ESE3400: Medical Devices Lab

Lec 1: September 6, 2023

Introduction and Medical Platforms/Systems

Where I come from

- Analog VLSI Circuit Design (analog design)
- Convex Optimization (system design)
  - System Hierarchical Optimization
- Biomedical Electronics
- Biometric Data Acquisition (signal processing)
  - Compressive Sampling
- ADC Design (mixed signal)
- Low Energy Circuits (digital design)
  - Adiabatic Charging

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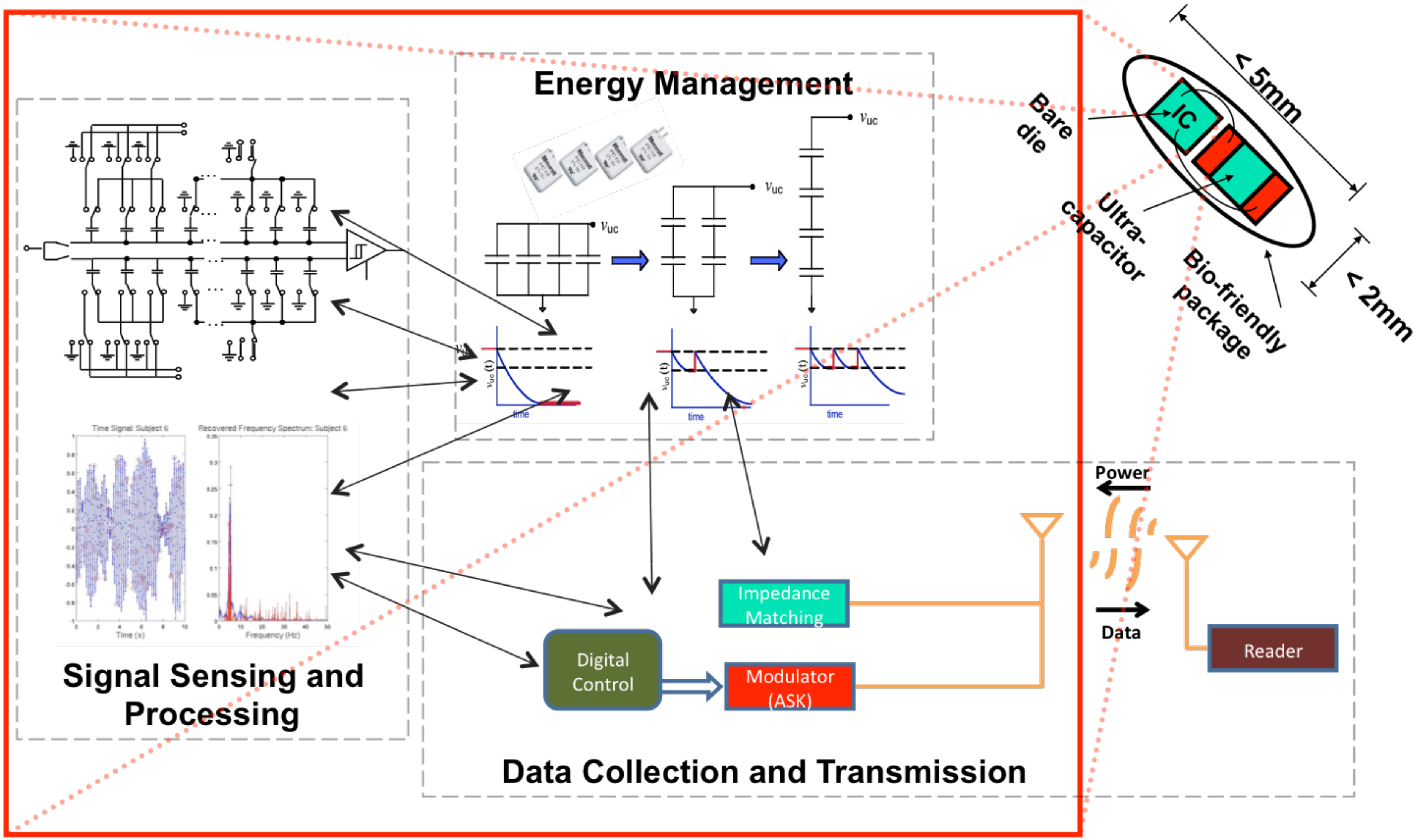
CIRCUITS, CIRCUITS, CIRCUITS

MicroImplant: An Electronic Platform for Minimally Invasive Sensory Monitors



Course Structure: Staff

- Course Staff (complete info on course website)
- Instructor: Tania Khanna (she/her)
  - In person OH: W 1-2:30 pm
  - Or OH by appointment
  - Email: taniak@seas.upenn.edu
    - Best way to reach me

TA Introduction: Henry Love

- Second year ESE PhD Student
  - Advised by Dr. Firooz Aflatouni
  - Current research is in mixed signal electronic-photonic circuits
- Before UPenn, I worked in industry at Cypress Semiconductor (now Infineon Technologies)
- I have a dog named Hank (pictured right)
- I enjoy running, working on hobby projects (current project is a nixie clock), and playing violin

Nixie clock

Where do you come from?

- Background?
- Interest?
- What do you want to learn from this class?

Lecture Outline

- Course Overview
  - Motivating questions and examples
  - What this course is about
  - Learning objectives
  - What you need to know
- Course Details
  - Course structure
  - Course policies
  - Course content

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

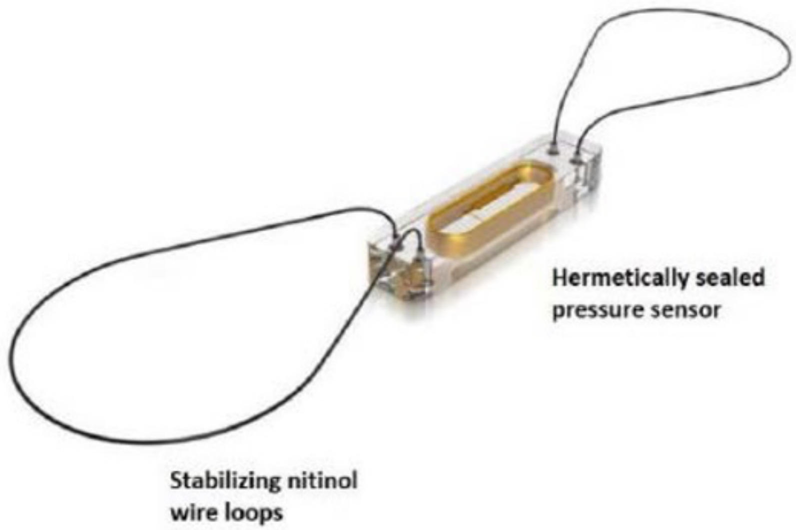
Sample Medical Device

- IV administration set

- Cosmetic filler injection

Electrical Medical Devices

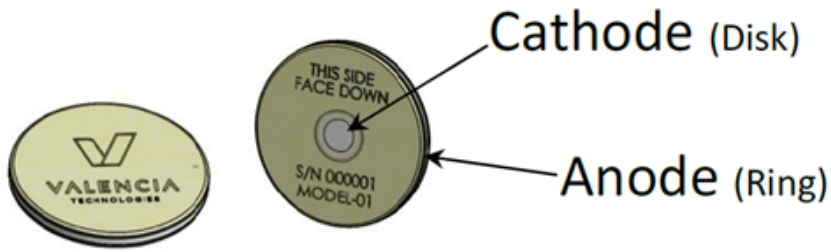
- CardioMEMS HF System



- 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.).

FDA Medical Device Approval

- FDA regulating medical devices since 1938
  - For safety since 1960s…

- List of recently approved medical devices:
  - https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Course Objective

- Acquire a thorough understanding of the basic principles and challenges of medical device design
  - Focus on concepts that are unlikely to expire
  - Preparation for further study of state-of-the-art "fine-tuned" realizations (I.e. Picking the right part for the right problem)
- Strategy
  - Acquire breadth via a complete system walkthrough and a survey of existing medical device systems
  - Acquire depth through hands-on lab based project
    - EKG with wireless communication via Bluetooth

Learning Objectives

- Utilize sensors to monitor biometric signals
- Design differential analog circuitry to acquire and condition biometric signal
- Employ circuitry to digitize and transmit data wirelessly via Bluetooth
- Build and populate a PCB given circuit schematic
- Extract biometrics (eg. Heart rate, respiration, etc.) from discrete-time signal
- Relate time-domain behaviour to frequency domain content of discrete time signals
- Implement simple digital filters
- Complete full system realization in package

Learning Objectives

- In other words…

- Hands on lab experience

What you need to know

- ESE 2150 and ESE 2240 are recommended, but not necessary
- We will cover what we think you need to know broadly

Course Structure: Websites

- Website (http://www.seas.upenn.edu/~ese3400/)
  - Course calendar is used for all handouts (lecture slides, lab handouts, and readings)
  - Canvas used for assignment submission and grades
  - Ed Discussion used for announcements and discussions

ESE3400 Fall 2023 Working Schedule

Wk	Lect.	Date		Lecture	Slides	Due	Reading
1		8/30	W	No Lecture (Will begin after Labor Day)			
2		9/4	M	Labor Day			
	1	9/6	W	Intro/Overview, Biomedical Platforms/Systems			review course webpage completely, 2.2.3
3		9/11	M	Lab 1: Sensors			
	2	9/13	W	Sensing Principle, Physical and Chemical Sensors			2.1.2, 2.2.1.1, 2.2.2, 3.1
4		9/18	M	Lab 2: Filters			
	3	9/20	W	Signal Conditioning, Interface Circuits			3.2-3.4
5		9/25	M	Lab 3: LT SPICE Tutorial			
	4	9/28	W	Electrical Safety and Isolation, Electrocardiogram and Heart Rate			3.4, 2.3
6		10/2	M	Lab 4: Signal Conditioning (Breadboard Level)			
	5	10/4	W	Sampling and Reconstruction, Fourier Transform			4.1-4.2
7		10/9	M	Lab 5: Altium: PCB Layout			

Course Structure: Lectures and Labs

- W 10:15-11:45am Lecture in Detkin
- W 10:15-1:15pm Lecture in Detkin
- Required Attendance
  - Contact me ahead of time for extenuating circumstances
- Individual Labs with deliverables
  - Data with findings and conclusions
  - Demo or video demo

Course Structure: Textbook

- Textbook
  - G. Baura, *Medical Device Technologies,* 2nd Edition, Academic Press, 2020
  - A. V. Oppenheim and R. W. Schafer (with J. R. Buck), *Discrete-Time Signal Processing*. 3rd. Edition, Prentice-Hall, 2010
  - S. Sonkusale, M. S. Baghini, S. Aeron, *Flexible Bioelectronics with Power Autonomous Sensing and Data Analytics*, Springer, 2023
- Not required, but readings on website corresponds to these texts if you want more information/further reading

Course Structure: Labs/Quizzes

- Labs – 11 total [30%]
  - Deliverables due by next lab period
  - Submit/demo in lab or submit in Canvas if more time is needed
- Final demo/presentation – Built-up through labs [40%]
  - Final demos and presentations in last week of class
- Quizes – 2 total [30%]
  - In class

Course Structure: Admin

- Use course calendar
  - Lectures online before class
    - Reserve the right to change them (usually minor)
  - Labs linked
  - Reading for whole term specified
    - Optional, mostly for more information/further reading

Course Policies

- Individual work (HW & Project*)
  - CAD drawings, simulations, analysis, writeups, presentations
  - May discuss strategies, but acknowledge help

Course Content

- Signal Sensing/Conditioning [6 weeks]
- Data conversion/Sampling [3 weeks]
- DSP/Digital Communication [3 weeks]
- CAD Package Design [1 week]

Course Content (con't)

- Signal Sensing/Conditioning
  - Biometric Signals
  - Sensing Principle
  - Signal Conditioning
    - Signal amplification
    - Continuous time filtering
- Labs: sensors, filters, signal conditioning (simulation and bread boarding), PCB design

Course Content (con’t)

- Data conversion/Sampling
  - Delta-Sigma Modulators and SAR ADCs
  - Sampling and reconstruction
  - Compressive Sampling
- Labs: Data convertor characterization

Course Content (con't)

- DSP/Digital Communication
  - Discrete time signals and systems
  - Oversampling and Noise Shaping
  - Digital Filters
  - Wireless communication (Bluetooth)
- Labs: Python DSP labs, Bluetooth communication

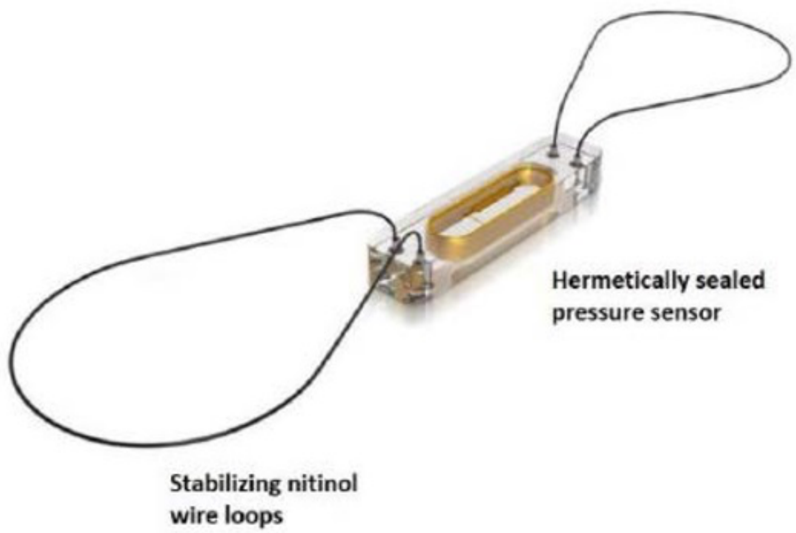
Course Content (con't)

- CAD Package Design
- Lab: Guest by Max Liecthy

Device Platforms

Electrical Medical Devices

- CardioMEMS HF System



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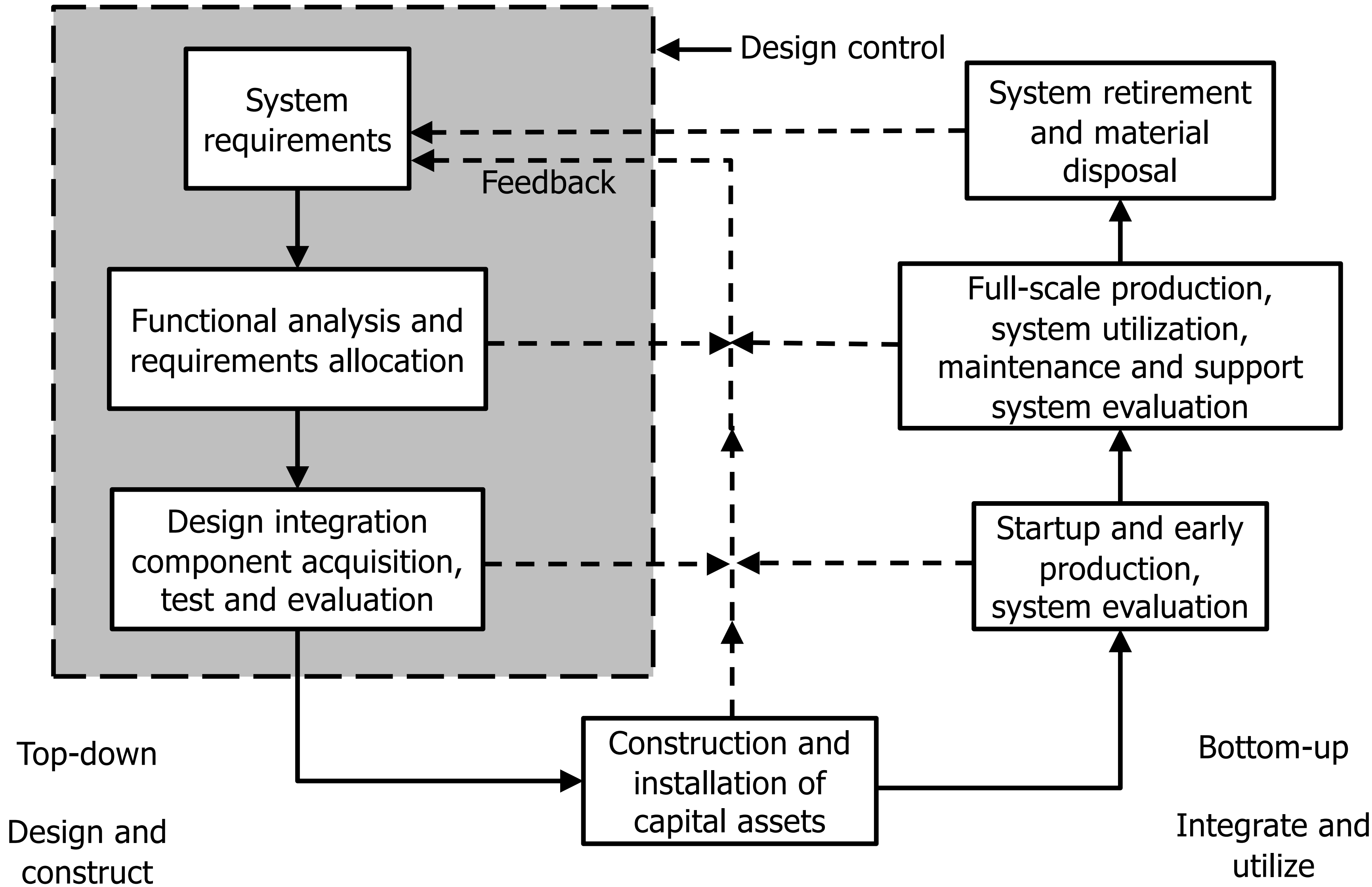
System

- 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

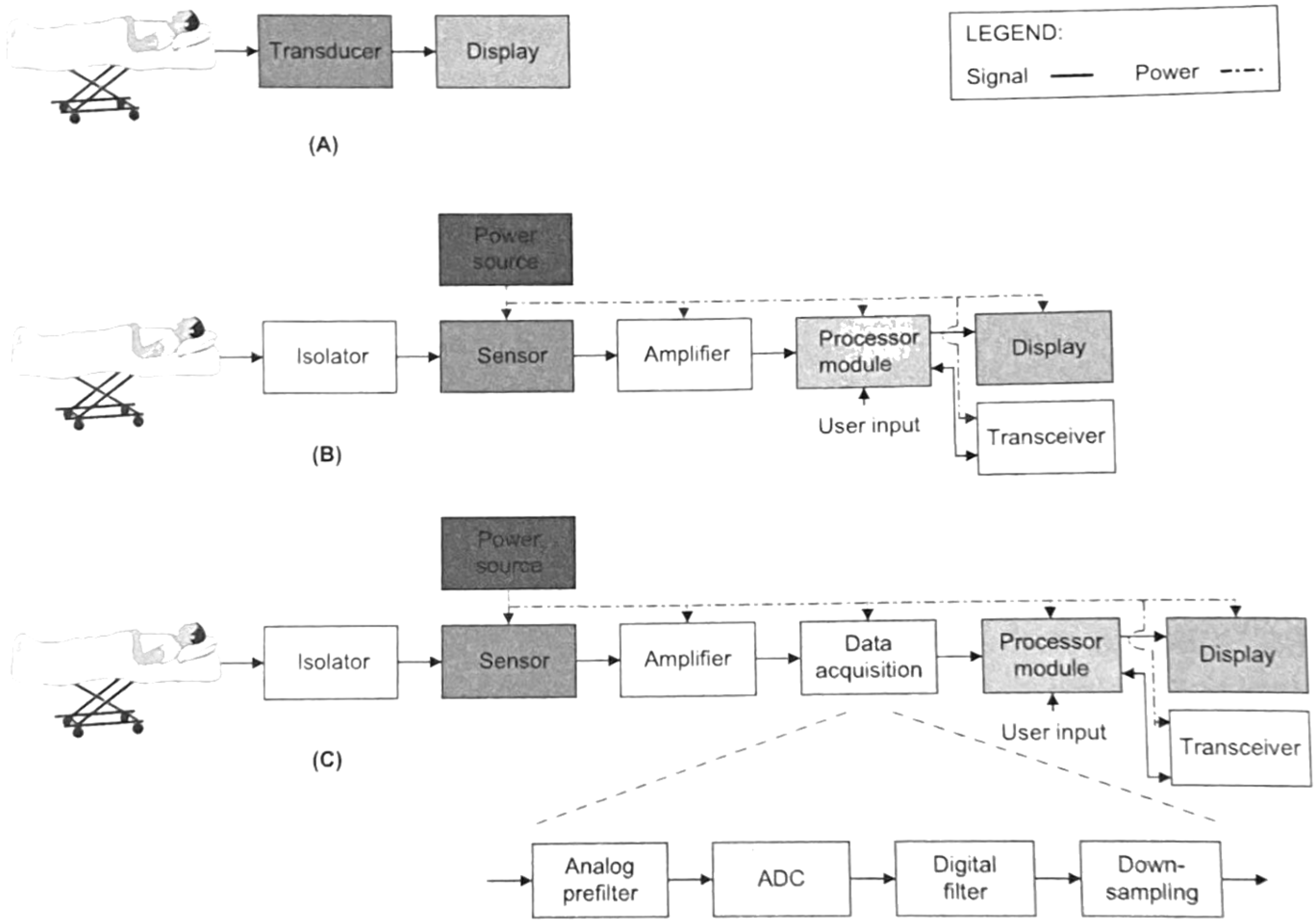


FIGURE 1.1

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

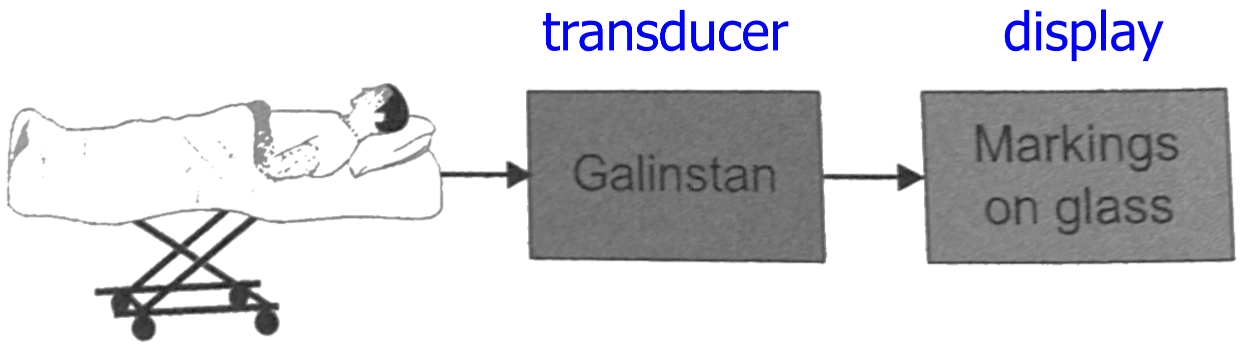
Thermometer Example

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

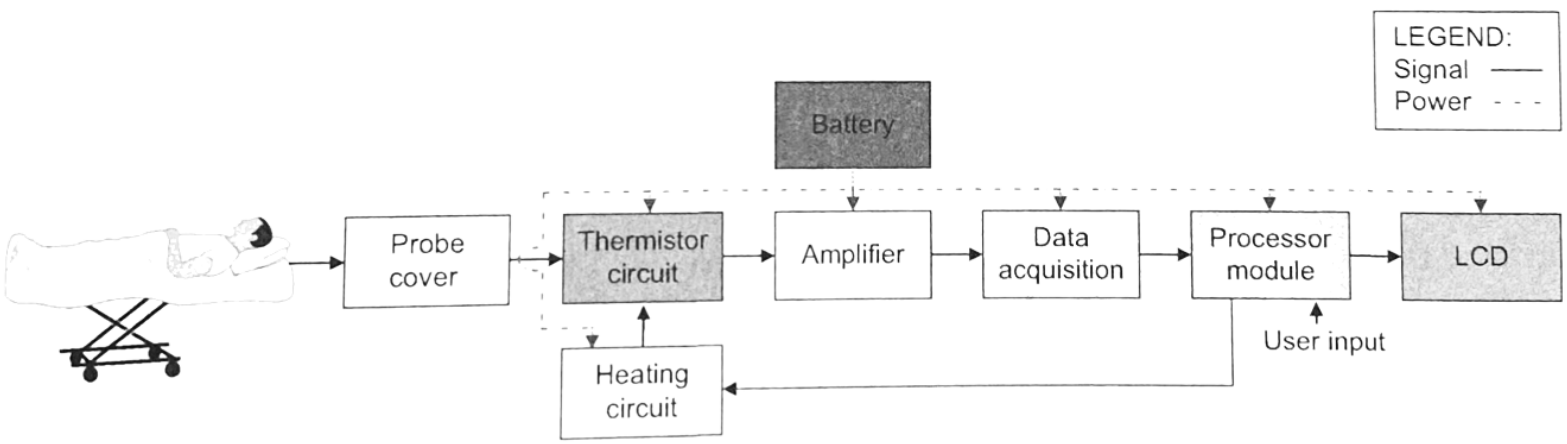
- Digital electronic thermometer
  - Same measurand
  - Sensor called a thermistor, variable resistor based on temperature

Thermometer Example Systems

- Galinstan thermometer



- Digital electronic thermometer



Blood Pressure Measurements

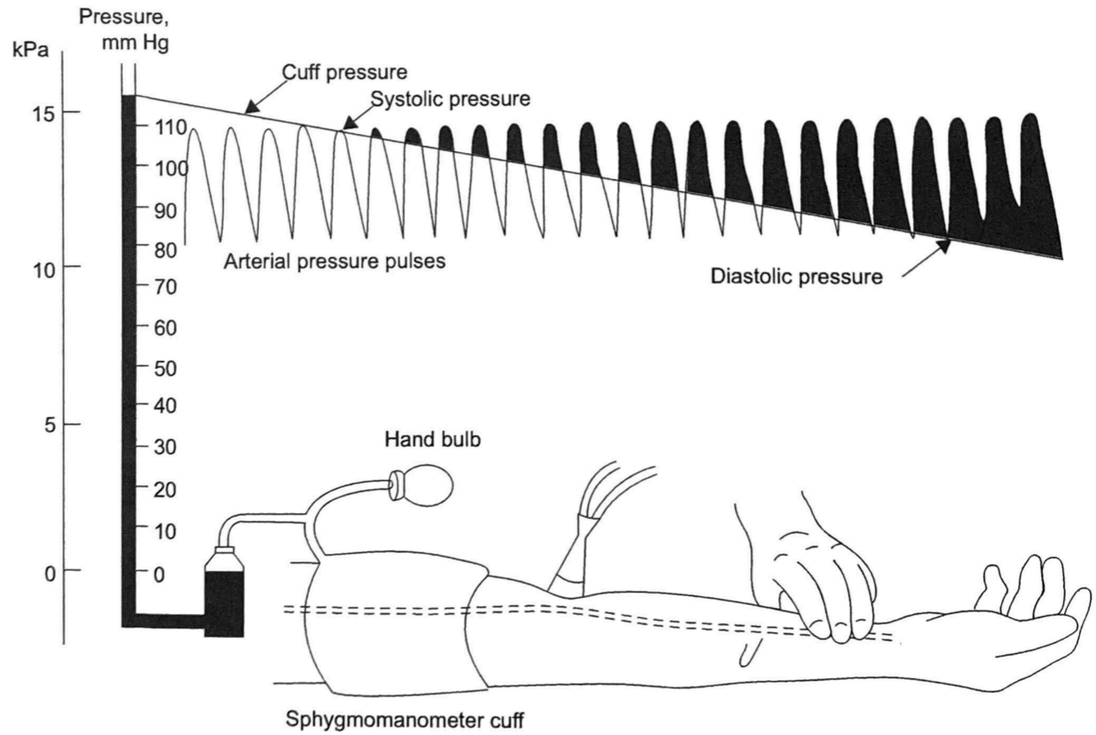
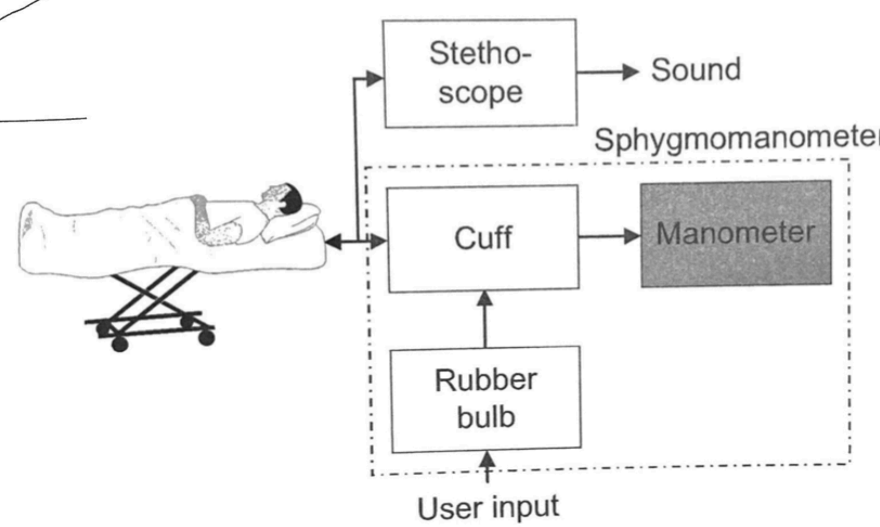


FIGURE 7.6

Auscultation measurement.



Automated BP Measurements

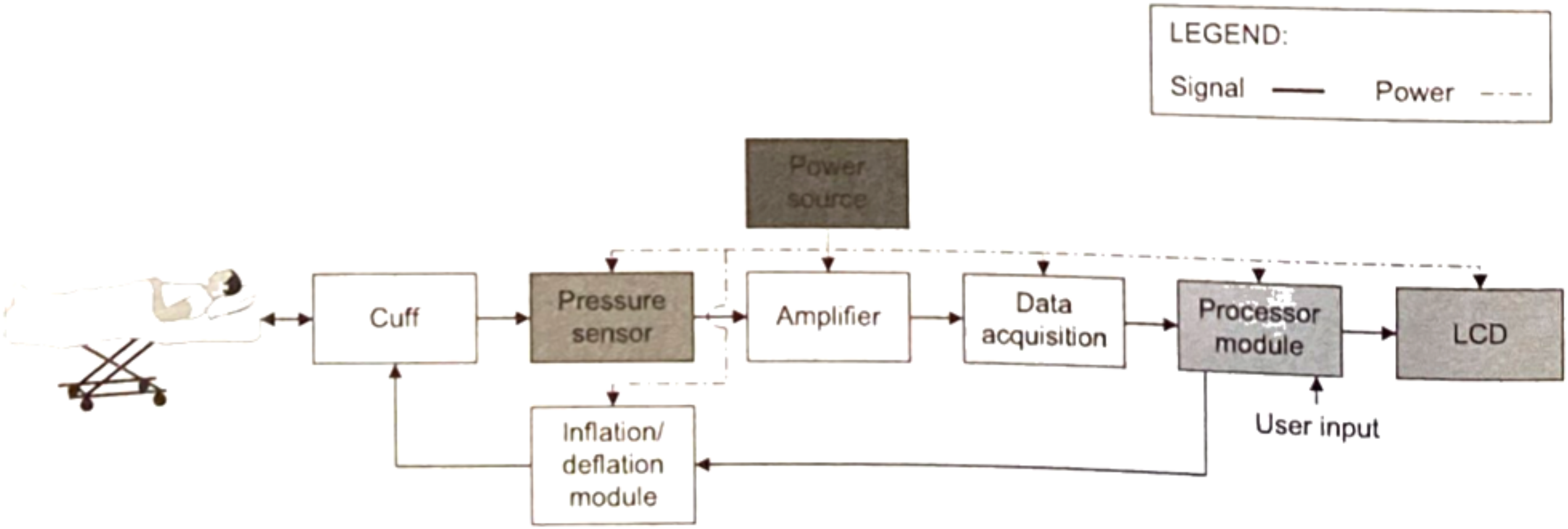


FIGURE 7.10

Oscillometry system diagram.

Automatic Blood Pressure Measurements

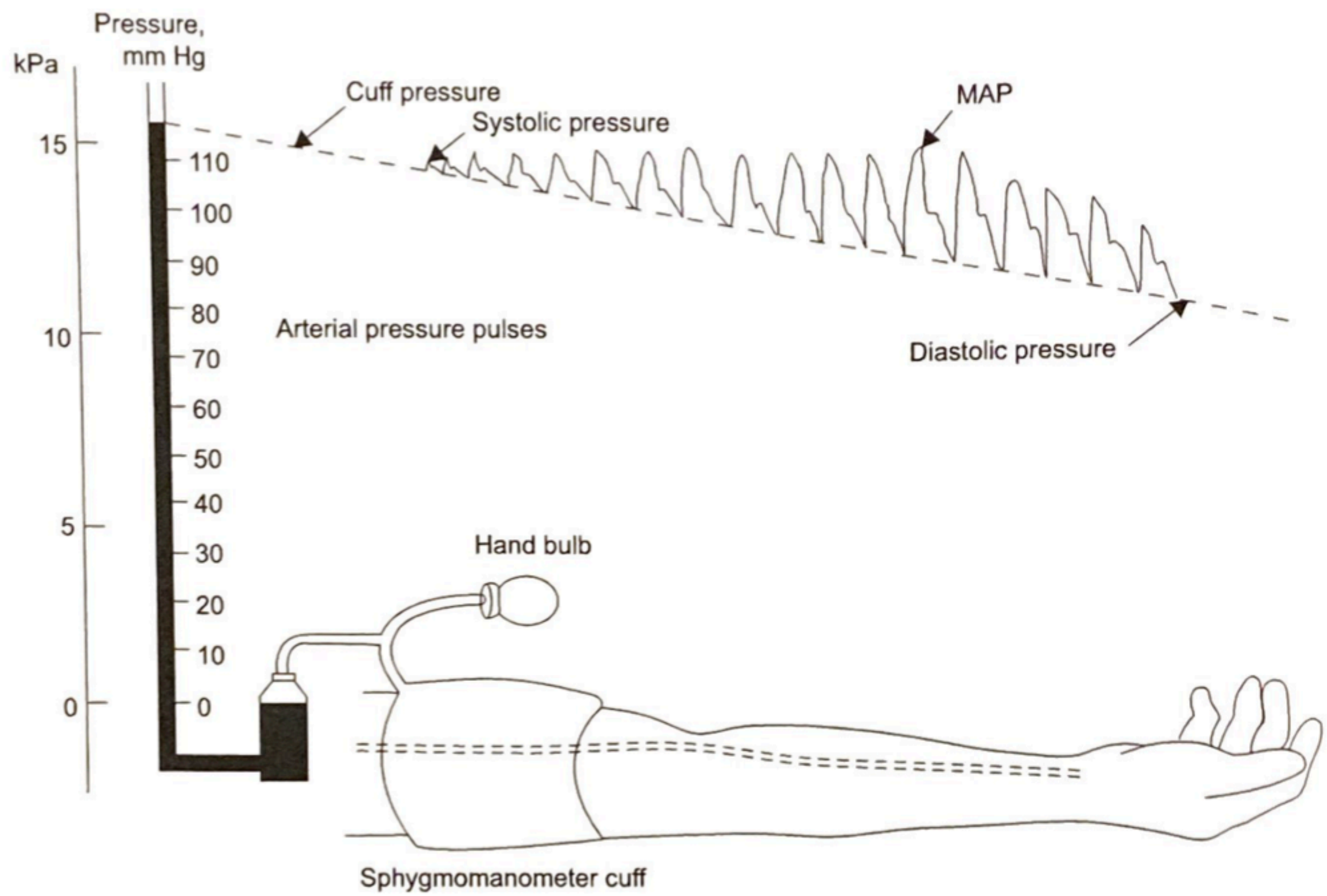


FIGURE 7.9

Oscillometry pressure measurement.

Modified from Rushmer (1970).

Pulse Oximeter System Digram

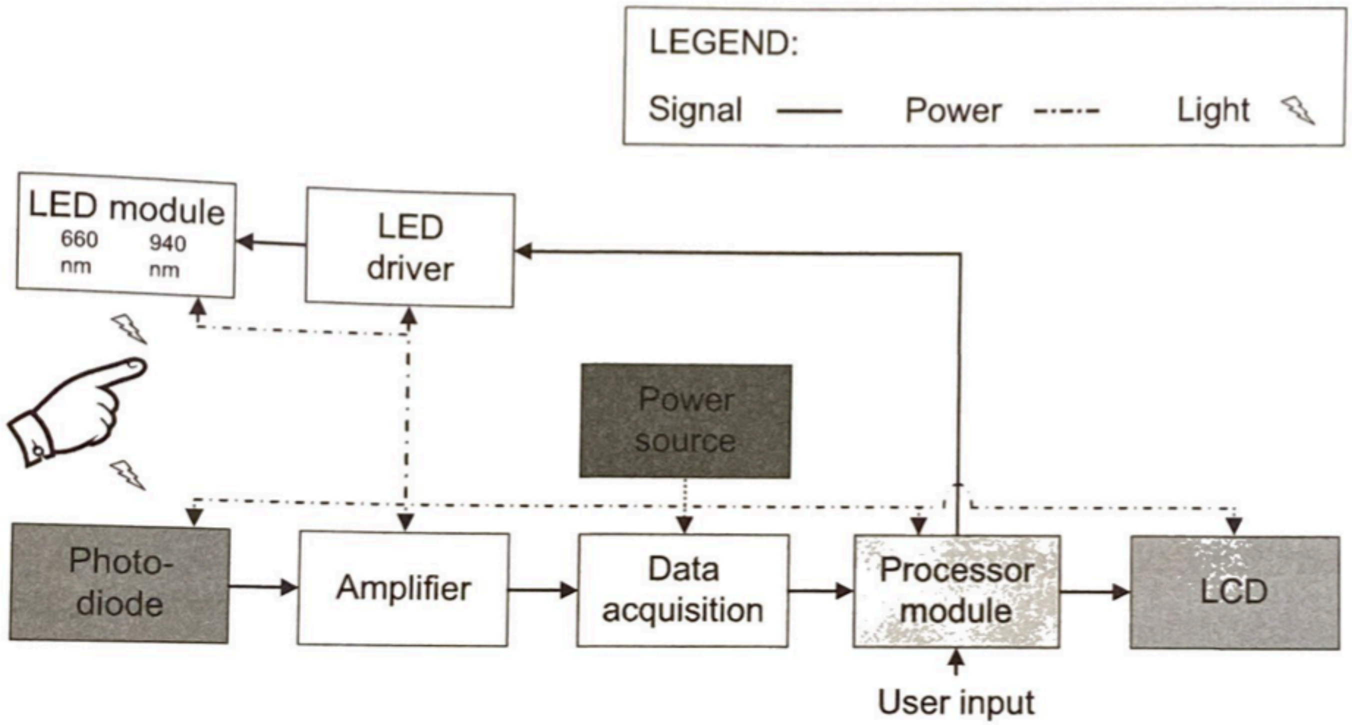
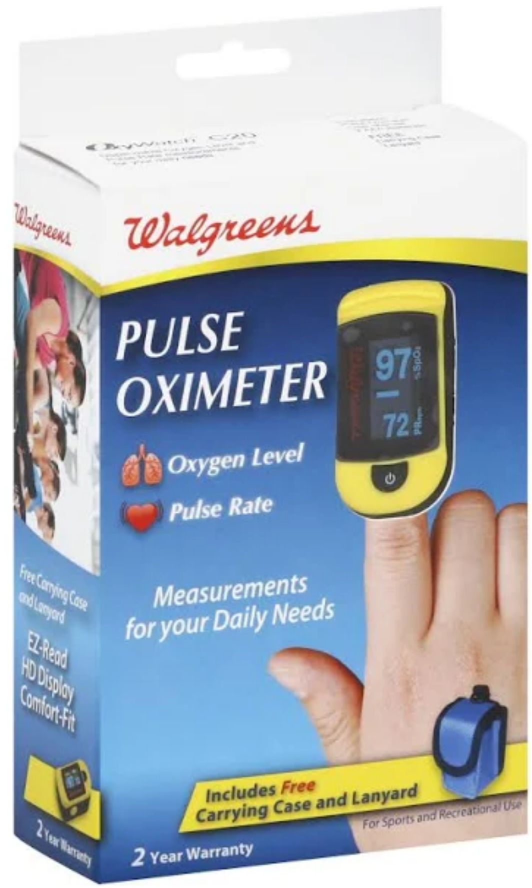


FIGURE 11.13

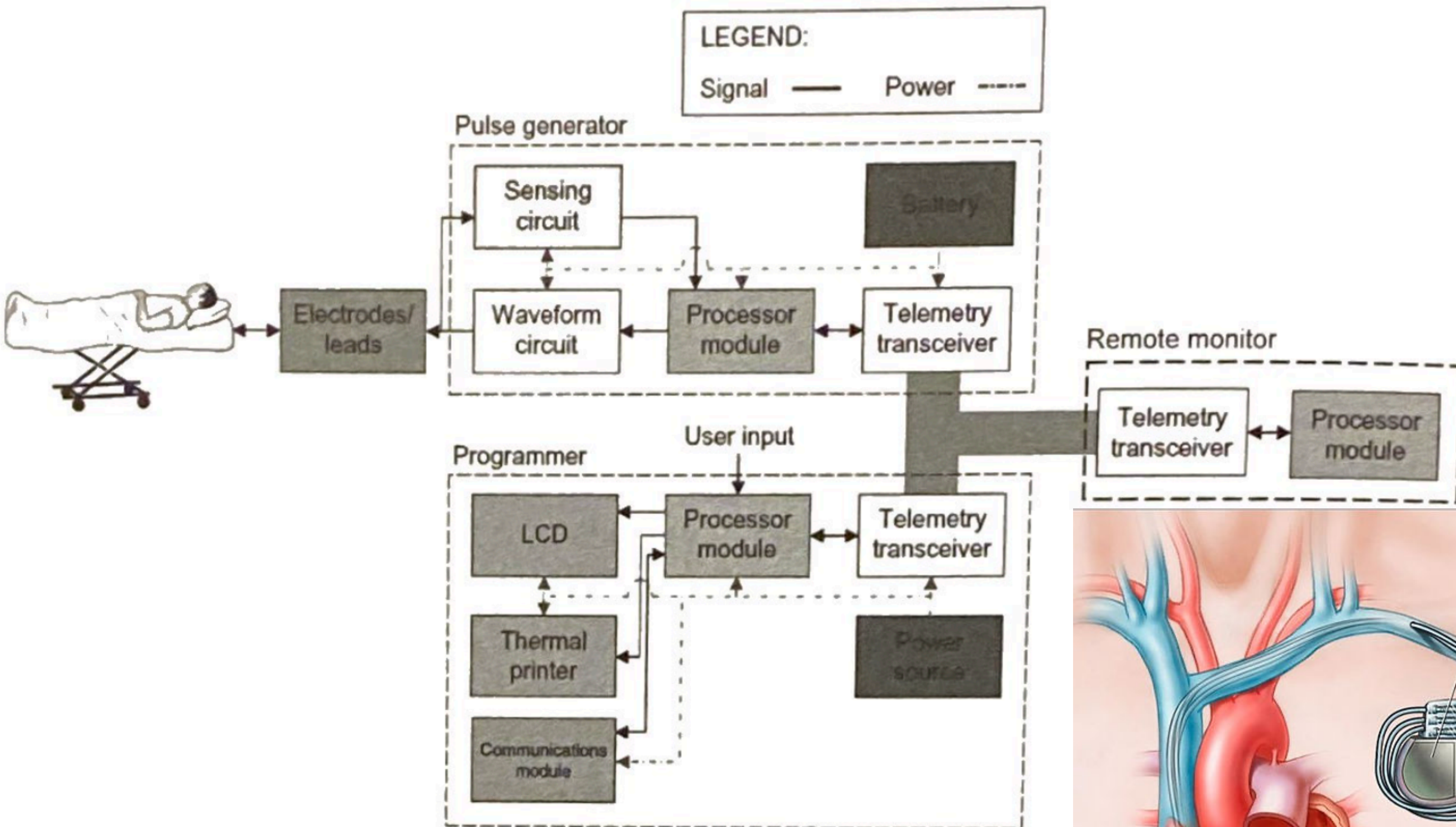
Pulse oximeter system diagram.

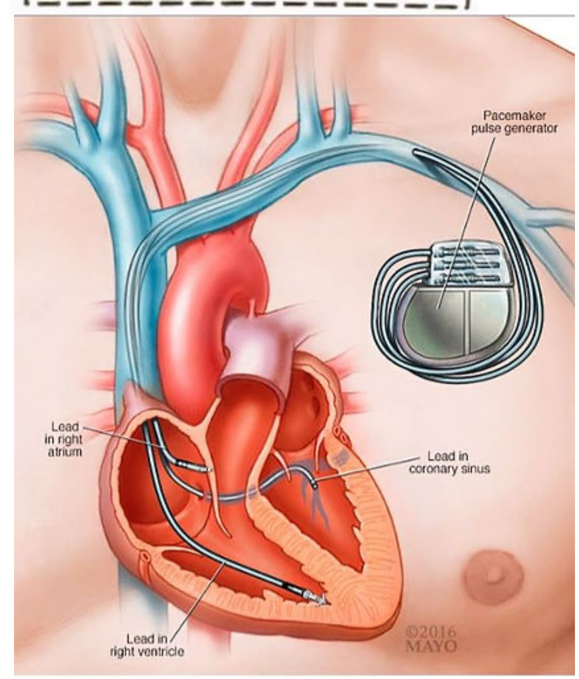
Home Pulse Oximeters

- 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

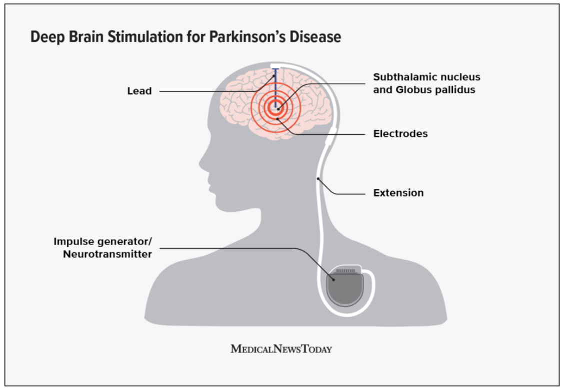


Pacemaker System Diagram





Deep Brain Stimulation System Diagram



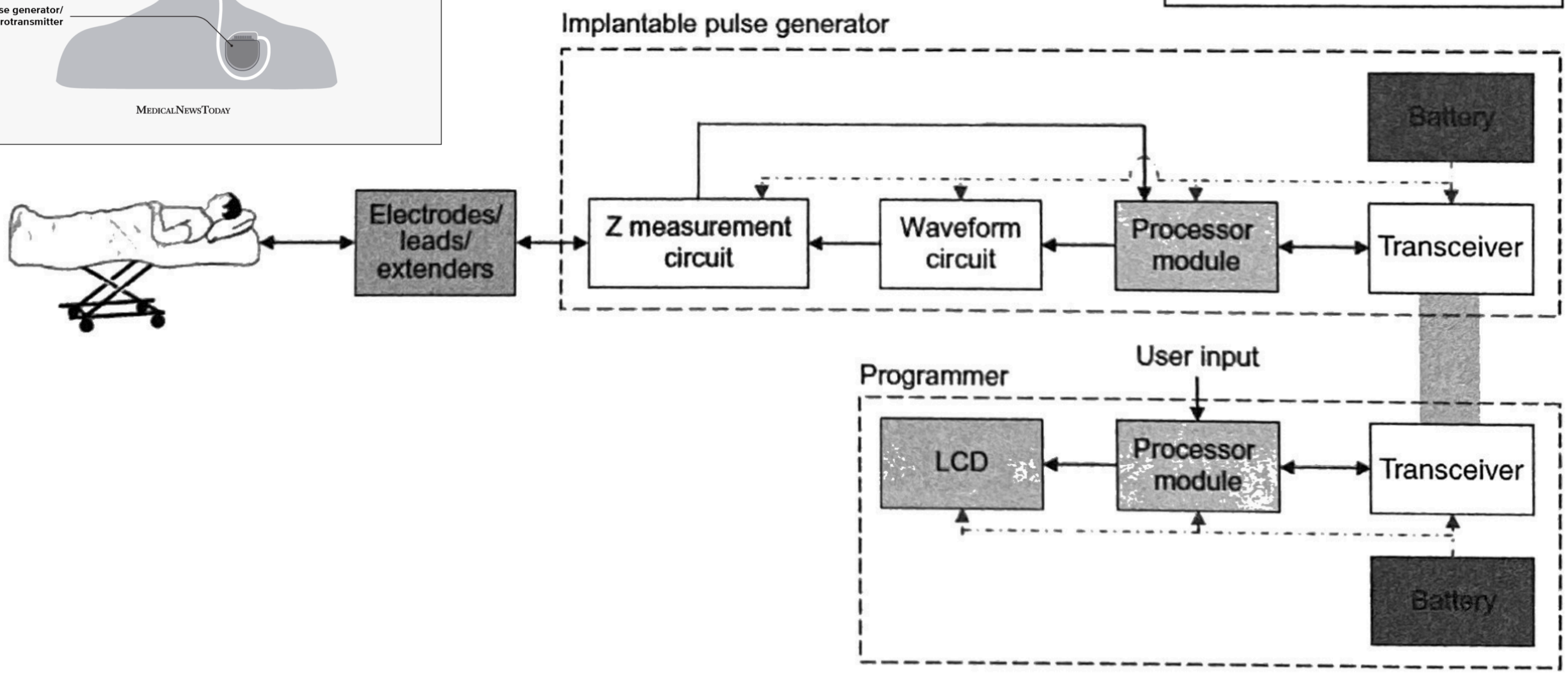


FIGURE 14.9

Deep brain stimulator system diagram.

Cochlear Implant System Diagram

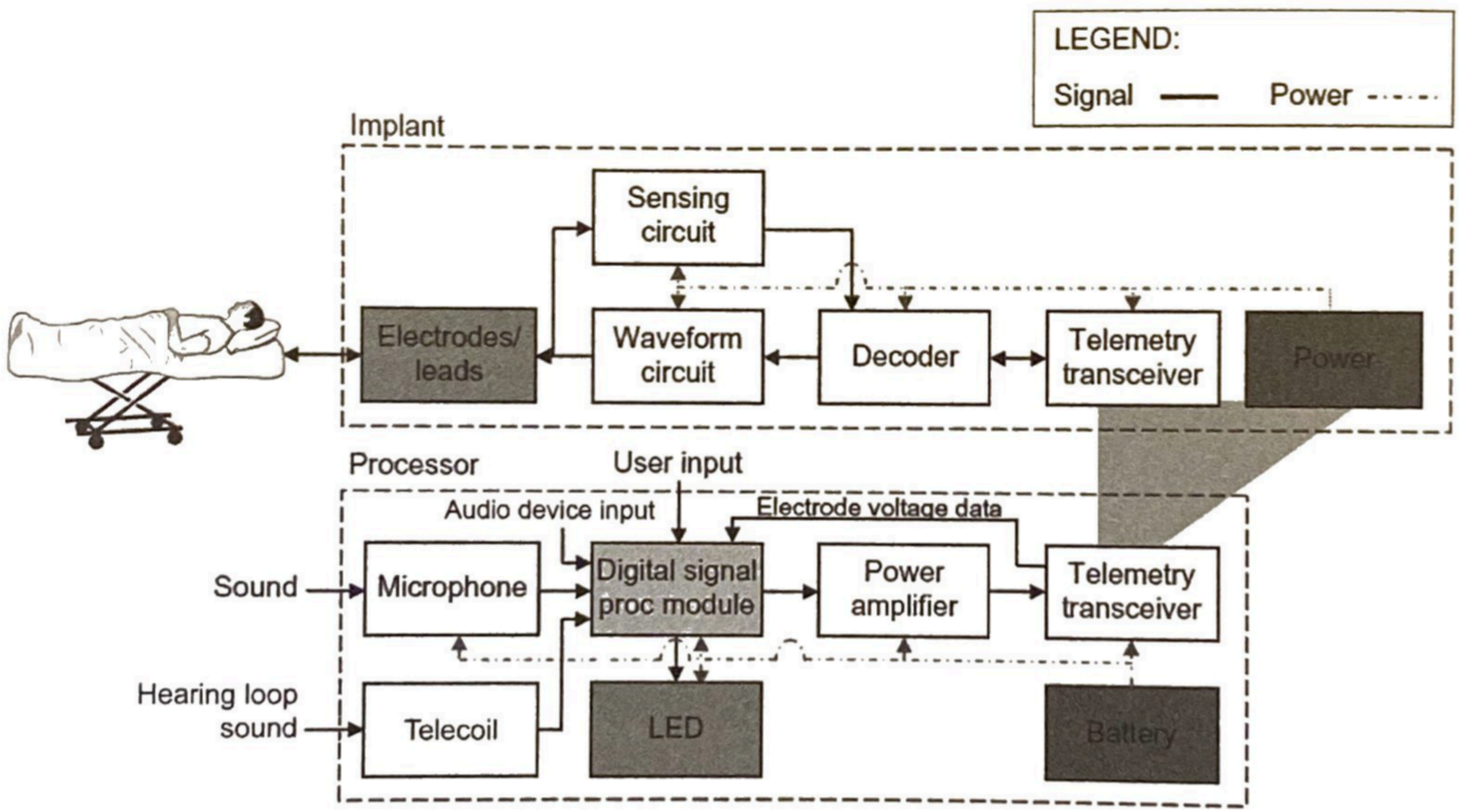


FIGURE 15.15

Cochlear implant system diagram.

Defibrilator System Diagram

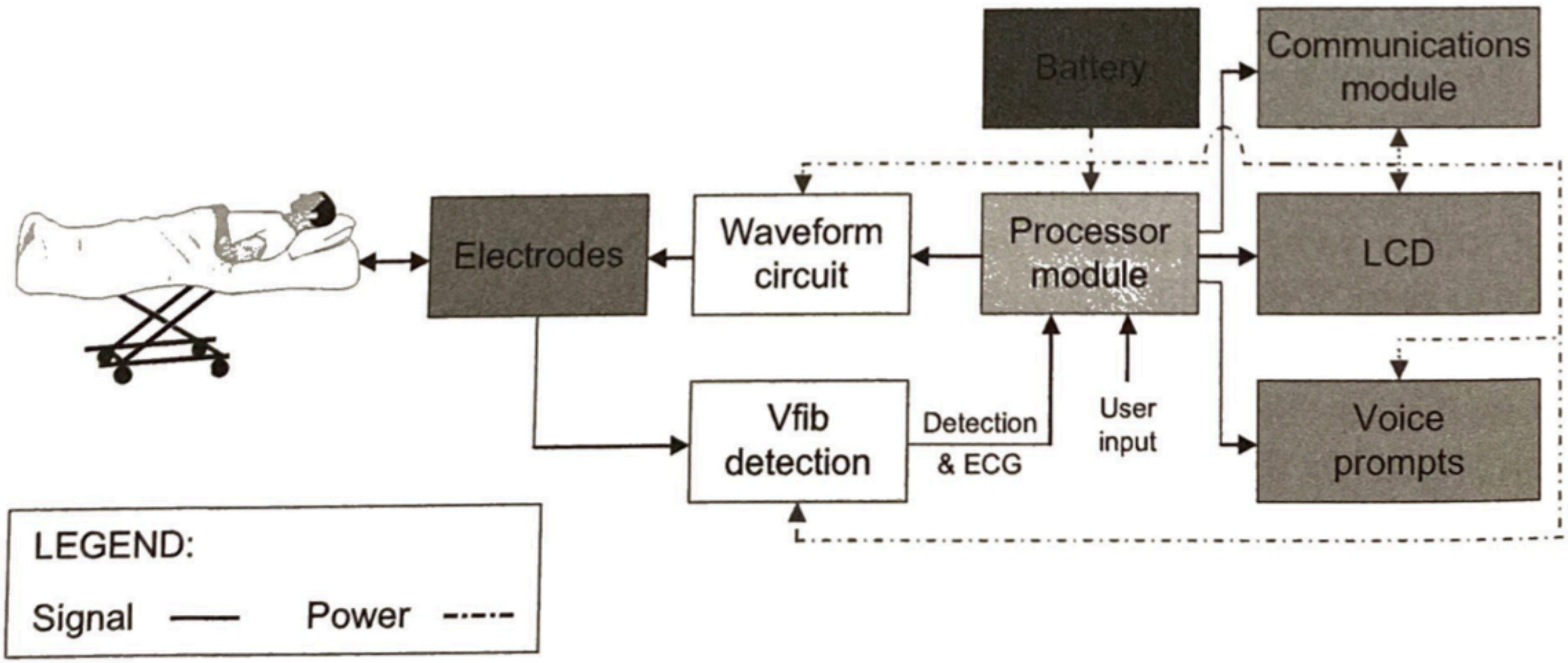


FIGURE 4.11

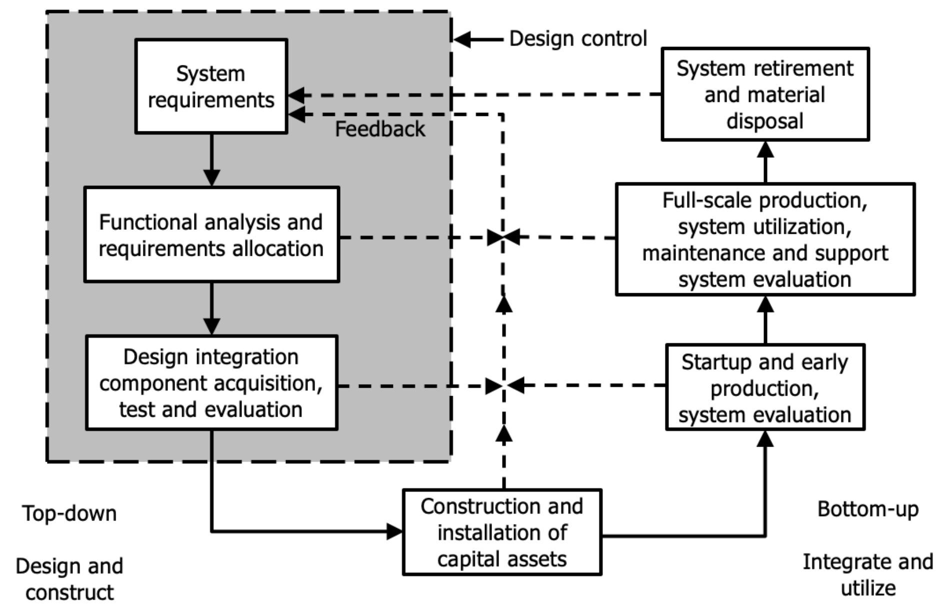
Automated external defibrillator system diagram.

Big Ideas

- Medical devices are used in diagnosis, mitigation, therapy and prevention
  - Broad definition and we will focus on the electrical component

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



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.

Admin

- Find web, get text, assigned reading…
  - http://www.seas.upenn.edu/~ese3400
  - https://edstem.org/us/courses/44876/discussion/
  - https://canvas.upenn.edu/courses/
- To do:
  - Come to lab on Monday!