Lecture 1
Chapter 1: Basic Concepts
and
Chapter 14: Safety

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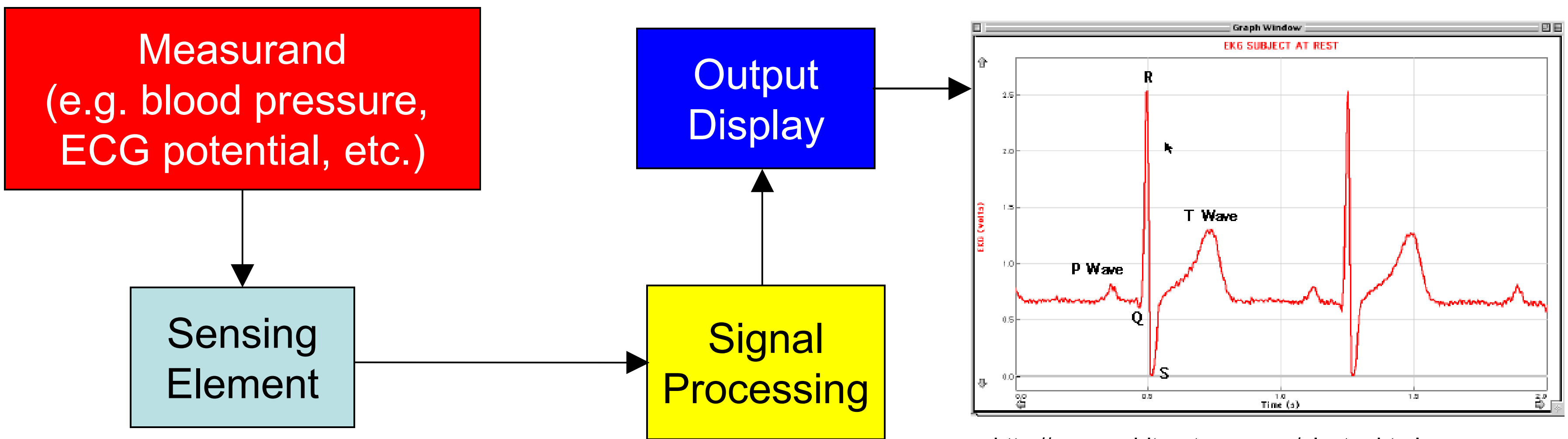
Introduction

- Medical Instrumentation Categories
  - Invasive, noninvasive; external, implanted
  - Diagnostic, therapeutic
- Examples
  - Endocardial catheter; ECG electrodes and monitor
  - External & implanted pacemakers, defibrillators
  - EEG based neurological monitor; deep brain stimulator for Parkinson’s disease
- Case studies (discuss, research)
  - Temperature measurement: mercury, electronic, IR
  - Blood pressure: pressure cuff, arterial pressure
  - Stethoscope, electronic stethoscope

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

Characteristics of Physiological Signals

Parameter	**Measurement Range**	**Frequency Range**	**Measurement Method**
Electrocardiogram (ECG)	0.5 – 4mV	0.01 – 250Hz	Skin electrodes
Electroencephalo-gram (EEG)	5 – 300μV	DC – 150Hz	Scalp electrodes
Electromyogram (EMG)	0.1 – 5mV	DC – 10KHz	Needle/skin electrodes
Electrooculogram (EOG)	50 – 3500μV	DC – 50Hz	Contact electrodes
Blood flow	1 – 300mL/sec	DC – 20Hz	Ultrasonic flowmeter
Respiratory Rate	2 – 50 breaths/min	0.1 – 10Hz	Strain guage
Body Temperature	32 – 40 ^{o}C	DC – 0.1Hz	Thermistor/thermocouple

Examples of Medical Instruments

Implanted pacemaker

External ECG monitor (Holter) for ambulatory subjects

Phrenic nerve stimulator

Laser for coronary angioplasty

Electrosurgical instrument

I.V. (intravenous) infusion bag

Infrared thermometer

Bedpan

Operating table

Eye protection glasses

X ray machine

Pulse oximeter

Defibrillation electrode

Automatic blood pressure

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

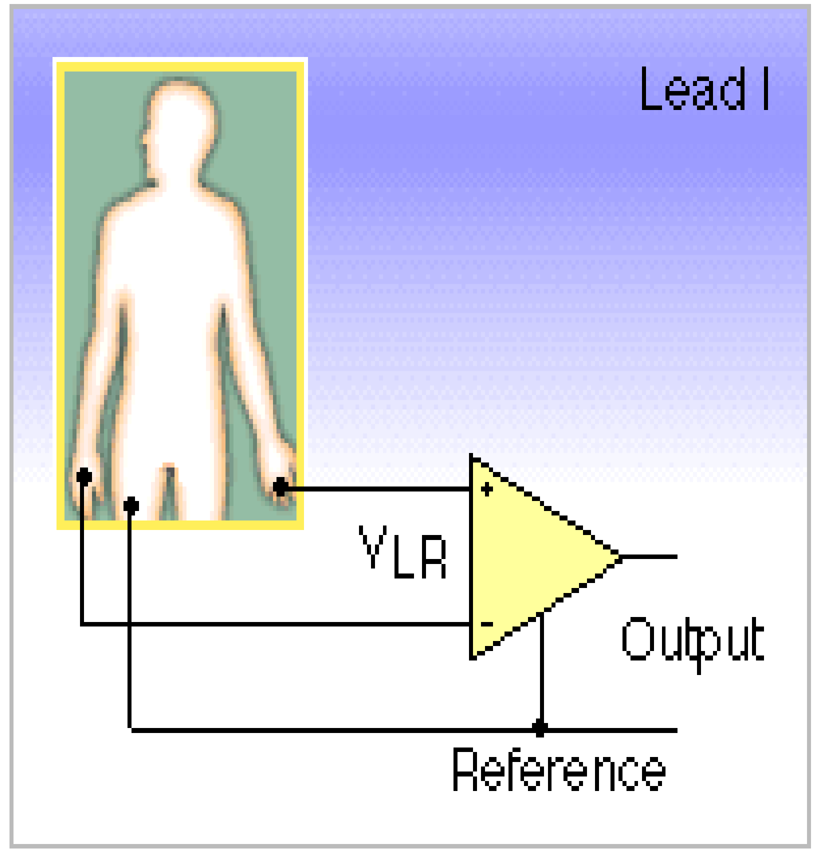
What FDA Categories do the Instruments in the Previous Slide Belong to?

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

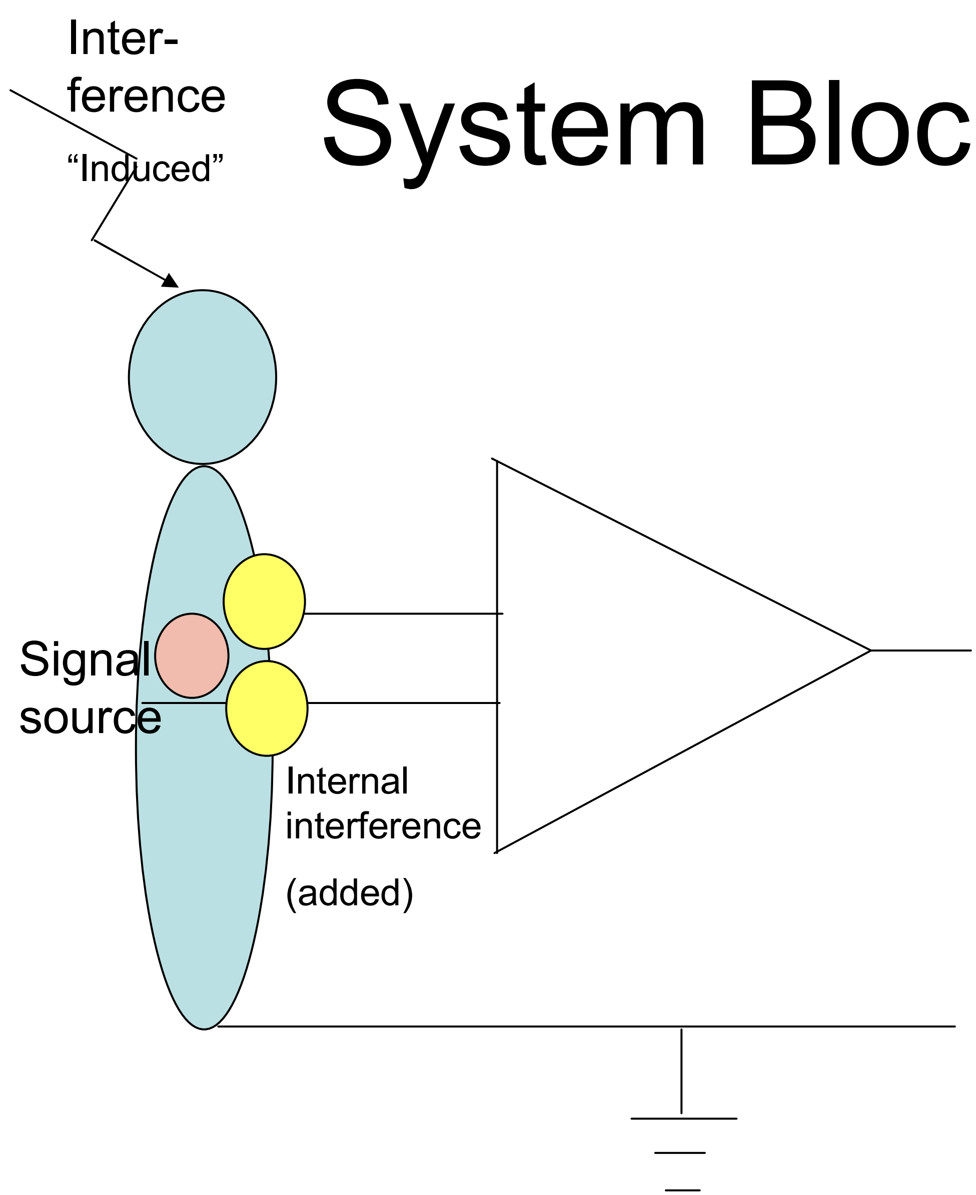
Sources of Signal Interference

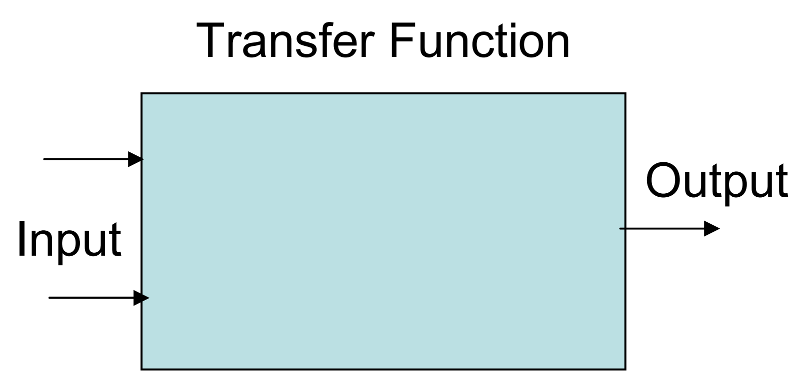
- Any measurement includes signal+noise
- Signal sources: ECG. EEG, blood pressure, temperature…
- Noise sources
  - External: 60 Hz, radio frequency (RF), magnetic…
  - Internal: muscle noise, motion artifact, eye blink artifact…



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

System Block Diagram



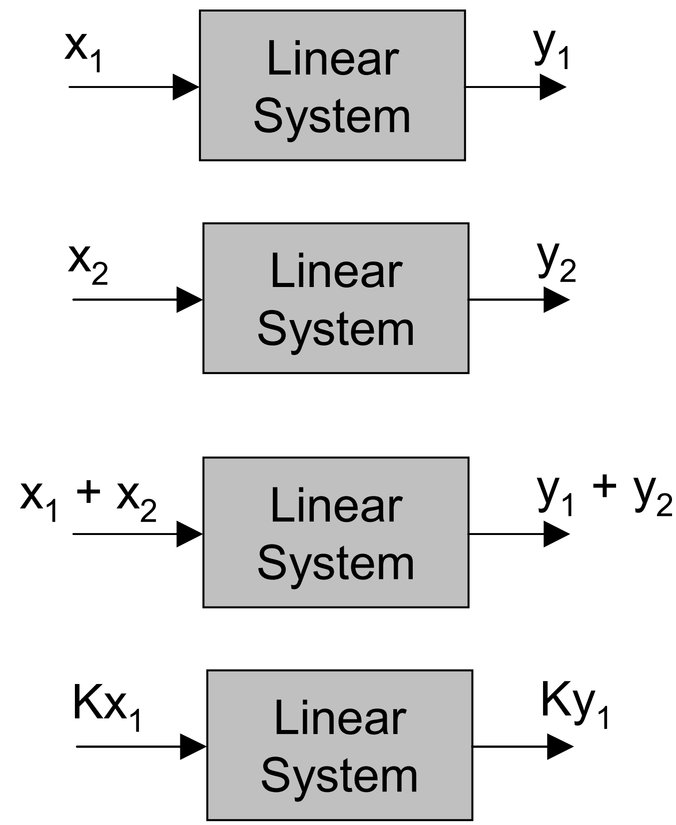


System Properties

- Accuracy, Precision
- Linearity, nonlinearity
- Response function (1^{st}, 2^{nd} order)
- Step response, transient response
- Stability, temperature response
- Noise, interference rejection

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 $a_n \frac{d^n y}{dt^n} + ... + a_1 \frac{dy}{dt} + a_0 y(t) = b_m \frac{d^m x}{dt^m} + ... + b_1 \frac{dx}{dt} + b_0 x(t)$
  - Transfer Function $H(j\omega) = \frac{Y(j\omega)}{X(j\omega)} = \frac{b_m (j\omega)^m + ... + b_1 (j\omega) + b_0}{a_n (j\omega)^n + ... + a_1 (j\omega) + a_0}$
- 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

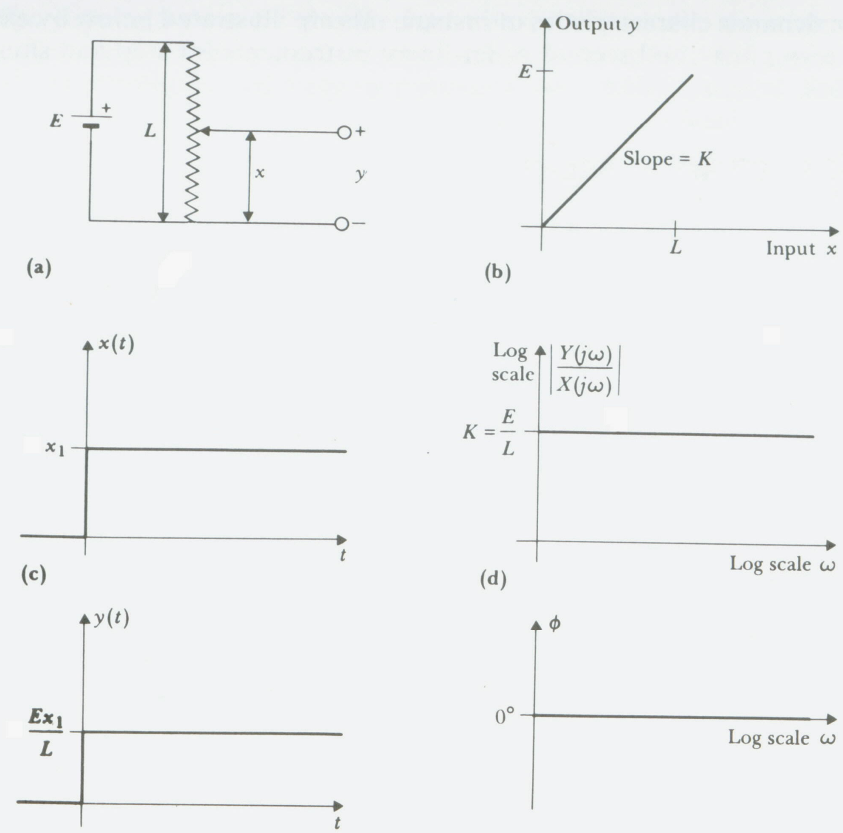


Figure 1.5 (a) A linear potentiometer, an example of a zero-order system. (b) Linear static characteristic for this system. (c) Step response is proportional to input. (d) Sinusoidal frequency response is constant with zero phase shift.

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

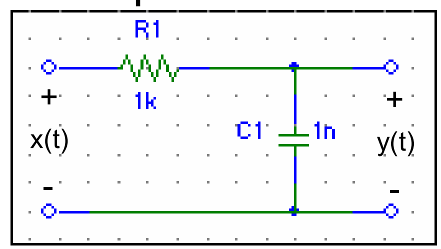
$$H(j\omega) = \frac{b_0}{a_1(j\omega) + a_0}$$

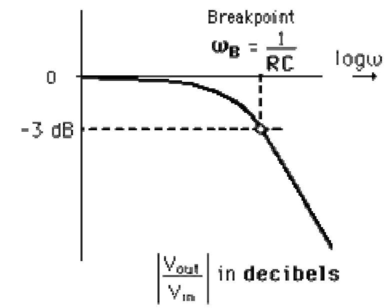
- Example
  - RC Low-pass or High-pass Filters

Simple First-Order Circuits

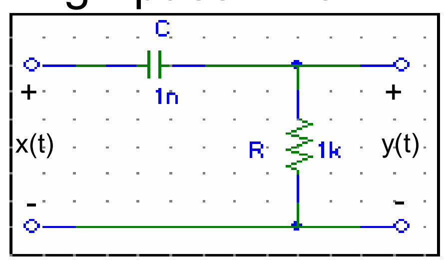
- Properties: attenuation, delay, transient response, loss of frequency (low or high)
- Think of the examples of first order systems?

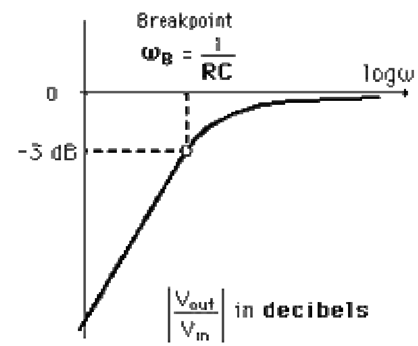
Low-pass Filter





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

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

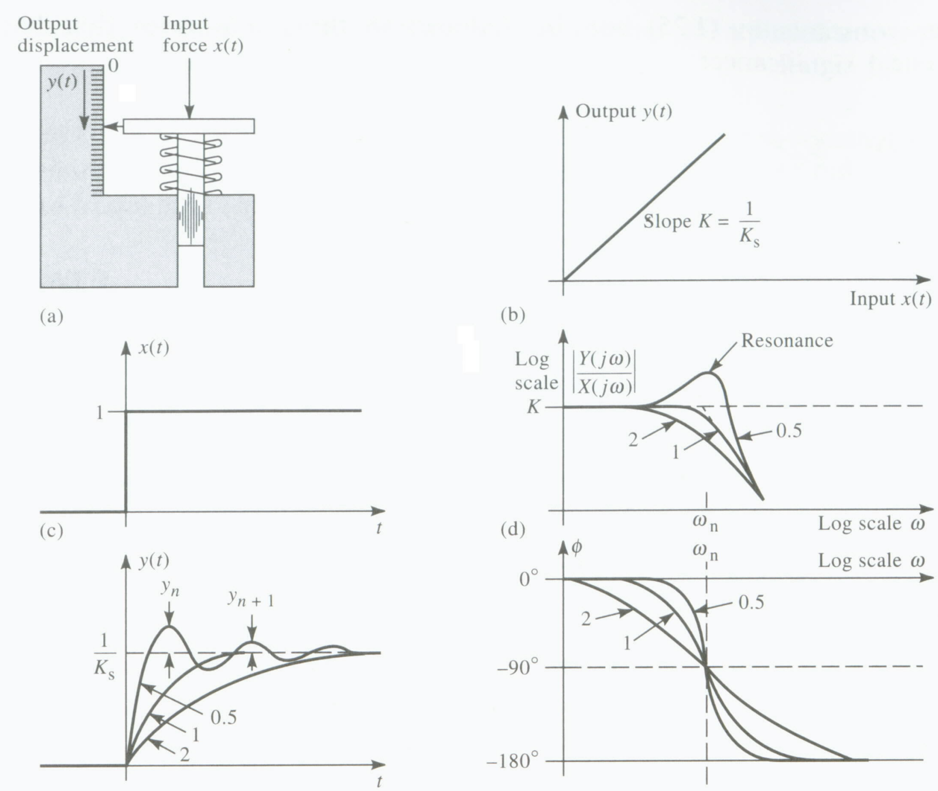


Figure 1.7 (a) Force-measuring spring scale, an example of a second-order instrument. (b) Static sensitivity. (c) Step response for overdamped case $\zeta = 2$, critically damped case $\zeta = 1$, underdamped case $\zeta = 0.5$. (d) Sinusoidal steady-state frequency response, $\zeta = 2$, $\zeta = 1$,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