



iNEMI

International Electronics Manufacturing Initiative

Medical Substrates Phase 1 Discussion

Based on input as of 12-Nov-08

**Medical Substrates
Formation Group**

Advancing manufacturing technology

Medical Substrates Project

Goal: Investigate the characteristics of substrates used for human implantable medical electronics and other critical medical devices

Strategy:

- Identify and analyze the specifications for substrates used in human implantable medical electronics and other like critical devices.
- Project Lead: Thomas Jacob, DYCONEX Inc



Tactics

- Phase 0: Develop SOW and Project Statement
- Phase 1: Data Mining - Identify gaps in the specifications needing further investigation
- Phase 2: Develop / design evaluation and/or test vehicle(s) for future phases
- Phase 3-6: Conduct experiments to determine the effects of:
 3. Feature size and materials on mechanical characteristics
 4. Harsh cleaning and rework of substrate assembly
 5. Bend radius, cracking, and mechanical fatigue for flexible substrates (only)
 6. High number of cycles under low stress-strain conditions on mechanical fatigue for flexible substrates (only)

Milestones & Issues

- Phase 0 Q407
- Phase 1 Q108
- Phase 2 Q208
- Phase 3-6 Q408
- Issues:

Medical Substrates Project

TIG:
Medical

Start:
TBD

Project Members As identified in 7/17/2007 Draft SOW



Non-iNEMI 2007 Members
Microchip
HEI Corp
Medtronic
Merix?
EIT?



Major Elements/Deliverables of the Project

Phase 0: Project Formation

Phase 1: Identify gaps in the specifications and material supply needing further investigation - Duration 6 months

Phase 2: Develop an evaluation and/or test vehicle(s) for future phases - Duration 6 months

Phase 3: Investigate feature size material effects - Duration 3 months

Phase 4: Investigate harsh cleaning and rework effects - Duration 3 months

Phase 5: Investigate effects of bend radius, cracking, and mechanical fatigue - Duration 3 months

Phase 6: Investigate effects of low strain-stress high cycle on mechanical integrity of the substrates - Duration 3 months

- **Technical reports outlining the substrate technologies for implantable medical electronics and other like critical devices provided as information becomes available**
- **Team to decide on what information will be shared with iNEMI membership and for any external publications/presentations**



Medical Substrates – Phase 1

Human implantable and other like critical medical devices

1. Define medical electronics covered for this project (complete)
 - Completely encased
 - No exposure to bodily fluids
 - Human implantable and other like critical devices
 - Collect, identify, and review the relevant specifications (use the specification list developed for the components project as the starting point for the substrates project) (1 month)
2. Identify gaps in the specifications that need further investigation/evaluation as part of Phase 3 – 6 (1 month)
3. Collect and compile materials, design rules, and board architecture for human implantable and other like critical devices (data collection, compilation and reduction will be done by a third party, such as NIST) (2 months)
 - Define data collection agent (NIST?)
4. Review or identify examples of failure modes (possible contributions from FDA?)
5. Define interdependencies for each specification area and the impact on the materials, design rules, and board architecture [Choose one and use as model for other technologies] (? month)

Medical Substrates – Phase 1 (Con't.)

Human implantable and other like critical medical devices

6. **Board acceptance criteria (Board Mfr., OEM, EMS) - - In coming inspection for suppliers**
 - **Raw material – incoming to board manufacturer (needs team review)**
 - **Biomaterials assurance act review**
 - **In process Quality Control Inspection criteria from Board Manufacturing point of view**
 - **Board material - - Suppliers side - supply to NIST materials - Third Party – possible substrate or product board data (flex and rigid substrates will be considered in Phase 1)**
 - **Test procedures – final inspection (electrical, visual, chemical, contamination) (Board Mfr., OEM, EMS)**
 - **Incoming inspection at OEM and EMS (gage R&R evaluations) – may be company specific (discussion point for Phase 1 & 2 and would impact later phases)**
 - **What are the common elements that should be considered**
 - **Assembly criteria**
 - **Final test procedures (OEM, EMS)**
 - **Use conditions**
7. **Definition of evaluation vehicle(s)**
8. **Define project tasks for Phase 2 (6 weeks) – requires approval from iNEMI Technical Committee**
9. **Provide Project Team with technical report identifying materials, design rules, board architectures and relevant specifications with a summary for the general iNEMI members (6 weeks)**

Technology Gaps

(Limited or Lack of Experimental Data Currently Available)

Parameters to be used in evaluation of substrates

- **Electrical characteristics**
 - Resistance
 - Capacitance
 - RF sensitivity
- **Fatigue**
 - Mechanical degradation
 - Thermal degradation
- **Fracture characteristics / fracture mechanics**
 - Shock and vibration
 - Izod impact test
 - Drop

How will these parameters be evaluated?

- **Test / evaluation modules**
 - Determine optimal sample size for testing
 - Substrate size
 - Populated / unpopulated substrates

Properties as a function of:

- Temperature
- Humidity
- Attachment / encapsulation
- Other environmental dependencies?

Substrate and attachment properties that will affect these parameters

- **Properties of individual substrates**
 - Material selection & stack-up
 - Patterning
 - Line width and spacing
 - Young's Modulus
 - Surface characteristics (hydrophobic, hydrophilic,)
 - Outgassing and moisture intake/sensitivity
 - Moisture insulation as function of SIR/MIR...
- Hierarchical characteristics (encapsulation and attachment dependencies)
- Operational environmental stresses (pollution, pressure [hypobaric] sensitivity, ...)

Technology Gaps

(Reliability)

- **Reliability tests need to be performed in accordance to common practice (IPC specs, etc.) unless determined to be inadequate**
- **Determine reliability tests needed (degradation of all mechanical, electrical, and thermal properties as a function of test conditions)**
 - **Accelerated thermal cycling**
 - **Electro migration**
 - **Outgassing**
 - **Power cycling**
 - **Shock and vibration testing**
 - **Accelerated life tests (are acceleration factors applicable?)**
 - **Environmental stress (temperature, humidity, vibration, etc.)**
 - **Impact from operational environmental**
 - **Electromagnetic radiation (RF interference, EMI, EMC, ...)**
 - **Nuclear / atomic / magnetic radiation (effects of diagnostic testing on implantable devices)**