



# INEMI

International Electronics Manufacturing Initiative

## 2009 Medical Electronics Technology Plan

April 3<sup>rd</sup>, 2009  
Anthony Primavera

Micro Systems Engineering -  
Biotronik

Advancing manufacturing technology

# Introduction

**Scope: Identification of specific and unique needs of Medical Electronics with an emphasis on high reliability applications.**

- **Background: Over the last several years, a large working group has participated in creation of the current TIG plan.**
- **A wide variety of medical products were represented to ensure accurate scope and coverage.**
- **A fundamental goal of the group was to identify technology needs that are unique or different to the medical product sector compared to other iNEMI sectors.**

# Previous Medical TIG Group Participants

- **Co-Chair: Anthony Primavera – MSEI - Biotronik**
- **Co-Chair: Vacant**
  - **Current Working Group ? Others**
    - Biotronik, Andreas Schweinzer, Ravi Subrahmanyam
    - Boston Scientific, Eric J.Peterson
    - Cochlear, Ltd, Edmond Capcelea
    - Dyconex, Pavlin Sabev, Thomas Jacob
    - FDA, William Regnault
    - GE Research, William Burdick
    - iNEMI, Chuck Richardson, David Godlewski
    - Intel, Celeste Null
    - MEDEL, Dominik Hammerer
    - Medtronic, Scott Savage, David Erhart
    - NIST, Barbara Goldstein, Grady White
    - Plexus, Bill Barthels
    - Sanmina-SCI, Fikreta Jusufagic, Robert Kinyanjui
    - St. Jude Medical, Brian Greig
    - Tyco Healthcare / Kendall, Jim Theodorou
    - Vishay, Roger Roberts
    - TI – Carol Primdahl

# Medical Market Drivers

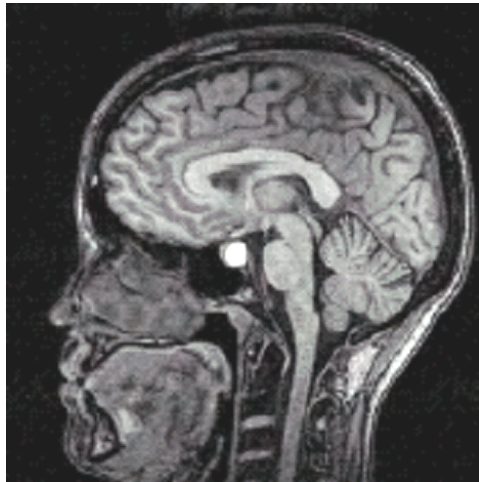
- **Current healthcare system is changing from disease treatment towards preventive and detection medicine. Systems are arising for wellness (prevention, early detection, compliance, caregiver support).**
  - **Some examples are diabetes glucose monitors, Web based medical advice sites, web pharmacy, remote-monitored ICDs.**
  - **Ex. Diabetes monitor strips are mass produced laser ablated 1 layer flex circuits produced in the billions per year.**
  - **These products are changing the supply needs and cost structures for medical to be more in line with consumer and portable products.**

# Medical Market Drivers

- **Technology is being put into patients hands, allowing for offloading formal institutions when appropriate while keeping physicians and informal caregivers “in the loop”.**
  - **For example remote monitoring of patients therapy.**
  - **Ex. An estimated 200,000 patients are currently enrolled in a home / remote monitoring system. These systems are communication devices that interact with the implanted device and a host network system.**
  - **This adds a new product focus and typically outsourced opportunity for CMs and EMS providers.**
  - **The “externals” are one of the first medical products to be shifted from OEM to EMS environments. SE-Asia will pick up the lowest cost of these products.**

# Current Market Drivers in Medical

- Trends toward increased health awareness and preventive care are leading to an increased demand for diagnostic and imaging systems.
- A significant trend in imaging is the development of higher power systems that are capable of higher patient throughput, higher resolution, and a greater ability to distinguish the various tissue types.
- Another trend in medical imaging is moving video for specific applications.



# Variation in Sector

- **For the purposes of this Medical TIG Technical Plan, the product types are too varied to define global trends within the medical sector. Therefore, medical products will be grouped into three general categories.**
  - 1) Implanted products (those devices implanted in a human body)
  - 2) Portable products (those devices that are easily transported)
  - 3) Diagnostic imaging devices and large scale equipment, e.g., Ultrasound, MR, etc.
  - 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

# Potential Projects Identified by Gaps

- This new TIG has support from a wide range of iNEMI member companies, involved in all facets of Medical Product management issues.
- The diversity of the medical device market has led to the development of *three* technical implementation plans and associated gap analyses.
- The Medical TIG members reviewed the implementation plans and the gap analyses and they identified four key areas of overlap (or commonality) that suggest project opportunities.

# Active Implantable Medical Devices

## Gaps

### Reliability

Standard implantable device use conditions

Medical component test methods

Medical component reliability standards

### Materials & Processing

RoHS compliant components

RoHS compatible implantable device processes

Nano materials for implantables

Advanced materials for implantables

Reaching physical limitations of interconnect technology

MEMS packaging for implantables

### Design

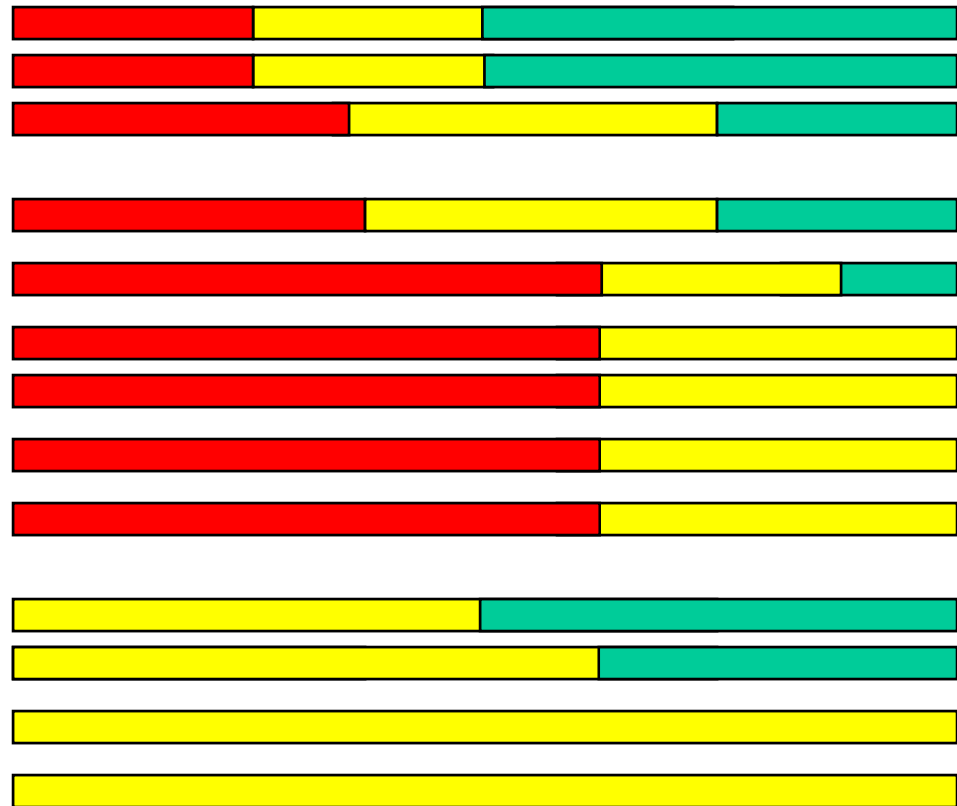
MEMS sensors

Higher capacity/alternative energy sources

Higher energy density, higher voltage charge delivery capacitors

Smaller volume (size) components

2008	2010	2012	2014	Need
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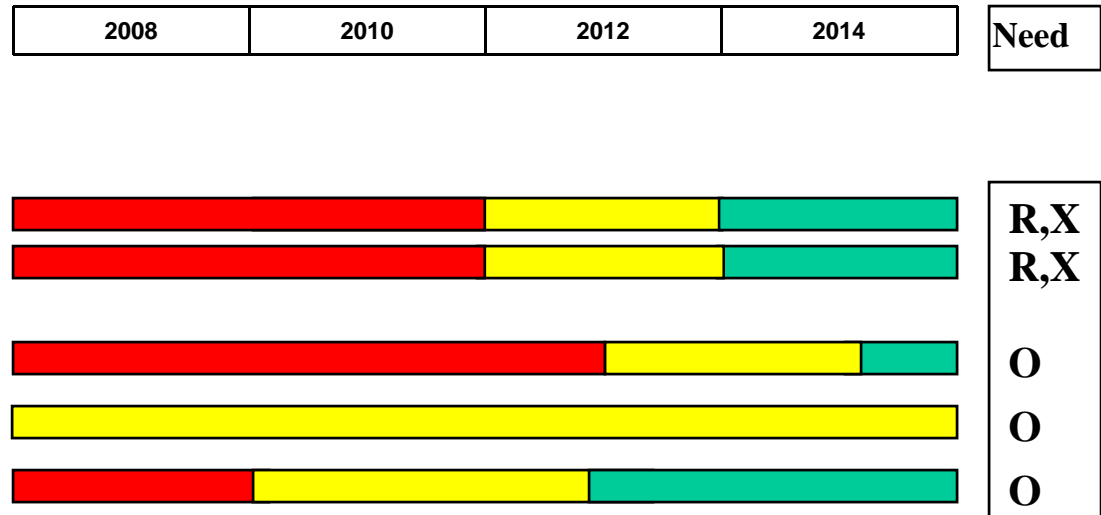
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**R = Research**  
**O = Optimization**  
**S = Standard**  
**X = No Action/Outsource**



# Active Implantable Medical Devices

## Gaps



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

**R = Research**  
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# Gaps Identified Across 3 Sectors

- **1) Component reliability standards and standard test methods that address the unique performance requirements and use environments that characterize the medical products sector.**
  - **Medical Grade Component Specifications Project: The goal of this project is to develop test and extrapolation methodologies leading to non-prescriptive specifications for high reliability medical grade components.**
  - **Initial focus is on surface mount multi-layer ceramic capacitors with subsequent sub-projects related to substrates, array interconnect components and hybrid electronics.**

# Potential Projects Identified by Gaps

- **2) RoHS-compliant components and manufacturing processes that would allow for the safe and effective transition for medical electronics from Pb-based terminal finishes and solders.**
  - Long term reliability of RoHS compliant electronic assemblies
  - Process capability /quality metrics for high reliability applications
  - Supplier, component and process transitions management
  - OTS components in implantable medical devices

# Potential Projects Identified by Gaps

- 3) **Connector and high density interconnects for medical imaging, implantable leads/wires and diagnostic equipment.**
- 4) **Increased RF traffic leading to unknown issues in an ever-increasing wireless clinical and home-health environment.**
- 5) **Global Supply chain. Both encouraging new suppliers to support medical market, and ensuring existing supply base longevity and stability.**

# What has changed

- **What changes have occurred in recent years (2-3)?**
  - **The previous Medical “roadmaps” were focused on larger scale diagnostic equipment (2004) and implantable device (2007). Substantial input from external / portables need to be considered and included.**
  - **Focus required in 3 areas: Sensors and micro/nano devices, high reliability products, and supply chain management. Many suppliers are looking towards high reliability as a means to provide a higher ROI / profit compared to other electronics product sectors.**
  - **Several medical related projects have been initiated to address reliability needs. However, no “supply side” efforts are underway.**
- **For 2009, the medical TIG group needs to engage a wider range of companies. More portable medical / consumer products producers and suppliers are suggested.**
- **More emphasis is required on identification of unique aspects of these products compared to “portable products sector”.**

# Summary

- **The medical group is well underway for it's first project (Component reliability specifications and standards).**
- **The first phase is complete, with phase 2 underway.**
- **Need input from key medical suppliers and OEMS to continue to refine roadmap and TIG plan.**
- **Group would benefit by leveraging knowledge already gained in other iNEMI activities, for example RoHS activities, as pending legislation and supply base shifting towards lead-free are affecting high reliability products.**
- **Expected refinement in TIG plan with some focus on market / supply chain required.**

# Hospital Insolvency

## Recent Trend in Healthcare Industry

### Study done with 4927 Hospitals

- 2,044 hospitals, or 53 percent of the sample, had negative patient care profitability
- 744 hospitals, or 19 percent of the sample, had EBITDA margins below 4 percent
- 737 hospitals, or 19 percent of the sample, had both negative care profitability and EBITDA margins below 4 percent.

Results – Delay or cancellation in capital equipment and monitoring system purchases. Delay payment on materials, supplies and implantable devices.

Source: Alvarez & Marsal Healthcare Industry Group  
March 2008 Study



# April 1<sup>st</sup> TIG Meeting

- **Topics / Potential Gaps Identified at TIG Meeting**
- **Termination Finish / Plating Quality**
- **Supply Chain Management**
- **Counterfeit Parts (Including suppliers of suppliers)**
- **Connector Density**
- **Sn Whiskers**
- **Conformal Coating of Active and “moving” parts**
- **RF Cross Talk**
- **Data Security**
- **MRI Safe Devices**
- **Hemetic Requirements**