ROHINI
COLLEGE OF ENGINEERING & TECHNOLOGY
(AUTONOMOUS)
Approved By AICTE & Affiliated to Anna University
NBA Accredited for All Eligible B.E/B.Tech Programs | NAAC Accredited with A+ Grade
Near Anjugramam - Kanyakumari Main Road, Palkulam, Variyoor P.O.-629401, Kanyakumari Dist, Tamil Nadu.

DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

BIOMEDICAL DEVICE DESIGN

UNIT- I INTRODUCTION TO BIOMEDICAL DEVICE DESIGN AND CLINICAL NEED IDENTIFICATION

1.1 Overview of Biomedical Devices and Healthcare Technology:

➢ Introduction

Biomedical engineering applies the principles of engineering, physics, electronics, materials science and computing to problems in biology and medicine. The most visible output of this discipline is the **biomedical (medical) device**: a product that helps clinicians to diagnose, monitor, treat or prevent disease, or that helps a person with an injury or disability to live more independently. Examples range from a simple clinical thermometer and a crepe bandage to a cardiac pacemaker, an MRI scanner or a surgical robot.

Definition (based on WHO / IMDRF / India Medical Devices Rules, 2017)

A **medical device** is any instrument, apparatus, implant, machine, appliance, in-vitro reagent, software or related article intended by its manufacturer, alone or in combination, for human use for one or more of these purposes: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of anatomy or of a physiological process; (iv) support or sustaining of life; (v) control of conception; (vi) disinfection of medical devices. Its principal action is **not** achieved by pharmacological, immunological or metabolic means (this is what separates a device from a drug).

➢ Medical device versus drug

Table 1.1 Distinguishing a medical device from a drug

Aspect	Medical Device	Drug (Pharmaceutical)
Principal mode of action	Physical, mechanical, electrical, optical or thermal action	Pharmacological, immunological or metabolic action
Examples	Stethoscope, ECG machine, stent, glucometer, hearing aid	Paracetamol, insulin, antibiotics, vaccines
Design basis	Engineering, materials, electronics, software	Chemistry, biology, pharmacokinetics
Development time	Typically 2-7 years; iterative design changes common	Typically 10-15 years; fixed molecular entity
Clinical evidence	Depends on risk class; low-risk devices may need little or none	Phase I-III clinical trials almost always required

Aspect	Medical Device	Drug (Pharmaceutical)
Regulation (India)	Medical Devices Rules, 2017 (CDSCO)	Drugs and Cosmetics Act, 1940 and Rules, 1945
Life of product	Short cycles; frequent upgrades (software, sensors)	Long; changes require fresh approval

➢ **Scope of healthcare technology**

Healthcare technology is a broader term than medical devices. It covers every tool, system or knowledge-based solution that is applied to improve the health of individuals and populations. Biomedical devices form its hardware core, but they now work alongside software, data and services.

- **Medical devices and equipment:** diagnostic, therapeutic, monitoring, surgical, implantable and assistive products.
- **In-vitro diagnostics (IVD):** reagents, analyzers and rapid tests that examine samples such as blood and urine outside the body.
- **Digital health:** mobile health apps, telemedicine, electronic health records (EHR), remote patient monitoring and Software as a Medical Device (SaMD).
- **Health information technology:** hospital information systems, PACS (picture archiving and communication system), interoperability standards such as HL7 FHIR.
- **Biotechnology and biomaterials:** tissue-engineered products, biosensors, bioresorbable materials, drug-device combination products.
- **Emerging technology:** artificial intelligence, robotics, 3D printing, nanotechnology, wearable and implantable electronics, digital twins.

➢ **Functional block diagram of a biomedical device**

Almost every electronic medical device can be understood as a chain of functional blocks that sense a physiological quantity, condition it, convert it into data, process it and present or act on the result. Therapeutic devices add an actuator that delivers energy or a substance to the patient and may close the loop through feedback.

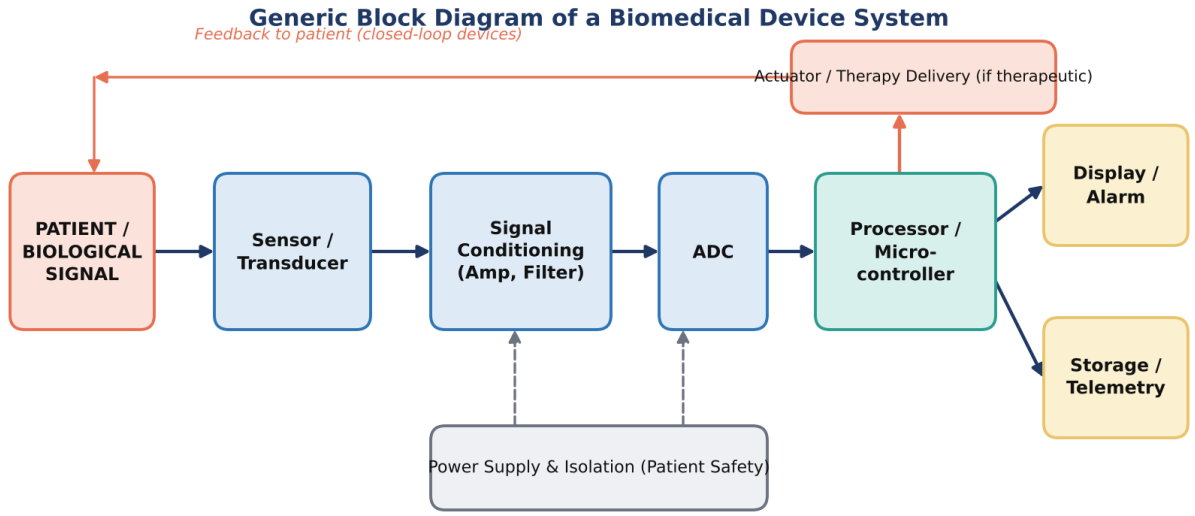

Fig. 1.1 Generic block diagram of a biomedical device system

Table 1.2 Functional blocks of a biomedical device

Block	Function	Typical Examples
Sensor / transducer	Converts a physiological quantity (pressure, light, potential, temperature) into an electrical signal	ECG electrodes, strain-gauge pressure sensor, photodiode, thermistor
Signal conditioning	Amplifies the weak bio-signal, removes noise and interference, provides isolation	Instrumentation amplifier, band-pass filter, notch filter (50 Hz)
ADC	Converts the conditioned analog signal into digital samples	12-bit or 24-bit sigma-delta ADC
Processor	Performs algorithms, control logic, decision making and communication	Microcontroller, DSP, FPGA, SoC running embedded software
Display / alarm	Presents information to the user and warns about abnormal conditions	LCD, waveform display, audible alarm, haptic alert
Storage / telemetry	Records and transmits data to other systems	SD card, Bluetooth Low Energy, Wi-Fi, HL7 interface
Actuator / therapy unit	Delivers energy, drug or mechanical action to the patient	Pump motor, defibrillator capacitor, laser, stimulator output stage
Power and safety	Provides regulated power, patient isolation and protection against electric shock	Medical-grade SMPS, isolation transformer, battery, fuses

➢ Categories of biomedical devices

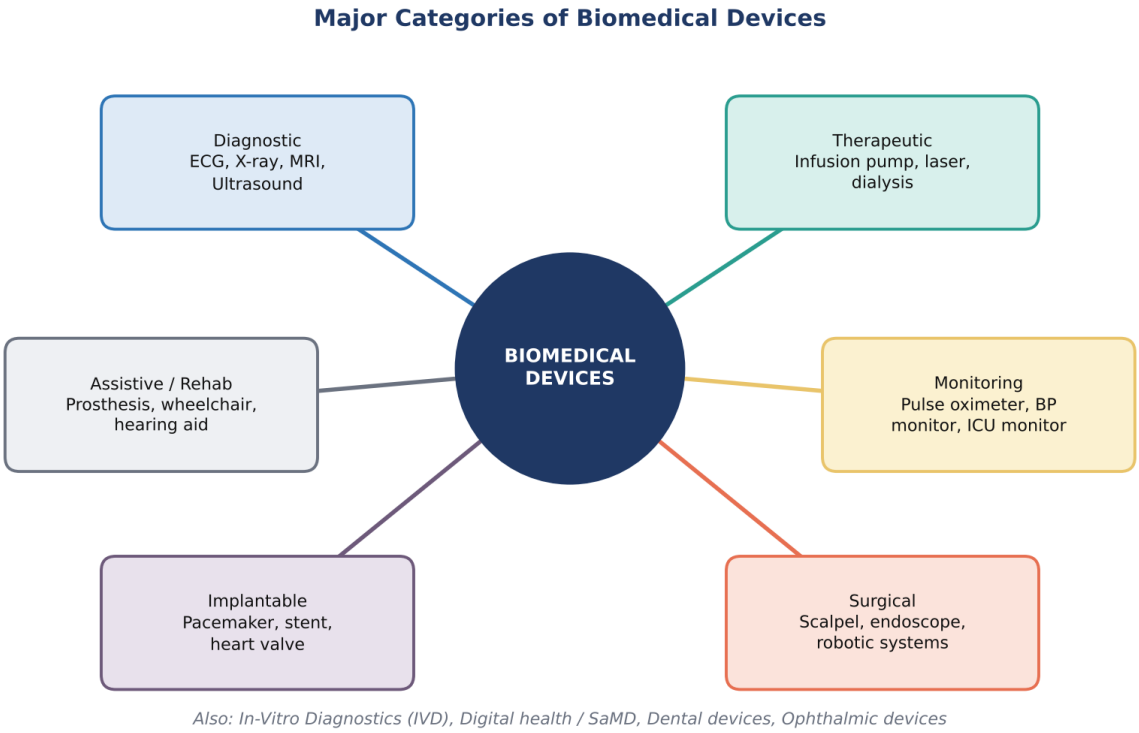

Fig. 1.2 Major categories of biomedical devices

Table 1.3 Categories of biomedical devices with examples

Category	Purpose	Examples
Diagnostic	Identify or confirm a disease, injury or physiological state	X-ray, CT, MRI, ultrasound, ECG, EEG, endoscope, glucometer
Therapeutic	Treat or manage a condition by delivering energy, drug or mechanical support	Infusion pump, ventilator, dialysis machine, defibrillator, laser, insulin pump
Monitoring	Continuously observe vital signs and trigger alarms	Pulse oximeter, patient monitor, BP monitor, capnograph, Holter monitor
Surgical	Assist in performing operations safely and precisely	Electrosurgical unit, laparoscope, surgical robot, bone saw, surgical navigation
Implantable	Remain inside the body for long duration to replace or support a function	Pacemaker, ICD, cochlear implant, heart valve, stent, joint prosthesis
Assistive and rehabilitation	Restore or compensate lost function and improve independence	Artificial limb, wheelchair, hearing aid, exoskeleton, walker
In-vitro diagnostic (IVD)	Test samples taken from the body	Haematology analyzer, rapid test kits, PCR systems, urine strips
Software / digital	Software with a medical purpose	AI for radiology reading, ECG interpretation app, insulin dose calculator

➢ Evolution of biomedical devices

Table 1.4 Milestones in the evolution of medical devices

Period	Milestone	Significance
1816	Stethoscope (Laennec)	First acoustic device for auscultation; began non-invasive diagnosis
1895	X-rays (Roentgen)	Allowed internal structures to be imaged without surgery
1903	ECG (Einthoven)	Quantitative recording of the heart's electrical activity
1940s-50s	Dialysis, heart-lung machine, external pacemaker	Machines could temporarily replace organ function
1958-60s	Implantable pacemaker	Beginning of long-term active implants
1970s	CT and MRI	Cross-sectional imaging of soft tissue; computing joins medicine
1980s-90s	Pulse oximetry, laparoscopy, programmable pumps	Non-invasive monitoring and minimally invasive surgery
2000s	Robotic surgery, telemedicine, drug-eluting stents	Precision, remote care and combination products
2010s-today	Wearables, smartphone diagnostics, AI-based SaMD, 3D-printed implants, IoMT	Personalised, connected and data-driven healthcare

➢ Healthcare technology ecosystem

A medical device never works in isolation. It is designed, approved, purchased, used and maintained within a network of stakeholders. A designer who ignores any of them risks building a technically good product that is never adopted.

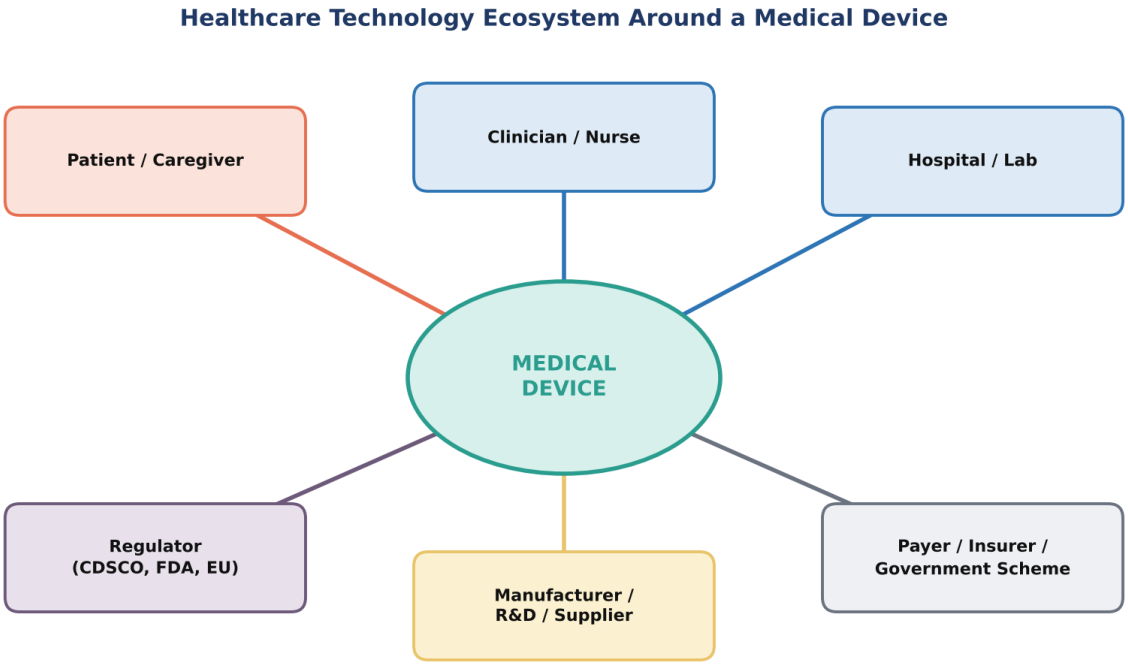

Fig. 1.3 Healthcare technology ecosystem around a medical device

Table 1.5 Stakeholders and what each expects from a device

Stakeholder	Role	Key expectation
Patient / caregiver	End beneficiary or user (especially for home-use devices)	Safety, comfort, ease of use, affordability, privacy
Clinician / nurse / technician	Operates the device and interprets results	Accuracy, workflow fit, minimal training, reliability
Hospital / laboratory	Buys, installs and maintains equipment	Cost of ownership, service support, integration with IT systems
Manufacturer / R&D	Designs, produces and supports the device	Market size, regulatory clarity, manufacturability, profit
Regulator	Approves devices and monitors safety (CDSCO, US FDA, EU notified bodies)	Evidence of safety and performance; quality system
Payer / government	Insurance companies, schemes such as Ayushman Bharat	Clinical and economic benefit; reimbursement justification

➢ **Current trends in healthcare technology**

- ❖ **Connected and wearable devices:** continuous monitoring outside the hospital using patches, watches and rings.
- ❖ **Artificial intelligence:** automated image reading, arrhythmia detection, risk prediction; regulated as SaMD.
- ❖ **Minimally invasive and robotic procedures:** smaller incisions, shorter stay, higher precision.
- ❖ **Point-of-care testing:** laboratory-quality tests at the bedside, clinic or home.

- **Personalised devices:** 3D-printed implants, patient-specific guides and prostheses.
- **Telehealth and home care:** devices must be safe for lay users without clinical supervision.
- **Cybersecurity and data privacy:** connected devices must be protected throughout their life.

➢ **Indian scenario**

India is a large and growing medical device market, but a significant share of high-end equipment (imaging, implants, advanced diagnostics) is imported, while the country is strong in consumables and low-cost devices. Several policy steps aim to build domestic design and manufacturing capability.

- **Medical Devices Rules, 2017:** a separate, risk-based regulatory framework administered by the Central Drugs Standard Control Organisation (CDSCO).
- **National Medical Devices Policy, 2023:** promotes domestic manufacturing, skill development, research and a single-window regulatory environment.
- **Production Linked Incentive (PLI) scheme and Medical Device Parks:** financial incentives and shared infrastructure for manufacturers.
- **Ayushman Bharat (PM-JAY and Health and Wellness Centres) and Ayushman Bharat Digital Mission:** create demand for affordable devices and digital health records.
- **Frugal innovation:** locally designed low-cost products (for example the Jaipur foot and low-cost infant warmers) show how design can fit resource-limited settings.

➢ **Role of the biomedical engineer in device design**

- ✓ Identify real clinical problems by working with doctors, nurses and patients.
- ✓ Translate clinical needs into measurable engineering requirements.
- ✓ Design, prototype, test and document the device in compliance with standards.
- ✓ Ensure safety through risk management and usability engineering.
- ✓ Support regulatory submission, clinical evaluation, manufacturing transfer and post-market feedback.

Remember

Exam tip: A 16-mark answer on "overview of biomedical devices" should include (1) definition, (2) functional block diagram, (3) classification by purpose with examples, (4) healthcare technology ecosystem and (5) current trends. Draw at least one neat labelled block diagram.