Sahand University of Technology

Lecture 1
Introduction to Bio-Instrument

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Definition

- **Instrument** in Merriam-Webster dictionary:
  1. A tool or device used for a particular purpose; *especially* : a tool or device designed to do careful and exact work
  2. A device that measures something (such as temperature or distance)
- **Bioinstrumentation** in Merriam-Webster dictionary:
  - The development and use of instruments for recording and transmitting physiological data (as from astronauts in flight); *also* : the instruments themselves

Basic Objectives of the Bioinstrumentation

- Information Gathering
- Diagnosis
- Evaluation
- Monitoring
- Control

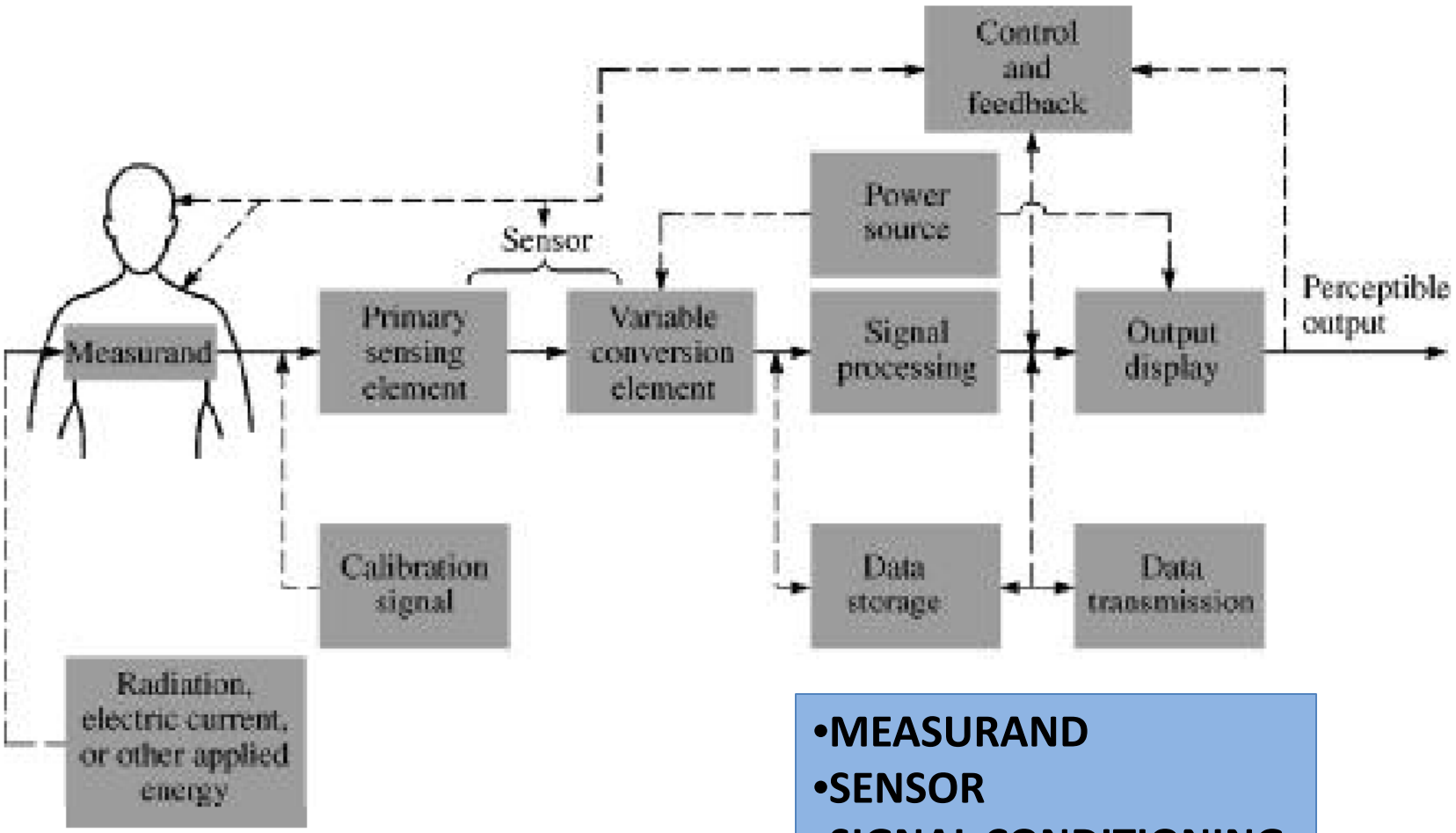
Basic Objectives of the Bioinstrumentation

- **INFORMATION GATHERING**
  - In this system, machine is used to measure natural phenomena & other variables to aid man in his search for the knowledge about himself and the universe in which he lives.
  - In this setting, the characteristic of the measurements may not be known in advance.
- **DIAGNOSIS**
  - Measurements are made to help in the detection & the correction of some malfunction of the system being measured.
  - In some applications, this type of instrumentation may be classed as – " Trouble shooting equipments."

Basic Objectives of the Bioinstrumentation

- **EVALUATION**
  - Measurements are used to determine the ability of a system to meet its functional requirements.
  - These could be classified as " Proof – of – performance" or " Quality control" tests.
- **MONITORING**
  - Instrumentation is used to monitor some process or operation in order to obtain continuous or periodic information about the state of the system being measured.
- **CONTROL**
  - Instrumentation is sometimes used to automatically control the operation of a system based on changes in one or more of the internal parameters or in the output of the system.

Generalized Instrumentation System



- **MEASURAND**
- **SENSOR**
- **SIGNAL CONDITIONING**
- **OUTPUT DISPLAY**

Generalized Instrumentation System

MEASURAND:

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

Accessibility of the measurand

- internal (blood pressure)
- Surface (ECG)
- Emanate (IR)
- Tissue Sample

Most medically important measurands:

- Biopotential
- Pressure
- Flow
- Dimensions (imaging)
- Displacement (velocity, acceleration, and force)
- Temperature,
- Chemical concentrations.

The measurand may be localized to a specific organ or anatomical structure

Generalized Instrumentation System

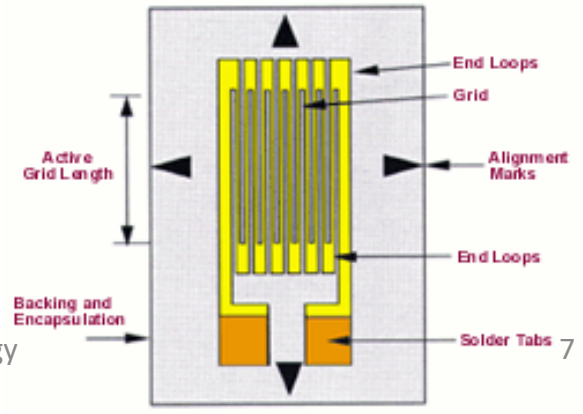
SENSOR:

Transducer is defined as a device that converts one form of energy to another.

Sensor converts a physical measurand to an electric output.

Actuator converts a electrical input to a physical output.

- The sensor responds to the form of energy present in the measurand
- The sensor interfaces with the living system in a way that minimizes the energy extracted, while being minimally invasive.
- Many sensors have a primary sensing element such as a diaphragm, which converts pressure to displacement
- A variable conversion element, such as a strain gage, then converts displacement to an electric voltage.
- Many variable conversion elements need external electric power to obtain a sensor output.



Generalized Instrumentation System

SIGNAL CONDITIONING:

- Usually the sensor output cannot be directly coupled to the display device.
- *Amplifiers and Filters* Simple signal conditioners:
- Match the impedance of the sensor to the display.
- Often sensor outputs are converted to digital form and then processed by specialized digital circuits or a microcomputer

OUTPUT DISPLAY:

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

The best form for the display :

- Numerical or graphical,
- Discrete or continuous,
- Permanent or temporary

- Depending on the particular measurand and how the operator will use the information.

Although most displays rely on our visual sense, some information (Doppler ultrasonic signals, for example) is best perceived by other senses (here, the auditory sense)

- User controls and the output display should conform to the *Human factors engineering guidelines and preferred practices for the design of medical devices (AAMI, 1993)*

Generalized Instrumentation System

ALTERNATIVE OPERATIONAL MODES:

- DIRECT-INDIRECT MODES
- SAMPLING AND CONTINUOUS MODES
- GENERATING AND MODULATING SENSORS
- ANALOG AND DIGITAL MODES
- REAL-TIME AND DELAYED-TIME MODES

MEDICAL MEASUREMENT CONSTRAINTS?

- The principal measurements and frequency ranges are the major factors that affects the components of the instrumentation svstem.

Parameter or Measuring Technique	Principal Measurement Range of Parameter	Signal Frequency Range, Hz	Standard Sensor or Method
Ballistocardiography (BCG)	0–7 mg	dc–40	Accelerometer, strain gage
	0–100 μm	dc–40	Displacement linear variable differential transformer (LVDT)
Bladder pressure	1–100 cm H_2O	dc–10	Strain-gage manometer
Blood flow	1–300 ml/s	dc–20	Flowmeter (electromagnetic or ultrasonic)
Blood pressure, arterial			
Direct	10–400 mm Hg	dc–50	Strain-gage manometer
Indirect	25–400 mm Hg	dc–60	Cuff, auscultation
Blood pressure, venous	0–50 mm Hg	dc–50	Strain gage
Blood gases			
P_{O_2}	30–100 mm Hg	dc–2	Specific electrode, volumetric or manometric
P_{CO_2}	40–100 mm Hg	dc–2	Specific electrode, volumetric or manometric
P_{N_2}	1–3 mm Hg	dc–2	Specific electrode, volumetric or manometric

Parameter or Measuring Technique	Principal Measurement Range of Parameter	Signal Frequency Range, Hz	Standard Sensor or Method
P_{CO}	0.1–0.4 mm Hg	dc–2	Specific electrode, volumetric or manometric
Blood pH	6.8–7.8 pH units	dc–2	Specific electrode
Cardiac output	4–25 liter/min	dc–20	Dye dilution, Fick
Electrocardiography (ECG)	0.5–4 mV	0.01–250	Skin electrodes
Electroencephalography (EEG)	5–300 μV	dc–150	Scalp electrodes
(Electrocorticography and brain depth)	10–5000 μV	dc–150	Brain-surface or depth electrodes
Electrogastrography (EGG)	10–1000 μV	dc–1	Skin-surface electrodes
	0.5–80 mV	dc–1	Stomach-surface electrodes
Electromyography (EMG)	0.1–5 mV	dc–10,000	Needle electrodes
Eye potentials			
Electro-oculogram (EOG)	50–3500 μV	dc–50	Contact electrodes
Electroretinogram (ERG)	0–900 μV	dc–50	Contact electrodes
Galvanic skin response (GSR)	1–500 kΩ	0.01–1	Skin electrodes
Gastric pH	3–13 pH units	dc–1	pH electrode; antimony electrode

Parameter or Measuring Technique	Principal Measurement Range of Parameter	Signal Frequency Range, Hz	Standard Sensor or Method
Gastrointestinal pressure	0–100 cm H_2O	dc–10	Strain-gage manometer
Gastrointestinal forces	1–50 g	dc–1	Displacement system, LVDT
Nerve potentials	0.01–3 mV	dc–10,000	Surface or needle electrodes
Phonocardiography	Dynamic range 80 dB, threshold about 100 μPa	5–2000	Microphone
Plethysmography (volume change)	Varies with organ measured	dc–30	Displacement chamber or impedance change
Circulatory	0–30 ml	dc–30	Displacement chamber or impedance change
Respiratory functions	0–600 liter/min	dc–40	Pneumotachograph head and differential pressure
Pneumotachography (flow rate)			
Respiratory rate	2–50 breaths/min	0.1–10	Strain gage on chest, impedance, nasal thermistor
Tidal volume	50–1000 ml/breath	0.1–10	Above methods
Temperature of body	32–40°C 90–104 °F	dc–0.1	Themistor, thermocouple

Characteristics of instrument performance

Characteristics of instrument performance are usually subdivided into two classes on the basis of the frequency of the inputs.

STATIC CHARACTERISTICS:
Static characteristics describe the performance of instruments for dc or very low frequency inputs.

DYNAMIC CHARACTERISTICS:
Dynamic characteristics require the use of differential and/or integral equations to describe the quality of the measurements.

Included: Accuracy, Precision, Resolution, Reproducibility, Statistical Control, Static Sensitivity, Zero Drift, Sensitivity Drift, Linearity, Input Ranges, Input Impedance.

Characteristics of instrument performance

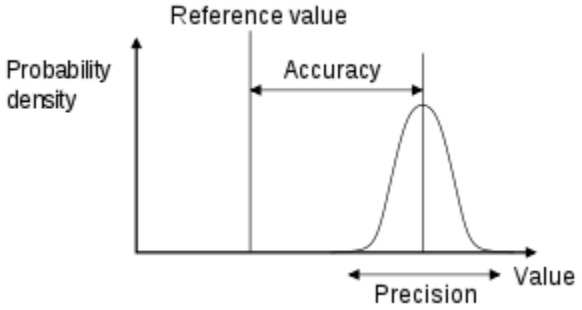
ACCURACY

The *accuracy of a single measured quantity is the difference between the* true value and the measured value divided by the true value.

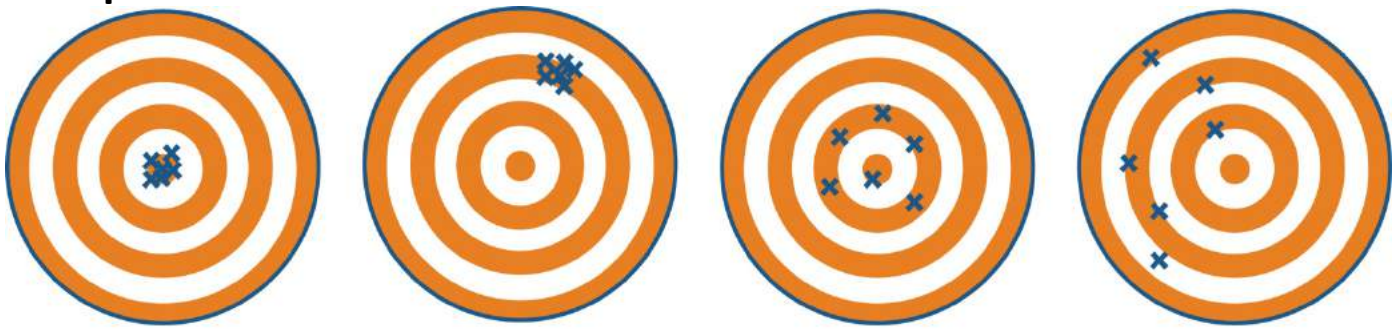
$$\text{Accuracy} = \frac{X_{True} - X_{Measured}}{X_{True}}(100)$$

PRECISION

The *precision of a measurement expresses the number of distinguishable* alternatives from which a given result is selected.



Another point of view:



High Accuracy High Precision | **Low Accuracy High Precision** | **High Accuracy Low Precision** | **Low Accuracy Low Precision**

CHARACTERISTICS OF INSTRUMENT PERFORMANCE

RESOLUTION

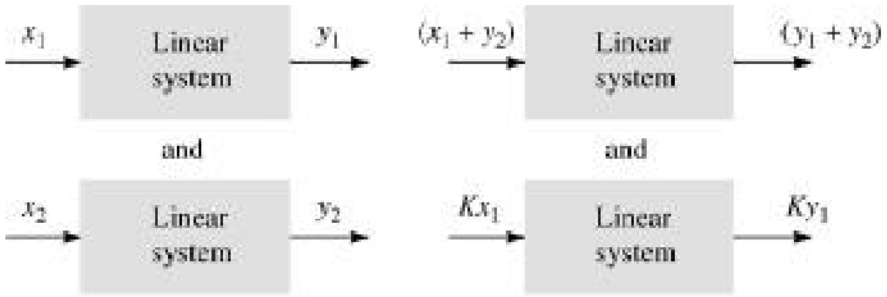
The smallest incremental quantity that can be measured with certainty is the *resolution.*

REPRODUCIBILITY

The ability of an instrument to give the same output for equal inputs applied over some period of time is called *reproducibility or repeatability.*

LINEARITY

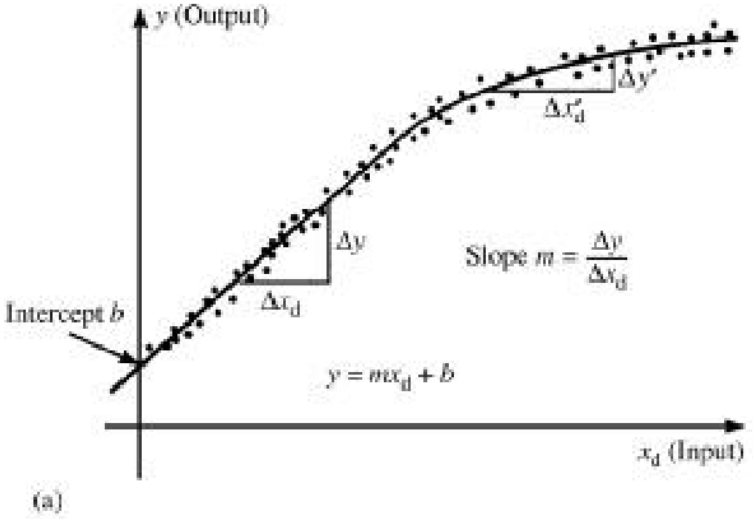
A system or element is linear if it has properties such that, if yl is the response to XI, and y2 is the response to x2, then yl + y2 is the response to xl + x2, and Kyl is the response to Kxl (Jay, 1988). These two requirements for system linearity are restated in Figure 1.6(a).



Characteristics of instrument performance

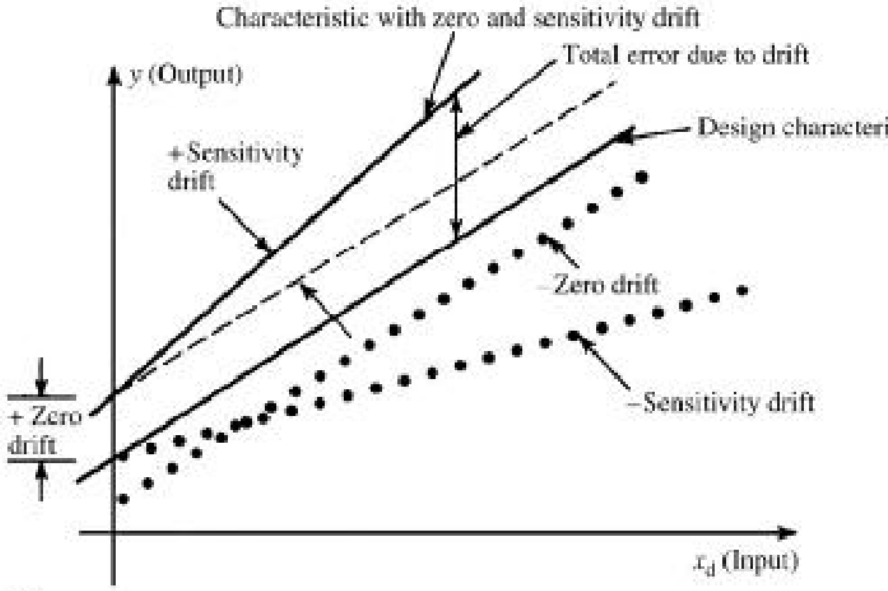
SENSITIVITY

The ratio of the incremental output quantity to the incremental input quantity, under static conditions, within the operating range of the instrument, e.g. 5V / mm Hg or 0.5V / mm Hg.



Sensituvity Drift

Zero Drift



GENERALIZED DYNAMIC CHARACTERISTICS

Most medical instruments must process signals that are **functions of time**.

It is this **time-varying** property of medical signals that requires us to consider dynamic instrument characteristics.

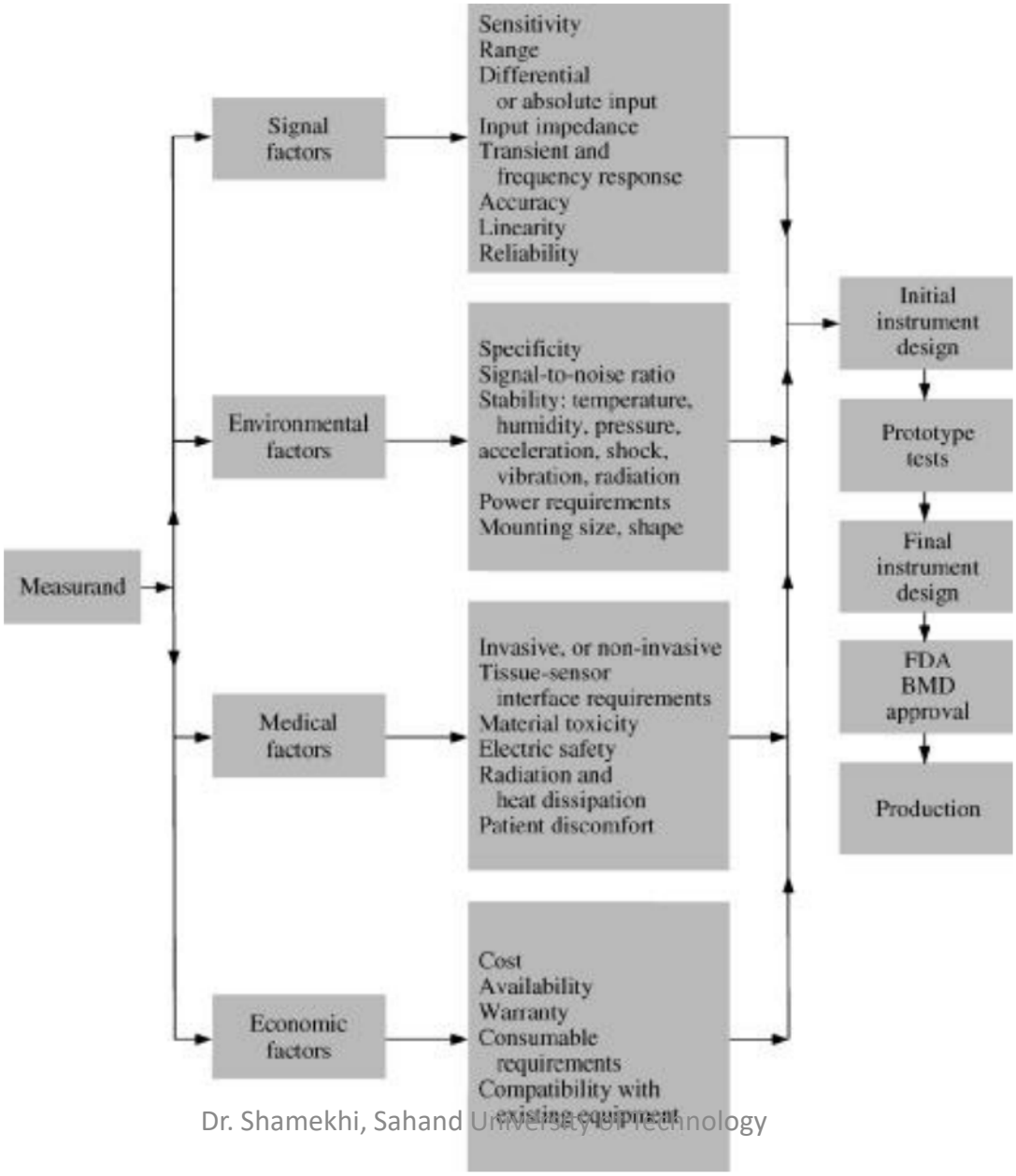
Differential or integral equations are required to relate dynamic inputs to dynamic outputs for continuous systems.

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

Fortunately, many engineering instruments can be described by **ordinary linear differential equations with constant coefficients.**

Zero order
First Order
Second Order

DESIGN CRITERIA



Medical Device Classification

- Medical devices are classified in two ways:
  1. Based on the principle that devices that pose greater potential hazards should be subjected to more regulatory requirements.

Class I general controls. Manufacturers are required to perform registration, premarketing notification, record keeping, labeling, reporting of adverse experiences, and good manufacturing practices. These controls apply to all three classes.

Class II performance standards. These standards were to be defined by the federal government, but the complexity of procedures called for in the amendments and the enormity of the task have resulted in little progress having been made toward defining the 800 standards needed. The result has been overreliance on the postamendment "substantial equivalence" known as the 510(k) process.

Class III premarketing approval. Such approval is required for devices used in supporting or sustaining human life and preventing impairment of human health. The FDA has extensively regulated these devices by requiring manufacturers to prove their safety and effectiveness prior to market release.

Table 1. Medical Device Classification

Device Classification	Examples	Safety/Effectiveness Controls	Required Submission
Class I	elastic bandages, examination gloves, hand-held surgical instruments	General Controls	Registration only unless 510(k) specifically required
Class II	powered wheelchairs, infusion pumps, surgical drapes	General Controls & Special Controls	510(k) notification unless exempt -IDE possible
Class III	heart valves, silicone gel-filled breast implants, implanted cerebella stimulators	General Controls & Premarket Approval	PMA application -IDE probable
	metal-on-metal hip joint, certain dental implants	*General Controls*	*510(k) notification*

2. Seven categories were established: Preamendment, Postamendment, Substantially, Equivalent, Implant, Custom, Investigational ,and transitional

Table 1.2 FDA Medical Device Categories

Category	Description	Classification Rules	Examples
Preamendment devices (or old devices)	Devices on the market before May 28, 1976, when the Medical Device Amendments were enacted.	Devices are assigned to 1 of 3 classes. A presumption exists that preamendment devices should be placed in Class I unless their safety and effectiveness cannot be ensured without the greater regulation afforded by Classes II and III. A manufacturer may petition the FDA for reclassification.	Analog electrocardiography machine; electrohydraulic lithotriptor; contraceptive intrauterine device and accessories; infant radiant warmer; contraceptive tubal occlusion device; automated heparin analyzer; automated differential cell counter; automated blood-cell separator; transabdominal aminoscope.
Postamendment devices (or new devices)	Devices put on the market after May 28, 1976.	Unless shown to be substantially equivalent to a device that was on the market before the amendments took effect, these devices are automatically placed in Class III. A manufacturer may petition the FDA for reclassification.	Magnetic resonance imager; extracorporeal shock-wave lithotriptor; absorbable sponge; YAG laser; AIDS-antibody test kit; hydrophilic contact lenses; percutaneous catheter for transluminal coronary angioplasty;

Table 1.2 *(Continued)*

Category	Description	Classification Rules	Examples
Substantially equivalent devices	Postamendment devices that are substantially equivalent to preamendment devices.	Devices are assigned to the same class as their preamendment counterparts and subject to the same requirements. If and when the FDA requires testing and approval of preamendment devices, their substantially equivalent counterparts will also be subject to testing and approval.	Digital electrocardiography machines; YAG lasers for certain uses; tampons; ELISA diagnostic kits; devices used to test for drug abuse.
Implanted devices	Devices that are inserted into a surgically formed or natural body cavity and intended to remain there for $\geq$ 30 days.	Devices are assumed to require placement in Class III unless a less-regulated class will ensure safety and effectiveness.	Phrenic-nerve stimulator; pacemaker pulse generator; intracardiac patch; vena cava clamp.

Table 1.2 *(Continued)*

Category	Description	Classification Rules	Examples
Custom devices	Devices not generally available to other licensed practitioners and not available in finished form. Product must be specifically designed for a particular patient and may not be offered for general commercial distribution.	Devices are exempt from premarketing testing and performance standards but are subject to general controls.	Dentures; orthopedic shoes.
Investigational devices	Unapproved devices undergoing clinical investigation under the authority of an Investigational Device Exemption.	Devices are exempt if an Investigational Device Exemption has been granted.	Artificial heart; ultrasonic hyperthermia equipment; DNA probes; laser angioplasty devices; positron emission tomography machines.
Transitional devices	Devices that were regulated as drugs before enactment of the statute but are now defined as medical devices.	Devices are automatically assigned to Class III but may be reclassified in Class I or II.	Antibiotic susceptibility disks; bone heterografts; gonorrhea diagnostic products; injectable silicone; intraocular lenses; surgical sutures; soft contact lenses.