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/MEMS devices
  - Sensors and actuators.
  - Point-of-care and human interface.
- Implanted 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 ($\text{H}_2\text{O}_2$).
- 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).
Alumina.
Zirconia.
Quartz.
Fused silica.
Bio-grade glass.
Silicon.
Certain polymers.
Encapsulation

- Polymers
  - Epoxies, silicones, polyurethanes, polyimides, silicon-polyimides, parylenes, polycyclic-olefins, silicon-carbons, benzocyclobutenes, and liquid crystal polymers.
  - Used for feedthroughs, covering leads and lining sensors.

- Glass-type Packages
  - Based on quartz, fused silica, and borosilicate.
  - 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

Steven S. Saliterman

Chip-on-Board (COB)
Flip-Chip & Solder Bumps

Image courtesy of Valtronics
Example: Artificial Vertebral Disk

Image courtesy of Valtronics
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

- Environmental Energy Harvesting
  - Solar Energy
  - Infrared Radiator
    - Wireless Transfer energy
      - Capacitive
      - Inductive
      - Ultra So.
  - Human Energy Harvesting
    - Kinetic Energy
    - Thermal Energy
      - Electrostatic
      - Piezoelectric Generator
Energy Harvesting or Scavenging

- 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.

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**Photovoltaic cells**

- **Electrical load**
- **Sun**
- **DC current flow**
- **Boron-doped (P-type)**
  - Silicon layer ~ 250 m
- **Phosphorous-doped (N-type)**
  - Silicon layer ~ 0.3 m
Voltage = $\int_{T_h}^{T_c} [S_B(T) - S_A(T)]dT$

Where

"A" material (p-type) and "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.

\[
\text{Anode: } C_6H_{12}O_6 + 24OH^- \rightarrow 6CO_2 + 18H_2O + 24e^- \\
\text{Cathode: } 6O_2 + 12H_2O + 24e^- \rightarrow 24OH^- \\
\text{Overall: } C_6H_{12}O_6 + 6O_2 \rightarrow 6CO_2 + 18H_2O
\]
Overlap Electrostatic Micro Generator

Under Normal Operation

Under Off-Axis Actuation

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Electromagnetic Generator

Rare Earth Permanent Magnets

Metallic Coils

Silicon Paddle

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Piezoelectric Generators

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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**

Implanted Devices

<table>
<thead>
<tr>
<th>device</th>
<th>location</th>
</tr>
</thead>
<tbody>
<tr>
<td>neurostimulator</td>
<td>1</td>
</tr>
<tr>
<td>cochlear implant</td>
<td>2</td>
</tr>
<tr>
<td>pacemaker</td>
<td>3</td>
</tr>
<tr>
<td>implantable cardiac defibrillator</td>
<td>4</td>
</tr>
<tr>
<td>cardiac resynchronization device</td>
<td>5</td>
</tr>
<tr>
<td>drug delivery system</td>
<td>6</td>
</tr>
<tr>
<td>bone growth generator</td>
<td>7</td>
</tr>
</tbody>
</table>

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.
Non-Regenerative Fuel Cells

- Proton exchange membrane (PEM) fuel cells:

![Diagram of PEM fuel cell](image-courtesy-of-tekion.jpg)

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:

\[ 2H_2 \Rightarrow 4H^+ + 4e^- \]

Oxygen combines with the electrons and hydrogen ions to produce water. The cathode reaction is:

\[ O_2 + 4H^+ + 4e^- \Rightarrow 2H_2O \]

The overall reaction is:

\[ 2H_2 + O_2 \Rightarrow 2H_2O \]

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

\[
\text{CH}_3\text{OH} + \text{H}_2\text{O} \rightleftharpoons \text{CO}_2 + 3\text{H}_2
\]
Wireless Powering

- Inductive coupling:

\[ Voltage = M \times \frac{di_1}{dt} \]

*Where* \( M \) is the mutual inductance between the coils and \( i_1 \) is the current in the primary conductor.

Combined Power & Data
Ultrasonic Energy

Capacitive Coupling Link
Implanting a Medical Device

*Syncope* is sudden loss of consciousness.
Normal Electrocardiogram Features
Atrial Fibrillation

Irregular-irregular rhythm

Apparent missing “P” waves
Insertion
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/cm$^2$)
- **Internal dosimetry**:
  - SAR (W/kg) or Specific Absorption Rate
  - Internal rms.
  - Peak electric field strength (V/m).
  - Internal current (A).
  - Current density (A/m$^2$).
### Limits for Maximum Permissible Exposure (MPE)

#### Occupational/Controlled Exposure

| Frequency Range (MHz) | Electric Field Strength (E) (V/m) | Magnetic Field Strength (H) (A/m) | Power Density (S) (mW/cm²) | Averaging Time $|E|^2$, $|H|^2$, or S (minutes) |
|----------------------|-----------------------------------|-----------------------------------|-----------------------------|----------------------------------|
| 0.3-3.0              | 614                               | 1.63                              | (100)*                      | 6                               |
| 3.0-30               | 1842/f                            | 4.89/f                            | (900/f²)*                   | 6                               |
| 30-300               | 61.4                              | 0.163                             | 1.0                         | 6                               |
| 300-1500             | --                                | --                                | f/300                       | 6                               |
| 1500-100,000         | --                                | --                                | 5                           | 6                               |

*Plane-wave equivalent power density
## Limits for Maximum Permissible Exposure (MPE)
### General Population/Uncontrolled Exposure

| Frequency Range (MHz) | Electric Field Strength (E) (V/m) | Magnetic Filed Strength (H) (A/m) | Power Density (S) (mW/cm²) | Averaging Time $|E|^2$, $|H|^2$, or S (minutes) |
|-----------------------|----------------------------------|----------------------------------|---------------------------|----------------------------------|
| 0.3-1.34              | 614                              | 1.63                             | (100)*                    | 30                               |
| 1.34-30               | 824/f                            | 2.19/f                           | (180/f²)*                 | 30                               |
| 30-300                | 27.5                             | 0.073                            | 0.2                       | 30                               |
| 300-1500              | --                               | --                               | f/1500                    | 30                               |
| 1500-100,000          | --                               | --                               | 1.0                       | 30                               |

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

<table>
<thead>
<tr>
<th>Thin Film Piezoelectric Material</th>
<th>Fabrication Method</th>
<th>Fabrication Difficulty</th>
<th>Piezoelectric Coefficient $d_{31}$ (pC/N)</th>
<th>Piezoelectric Coefficient $d_{33}$ (pC/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aluminum Nitride (AlN)</td>
<td>Sputtering</td>
<td>Easy (Sputtering)</td>
<td>0.7</td>
<td>2.0</td>
</tr>
<tr>
<td>Lead Zirconate Titatnate (PZT)</td>
<td>Sputtering, Sol-Gel Deposition, Metap1 Oxide Chemical Vapor Deposition (MOCVD)</td>
<td>Easy (Sputtering)</td>
<td>$-60$ (PZT-2)</td>
<td>152 (PZT-2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medium (Sol-Gel)</td>
<td>$-171$ (PZT-5)</td>
<td>374 (PZT-5)</td>
</tr>
<tr>
<td>Zinc Oxide (ZnO)</td>
<td>Sputtering</td>
<td>Easy (Sputtering)</td>
<td>$-5.43$</td>
<td>11.67</td>
</tr>
</tbody>
</table>
## 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>Photovoltaic</td>
<td>Regenerative, abundant power source.</td>
<td>Efficiency and output is tied to light intensity.</td>
<td>500 μW [11]–1 W [12]</td>
<td>Light/Photons</td>
<td>Applicable where sufficient light intensities are present. Not applicable otherwise.</td>
</tr>
<tr>
<td>Thermovoltaic</td>
<td>Regenerative</td>
<td>Size Requires large temperature difference for efficient generation.</td>
<td>4.5 μW–100 μW [16] (Thermopiles) 0.8 μW [22] (P³ Micro-heat engine)</td>
<td>Ambient or supplied heat.</td>
<td>Applicable</td>
</tr>
<tr>
<td>Micro Fuel Cells</td>
<td>Can be regenerative. Reasonable energy density. Hydrocarbon fuels (highest energy) are not biocompatible.</td>
<td></td>
<td>50 μW/cm²–430 μW/cm² [25] (Glucose based) 9 mW/cm²–750 mW/cm² [29,35] (Hydrocarbon Based)</td>
<td>Supplied fuels such as Glucose or Hydrocarbons</td>
<td>Glucose based micro fuel cells are applicable. Hydrocarbon micro fuel cells are not.</td>
</tr>
</tbody>
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<td>Electrostatic</td>
<td>Can be regenerative with electrets and charge pumps.</td>
<td>Requires energy to produce energy.</td>
<td>20 µW/cm²–116 µW/cm² [4] (In-plane gap closing type) 100 µW/cm² [45] (out-of-plane type)</td>
<td>Ambient or supplied vibration.</td>
<td>Applicable</td>
</tr>
<tr>
<td>Electromagnetic</td>
<td>Regenerative High power Density Poor length-scale based scaling.</td>
<td></td>
<td>12.5 µW [52] (Cantilever) 45 nW [50] (Membrane) 386.46 µW [53]–6.6 mW [54] 375 µW [60] (Bimorph)</td>
<td>Ambient or supplied vibration.</td>
<td>Applicable</td>
</tr>
<tr>
<td>Piezoelectric</td>
<td>Regenerative High power density Customizable</td>
<td>Possible bio-compatibility issue. Highly frequency dependant.</td>
<td>10 mW [69] (Membrane) 2.7 mW/cm³ [66] (ZnO Nanowire)</td>
<td>Ambient or supplied vibration.</td>
<td>Applicable</td>
</tr>
</tbody>
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