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DEPARTMENT OF BIOMEDICAL ENGINEERING

VI Semester

24BM501 BIOMEDICAL DEVICE DESIGN

UNIT- IV PROTOTYPING, TESTING AND VALIDATION OF BIOMEDICAL DEVICES

4.0 Introduction

Designing a biomedical device does not end with a good idea or a working circuit. Before a device can be used on a patient it must be **built as a prototype, tested, proven safe and effective, and approved by a regulator**. Unit IV covers this journey from the first physical model to a clinically evaluated product.

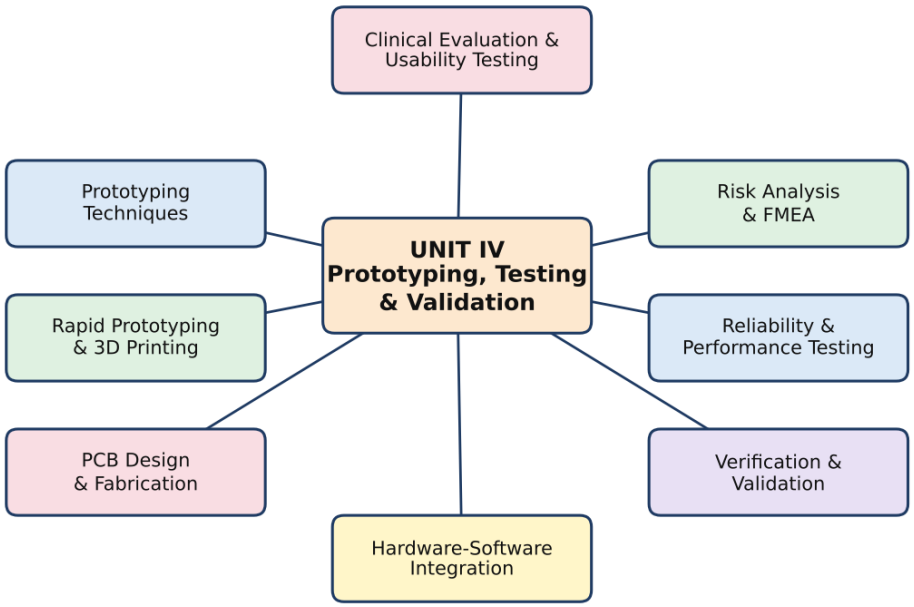
➢ **Why this unit matters**

- ✓ A device that works on the bench may fail on a patient because of motion, sweat, humidity, battery drop, or wrong user handling.
- ✓ Regulators (FDA, CDSCO, EU MDR) demand **objective evidence** of safety and performance, not just claims.

➢ Early prototyping and testing is far cheaper than redesign after launch. A design change found at the concept stage costs 1 unit, at the production stage nearly 100 units, and after recall many times more.

Scope of Unit IV

Fig. 4.0 Overview of Unit IV



Topic	What it answers
4.1 Prototyping techniques	How do we make a first physical model of the idea?
4.2 Rapid prototyping and 3D printing	How do we make it quickly and cheaply layer by layer?
4.3 PCB design and fabrication	How do we turn the circuit into a manufacturable board?
4.4 Hardware-software integration	How do the electronics and firmware work together?
4.5 Verification and validation	Did we build it right, and is it the right device?
4.6 Reliability and performance testing	Will it keep working accurately for its life?
4.7 Risk analysis and FMEA	What can go wrong and how bad is it?
4.8 Clinical evaluation and usability testing	Is it safe, effective and easy to use by real people?

4.1 Biomedical Device Prototyping Techniques

➢ **4.1.1 Definition of a Prototype**

A **prototype** is an early, working or non-working physical or virtual model of a device that is built to test an idea, check the design, and collect feedback before the final product is manufactured.

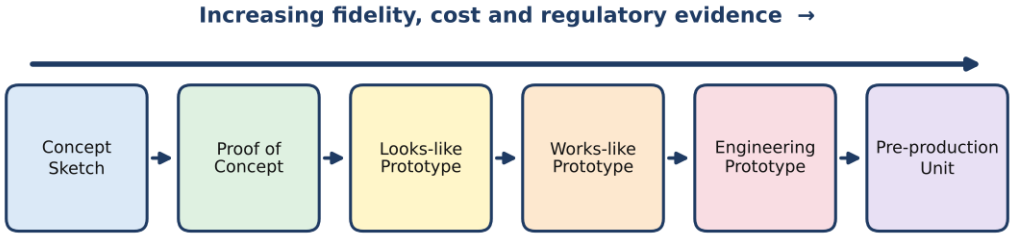
Prototyping is the process of creating such models in successive stages, each one closer to the final product.

➢ **4.1.2 Objectives of Prototyping**

- ✓ To check **technical feasibility** (will the sensor and circuit really measure the signal?).
- ✓ To check **form, fit and ergonomics** (size, weight, grip, comfort on skin).
- ✓ To **find design errors early** and reduce cost of change.
- ✓ To collect **feedback from clinicians and patients**.
- ✓ To test **manufacturability** and select materials and processes.
- ✓ To generate **early evidence** for verification, safety testing and regulatory files.
- ✓ To attract **investors and funding** by showing a demonstrable model.

➢ **4.1.3 Stages of Prototype Development**

Fig. 4.1 Stages of Medical Device Prototype Development



Each stage answers one question: Is it feasible? Is it usable? Does it work? Is it safe? Can it be made?

Stage	Purpose	Typical form in a biomedical device
Concept sketch	Capture the idea and user need	Hand sketches, block diagram, cardboard mock-up
Proof of concept (PoC)	Prove the core principle works	Breadboard with Arduino, sensor and a laptop
Looks-like prototype	Evaluate shape, size, ergonomics	3D-printed enclosure, foam model, no electronics
Works-like prototype	Evaluate function and performance	Soldered/PCB circuit, real firmware, bench tests
Engineering prototype	Combine looks and works; test against standards	Near-final device in final materials, used for V&V
Pre-production unit	Prove manufacturing process	Built using production tools and suppliers

➢ **4.1.4 Classification of Prototypes**

➢ **A. Based on fidelity**

✓ **Low-fidelity prototype:** paper sketches, cardboard, clay, wireframes. Cheap, fast, used for early user feedback.

✓ **High-fidelity prototype:** closely resembles the final device in look, material and function. Used for performance testing and usability studies.

➢ **B. Based on purpose**

✓ **Visual / aesthetic prototype:** shows only appearance and shape.

✓ **Functional prototype:** demonstrates the working principle (for example, pulse detection).

✓ **Form and fit prototype:** checks assembly, tolerance and ergonomics.

✓ **Pre-clinical / animal-testing prototype:** built to biocompatible standards for tests on models.

✓ **Clinical prototype:** manufactured under quality control for human investigation.

➢ **C. Based on how it is used**

✓ **Throw-away (rapid) prototype:** built to learn and then discarded.

✓ **Evolutionary prototype:** improved continuously until it becomes the final product.

✓ **Incremental prototype:** each sub-system is prototyped separately and then integrated.

➢ **4.1.5 Common Prototyping Techniques**

Technique	Description	Biomedical example
Sketching and paper models	Drawings, cardboard and paper mock-ups	Handheld ECG device outline
Breadboard prototyping	Solderless circuits using Arduino/ESP32 and sensors	Pulse sensor with ESP32
Foam / clay / wood models	Hand-shaped volume models	Grip shape of a glucometer
CAD virtual prototyping	3D digital model with simulation (FEA, CFD)	Stress analysis of a prosthetic socket
3D printing (additive)	Layer-by-layer manufacture from CAD	Custom surgical guide, enclosure
CNC machining	Material removed from a block by computer-controlled tools	Titanium orthopaedic implant prototype
Vacuum / silicone casting	Cast copies from a master pattern	Soft silicone wearable casings
Laser cutting	2D sheets cut and assembled	Acrylic housing for a monitor
Perfboard / PCB prototyping	Hand-soldered or milled boards	Wearable ECG patch circuit
Wizard-of-Oz / software mock-up	Simulated user interface	Mobile health app screens

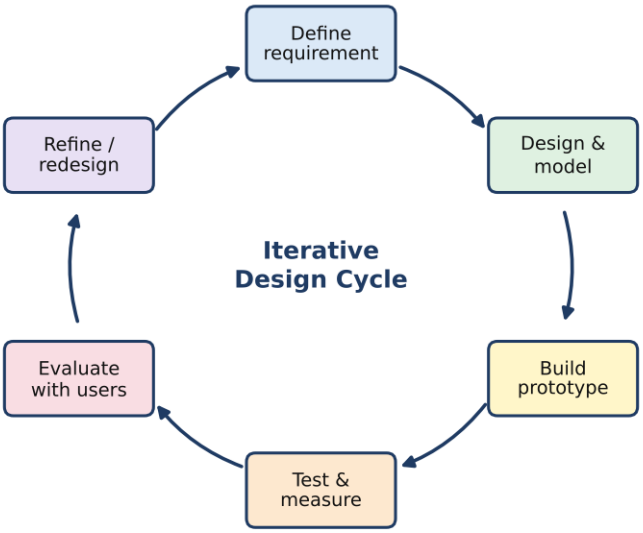
➢ **4.1.6 Virtual Prototyping and Simulation**

Virtual prototyping builds and tests a model on a computer before any material is used.

- ✓ **FEA (Finite Element Analysis):** stress, strain and fatigue in implants and prosthetics.
- ✓ **CFD (Computational Fluid Dynamics):** blood flow in stents, airflow in ventilators.
- ✓ **Circuit simulation (SPICE, Proteus, Multisim):** amplifier, filter and power circuit behaviour.
- ✓ **Digital twin:** a virtual copy of the device or patient used for what-if tests.

➢ 4.1.7 Iterative Prototyping Cycle

Fig. 4.2 Iterative Prototype-Test-Refine Cycle



The device is developed through repeated cycles of **design, build, test, evaluate and refine**. Each loop reduces uncertainty. Early loops are quick and cheap (paper, breadboard); later loops are accurate and costly (final materials, clinical use).

➢ 4.1.8 Factors in Choosing a Prototyping Method

- ✓ **Purpose of the prototype** (look, fit, function or clinical use).
- ✓ **Speed and cost** available at that stage.
- ✓ **Material requirements**, especially biocompatibility if it touches the body.
- ✓ **Accuracy and surface finish** required.
- ✓ **Quantity** needed for testing.
- ✓ **Sterilisation compatibility** (autoclave, ethylene oxide, gamma).
- ✓ **Regulatory needs** of the stage (documentation, traceability).

➢ 4.1.9 Advantages and Limitations

Advantages	Limitations
❖ Finds design faults early	❖ A prototype may not match final production performance
❖ Reduces cost and time	❖ Materials may differ from final
❖ Improves communication with clinicians	❖ Bench success may not prove clinical safety
❖ Enables patient-specific devices	❖ Poorly managed iterations can delay a project

➢ 4.1.10 Medical-Device Specific Considerations

- ✓ **Biocompatibility:** parts touching skin, blood or tissue need materials tested to ISO 10993 (cytotoxicity, sensitisation, irritation).
- ✓ **Electrical safety:** prototypes used on people must meet IEC 60601-1 limits for leakage current.
- ✓ **Documentation:** record each version, change and test result in the **Design History File (DHF)**.
- ✓ **Traceability:** label prototype builds, components and software versions.

Example: Prototype path of a wearable pulse oximeter

Idea sketch → breadboard with MAX30102 sensor and Arduino → 3D-printed finger clip (looks-like) → PCB with BLE and battery (works-like) → engineering prototype tested for accuracy against a reference oximeter → pre-production batch.