Lecture 2: Basic Concepts

580.470/580.670 Molecular and Cellular Instrumentation

<u>Instrumentation design and development</u>

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

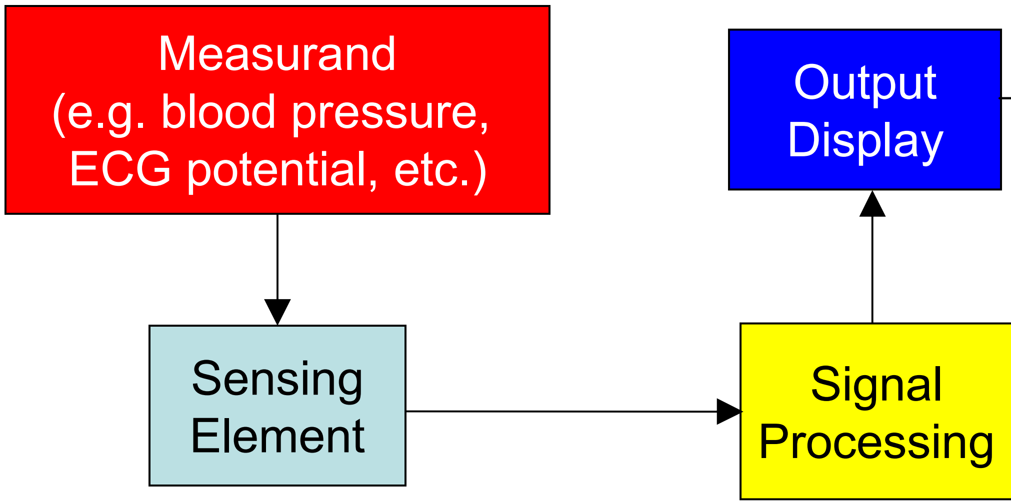
FDA regulates through Categories	FDA Instrumentation
Design Control	Class I
Process Control	Class II
Good Manufacturing Practices	Class III

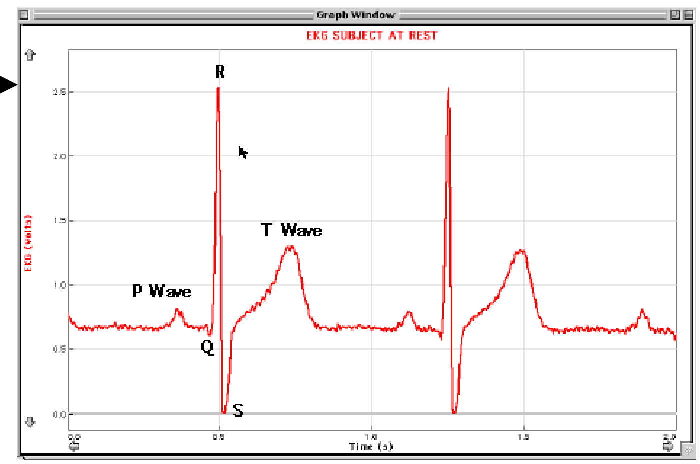
What FDA Categories do the Instruments in the Previous Slide Belong to?

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

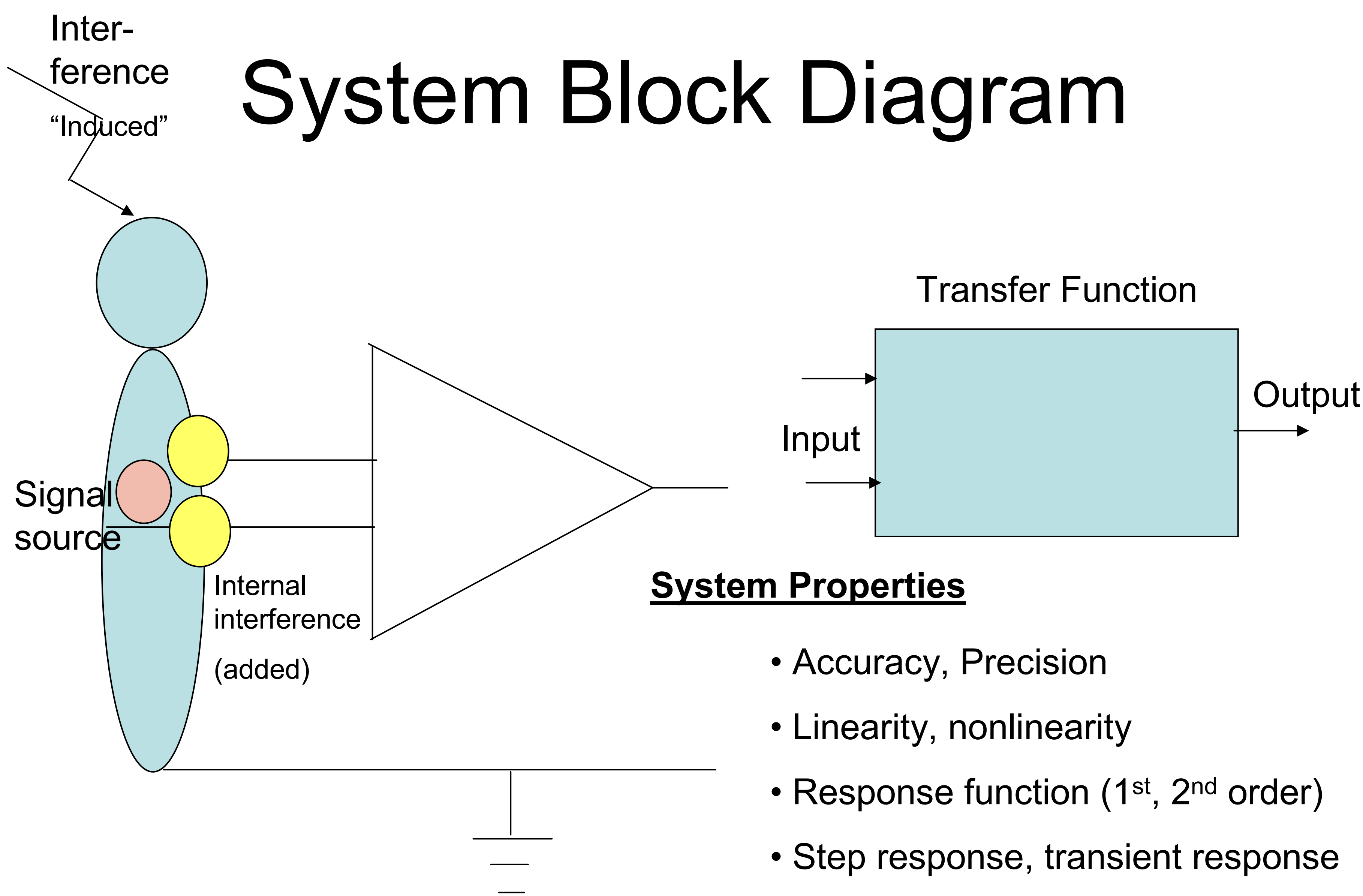




http://www.qubitsystems.com/electro.html

- 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

System Block Diagram

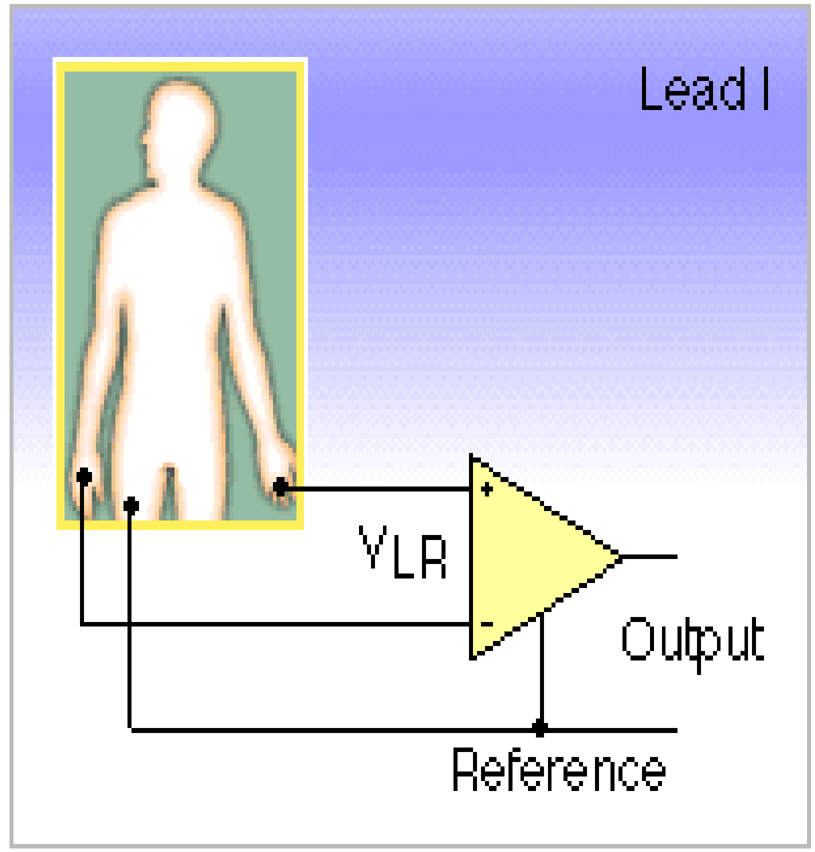


System Properties

- 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…



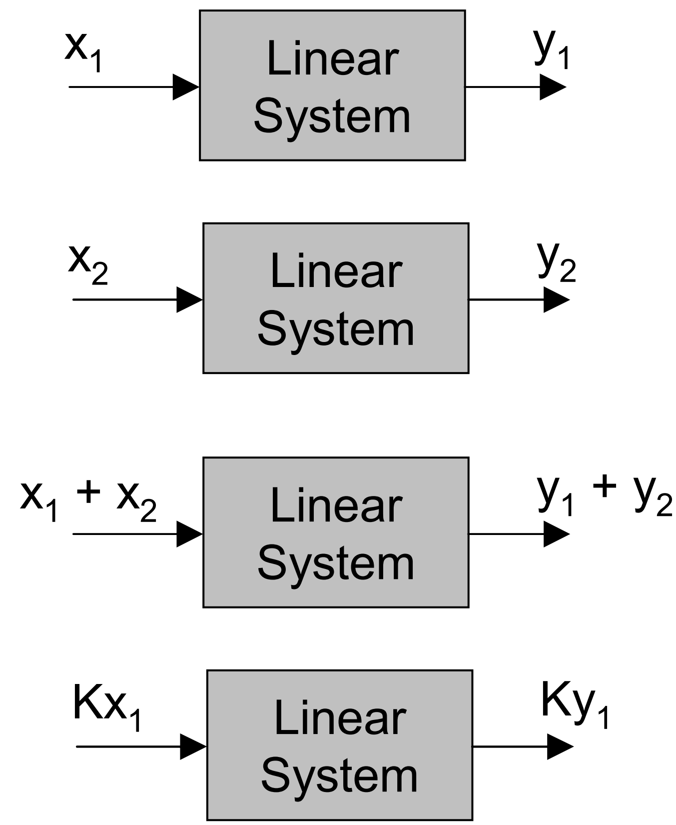
Taken from http://www.temple.edu/biomed/

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

    $$a_0 y(t) = b_0 x(t)$$

  - Transfer Function

    $$H(j\omega) = \frac{b_0}{a_0}$$

- Example
  - Linear potentiometer

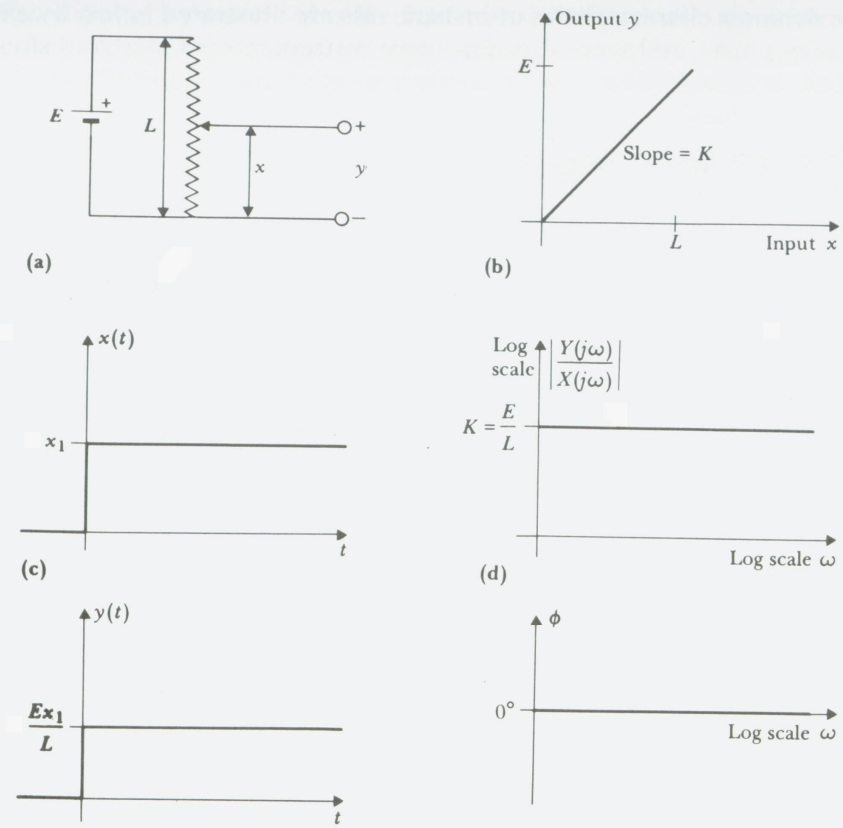


Figure 1.5 (a) A linear potentiometer, an example of a zero-order system. (b) Linear static characteristic for this system. (c) Step response is proportional to input. (d) Sinusoidal frequency response is constant with zero phase shift.

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

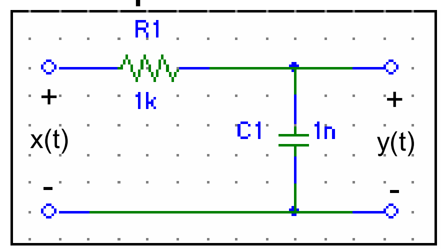
$$H(j\omega) = \frac{b_0}{a_1 (j\omega) + a_0}$$

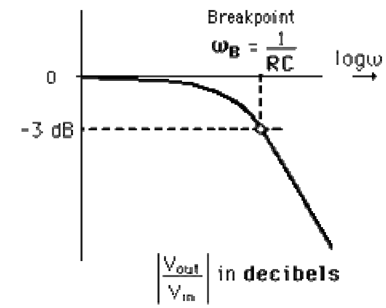
- Example
  - RC Low-pass or High-pass Filters

Simple First-Order Circuits

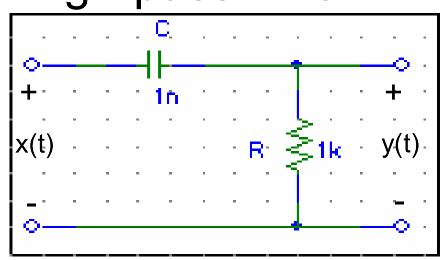
- Properties: attenuation, delay, transient response, loss of frequency (low or high)
- Think of the examples of first order systems?

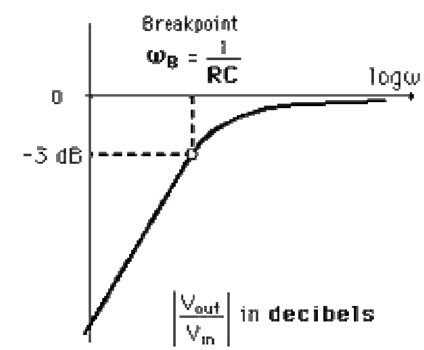
Low-pass Filter





High-pass Filter





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

$$\xi = \frac{a_1}{2\sqrt{a_0 a_2}} > 1$$

- Critically-damped

$$\xi = \frac{a_1}{2\sqrt{a_0 a_2}} = 1$$

- Under-damped

$$\xi = \frac{a_1}{2\sqrt{a_0 a_2}} < 1$$

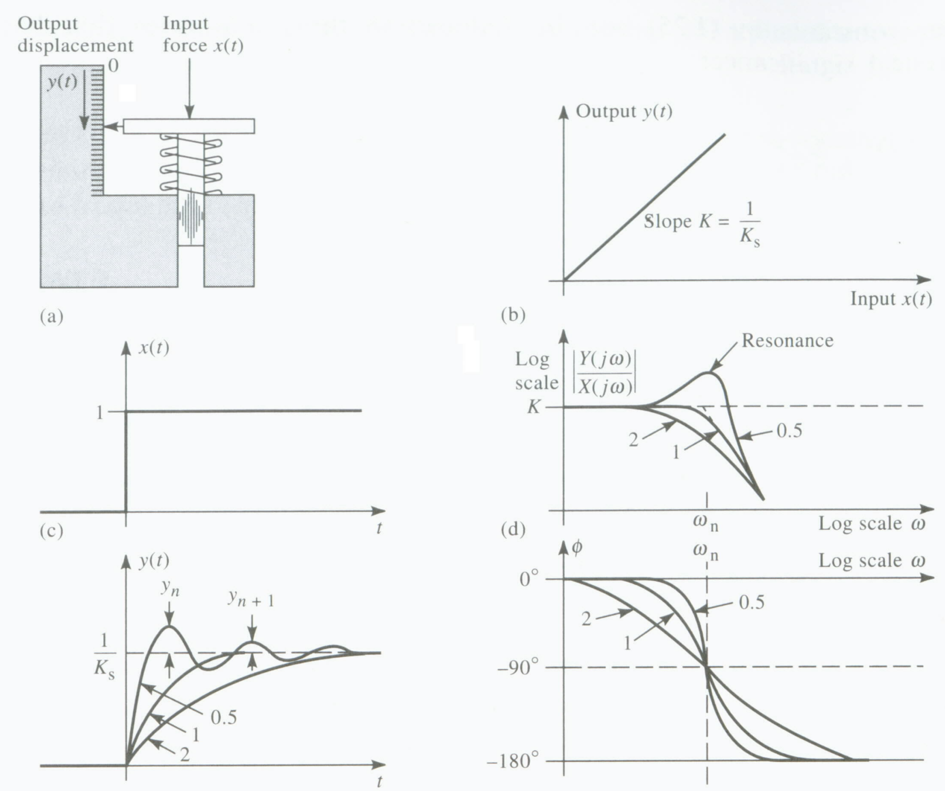


Figure 1.7 (a) Force-measuring spring scale, an example of a second-order instrument. (b) Static sensitivity. (c) Step response for overdamped case $\zeta = 2$, critically damped case $\zeta = 1$, underdamped case $\zeta = 0.5$. (d) Sinusoidal steady-state frequency response, $\zeta = 2$, $\zeta = 1$, $\zeta = 0.5$. [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?