

물 품 규 격 서

- ☐ 입찰공고번호 : (학)일송학원 관리국 제2025-110-1호
- ☐ 입찰건명 : 비뇨의학과(외래) 3D MR Fusion Prostate Biopsy System(3D MR 경직장 영상 합성 전립선 생검 시스템) 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
3D MR Fusion Prostate Biopsy system (3D MR 경직장 영상 합성 전립선 생검 시스템)	A or B	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

It is a mobile diagnostic and interventional ultrasound system, controlled by mapping software. Its function is to acquire 2D (B-mode, Color Doppler mode) or 3D ultrasound data and to display them as grayscale or colored, mono-slice or multislice images.

It incorporates the PROMAP application within the 3D software suite, enabling processing, visualization and recording of 3D ultrasound images of the prostate as part of procedures requiring the positioning of instruments, such as a prostate biopsy procedure. Software options enable fusion of transrectal ultrasound with other imaging methods. The results of this 3D multimodal treatment and fusion are displayed in the form of a "map", so that it can be described as "mapping software".

Its 3D Prostate Suite onboard software and the associated probes are intended for diagnostic ultrasound imaging, ultrasound guided procedures and the treatment, visualization and recording of multimodal images.

Its 3D Prostate Suite onboard software are intended to be used by clinicians qualified to perform ultrasound diagnoses and ultrasound-guided procedures, and their assistants, in public or private hospitals.

It is intended for:

- The generation of ultrasound images and the analysis of fluids from the human body in exams such as:
 - o abdominal
 - o gynecology
 - o musculoskeletal
 - o small organs
 - o soft tissues
 - o urology
 - o vascular
- The treatment, visualization and recording of 2D and 3D images acquired using various modes (such as ultrasound images, MRI)
- The fusion of images acquired using various modes
- Display of organs and measurements
- Display of prostate procedure mappings (instrument positions)
- Management of patient data • Import and export of data and images.

B. Specifications

1) MATERIAL

Operating system / Windows 10

Processor / Intel Core i7

Hard Drive (HDD) / 2 To SSD

Random Access Memory (RAM) / 8 Go

Monitor / 21.5 inch LCD touchscreen monitor - usable with medical gloves - Cleanable

Accessories / Footswitch - 2 pedals - USB connexion - cleanable , Touch pen - Aluminium and rubber - cleanable, Mouse - 4 buttons - USB connexion - cleanable, Virtual keyboard - Different languages available - Via touchscreen, Keyboard (optional) - Different languages available - USB connexion, Probe holder - Compatible with probes

2) INPUT/OUTPUT CONNECTIONS

Electrical separation of devices with independent power supply (battery/PSU) /Only connect independently powered devices that are compliant with the latest IEC 60601-1 or IEC 60950-1 safety norms (including applicable national deviations).

USB ports / 6 x USB 3.1 ; 2 x USB 2.0

Ethernet/LAN / 4 x Ethernet IEEE 802.3

Display output / 4 x Mini Display Port (including one output linked to the device screen)

Cable specifications/Ethernet/LAN≤10m, shielded, Power supply≤5m, Other cables≤3m

3) ELECTRICAL

Classification / Class 1

Power supply / 100-240 VAC, 6-3.75A, 50-60 Hz

Disconnection from electrical mains/ Manual disconnection of the power supply plug

Max. operating altitude ≤ 3000 m

Mains fuses / (x2) Voltage : 250 V, Current : 8 A, Operating speed: fast acting, Breaking capacity : 1500 A

4) ELECTRO-MAGNETIC COMPATIBILITY

CISPR 11 classification / Group 1, class A

IEC 60601-1-2 use environment classification/ PROFESSIONAL HEALTHCARE FACILITIES

EMC Compliance / Cf. TRINITY User Manual Volume 1

5) DIMENSIONS AND WEIGHT (w/o packaging)

Dimensions / 130 cm x 61 cm x 62 cm

Weight / approximately 65 kg

6) 3D ULTRASOUND SYSTEM

Advanced ultrasound system for urologic applications that provide the following functions.

- B-mode, Color Doppler and Power Doppler 2D imaging modes
- “Full 3D” B-mode for prostate imaging
- Factory and user ultrasound presets
- Distance and volume measurements
- Screenshots and cine loop video recording
- Instrument tract display
- Automatic procedure report

7) PROBE

3D ENDOCAVITY SIDE-FIRE PROBE FOR TRANSPERINEAL APPLICATION.

- Clinical Application : Prostate
- Frequency: 4- 9 MHz
- Field of view: 72 mm, linear lateral-fire
- Sweeping angle : 170°
- Shaft radius : 10 mm
- Imaging modes: B-mode 2D, B-mode 3D, Color Doppler, Power Doppler

8) PROBE

3D ENDOCAVITY END-FIRE PROBE FOR TRANSRECTAL END-FIRE® APPLICATION.

- Clinical Application : Prostate
- Frequency: 4- 9 MHz
- Field of view: 146°, convex End-fire
- Sweeping angle : 90°
- Radius of curvature: 10 mm
- Imaging modes: B-mode 2D, B-mode 3D, Color Doppler, Power Doppler

9) STEADY PRO

PROBE HOLDER

- Designed for transperineal and transrectal approaches, the probe holder has a specific probe interface for each 3D US probe in order to stop movement once the position is locked.

10) REUSABLE GUIDE

FOR 3D ENDOCAVITY END-FIRE PROBE

- Made for End-Fire needle access, the guide is straight and makes the needle insertion easy. It shows smooth angles for patient comfort.

This stainless steel guide is meant to be sterilized by autoclave.

C. Consist of(per 1Set)

1.	Main Unit	1Set
	21.5 inch Touch Screen	
	Articulated Screen Holder	
	Cable Holder	
	Document Holder	
	Touch Pen(Mouse, Key Board)	
	3D Ultrasound Unit	
	Probe Holder	
	Mobility	
	Foot Switch	
2.	KAPP-3000-P(Perine Software and probe)	1ea
3.	Reusable Guide(KRNG.EL1.18 Perine Guide)	1ea
4.	Steady Protm(KSP.PACK.TP)	1ea
5.	Trasnrectal Approach(KAPP-3000R)	1ea
6.	Disposable TR Guide(KDNG00)	1ea
7.	Linear Small Prats Probe	1ea

D. Remarks

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

<규격서 B>

A. Features

- 3D MR FUSION Prostate Biopsy System

1. Resistration of the patient
2. Entry of the correct MR or Ultrasound images via the integrated frame grabber or via any other track
3. Entry of DICOM CT or MR image
4. Template calibration, image dimensions calibration, image vortex calibration, organ contour positioning
5. Selection of gold marker and biopsy needle type used
6. Biopsy core and gold marker placement
7. The organ surfaces displayed in 3-D display are based on the organ contour drawn into the transvers images
8. Biopsy Report Setup or Marker Report Setup
9. Thumbnail Image
10. Biopsy course used for planning or the actual procedure including the display of the marker and needle
11. Biopsy Plan can be updated continuously
12. Device by which image are entered are entered into a computer via video output of the imaging device
13. Device that moves the ultrasound probe and passes information to BioJet on the exact position of the probe relative to a user defined position
14. Template calibrate the image
15. 4 types Image (Reference, Primary, Secondary and Overview Images)
16. Prostate Mapping
17. Draw ROI and Contour

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B. Specifications

1. 3D-MR/TRUS Fusion Prostate Biopsy System

가. 3D MR/TRUS Fusion Biopsy Program

Desktop PC with Cart

- OS : Windows 10 Pro
- Processor : Dual Core 2GHz or more
- Graphics Memory : 512MB or more
- RAM : 2GB or more
- Harddisk Capacity : 300GB or more
- Integrated Frame Grabber
- CD ROM R/W driver

Laptop PC for Biojet

PC Monitor (21" or more)

- Screen resolution : 1280 x 1024 pixels or more

ㄴ. Stepper

The precision stepper enables the user to advance, retract, and rotate an endo-rectal ultrasound probe in the rectum to image the prostate.

- The endo-rectal probe is inserted into and fixed to the stepper and positioned by moving the stepper/probe combination.
- Any endo-rectal probe from any producer can be fit to the stepper as far as the respective probe cradle is available.
- Probe can be rotated around the probe's long axis ($\pm 70^\circ$). The probe locks into the adjustable center position.
- Movable length of the probe with the stepper: 100 mm.
- Scale for position recognition.
- Step width: 2.5 mm or 5 mm selectable as well as free analog movement in and out of the rectum.
- Additional free analog movement of the probe to define the exact starting point for stepwise movement: 50 mm.
- Template is movable (100 mm) in the direction parallel to the ER probe's long axis and can be fixed in any position.
- Sterilizable: at least 200 times with steam at 115°C - 140°C (pressure 2 to 3 bar).

ㄷ. Articulate Arm (= Stabilizer)

Device that can carry objects for simple manual positioning.

- Free manual positioning in all directions
- Can be fixed to the OR-side rail on any OR table via the universal OR-side rail adapter if supplied.
- Can be locked in space in any position.
- The articulate arm includes 6 (in most cases) 360° rotating joints that are connected to one another by tubes of different length. All joints are unlocked or locked simultaneously by pulling (or pressing) a single lever (W) and then releasing it.
- A universal OR-side rail adapter is fastened to one end of the arm.
- A pistol-type handgrip is connected to the other end of the arm. All joints are unlocked or locked simultaneously by pulling (or pressing) a single lever (W) and then releasing it.
- The pistol-type handgrip includes an elevation slider that allows an object attached to the handgrip to be moved up to 10 mm from a central position.
- The pistol-type handgrip includes a swivel device that allows an object attached to the handgrip to be rotated left and right up to 15° from its central position.
- A lock that slides into the sliding block linkage on the underside of the stepper is positioned at the top of the handgrip
- The articulate arm is not waterproof
- The maximum torque that may be applied to any individual joint - on an arm with a tube diameter of 50 mm - may not exceed 6.5 Nm. That is equivalent to a work load of about 10.0 kg when the arm is fully extended horizontally to a length of about 65 cm.

ㄹ. Template

Needle guide grid system for biopsy, cryo- / brachytherapy needles: Matrix of 13 x 13

individual channels (all channels - depending on the template used - for 13 G, 15 G, 17 G or 18 G Gauge needles - standard). This template is mounted on a specially developed template holder.

- The annotation of the needle channel rows depends on the template selected.
Row spacing: 5 mm in both cases
- The annotation of the needle channel columns depends on the template selected.
Column spacing: 5 mm in both cases.
- The template is made of stainless steel.
- Sterilizable: at least 200 times with steam at 115°C - 140°C (pressure 2 to 3 bar), can be heated in air up to 200°C for an indefinite time span.
- Template size: approx. 85 x 85 x 20 mm (H x W x D).

2. Ultrasound Scanner

가. SCANNING MODES

- 1) B (2D)
- 2) M
- 3) PW
- 4) CFM (Color flow mapping)
- 5) P (Power Doppler)
- 6) THI (Tissue Harmonic Imaging)
- 7) CI (Contrast imaging) / (Optional)

나. SCANNING MODES (Combination)

- 1) B + M
- 2) B + PW (Duplex)
- 3) B + CW (Duplex)
- 4) B + C + PW (Triplex)
- 5) B + P + PW (Triplex)
- 6) B + E 7) 2B

다. SCANNING MODES (SIMULTANEOUS SPLIT)

- 1) B + B (Biplane Imaging)
- 2) B + (B + C)
- 3) B + THI
- 4) B + CI

라. 3D MODES

- 1) 3D reconstruction
- 2) Motorized 3D reconstruction

마. TECHNIQUES

- 1) Fully digital Beam-former
- 2) Speckle reduction
- 3) Compound imaging
- 4) Dynamic focusing
- 5) Dynamic apodization
- 6) Multibeam processing

바. QUALITIES

- 1) Frequency range : 2-20MHz
- 2) System dynamic range declared : >187
- 3) Composite focus transmit zones : 8
- 4) ADC bits : 12
- 5) Scanning depth, min, cm : 0.2
- 6) Scanning depth, max, cm : 30
- 7) Max Frame rate declared , fps : >200 (Transducer dependent)

- 8) Number of gray levels (shades of gray) : 256
- 9) Multi frequency in B-mode
- 10) B-mode gray scales : 21 (Transducer dependent)
- 11) Displayed dynamic range, dB : 50 - 90
- 12) Gain (Range), dB : 60
- 13) TGC sliders number : 8
- 14) TGC adjustment, dB : 20
- 15) Edge enhancement : 8 levels
- 16) Persistence : Auto
- 17) Multi-beam in B-mode : up to 4
- 18) Line density in B-mode : Auto
- 19) Noise reject : 6 levels

사. DOPPLER (COLOR MODE)

- 1) Sample points : up to 512
- 2) PRF range : 0.2 - 12kHz
- 3) Velocity range : 0.1 - 493 cm/s (Transducer dependent)
- 4) Wall Filter : digital, 8 steps
- 5) Baseline : Adjustable
- 6) Colors : 256 (Velocity)
- 7) Line density : Auto
- 8) Color Doppler interleave factor : 256 lines
- 9) Multi frequency in B-mode
- 10) Multifrequency in Doppler modes : up to 4 (Transducer dependent)
- 11) 2D filter smoothing : 6 steps

야. DOPPLER (POWER MODE)

- 1) Sample points : up to 512
- 2) PRF range : 0.2 - 3 kHz
- 3) Wall filter Digital
- 4) Colors : 256
- 5) Colors maps : 5
- 6) Persistence : 3 steps
- 7) Line density : 5 steps, Auto
- 8) 2D Filter, Color smoothing : 6 levels
- 9) Color priority : Automatic
- 10) Shots per estimate : up to 16, Auto

자. DOPPLER (PW MODE)

- 1) Gain control : 60 dB
- 2) Sample volume size : 1 - 20 mm
- 3) PRF range : 1- 20 kHz
- 4) HPRF : Automatic
- 5) Display kHz or cm/s (choice)
- 6) Flow inversion
- 7) Baseline offset
- 8) Wall filter : 8 steps, 0.5 - 20% PRF
- 9) Min detectable speed : 0.1 cm/s
- 10) Max detectable speed : 805 cm/s
- 11) Spectrum display : 256 levels, B/W or color
- 12) Color maps : 8
- 13) Doppler steering (\pm degreed) : 30 (Transducer dependent)
- 14) Angle correction : 90 degrees
- 15) Doppler audio output : 1 W
- 16) Curve auto tracing
- 17) Real-time Doppler measurements

차. DOPPLER (CW MODE)

- 1) Max scale : 48 KHz
- 2) Color maps : 8
- 3) Wall filter : 15 steps
- 4) Velocity range : 0.39 - 1970 cm/s
- 5) Steering : 90°

카. DOPPLER (M-MODE)

- 1) Presentation : Vertical or horizontal split
- 2) Sweep speed : 2 - 12 s per screen
- 3) Gain : 60 dB

타. 3D MODE

- 1) Resolution : 0.2 mm
- 2) 3D/Frame rate/Speed : Real-time reconstruction tracked
- 3) Measurement possible
- 4) Rendering (Surface)
- 5) Multiplanar

파. DOCUMENTATION, OTHER

- 1) Measure on stored images
- 2) Office printer support
- 3) CD-RW
- 4) DVD-RW
- 5) Built-in HDD : 500 GB
- 6) Storage capacity : > 100,000
- 7) Image and video format : BMP/AVI (lossless), DICOM
- 8) External HDD : up to 500 GB
- 9) USB storage : 8 ports
- 10) DVI Out (HDMI via connector)
- 11) VGA output
- 12) S-Video output
- 13) Composite output
- 14) Built-in patient archive
- 15) Clip storage
- 16) Maximum clip length : 600 Sec
- 17) Clip editing
- 18) Report storage

하. USER INTERFACE

- 1) Direct on-screen controls
- 2) Interactive keyboard light
- 3) Transducer buttons (SMART buttons)
- 4) User-defined hard keys

C. Consist of(per 1set)

1. Main Unit(3D MR Fusion Biopsy System)	1ea
2. Accessories	
Universal OR-Side Rail Adapter	1ea
Elevation/Swivel Handle	1ea
Stepperfor ER-probes	1ea
Universal Brachytherapy Stepper for transperineal Ultrasound Probe	1ea
Template	1ea
Universal Template Holder	1ea
Probe Receptacle for ER-Probe	1ea
Incremetal Encoder Set	1ea
Storage Caser Branchytherapy / Biopsy High Lithotomy	1ea
3. Ultrasound Scanner	1ea
4. Transducer	
Tri-Plane Transrectal	1ea
Bi-Plane Transrectal	1ea
Convex	1ea
Linear	1ea

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