPR⁸ reports 0.63% – other studies have shown higher failure rates⁹



⁵ – Boston Scientific Product Performance Report – April 13, 2012

⁶ – Medtronic CRDM Product Performance Report, February 2012

⁷ – http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/fidelis-lead-pub-may12.html

⁸ – St. Jude Medical Cardiac Rhythm Management Division Product Performance Report, May 1, 2012

⁹ – http://www.riatacommunication.com/us/-/media/Cardiac%20Pro/Landing%20Pages/Riata-Resource-Center/5242012-Pub-Summaries/Riata_Publications_05242012.ashx

In the body, PGs ultimately interact with other systems

- Some well known, with standards defining interaction
 - External defibrillators
 - Diagnostic and therapeutic radiation
 - Diagnostic and therapeutic acoustic energy (ultrasound and lithotripsy),
 - EMI
 - Scuba diving (pressure)
- Some well known, with emerging standards
 - MRI



- Some are discovered via their effects
 - BSC Pacers can use Minute Ventilation to drive pacing
 - Reports of patients in hospital beds with their pacers running at “Max Sensor Rate”
 - Root cause: External equipment to measure transthoracic impedance injects signals that interfere with the MV measurements
 - Issue corrected with latest pacer designs (Ingenio family)

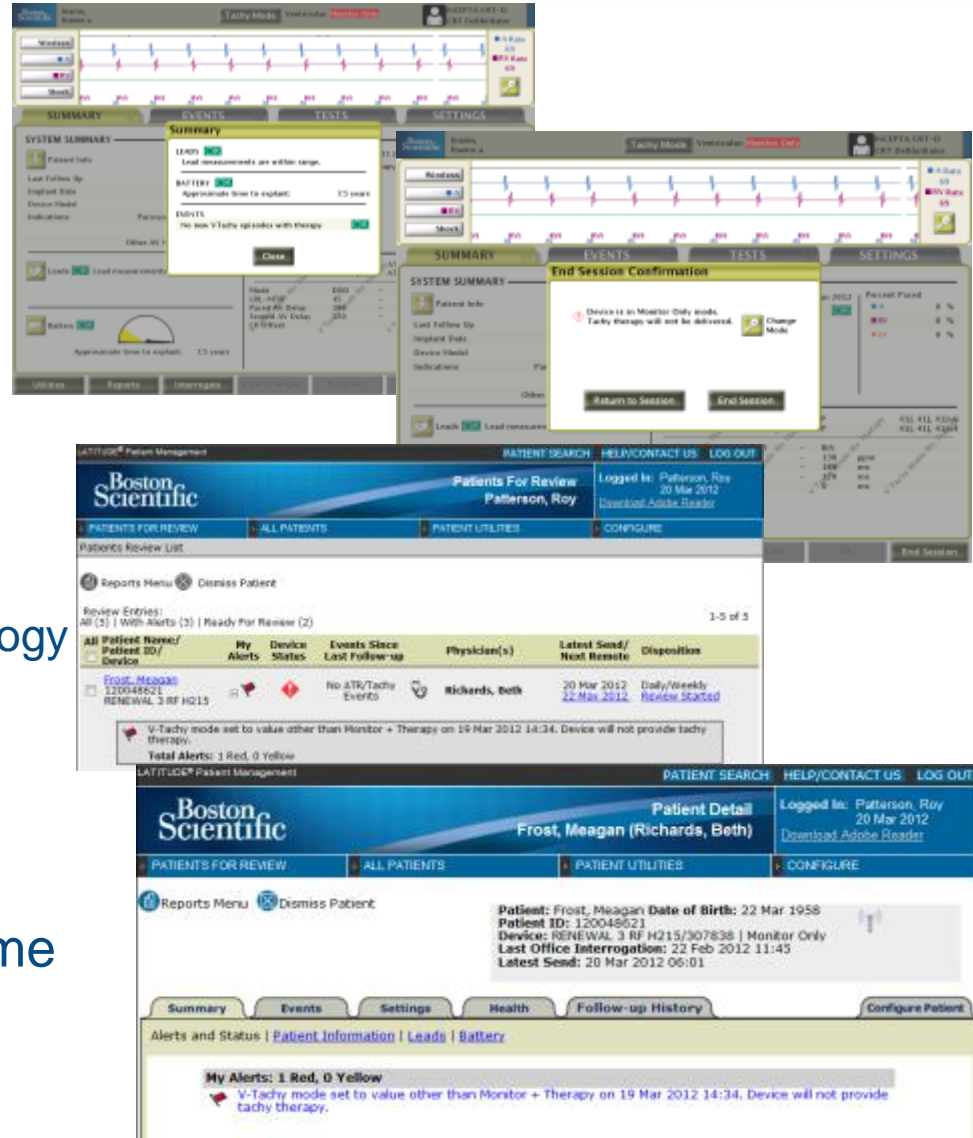


Need to anticipate “reasonable misuse”

- Field experience, simulated use testing, GLP testing

Example - Defibrillator turned off

- ICD patients undergoing certain procedures require temporary disabling of their defibrillator
 - May be done by local cardiology group, or manufacture representative
- Occasionally, the patient is sent home without getting defibrillator turned back on
- Mitigation designed into home monitoring system – alert if device is found turned off



Gross behavioral errors are rare

- Development and V&V processes
- Product maturity

Software faults may be exposed by:

- Environment (e.g. SEU)
- Feature interactions
- Patient physiology and pathophysiology
- User interactions

Risk attenuation

- While such faults are common-mode, trigger conditions are unlikely to occur in a broad population in a short time-period
 - But, field performance monitoring needs to be sensitive to even a single event
- Software updates can permanently eliminate the risk
 - Limiting risk exposure to the patch development/ approval/ deployment window

Example: Vitality AVT Functional Latching (BSC – 2005)

Identification

- Two devices found that could not be interrogated
 - One pacing at 100bpm
- Explanted and returned

Analysis

- Episode free-memory function not resilient to SEU
- Result: SEU on control variable when history memory full led to infinite loop
 - Physician Advisory: Set Atrial Storage to 0% until SW patch is issued

Recommendation exposed a second design flaw

- If atrial storage has episodes and atrial storage set <10%
- Second recommend – set Atrial storage to 20% until patch issued

Rates⁸:

- First flaw: 3 devices (0.01%)
- Atrial @ 0%: 43 devices (0.18%)
- Atrial @ 20%: 0 devices

Patch issued:

- OUS – Nov 17, 2005
- US – April 16, 2007



⁸ – Boston Scientific Product Performance Report – March 19, 2009

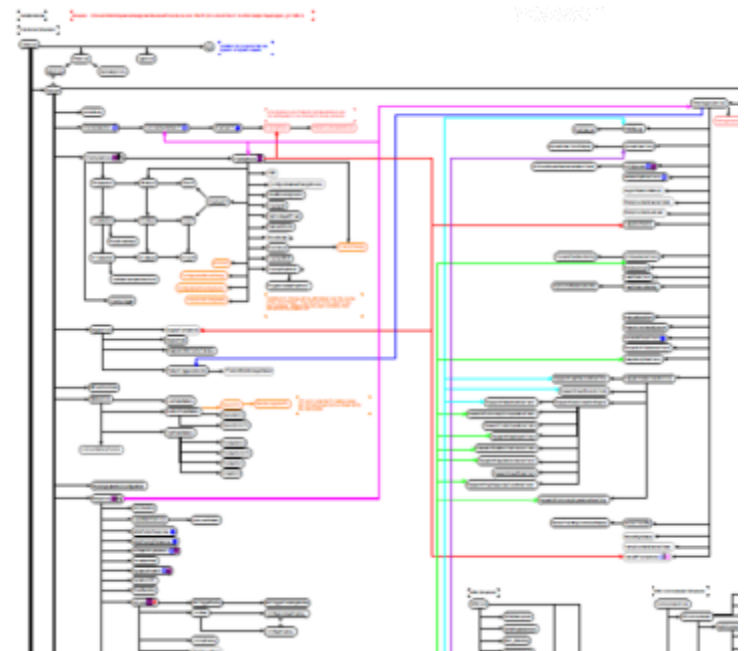
Techniques that we have applied to increase design assurance

Maps product models to their feature variations

- Pacer/Defib/CRT
- Product tiers
- Geographies
- Product generations

Integrated throughout the development process

- Requirements
- Models
- Software/firmware
- Tests



Models

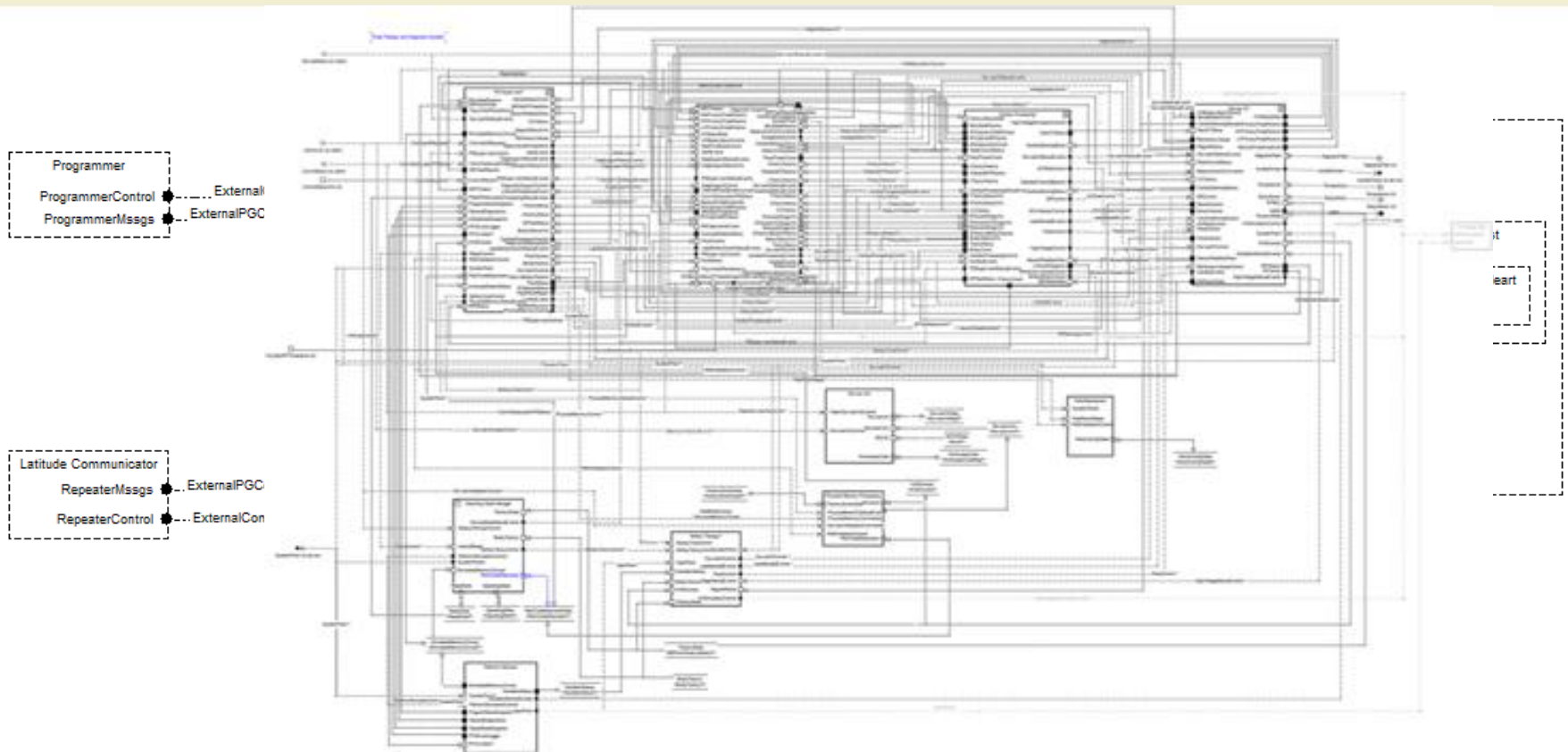
- Architecture
- Parameter Values
- Behavior
- Partitioning
- FW/HW Interface

Tools

- Authoring
- Publishing
- Analysis
- Scenario Generation
- Code Generation (skeleton)

Methods

- Requirements Generation
- Behavioral Model Development
- Model Integration
- Formal Test Development
- Formal Model Validation
- Firmware DVT

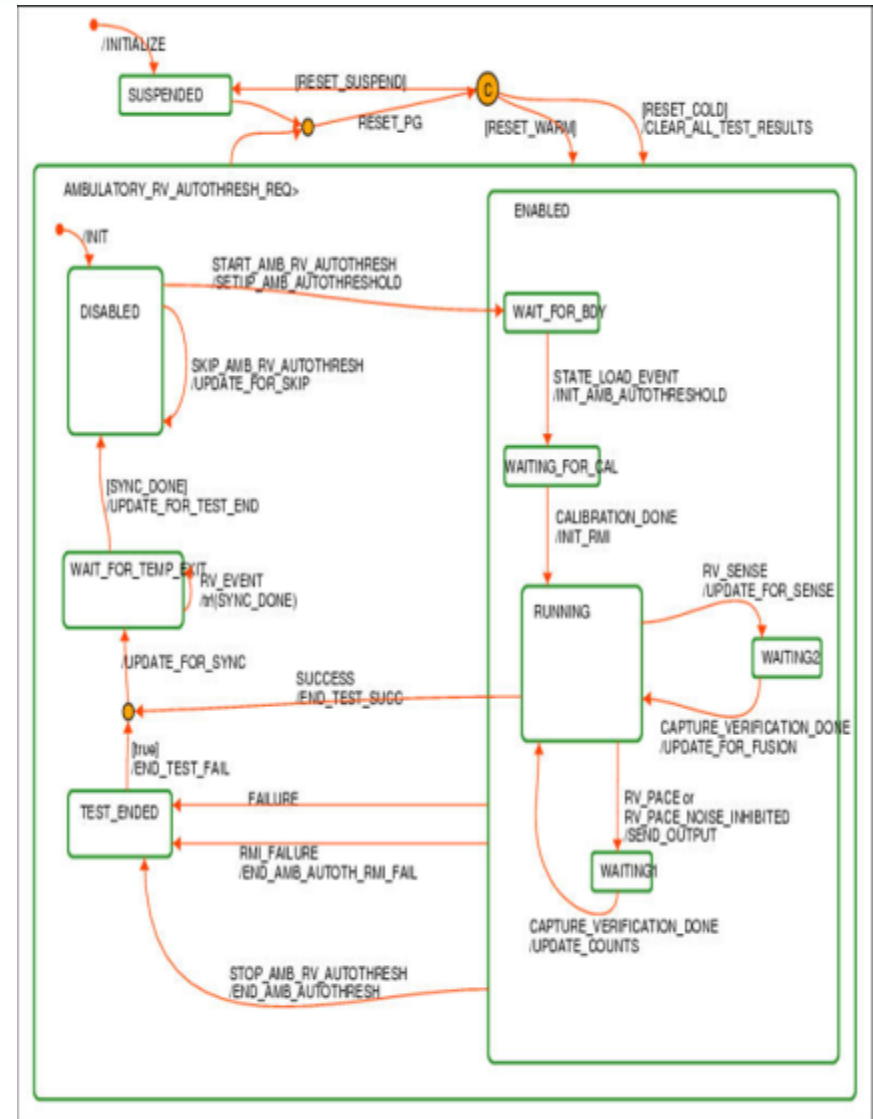


Defined in “PADL” – PG Architecture Description Language

- Similar to AADL
- Developed in DoME (DARPA funded Honeywell tooling)

Behavioral Model

- Adheres to the architecture's interfaces and activities, and the System Verification Interface
- Compiled to form an executable simulation
- Driven by timed stimuli (events and data)
- Generates timed events and data
- Operates in “simulation time” – effectively infinite processing speed



Firmware verification – “Model As Oracle Verifier” - MAOV

Large set of test scenarios

- “Tape tests”
- Typical Use Cases
- Product Line Variations

Executed against model

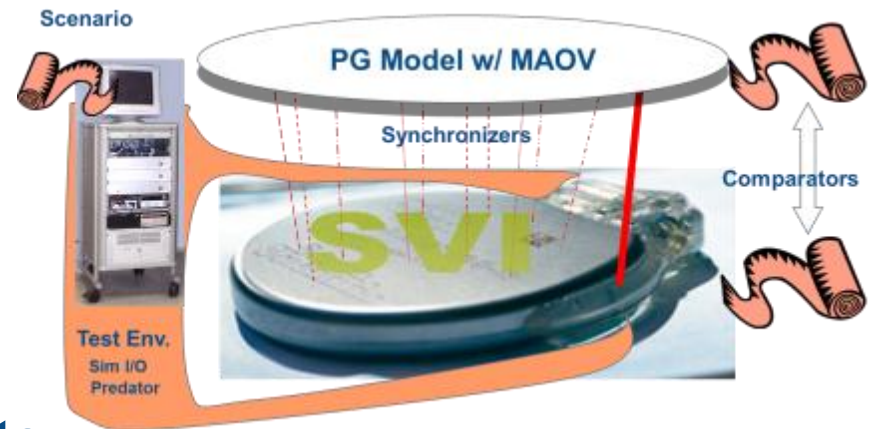
- Verified with domain experts

Executed against firmware

- Running on hardware
- Test stations with monitors

Output synched & compared

- Regular regression
- Deviations flagged and analyzed



Quality Metrics

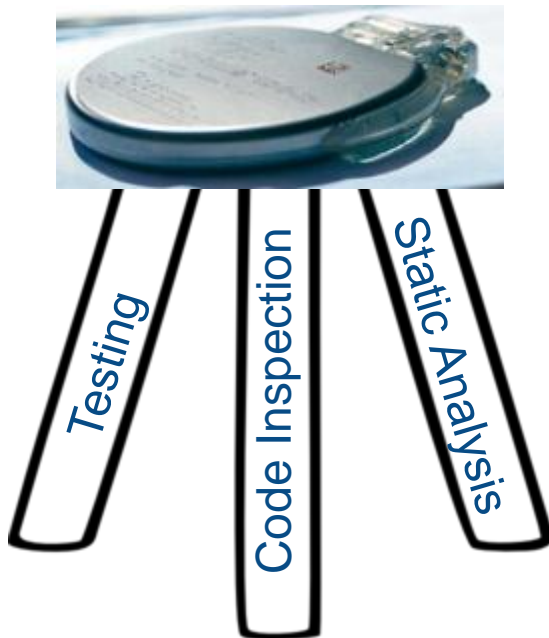
- Experience to date shows a reduction in defect density

Earlier Feature Validation

- Behavior can be confirmed with domain experts before HW/FW is complete

Limitations

- Limited formal verification of the model
- Model/Firmware correlation limited to dynamic test coverage
- Hard to reason about software design correctness
 - Focused on behavior



Testing

- Driven by MAOV
- Additional test scenarios focused on software design
- Longer term animal testing

Code Inspection

- Labor Intensive
- Repetitious
- Proliferation of Checklists

Static Analysis

- Automate laborious hand checking
- More thorough, less error prone

What to Analyze?

Off-the-Shelf Static Analysis tools

- Firmware not built on a standard RTOS
 - Domain-specific architecture
- Huge number of False Positives
 - Code was not already designed to pass a specific rule-set
 - Considerable manual labor to review results
 - Difficult to maintain as code base evolves
- Coding has not been historically the source of serious mistakes



Determined a blend of OTS and Customized tooling was required

- OTS tools for some analysis (QAC and CodeSonar)
- Contracted with Grammatech (CodeSonar) to create domain-specific analysis extensions

Design Criteria

Design Constraint Classes

DDCxxx – Scalable Resource Estimation and Allocation

Scalable resources must include safety margin, overflow detection, and monitoring.

Lessons learned

Design Constraints (~80)

- Mid-level design decisions driven by design criteria
- Traced to Criteria
- Design/Code analyzed to ensure all constraints are met

- PG Software Patch
- Periodic Check
- Resource Control, Resource Management, and Limiting Complexity
- HWIF
- CPU Timing

DDCyyy – Shared Data Access

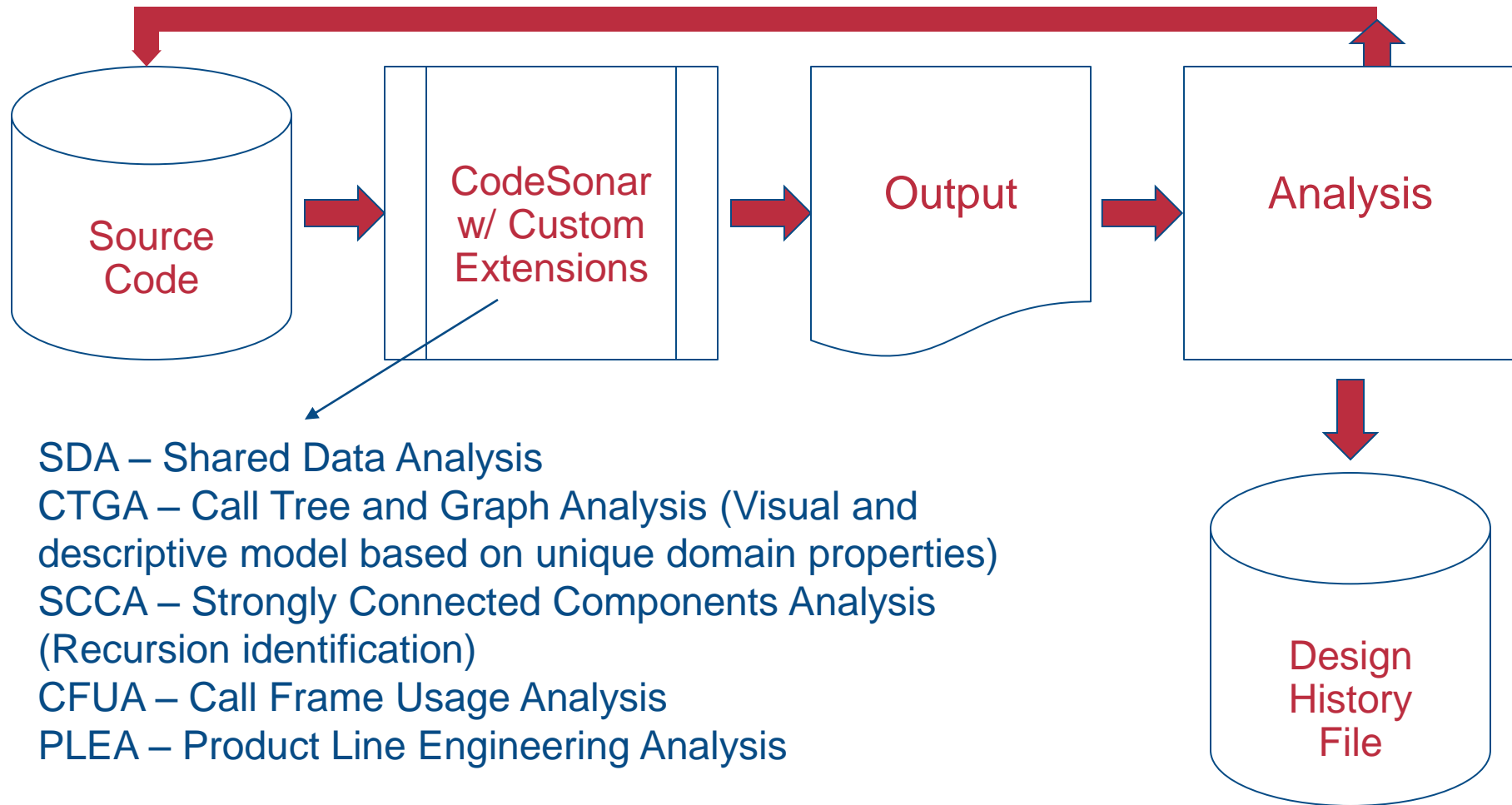
All data instances that are accessed (read or write) from multiple priority levels of threads must be protected with adequate guard constructs

Reset Recovery

- Dynamic and Static Data Structure



Analysis of Design Constraints Using Customized Static Tool



Design Constraint Analysis: ~40% Static Analysis, 40% checklists, 20% other means

Run time monitors ensure key constraints are met, including

- Thread execution timing
- Activity duration monitors
- Various memory monitors – e.g. stack size, code protection
- Watchdog timer

Tripping a monitor results in a device reset

Three resets in 48 hours results in fallback to “Safety Core”

- Hardware backup pacemaker – VVI @ 72.5ppm
- Hardware backup defibrillator – Single zone, max shock
- Processor and firmware are kept off
- Warnings via Programmer and Remote Monitor
- Memory preserved and analyzable post-explant

Formal Verification of Hardware/Software properties

Formal model checking performed on a key element of the design

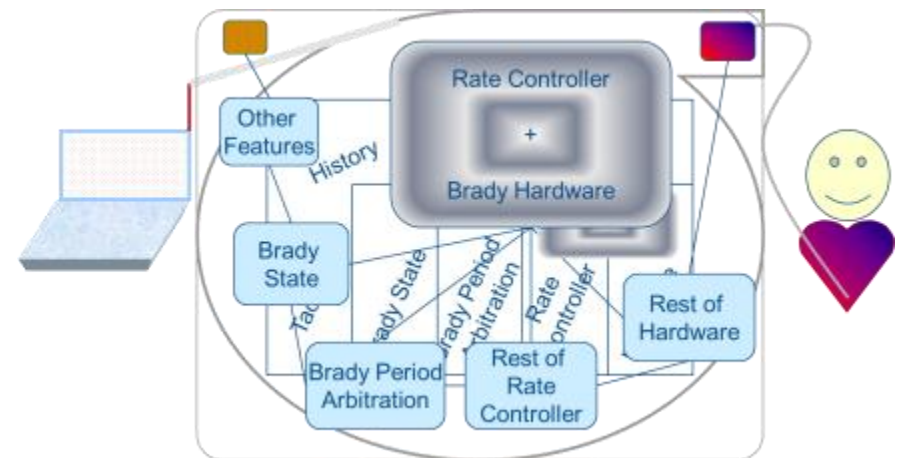
- Cardiac Rate Cycle Controller
- During a hardware design update, to enhance confidence in the correctness of the changes

Both Firmware and Hardware were modeled

- With appropriate abstractions

Issue identified

- Case where LV pacing may be lost when RV noise is present
- Issue corrected



Medical device security

Securing Device Access

Communication with the device has been through a very low power near-field inductive scheme

- Operates at 6 cm distance
- Mutual Coupling of wand coil and PG coil
- Uses H field, field strength drops off as $1/r^3$
- User Authentication through physical proximity

Addition of higher frequency RF telemetry and home monitoring (2005) led to need to manage security risk

- Worst case – security risk manifests results in patient harm



Security Risk Assessment Process

Security Risk process parallels safety risk

- Driven by IEC 14971

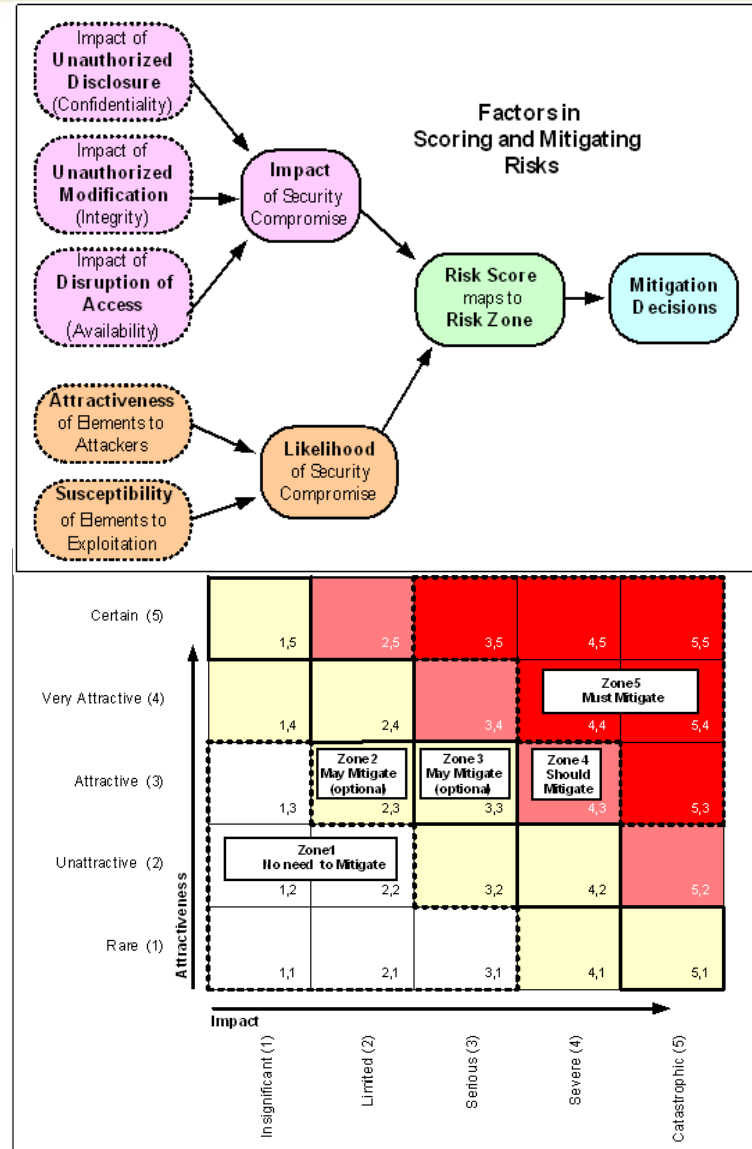
Cross-functional analysis, maintained across development lifecycle

- Starting at concept phase

Broad list of threat classes and protectable assets to consider

Risk axes

- Attractiveness (likelihood)
- Impact (severity)



Security Mitigation Challenges for Implantable Devices

Security management features need to balance several constraints:

- Fast access to the device in a medical emergency
- Limited processing power in existing implantable devices
 - Cryptographic algorithms need to be executable within appropriate time limits
 - Streaming data during a session
 - Session start-up times are acceptable for the use case
- Limited battery power
 - Security requirements should not have an unreasonable impact on device longevity

Example Mitigated Security Risks

Risk	
Unauthorized programming	Protection of patient PHI stored in the implanted device
Replay attack	Prevention of programming from home monitor
Programming session hijack	Protection of patient PHI within home monitoring system
Battery depletion attack	Protection of patient data stored on removable media

Important Device Information

Pacing Systems from Boston Scientific CRM



Indications

Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm or low cardiac output or congestive heart failure secondary to bradycardia.

Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients who have a separate implanted cardioverter-defibrillator (ICD); use of Minute Ventilation in patients with both unipolar atrial and ventricular leads single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 200 or $\geq 2000 \Omega$. If programmed to a fixed atrial sensitivity value of 0.15 mV, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. Inappropriate sustained high-rate pacing occurred in the PULSAR™ MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 □ ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments ; home and occupational environments; follow up testing; explant and disposal; TENS; electrocautery and RF ablation; ionizing radiation; elevated pressures. Advise patients to avoid sources of electric or magnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. P)

ICD Systems from Boston Scientific CRM



ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs (i.e. Vitality AVT) with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications

Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have sterile external and internal defibrillator protection available during implant. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Do not subject a patient with an implanted pulse generator to diathermy.. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias.. (applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments follow-up testing; explant and disposal; post-therapy pulse generator follow-up. Advise patients to avoid sources of electromagnetic interference (EMI).

Potential Adverse Events

Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only. (Rev. 0)

CRT-D Systems from Boston Scientific

CRM



Indications and Usage

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF \leq 35% and QRS duration \geq 120 ms Left bundle branch block (LBBB) with QRS \geq 130 ms, EF \leq 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Contraindications

There are no contraindications for this device.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system.. For single patient use only Do not reuse, reprocess, or resterilize. . Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning.. Do not subject a patient with an implanted pulse generator to diathermy, Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias.. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads.. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. P)

LATITUDE® Patient Management System from Boston Scientific CRM



Intended Use

The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database.

Contraindications

The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the pulse generator being interrogated.

Precautions

The LATITUDE system is designed to notify clinicians within 24 hours if new pulse generator alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. Pulse generator data is typically available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that pulse generator data will not be available and alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- The pulse generator and the Communicator cannot complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator is damaged or malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.

Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above. Additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by viewing information on the LATITUDE clinician website and reviewing supporting diagnostic information stored in the implanted device.

Adverse Effects

None known.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. K)