Introduction to BioMEMS & Medical Microdevices

Packaging, Power, Data & RF Safety

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Devices to Consider

- Lab-on-a-chip / µTAS
  - Interconnections
  - Biocompatibility with specimen
  - Reagent addition and waste removal
  - Date of expiration
- Other BioMEMS/NEMS devices
  - Sensors and actuators
  - Point-of-care and human interface
- Implantable devices
  - A device that is either partly or totally introduced, surgically or medically, into the human body and is intended to remain there after the procedure
  - Biocompatibility with the body
  - Power and wireless communication
- Microsurgical instruments

Environmental Factors

- Light (e.g. light may degrade reagents and drugs)
- Temperature, pressure and humidity
- Electromagnetic fields and radiation
- Mechanical stresses
- Interaction with other surrounding components
- Implant environment
Implanted Devices

- Medical devices are engineered to restore a body function, to detect a body signal, or to provide mechanical or electrical assistance to a human organ.
- Operations should be simple and minimally invasive, allowing rapid healing.
- Devices should function within the environment, have good longevity and serviceability.
- Sterilization to prevent introducing organisms.
- Minimizing an immune response.

Sterilization

- Dry heat.
- Pressured vapor.
- Ethylene oxide (EtO).
- Formaldehyde.
- Gas plasma (H$_2$O$_2$).
- Peracetic acid.
- Gamma radiation.
- E-beam sterilization.

Biocompatible Implant Materials

- Titanium and its alloys.
- Noble metals and their alloys.
- Bio-grade stainless steels.
- Some cobalt-based alloys.
- Tantalum, niobium, titanium-niobium alloys.
- Nitinol, MP35N (a nickel-cobalt-molybdenum alloy).
Continued…

- Alumina.
- Zirconia.
- Quartz.
- Fused silica.
- Bio-grade glass.
- Silicon.
- Certain polymers.

Encapsulation

- Polymers
  - Epoxies, silicones, polyurethanes, polyimides, silicone-polyimides, parylenes, polyimide-olefins, silicon-carbons, benzocyclobutanes, and liquid crystal polymers.
  - Used for feedthroughs, covering leads and lining sensors.
- Glass-type Packages
  - Based on quartz, fused silica, and boro-silicate.
  - Melting of the glasses done by local laser-focused heating.
  - Used for neuromuscular stimulators, radio frequency identification chips, endoscope pills, and implantable blood pressure sensors.
- Metallic
  - Accomplished by laser welding of the metals.
  - Applied for loop recorders, pacemakers, ICDs, and cochlear implants.

Helium Gas Permeability Testing
Electronic Assembly & Packaging

Chip-on-Board (COB)

Flip-Chip & Solder Bumps
Example: Artificial Vertebral Disk

3D Chip-Scale-Packaging

- Combines flip-chip technology and assembly on flexible circuits:
**Power Systems**

- **General Considerations**
  - Internal vs. external to the device.
  - Inside vs. outside the body.
  - Voltage and current requirements.
  - Operations performed e.g. sensing and actuation.

- **Technologies:**
  - Energy "harvesting" or "scavenging."
  - Batteries – single use vs. rechargeable
  - Electric fields and induction coils.
  - Photovoltaic cells.
  - Non-regenerative and regenerative fuel cells.

**Energy Harvesting Methods**

- Ambient light
  - Utilizing photovoltaic cells
  - Long-wavelength photodiodes
  - Fiber optics

- Thermoelectric generators.
  - Utilizing the Seebeck effect and non-uniform temperature gradients in the body.
  - Direct conversion of heat to mechanical action.

- Micro fuel cells
  - Self-sustaining/regenerative – e.g. glucose based.

- Electrostatic Vibration-to-Electricity - comb drive.

- Electromagnetic conversion – coils and magnets.

- Piezoelectric
  - Convert displacement and strain into electricity.
Photovoltaic cells

Thermo Energy - Multiple Thermocouples

Voltage = \left( S_A(T) - S_B(T) \right) \Delta T

Where

- \( S_A \) material (p-type) and \( S_B \) material (n-type).
- \( T_h \) hot junction temperature, \( T_c \) cold junction temperature, and
- \( S \) is the Seebeck coefficients of the two materials.

Regenerative Glucose Micro Fuel Cell

- Based on the reaction between oxygen and glucose.
  - Enzymatic, microbial or abiotic (other catalyst)
  - A theoretical energy harvesting technique.

Anode: \( \text{C}_6\text{H}_{12}\text{O}_6 + 24\text{OH}^- \rightarrow 6\text{CO}_2 + 18\text{H}_2\text{O} + 24\text{e}^- \)

Cathode: \( 6\text{O}_2 + 12\text{H}_2\text{O} + 24\text{e}^- \rightarrow 24\text{OH}^- \)

Overall: \( \text{C}_6\text{H}_{12}\text{O}_6 + 6\text{O}_2 \rightarrow 6\text{CO}_2 + 18\text{H}_2\text{O} \)
Overlap Electrostatic Micro Generator

Under Normal Operation

Under Off-Axis Actuation


Electromagnetic Generator

Rare Earth Permanent Magnets

Metallic Coils

Silicon Paddle

Piezoelectric Generators

February Beam Proof Mass

PZT Layers

Lueke, J. and W.A. Moussa. MEMS based power generation techniques for implantable biosensing applications. Sensors 2011, 11, 1433-1460

Lueke, J. and W.A. Moussa. MEMS based power generation techniques for implantable biosensing applications. Sensors 2011, 11, 1433-1460

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Batteries in Implantable Devices

- Lithium Iodine - Polyvinyl pyridine
  - Pacemakers
  - Microampere range
- Lithium/Manganese Dioxide
  - Neurostimulators, drug delivery, pacemakers.
  - Milliampere range.
- Lithium/Carbon Monofluoride
  - Milliampere range.
- Lithium/Silver Vanadium Oxide (defibrillators)
  - High current pulses of 2-3 amps.
  - Implantable cardioverter defibrillators.
- Lithium/CFx-SVD Hybrid
- Lithium Ion

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Implanted Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurostimulator</td>
<td>5</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>2</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>3</td>
</tr>
<tr>
<td>Pacemaker/nerve</td>
<td>4</td>
</tr>
<tr>
<td>Drug delivery</td>
<td>6</td>
</tr>
<tr>
<td>Drug delivery</td>
<td>6</td>
</tr>
<tr>
<td>Drug delivery</td>
<td>5</td>
</tr>
</tbody>
</table>

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Multiplate Cardiac Defibrillator Battery
Discharge Characteristic

Discharge of a lithium/iodine – polyvinyl pyridine battery under various constant resistive loads. Voltage vs Capacity in mAh at different resistive loads.

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Non-Regenerative Fuel Cells

- Proton exchange membrane (PEM) fuel cells:

  ![Image of PEM fuel cell](Image courtesy of Tekion)

- Hydrogen serves as the fuel and is split into hydrogen ions (protons) and electrons at the anode. The anode reaction is as follows:
  \[ 2\text{H}_2 \rightarrow 4\text{H}^+ + 4e^- \]

- Oxygen combines with the electrons and hydrogen ions to produce water. The cathode reaction is:
  \[ \text{O}_2 + 4\text{H}^+ + 4e^- \rightarrow 2\text{H}_2\text{O} \]

- The overall reaction is:
  \[ 2\text{H}_2 + \text{O}_2 \rightarrow 2\text{H}_2\text{O} \]

- An electric current is generated by the flow of electrons in the external circuit.

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**Methanol Reforming**

- Methanol reforming (a source of hydrogen):
  - The chemical reaction between methanol and water vapor in the presence of a metal oxide catalyst for the production of hydrogen gas:

  \[ \text{CH}_3\text{OH} + \text{H}_2\text{O} \rightarrow \text{CO}_2 + 3\text{H}_2 \]

**Wireless Powering**

- Inductive coupling:

  \[ \text{Voltage} = M \frac{d}{dt} \text{current} \]

  Where: \( M \) is the mutual inductance between the coils and \( i \) is the current in the primary conductor.

**Combined Power & Data**

- Power harvesting and telemetry in CMOS for implanted devices.
**Ultrasonic Energy**

- Skin
- Ultrasonic transducer
- Human body
- Energy generator
- Receiver

**Capacitive Coupling Link**

- $V_{in}$
- $C_1$
- $C_{th}$
- $V_{out}$
- $R_L$

**Implanting a Medical Device**

- *Syncope is sudden loss of consciousness.*
Normal Electrocardiogram Features

Atrial Fibrillation

Medtronic Reveal ® : Introduction
RF Safety - Key Concepts

- Occupational vs. General Population exposure.
- Near Field (and leakage) vs. Far Field measurements.
- Maximum Permissible Exposure (MPE)
  - Electric field strength (E) in (V/m).
  - Magnetic field strength (H) in (A/m).
  - Power density (S) in (mW/cm²)
- Internal dosimetry:
  - SAR (W/kg) or Specific Absorption Rate
  - Internal rms.
  - Peak electric field strength (V/m).
  - Internal current (A).
  - Current density (A/m²).

Maximum Permissible Exposure

<table>
<thead>
<tr>
<th>Frequency Range (MHz)</th>
<th>Electric Field Strength (E) (V/m)</th>
<th>Magnetic Field Strength (H) (A/m)</th>
<th>Power Density (S) (mW/cm²)</th>
<th>Averaging Time (E², H², or S)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5-3.5</td>
<td>114</td>
<td>1.63</td>
<td>1500</td>
<td>6</td>
</tr>
<tr>
<td>3 - 30</td>
<td>1842</td>
<td>4.08</td>
<td>(800)²</td>
<td>6</td>
</tr>
<tr>
<td>30 - 300</td>
<td>21.4</td>
<td>0.163</td>
<td>1.0</td>
<td>6</td>
</tr>
<tr>
<td>300 - 1500</td>
<td>2.3</td>
<td>--</td>
<td>0.05</td>
<td>6</td>
</tr>
<tr>
<td>1500 - 100,000</td>
<td>--</td>
<td>--</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

*Plane-wave equivalent power density

Limits for Maximum Permissible Exposure (MPE)

General Population/Uncontrolled Exposure

<table>
<thead>
<tr>
<th>Frequency Range (MHz)</th>
<th>Electric Field Strength (E) (V/m)</th>
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<th>Power Density (S) (mW/cm²)</th>
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</thead>
<tbody>
<tr>
<td>3.0 - 1.34</td>
<td>114</td>
<td>1.63</td>
<td>1500</td>
<td>30</td>
</tr>
<tr>
<td>1.34 - 30</td>
<td>824</td>
<td>2.151</td>
<td>(1800)²</td>
<td>30</td>
</tr>
<tr>
<td>30 - 300</td>
<td>27.5</td>
<td>0.073</td>
<td>0.2</td>
<td>30</td>
</tr>
<tr>
<td>300 - 1500</td>
<td>--</td>
<td>--</td>
<td>81500</td>
<td>30</td>
</tr>
<tr>
<td>1500 - 100,000</td>
<td>--</td>
<td>--</td>
<td>5</td>
<td>30</td>
</tr>
</tbody>
</table>

*Plane-wave equivalent power density
Specific Absorption Rate - SAR

- Measure of the rate of energy absorption per unit mass due to exposure to an RF transmitting source.
  - Portable devices are defined as transmitting devices used within 20 centimeters of the user.
- Occupation/controlled exposure is 0.4 W/kg as averaged over the whole-body and spatial peak SAR not exceeding 8 W/kg as averaged over any 1 gram of tissue.
  - Exceptions are the hands, wrists, feet and ankles where the spatial peak SAR must not exceed 20 W/kg, as averaged over 10 grams of tissue.

The limit for general population/uncontrolled exposure is 0.08 W/kg as averaged over the whole-body and spatial peak SAR not exceeding 1.6 W/kg as averaged over any 1 gram of tissue.
  - Exceptions are the hands, wrists, feet, and ankles where the spatial peak SAR must not exceed 4 W/kg, as averaged over 10 grams of tissue.

Resources

- National Council on Radiation Protection and Measurement.
- IEEE Recommended Practice for Measurements and Computations of Radio Frequency Electromagnetic Fields With Respect to Human Exposure to Such Fields, 100 kHz-300 GHz (IEEE Std C95.3-2002).
- American National Standards Institute.
Summary

- Packaging.
- Electronic assembly.
- Power systems.
  - Batteries, fuel cells
  - Wireless systems.
- Data transmission.
- Example Implant – the Medtronic Reveal
- RF safety:
  - Maximum Permissible Exposure.
- SAR
- Appendix
  - Tables of piezoelectric materials and energy harvesting comparison.

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### Piezoelectric Materials

**Table 1. Thin Film Piezoelectric Materials.**

<table>
<thead>
<tr>
<th>Material</th>
<th>Fabrication Method</th>
<th>Fabrication Difficulty</th>
<th>Piezoelectric Coefficient $d_{33}$ (pC/N)</th>
<th>Piezoelectric Coefficient $g_{33}$ (pC/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alumina Nitride (AlN)</td>
<td>Oxide Deposition</td>
<td>Easy</td>
<td>6.7</td>
<td>2.0</td>
</tr>
<tr>
<td>Lead Zirconium Titanate</td>
<td>Oxide Deposition</td>
<td>Easy</td>
<td>-96 (EOT-2)</td>
<td>132 (EOT-2)</td>
</tr>
<tr>
<td>(PZT)</td>
<td>Silica Oxide Deposition</td>
<td>Easy</td>
<td>-174 (EOT-2)</td>
<td>374 (EOT-2)</td>
</tr>
<tr>
<td>ZnO Oxide (ZnO)</td>
<td>Oxide Deposition</td>
<td>Easy</td>
<td>-1.40</td>
<td>10.47</td>
</tr>
</tbody>
</table>

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### Energy Harvesting Comparison

<table>
<thead>
<tr>
<th>Method of Micro-generation</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Power Generation Potential</th>
<th>Input Energy Source</th>
<th>Applicability to Implantable Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydroelectric</td>
<td>Efficient</td>
<td>Necessity</td>
<td>500 W [101] - 1 W [12]</td>
<td>Light Sources</td>
<td>Application when sufficient light sources are present. Not applicable otherwise.</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Method of Micro-processing</th>
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<th>Input Energy Source</th>
<th>Applicability to Implantable Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electroactive</td>
<td>Use of active materials and charge pumps</td>
<td>Requires energy to produce power</td>
<td>17.5 mW/cm² [19] (small piezoelectric)</td>
<td>Lithium or sodium batteries</td>
<td>Applicable</td>
</tr>
<tr>
<td>Electromagnetic</td>
<td>Non-contact, noise-free, non-recoiling</td>
<td>Requires high electrical power</td>
<td>53 W/cm² [20] (magnet)</td>
<td>Supercapacitors</td>
<td>Applicable</td>
</tr>
<tr>
<td>Electrogalvanic</td>
<td>Requires low electrical power, high efficiency</td>
<td>Requires special materials</td>
<td>10 mW/cm² [21] (galvanic)</td>
<td>Supercapacitors</td>
<td>Applicable</td>
</tr>
<tr>
<td>Bioelectrode</td>
<td>Requires low electrical power, high efficiency</td>
<td>Requires special materials</td>
<td>20 mW/cm² [22] (galvanic)</td>
<td>Supercapacitors</td>
<td>Applicable</td>
</tr>
</tbody>
</table>