Lecture 2:
Basic Concepts

580.470/580.670 Molecular and Cellular Instrumentation
Instrumentation design and development is a creative process involving an idea and then taking it to the implementation level (prototype => product). Key deliverable is also a patent. Medical Instrumentation development has more exacting demands since human health depends on the performance of the device. The key regulatory barriers are: animal/clinical protocol approval, investigational device examination/clinical engineering certification, FDA approval. The prototype to the medical product is a long, expensive, and highly regulated process.

- The key concerns of the FDA are: safety and efficacy
- The key categories of FDA regulation are: Class I (General controls=>labelling), Class II (Performance standards; grand-fathering before 1976), Class III (Premarketing approval).
• You should be familiar with the issue of Patents
• University/medical center regulations (animal, clinical)
• FDA
• In the development of the device, you should be familiar with
  • Measurement factors (instrumentation)
  • Environmental factors, social Medical factors; aesthetics, history, tradition, liability…
• Economic factors: cost-benefit, profit,
Food and Drug Administration (FDA)

Government body entrusted with the responsibility to regulated medical devices, drugs, etc.

Primary task: certify safety and efficacy

FDA regulates through FDA Instrumentation Categories

- Design Control: Class I
- Process Control: Class II
- Good Manufacturing Practices: Class III

What FDA Categories do the Instruments in the Previous Slide Belong to?
FDA Device Regulations

• Class I – General Controls
  – Required to perform registration, labeling, and good manufacturing practices and to report adverse effects

• Class II – Performance Standards
  – Required to prove “substantial equivalence” via the 510(k) process

• Class III – Pre-market Approval (PMA)
  – Requires extensive testing and expert scrutiny
  – PMA is necessary for devices used in supporting or sustaining human life
General Medical Instrumentation System

- Sensors such as electrodes, pressure transducer
- Instrumentation: amplifier, filter, signal conditioning
- Microprocessor, telemetry, Internet interface
- Case study (student project): Wireless heart rate alarm via cell phone

http://www.qubitsystems.com/electro.html
System Block Diagram

System Properties

- Accuracy, Precision
- Linearity, nonlinearity
- Response function (1st, 2nd order)
- Step response, transient response
- Stability, temperature response
- Noise, interference rejection
Sources of Signal Interference

• Any measurement includes signal+noise
• Signal sources: ECG, EEG, blood pressure, temperature…
• Noise sources
  – **External**: 60 Hz, radio frequency (RF), magnetic…
  – **Internal**: muscle noise, motion artifact, eye blink artifact…

Taken from http://www.temple.edu/biomed/
Principles of Measurements I

• Linearity, Accuracy, Stability… => apply to real problems, applications
• First order, second order systems… => apply to real problems, applications
System Linearity

- Properties required for a linear system
  - If \( y_1 \) and \( y_2 \) are the responses to \( x_1 \) and \( x_2 \), respectively, then \( y_1 + y_2 \) is the response to \( x_1 + x_2 \) and \( Ky_1 \) is the response to \( Kx_1 \), where \( K \) is a constant.

- Linearity is necessary for a system that has a linear calibration curve.
Dynamic System Characteristics

- General Form of Input-Output Relationship
  - Time-Domain
    \[ a_n \frac{d^n y}{dt^n} + \ldots + a_1 \frac{dy}{dt} + a_0 y(t) = b_m \frac{d^m x}{dt^m} + \ldots + b_1 \frac{dx}{dt} + b_0 x(t) \]
  - Transfer Function
    \[ H(j\omega) = \frac{Y(j\omega)}{X(j\omega)} = \frac{b_m (j\omega)^m + \ldots + b_1 (j\omega) + b_0}{a_n (j\omega)^n + \ldots + a_1 (j\omega) + a_0} \]

- Most instruments are of zero, first or second order
  - \( n = 0, 1, \) or 2; \( m = 0. \)

- Input is typically transient (step function), periodic (sinusoid), or random (bounded white noise)
Zero-Order System

- Expression of the input-output relationship
  - Time-domain Relationship
    \[ a_0y(t) = b_0x(t) \]
  - Transfer Function
    \[ H(j\omega) = \frac{b_0}{a_0} \]

- Example
  - Linear potentiometer

Figure 1.5  (a) A linear potentiometer, an example of a zero-order system. (b) Linear static characteristic for this system. (c) Step response is proportional to input. (d) Sinusoidal frequency response is constant with zero phase shift.
First-Order System

• System contains a single energy-storage element
• Time-domain relationship
  \[ a_1 \frac{dy}{dt} + a_0 y(t) = b_0 x(t) \]
• Transfer Function
  \[ H(j\omega) = \frac{b_0}{a_1(j\omega) + a_0} \]
• Example
  – RC Low-pass or High-pass Filters
Simple First-Order Circuits

- Properties: attenuation, delay, transient response, loss of frequency (low or high)
- Think of the examples of first order systems?

http://hyperphysics.phy-astr.gsu.edu/hbase/electric/filcap2.html
Second-Order System

• Second-order system can approximate higher-order systems

• Time-domain Relationship

\[ a_2 \frac{d^2 y}{dt^2} + a_1 \frac{dy}{dt} + a_0 y(t) = b_0 x(t) \]

• Transfer Function

\[ H(j\omega) = \frac{b_0}{a_2(j\omega)^2 + a_1(j\omega) + a_0} \]

• Example
  – Mechanical force-measuring instrument
  – Pressure transducer
Second-Order System

- **Over-damped**
  \[ \xi = \frac{a_1}{2\sqrt{a_0a_2}} > 1 \]

- **Critically-damped**
  \[ \xi = \frac{a_1}{2\sqrt{a_0a_2}} = 1 \]

- **Under-damped**
  \[ \xi = \frac{a_1}{2\sqrt{a_0a_2}} < 1 \]

*Figure 1.7* (a) Force-measuring spring scale, an example of a second-order instrument. (b) Static sensitivity. (c) Step response for overdamped case \( \xi = 2 \), critically damped case \( \xi = 1 \), underdamped case \( \xi = 0.5 \). (d) Sinusoidal steady-state frequency response, \( \xi = 2 \), \( \xi = 1 \), \( \xi = 0.5 \). [Part (a) modified from *Measurement Systems: Application and Design*, by E. O. Doebelin. Copyright © 1990 by McGraw-Hill, Inc. Used with permission of McGraw-Hill Book Co.]
Practice Questions

• Who do you file patent with? What is the basic style of a patent?
• What regulations are followed to do animal/clinical studies?
• Give several examples of each of the FDA categories.
• Give examples of negative feedback and positive feedback in medical sensors and instruments
• Pressure sensor may be modeled as a second order system. How does over/under/critically damped measurement affect Pressure reading?