Overview:
Regulatory, Market, Packaging, and Thermal Design for Wearable and Implantable Medical Devices

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Overview

This presentation is intended to provide an overview of packaging and thermal management design issues wearable, implantable, and ingestible medical devices in relation to the overall mobile electronics market.

Purpose:

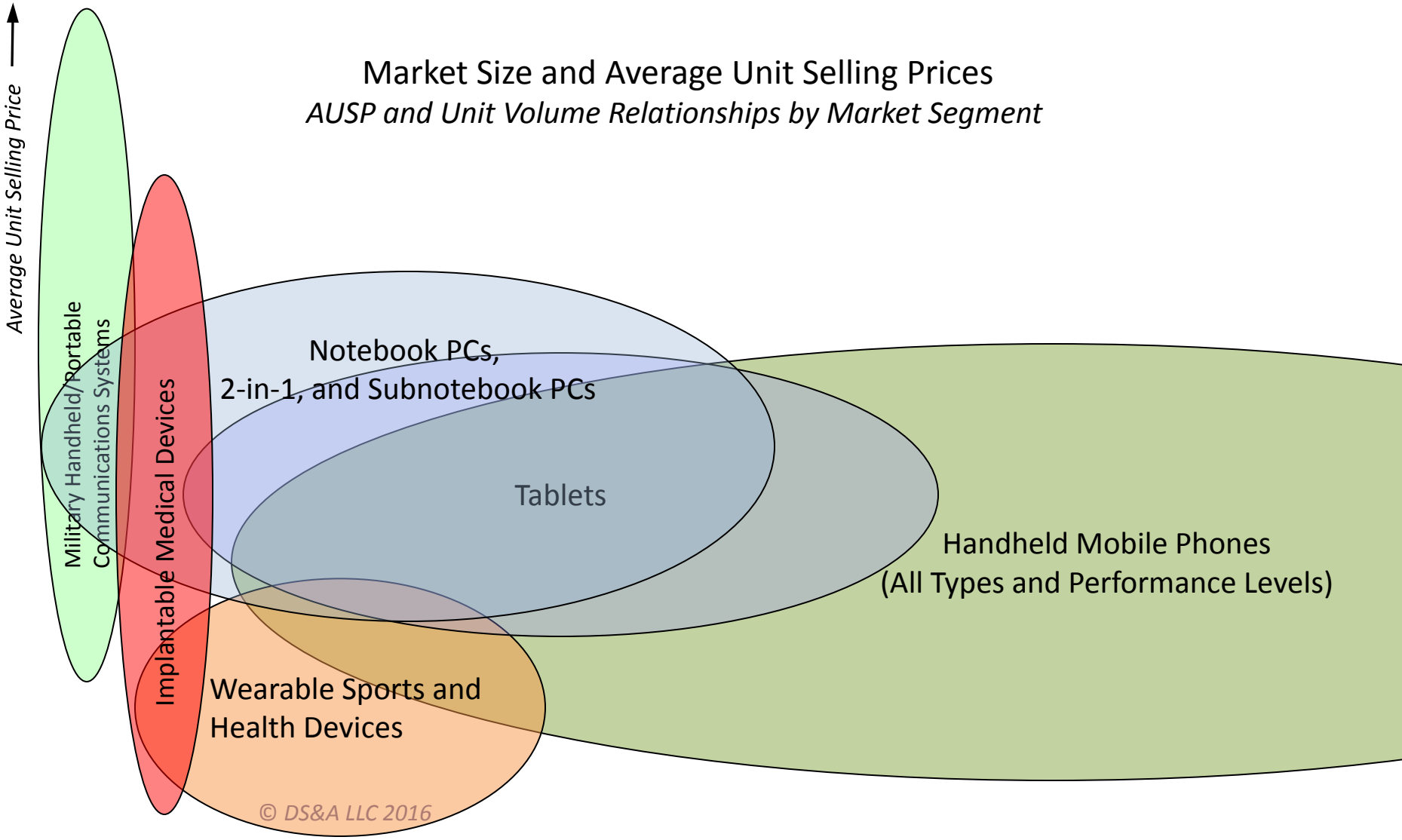
- Overview of wearable, mobile, and medical electronic devices in small form factors;
- Describe relative positioning of these market segments;
- Provide an overview of regulatory requirements for wearable, implantable, and ingestible medical electronics devices in small form factors;
- Provide examples of functional, packaging, and thermal characteristics and challenges for these types of devices in an expanding market.

Medical electronics devices in small form factors represent a significant market opportunity for the electronics and thermal management communities that is growing rapidly in relation to:

- Rapid new technological developments
- Aging populations in developed countries and rapid health care cost increases;
- Increasing public interest in health and health monitoring;
- Rapid change in technical requirements for wireless and power source capabilities and operating reliability and life.

Market Size and Average Unit Selling Prices

AUSP and Unit Volume Relationships by Market Segment



Concept and Data Value Source: DS&A LLC

Power Consumption: Average SmartPhone (2010)

Table 1. Mobile Electronic Devices – Typical Values, Smartphone			
Benchmark	Average System Power (mW)		
	Freerunner	HTC Dream One	Google Nexus One
Suspend	103.2	26.6	24.9
Idle	333.7	161.2	333.9
Call	1135.4	822.4	746.8
Email (Cell)	690.7	599.4	-
Email (WiFi)	505.6	349.2	-
Web (Cell)	500.0	430.4	538.0
Web (WiFi)	430.4	270.6	412.2
Network (Cell)	929.7	1016.4	825.9
Network (WiFi)	1053.7	1355.8	884.1
Video	558.8	568.3	526.3
Audio	419.0	459.7	322.4

Power Consumption: SmartPhone versus Smart Watch (2016)

Table 2. Mobile Electronic Devices – Typical Values, SmartPhone vs. Wearables			
Benchmark	**Galaxy S6**	**Moto360**	**Apple Watch**
Device Type	SmartPhone	Smartwatch	Smartwatch
Surface Area (mm^2)	24086	3468	4662
Power (mW)	3000	400	400
Power Density (W/cm^2)	12.5	11.5	8.6

Source: D. Gastelum, N. Nikfar, Qualcomm Technologies Inc., "Thermal Design Challenges of Wearables," IMAPS Advanced Technology Workshop on Thermal Management 2016, Los Gatos CA USA, October 25-27, 2016.

Context for Mobile/Handheld/Wearable/Implantable Electronic Devices

Mobile and handheld electronic devices have moved the global economy and lifestyles across developed and developing economies into the mobile and connected age:

- Notebook personal computers
- Subnotebooks and ultrabooks
- Tablets
- Cell phones and smart phones

Wearable electronic devices are now growing rapidly in market acceptance, driven primarily by sports- and health-related external electronics, with these general types:

- Wristband and ankleband
- Embedded
- Smart clothing

Wearable Sports Technology: General Types

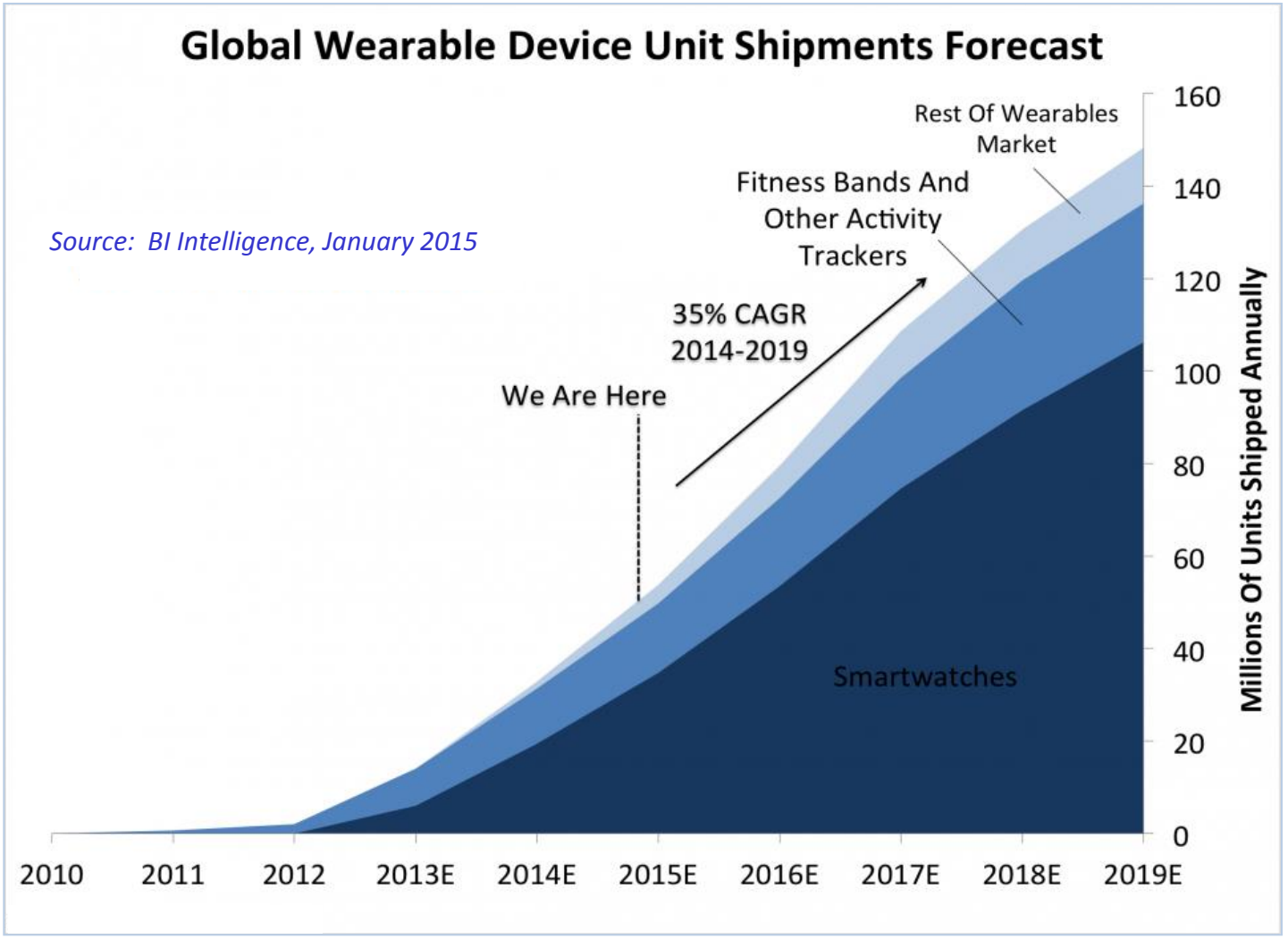
WRISTBAND

EQUIPMENT EMBEDDED

SMART CLOTHING

Source: Maxim 11-2015

Wearable Sports Technology



Medical Electronic Devices

Medical Devices: Mobile/Handheld/Wearable/Implantable

Medical electronics devices in small form factors, considered in context of all types of mobile devices, include:

- External health monitoring devices, handheld;
- External monitoring devices and sensors, wearable or implanted;
- Implantable medical electronic devices providing cardiac, nervous system, or intracranial stimulation;
- Ingestible monitoring and sensor medical electronic devices, including video.

Wearable, implantable, and ingestible medical electronic device technology development may be perceived as approximately where smart phone technologies were *circa 2010*.

See Table 2 as a reference for smart phone technologies and power dissipation for 2010. Compare these values with those shown in Table 3, for 2016.

Medical Devices: Mobile/Handheld/Wearable/Implantable

Key packaging and thermal management challenges for medical electronic devices are increasing due to several market trends:

- Continuing demand for device miniaturization;
- Rapid improvements in technical requirements for wireless data monitoring and transmission;
- Continuing demand for improvements in battery and power source capabilities and operating reliability and life.

Medical Devices: Definition

A "medical device" is defined by U.S. statute in the Food, Drug and Cosmetic [FD&C] Act as:

“An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them,
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

Medical Devices: Definition

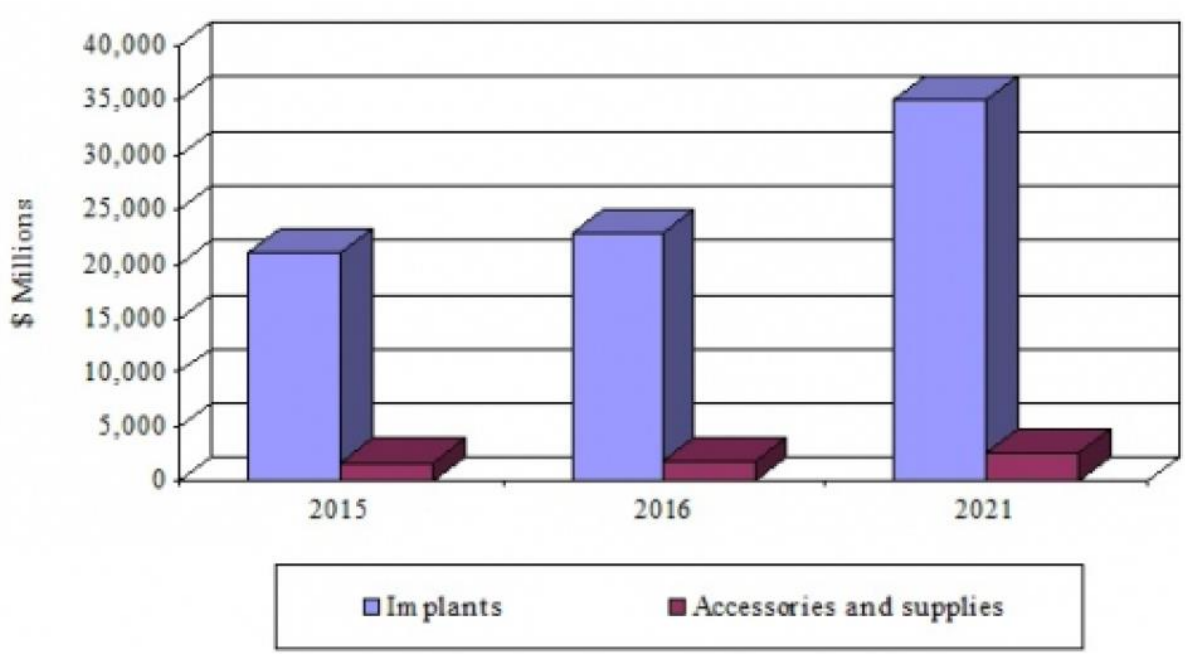
Important distinctions on definitions:

- Confusion sometimes exists between unregulated consumer products and medical devices. Products are not considered medical devices if they have general utility, but are neither dedicated to, nor intended or promoted for, medical applications.
- A medical device is subject to the Consumer Product Safety Act rather than the FD&C Act. For example, a screw is considered a medical device if it is promoted for holding bones together, rather than holding pieces of wood together.

Medical Devices: Market Forecast

SUMMARY FIGURE

GLOBAL MARKET FOR MICROELECTRONIC MEDICAL IMPLANTS, BY APPLICATION, 2015-2021
($ MILLIONS)



Source: BCC Research, "Microelectronics Medical Implants," May 2016.

Medical Devices: Wearable/Mobile Examples

IMEC, Holst Centre (2008, 2012):
Active Electroencephalogram (EED) Headset

Power sources: Photovoltaic cells, TEC generator (from heat of temples);

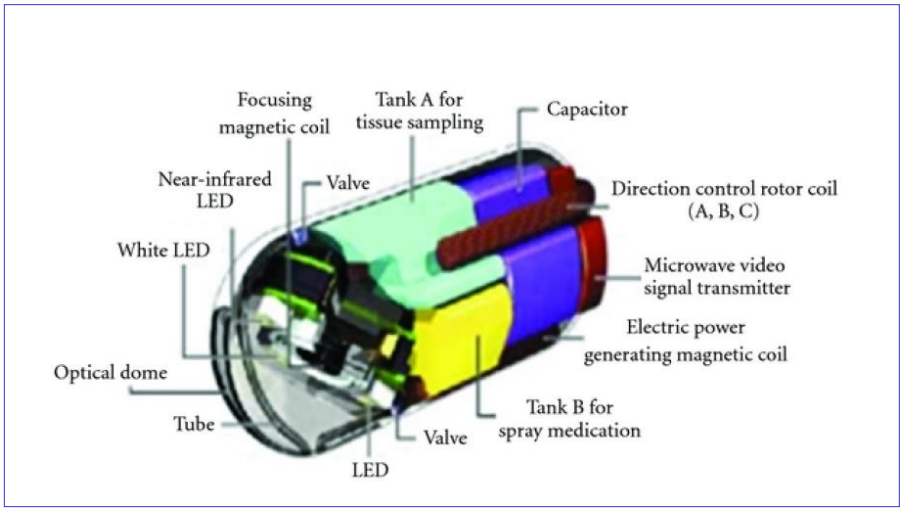
IMEC proprietary ASIC, (2) Si Photovoltaic Cell generators, TEC Generator, RF
Total: 1 mW power consumption

Preventice (2013):
BodyGuardian™ Electrocardiogram Remote Monitoring System for patients with cardiac arrhythmias.

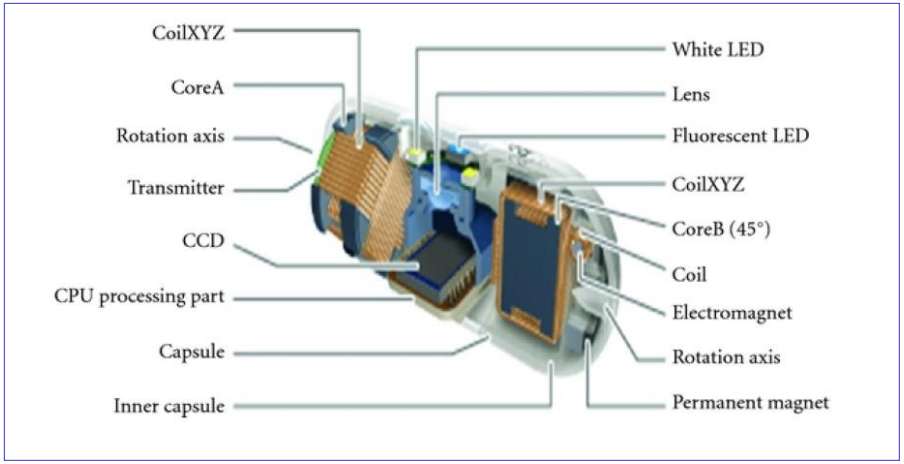
Tracks ECG, heart rate, respiration rate, and activity level; continuously records, stores, and periodically transmits physiological data for up to 30 days at a time. FDA 510 (k) approved to detects and monitors non-lethal cardiac arrhythmias in ambulatory patients.

Medical Devices: Ingestible Examples

Medtronic, PillCam Video Capsule

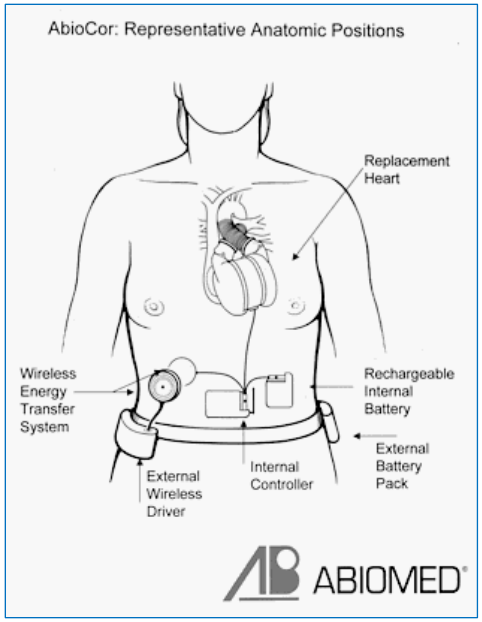


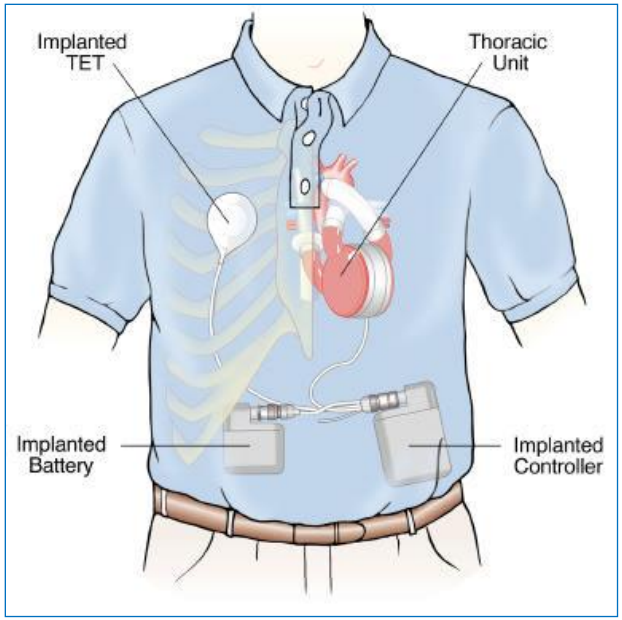
(Above) Norika, Video Capsule *(Below) Sayaka,* Video Capsule



Medical Devices: Implantables

Table 3. Implantable Medical Devices: Typical Global Unit Volumes (2005)		
Device	**Annual Units Implanted**	**Total Implants, Living Humans**
Cardiac Pacemaker	600,000	3,000,000
Cochlear Implant	60,000	N/A





Medical Devices: Implantable/Ingestible Design Challenges

Wireless devices:

- Wireless medical devices blur typical lines between healthcare IT and biomedical engineering departments within healthcare organizations;
- Demands for system reliability and performance have never been higher;
- "Device contention" issues:
  - Number of wireless devices in healthcare is growing rapidly;
  - Increase in devices is challenging many current environments;
  - Wireless quality of service is limited in functionality;
  - Wireless devices and networks support voice over WiFi
  - Spectrum usage for 2.4GHz unlicensed band is congested with devices;
  - Spectrum usage for future 5GHz band:
    - Increases demand and strain on battery life
    - Presents challenges for integrated antenna design;
- Security: Wireless medical device and data transmission and storage.

Source, quotations: Burwood Group, Inc., "Wireless Medical Device Challenges," AAMI FDA Summit, October 2012.

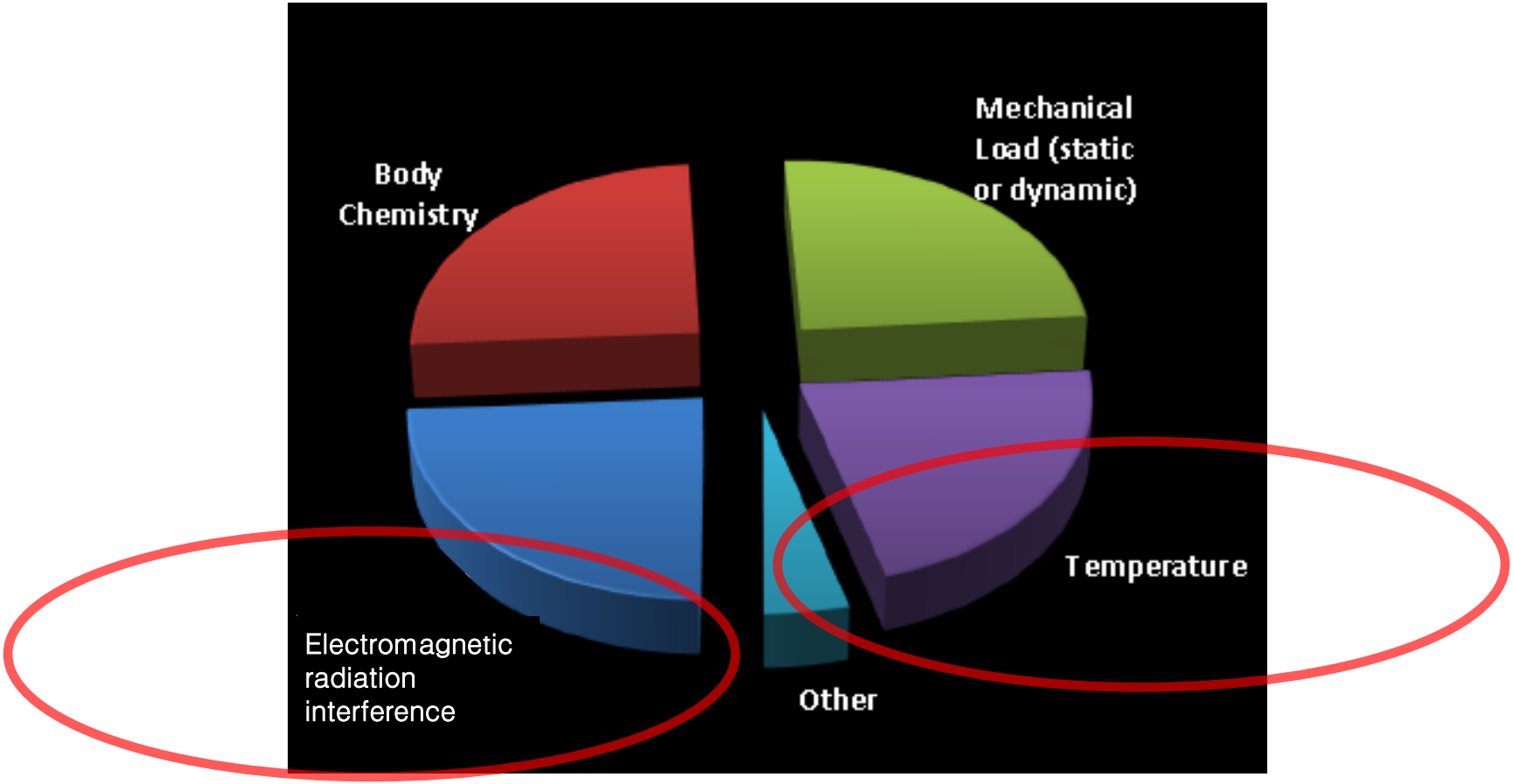
Medical Devices: Implantable/Ingestible Design Challenges

Wireless, wearable, implantable, ingestible medical devices:

- "Current battery life is a constant struggle and is one of the key constraints on wireless medical devices."
- "Tradeoffs are being made to increase battery life at the cost of functionality, performance, or device security."
- Long-term hermeticity for implantable devices and testing methodologies.
- Packaging materials for improved hermeticity, RF transparency, and signal/power feedthroughs;
- Improved thermal materials for heat spreading, battery thermal control.
- Packaging and thermal materials with corrosion resistance and moderate curing temperatures (if needed).

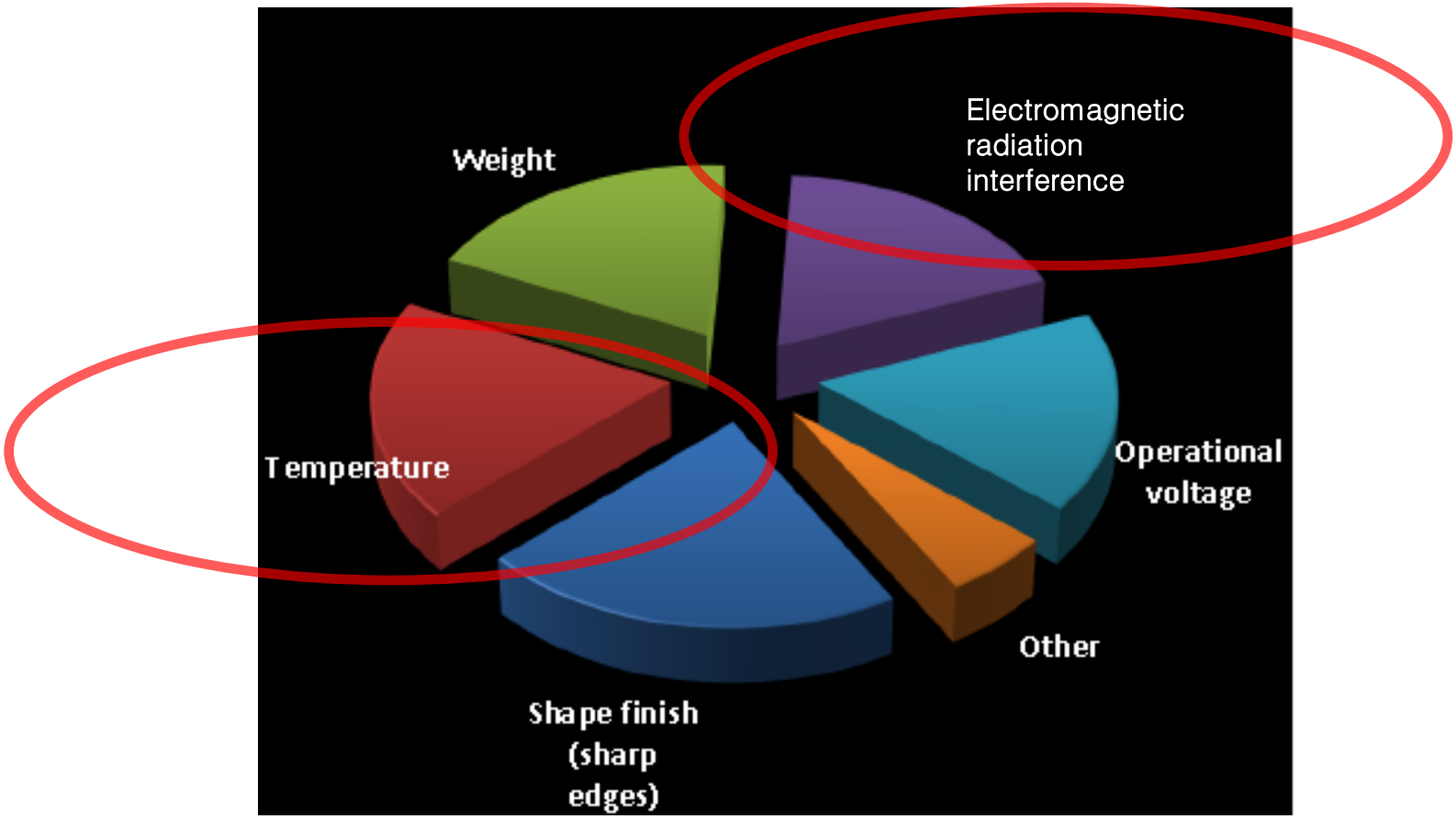
Source, quotations: Burwood Group, Inc., "Wireless Medical Device Challenges," AAMI FDA Summit, October 2012.

Implantable Medical Devices: Impact of Environment on Design



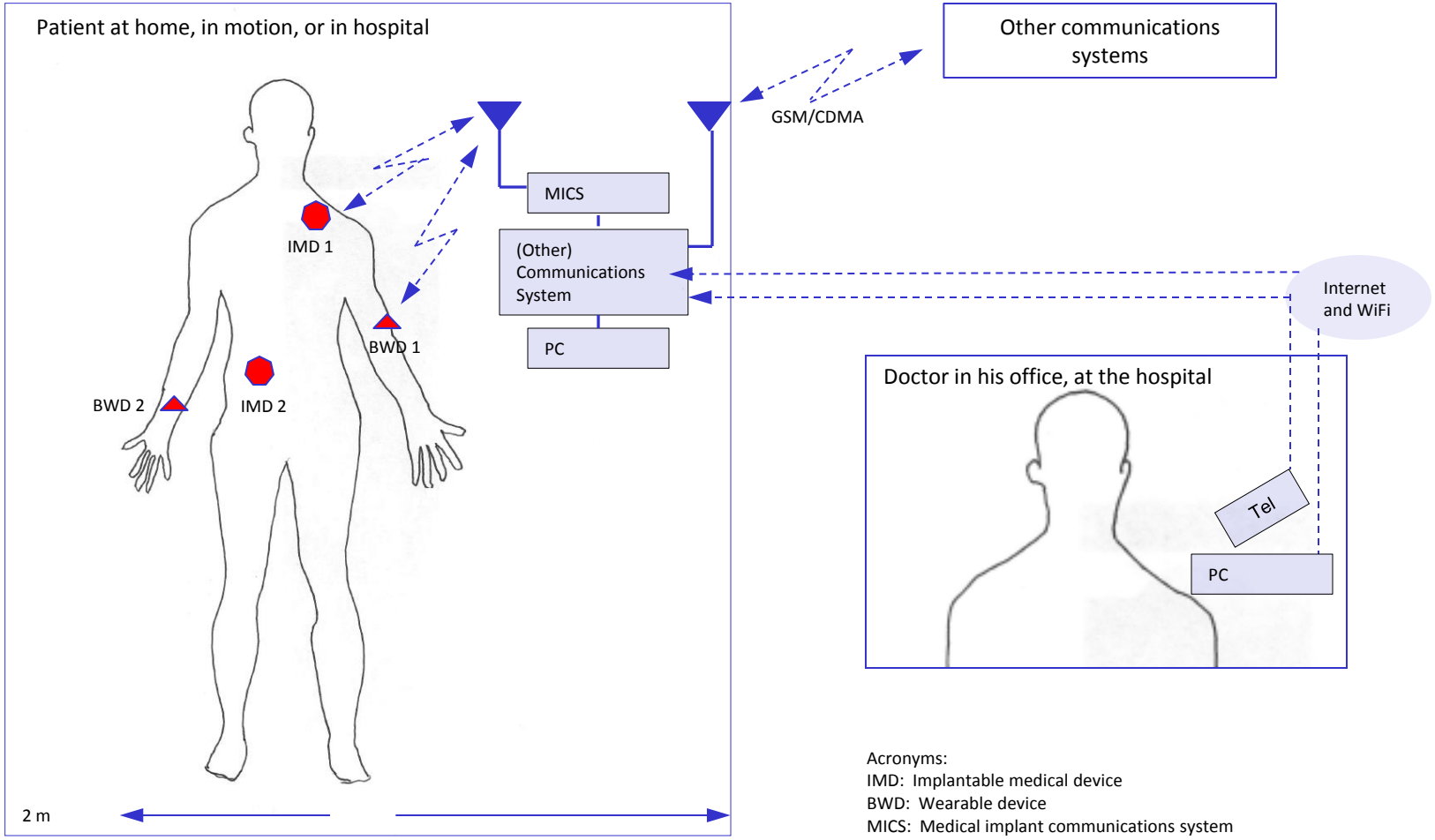
Source: B. Bader, J. McNulty, "Assessment of Reliability Standards and Test Methods for Implantable Devices, Part I" (2013)

Implantable Medical Devices: Impact of Design on Environment



Source: B. Bader, J. McNulty, "Assessment of Reliability Standards and Test Methods for Implantable Devices, Part I" (2013)

Wireless Medical Implants and Implant Communications Systems



Acronyms:
IMD: Implantable medical device
BWD: Wearable device
MICS: Medical implant communications system

Source: M.N. Islam, M.R. Yuce, "Review of Medical Implant Communications System (MICS) Band and Network," ICT Express, 2016. http://dx.doi.org/10.1016;j.icte.2016.08.010.

Wireless Medical Implants: Industry Trends

Table 4. Industry Trends and Implications	
Trend	**Implication**
Transcutaneous data transfer	Device enclosure RF transparency for wireless transmission
Increased (longer) implant life	Hermeticity, resistance to corrosion, power source life and reliability
Minimally invasive surgery (or ingestible)	Miniaturizations
High-density electrodes	Simplified interconnects
High power	Power source life and reliability

Implantable Medical Devices: Regulatory Requirements

Global Market Definition – Medical Device Regulation

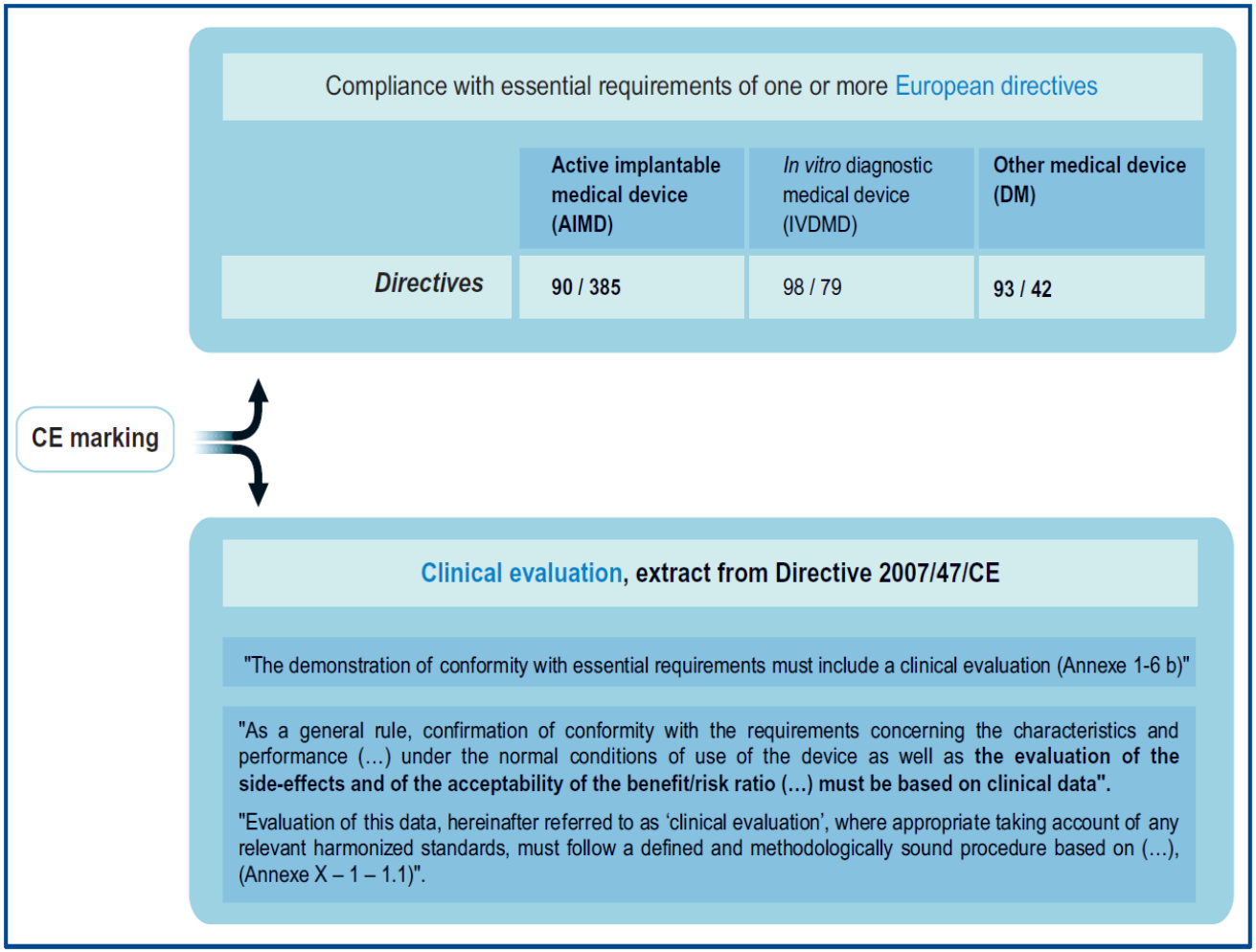
Table 5. Government Regulatory Agencies: Implantable Medical Devices	
Country	**Agency**
Australia	TGA – Therapeutic Goods Administration
Brazil	INMETRO
Canada	Health Canada
China	CFDA – China Food and Drug Administration; (was SFDA)
European Union	EMA – European Medicines Agency; MED-DEV 2.1/3 rev.3
France	HAS - Haute Autorité de Santé
Hong Kong	MDCO, PSDH
India	CDSCO – Central Drug Standards Control Organization
Japan	MHLW, PMDA – Pharmaceutical and Medical Devices Agency
Singapore	HAS – Health Sciences Authority
Taiwan	TFDA – Taiwan Food & Drug Agency
United Kingdom	MHRA – Medicines and Healthcare Products Regulatory Agency
United States	FDA, Center for Devices and Radiological Health

Source: DS&A LLC

Global Market Definition – Medical Device Regulation

Source: HAS

Global Market Definition – Medical Device Regulation



Source: HAS, "Medical Device Assessment in France," December 2009. Website: www.has-sante.fr

Global Market Definition – Medical Device Regulation

Table 6. Relevant Specifications: FDA Medical Device Classification *US Food and Drug Administration (Center for Devices and Radiological Health)*				
Classification	**Degree of Regulatory Control**	**Product Type Categorization**	**Premarket Notification 510(k)**	**Premarket Approval**
I		-	Exempt	Exempt
II		-	Required	Exempt
III		Life-sustaining	Required	Required

Source: United States Department of Commerce, Food and Drug Administration. See: www.fda.gov.

Global Market Definition – Medical Device Regulation

Table 7. Relevant Medical Device General Standards		
Specification	**Topic**	**Requirements**
ISO 14971:2007	Risk Management, Medical Devices	Risk Management Plan
EN ISO 14791:2012	European harmonized standard	Risk Management File
IEC 60601 -1:2005	Medical Electrical Equipment, Part I	Basic safety and essential performance
ISO 13485:2003	Medical Device Quality Management Systems	General quality management system for medical device design and manufacturing

Source: DS&A LLC; after PharmOut Pty Ltd., ABN

Global Market Definition – Medical Device Regulation

Table 8. Relevant Specifications: FDA (US) Materials and Packaging			
Topic	**Device Type**	**Value or Descriptor**	**Specification**
Sterility	Assembled device shall be	Sterile	ISO 14708-1/14.1
Biocompatibility	Implanted assembled device shall be	Biocompatible	ISO 14708-3/14.3
Surface/edge/corner compatibility	Shall be	Avoided or covered	IEC 60601-1/9.3
Reaction/inflammation	Implanted assembled device shall have no features that cause	Reaction or inflammation	ISO 14708-3/15.2

Implantable Medical Electronic Devices: Power Consumption

Relative Power Dissipation: Wearable, Mobile, Ingestible Devices

Table 19. Mobile Electronic Devices – Ranking by Typical Power Dissipation Values		
Device	**Typical Power Dissipation**	**Chronology by Relative Year of Introduction**
FitBit Flex – ST Micro ARM MCU 32L151C6	339 mW	5
Ingestible Colonoscopic Video Camera	150 – 500 mW	2
Entry-level Smartphone – Typical call processing w/backlight	1-2 W	3
Smartphone – High performance, call processing w/backlight	2 – 6 W	5
Entry-level Tablet *(1)*	9 W	4
Performance Tablet *(2)*	23.1 W	6
Notebook PC – Business	35-55 W	1

Sources:

1. *E. Rahim, A. Raghupathy, W. Maltz, "Thermal Characterization of a BGA Package Used in the Logic Board of a Handheld Device," IMAPS ATW Thermal 2012, Los Gatos CA, November12, 2012.*
2. *B. Nagendran, D, Moore, A. Raghupathy, W. Maltz, "Thermal Characterization of a Mobile Processor for Handheld Devices," IMAPS France Micropackaging and Thermal Workshop, La Rochelle, France, February 4, 2015*

Wearable/Implantable/Ingestible Devices: Power Consumption

Table 10. Medical Electronic Devices – Specifications, Typical Values			
Device Category	**Device Type**	**Physical Envelope (Typ.)**	**Power Consumption (Typ.)**
Implantable Medical	Brain Monitor/Stimulator	40 x 40 mm	
	Glucose Monitor	Range	>10 µW
	Neurological Stimulator		30 – 800 µW
			30µW – 4 mW
	Cardiac Defibrillator	Range	30 – 100 µW
		Range	30 – 500 µW
	Cardiac Monitor	Range	Range
	Cardiac Pacemaker	12 x 12 x 6mm	30 – 100 µW
	Drug Pump	10 x 12mm	10 µw – 2 mW
	Cochlear Implant	5 x 5 – 10 x 10mm	3 – 10 mW

Data Source, after: "Power Approaches for Implantable Medical Devices," A. Ben Amar, A. Kouki, H. Cao, Sensors Journal, 2015, 15, 28889-28914; doi: 10.3390/s151128889. ISSN 1424-8220.

Wearable/Implantable/Ingestible Devices: Power Consumption

Table 11. Medical Electronic Devices – Specifications, Typical Values			
Device Category	**Device Type**	**Physical Envelope (Typ.)**	**Power Consumption (Typ.)**
Ingestible Medical	Video Camera	26 x 11 mm	150 – 500 mW
	Microbattery	2.5 x 2.5 x 0.8mm	-
Wearable Medical	Hearing (Cochlear) Instrument		
	EED (Electroencephelagram) Headset	35 x 30 x 5mm	750 µW (plus battery)

Data Source, after: "Power Approaches for Implantable Medical Devices," A. Ben Amar, A. Kouki, H. Cao, Sensors Journal, 2015, 15, 28889-28914; doi: 10.3390/s151128889. ISSN 1424-8220.

Implantable Medical Electronic Devices: Power Sources

Wearable/Implantable/Ingestible Devices: Power Sources

Table 12. Potential Power Sources – Implantable Medical Devices		
General Category	**Category**	**Subcategory**
Independent Systems	Batteries, One-Time	Lithium
		Nuclear*
	Environmental Harvesting	Biofuel Cell
		TEC
		Piezoelectric
		Electrostatic
		Electromagnetic
Systems with Transfer Mechanism	Optical Charging	
	Inductive Coupling	
	Ultrasonic Transducers	

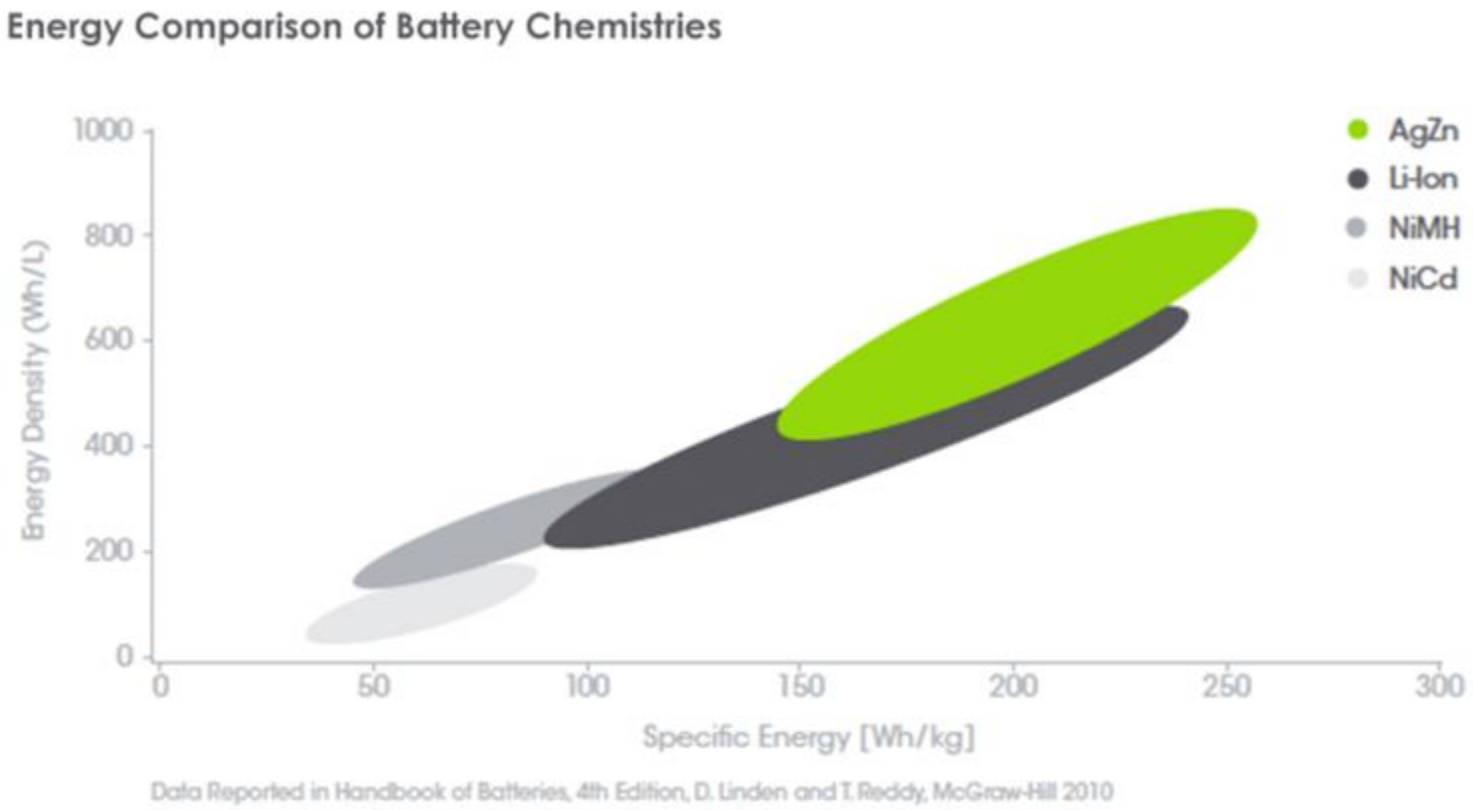
*Note: * Generally discontinued for use in implantable devices during 1980s.*
Data Source, after: "Power Approaches for Implantable Medical Devices," A. Ben Amar, A. Kouki, H. Cao, Sensors Journal, 2015, 15, 28889-28914; doi: 10.3390/s151128889. ISSN 1424-8220,

Wearable/Implantable/Ingestible Devices: Power Consumption

Table 13. Medical Electronic Devices – Power Source Specifications, Typical Values		
Device Category	**Device Type**	**Power Consumption (Typ.)**
Electrostatic	All	1-80 µW
Electromagnetic	All	1-150 µW
TEC	All	1µW – 1mW
Battery	Lithium, Nuclear	1-10+ mW
Charging/Transfer Methods	Optical Charging	1µW – 10+ mW
	Ultrasonic Transducers	1µW – 10+ mW
	Inductive Coupling	1µW – 10+ mW

Data Source, after: "Power Approaches for Implantable Medical Devices," A. Ben Amar, A. Kouki, H. Cao, Sensors Journal, 2015, 15, 28889-28914; doi: 10.3390/s151128889. ISSN 1424-8220,

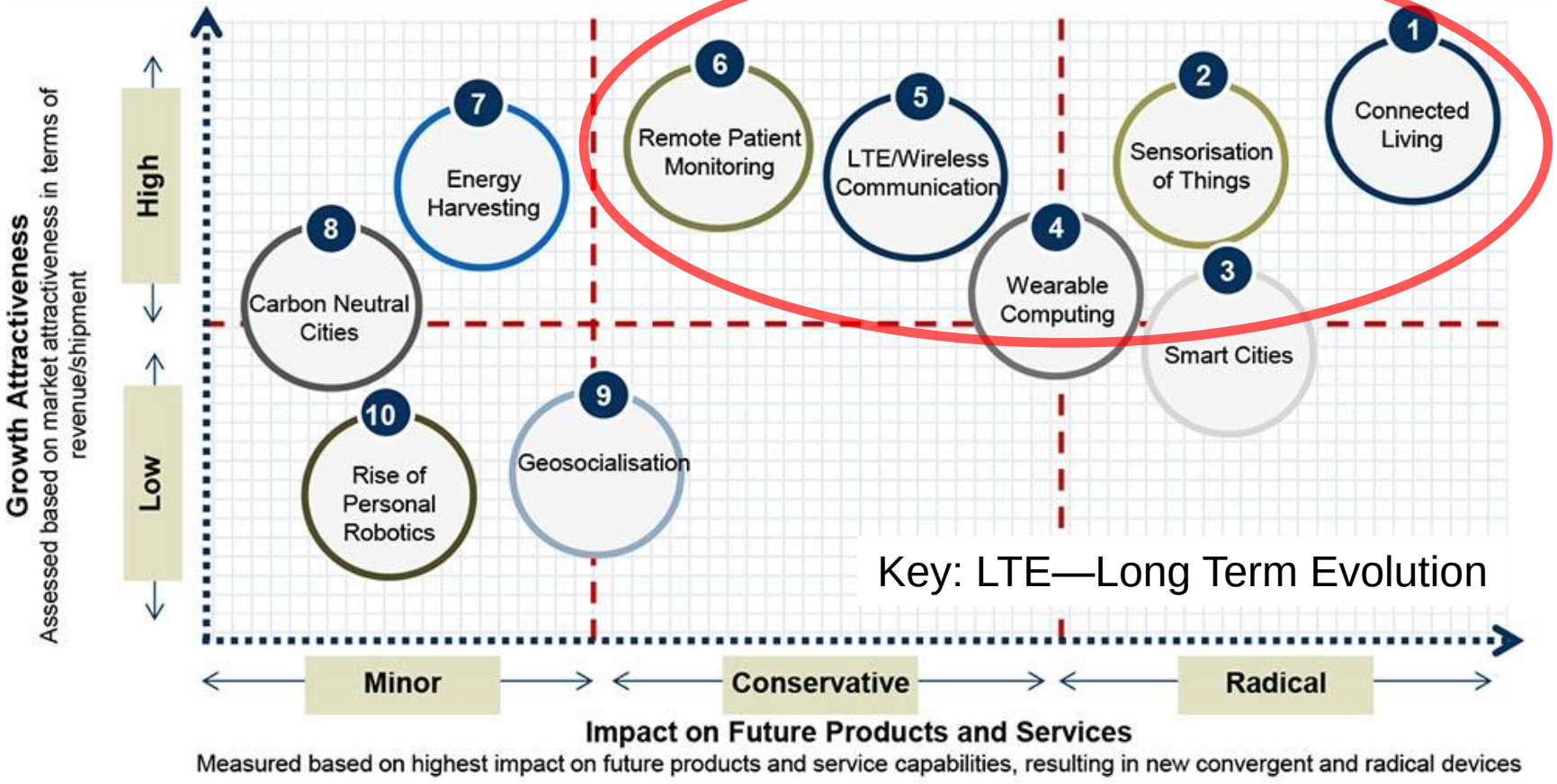
Power Sources: Battery Chemistry Energy Density



Battery and Power Source Development Opportunities

Market growth attractiveness and potential for impact on future devices and services:

- Top ten transformational trends in battery development by 2020



Source: Frost & Sullivan, "The Highly Innovative Battery Market Rolls Out Novel Solutions that are Customisable and Reliable" (August 5, 2015)

Implantable Medical Electronic Devices: Packaging and Thermal Materials

Wearable, Implantable, Ingestible Devices: Packaging Materials

Electronic medical device development is driving new challenges for packaging and thermal materials, processing, and testing methodologies:

- Package materials
- Flex-to-package attachment methods and materials
- Package (enclosure) sealing
- Package encapsulation and hermeticity and testing methodologies
- Battery encapsulation

Examples follow for cranial implants for brain therapeutic stimulation and cooling, to illustrate components and materials for an implantable medical electronic system.

Sources:
1. C. Bjune, T. Marinis, T. Sriram, J. Brady, J. Moran, P. Parks, A. Widge, D. Dougherty, E. Eskandar, "Packaging Architecture for an Implanted System that Monitors Brain Activity and Applies Therapeutic Stimulation," IMAPS 48th Symposium, Orlando FL USA, 2015.
2. Green R.A., et al.,"Integrated Electrode and High Density Feedthrough System for Chip-scale Implantable Devices," Biomaterials (2013), http://dx.doi.org/10.1016/j.biomaterials.2013.04.054.
3. Dunn, H., "Hermetic Packaging of Implantable Devices: How Did We Get Here?" IMAPS New England Regional Symposium, Boxborough MA USA, May 2016.

Brain Therapeutic Stimulation and Cooling

Epilepsy and related afflictions are measured by brain electrical and thermal activity.

- One indicator for impending seizure is rapidly increased brain electrical activity;
- A second is change in brain temperature;
- Cooling of the brain assists in reducing seizure severity
  - Example: An increase in temperature in the epileptogenic zone of the brain of ~1.5 K occurs about thirty seconds prior to seizure onset. [1]
  - Brain cooling reduces synaptic electrical conductivity and inter-neuronal coupling, one of several probable mechanisms of action. [2]
- An active human brain consumes 20W of electrical power in an average adult.
- A brain cooling device must rapidly cool 1 cu. in. of brain tissue:
  - From 37°C to ~16°C in ~ 30 seconds.
  - Rapid cooling is necessary in order to prevent one seizure from triggering other seizures.

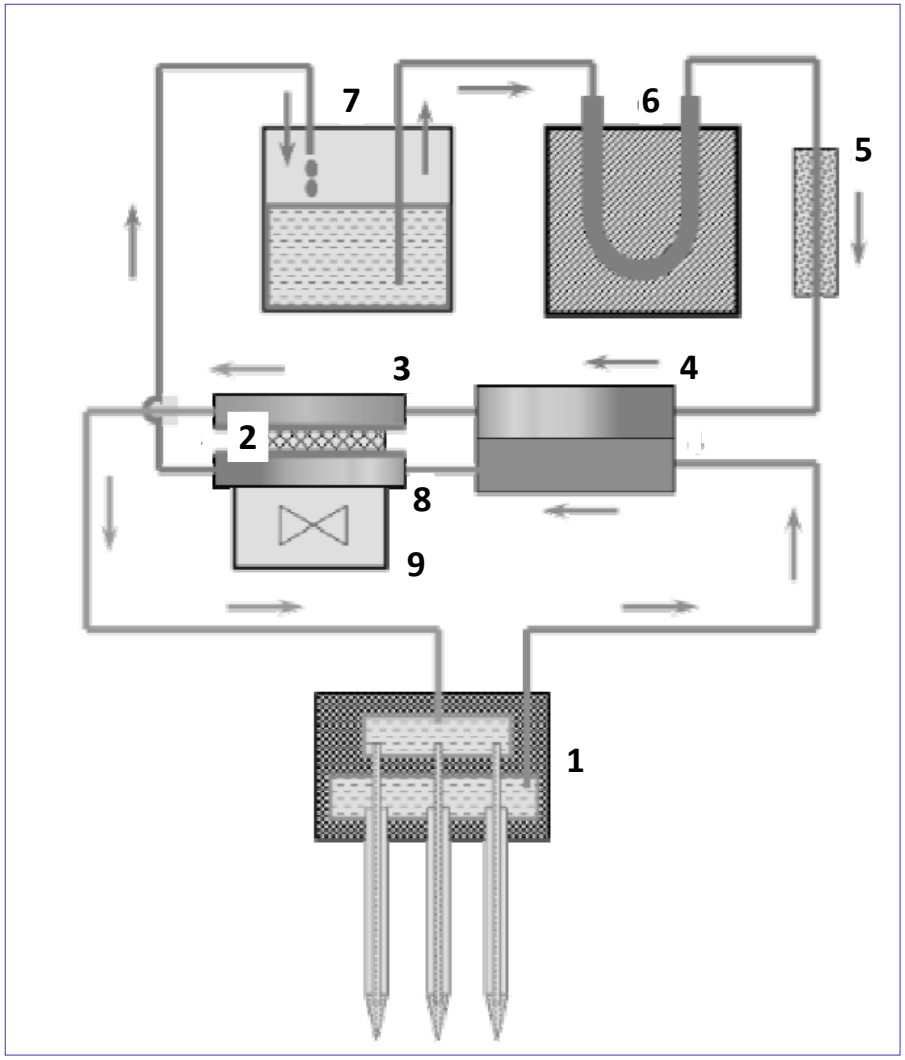
Sources:
1. Dymond, A., Crandall, P., "Intracerebral temperature changes in patients during spontaneous epileptic seizures," Brain Research, Vol. 60, 1973, pp. 249 – 254.
2. Osorio, I, et. Al, "Development of Closed-Loop Implantable Cooling System for Epileptic Seizure Blockage," First International Conference on Biomedical Electronics and Biomedical Informatics, Rhodes, Greece, August 20-22, 2008.

Brain Therapeutic Cooling

Implantable neurological liquid cooling thermal system design:

- Coolant: distilled water
- Flow rates:
  - 400 ml/hr
  - 800 ml/hr

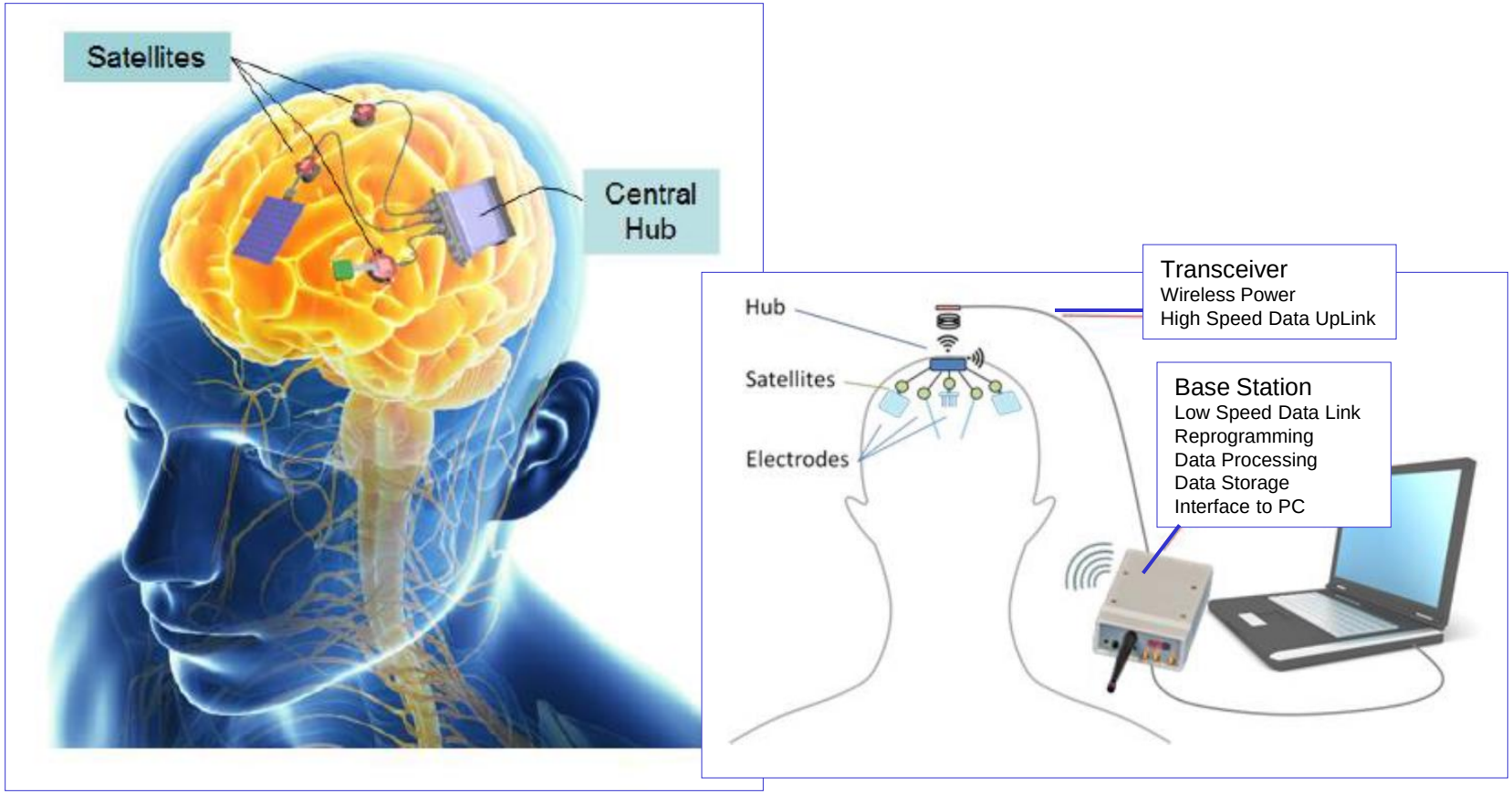
1	Seven-element minicooler
2	TEC Module
3	Main heat exchanger
4	Pre-cooling heat exchanger
5	Porous filter
6	Peristaltic pump
7	Coolant reservoir
8	Heat exchanger, TEC hot side cooling
9	Fan



Source: Osorio, I, et. Al, "Development of Closed-Loop Implantable Cooling System for Epileptic Seizure Blockage," First International Conference on Biomedical Electronics and Biomedical Informatics, Rhodes, Greece, August 20-22, 2008.

Deep Brain Stimulation and Therapeutic Implant

Development of a deep brain stimulation and therapeutic system has been described in detail by Draper Labs that provides excellent illustration of packaging and thermal materials utilized.



Source: C. Bjune, T. Marinis, T. Sriram, J. Brady, J. Moran, P. Parks, A. Widge, D. Dougherty, E. Eskandar, "Packaging Architecture for an Implanted System that Monitors Brain Activity and Applies Therapeutic Stimulation," IMAPS 48th Symposium, Orlando FL USA, 2015.

Deep Brain Stimulation and Therapeutic Implant

Development of a deep brain stimulation and therapeutic system has been described in detail by Draper Labs that provides excellent illustration of packaging and thermal materials utilized.

Table 14. Deep Brain Stimulation Implant: System Design Requirements	
Parameter	**Phase I**
Number of sites	4 recording, 1 stimulating
Electrodes per site	25 recording, 25 stimulating
Duration of implant	90 days
Time between recharge/battery replacement	30 days
Size of implant	40 x 40 mm
Weight of implant	35 g

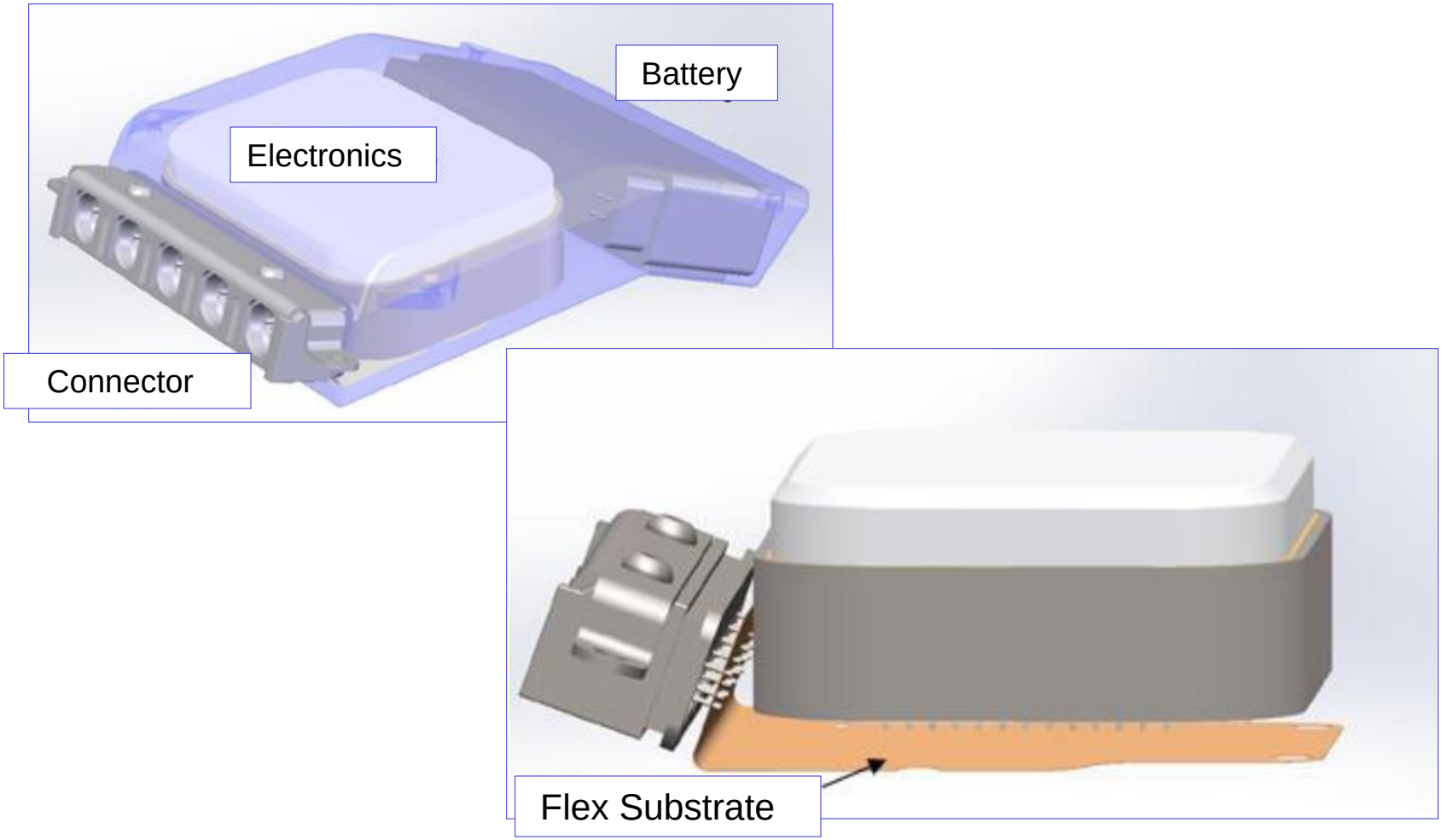
Source: C. Bjune, T. Marinis, T. Sriram, J. Brady, J. Moran, P. Parks, A. Widge, D. Dougherty, E. Eskandar, "Packaging Architecture for an Implanted System that Monitors Brain Activity and Applies Therapeutic Stimulation," IMAPS 48th Symposium, Orlando FL USA, 2015.

Deep Brain Stimulation Implant: Packaging Specification, Materials

Table 15. Deep Brain Stimulation Implant: Hub System Packaging materials		
Feature	**Value**	**Comment**
I/O	64 on 1.27mm (0.050 in.) pitch Material: 90/10 Pt/Ir, Au braze on ceramic D = 0.010 in.	Value dependent on number of I/O between Hub and satellite; battery and ground contact
Package materials	95% alumina plate and cover with titanium seal ring; LCP or polyimide flex; titanium battery housing	To meet hermeticity, impact, biocompatibility specifications. Ceramic cover for RF transparency.
Flex-to-package attachment	Conductive silver epoxy	
Package seal	Titanium band for laser welding	To meet hermeticity specification
Package encapsulation	Silicone rubber	To meet hermeticity specification; strain relieve; device comfort.
Battery encapsulation	Titanium can, laser-welded	Biocompatibility and impact specification

Source: C. Bjune, T. Marinis, T. Sriram, J. Brady, J. Moran, P. Parks, A. Widge, D. Dougherty, E. Eskandar, "Packaging Architecture for an Implanted System that Monitors Brain Activity and Applies Therapeutic Stimulation," IMAPS 48th Symposium, Orlando FL USA, 2015.

Deep Brain Stimulation Implant: Central Hub Module Packaging



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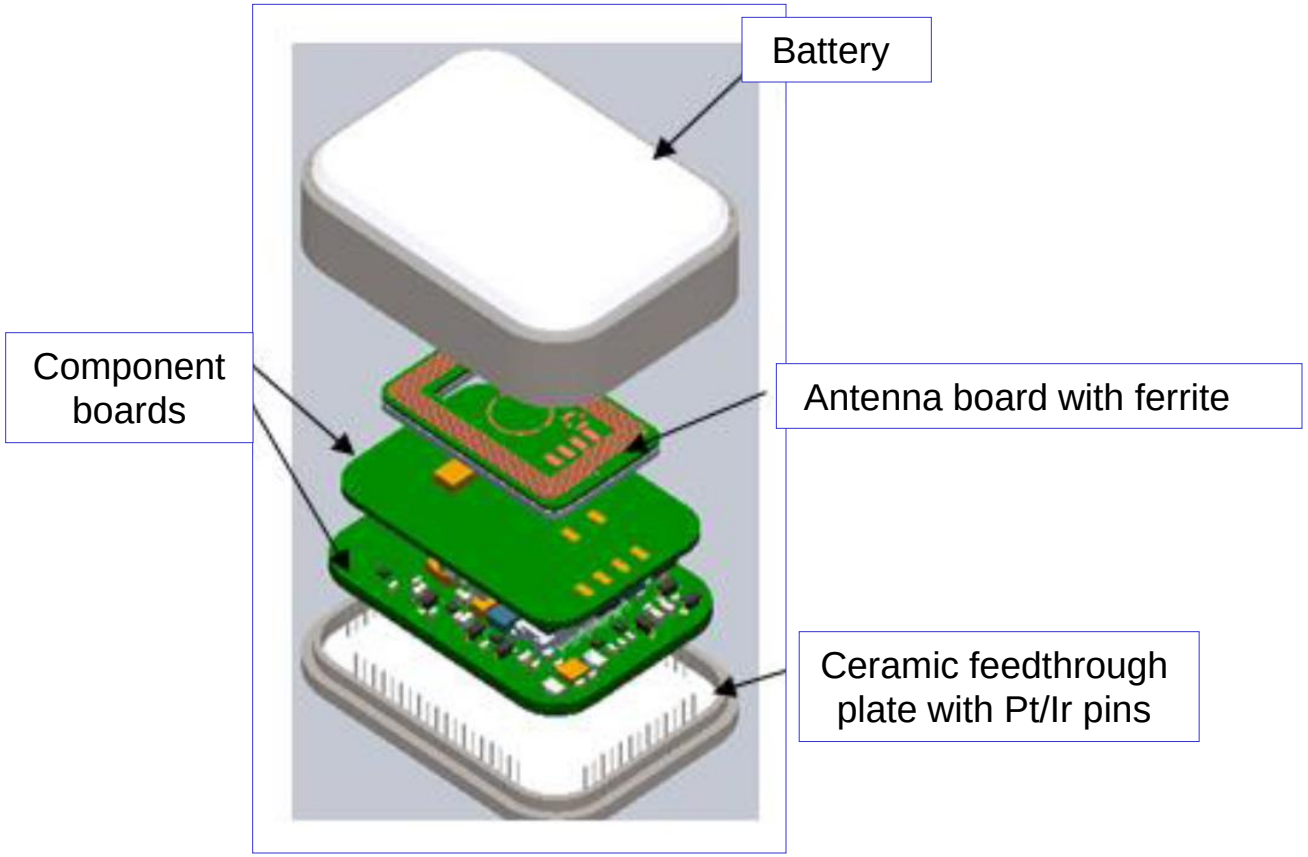

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Summary:
Implications for Packaging and Thermal Development

Implications for Power Sources

Critical need for continual improvements in power sources:

- Power density
- Life and reliability
- Temperature control

Two technology areas are too complex to include here:

- Reliable, safe, and higher power density battery chemistries and structures;
- Battery thermal management systems development.

The recent Samsung S7 smartphone recall is an example of how critical each of these areas are for mobile device applications, extending also to implanted and ingestible medical electronic devices.

Ref: A.B. Amar, et al; "Power Approaches for Implantable Medical Devices," Sensors, 15 (11):28889-28914, November 2015.

Implications for Packaging and Packaging Materials

Implantable and ingestible electronic devices require hermeticity.

- Increased emphasis on hermetic packaging, processes, and process control;
- Evaluation of ceramics vs. titanium, other metals, for enclosures for RF transparency;
- Increased emphasis on glass and ceramic materials for feedthroughs, as well as moderate-temperature processes; and process controls;
- New investigations of polymer encapsulants, driven in part by need for RF transparency:
  - Encapsulants desired which may be cured free of voids
  - Low modulus encapsulants to withstand thermal stress
  - Stability and adhesion in present of moisture (hydrolytic stability)
  - Moderate curing temperatures
- Polymer-encapsulated materials require:
  - Corrosion resistance
  - Good adherend performance

Sources:
1. Kenney, LPJ, et. al; "Encapsulation Materials for Implantable FES System: A Case Study," Proceedings, IFESS 2000, 5th Annual Conference, International Functional Electrical Stimulation Society, Aalborg DK 2000.
2. Saeidi, N., Donaldson, N., et. al, "Technology Review: Challenges Facing Packaging of Small Scale Biomedical Implants," Proceedings, IFESS 2008, 13th Annual Conference, International Functional Electrical Stimulation Society, Freiburg, Germany, 2008
3. Green R.A., et al.,"Integrated Electrode and High Density Feedthrough System for Chip-scale Implantable Devices," Biomaterials (2013), http://dx.doi.org/10.1016/j.biomaterials.2013.04.054.
4. Dunn, H., "Hermetic Packaging of Implantable Devices: How Did We Get Here?" IMAPS New England Regional Symposium, Boxborough MA USA, May 2016.

Implications for Packaging and Packaging Materials

Implantable and ingestible electronic devices require hermeticity.

- Polycrystalline ceramics for encapsulation packages for implantable devices:
  - Inherent low water permeability
  - High stability, especially in corrosive environments
  - Incorporated into (US FDA Class III) implantable devices requiring hermetic sealing.
  - Ceramic-to-metal seal feedthrough assemblies are considered to be promising:
    - Robust and durable
    - Tighter hermeticity than glass-to-metal feedthroughs, polymer encapsulation;
    - Processing challenges (higher temperature firing, potential for material shrinkage and internal stresses) must be dealt with.
    - Typically, only used for relatively large feedthroughs with modest density (pitches of 200 – 600 μm).

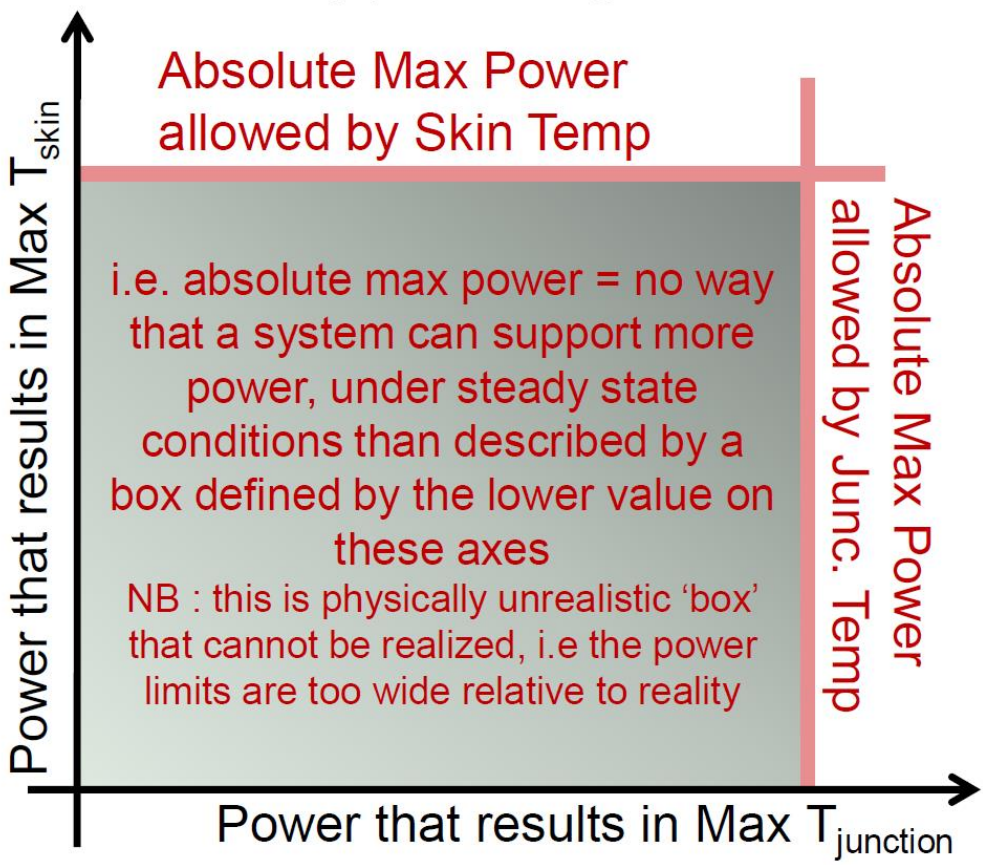
Wearable, implantable, and ingestible medical devices are limited in performance by power dissipation, case temperature limits, and internal thermal management design.

Sources:
1. Green R.A., et al.,"Integrated Electrode and High Density Feedthrough System for Chip-scale Implantable Devices," Biomaterials (2013), http://dx.doi.org/10.1016/j.biomaterials.2013.04.054.
2. Dunn, H., "Hermetic Packaging of Implantable Devices: How Did We Get Here?" IMAPS New England Regional Symposium, Boxborough MA USA, May 2016.

Implications for Thermal Design, Components, Materials

Major limitations for smartphones apply to *any* medical or other wearable electronic device that is potentially in contact with human skin or tissue:

- Absolute maximum power dissipation allowed by skin temperature impact;
- Absolute maximum power dissipation allowed by T_J operating limit.



Source: Riko Radojcic, Senior Director, Qualcomm Inc., San Diego CA USA. Keynote, "Managing Thermal and Mechanical Interactions with 2.5D and 3D ICs," IMAPS ATW Thermal 2014, October 28-30, 2014, Los Gatos CA USA.

Implications for Thermal Design, Components, Materials

Continued need for developments in:

- Advanced thermal materials as heat spreaders and/or biocompatible enclosures;
- Advanced thermal interface materials and heat spreaders for:
  - Heat spreading
  - Heat adsorption and storage
- Embedded miniature thermoelectric devices for:
  - Temperature control
  - Energy conversion
  - Improved efficiency

Author

Dave Saums, Principal and Founder, DS&A LLC

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  - Founder, Principal – DS&A LLC (2002 – 2017)
  - Previously, Vice President, Marketing, CPS Technologies Inc.
  - Director of Marketing, Phase-change Thermal Interface Materials, Henkel Electronic Materials
  - Program Manager, IC Thermal Management, EG&G Wakefield Engineering, Inc.
  - Marketing Manager, EG&G Rotron Inc.

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Consulting for business and product development strategy for electronics thermal management:

- Advanced thermal materials
- Thermal interface materials
- Thermal components
- Two-phase liquid cooling systems

