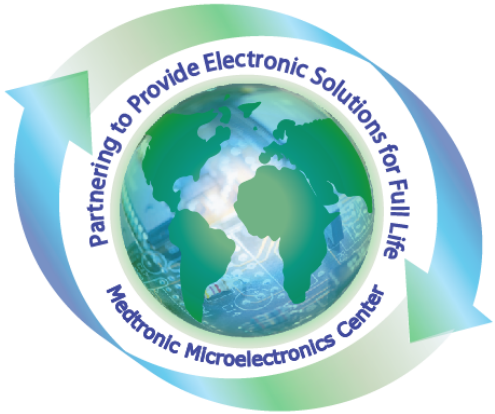


Medical Device Reliability and Qualification

Mark Porter
Medtronic Tempe Campus
Materials Physics & Design Reliability

27 September, 2011

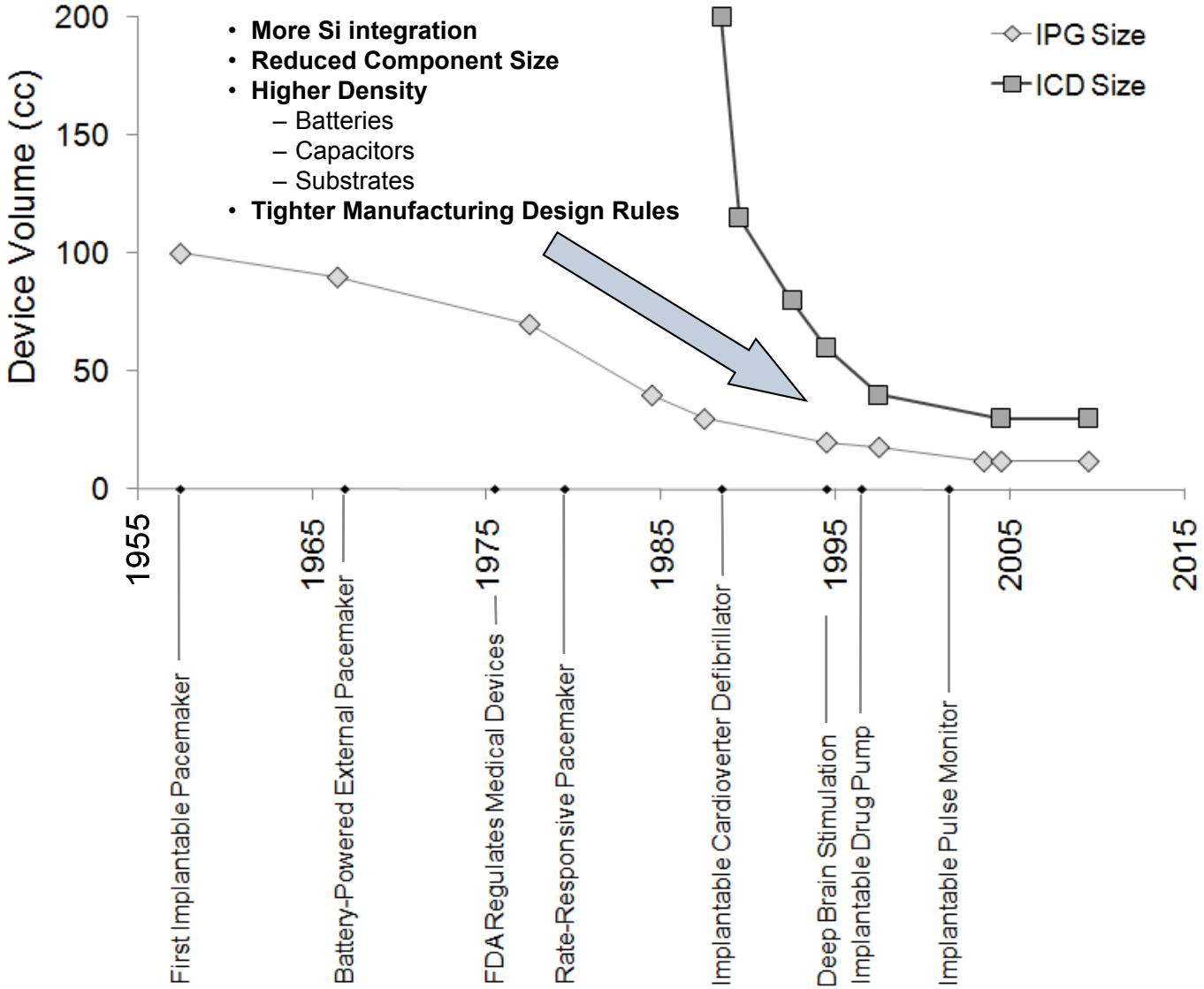
Medtronic

Medtronic has been very successful operating in a competitive and highly regulated industry

- **Founded in 1948 in Minneapolis**
- **Restoring patients to full life from chronic disease states**
- **Greater than 50% share in many markets**
- **Implantable electronic devices**
  - Pacemakers (Implantable Pulse Generators – IPG)
  - Implantable Cardiac Defibrillators (ICD)
  - Neurological stimulators for pain and functional disorders
  - Implantable drug pumps
  - Implantable pulse monitors

- **External electronic devices**
  - Automated External Defibrillators (AED)
  - Glucose meters and insulin pumps
  - Cardiac surgery devices
- **Non-electronic products**
  - Coronary stents; heart valves; spinal products; ear, nose, and throat surgical equipment
- **Marketing products requires a deep understanding of regulatory requirements across the globe**
  - Many different entities
    - US (FDA), Japan (MHLW), Europe (TUV), etc.
  - Strict guidelines for therapy effectiveness, patient safety, and long-term surveillance

Implantable device volume has been a major driver for new technology adoption



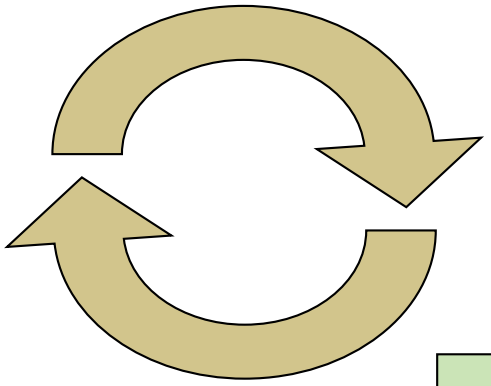
Product qualification is embedded within a larger development, clinical, and regulatory submission process

Therapy Development

- Doctors
- Clinicians
- Medtronic Technologists & Business Leaders

Product Development

- Characterization
- Verification
- Validation
- Qualification



Clinical Trials

- Limited release
- Early physician adoptors
- Extensive data review and analysis

Surveillance

- Device registries
- Patient follow-up
- Clinical and safety monitoring

Market Release

- Product launch
- Training
- Marketing
- Hospital Buying Groups

As the pace of technology advancement accelerates, device manufacturers must become more efficient while improving reliability and performance

More features and automaticity

- New therapies for better patient outcomes
- Quicker implant procedures
- More diagnostics for both patient and device history
- Faster, less frequent follow-ups

Drives the need for…

Advanced technology enablers

- Deep submicron CMOS
- MEMS
- Power supplies
- Charge storage
- Digital Signal Processing
- Packaging
- Etc.

While working within…

Increasingly demanding constraints

- Low power dissipation
- Device volume and shape
- Design and test costs
- Characterization
- Verification
- Validation
- Qualification

How do we ensure continued success with a rapidly-changing technology landscape?

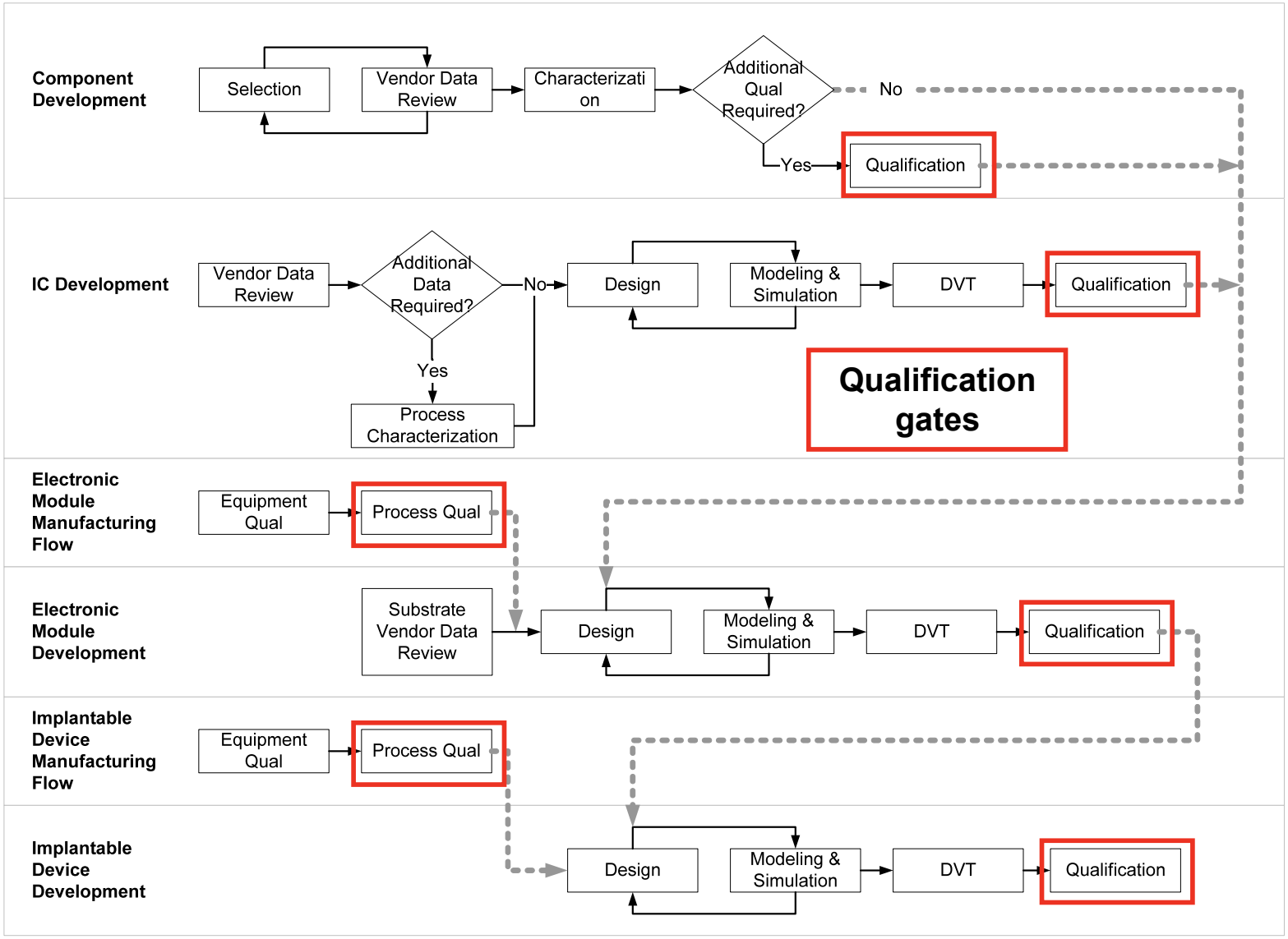
- **The use of commercial components and processes is increasing in order to achieve performance goals**
  - Integration of supplier design systems with Medtronic expertise is essential
  - Internally developed requirements supplemented or modified with industry standards
  - Dialog with external experts shortens learning cycles

Technology	Issues	Solutions
Integrated Circuits	Shrinking reliability margins Yielded design success Commercial foundries	Design library qualification Design For Manufacturing rule implementation Vendor environment customization
Components	Use condition disparity with commercial products	Map industry standards to Medtronic requirements (JEDEC, IEC, etc.)
Packaging and Assembly	Tight layout pitches New materials and techniques	More silicon integration Stringent screening processes
System Integration	Increasing reliability requirements Shortened product development cycles	Physics of Failure modeling for early reliability checks Adoption of industry accepted test methods (drop, shock, vibration, radiation, etc.).

Outline

- **Agenda**
  - Qualification Flow
  - Relevant Failure Mechanisms
  - Future Technology Considerations
  - Implantable Device Qualification
  - Summary

Qualification of the manufacturing processes and components serve as gates before each successively more complex system can be qualified



Historically, qualification consisted of a series of semi-empirical checks…

- **FMEA Drives Activities**

Samples from Production

HTOL

Operating Life
High-Temperature Reverse Bias
EEPROM Retention/Endurance

Mechanical Stresses

Drop
Shock
Vibration
Assembly Strain
Cyclic Deflection
Barometric Pressure

Other

High-Voltage Charge/Delivery
Parameter Shift Analysis
Temperature Cycling
Over-Voltage Stress
Radiation Exposure
Battery Longevity
ESD Sensitivity
Moisture Loading
Repeated Reflow
Solderability
Etc.

- Sample sizes range from 77 to 200+
- Typically pass on zero failures
- Not very different than commercial component practices

…where the test protocols are based upon failure mechanisms of concern

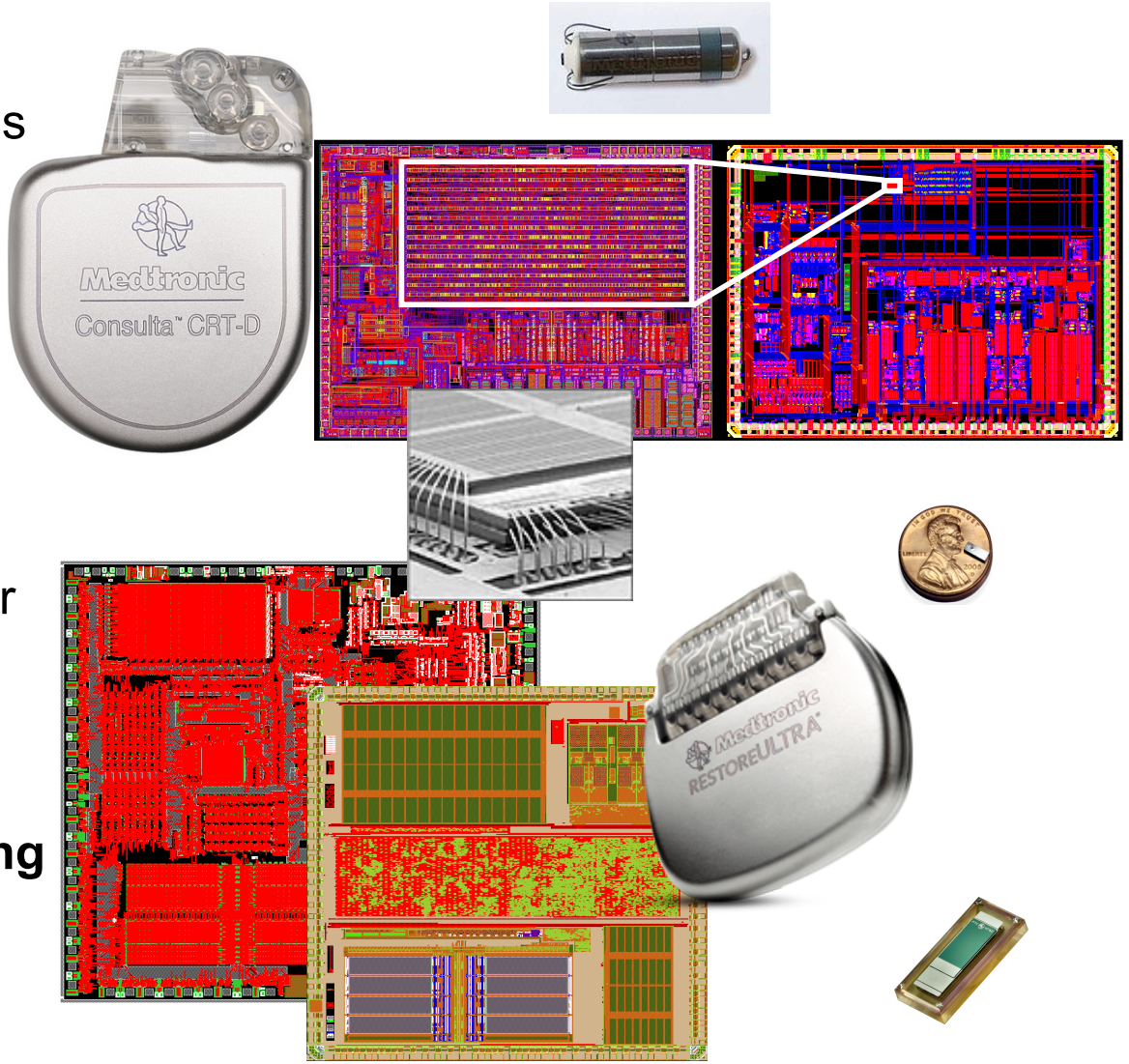
Failure Mechanism	Accelerating Stresses	Qualification Test	Applicable to
Cautery/Defib damage	Voltage	Saline tank high-voltage pulse testing	Final device
Ceramic capacitor cracking	Mechanical stress	Vibration testing, 4-point bend, Drop testing	Electronic module
CMOS failure mechanisms (SILC, NBTI, TDDB)	Temperature, Voltage	HTOL	CMOS integrated circuits
Component fracture inside final device	Pressure	Barometric pressure testing	Final device
Corrosion	Temperature, Relative humidity, Contaminants	Hermetic environment of implantable device makes this an insignificant failure mechanism.	NA
Creep	Mechanical stress, Temperature	HTOL	Electronic module, Final device
Current leakage increase due to component degradation	Temperature, Voltage, Ambient environment	HTOL, Bias/environmental testing	Component, Electronic module
Delamination	Humidity, Contamination, Temperature cycling, Mechanical stress	HTOL, Temperature cycling, 85/85, Vibration testing, 4-point bend	Component, Electronic module, Final device
Dendritic growth	Temperature, Voltage differential	Hermetic environment of implantable device makes this an insignificant failure mechanism.	NA

Failure mechanisms continued

Failure Mechanism	Accelerating Stresses	Qualification Test	Applicable to
Electromigration	Current density, Temperature, Temperature gradient	IC-level conducted by foundry. This is generally not a failure mechanism of concern in implantable cardiac devices due to low current densities. Neuromodulation devices may require additional testing.	Component, Electronic module, Final device
ESD damage	Voltage	ESD testing	CMOS electronics, Electronic module
Fatigue cracking	Mechanical stress, Strain range	Vibration testing, 4-point bend, Drop testing, Low-frequency/Low-amplitude repetitive cycling	Electronic module, Final device
High-voltage component failure	Temperature, Voltage cycling	Repetitive defibrillator charge/discharge cycling	Electronic module, Final device
Intermetallic formation (e.g. purple plague)	Temperature	HTOL	Electronic module
Popcorning due to moisture absorption (plastic packages or epoxy over-mold)	Temperature	MSL testing	Component, Electronic module
Radiation degradation	Radiation intensity	X-Ray radiation testing, MRI susceptibility, CT testing	Component, Electronic module, Final device
Soft Error Upset	Particle impingement rate	Alpha foil, Neutron beam, Proton beam, heavy ion testing	Component, Electronic module

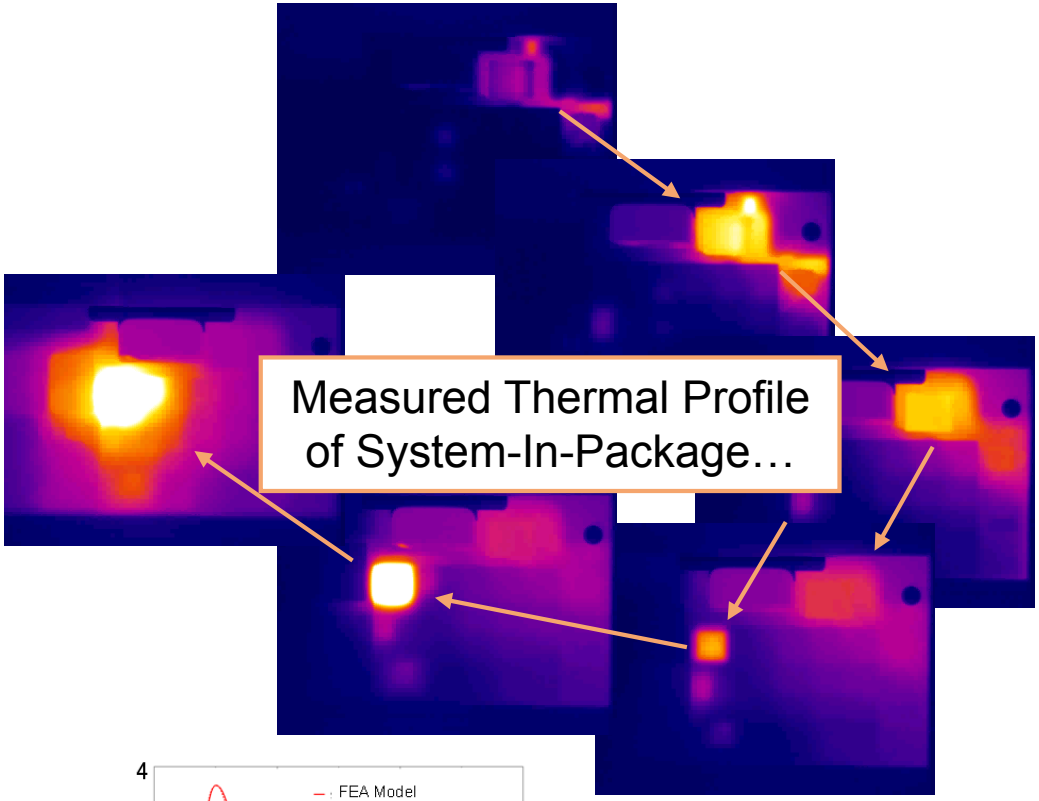
New technologies and more complex devices require increasingly sophisticated qualification activities

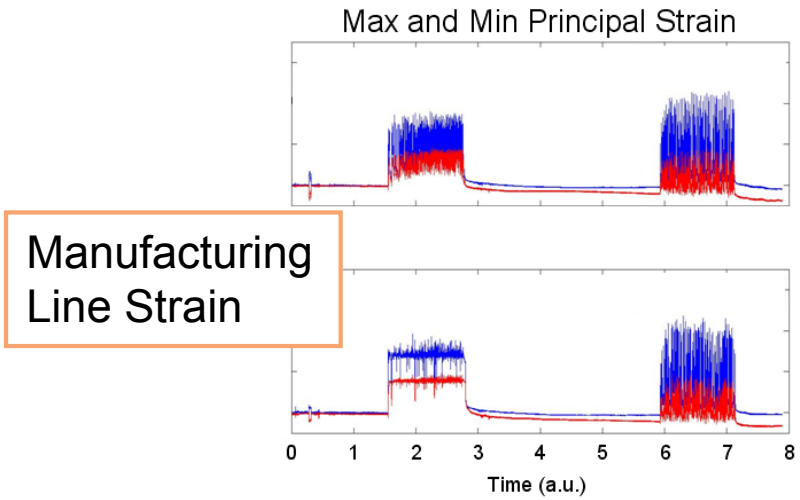
- **Increasing Si integration continues**
  - Deep submicron technologies
  - High-density passives
  - System-in-Package
- **Device volumes are radically shrinking**
- **Input/Output throughput and content are growing**
  - Multiple channels and sensor modalities
  - Data storage for therapeutic diagnostics
- **New technologies are emerging**
  - Bio-materials
  - MEMS
  - Energy Harvesting

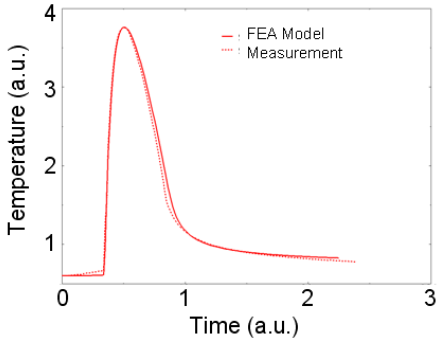


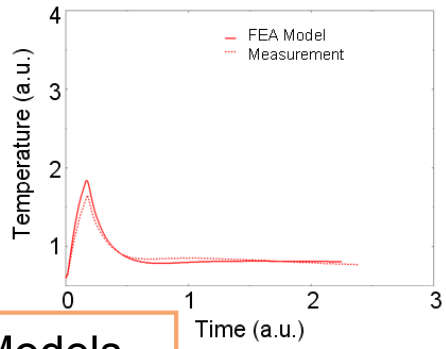
In order to maintain and improve field performance, qualification activities must also advance

- **Modeling activities begin with technology development**
  - Supplier and material choices
  - Intrinsic failure mechanisms identification
  - Manufacturing and assembly processes





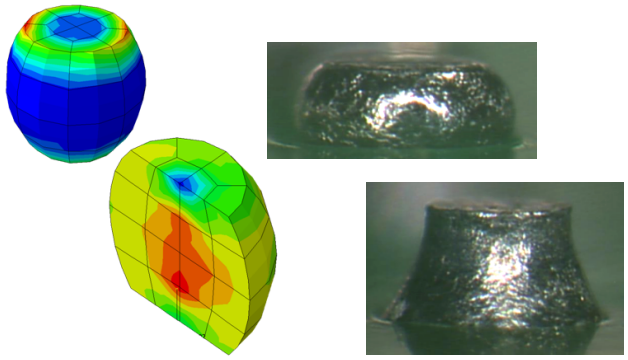




…Correlated with FEA Models

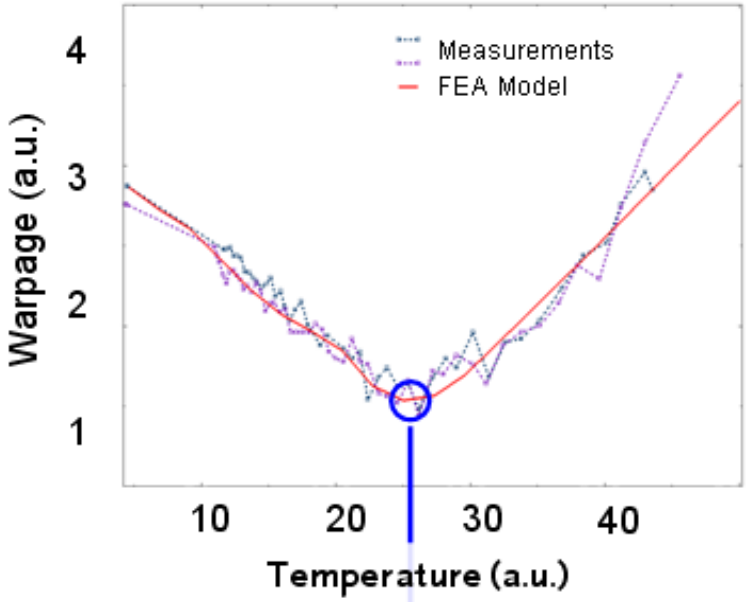
Design choices are evaluated on early prototypes

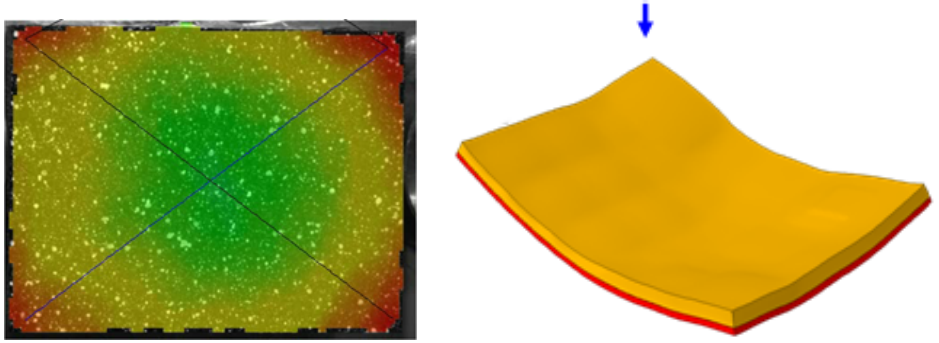
- **A variety of Finite Element Models and experimental techniques are employed**
  - Digital Image Correlation (DIC)
  - Strain-to-Failure
  - Failure Analysis methods



Solder Joint Stress vs. Measured Deformation

Component warpage vs. temperature





Warpage Profile vs. DIC Measurements

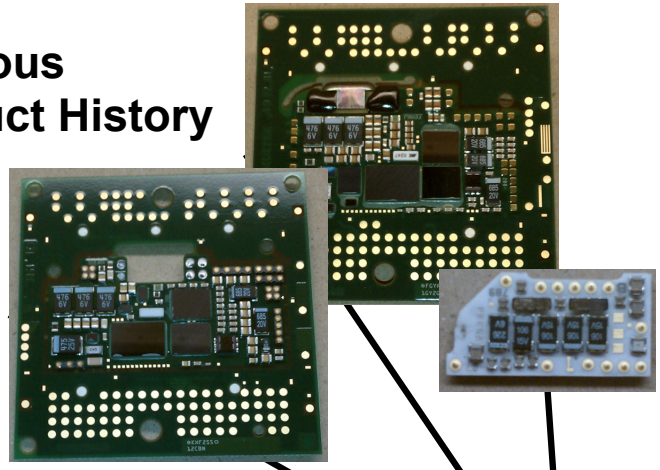
Now the question becomes how to pull all this early information together to support formal qualification

- **Early concepts often lack formal documentation processes**
  - Material Traceability
  - Supplier specifications
  - Rigorous test releases
- **This is a challenge due to highly-regulated implantable medical device industry requirements**

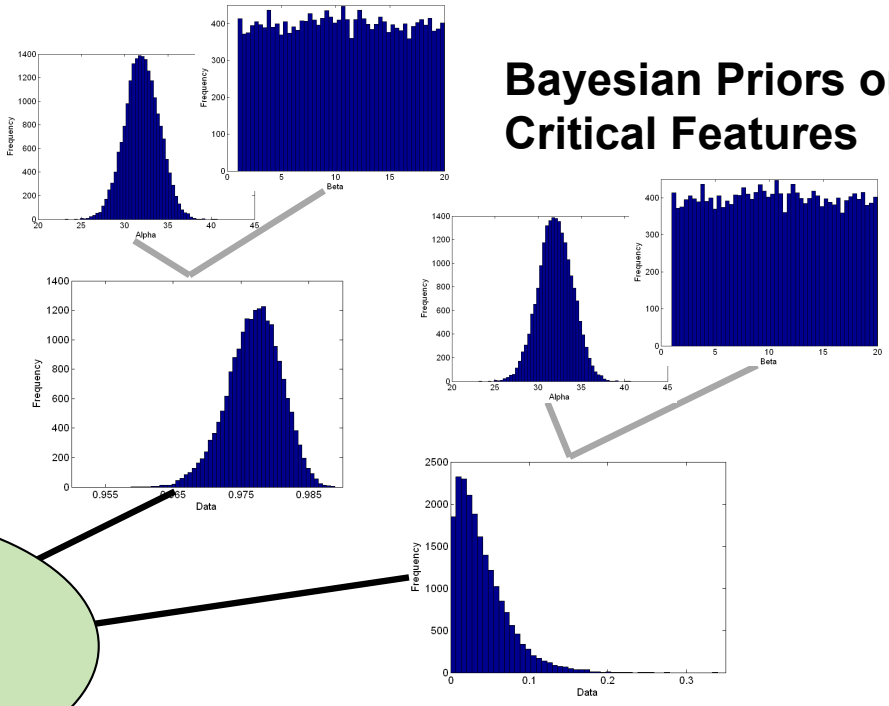
- **And yet, early design iterations come with a wealth of characterization data that can be informative**

Bayesian methods offer a potentially promising option for using early data, along with previous product performance

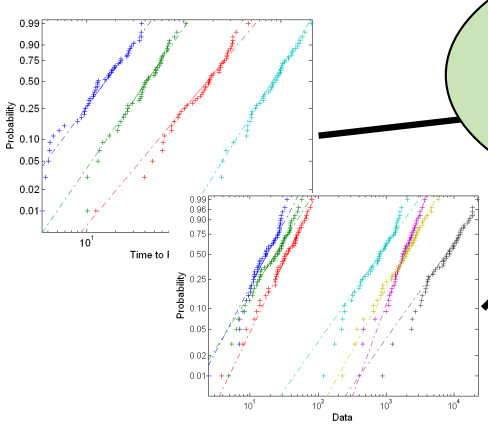
Previous Product History



Bayesian Priors on Critical Features



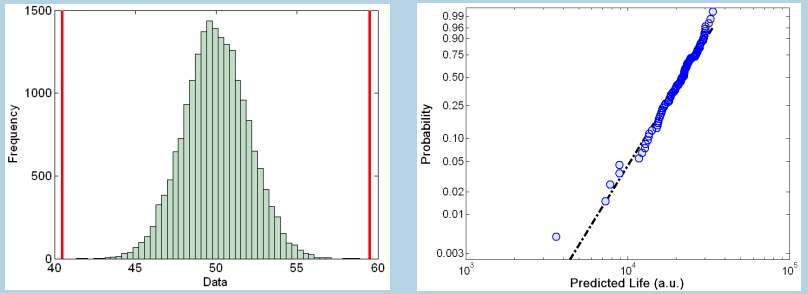
Bayesian Modeling Methods



Early Prototype Model Predictions

Subset of Qualification Procedures

Predicted Performance



Completed devices (IPG, ICD) are subjected to a range of assurance testing

- **Design Assurance Testing (DAU)**
- **CENELEC standards used for test conditions, as well as internally-developed standards**
  - EN 45502-1, EN 45502-2-1
  - Electromagnetic Interference (EMI)
  - Magnetic Resonance Imaging (MRI) performance
  - Shock, drop, vibration
  - Humidity, pressure, bend test
- **External defibrillation robustness**
- **X-ray dose and dose rate exposure**
- **There are ongoing efforts to move as much of this type of testing earlier in the development process as possible**
  - Allows for design modifications
  - Requires a very good understanding of
    - Device → Hybrid → IC correlation
    - Physics of Failure
    - Completeness of design specifications

Final Thoughts

- **Medtronic continues to move from an empirical qualification approach, to a physics of failure, data-driven approach**
  - Leverage industry data wherever possible
  - Comprehend Medtronic application space
    - Ultra-low power requirements
    - Mechanical environment
    - Radiation environment
  - Obtain data as early as possible
    - Literature search, industry/university partnerships, etc.
    - Design-phase versus production phase
    - Component/sub-assembly test results that can be translated to device-level performance requirements
    - Bayesian methods that utilize previous design history

Questions

- **Questions?**

- **Thanks to**
  - Dave Ruben (Medtronic)
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