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*

- Military Handheld/Portable Communications Systems
- Implantable Medical Devices
- Wearable Sports and Health Devices
- Notebook PCs, 2-in-1, and Subnotebook PCs
- Tablets
- Handheld Mobile Phones (All Types and Performance Levels)

*Overview: Handheld, Mobile, Implantable Medical Devices*

*Concept and Data Value Source: DS&A LLC*
## Power Consumption: Average SmartPhone (2010)

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Freerunner</th>
<th>HTC Dream One</th>
<th>Google Nexus One</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspend</td>
<td>103.2</td>
<td>26.6</td>
<td>24.9</td>
</tr>
<tr>
<td>Idle</td>
<td>333.7</td>
<td>161.2</td>
<td>333.9</td>
</tr>
<tr>
<td>Call</td>
<td>1135.4</td>
<td>822.4</td>
<td>746.8</td>
</tr>
<tr>
<td>Email (Cell)</td>
<td>690.7</td>
<td>599.4</td>
<td>-</td>
</tr>
<tr>
<td>Email (WiFi)</td>
<td>505.6</td>
<td>349.2</td>
<td>-</td>
</tr>
<tr>
<td>Web (Cell)</td>
<td>500.0</td>
<td>430.4</td>
<td>538.0</td>
</tr>
<tr>
<td>Web (WiFi)</td>
<td>430.4</td>
<td>270.6</td>
<td>412.2</td>
</tr>
<tr>
<td>Network (Cell)</td>
<td>929.7</td>
<td>1016.4</td>
<td>825.9</td>
</tr>
<tr>
<td>Network (WiFi)</td>
<td>1053.7</td>
<td>1355.8</td>
<td>884.1</td>
</tr>
<tr>
<td>Video</td>
<td>558.8</td>
<td>568.3</td>
<td>526.3</td>
</tr>
<tr>
<td>Audio</td>
<td>419.0</td>
<td>459.7</td>
<td>322.4</td>
</tr>
</tbody>
</table>
## Power Consumption: SmartPhone versus Smart Watch (2016)

### Table 2. Mobile Electronic Devices – Typical Values, SmartPhone vs. Wearables

<table>
<thead>
<tr>
<th>Benchmark</th>
<th>Galaxy S6</th>
<th>Moto360</th>
<th>Apple Watch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Type</td>
<td>Smartphone</td>
<td>Smartwatch</td>
<td>Smartwatch</td>
</tr>
<tr>
<td>Surface Area (mm$^2$)</td>
<td>24086</td>
<td>3468</td>
<td>4662</td>
</tr>
<tr>
<td>Power (mW)</td>
<td>3000</td>
<td>400</td>
<td>400</td>
</tr>
<tr>
<td>Power Density (W/cm$^2$)</td>
<td>12.5</td>
<td>11.5</td>
<td>8.6</td>
</tr>
</tbody>
</table>

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

Global Wearable Device Unit Shipments Forecast

Source: BI Intelligence, January 2015
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)

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

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

Medtronic, PillCam Video Capsule
Medical Devices: Implantables

Table 3. Implantable Medical Devices: Typical Global Unit Volumes (2005)

<table>
<thead>
<tr>
<th>Device</th>
<th>Annual Units Implanted</th>
<th>Total Implants, Living Humans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac Pacemaker</td>
<td>600,000</td>
<td>3,000,000</td>
</tr>
<tr>
<td>Cochlear Implant</td>
<td>60,000</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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;

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).

Implantable Medical Devices: Impact of Environment on Design

Implantable Medical Devices: Impact of Design on Environment

Wireless Medical Implants and Implant Communications Systems

Overview:
Handheld, Mobile, Implantable Medical Devices


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

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### Table 4. Industry Trends and Implications

<table>
<thead>
<tr>
<th>Trend</th>
<th>Implication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transcutaneous data transfer</td>
<td>Device enclosure RF transparency for wireless transmission</td>
</tr>
<tr>
<td>Increased (longer) implant life</td>
<td>Hermeticity, resistance to corrosion, power source life and reliability</td>
</tr>
<tr>
<td>Minimally invasive surgery (or ingestible)</td>
<td>Miniaturizations</td>
</tr>
<tr>
<td>High-density electrodes</td>
<td>Simplified interconnects</td>
</tr>
<tr>
<td>High power</td>
<td>Power source life and reliability</td>
</tr>
</tbody>
</table>
Implantable Medical Devices: Regulatory Requirements
### Global Market Definition – Medical Device Regulation

#### Table 5. Government Regulatory Agencies: Implantable Medical Devices

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

*Source: DS&A LLC*
Global Market Definition – Medical Device Regulation

Medical device assessment in France
Guidebook

Source: HAS

December 2019
Global Market Definition – Medical Device Regulation

Compliance with essential requirements of one or more European directives

<table>
<thead>
<tr>
<th>Directives</th>
<th>Active implantable medical device (AIMD)</th>
<th>In vitro diagnostic medical device (IVDMD)</th>
<th>Other medical device (DM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>90 / 385</td>
<td>98 / 79</td>
<td>93 / 42</td>
</tr>
</tbody>
</table>

CE marking

Clinical evaluation, extract from Directive 2007/47/CE

"The demonstration of conformity with essential requirements must include a clinical evaluation (Annexe 1-6 b)"

"As a general rule, confirmation of conformity with the requirements concerning the characteristics and performance (...) under the normal conditions of use of the device as well as the evaluation of the side-effects and of the acceptability of the benefit/risk ratio (...) must be based on clinical data".

"Evaluation of this data, hereinafter referred to as ‘clinical evaluation’, where appropriate taking account of any relevant harmonized standards, must follow a defined and methodologically sound procedure based on (...), (Annexe X – 1 – 1.1)".

## 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)**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Degree of Regulatory Control</th>
<th>Product Type Categorization</th>
<th>Premarket Notification 510(k)</th>
<th>Premarket Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Increasing</td>
<td>Exempt</td>
<td>Exempt</td>
<td>Exempt</td>
</tr>
<tr>
<td>II</td>
<td></td>
<td>Required</td>
<td>Exempt</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Life-sustaining</td>
<td>Required</td>
<td>Required</td>
<td></td>
</tr>
</tbody>
</table>

### Table 7. Relevant Medical Device General Standards

<table>
<thead>
<tr>
<th>Specification</th>
<th>Topic</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 14971:2007</td>
<td>Risk Management, Medical Devices</td>
<td>Risk Management Plan</td>
</tr>
<tr>
<td>EN ISO 14791:2012</td>
<td>European harmonized standard</td>
<td>Risk Management File</td>
</tr>
<tr>
<td>IEC 60601-1:2005</td>
<td>Medical Electrical Equipment, Part I</td>
<td>Basic safety and essential performance</td>
</tr>
<tr>
<td>ISO 13485:2003</td>
<td>Medical Device Quality Management Systems</td>
<td>General quality management system for medical device design and manufacturing</td>
</tr>
</tbody>
</table>

*Source: DS&A LLC; after PharmOut Pty Ltd., ABN*
### Global Market Definition – Medical Device Regulation

**Table 8. Relevant Specifications: FDA (US) Materials and Packaging**

<table>
<thead>
<tr>
<th>Topic</th>
<th>Device Type</th>
<th>Value or Descriptor</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterility</td>
<td>Assembled device shall be</td>
<td>Sterile</td>
<td>ISO 14708-1/14.1</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Implanted assembled device shall be</td>
<td>Biocompatible</td>
<td>ISO 14708-3/14.3</td>
</tr>
<tr>
<td>Surface/edge/corner compatibility</td>
<td>Shall be</td>
<td>Avoided or covered</td>
<td>IEC 60601-1/9.3</td>
</tr>
<tr>
<td>Reaction/inflammation</td>
<td>Implanted assembled device shall have no features that cause</td>
<td>Reaction or inflammation</td>
<td>ISO 14708-3/15.2</td>
</tr>
</tbody>
</table>
Implantable Medical Electronic Devices: Power Consumption
Relative Power Dissipation: Wearable, Mobile, Ingestible Devices

Table 19. Mobile Electronic Devices – Ranking by Typical Power Dissipation Values

<table>
<thead>
<tr>
<th>Device</th>
<th>Typical Power Dissipation</th>
<th>Chronology by Relative Year of Introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>FitBit Flex – ST Micro ARM MCU 32L151C6</td>
<td>339 mW</td>
<td>5</td>
</tr>
<tr>
<td>Ingestible Colonoscopic Video Camera</td>
<td>150 – 500 mW</td>
<td>2</td>
</tr>
<tr>
<td>Entry-level Smartphone – Typical call processing w/backlight</td>
<td>1-2 W</td>
<td>3</td>
</tr>
<tr>
<td>Smartphone – High performance, call processing w/backlight</td>
<td>2 – 6 W</td>
<td>5</td>
</tr>
<tr>
<td>Entry-level Tablet (1)</td>
<td>9 W</td>
<td>4</td>
</tr>
<tr>
<td>Performance Tablet (2)</td>
<td>23.1 W</td>
<td>6</td>
</tr>
<tr>
<td>Notebook PC – Business</td>
<td>35-55 W</td>
<td>1</td>
</tr>
</tbody>
</table>

Sources:

## Table 10. Medical Electronic Devices – Specifications, Typical Values

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Device Type</th>
<th>Physical Envelope (Typ.)</th>
<th>Power Consumption (Typ.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable Medical</td>
<td>Brain Monitor/Stimulator</td>
<td>40 x 40 mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Glucose Monitor</td>
<td>Range</td>
<td>&gt;10 µW</td>
</tr>
<tr>
<td></td>
<td>Neurological Stimulator</td>
<td></td>
<td>30 – 800 µW</td>
</tr>
<tr>
<td></td>
<td>Cardiac Defibrillator</td>
<td>Range</td>
<td>30µW – 4 mW</td>
</tr>
<tr>
<td></td>
<td>Cardiac Monitor</td>
<td>Range</td>
<td>Range</td>
</tr>
<tr>
<td></td>
<td>Cardiac Pacemaker</td>
<td>12 x 12 x 6mm</td>
<td>30 – 100 µW</td>
</tr>
<tr>
<td></td>
<td>Drug Pump</td>
<td>10 x 12mm</td>
<td>10 µw – 2 mW</td>
</tr>
<tr>
<td></td>
<td>Cochlear Implant</td>
<td>5 x 5 – 10 x 10mm</td>
<td>3 – 10 mW</td>
</tr>
</tbody>
</table>

### Wearable/Implantable/Ingestible Devices: Power Consumption

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Device Type</th>
<th>Physical Envelope (Typ.)</th>
<th>Power Consumption (Typ.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestible Medical</td>
<td>Video Camera</td>
<td>26 x 11 mm</td>
<td>150 – 500 mW</td>
</tr>
<tr>
<td></td>
<td>Microbattery</td>
<td>2.5 x 2.5 x 0.8mm</td>
<td>-</td>
</tr>
<tr>
<td>Wearable Medical</td>
<td>Hearing (Cochlear) Instrument</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EED (Electroencephalogram) Headset</td>
<td>35 x 30 x 5mm</td>
<td>750 µW (plus battery)</td>
</tr>
</tbody>
</table>

Implantable Medical Electronic Devices: Power Sources
Table 12. Potential Power Sources – Implantable Medical Devices

<table>
<thead>
<tr>
<th>General Category</th>
<th>Category</th>
<th>Subcategory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Systems</td>
<td>Batteries, One-Time</td>
<td>Lithium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nuclear*</td>
</tr>
<tr>
<td></td>
<td>Environmental Harvesting</td>
<td>Biofuel Cell</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TEC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Piezoelectric</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Electrostatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Electromagnetic</td>
</tr>
<tr>
<td>Systems with Transfer Mechanism</td>
<td>Optical Charging</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inductive Coupling</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ultrasonic Transducers</td>
<td></td>
</tr>
</tbody>
</table>

Note: * Generally discontinued for use in implantable devices during 1980s.

## Wearable/Implantable/Ingestible Devices: Power Consumption

### Table 13. Medical Electronic Devices – Power Source Specifications, Typical Values

<table>
<thead>
<tr>
<th>Device Category</th>
<th>Device Type</th>
<th>Power Consumption (Typ.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic</td>
<td>All</td>
<td>1-80 µW</td>
</tr>
<tr>
<td>Electromagnetic</td>
<td>All</td>
<td>1-150 µW</td>
</tr>
<tr>
<td>TEC</td>
<td>All</td>
<td>1µW – 1mW</td>
</tr>
<tr>
<td>Battery</td>
<td>Lithium, Nuclear</td>
<td>1-10+ mW</td>
</tr>
<tr>
<td>Charging/Transfer Methods</td>
<td>Optical Charging</td>
<td>1µW – 10+ mW</td>
</tr>
<tr>
<td></td>
<td>Ultrasonic Transducers</td>
<td>1µW – 10+ mW</td>
</tr>
<tr>
<td></td>
<td>Inductive Coupling</td>
<td>1µW – 10+ mW</td>
</tr>
</tbody>
</table>

Power Sources: Battery Chemistry Energy Density

Energy Comparison of Battery Chemistries

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

**Overview:**
Handheld, Mobile, Implantable Medical Devices

**Key Takeaway:** While all Mega Trends are important, the selection and ranking of these trends indicate which shifts will have relevance in shaping the global evolutionary landscape.

**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:
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:
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

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.

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Table 14. Deep Brain Stimulation Implant: System Design Requirements

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Phase I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of sites</td>
<td>4 recording, 1 stimulating</td>
</tr>
<tr>
<td>Electrodes per site</td>
<td>25 recording, 25 stimulating</td>
</tr>
<tr>
<td>Duration of implant</td>
<td>90 days</td>
</tr>
<tr>
<td>Time between recharge/battery replacement</td>
<td>30 days</td>
</tr>
<tr>
<td>Size of implant</td>
<td>40 x 40 mm</td>
</tr>
<tr>
<td>Weight of implant</td>
<td>35 g</td>
</tr>
</tbody>
</table>

# Deep Brain Stimulation Implant: Packaging Specification, Materials

## Table 15. Deep Brain Stimulation Implant: Hub System Packaging materials

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

Deep Brain Stimulation Implant: Central Hub Module Packaging

Deep Brain Stimulation Implant: Central Hub Module Packaging

Component boards

Battery

Antenna board with ferrite

Ceramic feedthrough plate with Pt/Ir pins

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.

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 presence of moisture (hydrolytic stability)
  - Moderate curing temperatures
- Polymer-encapsulated materials require:
  - Corrosion resistance
  - Good adherend performance

Sources:
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:
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

- Thirty-nine years of electronics thermal management technical marketing, business strategy development, product development management.
  - 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.
Overview:
Handheld, Mobile, Implantable Medical Devices