ESE 3400: Medical Devices Lab

Lec 2: September 7, 2022

Device Platforms/Systems

Lecture Outline

- Medical Devices Review
- Lab 1: Sensors Recap
- System Development Process
- System Examples

Medical Devices

- An apparatus used in the diagnosis, mitigation, therapy, or prevention of a disease not through a chemical action (i.e is not a drug)
- Eg.
  - Blood pressure monitor *diagnoses* hypertension
  - Ablation catheter destroys Barret's esophagus precancerous cells *mitigates* the spread of cancer
  - Cochlear implant is *therapy* for hearing ability
  - A condom *prevents* STI infection

Motivating Questions

- What is the clinical need?
- What biometric signals are needed if any?
  - What sensors can acquire this?
  - Is diagnosis needed?
- What medical intervention/stimulation is needed?
  - Electrical stimulation for mitigation or therapy?

Motivating Questions (con't)

- What is the use model of the device?
  - Long term/short term use?
  - Does it need to be mobile?
  - Power source/management?
  - Is it wearable or implantable?
  - Data management/transmission?
- Patient and operator safety concerns?

Sample Medical Device

- Surgical/N95 masks

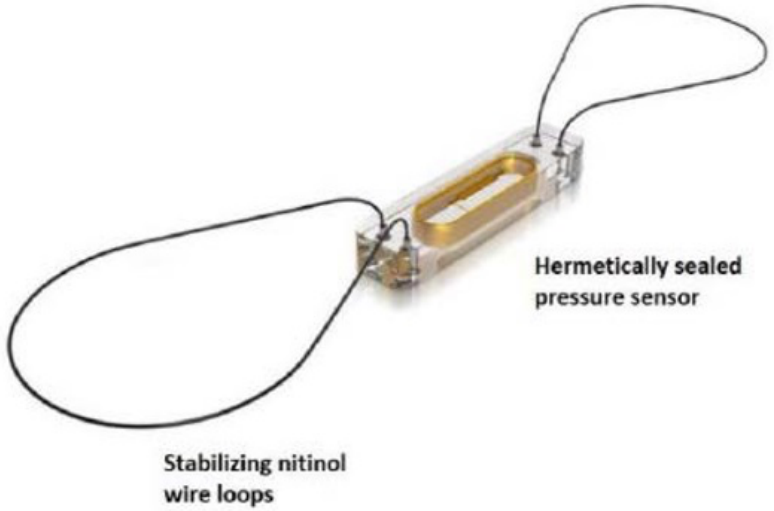
Sample Medical Device

- IV administration set

- Cosmetic filler injection

Electrical Medical Devices

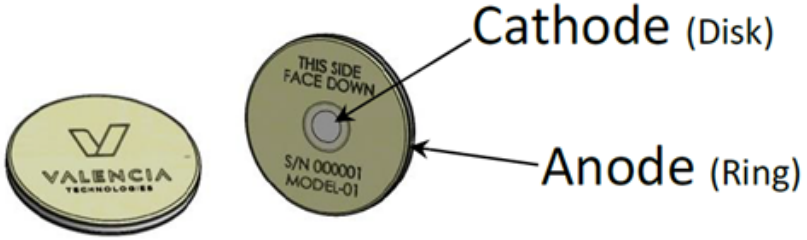
- CardioMEMS HF System



- The CardioMEMS HF System wirelessly measures and monitors pulmonary artery (PA) pressure and heart rate for patients with heart failure. The system consists of an implantable pulmonary artery (PA) sensor, delivery system, and patient electronics system.

Electrical Medical Devices

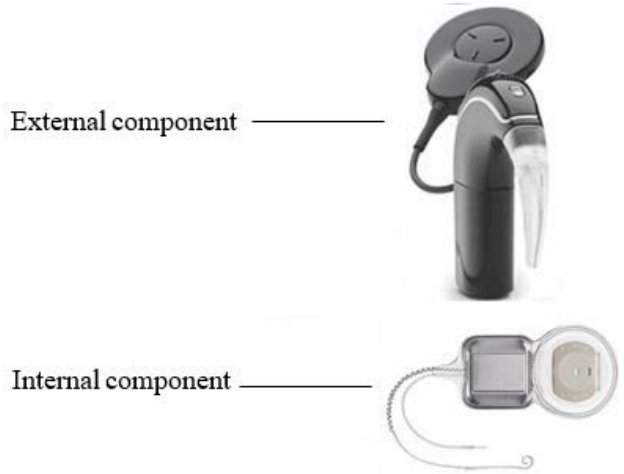
- eCoin Peripheral Neurostimulator



- The eCoin Peripheral Neurostimulator System generates electrical pulses to help stimulate nerves related to bladder control in people with urgency urinary incontinence, or a sudden urge to urinate that causes some urine to leak out. The device is implanted under the skin near the ankle and is controlled by a healthcare provider using a remote control.

Electrical Medical Device

- Nucleus 24 Cochlear Implant System



- The Nucleus 24 Cochlear Implant System is an implant that gives a person access to sound by directly stimulating the hearing nerve (auditory nerve). The cochlear implant system consists of an internal and an external component.

Electrical Medical Devices

- Eversense E3 Continuous Glucose Monitoring System

- The Eversense E3 Continuous Glucose Monitoring (CGM) System gives real-time blood sugar (glucose) readings every five minutes for people with diabetes. The system consists of an implantable fluorescence-based sensor, a transmitter, and a mobile app for displaying glucose values, trends and alerts on the patient's compatible mobile device (smart phone, tablet, etc.).

Lab 1 Sensors

- Hall Sensor
  - Measures magnetic field present
  - Used for position measurements in medical devices
    - Eg. proper location of needles in medical syringes, track position of components in blood analysis machines, applications where a position, gap, alignment, orientation need to be measured without contact
- Photo Resistor
  - Measures intensity of light present
  - Used for sensing reflected or transverse light
    - Eg. Measure blood oxygenation by sensing light pass through finger or ear lobe, heart rate by measuring reflected/passed light

Lab 1 Sensors (con't)

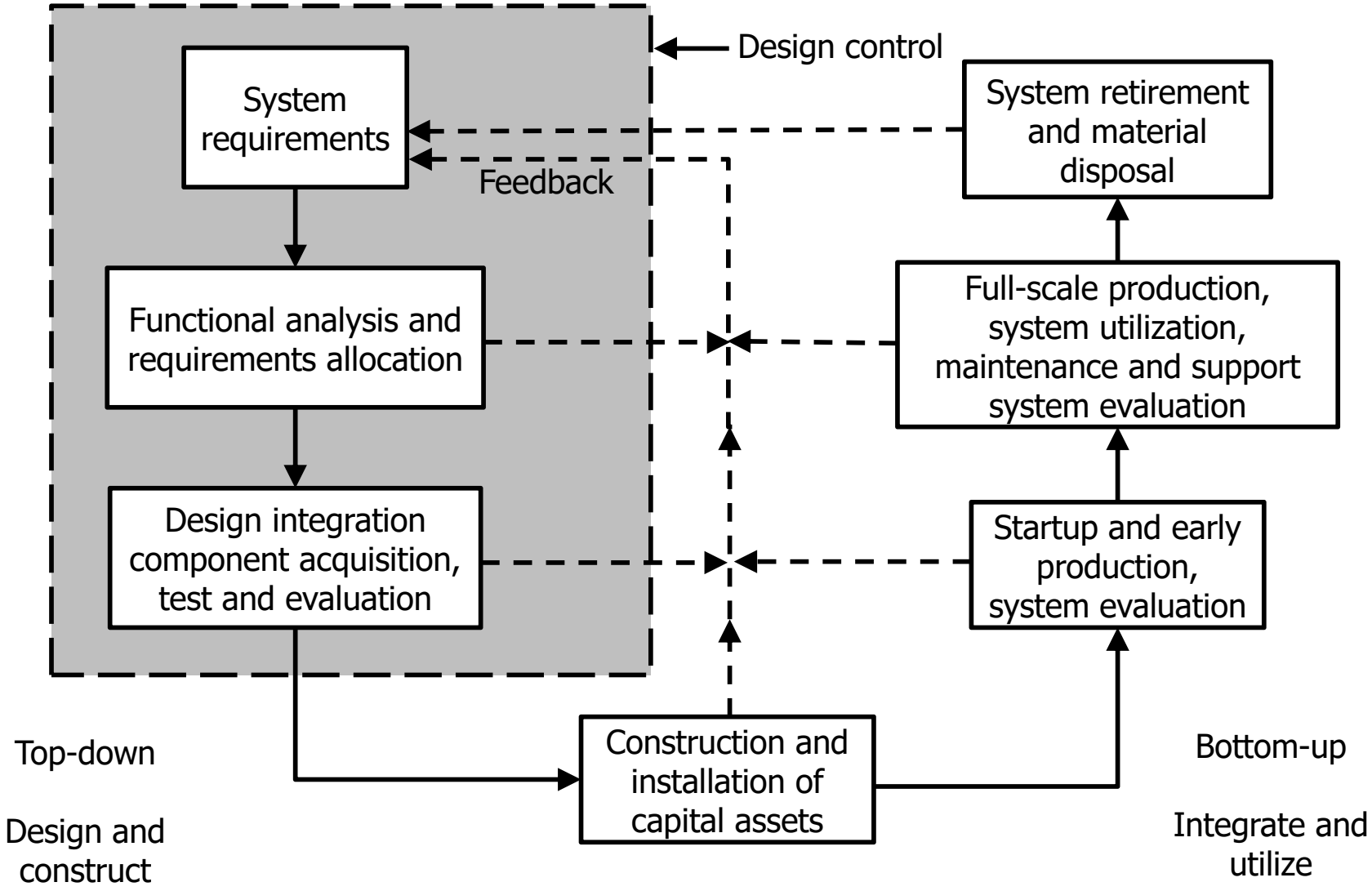
- Accelerometer
  - Measure lateral and rotational acceleration (ie. Movement)
  - Used for sensing motion and direction
    - Eg. Fitness trackers, sleep monitors, tremor monitoring, gait analysis and balance
- Other sensors: temperature, pressure, blood glucose, etc.

System

- A system is a "construct or collection of different elements that together produce results not obtainable by the elements alone. The elements, or parts, can include people, hardware, software, facilities, policies, and documents; that is, all things required to produce system-level results" (INCOSE 2018)

- INCOSE = International Council on Systems Engineering

Systems Development Process



Medical Instrument Systems

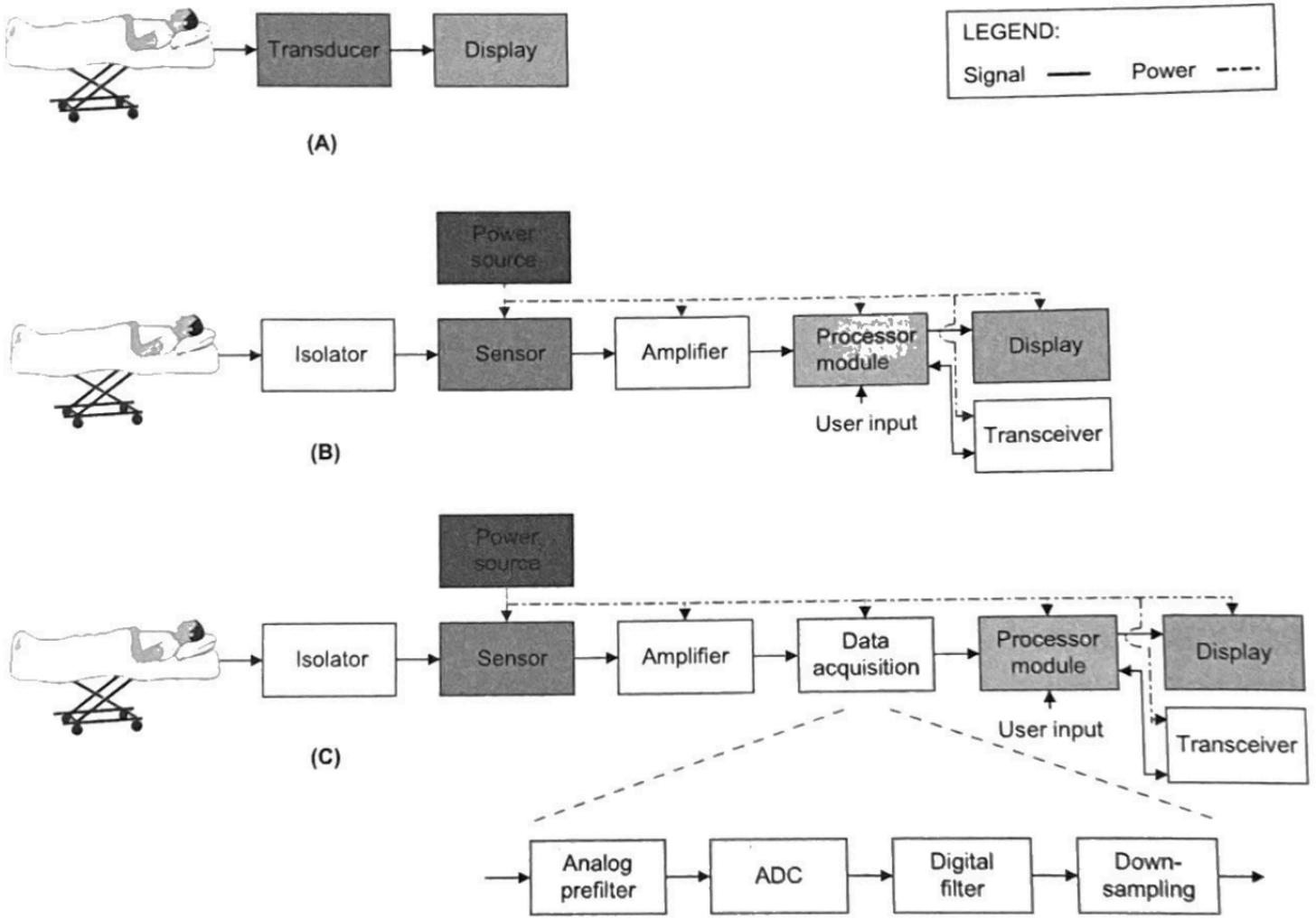


FIGURE 1.1

Three types of medical instruments. (A) Simple. (B) Analog. (C) Digital.

Definitions

- Medical instrument
  - Medical device that makes measurements
- Measurand
  - The physiologic quantity, property or condition that the system measures
- Transducer
  - Converts the energy or information from a measurand to another form
- Sensor
  - Device that transform biologic, chemical, electrical, magnetic, mechanical, optical or other stimuli input into an electrical signal output

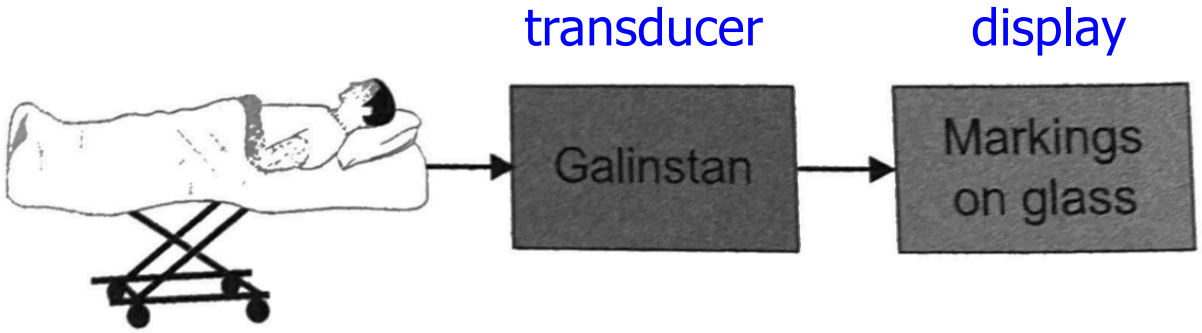
Thermometer Example

- Galinstan thermometer
  - Measurand is patient temperature
  - Transducer is the Galinstan which expands with temperature
  - Temperature scale markings on the glass tube enable display

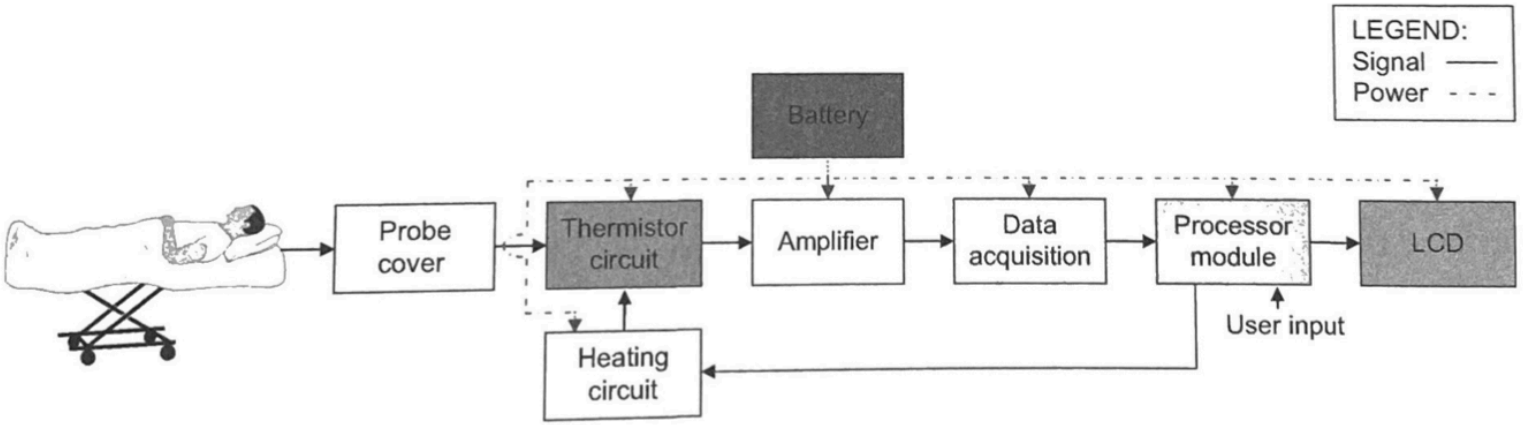
- Digital electronic thermometer
  - Same measurand
  - Sensor called a thermistor, variable resistor based on temperature

Thermometer Example Systems

- Galinstan thermometer



- Digital electronic thermometer



Blood Pressure Measurements

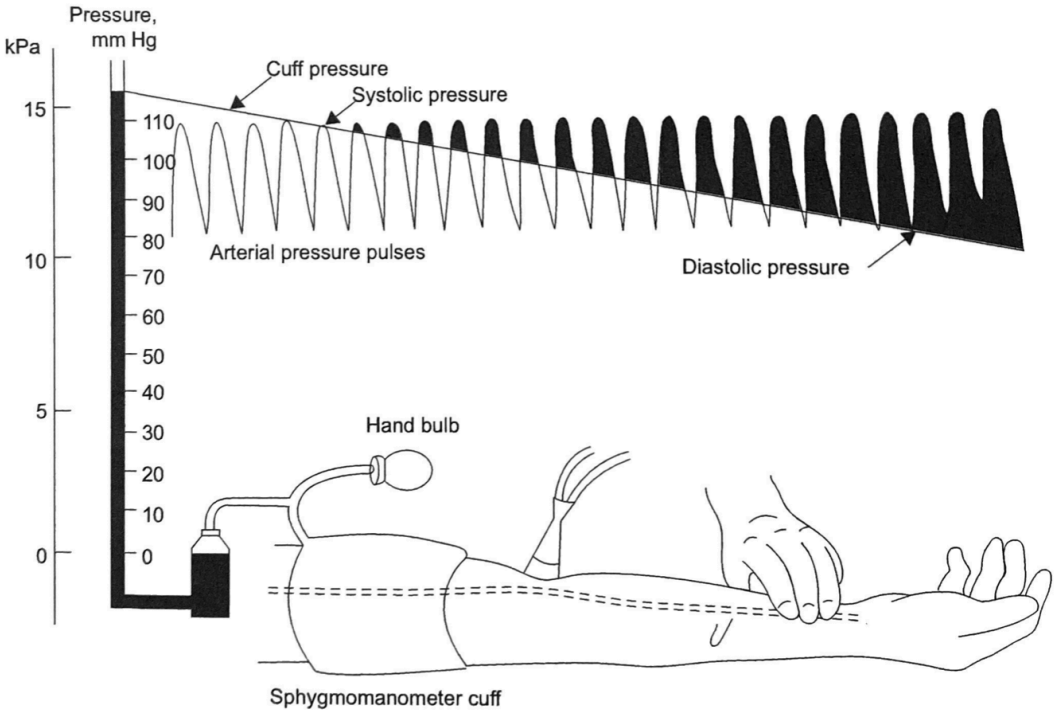
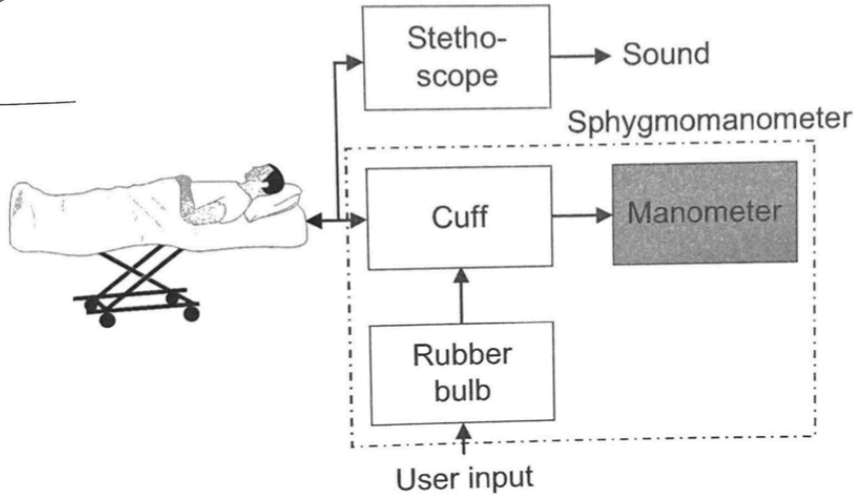


FIGURE 7.6

Auscultation measurement.



Automated BP Measurements

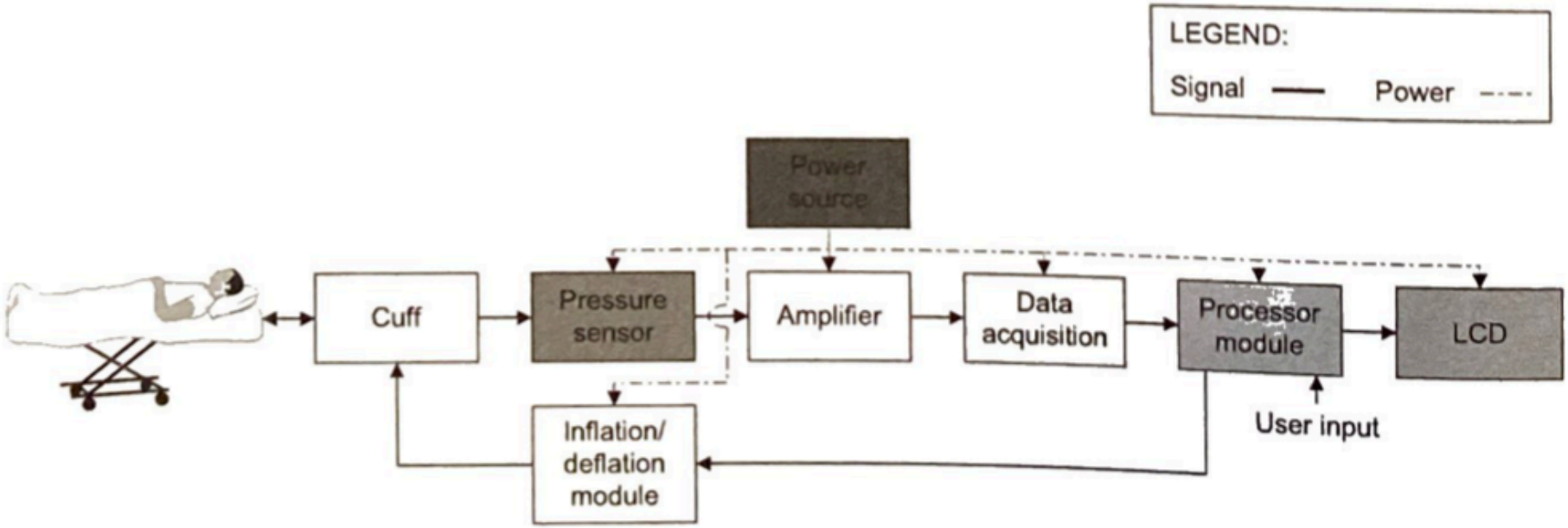


FIGURE 7.10

Oscillometry system diagram.

Automatic Blood Pressure Measurements

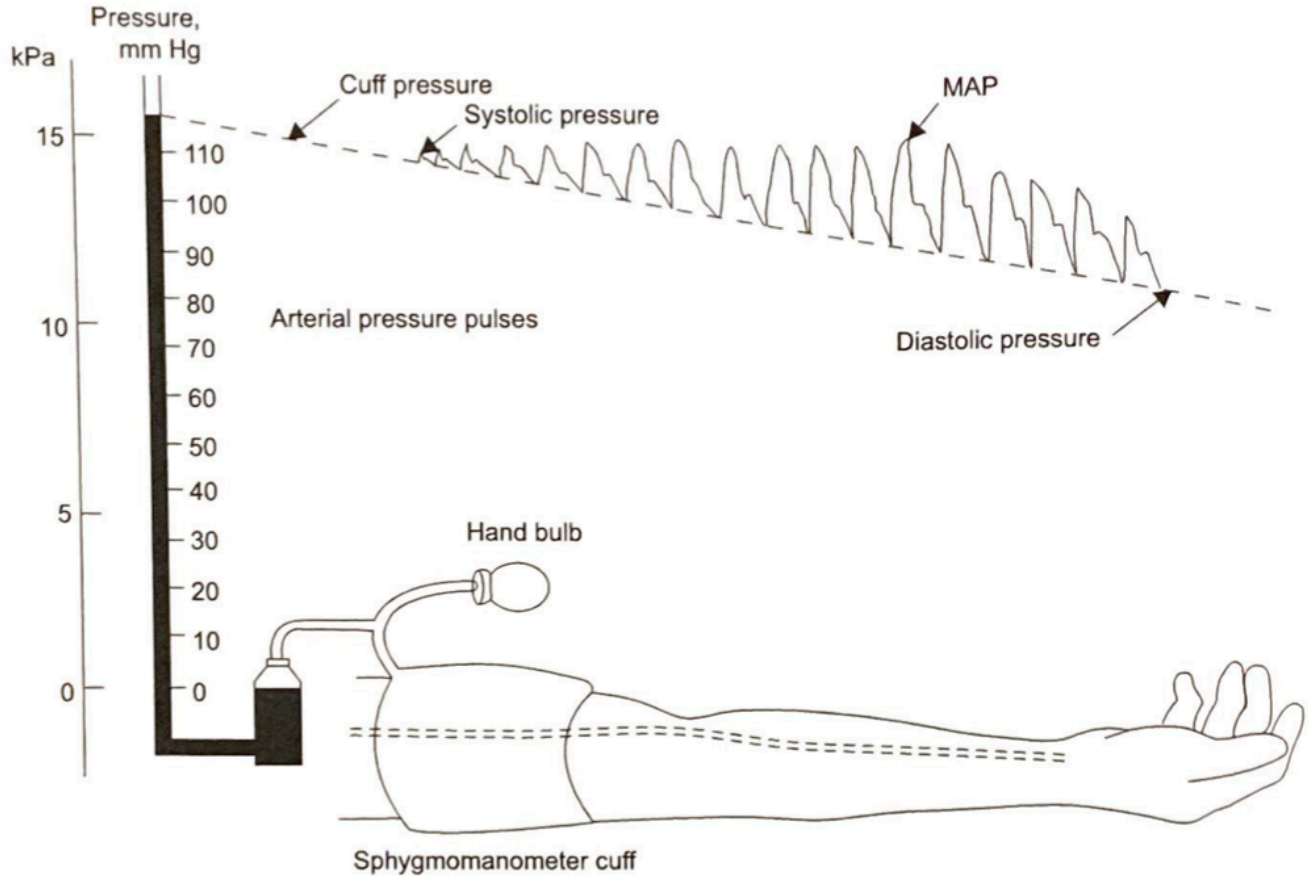


FIGURE 7.9

Oscillometry pressure measurement.

Modified from Rushmer (1970).

Pulse Oximeter System Digram

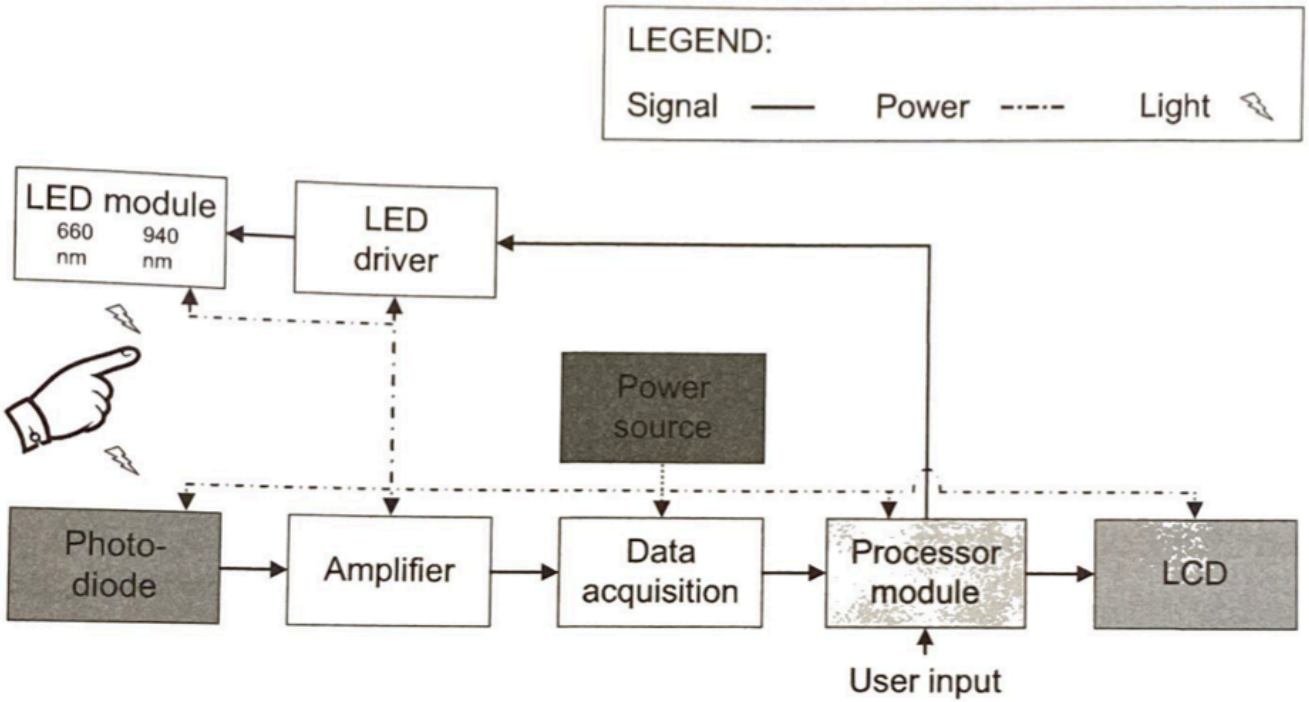


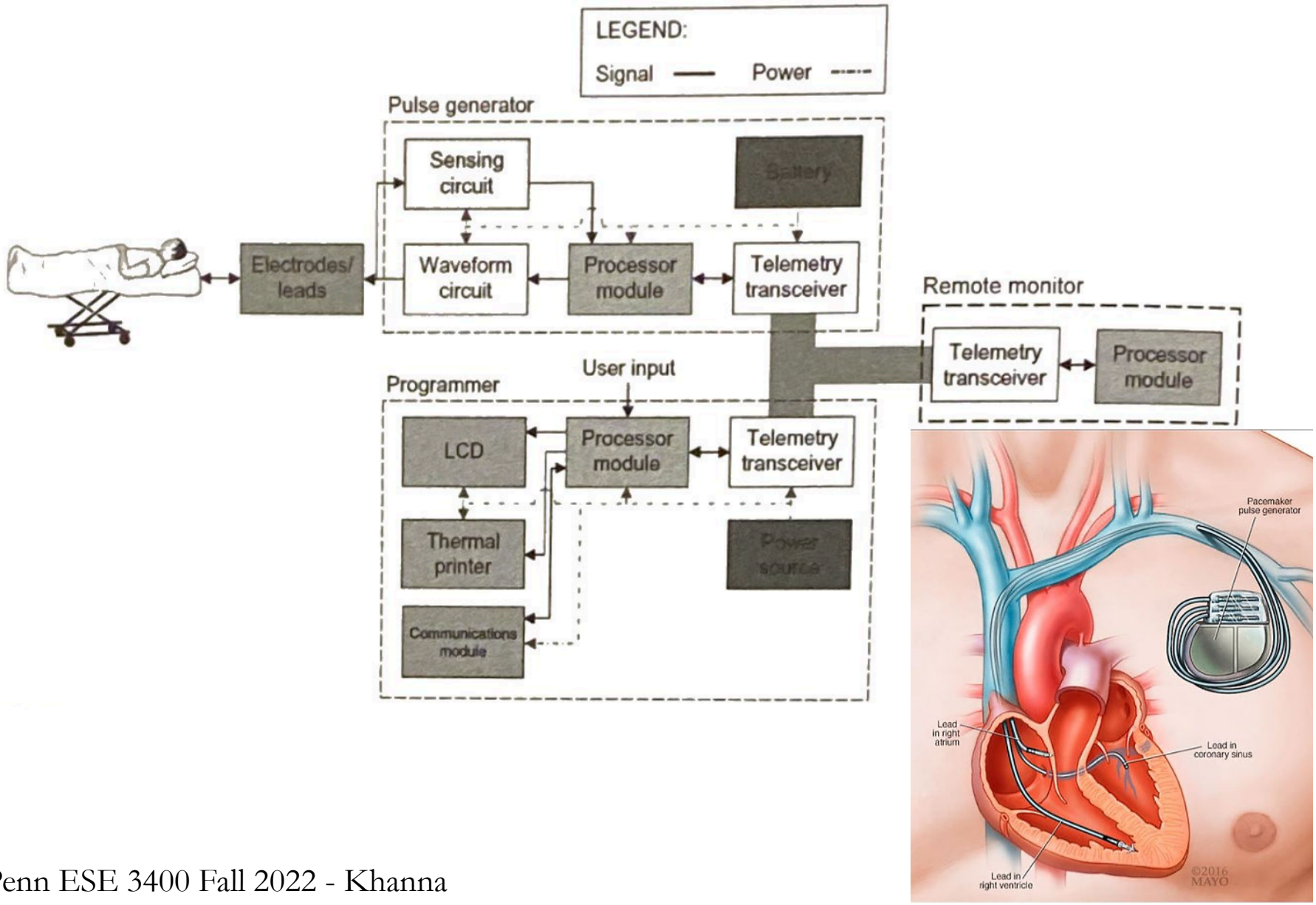
FIGURE 11.13

Pulse oximeter system diagram.

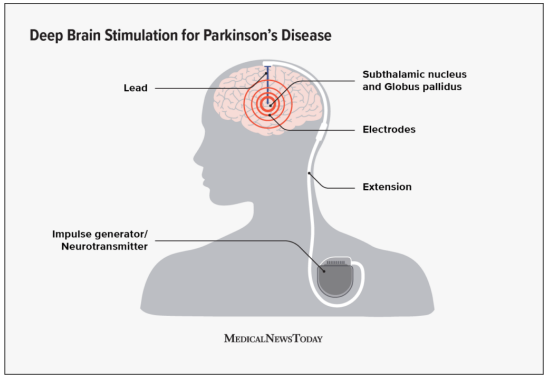
Home Pulse Oximeters

- Low cost (<$50) fingertip pulse oximeters are used in the home
- Can monitor oxygenation for ventilator dependent patients, monitor patients with conditions that may impair ventilation, and guide home oxygen management
- Still have accuracy issues

Pacemaker System Diagram



Deep Brain Stimulation System Diagram



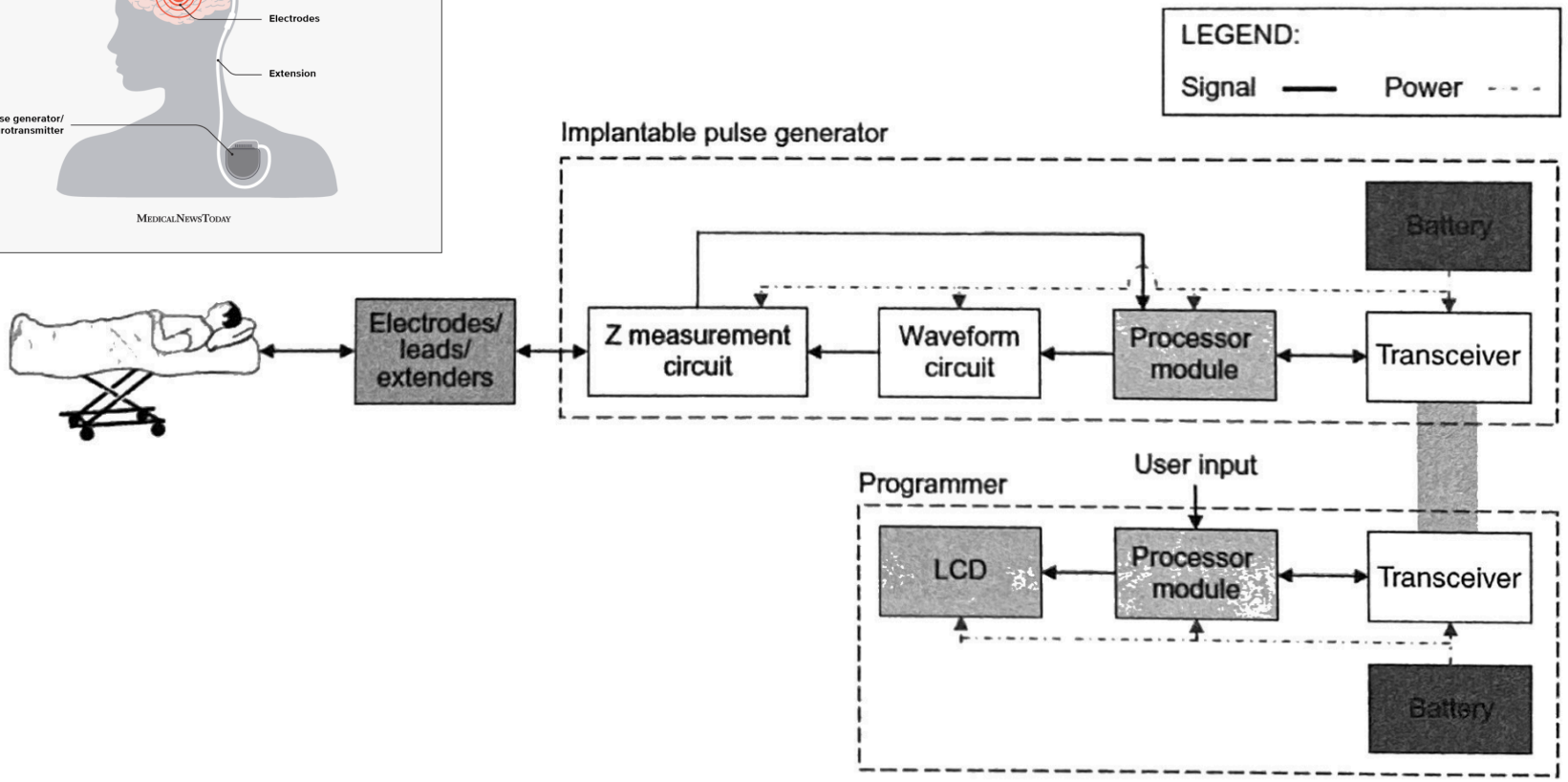


FIGURE 14.9

Deep brain stimulator system diagram.

Cochlear Implant System Diagram

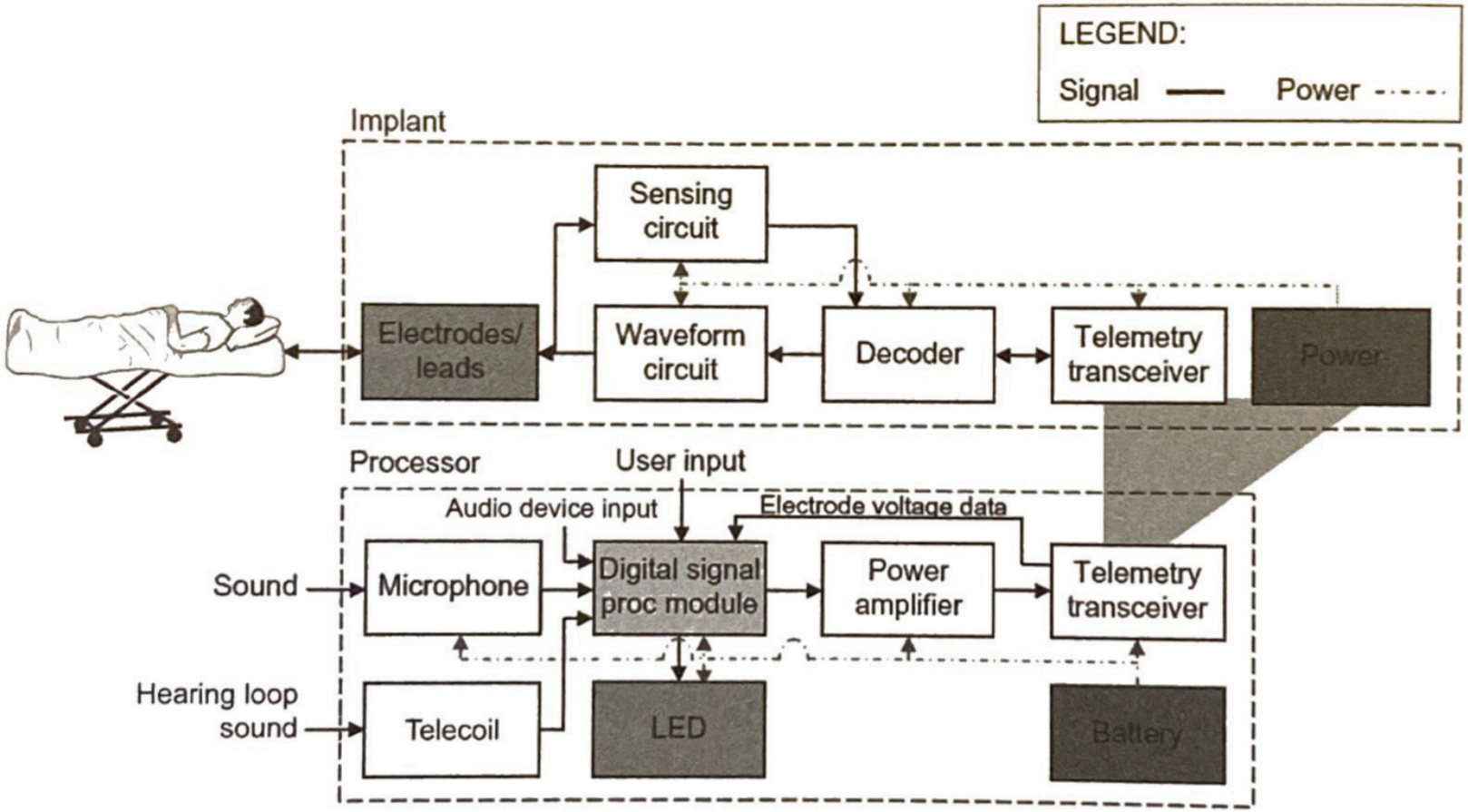


FIGURE 15.15

Cochlear implant system diagram.

Defibrilator System Diagram

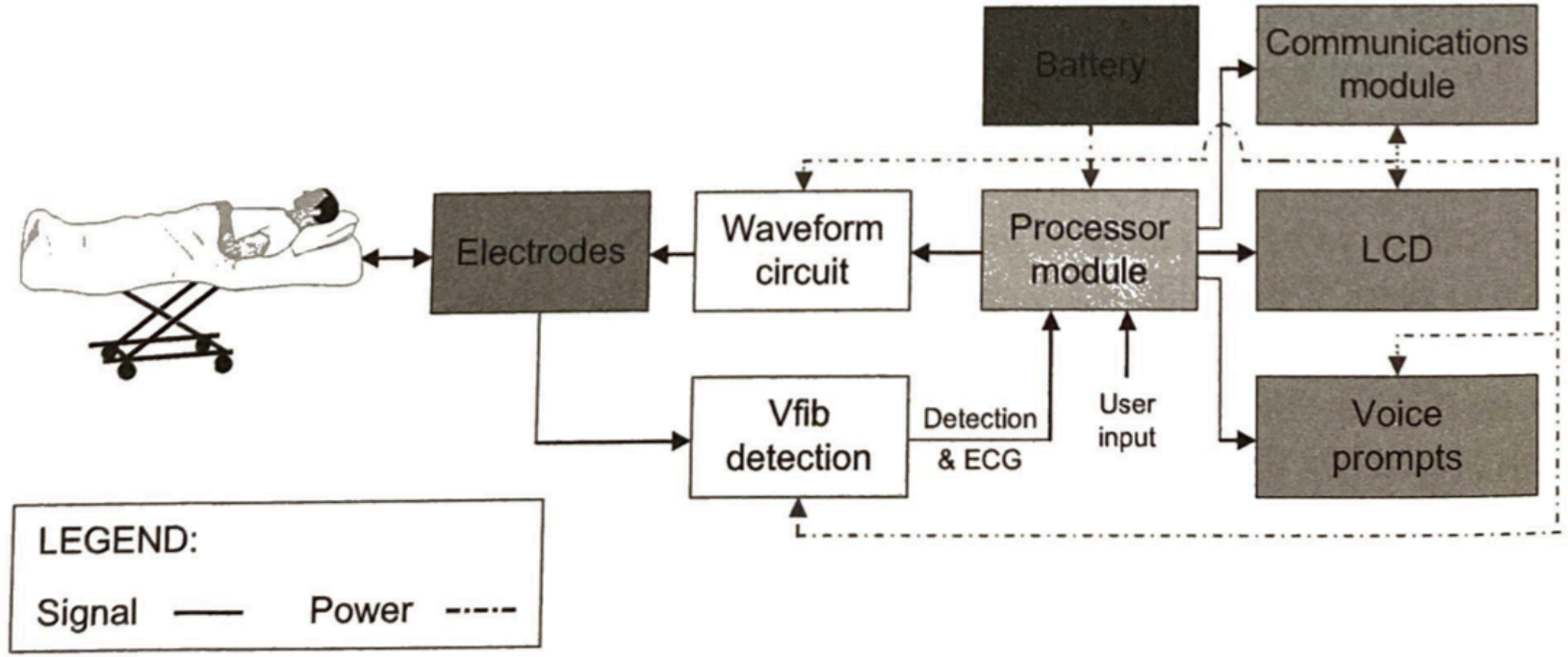
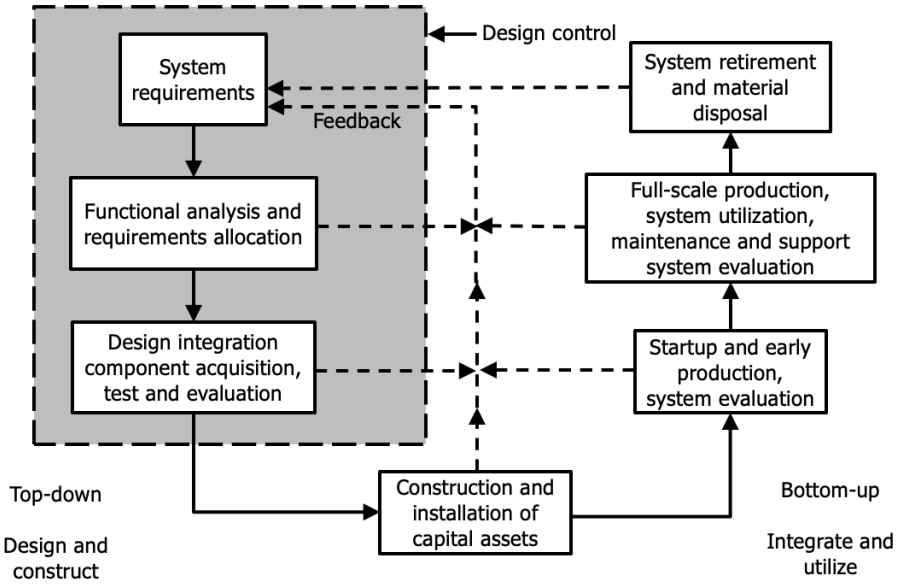


FIGURE 4.11

Automated external defibrillator system diagram.

Big Ideas

- Medical device system designed from top-down and implemented bottom-up
- System block diagrams help break down system into subsystems and individual components
- Sensors convert measurand into electrical signal



Admin

- Submit Lab 1 deliverables in Canvas by next lab day at midnight