Component Specifications for Medical Products

Welcome to the Webinar on

Task 1 - Outcome: Industry Survey
Agenda

• iNEMI Overview
• Project Background
• Survey Results
• Components Identified
• Participants needed for sub groups
• Summary
• Contact details
**About iNEMI**

**Mission:** Forecast and Accelerate improvements in the Electronics Manufacturing Industry for a Sustainable Future.

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**5 Key Deliverables:**
- Technology Roadmaps
- Collaborative Deployment Projects
- Research Priorities Documents
- Proactive Forums
- Position Papers

**3 Major Focus Areas:**
- Miniaturization
- Environment
- Medical Electronics

International Electronics Manufacturing Initiative (iNEMI) is an industry-led consortium of around 107 global manufacturers, suppliers, industry associations, government agencies and universities. A Non Profit Fully Funded by Member Dues; All Funding is Returned to the Members in High Value Programs and Services; In Operation Since 1994.

Visit us at [www.inemi.org](http://www.inemi.org)
International Membership Across The Total Supply Chain

<table>
<thead>
<tr>
<th>The International Membership</th>
<th>Incorporated Location; Number of Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>INEMI Member Business Type</td>
<td>North America</td>
</tr>
<tr>
<td>OEM</td>
<td>14</td>
</tr>
<tr>
<td>ODM/EMS (inc. pkg. &amp; test services)</td>
<td>5</td>
</tr>
<tr>
<td>Suppliers (materials, software, services)</td>
<td>9</td>
</tr>
<tr>
<td>Equipment</td>
<td>8</td>
</tr>
<tr>
<td>Universities &amp; Research Institutes</td>
<td>8</td>
</tr>
<tr>
<td>Organizations</td>
<td>11</td>
</tr>
<tr>
<td>Totals</td>
<td><strong>55</strong></td>
</tr>
</tbody>
</table>

✓ Total **Global** Supply Chain Integration
✓ 70% Growth in past 3 years
Background

- Medical Electronics is one of iNEMI’s focus areas
- Many members working in the fast growing area
- iNEMI has been producing a Medical PEG for a number of Roadmap Cycles, identifying the midterm and long term research needs of the industry
- Industry consensus that there are opportunities for collaboration that will help speed up the adoption of new technologies in medical devices. Seven potential projects/initiatives were indentified.
Component Specifications for Medical Products
**Goal:** To develop a standard reliability method that can be implemented by medical device manufacturers within their component management process

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Tactics</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Develop a test and screen matrix for electronic components for qualifying the reliability performance of components for electronic medical devices</td>
<td>• Define a set of reliability qualification methods on a component level</td>
</tr>
<tr>
<td>• Provide standard reliability method that can be implemented by medical device manufacturers within their component management process</td>
<td>• Survey conducted to identify critical components of interest.</td>
</tr>
<tr>
<td></td>
<td>• Webinar on survey results Jan 29th.</td>
</tr>
<tr>
<td></td>
<td>• Sub groups will focus on particular components</td>
</tr>
</tbody>
</table>

**Issues**

• Need for Common Specifications for Medical Electronics Products
  - Every electronic component that is purchased for high reliability medical products today must be individually qualified – no medical industry specifications exist for qualification of components or their suppliers
  - This situation increases costs for component manufacturers

**Graphics**
Problem Statement

• There are few medical industry specifications for the qualification of electronics components or their suppliers.
Purpose of the Project

• The primary purpose of the project will be to develop a method for developing a test and screen matrix for electronic components that can be used to qualify the reliability performance of components for electronic medical devices. Several example screen and test matrices will be included in the report as validation of the practicality of the method.

• This project will result in a standard reliability method that can be implemented by medical device manufacturers within their component management process. In those cases when critical defects and failure mechanisms or test methodologies are already known, the implementation process will be easier.

• For those situations in which the failure mechanisms or test methodologies are not known, this project will be part of a more complex solution.

http://www.inemi.org/project-page/component-specifications-medical-products
Anticipated Outcomes and Benefits

Recommendations for common specifications for electronic components for use in medical devices that meet the test, performance, and reliability needs of medical electronic devices.

- Reduce the resources expended presently on testing to unique requirements.
- Enable the faster introduction of new components and suppliers into the supply chain.
- Enhance the relationships along the supply chain.
## Project Scope
**What the Project IS / IS NOT:**

<table>
<thead>
<tr>
<th>This Project IS:</th>
<th>This Project IS NOT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To define a set of reliability qualification methods on a component level accepted by OEMs (original equipment manufacturers) and supported by suppliers</td>
<td>To define reliability qualification methods for medical devices</td>
</tr>
<tr>
<td>To define: What is acceptable aging of components and what is failure</td>
<td>A qualification effort for a specific product line at a specific supplier</td>
</tr>
<tr>
<td>To quantify reliability within a suitable framework in defined operating conditions</td>
<td>Further work on already known aging/failure mechanisms</td>
</tr>
<tr>
<td>To re-use qualification methods successfully employed and rationalized in other industries</td>
<td>To recreate the wheel of component qualification test methods and processes</td>
</tr>
<tr>
<td>To create guidelines for OCMs (original component manufacturers) to utilize physics of failure based reliability assessment</td>
<td></td>
</tr>
<tr>
<td>To create guidelines for medical OEMs on how to assess OCMs</td>
<td></td>
</tr>
<tr>
<td>To create guidelines on minimum levels of tests for various component types</td>
<td></td>
</tr>
</tbody>
</table>
Project Tasks & Timeline

- **Task 1** Determine the coverage of the components for the first phase
- **Task 2** Identify the most common defects, degradation and failure mechanisms of the selected items under medical device applications
- **Task 3** Determine the screens for identification of the defects and tests for precipitation of the mechanisms
- **Task 4** Create a minimum set of tests and screens related for each part referring to industry standard methods whenever possible
- **Task 5** Final report including a methodology description on the process of developing the tests and screens for other parts
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Project status

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Task 1</th>
<th>Task 2</th>
<th>Task 3</th>
<th>Task 4</th>
<th>Task 5</th>
<th>Next Phases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Determine the coverage of the components</td>
<td>Identify the most common defects, degradation and failure mechanisms</td>
<td>Determine the screens for identification of the defects and tests</td>
<td>Create a minimum set of tests and screens</td>
<td>Final report including a methodology description</td>
<td></td>
</tr>
<tr>
<td>Q1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Q5</td>
<td></td>
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<td></td>
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<tr>
<td>Q6</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Q7</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

INEMI

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Component Specifications for Medical Products

Executive summary

• Industry survey Aug 2012 / Sep 2012
  – 32 questions
  – 67 respondents

• Recommendation for subsequent project tasks could be developed

- Medical device manufacturer
- Medical devices supply chain
- Research organizations, consultants
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Survey Analysis – Outline

- Survey demographics
- Regulatory environment
- Supply chain
- Existing standards
- Identification of critical components
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Survey Summary – Demographics

- Respondents drawn from across the medical industry:
- All Geographical markets served by respondents: largest being North America and Europe
Primary Uses of Medical Devices

Primary use:
- Assistive technology
- Diagnostic
- Life supporting
Primary Locations of Use

Locations of use:

- Hospital
- Home healthcare
- In Vivo

![Bar chart showing primary locations of use with percentages for different categories: Home healthcare (Patient controlled), Hospitals / clinics, In Vivo, Laboratory, and Other (Specify below).]
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Survey Summary – Regulatory Environment

• To the best of your knowledge, what regulatory bodies govern the acceptance and/or use of your products or products you support?

Suppliers:
  – 69% Did not know;
  – 31% Referenced the FDA

OEMs:
  – See following Slide
Component Specifications for Medical Products

Survey Summary – Regulatory Environment

• OEMs response to question on regulatory bodies governing the acceptance and/or use of their products:

<table>
<thead>
<tr>
<th>Regulatory Body</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA - USA</td>
<td>78.2%</td>
</tr>
<tr>
<td>EMEA - EU</td>
<td>50.9%</td>
</tr>
<tr>
<td>Health Canada - Canada</td>
<td>32.7%</td>
</tr>
<tr>
<td>TGA - Australia</td>
<td>29.1%</td>
</tr>
<tr>
<td>MHLW - Japan</td>
<td>23.6%</td>
</tr>
<tr>
<td>SFDA - China</td>
<td>20.0%</td>
</tr>
<tr>
<td>Unknown or Does Not Apply</td>
<td>18.2%</td>
</tr>
<tr>
<td>INMETRO - Brazil</td>
<td>14.5%</td>
</tr>
<tr>
<td>HSA - Singapore</td>
<td>9.1%</td>
</tr>
<tr>
<td>KFDA - South Korea</td>
<td>9.1%</td>
</tr>
<tr>
<td>Other - Please Specify</td>
<td>9.1%</td>
</tr>
<tr>
<td>TFDA - Taiwan</td>
<td>9.1%</td>
</tr>
<tr>
<td>CDSCO - India</td>
<td>7.3%</td>
</tr>
<tr>
<td>MDCO &amp; PSDH - Hong Kong</td>
<td>7.3%</td>
</tr>
</tbody>
</table>
Component Specifications for Medical Products

Survey Summary – Regulatory Environment

• Are you familiar or informed about what the regulatory requirements are for the medical products you produce or support?

<table>
<thead>
<tr>
<th></th>
<th>OEMs</th>
<th>Suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>78%</td>
<td>40%</td>
</tr>
<tr>
<td>No</td>
<td>22%</td>
<td>60%</td>
</tr>
</tbody>
</table>

• Are you aware of any regulatory controls required to maintain or establish component performance, for example ISO 13485?

<table>
<thead>
<tr>
<th></th>
<th>OEMs</th>
<th>Suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>70%</td>
<td>19%</td>
</tr>
<tr>
<td>No</td>
<td>30%</td>
<td>81%</td>
</tr>
<tr>
<td>No/Skipped Question</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Component Specifications for Medical Products

Survey Summary – Regulatory Environment

• What regulatory controls govern your products or products you support?

ISO 13485 (Quality Management Systems) 36%
FDA (Quality System Regulation) 25%
Certified Component 18%
IEC 60601 (Medical Devices) 14%
ISO 14971 (Risk Management) 11%
IEC/EN 45502 (Active Implantable Med Devices) 11%
MDD 7%
Others 3.6%
Component Specifications for Medical Products
Survey Summary – Regulatory Environment

Summary for Regulatory:

OEMs are well aware of the requirements and expectations of Regulators

The Medical device industry could benefit from suppliers having additional guidance into their purchaser’s (OEMs) Regulatory needs
A number of questions were asked regarding the impact on component reliability of conditions and changes in the supply chain:

- Changes in the supply chain
- Storage
- Transportation

The response data is not covered in detail here but the information can be used by the subgroups or other projects in the future to drive further investigation on particular components.
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Survey Summary – Supply Chain Related

Which of the following supply chain factors are most critical? Rank in order of sensitivity.

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Weighted Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in manufacturing equipment or manufacturing process</td>
<td>22.4%</td>
</tr>
<tr>
<td>Single Source of Supply</td>
<td>22.2%</td>
</tr>
<tr>
<td>“Disaster Preparedness” or “Risk Management”</td>
<td>12.5%</td>
</tr>
<tr>
<td>Alternate suppliers</td>
<td>11.7%</td>
</tr>
<tr>
<td>Relocation of manufacturing sites</td>
<td>11.7%</td>
</tr>
<tr>
<td>Changes in the outsourced testing</td>
<td>10.2%</td>
</tr>
<tr>
<td>Other:</td>
<td>9.4%</td>
</tr>
<tr>
<td>- Manufacturing controls</td>
<td></td>
</tr>
<tr>
<td>- Lack of technical expertise in suppliers</td>
<td></td>
</tr>
<tr>
<td>- Location of manufacturing site.</td>
<td></td>
</tr>
<tr>
<td>Intellectual Property Protection</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Component Specifications for Medical Products

Survey Summary – Example of Supply Chain Related

- Are you aware of any storage or transportation conditions that your products or components must withstand?

- Are your products or components stored for prolonged periods prior to use or deployment?

![Storage or Transportation Conditions](image)
- Yes 61%
- No 39%

![Prolonged Storage Conditions](image)
- Yes 54.8%
- No 45.2%
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Survey Summary – Example of Supply Chain Related

• For transporting large systems, is specialized testing required at the component or system level, for example, shock or vibration testing?

Required Specialized Testing

- Mechanical shock, drop, Random Vib Shock, vibration
- Vibration, droptest
- Shipping tests
- Free fall test, shaker test
- Shock and vibe per MIL STD and ASTM IEC61010
- Shock of 500g, appr 1msec
- Vibration random approx 10-2,000Hz

Summary: Shipping concerns regarding mechanical type damage
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Survey Summary – Supply Chain Related

• For the design or in-use of medical devices, which of the following do you consider most important? Rank from highest to lowest.

Summary: Failure of component to meet requirements as specified and over time are the key issues.
To the best of your knowledge, which component types are used in the largest quantities in Medical Electronics (relative to each other)?

- **Passives (Including Circuit Boards)**: 42%
- **Semiconductors**: 26%
- **Sensors and MEMS**: 8%

Passives is the area of most interest.
Component Specifications for Medical Products

Survey Summary – Existing Standards

• Use of standards / specifications as reported by medical device OEMs and suppliers:

Are MIL standards relevant to Medical or is it just because they exist that they are used?
Component Specifications for Medical Products

Survey Summary – Identification of Critical Components

- To the best of your knowledge, have any of your products or products you support experienced unexpected early component failures?
Component Specifications for Medical Products

Survey Summary – Identification of Critical Components

- Which of the following components are most problematic? Rank them from most problematic to the least:

<table>
<thead>
<tr>
<th>Component Category</th>
<th>Most Problematic</th>
<th>Least Problematic N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistors</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Tantalum Capacitors</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Y-Capacitors</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Multilayer Ceramic Capacitors (MLCCs)</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Inductors</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Substrates (with printed and embedded passive devices)</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Substrates (without embedded devices)</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Flex Circuits</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Rigid Flex Circuits</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Resonators</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Substrate integrated passives</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Connectors</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Opto-isolators</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
<tr>
<td>Feed-throughs</td>
<td>○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○ ○</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any other components not listed above.
### Component Specifications for Medical Products

#### Survey Summary – Identification of Critical Components

- Which of the following components are most problematic? Rank them from most problematic to the least:

<table>
<thead>
<tr>
<th>Component Description</th>
<th>Most Problematic</th>
<th>Least Problematic/N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistors</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Tantalum Capacitors</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Y-Capacitors</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Multilayer Ceramic Capacitors (MLCCs)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Inductors</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Substrates (with printed and embedded passive devices)</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Substrates (without embedded devices)</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Flex Circuits</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Rigid Flex Circuits</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Resonators</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Substrate integrated passives</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Connectors</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Opto-isolators</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Feed-throughs</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Please provide any other components not listed above.
Component Specifications for Medical Products
Survey Summary – Identification of Critical Components

• The ranks provided by the respondents were weighted
  – First three ranks were overweighted
  – Last three ranks were underweighted
• An overall „weighted rating“ was assigned to each component type
• Normalized weighted rating is reported
• Several different analysis methods (e.g. different weights, no weighting) were performed
  – Overall result did not change
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Survey Summary – Identification of Critical Components

- Tantalum Capacitors: 14.6%
- Connectors: 12.6%
- Feed-throughs: 9.4%
- Rigid Flex Circuits: 8.9%
- Multilayer Ceramic...: 8.7%
- Flex Circuits: 8.6%
- Substrates...: 8.1%
- Y-Capacitors: 6.0%
- Inductors: 4.5%
- Resonators: 4.2%
- Opto-isolators: 3.9%
- Substrates (with printed...: 3.7%
- Resistors: 3.7%
- Substrate integrated...: 3.1%
- Custom Semiconductor: 20.9%
- Analog and mixed-signal ICs (e.g., voltage regulators,...: 17.6%
- Non-volatile memory components (EEPROM,...: 13.2%
- Discrete semiconductors: 11.0%
- Digital circuits (FPGAs, digital ASICs, logic gates): 10.8%
- DRAM: 10.4%
- Microprocessors: 8.3%
- Microcontrollers: 7.8%
- Other (Please specify below): 0.0%

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Survey Summary – Identification of Critical Components

• Tantalum capacitors
  – Identified as the most critical passive component type in the survey.

• Connectors
  – Very widespread use, good potential for a collaborative effort.

• Feedthroughs
  – Proposal based on team review and survey result.
  – Important component in most implantable ME devices.
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Survey Summary – Identification of Critical Components

• Analog and mixed-signal ICs
  – High ranking in active electronic components. Custom semiconductors rank higher, but the team agrees that they are not suitable for a collaborative effort.

• Flex circuits
  – Widespread use in medical devices
  – When combined with rigid-flex: High priority / criticality in the survey.
Component Specifications for Medical Products

Survey Summary – Invitation to Participate

• The survey has proved a valid starting point for further focus and investigation on the critical components identified

• Expertise and experience in each of these 5 sub groups areas, is needed in order to develop recommendations for common specifications for these electronic components that meet the test, performance, and reliability needs of medical products
Component Specifications for Medical Products

Expectations for Sub-Group Members

- iNEMI membership (Required)
- Weekly 1 hr meetings by WebEx for 6 - 8 months
- Report to project chair and team between July & Sept 2013.
Next Steps

• iNEMI to contact webinar attendees and others to assess interest (Feb)

• Form sub groups around the 5 critical components groups identified.

• Start sub group meetings in March

• For more information contact: gomalley@inemi.org

http://www.inemi.org/project-page/component-specifications-medical-products
www.inemi.org

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