DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

24BM501 BIOMEDICAL DEVICE DESIGN

UNIT- III WEARABLE, IoT AND AI-ENABLED MEDICAL DEVICES

Wearable Healthcare Technologies:

Introduction and Definition

Wearable healthcare technologies are small, light-weight, battery-powered electronic devices that are **worn on the body** (on the wrist, finger, chest, head, in clothes) or are **attached to or placed inside the body** and that continuously measure physiological, biochemical or motion signals, process them and communicate the results wirelessly to the user, a smartphone or a clinician.

> **Definition:** A **wearable health device** is a body-worn or body-attached sensing system that unobtrusively and continuously monitors a person's health parameters (heart rate, ECG, SpO_2, temperature, glucose, activity, sleep, etc.), processes the data locally or remotely, and provides feedback or alerts for health management and clinical decision-making.

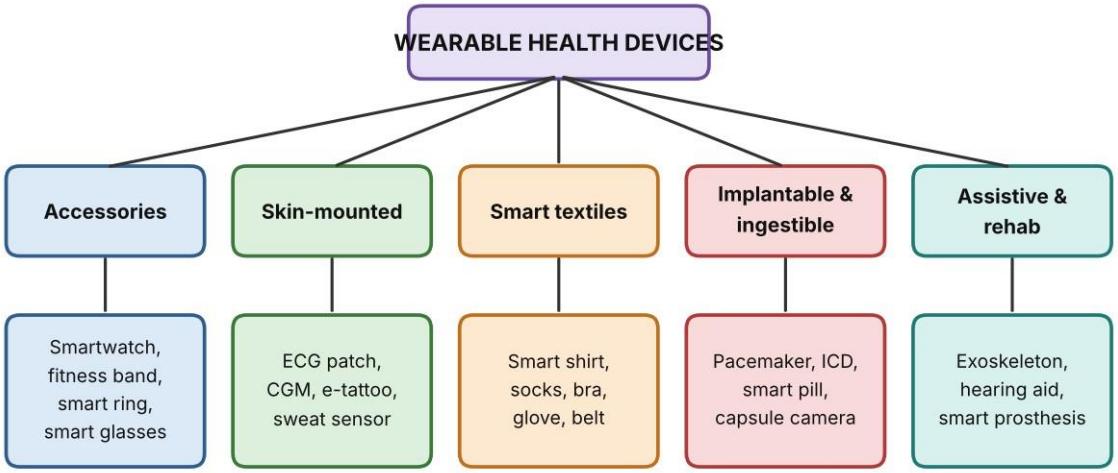
Wearables bridge **wellness devices** (fitness trackers for the general public) and **medical-grade devices** (cleared by regulators for diagnosis or monitoring). A device is regulated as a medical device only when it makes a medical claim, for example "detects atrial fibrillation".

Evolution of Wearable Health Technology

- **Early stage:** mechanical pedometers and the Holter monitor (1940s-1960s), a bulky portable ECG recorder worn for 24-48 hours.
- **1990s-2000s:** pulse oximeters, wrist-type BP monitors, first wireless heart-rate chest straps.
- **2010s:** MEMS accelerometers, optical heart-rate sensors and Bluetooth Low Energy led to consumer fitness bands and smartwatches.
- **Late 2010s onwards:** regulator-cleared features such as smartwatch ECG and irregular-rhythm notification, CGM patches, smart rings, e-textiles.
- **Present and future:** multi-sensor, AI-enabled, flexible and battery-free devices integrated with IoMT platforms.

Classification of Wearable Devices

Fig. 3.8 Classification of Wearable Healthcare Devices

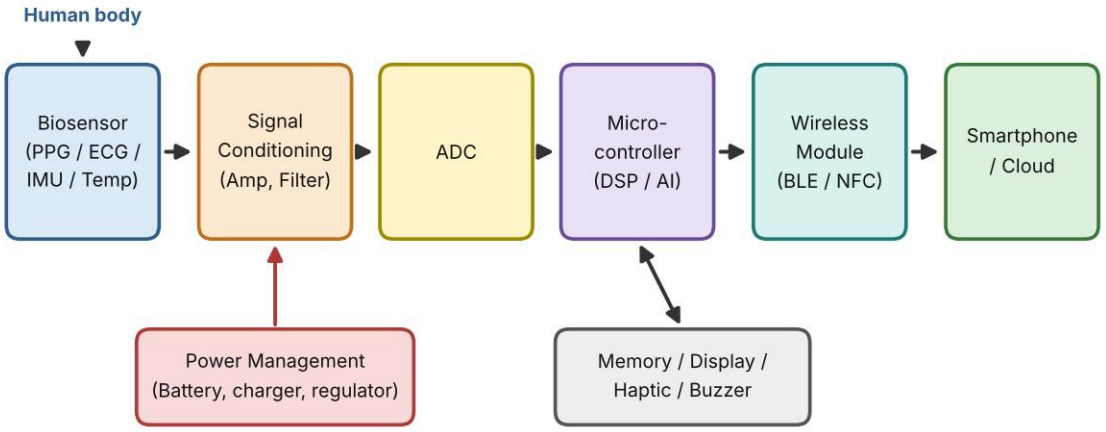


- **Accessories (wrist/finger/head-worn):** smartwatch, fitness band, smart ring, smart glasses, headband EEG.
- **Skin-mounted patches and e-tattoos:** adhesive ECG patches, CGM sensors, sweat-analysis patches, temperature patches - thin, flexible and disposable.
- **Smart textiles / e-textiles:** sensors and conductive threads woven into shirts, bras, socks, gloves and belts for ECG, respiration and posture monitoring.
- **Implantable and ingestible devices:** pacemakers, ICDs, cochlear implants, smart pills, capsule endoscopes; these are invasive but communicate wirelessly.
- **Assistive and rehabilitation wearables:** hearing aids, exoskeletons, smart prosthetics, haptic gloves.

Wearables can also be classified by **sensing modality** as physical (motion, temperature, pressure), electrophysiological (ECG, EEG, EMG), optical (PPG, SpO_2) and biochemical (glucose, lactate, sweat electrolytes) wearables.

General Block Diagram of a Wearable Health Device

Fig. 3.9 Generic Block Diagram of a Wearable Health Device



➢ Working of each block

- **Biosensor / transducer:** converts the physiological quantity (light absorption, bio-potential, acceleration, temperature) into an electrical signal.
- **Signal conditioning:** the signal from the body is very small (ECG is about 1 mV) and noisy. An instrumentation amplifier with high CMRR amplifies it; band-pass, low-pass and notch (50 Hz) filters remove interference and motion artefact.
- **ADC:** converts the analogue signal to digital form (typically 12-24 bit).
- **Microcontroller / DSP:** runs algorithms for filtering, peak detection, feature extraction and, in modern devices, embedded machine-learning inference. Ultra-low-power ARM Cortex-M class processors are common.
- **Wireless module:** BLE or NFC sends the processed data to a smartphone or gateway.
- **Memory, display and alert unit:** stores data, shows readings and gives haptic/audible alarms.
- **Power management unit:** Li-ion/Li-polymer battery, charger, voltage regulators and sleep-mode control to extend battery life.

Sensors Used in Wearable Devices

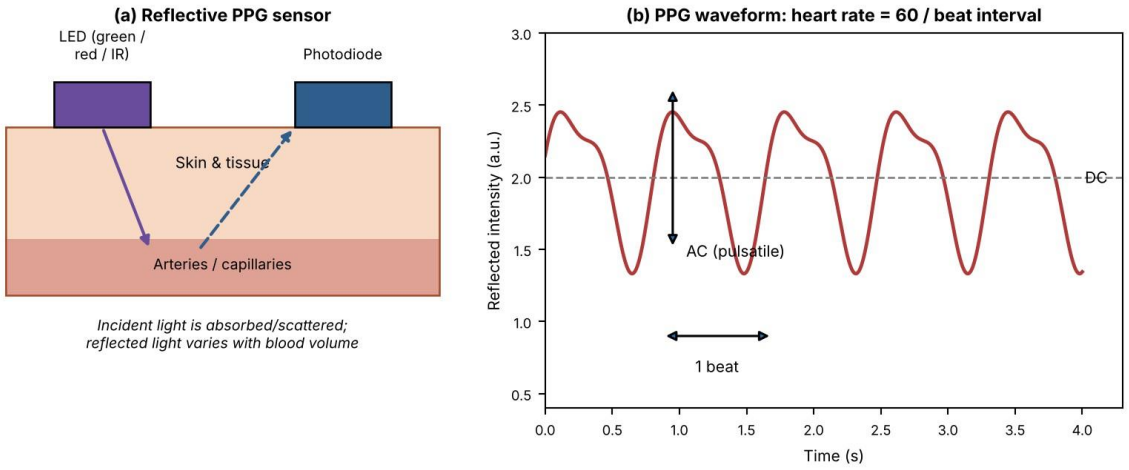
Sensor	Principle	Parameter measured
Photoplethysmography (PPG) sensor	LED + photodiode measure blood-volume changes through light absorption	Heart rate, HRV, SpO_2, respiration rate, blood pressure trend
ECG electrodes (Ag/AgCl, dry, textile)	Pick up cardiac bio-potential on the skin surface	ECG, arrhythmia, heart rate
MEMS accelerometer / gyroscope (IMU)	Capacitive sensing of acceleration and angular rate	Steps, activity, gait, falls, posture, sleep
Thermistor / IR sensor	Resistance or IR radiation changes with temperature	Skin and body temperature, fever

Sensor	Principle	Parameter measured
Electrodermal activity (EDA/GSR)	Skin conductance changes with sweat gland activity	Stress, emotional arousal
Bio-impedance sensor	Impedance of tissue to small AC current	Respiration, body composition, hydration
Electrochemical sensor	Enzyme-based redox reaction produces current	Glucose, lactate, sweat electrolytes
Strain / pressure sensor (flexible)	Resistance or capacitance changes on deformation	Breathing, pulse wave, joint movement
EEG / EMG electrodes	Bio-potentials of brain and muscle	Sleep stages, seizures, muscle fatigue

Photoplethysmography (PPG) and Pulse Oximetry

PPG is the most widely used optical technique in wrist-worn devices. A green LED (about 525 nm) or red/infrared LED illuminates the skin and a photodiode measures the light that is reflected back (Fig. 3.10). When the heart contracts, blood volume in the arterioles increases and absorbs more light, so the detected intensity falls; during diastole it rises. The result is a pulsatile waveform whose **AC component** gives the heart rate and whose amplitude ratio gives SpO_2, while the slowly varying **DC component** depends on tissue and venous blood.

Fig. 3.10 Principle of Photoplethysmography (PPG)



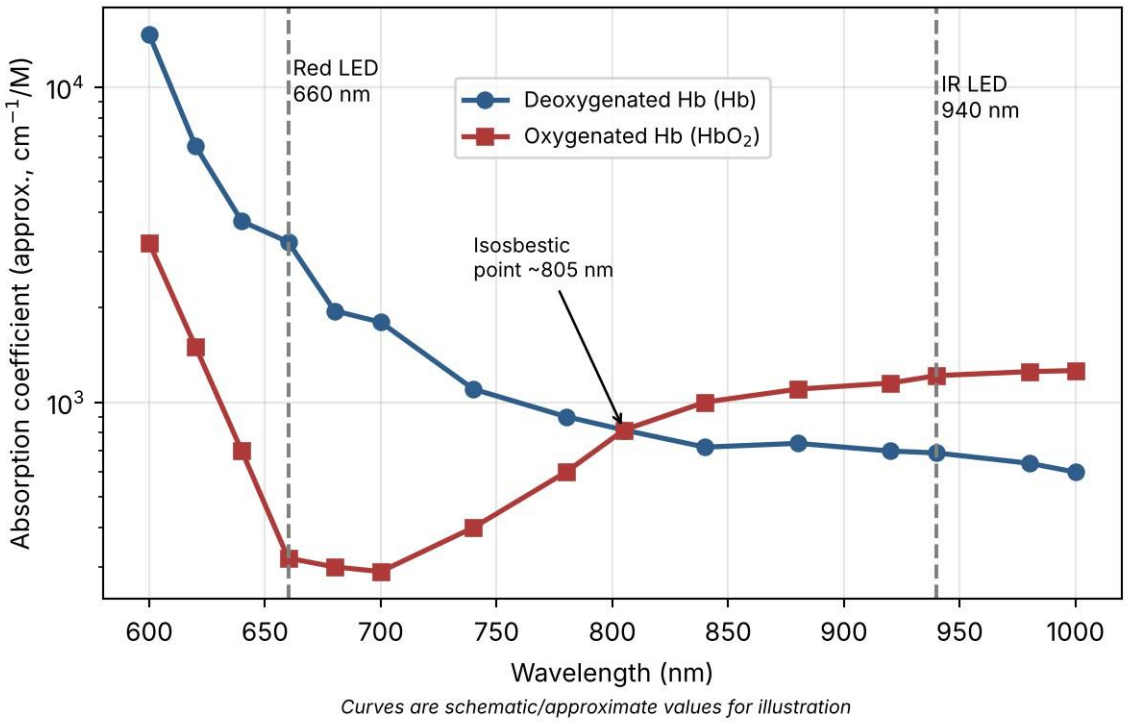
- **Heart rate** = 60 / (time between successive pulse peaks in seconds).
- **Heart-rate variability (HRV)** is obtained from the variation of beat-to-beat intervals and is used for stress and autonomic-function assessment.
- Green light is preferred for wrist heart-rate because of high signal-to-noise ratio in superficial capillaries; red and infrared light penetrate deeper and are used for oxygen saturation.

➢ **Principle of SpO_2 measurement**

Oxygenated haemoglobin (HbO_2) and deoxygenated haemoglobin (Hb) absorb red (660 nm) and infrared (940 nm) light differently (Fig. 3.11): Hb absorbs more red light, HbO_2 absorbs more infrared light. The device calculates the **ratio of ratios**:

> **Formula:** $R = (AC_{660} / DC_{660}) / (AC_{940} / DC_{940}) \rightarrow SpO_2\ (\%) \approx 110 - 25 \times R$ (empirical calibration curve)

Fig. 3.11 Light Absorption of Hb and HbO_2 (Basis of Pulse Oximetry)



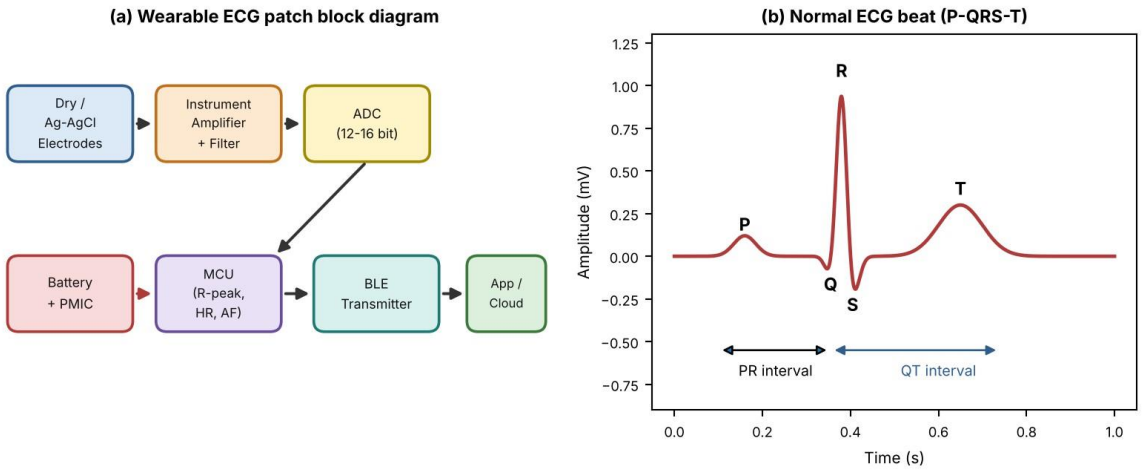
Curves are schematic/approximate values for illustration

Normal SpO_2 is **95-100 %**. Values below about 90 % indicate hypoxaemia and need medical attention.

Wearable ECG Monitors

Conventional 12-lead ECG is available only in hospitals, and a Holter monitor records for just 24-48 hours with bulky wires. Modern wearable ECG devices include **adhesive ECG patches** (worn for 7-14 days), **chest straps**, **smart-textile shirts** and **smartwatches / smart rings** with metal electrodes (single-lead ECG on touching the crown). The block diagram of an ECG patch is shown in Fig. 3.12.

Fig. 3.12 Wearable ECG Patch and ECG Waveform



- **Electrodes** pick up the 0.5-1 mV cardiac potential; dry or textile electrodes avoid skin irritation but have higher contact impedance.
- **Instrumentation amplifier + filters** (0.5-40 Hz band-pass, 50 Hz notch) provide high CMRR and remove baseline wander and motion artefact.
- **MCU** detects R-peaks (Pan-Tompkins algorithm), computes heart rate and flags atrial fibrillation (AF), bradycardia or tachycardia.
- **BLE** sends data to the phone and cloud where a cardiologist reviews the report.
- **Clinical use:** detection of paroxysmal AF, unexplained syncope, palpitations, post-ablation follow-up and cardiac rehabilitation.

Smartwatches, Fitness Bands and Smart Rings

Smartwatches integrate PPG, accelerometer, gyroscope, barometer, temperature sensor, GPS and sometimes ECG electrodes. Features such as heart-rate alerts, **irregular-rhythm notification**, SpO_2 spot-checks, sleep tracking and fall detection have been cleared or authorised by regulators in several countries for specific uses. For example, the Apple Watch ECG app received US FDA authorisation in 2018 as an over-the-counter software for classifying a single-lead ECG into sinus rhythm or AF. **Smart rings** (e.g. Oura) are worn on the finger, where the palmar arteries give a good PPG signal, and are mainly used for sleep, readiness and temperature trend monitoring.

Skin Patches, Flexible and Stretchable Electronics

- **Flexible electronics** use thin polymer substrates (polyimide, PDMS) and stretchable interconnects so that devices conform to curved, moving skin.
- **Electronic tattoos and e-skin:** ultra-thin patches for ECG/EMG, temperature, hydration and strain; comfortable for several days.
- **Sweat sensors:** microfluidic patches analyse sodium, potassium, lactate and cortisol in sweat for hydration, fatigue and stress.
- **Smart bandages:** monitor wound temperature, pH and moisture and can release drugs.
- **Smart contact lens:** under research for tear-glucose and intra-ocular pressure monitoring.

Smart Textiles (E-textiles)

In e-textiles, conductive yarns (silver-coated nylon, carbon fibre) act as electrodes and interconnects, and strain-sensitive fabric measures breathing. Smart shirts record ECG, respiration, posture and activity during daily life or sports and are useful for firefighters, soldiers, athletes, infants (apnoea monitoring) and cardiac patients. Washability, durability and motion artefact are their main challenges.

Implantable and Ingestible Wearables

- **Cardiac implants:** pacemakers and ICDs have wireless telemetry so that device data and arrhythmia logs are sent to the hospital remotely.
- **Neuro-stimulators and cochlear implants** are programmed through inductive or radio links.
- **Ingestible sensors:** the capsule endoscope (PillCam) takes images of the gastrointestinal tract; smart pills sense temperature, pH and drug-adherence.

Power Supply and Energy Harvesting

Battery size determines the comfort of a wearable. Typical wearables use small Li-ion/Li-polymer cells charged wirelessly or by cable. To reduce charging, designers use **duty-cycling** (sensor sleeps between samples), low-power MCUs, BLE and **energy harvesting** from body heat (thermoelectric generators), motion (piezoelectric/triboelectric), light (flexible solar cells) and radio-frequency energy. Battery-free NFC patches power themselves from the phone.

Connectivity of Wearables

Wearables mostly use **BLE** to connect to a smartphone, which acts as gateway to the cloud via Wi-Fi/4G. Several wearables on one person form a **Wireless Body Area Network (WBAN)** (see Section 3.3). NFC is used for glucose-sensor read-out, and standalone smartwatches may carry an eSIM for direct cellular connectivity.

Applications of Wearable Healthcare Technologies

Area	Wearable used	Benefit
Cardiology	ECG patch, smartwatch ECG, PPG band	Early detection of AF, arrhythmia, heart-failure monitoring

Area	Wearable used	Benefit
Diabetes	CGM patch, smart insulin pen	Glucose trends, hypoglycaemia alerts, automated insulin delivery
Respiratory / COVID-19	Finger/wrist oximeter, respiration patch	Home monitoring of hypoxia and breathing rate
Sleep medicine	Smart ring, wrist band, headband EEG	Sleep stages, apnoea screening
Neurology	EEG headband, wrist accelerometer	Seizure detection, tremor and Parkinson's gait monitoring
Elderly care	Fall-detection watch, pendant	Automatic emergency call
Rehabilitation and sports	IMU suits, EMG bands, exoskeleton	Movement analysis, injury prevention, tele-rehabilitation
Mental health	HRV and EDA wearables	Stress and anxiety monitoring, biofeedback
Maternal and child health	Smart belts, infant-monitor socks	Foetal movement, infant SpO_2 and breathing

Advantages and Limitations

Advantages	Limitations
Continuous, non-invasive, real-time data in daily life	Accuracy lower than clinical devices; motion artefact
Early detection and prevention; patient empowerment	PPG accuracy affected by skin tone, tattoos, perfusion and fit
Reduces hospital visits and cost; supports telemedicine	Limited battery life; frequent charging
Large datasets for AI and research	Data privacy, ownership and security concerns
Improves adherence and lifestyle change through feedback	False alarms, anxiety, alarm fatigue; digital divide; cost

Design Challenges and Future Trends

- **Accuracy and validation:** need for clinical trials against gold-standard devices and standards such as ISO 80601-2-61 (pulse oximeters) and ISO 81060 (blood pressure monitors).
- **Motion artefact removal** using accelerometer-referenced adaptive filtering and AI.
- **Comfort, biocompatibility and skin-safe adhesives** for multi-day wear.
- **Regulation:** differentiating wellness vs medical claims, software as a medical device (SaMD).
- **Future:** cuff-less BP, non-invasive glucose sensing, battery-free skin patches, multimodal AI health "digital twin", integration with electronic health records.