Elastography Machine For Noninvasive Assessment of Liver Fibrosis
Medical Equipment - Technical Specifications

1	Elastography Machine For Assessment of Liver Fibrosis	Manufacturer ↓	Model No ↓

No.	Item Specifications	Compliance	Your Specifications
1	Objective- An active non implantable medical diagnostic aid to make non-invasive painless and immediate measurements of the stiffness or elasticity of hepatic parenchyma and a simultaneous non-invasive assessment and quantification of steatosis.		
2	The stiffness and steatosis of liver is measured at the same time.		
3	The ultrasound output should be less than 3.9m W and the mechanical index of 0.5.		
4	The ultrasound transducer should be placed in contact with patients skin and the vibrator should generate a completely painless vibration (frequency 50Hz and amplitude 2mm peak to peak) which is similar to a flick , maximum mean output of the vibrator being 16Mw.		
5	Floor mounted standalone system on inbuilt 4 castors meant for use on liver only and no PNDT clearance / approval required.		
6	Should be floor standing with minimum 19 inches LED screen having wide viewing angle & system should be supported on inbuilt castors for all side stability.		
7	Separate probes with separate frequencies for 3 categories of patients-adults, children &obese patients.		
8	All the above 3 probes should have different frequencies for each category of patients viz-3.50MHz, 5MHz &2.5MHz respectively.		
9	Each probe to be compulsorily calibrated at every 12 months interval for accurate results.		
10	Pediatric probe should be such that even 1 month child having thoracic perimeter >45cm should also be able to be examined &should have clear indication for selection for a child /teenager having thoracic perimeter 45cm > thoracic perimeter >75cm.		
11	Machine should have Controlled Attenuation Parameter (CAP) for steatosis quantification.		
12	**Electrical Characteristics:**		
12.1	A) Power Supply: 100 - 240V ~ 50-60 Hz.		
12.2	B) Apparent power: 130 -150 VA.		
13	**Probe properties: probe size and features should be as below:**		
13.1	**Adult Probe M +**		
	Type: for adults from 14 years age onwards.		
	IP Code: IP x 1 .		
	Metrological performance: Ultrasound Transducer .		
	Central frequency: 3.5 MHz .		
	Measurement depth: 25 to 56 mm .		
	Usage: To measure hepatic stiffness and steatosis compulsory probe calibration at every 12 months.		
13.2	**Child Probe S+**		
	Type: for children from 1 month age onwards.		
	IP code: IP x 1.		
	Metrological performance: Ultrasound Transducer .		

	Central frequency: 5 MHz.		
	Measurement depth:		
	S1: from 15 to 40mm		
	S2: from 20 to 50mm		
	Usage: To measure hepatic stiffness Compulsory probe calibration at every 12 months.		
13.3	**Obese Probe XL+**		
	Type: for obese people.		
	IP code: IP x 1 .		
	Metrological performance: Ultrasound Transducer .		
	Central frequency: 2.5 MHz.		
	Measurement depth: 35 to 75mm .		
	Usage: to measure hepatic stiffness and steatosis compulsory probe calibration at every 12 months.		
14	**CAP**		
14.1	Controlled attenuation parameter for fatty liver/steatosis quantification Expressed in decibel per meter (db/m).		
14.2	Powered by sophisticated guidance process based on vibration controlled transient elastrography, being measured simultaneously during stiffness measurement of hepatic parenchyma.		
15	**Fibro view: Patient's data management software should be provided with the system.**		
16	**Accessories required to operate the system:**		
16.1	Examination couch: Overall approximate size: 1840mml x 575mmW x 860mm H.		
16.2	CRCA rectangular tube frame with CRCA sheet cabinets.		
16.3	100mm thick foam mattress with reversible rexine cover.		
16.4	3 cabinets: 1 with lock, 1 drawer with lock.		
16.5	Retractable step stool & writing pad.		
16.6	Height adjustable DR'S Stool, Gas/Spring assisted.		
16.7	Branded 1 KVA online UPS.		
16.8	Color laser jet printer.		
16.9	Ultrasound Jelly (250ML Tube / Bottle x 10).		
16.10	Extension Cord With Surge protection.		
17	**Operating Environment**		
17.1	The system offered shall be designed to be stored and to operate normally under the conditions of Sudan. The conditions include Power Supply, Climate, Temperature, Humidity, etc.		
18	**Standards & Safety Requirements**		
18.1	Must submit ISO 13485:2003/AC: 2007 **AND CE or USFDA approved product certificate.**		
19	**User Training**		
19.1	External Training for 3 (Engineers - "Professional Service Training" + Doctors - "Application Training") and the Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.		
20	**Warranty**		
20.1	Comprehensive warranty for 2 years after acceptance.		
21	**Maintenance Service During Warranty Period**		
21.1	During warranty period supplier must ensure preventive maintenance & corrective/breakdown maintenance whenever required.		

22	**Installation and Commissioning**		
22.1	The bidder must arrange for the equipment to be installed by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.		
23	**Documentation**		
23.1	User (Operating) manual in English.		
23.2	Service (Technical / Maintenance) manual in English.		
23.3	List of important spare parts and accessories with their part numbers and costing.		