

Q1)

- **Identify Stakeholders:** List all parties affected—patients, clinicians, IT staff, regulators, payers.
- **Gather Requirements:** Collect needs via interviews, surveys, observations, and regulatory guidelines.
- **Prioritize Needs:** Rank requirements based on safety, usability, compliance, and clinical impact.
- **Analyze Conflicts:** Detect conflicts between stakeholder goals (e.g., patient usability vs. regulatory constraints).
- **Document & Trace:** Maintain a requirements traceability matrix linking features to stakeholders.
- **Importance:** Ensures safety, compliance, adoption, and effectiveness by addressing diverse clinical, technical, and legal needs.

Q2)

Functional Requirements (what the system should do):

- Patients can submit daily vital signs (weight, BP).
- Clinicians receive alerts for abnormal readings.
- Secure messaging between patients and clinicians.

Non-Functional Requirements (how the system performs):

- Response time under 2 seconds for dashboard updates.
- System uptime $\geq 99.9\%$.
- Compliance with HIPAA and GDPR for data security.

Q3)

- **Role in Requirements:** HFE ensures software design considers human capabilities, limitations, and workflows.
- **Impact of Poor Usability:** Confusing interfaces can lead to misentered data, delayed responses, or missed alerts.

Q4)

- **Identify Hazards:** List all potential sources of harm related to device use.
- **Estimate Risks:** Assess severity and likelihood of each hazard.
- **Determine Causes:** Analyze how each hazard could occur (hardware, software, human error).
- **Evaluate Existing Controls:** Check current design features mitigating the risks.
- **Prioritize Hazards:** Rank based on risk level to focus on critical safety issues.
- **Define Safety Requirements:** Translate high-risk hazards into specific design, software, and procedural requirements to prevent or mitigate harm.

Q5)

- **Definition:** RTM is a table linking each software requirement to design, implementation, and testing artifacts.
- **Purpose:** Ensures all requirements are fulfilled, verifiable, and compliant with regulations like FDA or IEC 62304.
- **Importance:** Supports audits, reduces risk of missed requirements, and provides traceable evidence for safety and compliance.
- **Hypothetical RTM Entry:**

Requirement ID	Requirement Description	Design Module	Test Case ID	Verification Status
RQ-005	Patient must be able to securely upload daily weight data	DataInputModule	TC-205	Passed

Q6) c) The system shall be available 99.9% of the time.

Q7) F

Q8) a) To identify potential sources of harm before they occur.

Q9) T

Q10) d) Competing Hospital Systems