Lecture One, Part 1

Terminology of Medical Devices

According to WHO: 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

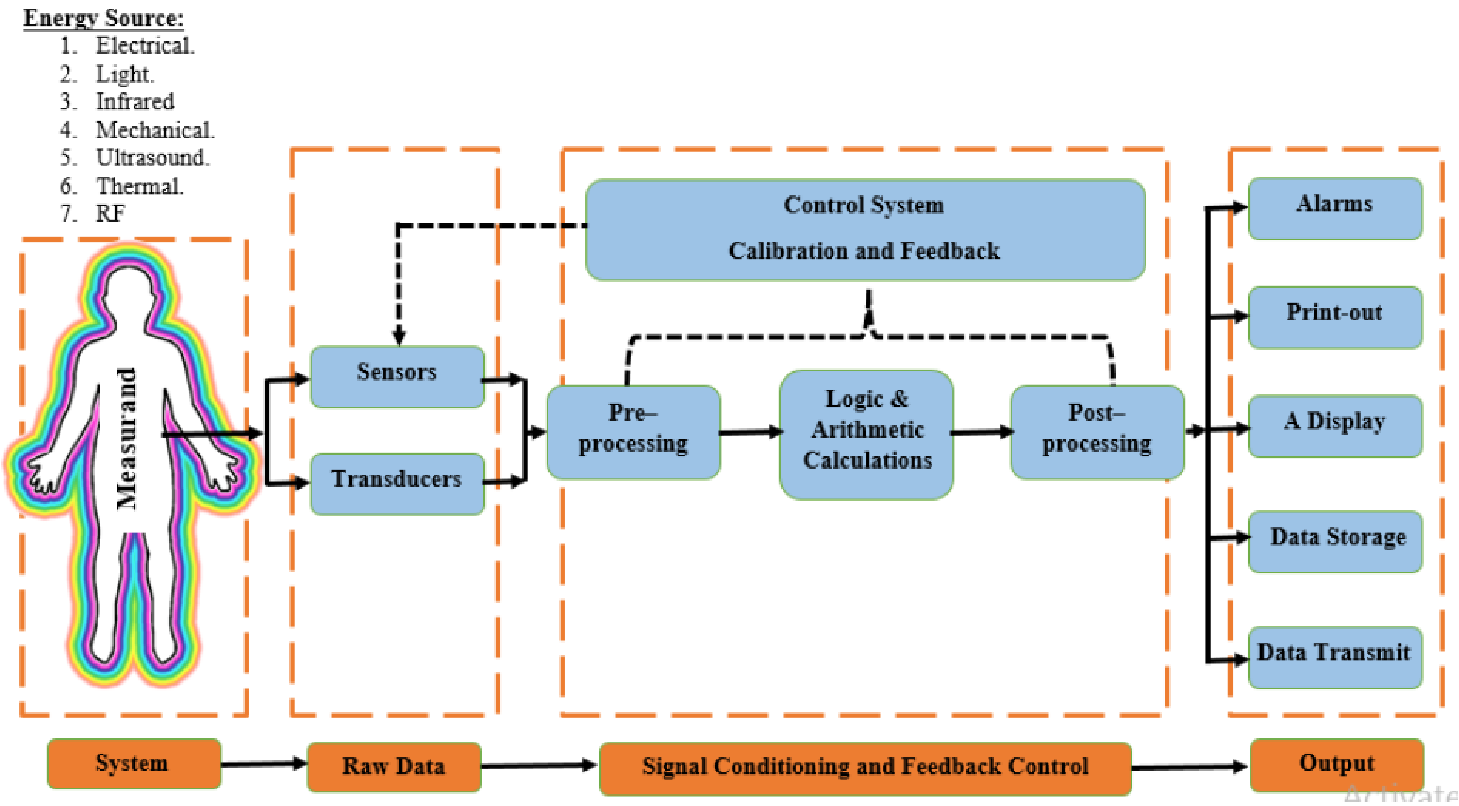
Medical devices don't achieve their primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but they may be assisted in their intended function by such means. Products that may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection of substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproduction technologies.

Generalized Medical Instrumentation System

The major difference between this system of medical instrumentation and the conventional instrumentation system is that the source of the signals is living tissue or energy applied to living tissue. The design of the instrument must match:

- Measurement needs (environmental conditions, safety, reliability, etc.)
- Instrument performance (speed, power, resolution, range, etc.)

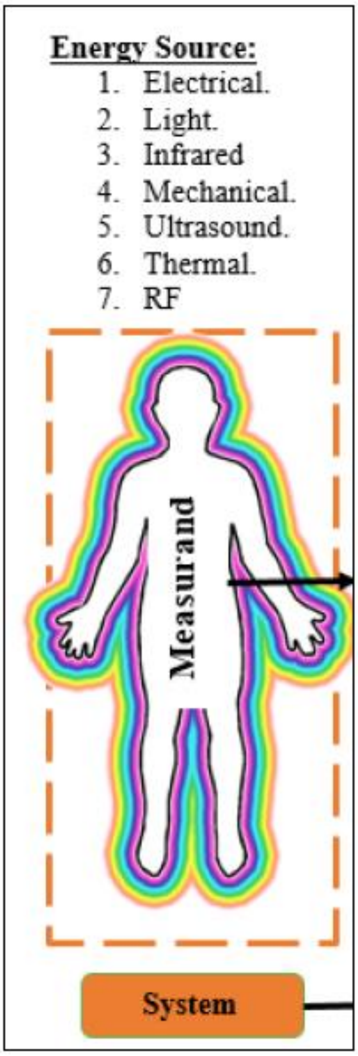


Measurand

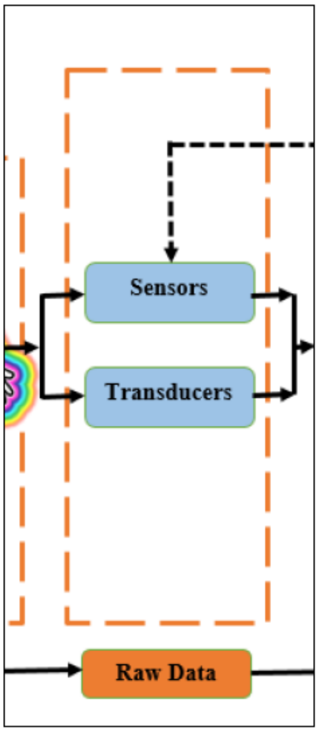
Measurand: the physical quantity, property, or condition that the system measures. Types of biomedical measurands:

- Internal – Blood pressure.
- Body surface – ECG or EEG potentials.
- Peripheral – Infrared radiation.
- Offline – Extract tissue samples, blood analysis, or biopsy.

Typical biomedical measurements quantities: Biopotential, pressure, flow, dimensions (imaging), displacement (velocity, acceleration, and force), impedance, temperature, and chemical concentration. The measurand may be restricted to an exact organ or anatomical structure.



Sensor and transducer



- ***A sensor*** is a device that converts physical measurand to an electrical output, in contrast, ***a transducer*** is a device that converts one form of energy to another.
- ***Sensor requirements:***

✓ Selective – should respond to a specific form of energy in the measurand.

✓ Minimally invasive (invasive = requiring entry into a part of the body).

Sensor should not affect the response of the living tissue. Most common types of sensors in biomedical systems: displacement and pressure.

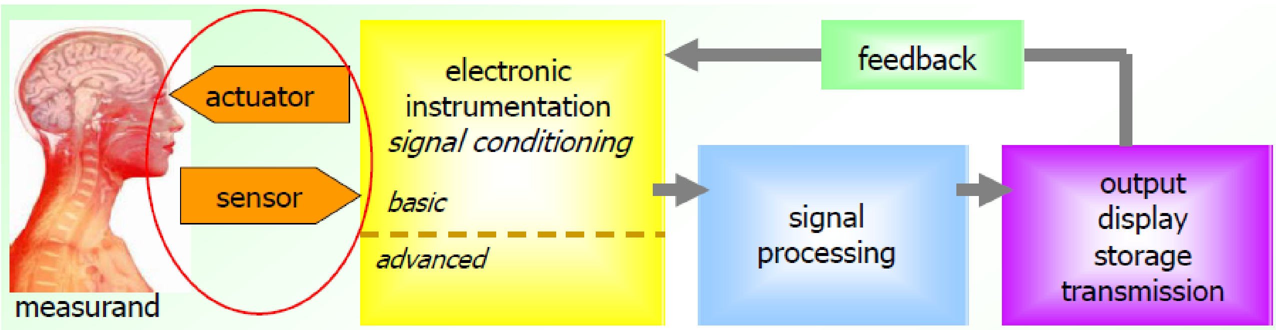
Many sensors have:

✓ 1. A primary sensing element such as a diaphragm, converts pressure to displacement.

✓ 2. A variable conversion element, such as a strain gage, then converts displacement to an electrical voltage

✓ 3. Sometimes the sensitivity of the sensor can be adjusted over a wide range by altering the primary sensing element.

✓ 4. Many variable conversion elements need external electric power to obtain a sensor output.



Signal conditioning

- ***Signal Conditioning:*** Amplification and filtering of the signal acquired from the sensor to make it suitable for display
- ***General categories:***

➢ Analog, digital, or mixed-signal signal conditioning

➢ Time/frequency/spatial domain processing (e.g., filtering)

➢ Calibration (adjustment of output to match theparameter measured)

➢ Compensation (remove undesirable secondary sensitivities)

Preprocessing:

Usually, the sensor/transducer output had a range of millivolts, so it should be amplified initially (pre-amplification) in order to meet the hardware requirements for further processing. The gain of the amplifier on this stage depends strongly on the next stage's requirements. Often the output is converted to digital form and then processed by specialized digital circuits or a microcomputer as there will be logic and arithmetic units.

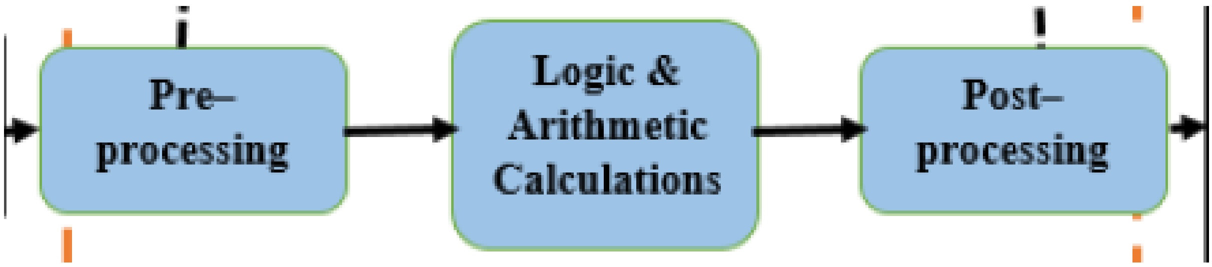
Logic and arithmetic control:

here in this block, the basic and complicated modes of calculations for the raw amplified data gathered from the patient's body through the sensor/transducer are performed.

- For example: signal filtering adjustment, based on operator selection mode, mathematical manipulation between inputs to calculate required parameter and so on.

Postprocessing:

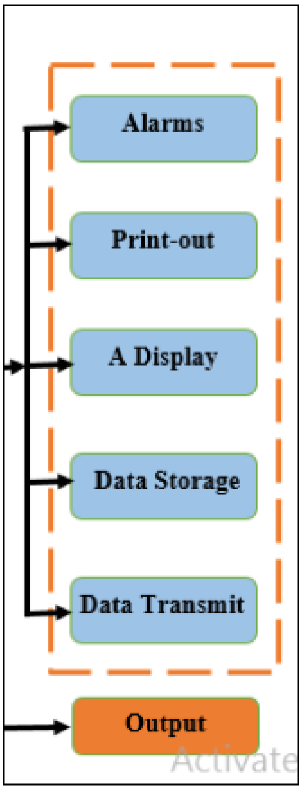
here the final processing is performed. Either based on manipulating the signal to match the requirement of the output elements or to adjust the scale of: time, frequency, and signal level for the real shape mode. Specialized digital circuits or a microcomputer are used to perform several functions like: average repetitive signal, reduce noise, and converting information from the time domain to the frequency domain.



Output:

The results of the measurement procedure must be demonstrated to an arrangement that the human operator can identify. The finest form of the display may be:

- ✓ a. Arithmetical or graphical,
- ✓ b. Discrete or continuous,
- ✓ c. Long-lasting or brief,
- ✓ d. Depending on the specific Measurand and how the operator will use the evidence.



Although most displays depend on our past experience, some information (Doppler ultrasound signals, for example) is best perceived by the other senses (here, the auditory sense). The different modes suggested In Figure are almost used in most of the medical devices, either alone or by matching number of them according to the device design criteria.

Control system

- A calibration signals with the properties of the Measurand should be applied to the sensor/transducer input, or
- As early in the signal–processing series as possible.
- Many forms into control and feedback may be requisite to elicit the Measurand, to fine-tune the sensor and signal conditioner, and to direct the flow of output for display, storage, or transmission.
- Control or feedback may be automatic or manual.
- Data may be stored concisely to meet the requirements of the signal conditioning or to allow the operator to examine data that precede alarm conditions.
- Otherwise, data may be stored before the signal conditioning, so that different processing arrangements can be used.
- Conventional principles of communications can often be used to transmit data on to remote displays at nurses' stations, medical centers, or medical data–processing facilities.