iNEMI

International Electronics Manufacturing Initiative

Medical PEG

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Advancing manufacturing technology

Introduction

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

- **Background: The TIG and PEG for the Medical Electronics Sector has a few changes since the last roadmap. These course correction or directional changes are highlighted in this update. Those specific items will be addressed in the next Medical PEG update and will be the focus of this year's efforts.**

Medical Market

- By 2010 there will be an expected 40 million persons in the U.S. over 65 (U.S. Census Bureau)
- Currently the nation is spending 15% of the gross domestic product on health care.
- This 15% represents 1.55 trillion dollars spent on health care. By 2010 it is expected the United States will spend over 17%.
- It is estimated that 50 Billion $ is currently spent annually on medical devices / electronics

Medical Market Drivers

- **Current healthcare system is optimized for treating disease; innovation is clinic-and-pharma centric.**

- **Industry has begun to focus on preventive and detection medicine. System need to be created 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 PEG 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 100,000 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.**

Variation in Sector

- For the purposes of the PEG, common elements were grouped together such as the need for discretes and PCB substrates, however, for the Medical TIG Technical Plan, the product types are too varied to define global trends within the medical sector. Therefore, medical products were 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

Issues Driving Future Trends

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

Of the the 10 fastest-growing occupations, medical related jobs are growing the fastest.

However, there is a short supply of qualified medical professionals.

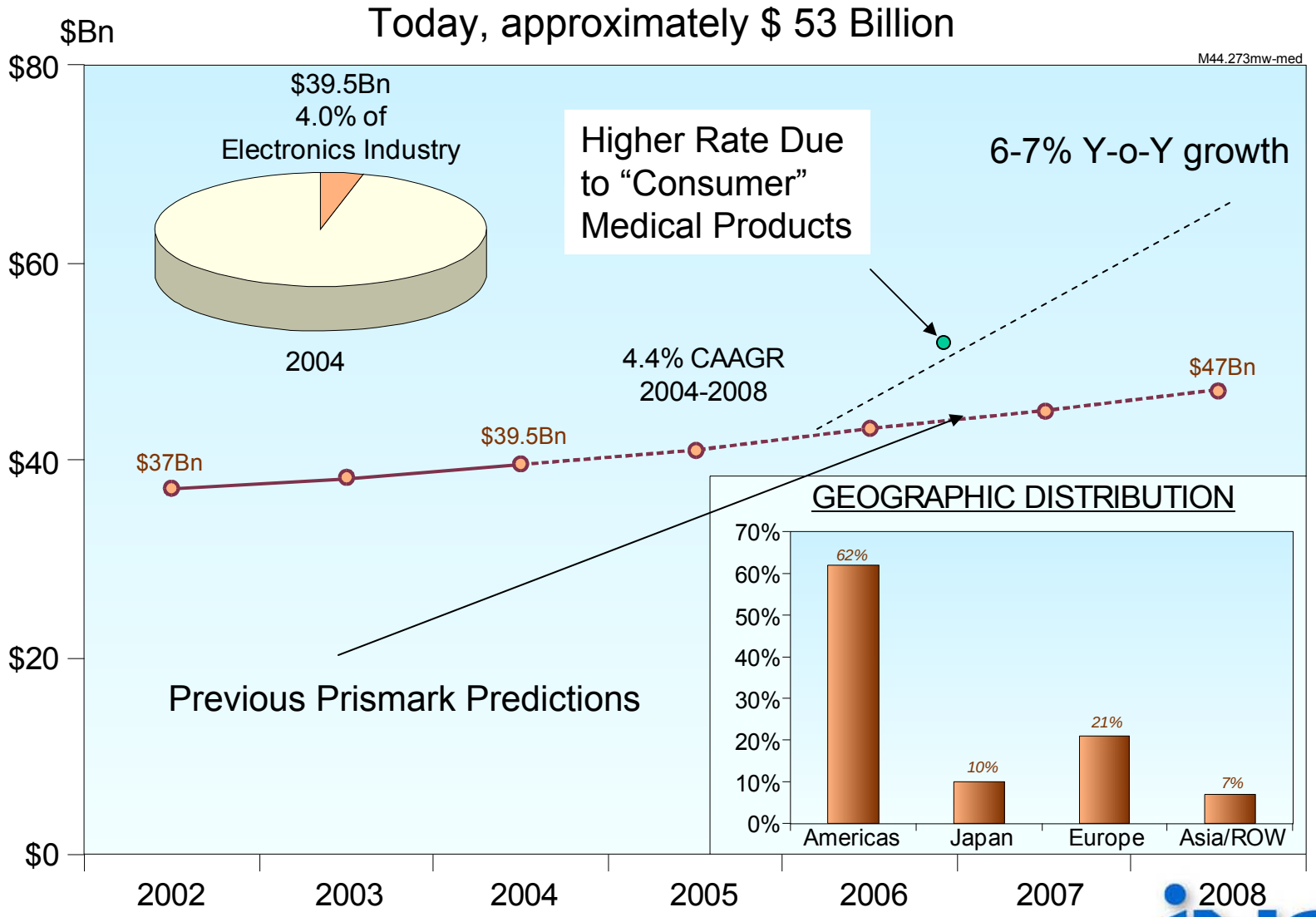
In addition, rising hospital care costs, escalation in the number of un-insured, rise in HMO providers, and other factors contribute to shorter healthcare giver – patient interaction time.

These factors and others are giving rise to a growing “Consumer Medical Electronics Market”

For example, home diagnostic equipment, wearable patient monitoring equipment, etc.

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.

Estimated Market Growth

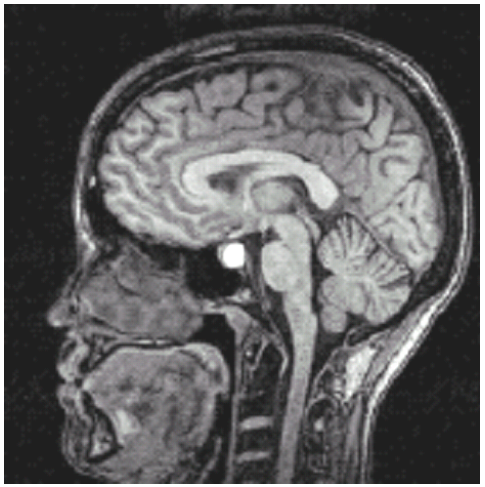


Current Market Drivers in Medical

- **Over the longer-term, the medical electronics equipment market is driven by increased spending on medical care.**
- **Some of the growth drivers for this segment include medical imaging systems, implantable therapy systems, and patient monitoring systems**
- **Large Growth in wireless and portable systems.**
- **Prismark estimates a 6% growth in medical sector spending on electronics**
- **Focus on 2 primary markets: Mature USA, EU and Japan as well as lower featured diagnostic equipment for India, China and other under penetrated markets.**
  - **Ex. Sonogram: target is for a sub 1000$ sonogram unit to be fabricated and sold in India. Best estimates are for 1M + units**

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.



Current Market Drivers in Medical

Implantable therapy devices continue to be a growing market area and have expanded beyond pacemakers and implantable cardioverter defibrillators (ICDs). Note, however, that the implantable defibrillator market showed some weakness in 2006 due to a slowdown in the US market.

Digital Health

•In the past 10 years, growth, innovation and miniaturization have lead to major advances in medical electronics manufacturing and the therapies they deliver.

•Patient care enhancement

- New and Unique Medical Products
- Monitor Systems
- Sensor Technology
- Improved Diagnostics

•Wireless technology for data transfer

- Instant and remote monitoring
- Power can be transmitted via RF signals
- Can off-load computing and data storage to remote host system outside the device.

Medical PEG Roadmap Highlights

- **Non-Implantable Category**
  - **Larger Scale (Often similar to servers or telecom equip.)**
  - **Often requires thermal management & heat sinking**
  - **Utilizes commercial off the shelf components when possible**
  - **Development cycle much shorter than implantables**
  - **Application / design well suited to EMS environment**
  - **Often does not require clean room or sterile assembly floor**

Medical PEG Roadmap Highlights

- **Implantable / Life Critical Category**
  - **Small Scale**
  - **Operating conditions – 37C**
  - **Many custom components**
  - **Development cycle on the order of years**
  - **Application / design currently not well suited to EMS environment**
  - **Requires clean room and sterile assembly floor**
  - **Driven by battery life (low power loss) – this limits the use of certain components such as DRAM due to high energy consumption.**
  - **Reliability paramount due to life critical nature of device**

Medical PEG Roadmap Highlights

- **Example of Differences**

Dominant US regions: MA, MN,CA, AZ
Dominant EU regions: Ireland and Germany
Dominant SEA regions: Malaysia, Singapore

Supply Chain Locations						
Implantable		2005	2007	2009	2011	2017
System Design	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU
System Fabrication	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU
Processor Design/Fab	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	Asia	Asia
Component Design	Dominant Geography	N.Amer./ EU	N.Amer./ EU	Asia	Asia	Asia
Board Assembly	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU
Component Procurement	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU
Final Product Assembly	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU
Non-Implantable		2005	2007	2009	2001	2017
System Design	Dominant Geography	N.Amer./ EU	N.Amer./ EU	N.Amer./ EU	Asia	Asia
System Fabrication	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Processor Design/Fab	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Display Design/Fab	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Memory Subsystems	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Component Design	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Board Assembly	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Component Procurement	Dominant Geography	Asia	Asia	Asia	Asia	Asia
Final Product Assembly	Dominant Geography	Asia	Asia	Asia	Asia	Asia

Future Dominant Regions: China, India

Medical PEG Roadmap Highlights

- **Example of Differences**
- **Implantables on a much longer time scale**
  - **Heavily influenced by regulatory**
  - **Product qualification time lengthy**
  - **Long production times (Geography Dependant)**

Cycle Time - Implantable	*Metric*	*2007*	*2009*	*2011*	*2015*	*2017*	
Time to add EMS	Months	24	24	18	18	18	Implantable, includes validation protocols and regulatory submissions
NPI Cycle Time	Months	24	24	18	18	18	Implantable, includes validation protocols and regulatory submissions
Production length of run	Years	10	9	7	7	7	7 year minimum in some geographic locations

External and Portable Medical	*Metric*	*2007*	*2009*	*2011*	*2015*	*2017*	
Time to add EMS	Current (weeks)	12	8	6	6	4	Externals
NPI Cycle Time	Current (weeks)	16 (104)	14 (78)	12 (78)	10 (78)	6 (52)	Consumer and portable, (Class 3 externals in brackets)

Estimated PCB Needs/Costs

Driven by Implantables

Parameter	Descriptions	Metric	2005	2007	2009	2011	2017	Comments
PWB Costs								
Single Side Dynamic Flex	State of the Ar	$ per cm2						Consumer External Monitoring (ex glucose test stri
Double Side Dynamic Flex	State of the Ar	$ per cm2	0.25	0.24	0.23	0.22	0.2	Connectors, sub-assemblies, components, etc.
2 layer Rigid	State of the Ar	$ per cm2						Sensors, sub assemblies, components
3 layer flex	State of the Ar	$ per cm2	0.4	0.4	0.35	0.35	0.3	3d packaging, subassemblies, implantables
4 layer conventional	State of the Ar	$ per cm2	0.15	0.14	0.13	0.13	0.12	externals, patient monitoring
4 layer flex	State of the Ar	$ per cm2	0.5	0.5	0.45	0.45	0.4	implantables
4 layer Rigid (with micro vias)	State of the Ar	$ per cm2	0.18	0.18	0.15	0.12	0.12	implantables, patient monitoring, wearables
4 layer - embedded capacitor / resistor	High End	$ per cm2		0.25	0.25	0.23	0.2	implantables
6 layer conventional	State of the Ar	$ per cm2	0.018	0.018	0.018	0.018	0.018	externals, patient monitoring, wearables
6 layer flex (with micro vias)	State of the Ar	$ per cm2	1	0.9	0.85	0.8	0.75	implantables - High Power
6layer rigid (with micro vias)	State of the Ar	$ per cm2	0.2	0.2	0.18	0.15	0.15	implantables - low power
6 layer - embedded capacitor / resistor	High End	$ per cm2		0.3	0.3	0.28	0.2	Implantables
8 layer	State of the Ar	$ per cm2						
12 layer Conventional (FR4)	State of the Ar	$ per cm2						
12 layer conventional (FR4) with buried vias	State of the Ar	$ per cm2						
12 layer conventional (FR4) with buried and m-vias	State of the Ar	$ per cm2						
12 layer conventional (Aramid)	State of the Ar	$ per cm2						
12 layer conventional (Aramid) with buried vias	State of the Ar	$ per cm2						
12 layer conventional (Aramid) with buried and m-vias	State of the Ar	$ per cm2						
14 layer, no blind/buried	State of the Ar	$ per cm2	0.45	0.43	0.41	0.39	0.36	Diagnostic, telecom
18 layer conventional (FR4) with blind vias	State of the Ar	$ per cm2						
18 layer conventional (FR4) with blind and buried vias	State of the Ar	$ per cm2						
18 layer conventional (FR4) with blind, buried and micro	State of the Ar	$ per cm2						
18 layer conventional (Aramid) with blind vias	State of the Ar	$ per cm2						
18 layer conventional (Aramid) with blind and buried vias	State of the Ar	$ per cm2						
18 layer conventional (Aramid) with blind, buried and mic	State of the Ar	$ per cm2						
18 layer (FR4) rigid-flex with X flex layers	High End	$ per cm2						
26 layer rigid-flex (FR4) with blind, buried and microvia, b	State of the Ar	$ per cm2						
28 layer, blind & buried vias	State of the Ar	$ per cm2	1.17	1.1	1.05	1.05	0.95	High end imaging, high speed telecom, data storag
48 layer, blind & buried vias	State of the Ar	$ per cm2						

Specific PCB Needs:

PCB Type	2005	2007	2009	2011	2017	
Single Side Dynamic Flex						Consumer External Monitoring (ex glucose test strip
Double Side Dynamic Flex	0.25	0.24	0.23	0.22	0.2	Connectors, sub-assemblies, components, etc.
2 layer Rigid						Sensors, sub assemblies, components
3 layer flex	0.4	0.4	0.35	0.35	0.3	3d packaging, subassemblies, implantables
4 layer conventional	0.15	0.14	0.13	0.13	0.12	externals, patient monitoring
4 layer flex	0.5	0.5	0.45	0.45	0.4	implantables
4 layer Rigid (with micro vias)	0.18	0.18	0.15	0.12	0.12	implantables, patient monitoring, wearables
4 layer - embedded capacitor / resistor		0.25	0.25	0.23	0.2	implantables
6 layer conventional	0.018	0.018	0.018	0.018	0.018	externals, patient monitoring, wearables
6 layer flex (with micro vias)	1	0.9	0.85	0.8	0.75	implantables - High Power
6layer rigid (with micro vias)	0.2	0.2	0.18	0.15	0.15	implantables - low power
6 layer - embedded capacitor / resistor		0.3	0.3	0.28	0.2	Implantables

Trends in Medical Products

- Flex PCBs – both low,end 1 layer and high end 6+ layer PCBs
- Higher Class Materials
- Embedded Passives
- Ceramic Substrates still used!

Medical Substrates Project Being formed – Need Participation from other iNEMI members

Estimated Assembly Costs

Implantables have very special assembly needs
Traceability
Hermetically Sealed
Clean Room Assembly

Parameter	Descriptions	Metric	2005	2007	2009	2011	2017	Comments
Assembly Cost - Non Implantable								
Board Assembly Cost	State of the Ar	¢ per I/O	0.28	0.25	0.23	0.19	0.19	Can be several X cost, due to traceability and clean room assembly
Final Product Assembly Cost	State of the Ar	$/unit	12	10	8	6	5	Can be 10 to 50X cost for implantables, due to welding and hermetic container assembly, clean room requirements and traceability
Package Cost - Non Implantable								
IC Package Cost	State of the Ar	¢ per I/O	0.21	0.18	0.16	0.15	0.15	
Package Cost (High Density Ceramic/w/ Area Connecto	State of the Ar	¢ per I/O	6	5	4	3	2	
Package Cost (High Density µvia Laminate w/ Area Con	State of the Ar	¢ per I/O	5	4	3	2	2	
Connector Cost	State of the Ar	¢ per I/O	2.1	1.9	1.6	1.3	1	
Energy Cost	State of the Ar	$/Wh	0.5	0.4	0.3	0.25	0.2	
Memory Cost	State of the Ar	$/MB	0.23	0.2	0.18	0.15	0.1	
Cost of Test as a ratio to assembly	Total cost of te	ratio	0.4	0.4	0.5	0.6	0.6	

General Assembly Cost is Driven by Diagnostic and Externals

Product Needs

Size constraints on implantables will drive M0402, 1005 and embedded passives in next few years.

Parameter	Descriptions	Metric	2005	2007	2009	2011	2017
Passive Components - Implantables							
Passive Devices:	State of the Art (productic	Type/Size	0201 case	0201 case	M0402	M0402	1005 case
Embedded Passives	Passives fabricated into th	# per sq. cm		2	4	8	16
Max. Ohms	State of the Art (productic	ohms / sq.	400	600	700	1M	1.2M
Max. Capacitance	State of the Art (productic	µF / sq.	0.1	0.1	0.2	0.3	0.5
Min. % tolerance	State of the Art (productic	%	0.05	0.05	0.04	0.04	0.03
Passive Components - Externals							
Passive Devices:	State of the Art (productic	Type/Size	0201 case	0201 case	0201 case	0201 case	0201 case
Embedded Passives	Passives fabricated into th	# per sq. cm	NA	NA	NA	NA	NA
Max. Ohms	State of the Art (productic	ohms / sq.	400	600	600	700	1M
Max. Capacitance	State of the Art (productic	µF / sq.	0.1	0.1	0.1	0.2	0.2
Min. % tolerance	State of the Art (productic	%	0.05	0.05	0.05	0.05	0.05

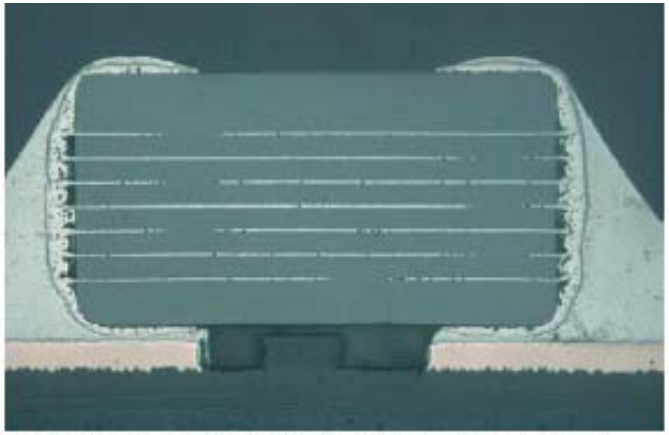


Photo 15 mag.200X-C0201-2 section 4 pos.1

Major Focus currently on “Medical Grade” Capacitors. iNEMI Medical Component Project Currently underway.

Goal:

To determine Reliability test requirements for Medical Grade classifications

Product Needs

Reliability Needs are
Driven by Implantables

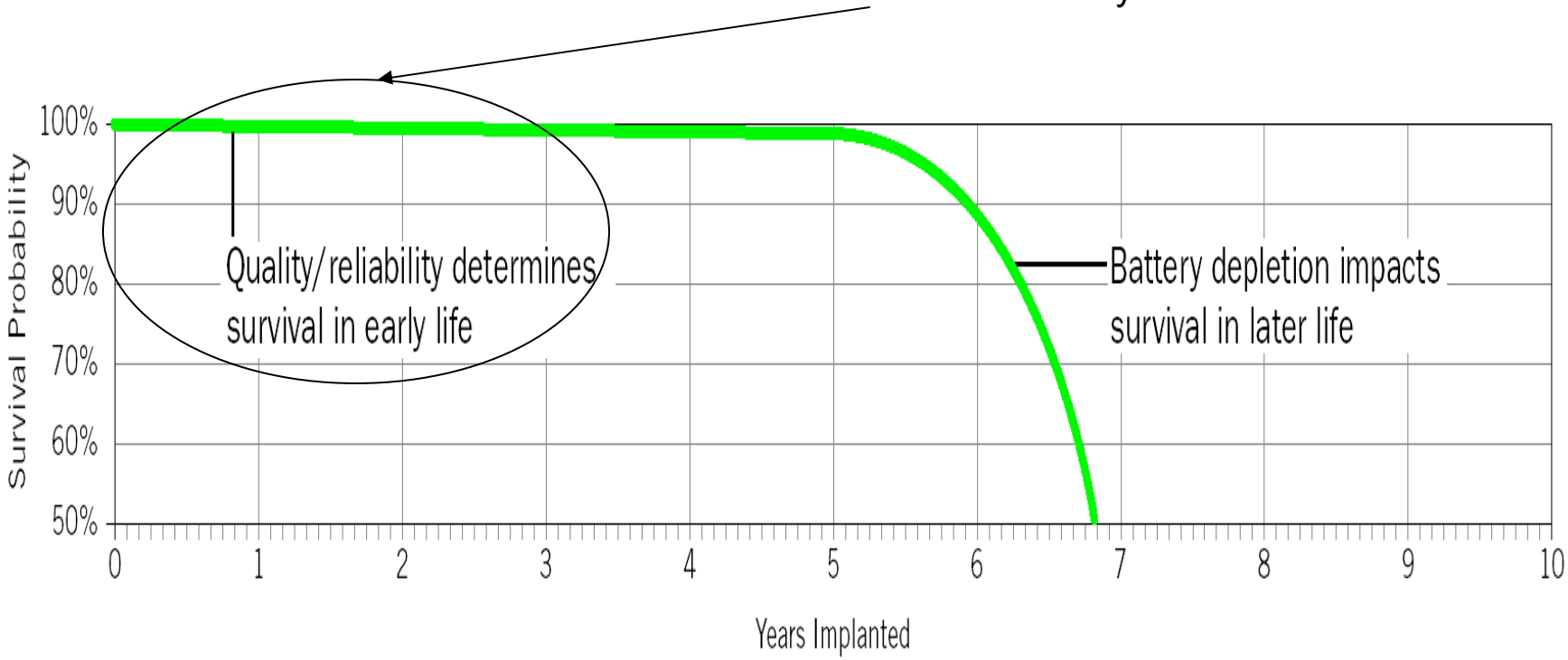
Reliability - Implantable	Metric	2007	2009	2011	2015	2017	
Temperature Range	Deg C - Deg C	"-40 to 80	"-40 to 80	"-40 to 80	"-40 to 80	"-40 to 80	Product Screening Test
Temperature Range	Deg C - Deg C	"-55 to 150	"-55 to 150	"-55 to 150	"-55 to 150	"-55 to 150	Qual.Test
Temperature Range	Deg C - Deg C	"0 to 100	"0 to 100	"0 to 100	"0 to 100	"0 to 100	Ship / Shock Test
Mechanical Flex Test Number of Cycles	Cycles to Pass	250,000	1M+	2M+	2M+	2M+	Simulate Sub-pectoral implant movement
Vibrational Environment (PWB level)	G^2/Hz	1000	1000	1000	1000	1000	Random Vibration
Use Shock Environment	Gs & ms to Pass	500G 3 axis	500G 3 axis	1000G	1000G	1000G	Impact Resistance
Altitude	Feet	40,000	40,000	40,000	45,000	45,000	Must be Gamma Emmision Safe for Shipping

Medical Often uses “Harsh Condition Testing” for Reliability
1000G drop / shock 3 Axis
2,000,000 plus bend / deflection cycles
-55 to + 150C thermal cycle testing
Scuba and hyper baric chamber

Cumulative Survival Statistics

In Implanted devices,
Substantial effort is expended on testing for early failures

New High Density Batteries MnO_2, may lead to 10+ year life.



A cumulative survival plot of a typical implanted ICD

Medical Products Future

- Divergent paths
- Implantable – Small, smaller and did I mention small?
- Implantable devices on order of 1-2 cc's, pacemakers on order of 10 cc's, defibrillators on order of 30 cc's
  - Need 0201 and M0402's now in multiple capacitive and resistive values. 01005's around the corner.
  - Embedded technology critical to future development
  - Need inexpensive 3 layer flex tape
  - Low power consumption – (need attention from major memory manufacturers)
  - Need a truly reworkable underfill (non-mechanical)
  - SIP is everywhere in medical (base platform with many sub-systems to increase functionality and deliver a specific therapy)
  - Need very small connectors that can handle high power. Defibrillators deliver up to 40 Joules at 1000V.

Medical Products Future

- Divergent paths
- External and Monitoring Equipment
  - More functionality, graphics drivers and memory
  - Need high-end multi-layer boards like servers and telecom
  - Memory, hard drive and data transmission rates similar need to telecom
  - Thermal management a must with large BGA and CGA devices
  - Need very large connectors that can handle moderate to high power (ex. MRI's).
  - Require mass storage and backup systems similar to large scale office equipment, banking, etc.

Input for/from others

- **External Systems rely heavily on other related systems**
  - **Displays, mass storage, wireless and hard-wire data transfer systems, telecom, network systems.**
- **Implantables**
  - **Auto & Military – Input to harsh environment reliability. Especially in shock, impact and long term low level fatigue**
  - **Portables – wireless medical device systems now becoming standard. Personal data device transmits implanted or worn device output to medical monitoring facility and physician.**
  - **SiP – Need to better correlate with medical product needs.**
  - **Connector group need to help drive header / wire attachment process away from manual soldered wires to connector attachment.**

Issues Driving Future Trends

- **MEM's and Implantable Devices are a rapidly growing market segment.**
  - **New Research / Growth Areas**
    - **Bio-Chemical Sensors**
    - **Alternative Power and Rechargable Batteries**
    - **Wearable, patient monitoring systems**
    - **RF telemetry, offloading diagnostics from primary device**
    - **Nano-scale materials, coatings and conductors**
    - **Very small scale systems:**
      - **Battery for artificial retina (Sandia)**

Areas of Opportunity in Medical Market

IMPLANTABLE PRODUCTS

Pacemakers

AICDs

Leads

Cochlear devices

Pin and drug

VASCULAR INTERVENTION

Stents

PTCA Systems

Intravascular Brachytherapy

Atherectomy

ENDO-VASCULAR SOLUTIONS

AAA Systems

Peripheral Stents

Neurovascular

EQUIPMENT FOR SURGERY

Beating Heart Bypass Surgery

Minimally - Invasive Vein Harvesting

DIAGNOSTIC AND MONITORING

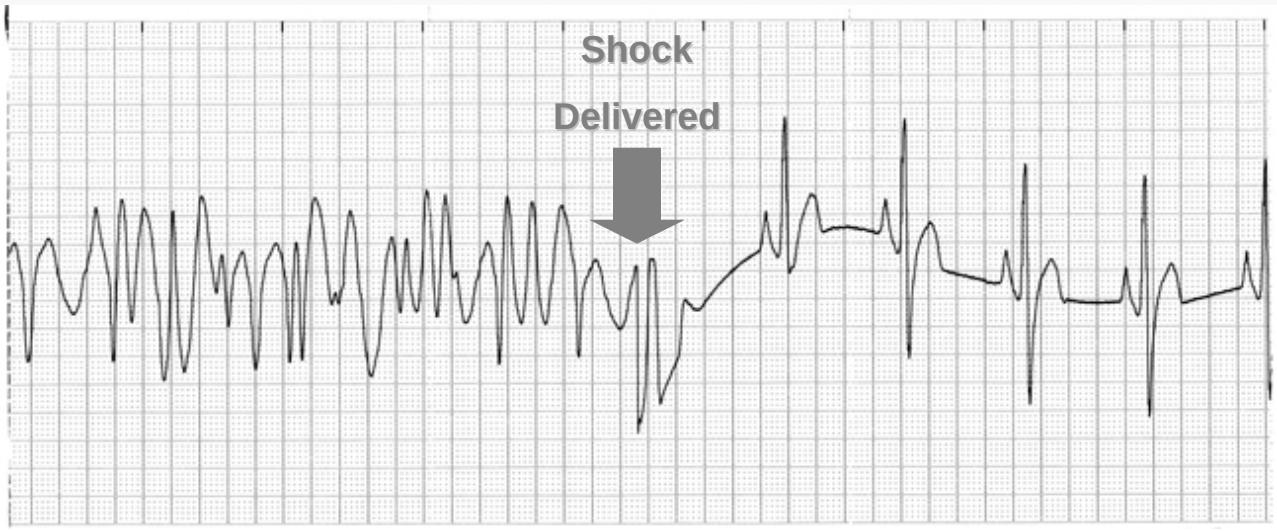
MRI

SONOGRAM

BLOOD - ANALYZER

DATA TRANSFER AND ANALYSIS

Medical Market: Example Technology



Tachy Arrhythmia Therapy

Extending the lives of people whose hearts beat too fast

Implantable Defibrillators—US Annual

- **350,000 people newly indicated for this therapy**
- **100,000 + defibrillator implants per year**

Medical Market: Example Technology

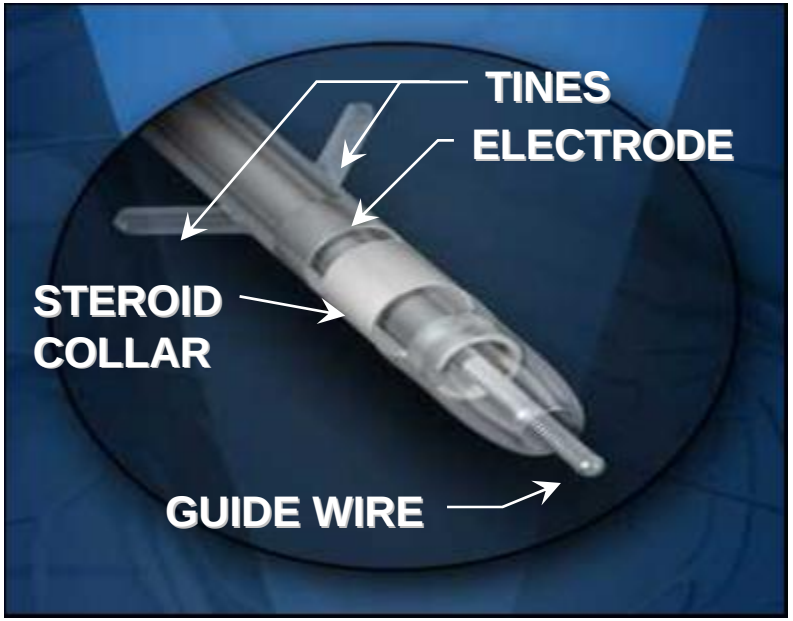
Pacemakers – Currently the largest medical device market

US Annual

- 650,000 patients diagnosed with this condition annually
- 300,000 implants annually

Heart Failure Therapy

- 5 year mortality rates as high as 50%
- Affects > 14M people (US, Europe & Japan)



Lead Technology

Digital Health: New Horizons

- **Miniaturization / Nano**
  - **MEMS**
  - **Self or bio powered systems**
  - **Localized measurement – ex lab on a chip**
  - **Gaseous and biological sensors – military and homeland security applications.**

- **And many more….**

- **All these advancements lead to complex problems involving materials management, energy constraints, data security, reliability and above all patient safety.**

Medical PEG Summary

- **Attribute Needs (2007 – 2017)**
  - **Major differences from 2007 Roadmap**
    - **Focus on implantable devices other than "Life Critical Products" – These products still require high reliability due to the implanted nature of their applications.**
    - **Miniaturization of large diagnostic equipment for "low cost target markets". Much larger focus on cost.**
    - **Portable equipment and wearable electronics have similar needs to many "mobile computing and hand held commercial" equipment. Huge potential market for "Home Medical Electronics"**
  - **Status of Completion**
    - **In progress, need additional help / input from each sector.**
    - **Need co-chair for PEG / TIG**

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