BME 3402
Medical Instrumentation

- Office hours : 10:00-11:00 /Monday/ C-308
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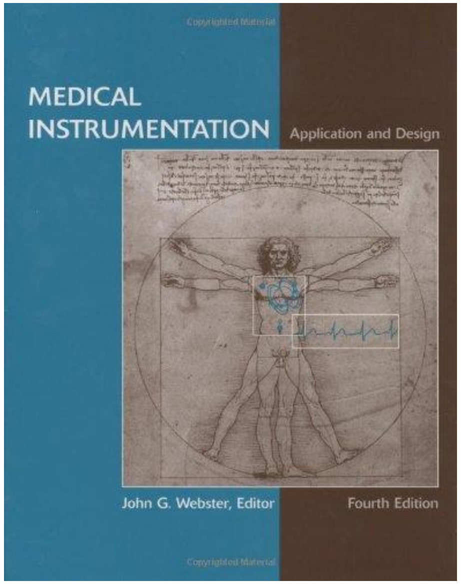
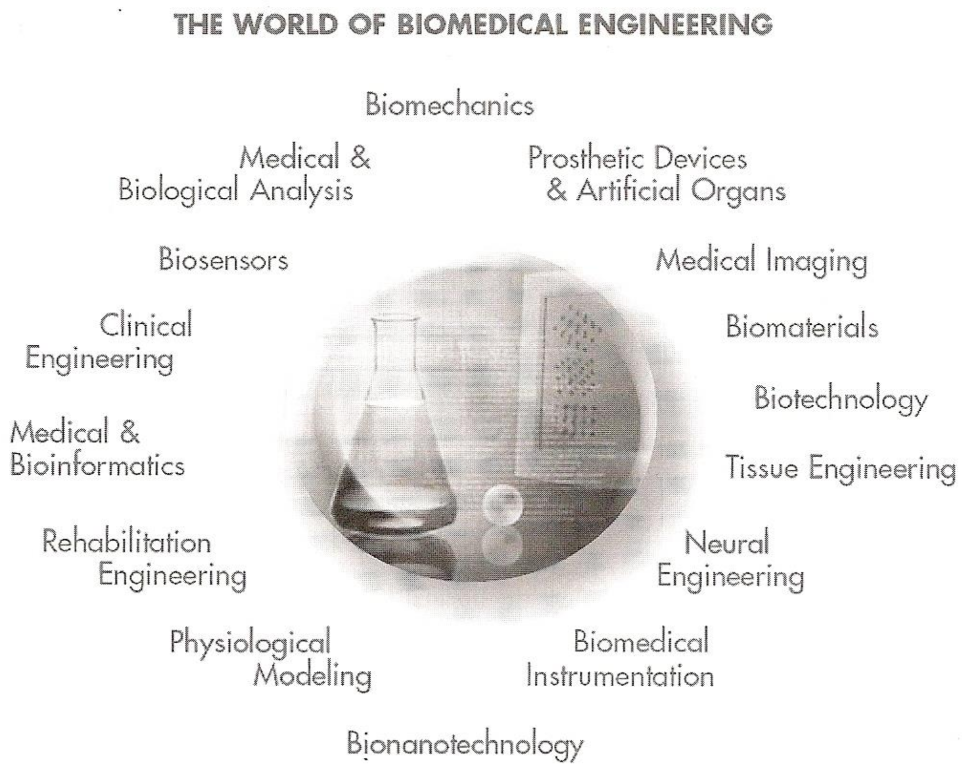
- Class hours : T 09:00-11:50
- Prerequisite : BME2312
- Textbooks :
  - Medical Instrumentation Application and Design, John G. Webster, 4th Edition, John Wiley & Sons, ISBN: 978-0471676003.



What is the Biomedical Engineering?



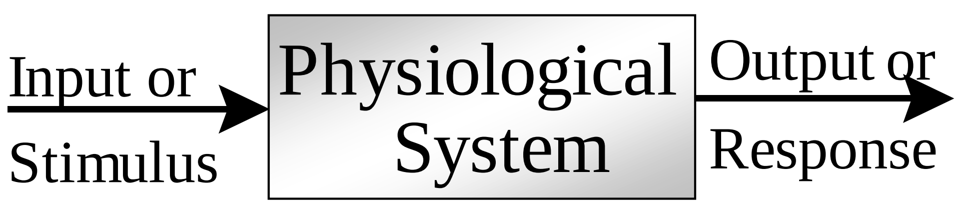
- Biomedical engineering (BME) is the application of engineering principles and techniques to the medical fields.
- Biomedical engineers apply electrical, chemical, optical, mechanical, and other engineering principles <u>to understand, modify, or control biological systems.</u>

Biological Systems and Biosignals

- Living organisms are made of many systems – e.g. human body:
  - Nervous, cardiovascular, gastrointestinal, endocrine, respiratory, etc
  - Each system is made of subsystems (organs, tissues, etc.) that are responsible for certain physiological processes
    - Cardiovascular system pumps blood to deliver nutrients to the body

- Irrespective of the type of biological system, its scale, or its function, we must have some way of interacting with that system.

- Interaction or communication with a biological system is done through signals.



- Signals are variations in energy that carry information.

Signals (Energy Types)

Table 1-1 Energy Forms and Associated Information-Carrying Variables

Energy	Variables (Specific Fluctuation)	Common Measurements
Chemical	Chemical activity and/or concentration	Blood ion, O_2, CO2, pH, hormonal concentrations and other chemistry.
Mechanical	Position Force, torque or pressure	Muscle movement, Cardiovascular pressures, muscle contractility Valve and other cardiac sounds
Electrical	Voltage (potential energy of charge carriers) Current (charge carrier flow)	EEG, ECG, EMG, EOG, ERG, EGG
Thermal	Temperature	Body temperature, thermography

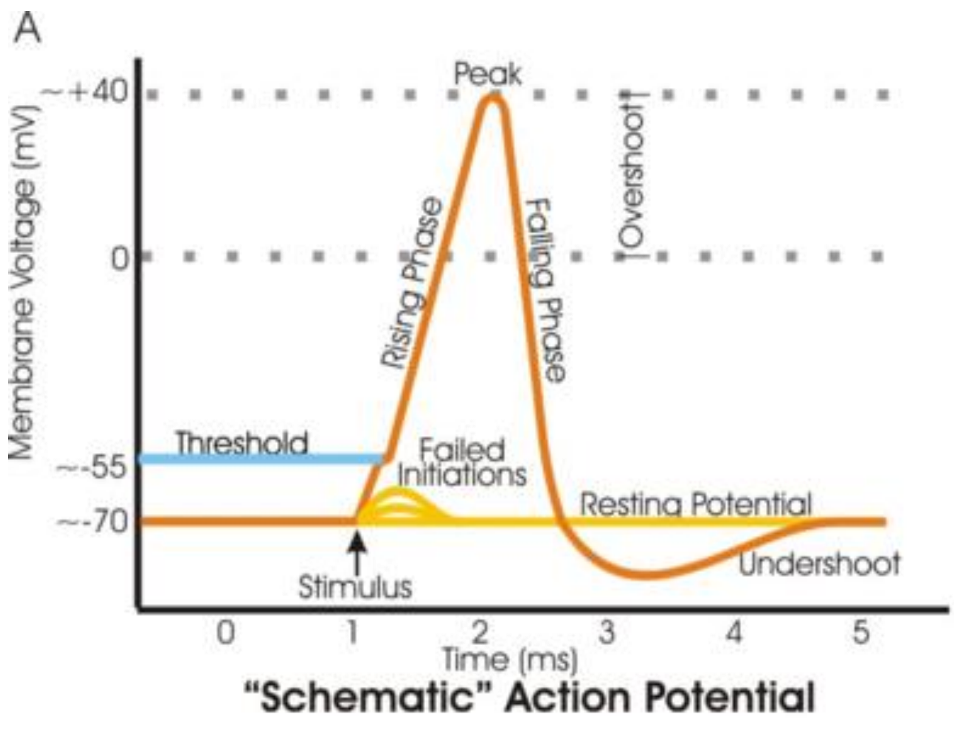
- Each physiological process is associated with certain types of signals that reflect their nature and activities
- Any deviation of these signals from their normal parameters typically represents a disease / disorders → pathological condition
  - Observing these signals and comparing them to their known norms, we can often detect these pathological conditions
- For example:
  - Most infections → an increase in body-core temperature
  - Cardiovascular disorders → arrhythmias in electrocardiogram (ECG), or changes in blood pressure
  - Certain neurological disorders (such as epilepsy) → electroencephalogram (EEG)
- When such measurements are observed over a period of time, a one-dimensional time-series is obtained → this is a physiological signal.

Biomedical Signals

- The electrocardiogram (ECG)→ electrical activity of the heart / cardiac cells
- The electromyogram (EMG)→electrical activity of the muscle cells
- The electroencephalogram (EEG)→electrical activity of the brain
- The electroneurogram (ENG)→propagation of nerve action potential
- The electrogastogram (EGG)→electrical activity of the stomach
- The phonocardiogram (PCG)→audio recording of the heart’s mechanical activity
- The carotid pulse (CP)→pressure of the carotid artery
- The electoretinogram (ERG)→electrical activity of the retinal cells
- The electrooculogram (EOG)→ electrical activity of the eye muscles

The Action Potential-AP

- The action potential is the origin of all biopotentials.
- All biological signals of electrical origin are made up from integration of many action potential.
- The AP is the electrical signal that is generated by a single cell when it is mechanically, electrically, or chemically stimulated.



BASIC CONCEPTS OF MEDICAL INSTRUMENTATION

GENERALIZED MEDICAL INSTRUMENTATION SYSTEM

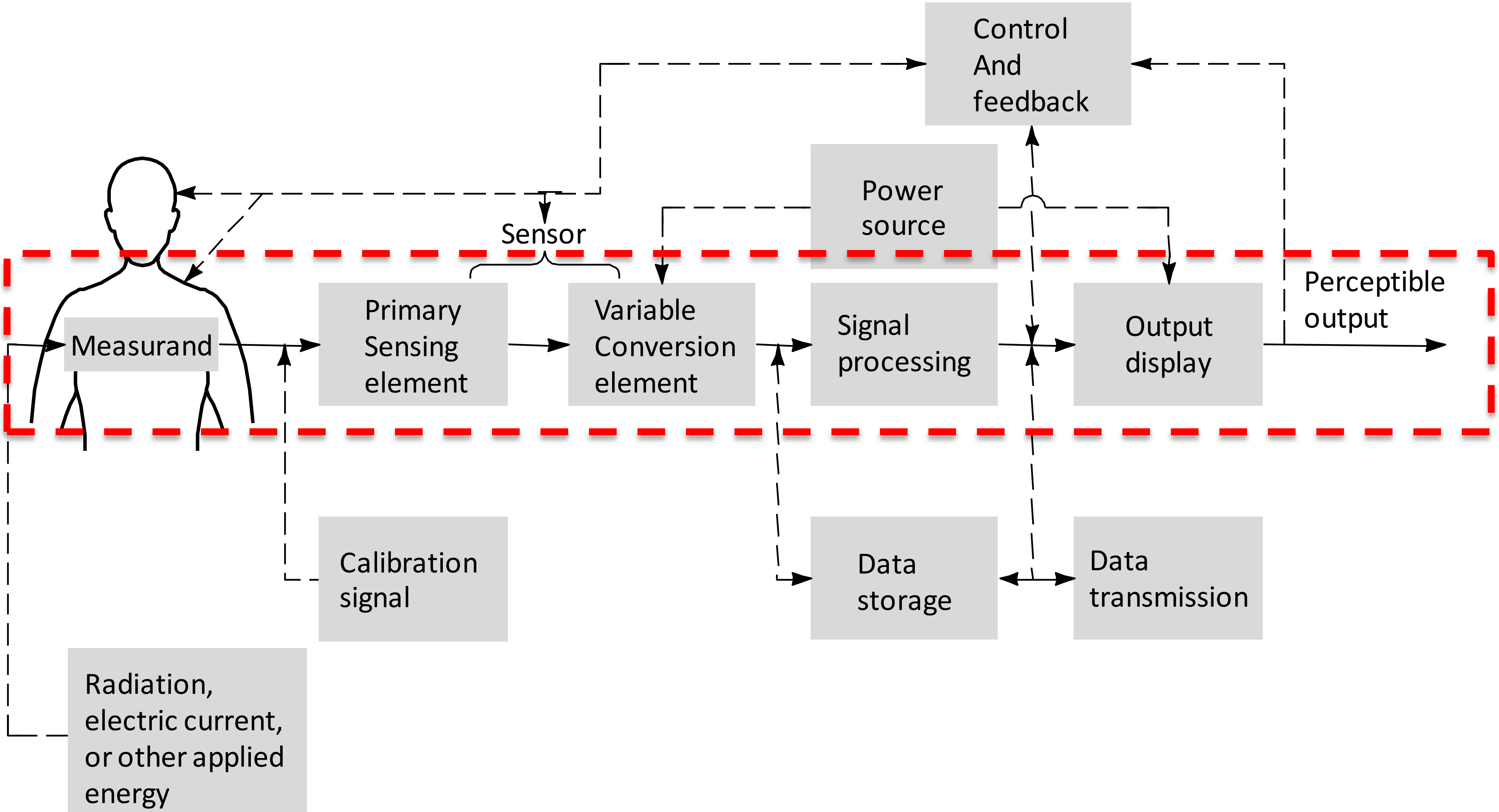


Figure 1.1 The sensor converts energy or information from the measurand to another form (usually electric). This signal is the processed and displayed so that humans can perceive the information. Elements and connections shown by dashed lines are optional for some applications.

➢ Measurand

- The physical quantity, property, or condition that the system measures is called the measurand.

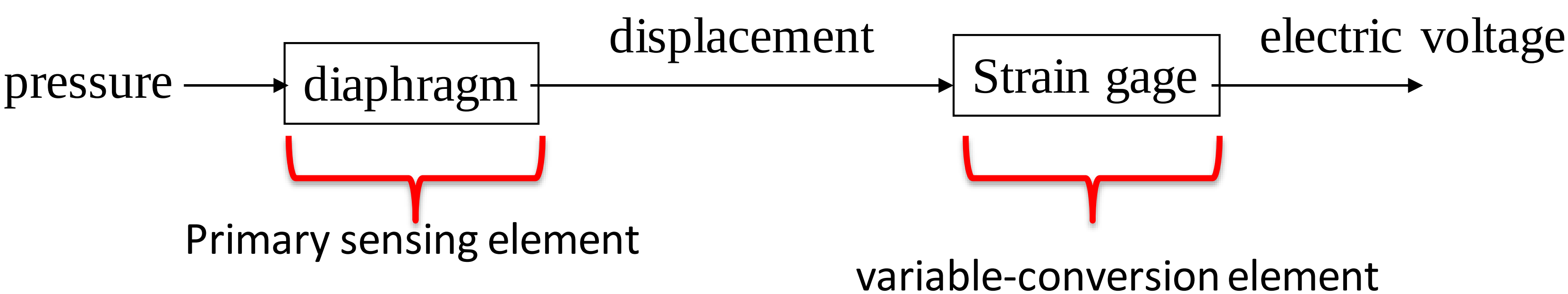
    - it may be internal (blood pressure), it may be on the body surface (electrocardiogram potential), it may emanate from the body (infrared radiation), or it may be derived from a tissue sample (such as blood or a biopsy) that is removed from the body

- Most medically important measurands can be grouped in the following categories:

    - Biopotential
    - Pressure
    - Flow
    - Dimensions (imaging)
    - Displacement (velocity, acceleration, force)
    - Impedance
    - Temperature
    - Chemical Concentration

Sensor and Transducer

- Transducer
  - Converts one form of energy to another
- Sensor
  - Converts a physical measurand to an electrical output
  - Interface with living system
  - Minimally invasive



Signal Conditioning

- Usually the sensor output cannot be directly coupled to the display device.

  - Amplification
  - Filtering
  - Impedance matching
  - Analog/Digital for signal processing
  - Signal form (time and frequency domains)

Output Display

- The results of the measurement process must be displayed in a form that the human operator can perceive.

  - Numerical
  - Graphical
  - Discrete or continuous
  - Visual
  - Hearing

➢ Auxiliary Element

- **Calibration Signal** with the properties of the measurand should be applied to the sensor input or as early in the signal-processing chain as possible

- **Control and Feedback** (auto or manual)
  - may be required to elicit the measurand
  - to adjust the sensor and signal conditioner,
  - to direct the flow of output for display, storage, or transmission.

ALTERNATIVE OPERATIONAL MODES

- **Direct Mode:** Measurand is readily accessible
  - Temperature
  - Heart Beat

- **Indirect Mode:** desired measurand is measured by measuring accessible measurand.
  - Morphology of internal organ: X-ray shadows
  - Volume of blood pumped per minute by the heart: respiration and blood gas concentration
  - Pulmonary volumes: variation in thoracic impedance

▪ Sampling and Continuous Modes

- Sampling and collecting data will depend on:

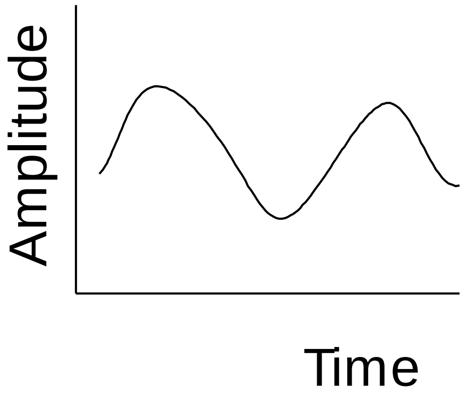
  - ➢ The rate of change in the measurand
  - ➢ Condition of the patient

✓ Some measurands—such as body temperature and ion concentrations— change so slowly that they may be sampled **infrequently.**

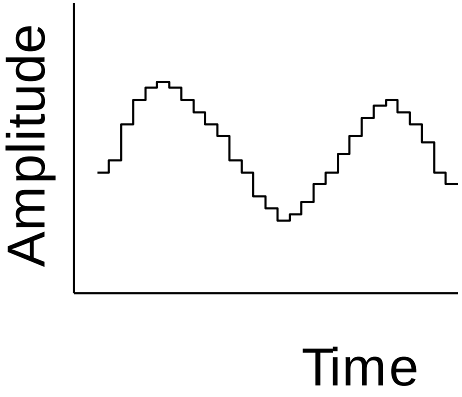
✓ Other quantities— such as the electrocardiogram and respiratory gas flow—may require **continuous monitoring**.

▪ Analog and Digital Modes

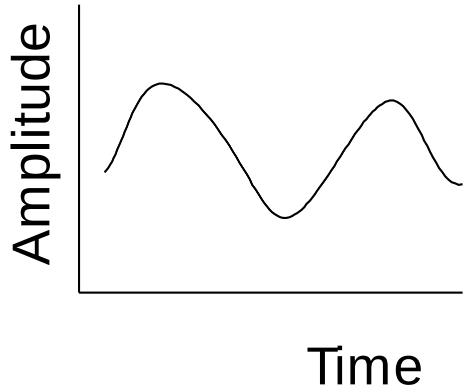
- Signals that carry measurement information are either *analog* or *digital*.
- ***Analog signal***: continuous and able to take on any value within the dynamic range



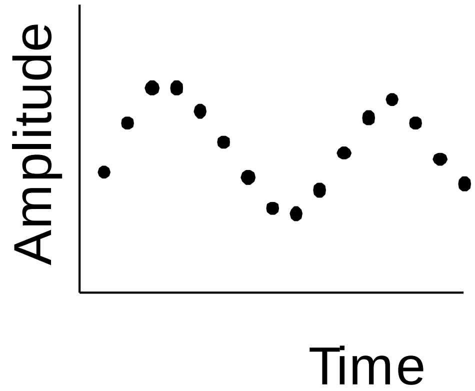
- ***Digital signal***: discrete and able to take on only a finite number of different values.



Continuous and discrete-time signals:



Continuous signals have values at every instant of time



Discrete-time signals are sampled periodically and do not provide values between these sampling times.

▪ Real-Time and Delayed-Time Modes

- The output of the measurement system may not display the result immediately, however, because some types of signal processing, such as averaging and transformations, need considerable input before any results can be produced.

- *Real time mode:* short processing time
- *Delayed time:* long processing time

MEDICAL MEASUREMENT CONSTRAINTS

- Magnitude and frequency range of medical measurand are very low
- Proper measurand-sensor interface cannot be obtained
- Medical variables are seldom deterministic
- External energy must be minimized to avoid any damage
- Equipment must be reliable

Measurement	Range	Frequency, Hz	Method
Blood flow	1 to 300 mL/s	0 to 20	Electromagnetic or ultrasonic
Blood pressure	0 to 400 mmHg	0 to 50	Cuff or strain gage
Cardiac output	4 to 25 L/min	0 to 20	Fick, dye dilution
Electrocardiography	0.5 to 4 mV	0.05 to 150	Skin electrodes
Electroencephalography	5 to 300 μ V	0.5 to 150	Scalp electrodes
Electromyography	0.1 to 5 mV	0 to 10000	Needle electrodes
Electroretinography	0 to 900 μ V	0 to 50	Contact lens electrodes
pH	3 to 13 pH units	0 to 1	pH electrode
pCO_2	40 to 100 mmHg	0 to 2	pCO_2 electrode
pO_2	30 to 100 mmHg	0 to 2	pO_2 electrode
Pneumotachography	0 to 600 L/min	0 to 40	Pneumotachometer
Respiratory rate	2 to 50 breaths/min	0.1 to 10	Impedance
Temperature	32 to 40 °C	0 to 0.1	Thermistor

CLASSIFICATIONS OF BIOMEDICAL INSTRUMENTS

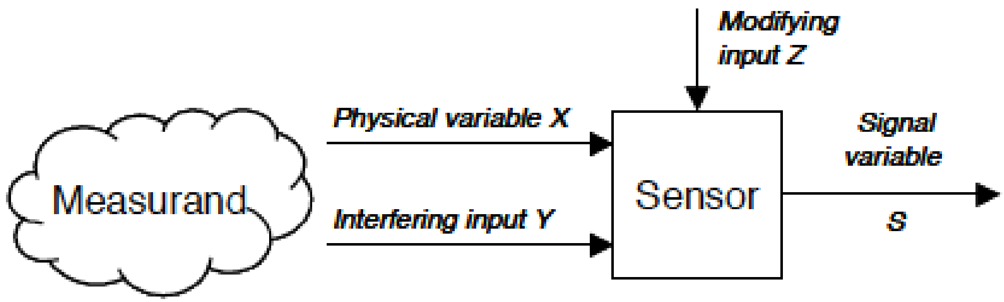
Techniques of biomedical measurement can be grouped according to the:

- **Quantity that is sensed**
    - pressure, flow, temperature
- **Principle of transduction**
    - resistive, capacitive, electrochemical, ultrasound
- **Organ system**
    - cardiovascular, pulmonary, nervous
- **Medicine specialties**
    - pediatrics, cardiology, radiology

INTERFERING AND MODIFYING INPUTS

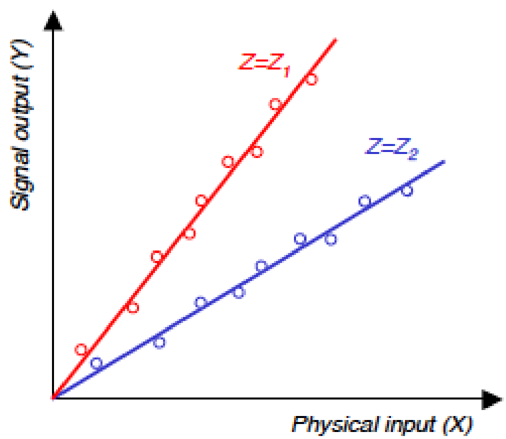
Desired Inputs: measurands that the instrument is designed to isolate.

Interfering Inputs: quantities that inadvertently affect the instrument as a consequence of the principles used to acquire and process the desired inputs.



Modifying Inputs: undesired quantities that indirectly affect the output by altering the performance of the instrument itself.

Modifying input changes calibration curve of the instrument



Desired input: Electrocardiographic voltage V_{ecg}

Interfering input: 60 Hz noise voltage, displacement currents

Modifying input: orientation of the patient cables

- when the plane of the cable is perpendicular to the magnetic field the magnetic interference is maximal

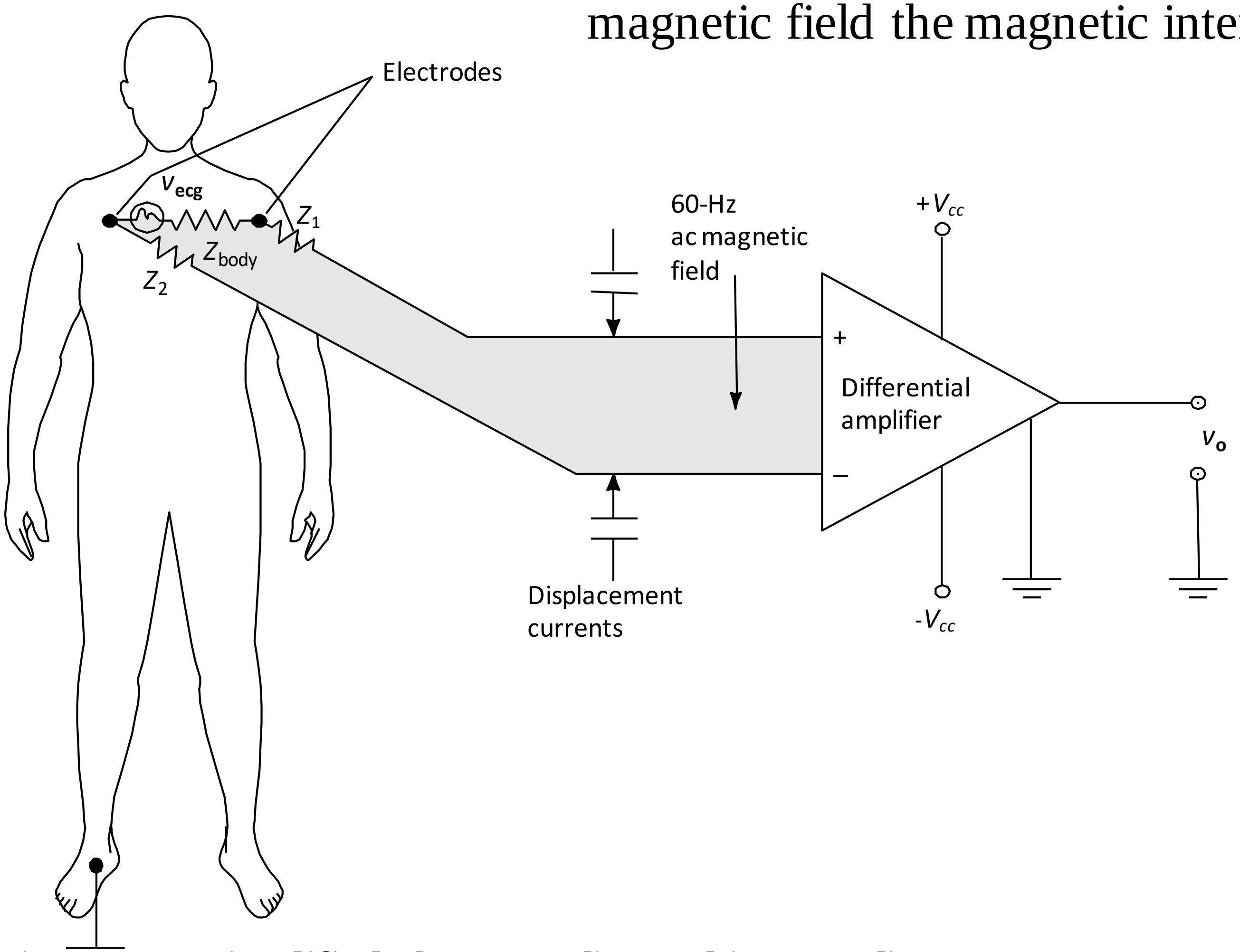


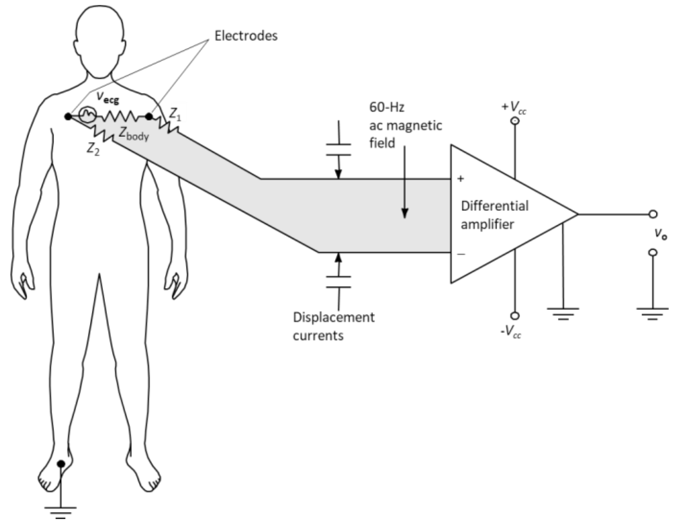
Figure 1.2 Simplified electrocardiographic recording system Two possible interfering inputs are stray magnetic fields and capacitively coupled noise. Orientation of patient cables and changes in electrode-skin impedance are two possible modifying inputs. Z_1 and Z_2 represent the electrode-skin interface impedances.

COMPENSATION TECHNIQUES

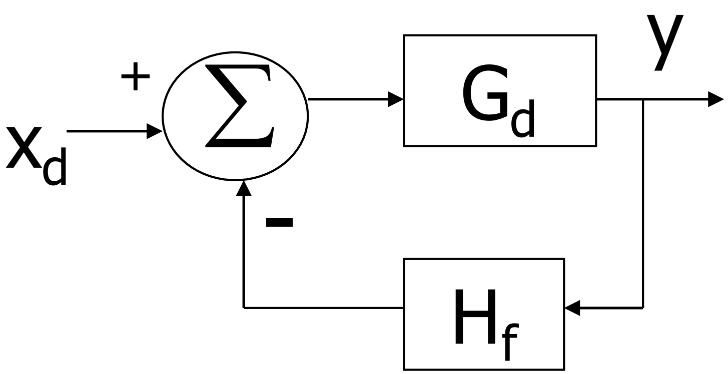
➢ **There are several compensation methods for eliminating the effects of interfering and modifying inputs**

- Inherent Insensitivity: If all instrument components are inherently sensitive only to desired inputs, then interfering and modifying inputs obviously have no effect.

  - ❑ twisting of the electrode wires to reduce the number of magnetic flux lines that cut the shaded loop in Figure 1.2 as the voltage of the induced noise is proportional to the area of that loop



- Negative Feedback: The negative feedback method takes a portion of the output, H_f, at any instant of time and feeds it back to the input of the instrument. This output-dependent signal is subtracted from the input, and the difference becomes the effective system input.

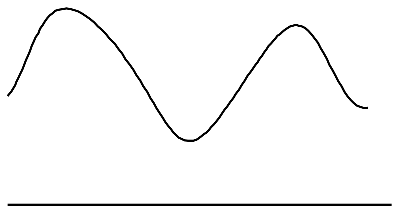


$$(x_d - H_f y)G_d = y$$

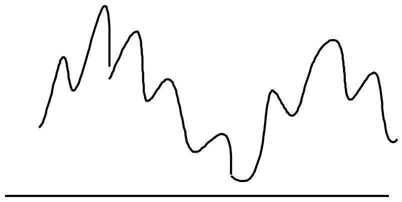
$$x_d G_d = y(1 + H_f G_d)$$

$$y = \frac{G_d}{1 + H_f G_d} x_d$$

- Signal Filtering: Filter is a device or program that separates data, signals, or material in accordance with specified criteria. (electric, mechanical, magnetic). Filters may be inserted at the instrument input, at some point within the instrument, or at the output of the instrument

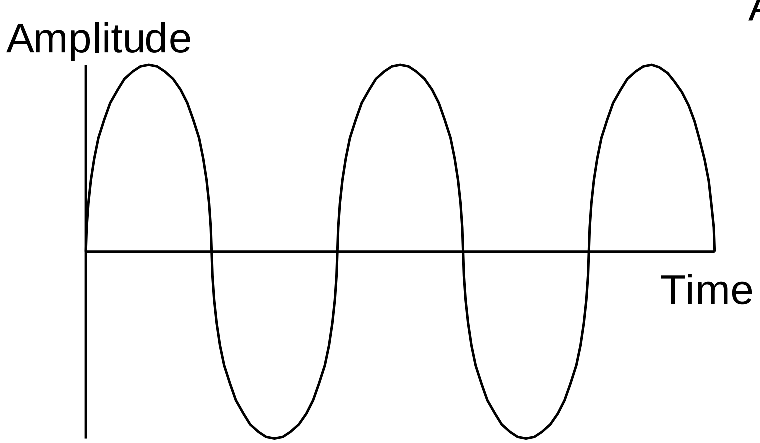


Signals without noise

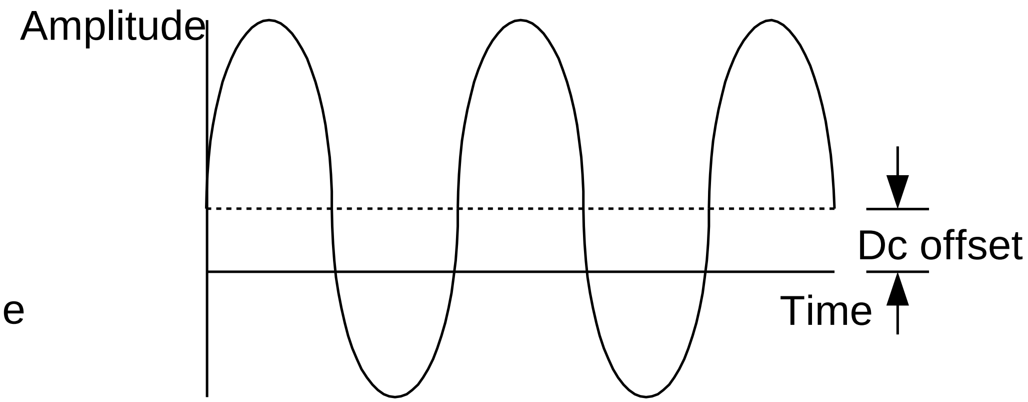


Interference superimposed on signals. Frequency filters can be used to reduce noise and interference

- Opposing Inputs: When interfering and/or modifying inputs cannot be filtered, additional interfering inputs can be used to cancel undesired output components.



An input signal without dc offset



An input signal with dc offset

CHARACTERISTICS OF INSTRUMENT PERFORMANCE

- To enable purchasers to compare commercially available instruments and evaluate new instrument designs, quantitative criteria for the performance of instruments are needed.

- These criteria must clearly specify how well an instrument measures the desired input and how much the output depends on interfering and modifying inputs

- Characteristics of instrument performance are usually subdivided into two classes on the basis of the frequency of the input signals.

  - Static Characteristics: describe the performance for *dc* or very low frequency input.

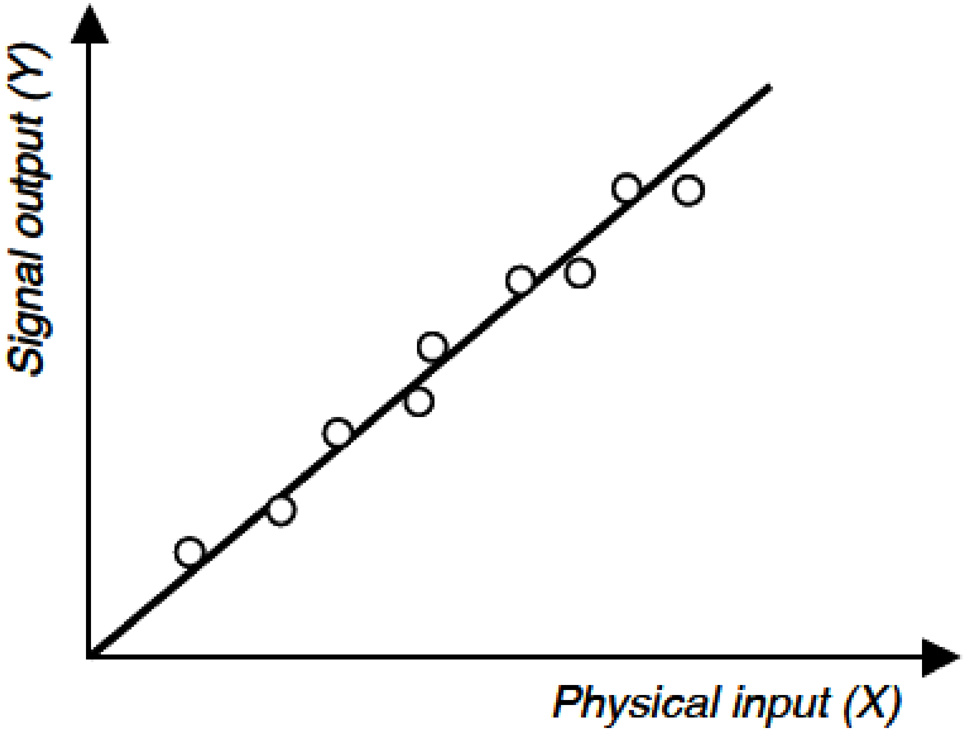
  - Dynamic Characteristics: describe the performance for *ac* and high frequency input.

GENERALIZED STATIC CHARACTERISTICS

- Error
- Accuracy
- Tolerance
- Precision and reproducibility
- Resolution
- Statistical control
- Static sensitivity
- Zero drift
- Sensitivity drift
- Linearity
- Input ranges
- Input impedance

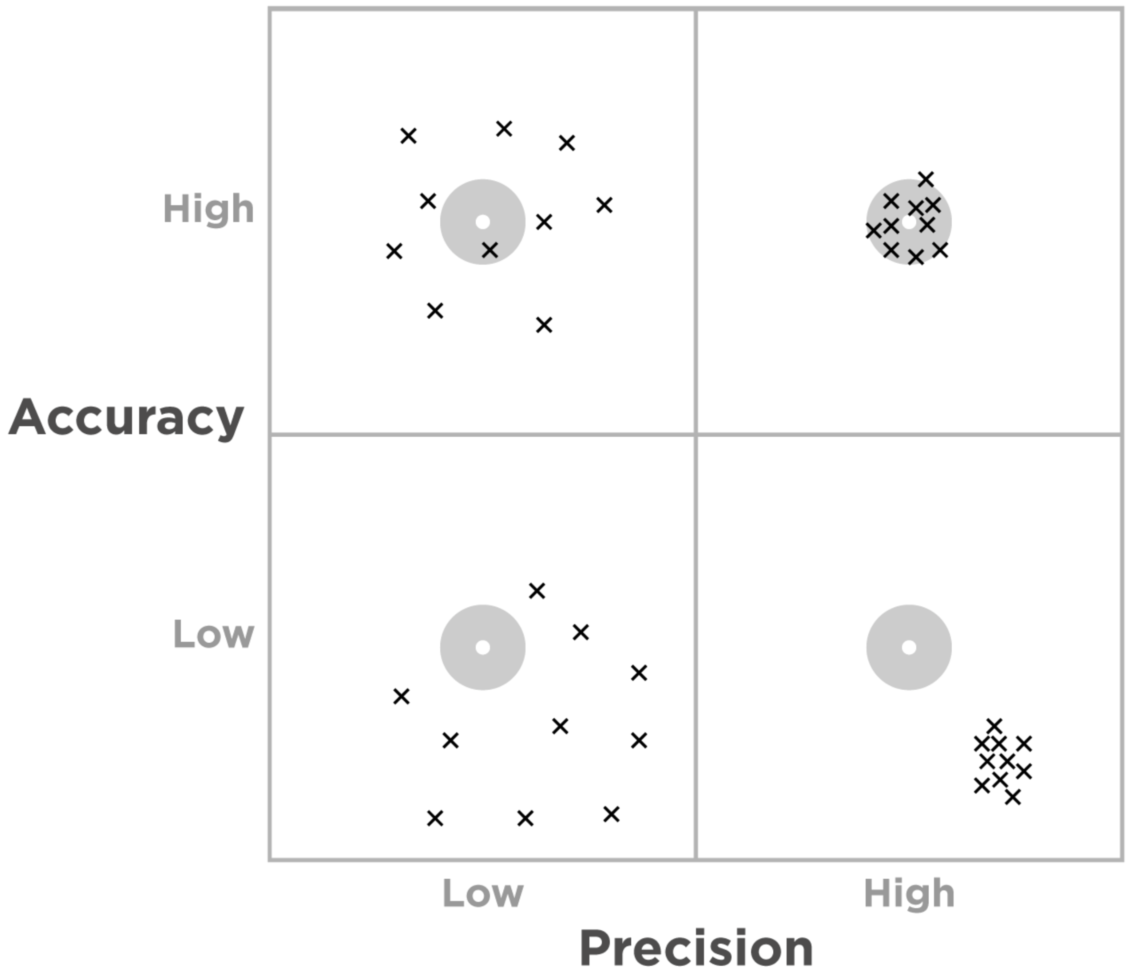
Calibration

- In order to determine the relationship between the physical measurement variable (X) and the signal variable (S), a sensor or instrument is calibrated by applying a number of KNOWN physical inputs and recording the response of the system



- **Accuracy:** The difference between the true value and the measured value divided by the true value

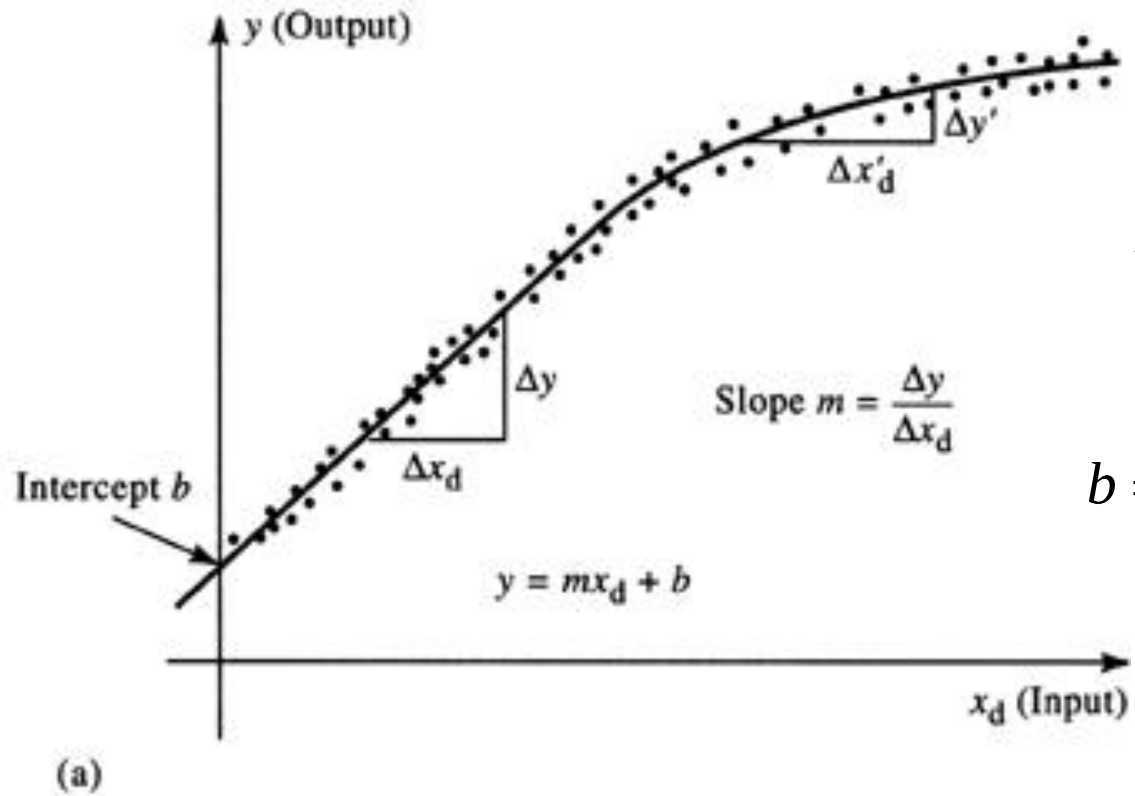
- **Precision:** The number of distinguishable alternatives from which a given results is selected {2.434 or 2.43}



Tolerance

- Maximum deviation allowed from the conventional true value.
- It is not possible to built a perfect system or make an exact measurement. All devices deviate from their ideal (design) characteristics and all measurements include uncertainties (doubts).
- Hence, all devices include tolerances in their specifications. If the instrument is used for high-precision applications, the design tolerances must be small.

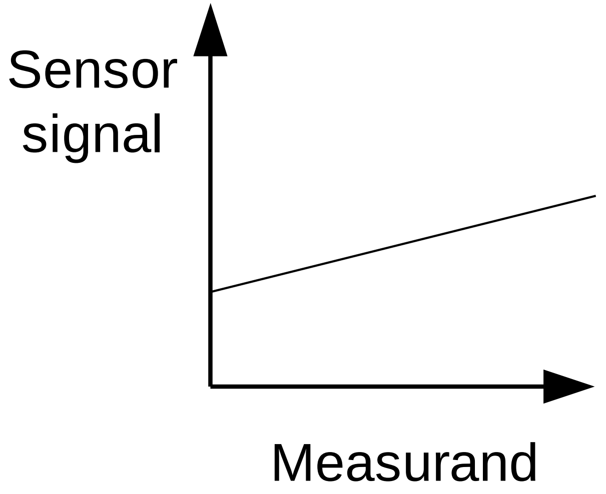
- **static sensitivity:** the ratio of the incremental output quantity to the incremental input quantity and it may be constant for only part of the normal operating range of the instrument



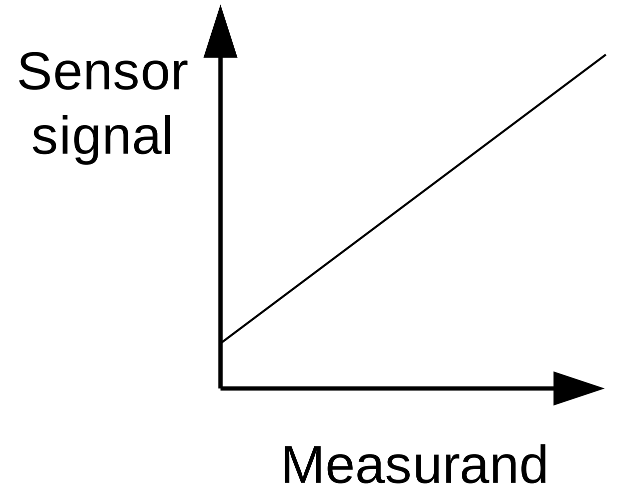
$$m = \frac{n\sum x_d y - \left(\sum x_d\right)\left(\sum y\right)}{n\sum x_d^2 - \left(\sum x_d\right)^2}$$

$$b = \frac{\left(\sum y\right)\left(\sum x_d^2\right) - \left(\sum x_d y\right)\left(\sum x_d\right)}{n\sum x_d^2 - \left(\sum x_d\right)^2}$$

Figure 1.3 (a) Static-sensitivity curve that relates desired input x_d to output y. Static sensitivity may be constant for only a limited range of inputs.



A low-sensitivity sensor has low gain



A high sensitivity sensor has high gain

- **Zero Drift:** all output values increase or decrease by the same amount due to manufacturing misalignment, variation in ambient temperature, vibration,…. Slope of the sensitivity is unchanged. For instance, DC-offset voltage in ECG.

- **Sensitivity Drift:** the slope of the calibration curve changes as a result of an interfering and/or modifying input. Sensitivity drift can result from manufacturing tolerances, variations in power supply, nonlinearities, and changes in ambient temperature and pressure. For instance, in the electrocardiograph-amplifier voltage gain as a result of fluctuations in dc power-supply voltage or change in temperature

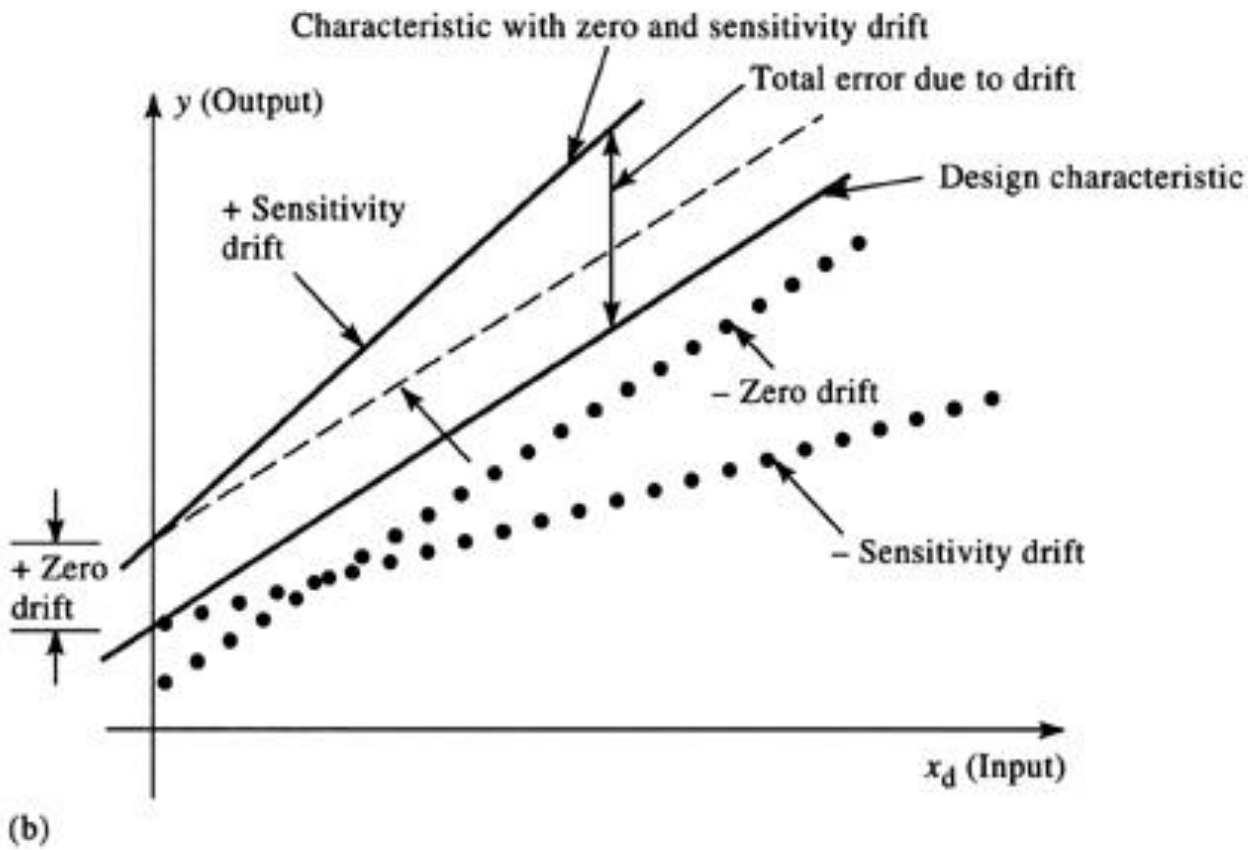
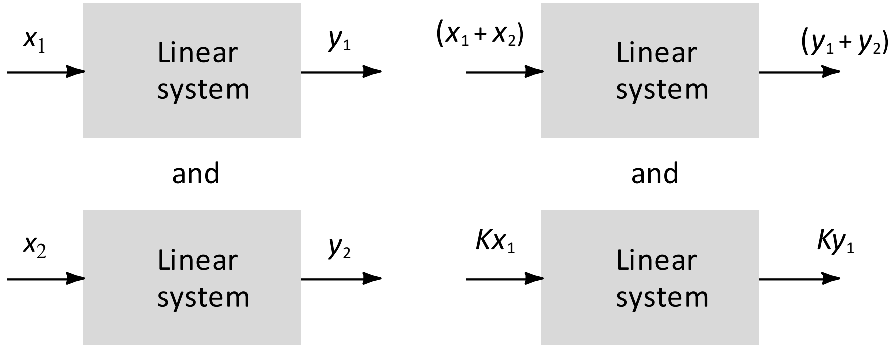


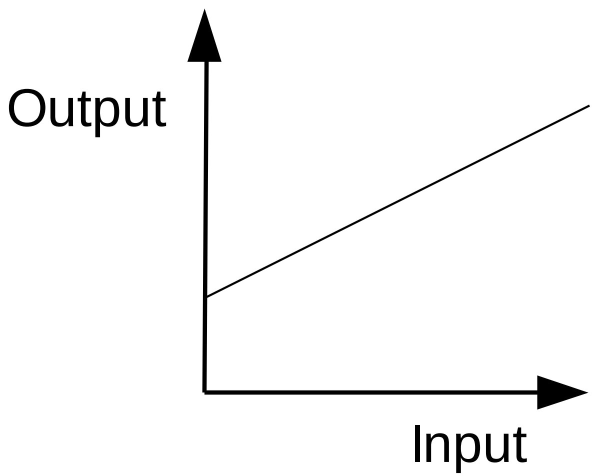
Figure 1.3 (b) Static sensitivity: zero drift and sensitivity drift. Dotted lines indicate that zero drift and sensitivity drift can be negative.

- **Linearity :** A system or element is linear if it has properties such that if y_1 is the response to x_1 and y_2 is the response to x_2,then $y_1 + y_2$ is the response to $x_1 + x_2$, and Ky_1 is the response to Kx_1.

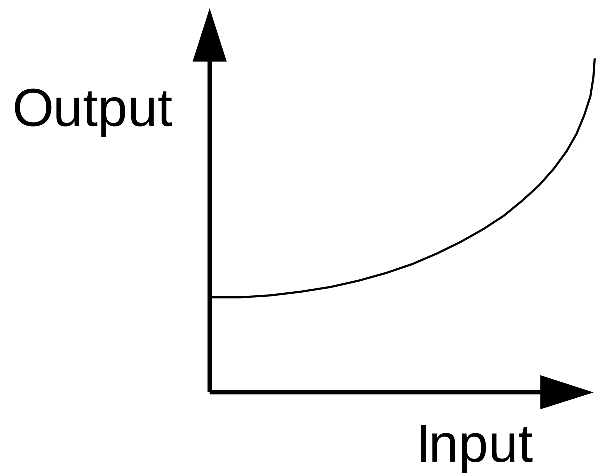


(a)

Figure 1.4 (a) Basic definition of linearity for a system or element. The same linear system or element is shown four times for different inputs.

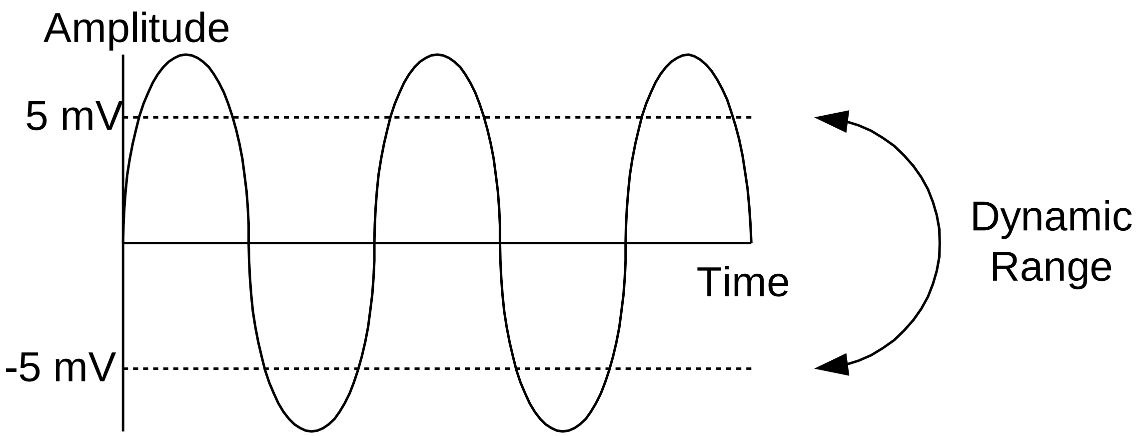


A linear system fits the equation $y = mx + b$.

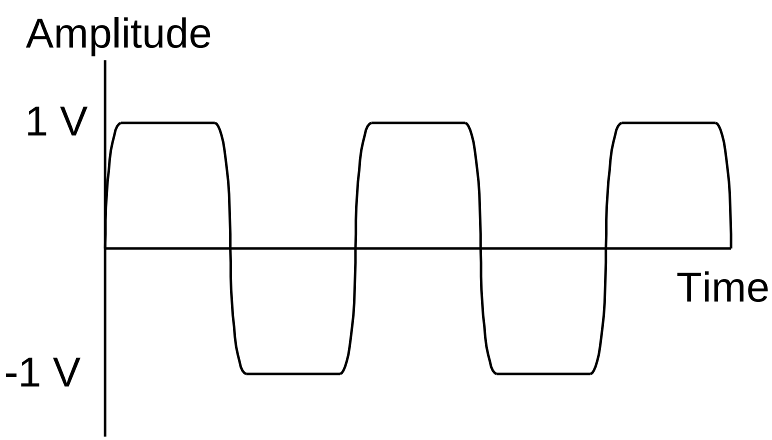


A nonlinear system does not fit a straight line

➢ Input ranges



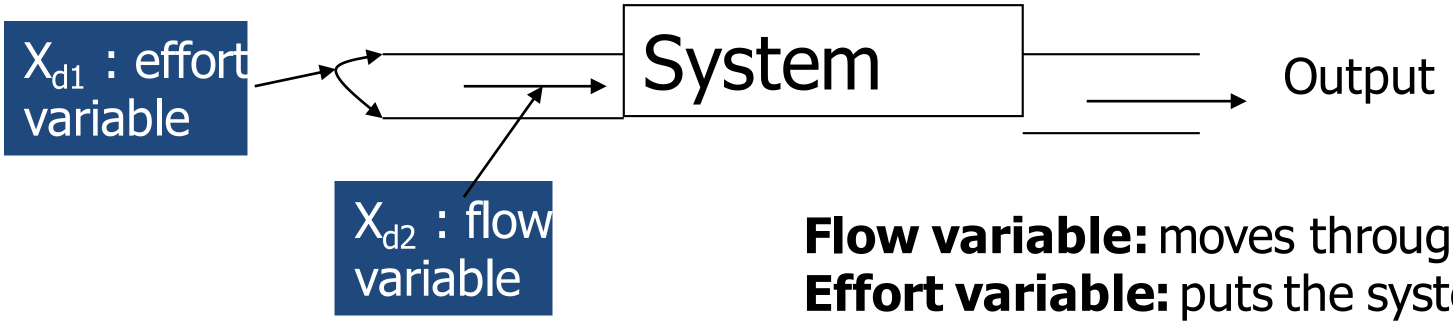
An input signal which exceeds the dynamic range



The resulting amplified signal is saturated at ± 1 V

➢ Input Impedance:

- disturb the quantity being measured.



Flow variable: moves through the system
Effort variable: puts the system into action

- X_{d1} : desired input (voltage, force, pressure)
- X_{d2} : implicit input (current, velocity, flow)

- $P = X_{d1}.X_{d2}$:Power transferred across the tissue-sensor interface

• Generalized input impedance Z_x

$$Z_x = \frac{X_{d1}}{X_{d2}} = \frac{\text{effort variable}}{\text{flow variable}} \qquad P = X_{d1} \cdot X_{d2} = \frac{X_{d1}^2}{Z_x} = Z_x X_{d2}^2$$

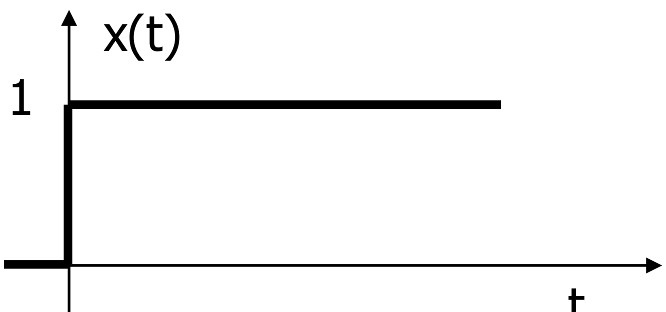
- **Goal:** Minimize *P*, when measuring effort variable X_{d1}, by maximizing Z_x which in return will minimize the flow variable X_{d2}.
- Loading effect is minimized when source impedance Z_s is much smaller then the Z_x

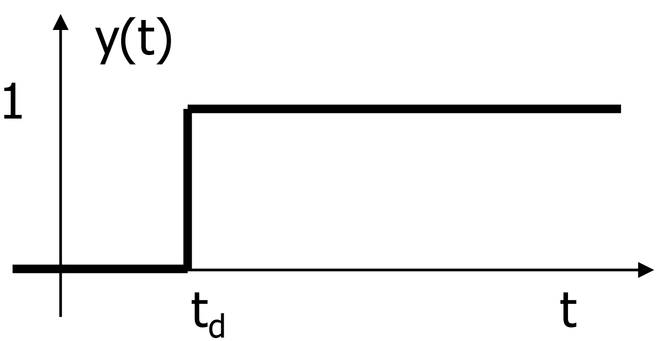
➢ Time delay

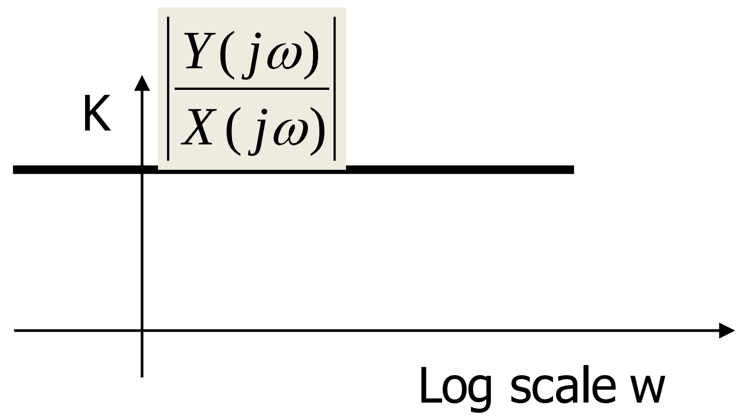
Instrument elements that give an output that is exactly the same as the input, except that it is delayed in time by τ_d, are defined as time-delay elements.

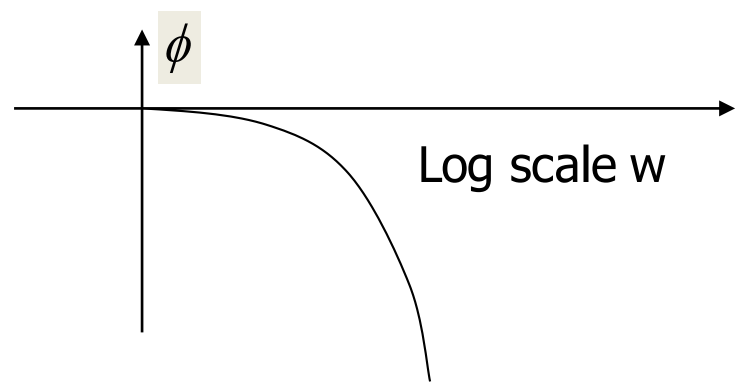
$$\frac{Y(j\omega)}{X(j\omega)} = Ke^{-j\omega\tau_d} = K\underline{/-j\omega\tau_d}$$

$$y(t) = Kx(t-\tau_d), t > \tau_d$$





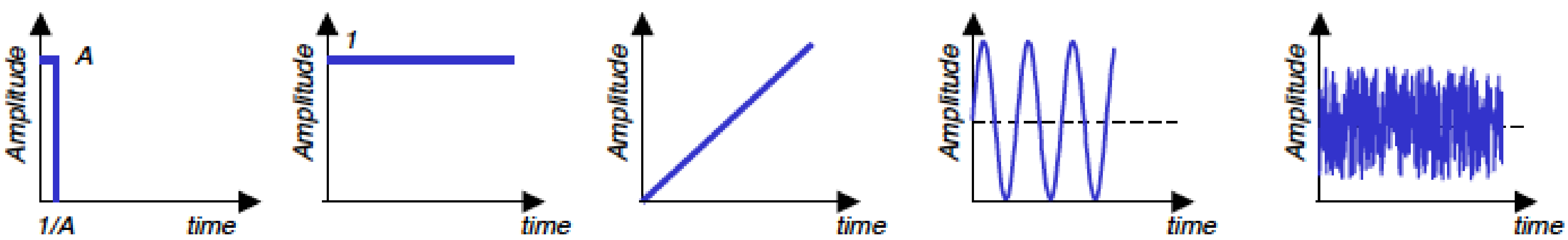




GENERALIZED DYNAMIC CHARACTERISTICS

- The instrument response to a variable input is different from that exhibited when the input signals are constant (the latter is described by the static characteristics)

- The reason for dynamic characteristics is the presence of energy-storing elements
    - Inertial: masses, inductances
    - Capacitances: electrical, thermal
- Dynamic characteristics are determined by analyzing the response of the sensor to a family of variable input waveforms:
    - Impulse, step, ramp, sinusoidal, white noise…



- Most medical instrument process signals that are functions of time.
- The input $x(t)$ is related to the output $y(t)$ by

$$a_n \frac{d^n y}{dt^n} + \cdots + a_1 \frac{dy}{dt} + a_0 y(t) = b_m \frac{d^m x}{dt^m} + \cdots + b_1 \frac{dx}{dt} + b_0 x(t)$$

$$\left(a_n D^n + \cdots + a_1 D + a_0\right) y(t) = \left(b_m D^m + \cdots + b_1 D + b_0\right) x(t)$$

➢ a_i and b_i depend on the physical and electrical parameters of the system.

➢ Transfer Functions

- The transfer function for a linear instrument or system expresses the **relationship between the input signal and the output signal mathematically**. If the transfer function is known, the **output can be predicted for any input** (transient, periodic, or random)

Operational transfer function

$$\frac{y(D)}{x(D)} = \frac{b_m D^m + \cdots + b_1 D + b_0}{a_n D^n + \cdots + a_1 D + a_0}$$

Frequency transfer function

➢ Can be found by replacing D by $j\omega$

$$H(j\omega) = \frac{Y(j\omega)}{X(j\omega)} = \frac{b_m (j\omega)^m + \cdots + b_1 (j\omega) + b_0}{a_n (j\omega)^n + \cdots + a_1 (j\omega) + a_0}$$

✧ Zero-Order Instrument

$$(a_n D^n + \cdots + a_1 D + a_0)y(t) = (b_m D^m + \cdots + b_1 D + b_0)x(t)$$

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

$x(t)$: input to the system
$y(t)$: output to the system

$$\frac{y(D)}{x(D)} = \frac{Y(jw)}{X(jw)} = \frac{b_0}{a_0} = K$$

K: static sensitivity

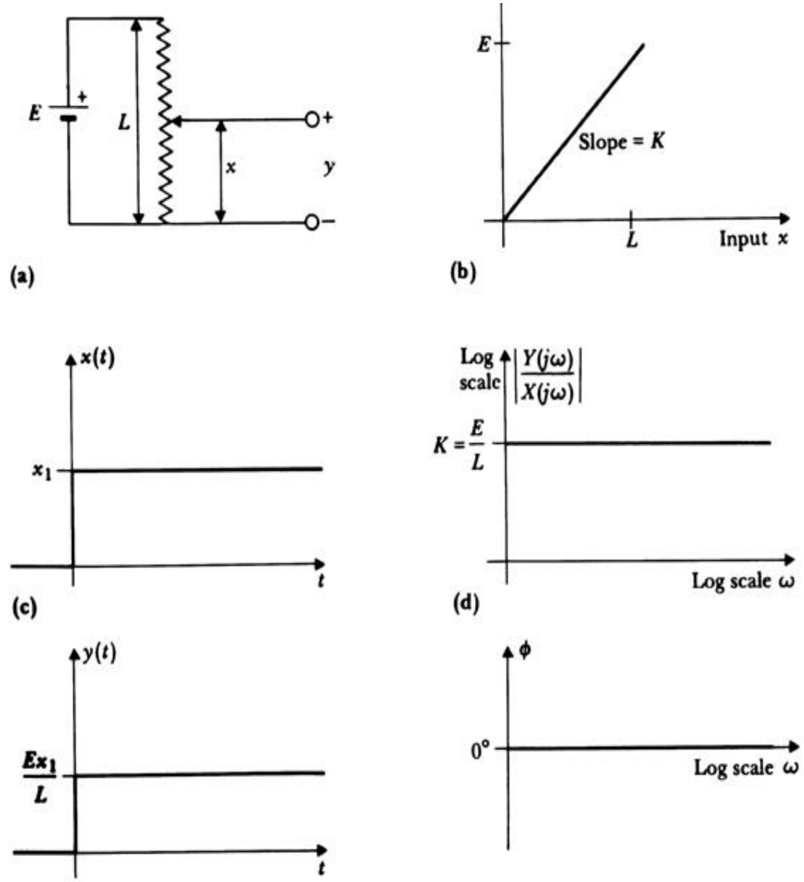


Figure 1.5 **(a) A linear potentiometer, an example of a zero-order system.** (b) Linear static characteristic for this system. (c) Step response is proportional to input. (d) Sinusoidal frequency response is constant with zero phase shift.

- **Zero-order systems do not include energy-storing elements**

✧ First-Order Instrument

- If the instrument contains a single energy-storage element, then a first-order derivative of y(t) is required in the differential equation.

$$\left(a_n D^n + \cdots + a_1 D + a_0\right) y(t) = \left(b_m D^m + \cdots + b_1 D + b_0\right) x(t)$$

$$a_1 \frac{dy(t)}{dt} + a_0 y(t) = b_0 x(t)$$

$$(\tau D + 1) y(t) = K x(t)$$

$$\tau = \frac{a_1}{a_0} \qquad K = \frac{b_0}{a_0}$$

where
τ is the time constant
K: static sensitivity

$$\frac{y(D)}{x(D)} = \frac{K}{1 + \tau D}$$

Operational Transfer Function

$$\frac{Y(j\omega)}{X(j\omega)} = \frac{K}{1 + j\omega\tau}$$

$$\left|\frac{Y(j\omega)}{X(j\omega)}\right| = \frac{K}{\sqrt{1 + \omega^2 \tau^2}} \qquad \phi = \arctan(-\omega\tau/1)$$

Frequency Transfer Function

$$RC\frac{dy(t)}{dt} + y(t) = x(t)$$

$$\tau = RC \quad K = 1 \quad x(t) = 1$$

$$\frac{y(D)}{x(D)} = \frac{K}{1+\tau D}$$

$$y(t) = K\left(1 - e^{-t/\tau}\right)$$

$$\frac{Y(j\omega)}{X(j\omega)} = \frac{K}{1 + j\omega\tau}$$

$$\left|\frac{Y(j\omega)}{X(j\omega)}\right| = \frac{K}{\sqrt{1+\omega^2\tau^2}}$$

$$\phi = \arctan(-\omega\tau/1)$$

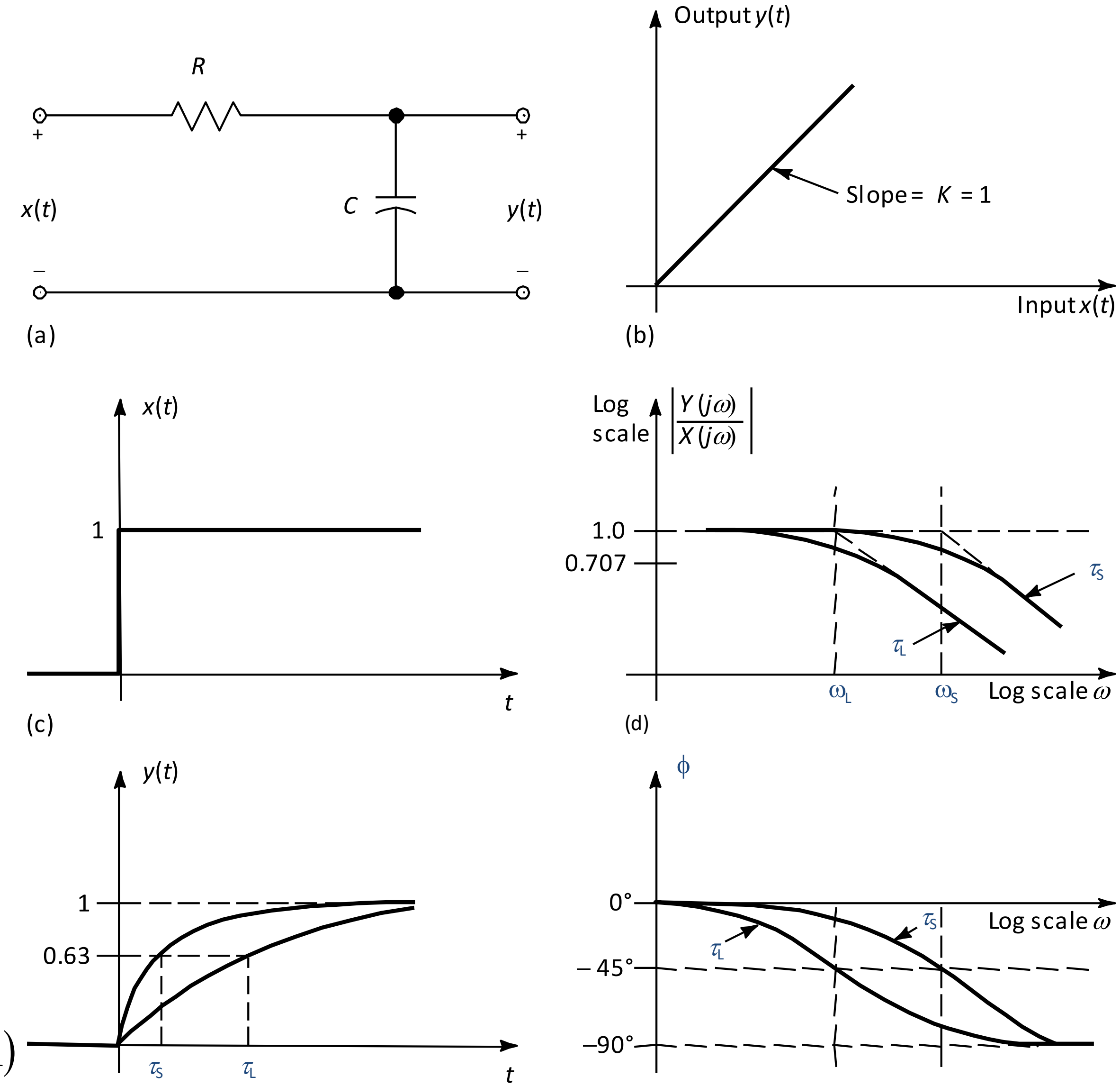


Figure 1.6 **(a) A low-pass RC filter, an example of a first-order instrument**. (b) Static sensitivity for constant inputs. (c) Step response for large time constants (τ_L) and small time constants (τ_s). (d) Sinusoidal frequency response for large and small time constants.

✧ Second-Order Instrument

Many medical instrument are 2nd order or higher

$$a_2 \frac{d^2 y(t)}{dt^2} + a_1 \frac{dy(t)}{dt} + a_0 y(t) = b_0 x(t) \longrightarrow \left[\frac{D^2}{\omega_n^2} + \frac{2\zeta D}{\omega_n} + 1\right] y(t) = Kx(t)$$

$$K = \frac{b_0}{a_0} = \text{static sensitivit y, output units defined by input units}$$

$$\omega_n = \sqrt{\frac{a_0}{a_2}} = \text{undamped natural frequency, rad/s}$$

$$\zeta = \frac{a_1}{2\sqrt{a_0 a_2}} = \text{damping ratio, dimensionl ess}$$

Operational Transfer Function

$$\frac{y(D)}{x(D)} = \frac{K}{\dfrac{D^2}{\omega_n^2} + \dfrac{2\zeta D}{\omega_n} + 1}$$

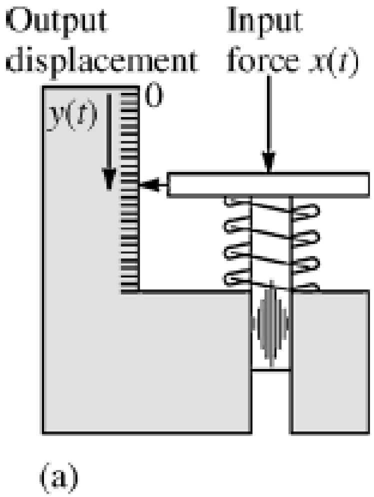
Frequency Transfer Function

$$\frac{Y(j\omega)}{X(j\omega)} = \frac{K}{(j\omega / \omega_n)^2 + (2\zeta j\omega / \omega_n) + 1}$$

$$\left|\frac{Y(j\omega)}{X(j\omega)}\right| = \frac{K}{\sqrt{\left[1 - (\omega / \omega_n)^2\right]^2 + 4\zeta^2 \omega^2 / \omega_n^2}}$$

$$\phi = \arctan \frac{2\zeta}{\omega / \omega_n - \omega_n / \omega}$$

2^{nd} order mechanical force-measuring Instrument



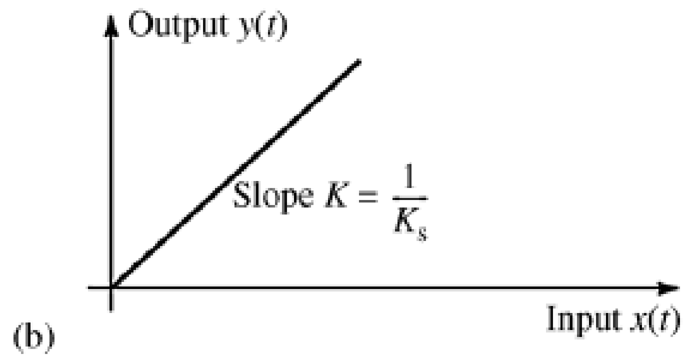


Figure 1.7 (a) Force-measuring spring scale, an example of a second-order instrument. (b) Static sensitivity.

$$x(t) - B\frac{dy(t)}{dt} - K_s y(t) = M\frac{d^2 y(t)}{dt^2}$$

B = viscosity constant

K_s = spring constant

$K = 1/K_s$

$$\omega_n = \sqrt{\frac{K_s}{M}}$$ Natural freq.

$$\zeta = \frac{B}{2\sqrt{K_s M}}$$ Damping ratio

2^{nd} order mechanical force-measuring Instrument

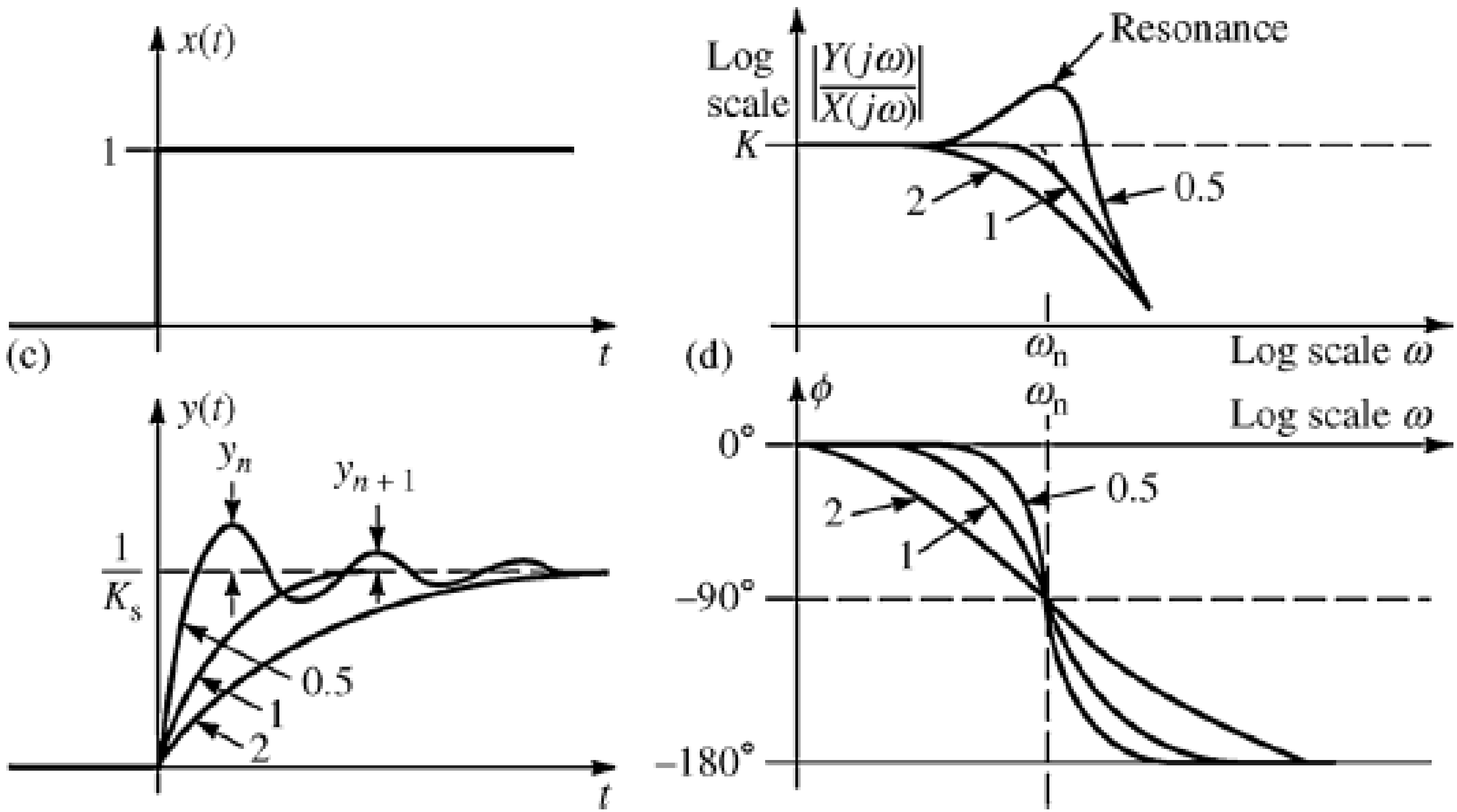


Figure 1.7 (c) Step response for overdamped case ζ = 2, critically damped case ζ = 1, underdamped case ζ = 0.5. (d) Sinusoidal steady-state frequency response, ζ= 2, ζ= 1, ζ= 0.5.

Overdamped $\zeta > 1$:

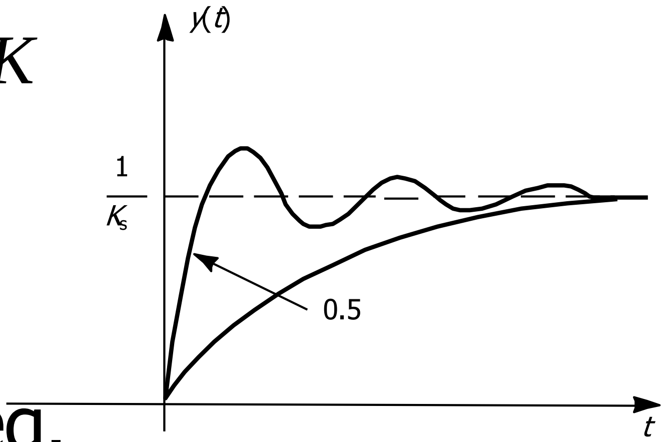
$$y(t) = -\frac{\zeta + \sqrt{\zeta^2 - 1}}{2\sqrt{\zeta^2 - 1}} K e^{\left(-\zeta + \sqrt{\zeta^2 - 1}\right)\omega_n t} + \frac{\zeta - \sqrt{\zeta^2 - 1}}{2\sqrt{\zeta^2 - 1}} K e^{\left(-\zeta - \sqrt{\zeta^2 - 1}\right)\omega_n t} + K$$

Critically damped $\zeta = 1$:

$$y(t) = -(1 + \omega_n t) K e^{-\omega_n t} + K$$

Underdamped $\zeta < 1$:

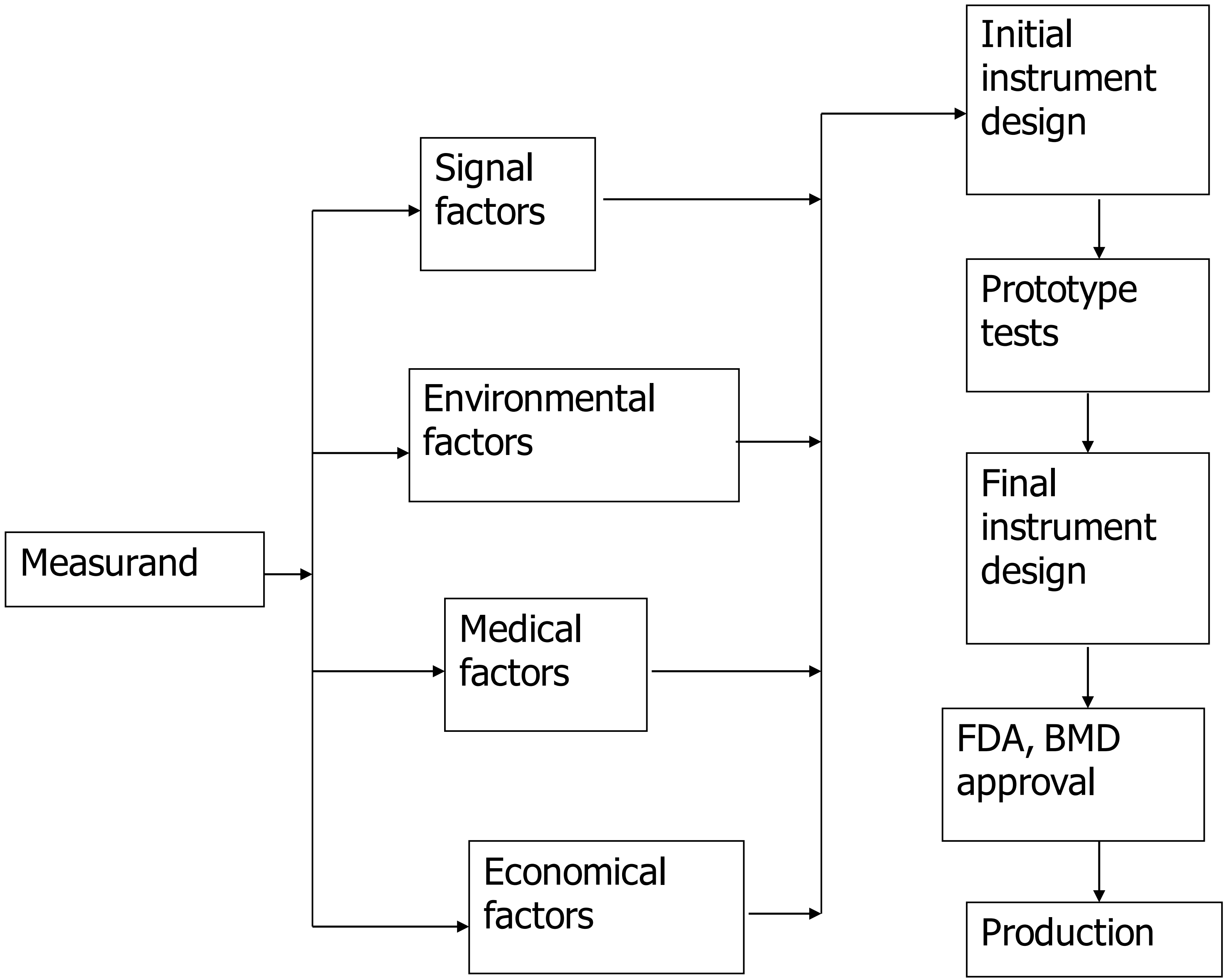
$$y(t) = -\frac{e^{-\zeta\omega_n t}}{\sqrt{1-\zeta^2}} K \sin\left(\sqrt{1-\zeta^2}\,\omega_n t + \phi\right) + K$$



$$\phi = \arcsin\sqrt{1-\zeta^2}$$

$$\omega_d = \omega_n\sqrt{1-\zeta^2}$$ Damped natural freq.

DESIGN CRITERIA



➢ Signal factors

- Sensitivity
- Range
- Input impedance
- Transient and frequency response
- Accuracy
- Linearity
- Reliability

Environmental factors

- Specificity
- Signal-to-noise ratio
- Stability
  - Temperature
  - Humidity
  - Pressure
  - Acceleration
  - Shock
  - Vibration
  - Radiation
- Power requirements
- Mounting size, shape

➢ Medical factors

- Invasive or non-invasive
- Tissue-transducer interface requirements
- Material toxicity
- Electrical safety
- Radiation and heat dissipation
- Patient discomfort

➢ Economic factors

- Cost
- Availability
- Warranty
- Consumable requirements
- Compatibility with existing equipment

COMMERCIAL MEDICAL INSTRUMENTATION DEVELOPMENT PROCESS

•**Ideas:** come from people working in the health care

•**Detailed evaluation** and signed disclosure

•**Feasibility** analysis and product description

•Medical need

•Technical feasibility

•**Brief business plan** (financial, sales, patents, standards, competition)

•**Product Specification** (interface, size, weight, color)

"What" is required but nothing about "how"

•**Design and development** (software and hardware)

•**Prototype** development

•**Testing on animals or human subjects**

•**Final design review** (test results for, specifications, subject feedback, cost)

•**Production** (packaging, manual and documents)

•**Technical support**