# 1. General Information

- **Equipment:** Transient Elastography (TE) / Liver Stiffness Measurement System.
- **Clinical Purpose:** Non-invasive diagnostic system designed to measure the stiffness of liver tissue and ultrasound wave attenuation. Used for screening, staging, and monitoring chronic liver diseases.
- **Primary Modality:** Vibration-Controlled Transient Elastography (VCTE).
- **Secondary Modality:** Controlled Attenuation Parameter (for steatosis assessment).
- **Clinical Output:** Liver Stiffness Measurement (LSM) and Steatosis Quantification.

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# 2. Technical Specifications

## A. Core Measurement Parameters

| Parameter | Specification Range | Unit |
|---|---|---|
| **Liver Stiffness (LSM)** | 1.5 to 75.0 | Kilopascals (kPa) |
| **Shear Wave Frequency** | 50 (Fixed/Controlled) | Hertz (Hz) |
| **Steatosis Measurement** | 100 to 400 | Decibels per meter (dB/m) |
| **Measurement Volume** | Approx. 3 $cm^3$ | $cm^3$ |
| **Ultrasound Frequency** | 2.5 MHz to 5.0 MHz (Probe dependent) | MHz |



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### B. Hardware & Ergonomics

- **Display:** High-definition color touchscreen (minimum 12 inches) for real-time wave visualization.
- **Connectivity:** Ethernet, USB ports, and DICOM 3.0 compliance for PACS/HIS integration.
- **Portability:** Integrated battery and lightweight chassis for bedside or mobile clinic use.
- **Guidance:** Real-time A-Mode ultrasound guidance for precise anatomical positioning of the measurement volume.

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## 3. Specialized Transducer (Probe) Suite

The system must support interchangeable, intelligent probes to accommodate varying patient morphologies:

1. **Standard Probe (M-Type):** Optimized for adult patients with a skin-to-liver capsule distance (SCD) of ≤ 2.5 cm.
2. **Extra-Large Probe (XL-Type):** Optimized for overweight or obese patients (SCD>2.5 cm) with a larger vibration amplitude and deeper focal depth.
3. 

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## 4. Software & Quality Indicators

To ensure clinical validity, the system software must provide the following real-time quality control metrics:

- **Success Rate:** Calculation of the percentage of valid measurements versus total attempts.
- **Interquartile Range (IQR):** Calculation of the spread of measurements; results are considered valid only if IQR/Median≤30%.

- **Automated Probe Selection:** Software algorithms that recommend the appropriate probe (M or XL) based on real-time sensing of the patient's subcutaneous fat layer.
- **Integrated Score Interpretation:** Access to clinical score charts (Metavir, F0-F4) based on the specific underlying etiology (HCV, HBV, NAFLD).

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## 5. Regulatory & Safety Standards

- **Classification:** Class IIa Medical Device (CE/FDA).
- **Safety Standards:** Compliance with IEC 60601-1 (Medical Electrical Safety) and IEC 60601-1-2 (EMC).
- **Data Protection:** HIPAA-compliant encryption and secure user authentication protocols.
- **Calibration:** Automated hardware self-test on startup; annual factory-certified calibration required for transducers.