



International Electronics Manufacturing Initiative

Medical TIG Review

*Tony Primavera/Boston Scientific
Scott Zellmer/Micro Systems Engineering, Inc.
Lake Oswego, OR
November 13, 2006*

- **Co-Chairs: Anthony Primavera – Boston Scientific and David Erhart – Medtronic**
 - **Large Working Group**
 - 3M, Barbara Birrell, Bill Ballard, Denny Aeschliman, Tom Johnson
 - Biotronik, Andreas Schweinzer
 - Boston Scientific, David Yonce, Eric J. Peterson, Louis Skarda, Matthew Stonehouse, Ron Reimann, Anthony Primavera
 - Cochlear, Ltd, Edmond Capcelea
 - Dyconex, Mark Hauer, Pavlin Sabev, Thomas Jacob
 - FDA, Mitchell Shein, William Regnault
 - GE Research, William Burdick
 - iNEMI, Chuck Richardson, David Godlewski
 - Intel, Celeste Null
 - MEDEL, Dominik Hammerer
 - Medtronic, Scott Savage, David Erhart
 - Micro Systems Engineering, INC., Ravi Subrahmanyam
 - NIST, Barbara Goldstein, Dennis Leber, Perry Wilson, Ron Goldfarb, Liz Drexler
 - Plexus, Michael Tendick
 - Sanmina-SCI, Fikreta Jusufagic, Robert Kinyanjui
 - St. Jude Medical, Brian Greig, Stephen Meeks
 - Tyco Healthcare / Kendall, Jim Theodorou
 - Universal Instruments Corporation, Peter Borgesen
 - Vishay, Clark Smith, Roger Roberts

- **Medical Electronics Trends**
 - Growth Drivers
 - Technology Trends
- **Technology Integration Plans**
 - Key Technology Gaps
 - Initial Projects
- **Component Reliability Specifications Project**
 - Project Overview
 - Opportunities

- **Impact to national economy on healthcare will force the need for less expensive systems.**
 - **74 Million elders in US, 1.2 Billion world wide by 2025**
 - **US spending is currently 15-16% of federal budget on health care.**
 - **By 2025, there will be 1 retiree for every 3 workers.**
 - **Higher spending will be required if current model is continued to be followed.**
 - **long term impact is an international trend toward home health technologies and preventive health care**

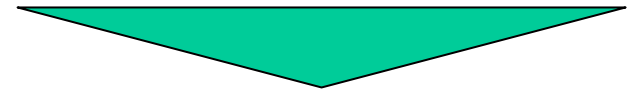
Fastest-growing occupations 2002-2012

(projected)	GROWTH	# OF NEW JOBS
Medical assistants	59%	215,000
Network systems, data communications analysts	57%	106,000
Physician assistants	49%	31,000
Social and human service assistants	49%	149,000
Home health aides	48%	279,000
Medical records and health information technicians	47%	69,000
Physical therapist aides	46%	17,000
Computer software engineers, applications	46%	179,000
Computer software engineers, systems software	45%	128,000
Physical therapist assistants	45%	22,000

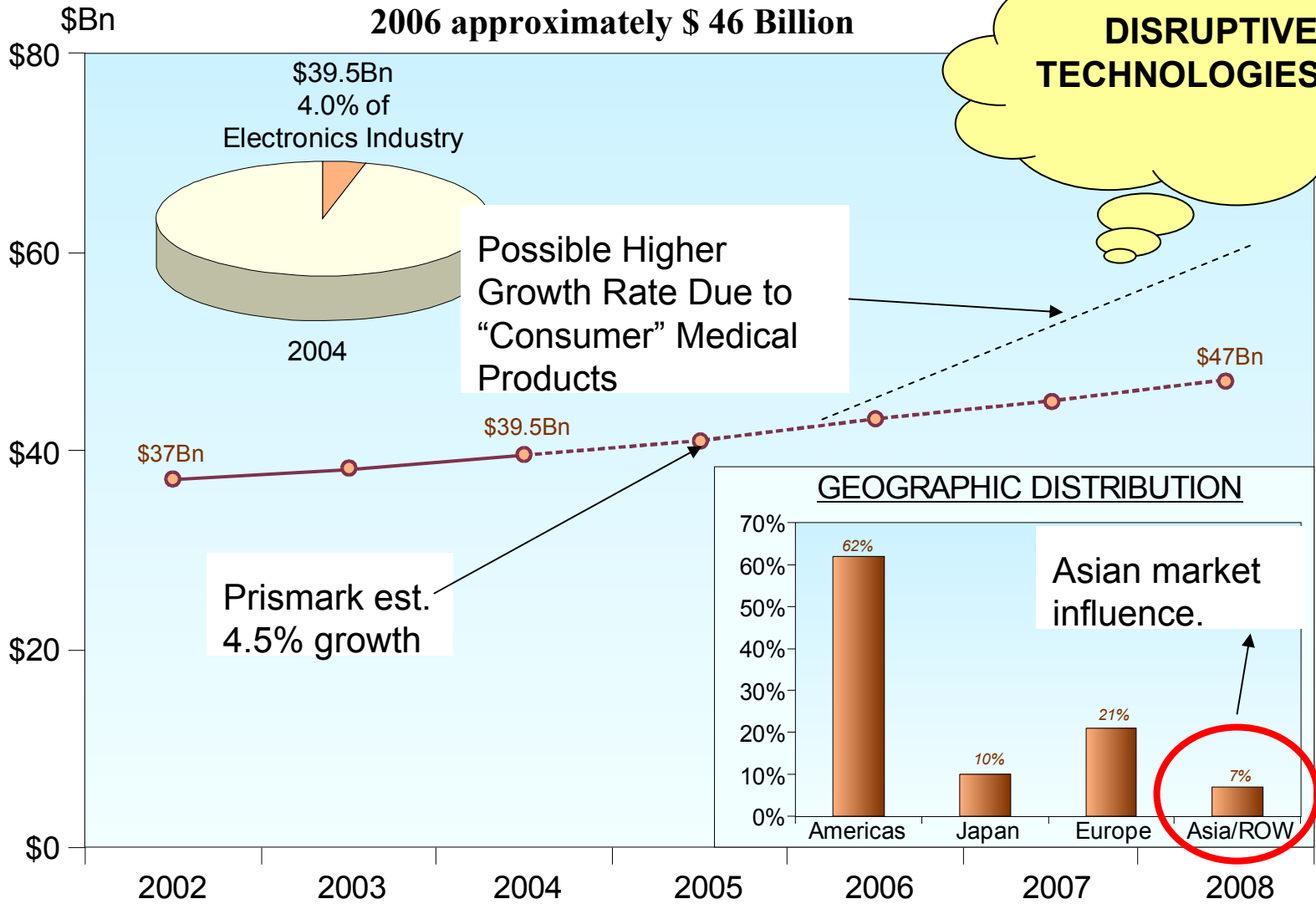
Source: BLS

Source: Bureau of Labor Statistics, pub in CNN/Money.com, "Where the jobs will be Greatest employment growth is likely to be in service industries, according to new labor study." By Jeanne Sahadi, Feb 13, 2004.

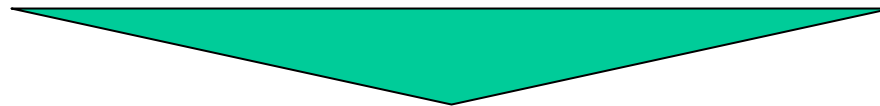
- Medical related job demand fastest growing
 - Inadequate supply of labor
- Costs are critical
 - Rising hospital care costs,
 - Escalation in the number of un-insured,
 - Shorter healthcare giver – patient interaction time.



- Growing “Consumer Medical Electronics Market”
 - home diagnostic equipment, wearable patient monitoring equipment, etc.



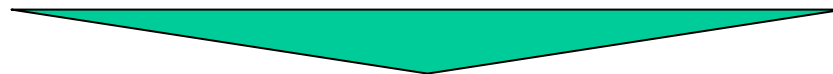
Category	Description	Before	Today (2006)	Future (2012)
MARKET	Medical Therapy	Necessity	Reactive	Prophylactic
	Therapy management	Caregiver	Caregiver/patient	Automated
	Patient Eligibility	Criticality driven	Comfort driven	Wellness/risk driven
	Availability		Developed Nations	Developing Nations
SOLUTION	Hardware & Software	Device Therapy specific	System Limited convergence	Multi-system Integrated / convergent
SUPPORT	Technology Access	Local	Global	Global <--> g'local



**Newly formed markets, new technologies are in development
PRE-COMPETITIVE INDUSTRY COLLABORATION IS VITAL**

- **Global trends defined within three medical sectors**
 - Diagnostic imaging devices and large scale equipment, e.g., Ultrasound, MRI, etc.
 - Portable products (those devices that are easily transported)
 - Implanted products (those devices implanted in a human body)

Some product solutions will necessarily consist of combinations of all three categories of devices.
- **Main differences**
 - Product size, features and form factor
 - Energy type, source and usage
 - Reliability requirements
 - Regulatory issues
 - Supply chain



**MEDICAL APPLICATIONS ARE VARIED
SIZE/FUNCTIONALITY DRIVES DIFFERENCES IN TECHNOLOGY GAPS**

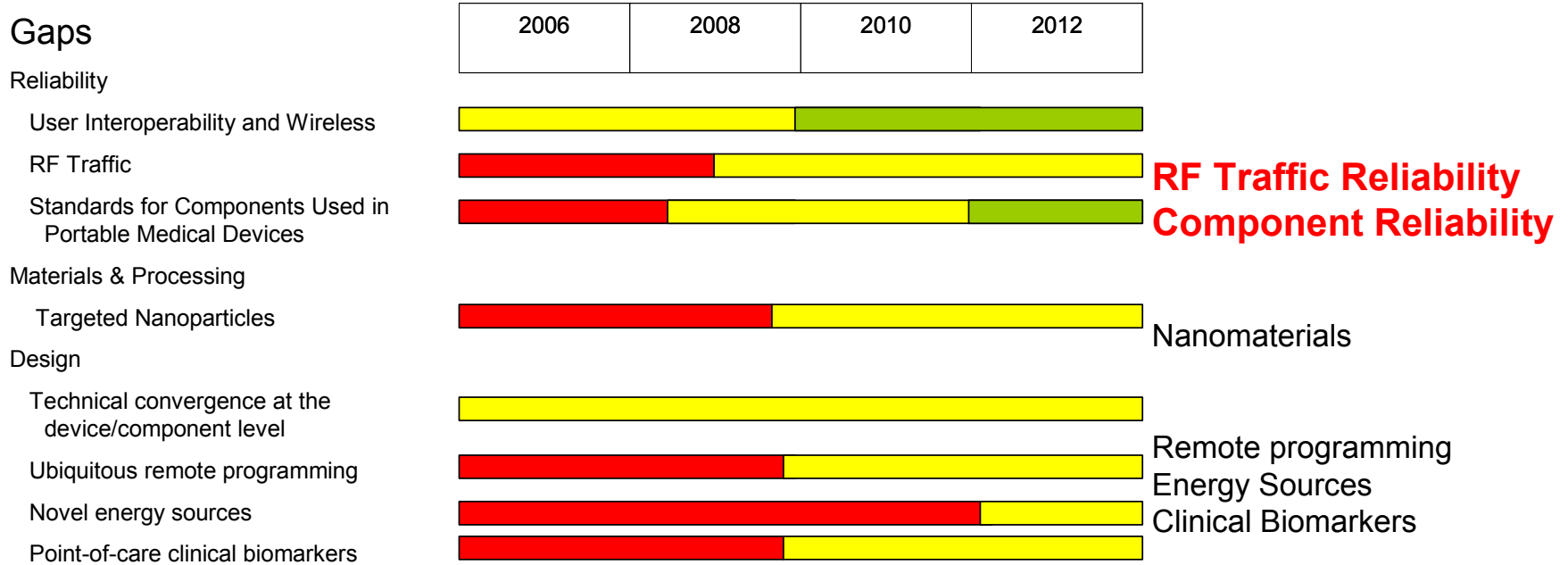
Diagnostic Imaging Systems



Interconnect Density

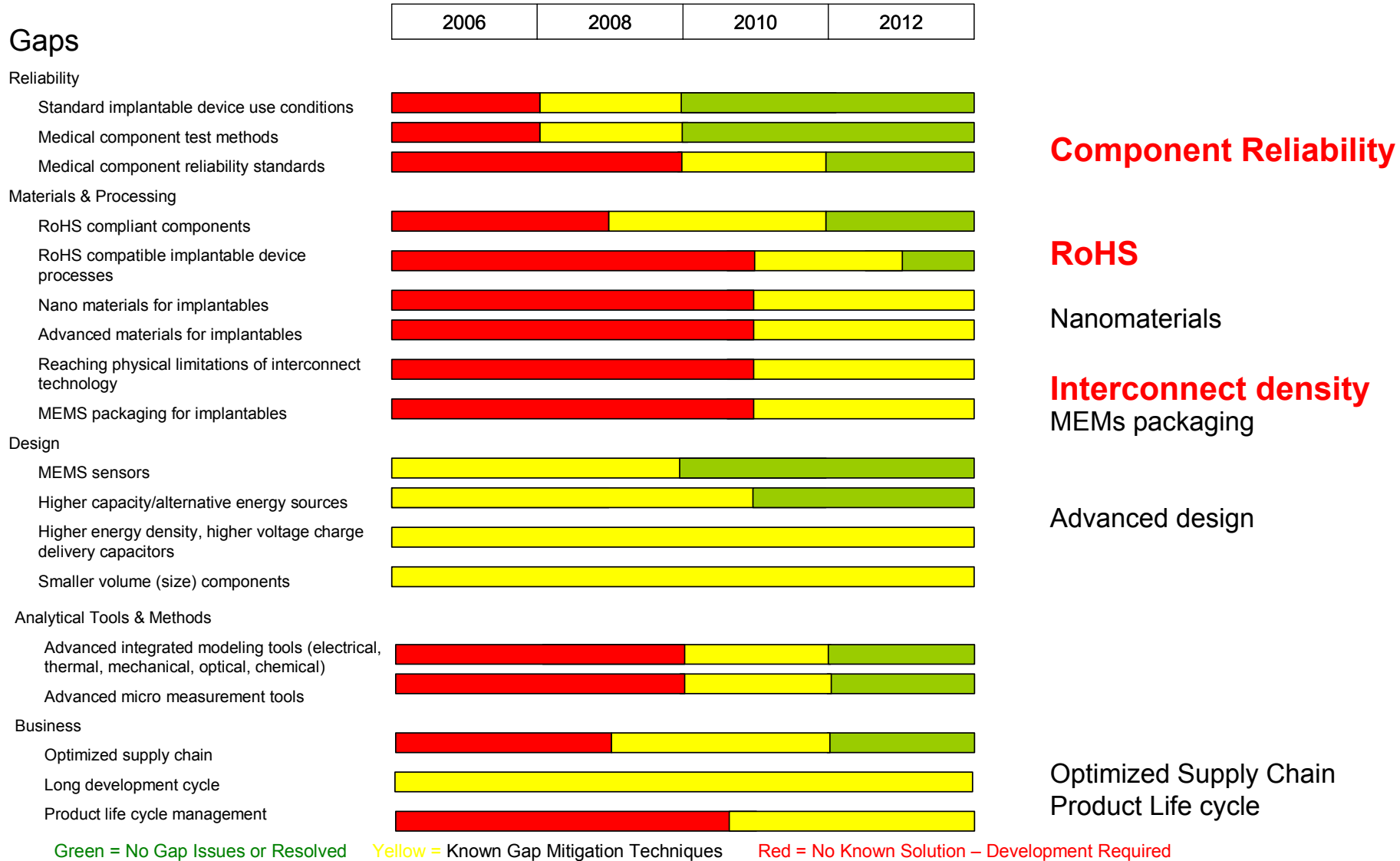
Green = No Gap Issues or Resolved Yellow = Known Gap Mitigation Techniques Red = No Known Solution – Development Required

Portable Medical Devices



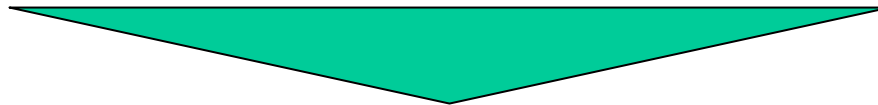
Green = No Gap Issues or Resolved Yellow = Known Gap Mitigation Techniques Red = No Known Solution – Development Required

Active Implantable Medical Devices



Common between multiple medical product sectors:

- **Component reliability: Medical Electronics Components Reliability Specifications Project**
- **RoHS compliance for medical electronics**
- **Interconnect density: Advanced Printed Wiring boards**
- **RF Reliability: Impact of increasing RF traffic in increasing clinical and home environments**



ONGOING FOCUS ON COMPONENT RELIABILITY PROJECT

- **SCOPE: Test and extrapolation methodologies for electronics components leading to non-prescriptive specifications for medical reliability assessment**
 - Discretes (MLCC, Ta, Resistors etc.)
 - Array Interconnect Components (BGA, WLCSP, DCA)
 - Substrates (Flex, Rigid Flex, Rigid)
 - Hybrids & Modules

- **TEAM:**
 - **OEMs: Boston Scientific, Cochlear Ltd, Med-El, Micro Systems Engineering**
 - **Suppliers: AVX, Dyconex, Intel, Johansen Dielectric, Kemet, Novacap, Texas Instruments, Vishay, Zarlink**
 - **Institutes: NIST, FDA**

INPUTS

Use Conditions

- Manufacturing Process & Testing
- Storage (before / after assembly)
- RoHS Compliant Requirements
- Operating (In Use)

USERS SUBGROUP

Existing Standards

- Supplier Plan
- Component Reliability and Assessment

SUPPLIERS SUBGROUP

Supplier Methods, Processes, Risks

- Raw Materials (e.g. for capacitors, Ceramic, Tantalum, Terminations)

COMPONENT RELIABILITY PROJECT TEAM
(Bi Weekly Telcon, Face-to-face 4-6weeks)

OUTPUTS

Accelerated Testing and Extrapolation Methodology

- Sampling/population assessment
- Conditions of Applicability
- Test Methodology and Criteria

LIFETIME PREDICTION & LOT HOMOGENEITY SUBGROUPS

Medical Grade Specifications

STANDARDS BODY

	Q1	Q2	Q3	Q4	Q5	Q6
<u>DISCRETES (MLCC)</u>						
Form Team, Assign tasks						
Define Use Conditions						
Define Existing Standards						
Define Supplier Risks						
Define Accl. Testing/Extr Method.						
Team Review						
Make Revisions per Team Review						
Assemble into a draft document						
Review Draft						
Approve Daft						
<u>SUBSTRATES</u>				TENTATIVE (18months)		
<u>AREA ARRAY</u>				TENTATIVE (18months)		
<u>HYBRIDS</u>				TENTATIVE (18months)		

- Initial focus on SMT MLCC for active implants
- Additional scope based on participation
- Project formally initiated on July 24, 2006

- **OBJECTIVE:**
 - Establish use conditions of life critical implantable medical devices using published literature.

- **OUTPUT**
 - Extensive literature based definition of post-implant and pre-implant operating conditions
 - Comprehensive thermal, mechanical, electrical, environmental and biocompatibility conditions (>40 sections)
 - Prioritized gaps in definitions

- **OBJECTIVE:**
 - **Assess the contribution of each Use Condition, and combinations thereof, to enable measurement of realistic mechanisms for input into Monte Carlo simulations → Accurate prediction, Consistent reporting**
- **OUTPUT**
 - **Define what constitutes failure**
 - **Identify key parameter(s) controlling life times**
 - **Determine acceleration/extrapolation mechanisms**
 - **Develop methodology for experimental tests**
 - **Enlist experimental and numerical contributors**

- **OBJECTIVE:**
 - **Statistically sound sampling and testing methodologies to minimize, and essentially eliminate, the introduction of defective Multi-Layer Ceramic Chip (MLCC) Capacitors to ... implanted or life critical devices**
- **OUTPUT**
 - **Failure Mode and Effects Analysis requirements**
 - **Statistical methods to establish quality (initial) performance**
 - **Statistical methods to establish reliability (time dependent) performance**
 - **Process capability assessment tools / process control**
 - **Acceptance criteria (within lot and lot-to-lot)**

- **ACCOMPLISHMENTS**

- **Industry First collaboration within medical electronics supply / value chain**
- **Significant participation from international supply base and end user groups**
- **Substantial progress toward targeted completion date (Feb 2008)**

- **OPPORTUNITIES**

- **Expand participation profile – Suppliers, Medical manufacturers, Institutions and Universities**
- **Leveraged focus on portable and large equipment needs**

- **iNEMI General / Membership**
 - Jim McElroy – Jim.McElroy@iNEMI.org
 - Bob Pfahl – Bob.Pfahl@iNEMI.org
- **iNEMI Medical Electronics Projects**
 - David Godlewski – David.Godlewski@iNEMI.org
- **iNEMI Medical Electronics Members**
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