

물 품 규 격 서(긴급)

- ☐ 입찰공고번호 : (학)일송학원 관리국 제2025-127-1호
- ☐ 입찰건명 : 소화기내과(내시경실) Hepatic & Spleen Fibrosis Diagnostc Device(간, 비장 섬유화 진단장치) 구매
- ☐ 수요기관 : 한림대학교 동탄성심병원
- ☐ 납품장소 : 수요기관 희망장소 입고도
- ☐ 물품내역 등

품명(영문, 국문)	규격 및 사양	총 구매예정수량 (Q'TY)	1회 최대 발주수량	WARRANTY 기간
Hepatic & Spleen Fibrosis Diagnostic Device (간, 비장 섬유화 진단장치)	A	1 Set	1 Set	검수(합격)일로부터 3년 종료일 말일 까지

☐ 공통사항

- 장비의 설치와 작동 및 교육은 무상으로 제공한다.
- 수요기관 담당자 입회 하에 계약상대자는 제품의 설치 테스트 및 시험작동을 실시하여야 한다.
- 무상 하자담보 책임기간은 물품 검수(합격)완료일로부터 3년 종료일 말일 까지를 기본 원칙으로 하며 계약상대자의 추가 제안에 따라 3년을 초과하여 설정할 수 있다.
- 무상 하자담보 책임기간 중 수요기관의 사정으로 인하여 부서 및 장비의 위치가 불가피하게 이동을 필요로 할 경우 설치 시 협의 하에 무상 또는 부득이한 경우 실비 기준으로 이루어진다.
- 무상 하자담보 책임기간 중 중 공급된 장비의 부속품이 단종된 경우 수요기관이 인정하는 동등이상의 장비로 무상교체가 이루어져야한다.
- 계약상대자는 어떠한 상황에서도 애프터서비스를 위하여 전문서비스 인력을 제공하여야 하며 애프터서비스를 위하여 교체 부품을 보관하여야 한다.
- 계약상대자는 장비 납품 시 납품일을 기준하여 제품 제조년월이 6개월 이내인 장비를 납품 하고 납품장비에 해당 제조년월이 명시되어야 한다.
- 기존 사용 중인 의료장비 철거 및 회수 또는 보상판매 조건으로 제안할 수 있다.

<규격서 A>

A. Features

1. The Ultrasound and its probes make up an active, non-implantable medical device using ultrasound. The Ultrasound provides an instantaneous, painless and totally non-invasive measurement of hepatic fibrosis caused by chronic liver disease with no ascites.
2. The Ultrasound measures liver & spleen fibrosis(stiffness) by VCTETM (Vibration Controlled Transient Elastography) :
Vibrations create elastic waves in the studied organs and their propagation is then tracked by means of ultrasound. The speed of propagation of the elastic waves thus measured by the ultrasound is directly linked to the stiffness of the organs.
3. New spleen stiffness measurement and embedded ultrasound guidance system for risk stratification of patients with advance chronic liver disease
4. Steatosis measurement S/W : Controlled Attenuation Parameter(CAP) is a tool for non invasive and quantification of steatosis which is integrated within Ultrasound. CAP is a measure of the ultrasound attenuation which corresponds to the decrease in amplitude of ultrasound waves as they propagate through the liver. CAP and Stiffness are simultaneously measured in the same volume and is expressed in decibel per meter (dB/m)
5. The Ultrasound meets physician's need for reliable and efficient instrument :
 - Reliable measurement because it is made directly of the liver, independently of any extra-hepatic conditions.
 - Discriminatory measurement : high sensitivity and specificity.
 - Regular monitoring possible, even during treatment, thus enabling the anti-fibrosis effects of therapy to be assessed.
 - Measurement repeatable as often as needed.
6. The Ultrasound meets the wishes of both patients and doctors, offering :
 - Completely non-invasive examination : no intrusion, not even blood testing
 - Examination without side effect.
7. Result is easy to understand : liver stiffness is a single and precise physical parameter expressed in Pascal.
8. Examination is very simple : Intercostal measurement on the right lobe of the liver. Duration of examination is Maximum 5 minutes
9. The device is controlled by software that enables hepatic stiffness to be measured and patient data to be managed.

10. Equipped with 19" color LCD screen to monitor a measurement for user and touch screen can be easily controlled. It is automatically loaded when the Ultrasound is turned on. It performs examinations and management of archived examination.

11. Smart tools :

Automated probe selection : an indication to recommend the probe best suited to the patient's morphology.

Ultrasound reports : personalize reports with hospital logo, address.. and print examination history

12. Embedded ultrasound localization system : easier targeting of liver & spleen with single localization probe.

13. Advanced Hardware :

2 probe holders and connectors : connect two probes simultaneously

Advanced connectivity options : save & export data to removable drive (USB key...) or network Advanced electronic for fast and effective examination : high speed elastometry engine

B. Specifications

1. Display & input : 19 inch color LCD touch screen & keypad

2. Liver Stiffness measurement range : Min. 1.5 to Max. 75 kPa

3. CAP (steatosis measurement) range : Min. 100 to Max. 400 dB/m

4. Spleen Stiffness measurement range : Min. 6 to Max.100kPa

5. Spleen and Liver localization probe : B-mode probe, IPX7, 2~3MHz frequency(central 3.5MHz)

6. RAM / Hard Drives : 8 GB, SSD OS128 GB / SSD Data 512GB

7. QR (Bar) code reader : Class 1 Laser device

8. Connectivity : Ethernet RJ45, 3xUSB 3.0 ports, 2 probe connectors, 1 ultrasound probe connector, 1 HDMI output, 1 Footswitch connector, 1 ground connector

9. Dedicated Probe : M+ type probe (3.5 MHz frequency), XL+ type probe (2.5 MHz frequency)

10. Data transmission to PACS : Compatible DICOM S/W

11. Power supply : 100~ 240 V / 50/60Hz / 250 Watts

12. Dimension : 642mm (Length) x 584mm (Width) x 1365mm (height)

13. Weight : 46 Kg (including accessories)

C. Consist of(per 1Set)

1.	Main Unit	1Set
2.	Dedicated Probe	1ea
3.	Steatosis Measurement Module	1ea
4.	Spleen Stiffness Measurement Module	1ea
5.	Dedicated Probe For Overweight Patient	1ea
6.	DICOM	1ea

D. Remarks

1. 장비의 운송, 설치, 교육은 공급자가 책임진다.
2. 제품 하자에 관하여 검수합격일로부터 3년 종료월 말일까지 보증(Warranty)기간으로 한다.