

물 품 규 격 서

- ☐ 입찰공고번호 : (학)일송학원 관리국 제2021-052호
- ☐ 입찰건명 : 순환기내과(심혈관조영실) EP Recording System 구매
- ☐ 수요기관 : 한림대학교춘천성심병원
- ☐ 납품장소 : 수요기관 희망장소 입고도
- ☐ 물품내역 등

연 번	품명(영문, 국문)	규격 및 사양	총 구매예정수량 (Q'TY)	1회 최대 발주수량	WARRANTY 기간	단위 (UNIT)
1	EP Recording System (심전도 감시기)	A or B	1	1	검수완료(합격)일로부터 3년 종료 월 말일까지	SET

☐ 공통사항

1. 장비의 설치와 작동 및 교육은 무상으로 제공한다.
2. 수요기관 담당자 입회 하에 계약상대자는 제품의 설치 테스트 및 시험작동을 실시하여야 한다.
3. 하자담보책임기간은 물품 검수완료(합격)일로부터 3년 종료월 말일까지를 기본 원칙으로 하며 계약상대자의 추가 제안에 따라 3년 종료월 말일까지의 기간을 초과하여 설정할 수 있다.
4. 하자담보책임기간 중 수요기관의 사정으로 인하여 부서 및 장비의 위치가 불가피하게 이동을 필요로 할 경우에는 설명 및 설치가 무상으로 이루어진다.
5. 하자담보책임기간 중 공급된 장비의 부속품이 단종된 경우 수요기관이 인정하는 동등 이상의 장비로 무상교체가 이루어져야한다.
6. 계약상대자는 어떠한 상황에서도 애프터서비스를 위하여 전문서비스 인력을 제공하여야 하며 애프터서비스를 위하여 교체 부품을 보관하여야 한다.
7. 계약상대자는 장비 납품 시 납품일을 기준하여 제품 제조년월이 6개월 이내인 장비를 납품하고, 납품장비에 해당 제조년월이 명시되어야 한다.

<규격·사양 A>

○ Features

본 기기는 심장 활동 전위를 감시하는 기구로써, 진단용 전기자극기와(Cardiac Stimulator) 전달된 전기적 신호를 분석, 저장, 출력하는 워크스테이션(WorkStation)으로 구성되어 있습니다. Recording System은 환자의 생리학적인 데이터를 획득하고 계산하기 위한 컴퓨터 시스템이며, 모든 신호를 증폭하여 조정하는 중앙 제어장치(Amplifier)가 포함되어 있습니다.

○ Specifications

1. 모든 종류의 study를 쉽게 분석 가능하며, 단축키를 통해 Recodring System의 모든 기능을 보다 쉽게 사용할 수 있습니다.
2. Cardiac Stimulator는 통합형으로 사용할수도 있고, 독립적으로 사용할 수도 있습니다.
프로그래밍 되어 있는 protocol은 여러 사용주가 각자의 특성에 맞게 구성하여 사용할 수 있도록 protocol 사용자가 정의하여 쓸수 있습니다.
3. Ablation window는 워크스테이션의 실시간 화면에서 그래픽과 수치가 나타나며, Radiofrequency와 cryo ablation용 제너레이터와 호환 가능합니다.
Recodring System 각각의 채널에서 실시간으로 R-R, A-A, V-V, V-A, stimulation& pressure 파형 등의 인터벌 측정이 이루어집니다.
4. 타 IT 제품들과의 연결이 쉽고, 비용이 저렴하여, 네트워크가 용이합니다.
5. WorkStation : 워크스테이션이 있는 메인 카트는 CPU, 두 개의 모니터, 하나의 Stimulator 터치스크린과 프린터가 있습니다. 그리고 이동식 카트에서 사용하거나, 고정된 상태에서 사용 가능합니다. 외부의 노이즈를 차단하는 Isolation trasformer(절연트랜스)도 함께 구성됩니다.

COMPONENT	WEIGHT (kg)	DIMENSIONS (centimetre)		
		Width	Depth	Height
Display Workstation CPU	18	17	46.4	44.4
16:9 LCD Monitor without Stand (Qty 2)	4.8	55.1	7.1	33
Stimulator Touchscreen Computer	4.9	40.1	5	28.6
Main Insolation Transformer, 1500VA, 220VAC	19	40.8	28.4	14.2
Main WorkStation Cart, 48inches wide	96.6	121.9	71.1	110.7
Laser Printer (Domestic)				

6. Amplifier : Amplifier가 (환자의 아날로그 신호를 디지털 신호로 변환하여 워크스테이션으로 보내준다) 있는 보조 카트에는 Stimulator 프로그램과 절연트랜스로 구성됩니다. 이 구성품들은 주로 환자 침대 옆에 위치 시킵니다.

COMPONENT	WEIGHT (kg)	DIMENSIONS (centimetre)		
		Width	Depth	Height
Amplifier(SCU), Base 120ch	15.1	42.6	42.71	21.5
Programble Stimulator	4.9	42.2	35.5	8.8
Beside Isolation Transformer, 500VA, 220VAC	7.2	20.5	29.9	10.9
Beside Cart, 24 inches	46.2	60.9	53.3	86.3

○ Consist of

1. Display WorkStation CPU	SET	1
- Windows™ 7		
- Intel™ Xeon™ Dual Quad Core		
- Dual SATA hard drives with RAID mirroring		
- Custom Keyboard & Mouse	EA	1
2. Amplifier(SCU), Base 120ch	SET	1
- 2 Catheter Interface Input		
- 12 Surface ECG Channels Input		
- Pressure Input		
- Analogue Input/output		
- 12Lead ECG Cable	EA	1
- Catheter Interface Module 56pin	EA	1
- Catheter Interface Module 64pin	EA	1
- Pressure Cable	EA	1
3. Integraed Cardiac Stimlator	SET	1
- Stimulator Touchscreen Computer		
- Programmable Stimulator		
4. High Resolution LCD Monitor (1920*1080)	EA	2
5. Isolation Transformer	EA	2
6. LaserJet Printer (Domestic)	EA	1
7. Cart	EA	2
8. Manual	EA	1

○ Remarks

1. warranty : 검수완료(합격)일로부터 3년 종료 월 말일까지
2. 제품의 설치는 자격을 갖춘 기술자에 의해 최종 사용 장소의 무상으로 설치됩니다.

<규격·사양 B>

○ Features

1. Advanced EP Recording system

- 1) Automated electrophysiology
- 2) Electronic time and amplitude calipers for on-screen waveform measurements
- 3) Automatic measurement of data on both real-time and review screen and full image save.
- 4) Full disclosure retrieval
- 5) Automatic save function during the RF ablation and pacing, including emergency save on events
- 6) Real time output of 128 channels of digital waveform data to peripheral monitoring and recording device
- 7) Pediatric analysis and report
- 8) Database query and storage
- 9) Automatic procedure note and laser printout
- 10) Re-analysis
- 11) User configurable report format and laser printout
- 12) 64 channels displayed simultaneously on one page
- 13) 1K, 2K, and 4K sampling rates
- 14) 1000Hz low pass filter for better clarity and resolution
- 15) 12 lead ECG with 4 IBP with mean pressure, Pulse Oximetry(SpO2), Multiple analog outputs.

2. Windows 7 based application

- 1) System stability
- 2) Open architecture for flexibility
- 3) Multi-tasking for signal acquisition, data storage, data review, data analysis, and viewing of study log

3. User interface

- 1) Customizable procedural list/Macros
- 2) Simple menu hierarchy

4. Connectivity

- 1) Client/Server networking capabilities for multiple systems
- 2) Interfaces with Cardiovascular Information System, ECG Management system, and 3rdpartydatabases.

5. System Reliability

- 1) Windows 7 Ultimate[®] operating system.
- 2) Storage of entire Full-disclosure on hard drive or SD card
- 3) Remote online support and software upgrades

6. Reporting

- 1) Patient reports using Microsoft Office Professional Plus 2010[®]
- 2) Statistics using local database for Lab efficiency
- 3) Laser printout
- 4) Integration with hospital EMR

7. Image Integration

- 1) Integration of Fluoro images into the patient record in real-time
- 2) Automatic incorporation of images into Microsoft Office Professional Plus 2010[®] patient report

with the case data and waveforms.

3) Full Image save

8. Enhanced Pediatric Capabilities

- 1) Detailed shunt analysis and resistant values
- 2) Easily separates and sorts hemodynamic conditions.
- 3) Interface to the PedCath heart diagramming module

9. Integrated signal acquisition

- 1) Acquisition of 12Lead ECG with ST segment analysis, HR, RR, SpO2, IBP, NIBP, Thermodilution CO is from 1 device, TRAM module without the need of additional external device.
Automatic Fick CO calculation.

10. User Configurability

- 1) User-configurable signal parameters, including gain and sweep speed
- 2) Customizable site label keys
- 3) Creates different hemodynamic conditions to meet the needs of the Lab

11. True Colors

- 1) 32 bit true colors
- 2) 15 color selections for signals

12. Cath and EP in a single system

- 1) Single database and network
- 2) Interface from Hemo and EP System to Innova
- 3) Standardized on a single platform with upgradeability

13. Others

- 1) Valve gradients and areas are instantaneously displayed graphically and numerically
- 2) The system record a 12 lead printout by selecting an Icon or by pressing a single key on the keyboard also print a 12 lead for any data which have been previously recorded.
- 3) The system is able to print reports, plots, waveforms and other items in a background mode so that the operator may continue to use the system for analysis and review even during the printing.
- 4) The report facility should include the capability to combine word processing, user definable text dictionary, templates and automatic summarization of study data.
- 5) Ability to include multiple customer-defined set-ups.
- 6) Multiple timers and stopwatches
- 7) Single or multiple pullbacks automatically
- 8) Splice capability
- 9) Automatic shunt calculation including Qp/Qs
- 10) Report sharing with another site through network
- 11) Display up to 64 channel simultaneously
- 12) Laser printer: 16ppm up to 24ch.
- 13) RSS modem for remote service

○ Specifications

1. Main unit

- 1) Fully integrated electrophysiology monitoring
- 2) Seamless data integration from all pacing device and multiple RF ablation devices with

multi-temperature
capabilities

- 3) Operator can select parameters for waveform size, BP scale, display and recording format
- 4) Clinical patient information entry and archiving
- 5) All waveform baseline can be positioned
- 6) Built-in HIS interface capability
- 7) Environmental/ electrical specifications
 - Operating temperature: 10 to 30°C
 - Storage temperature: -10 to 45°C
 - Humidity: 30 to 75%
 - Maximum current draw: 15A/ 115V, 7A/ 230V
 - Power: 220V/ 60Hz

2. Software

- 1) Electrophysiology software
- 2) Microsoft Office software
- 3) Modem communication software
- 4) Automatic RF ablation and stimulus detection
- 5) RF window
- 6) Digitize and store selected fluoroscopy image with patient electrograms
- 7) Multiple caliper display and beat to beat function
- 8) User-defined protocols
- 9) Backup and restore capability
- 10) Automatic procedure note and laser printout

3. Controller

- 1) Intel 2.0 GHz Quad-core or Better
- 2) 16 GB RAM
- 3) Dual 500 GB in RAID 1
- 4) SD Card
- 5) Optical Scroll Mouse
- 6) OS: Windows 7 Ultimate®
 - Microsoft Office professional Plus 2010
- 7) 100/1000 Base -T Ethernet,TCP/IP

4. Amplifier

- 1) Superior RF Filtering and 224 catheter input capability w/7 catheter input modules
- 2) 12 lead ECG
- 3) 4 pressure inputs, and 75 fiber optic cable
- 4) The amplifier unit meets UL2601-1 standards for medical equipment and has been independently tested by ETL testing laboratories
- 5) ECG input:
 - High pass filter: DC, 0.05Hz, 0.5 HZ, 5Hz
 - Low pass filter: 100Hz
 - Gain: 50 - 10,000 in 8 settings
- 6) Catheter/Intracardiac:
 - High pass filter: DC, 0.05Hz, 0.5Hz, 5Hz, 30Hz, and 100Hz
 - Low pass filter: 150Hz, 500Hz, 1000Hz
 - Gain: 50 - 10,000 in 8 settings

- 7) Pressure(4 inputs):
Range: -400 mmHg TO 400mmHg
- 8) Design:
Sampling rate: 1K, 2K, 4K
CMRR: 100db min
Input Impedance: > 1 billion Ohms

5. Cardiolmage Fluoroscopy Image Management System

- 1) View real-time images from X-ray, IVUS, Echo, or any standard video source on a dedicated 1900 x 1200 monitor
- 2) Acquires up to 1280 x 1024 images at 72 Hz sampling from up to 4 separate inputs with a maximum input Frequency of 135 MHz

6. Patient Data Module(PDM)

- 1) Amplifiers: Modular transport design
- 2) ECG: 12 lead with ST segment analysis
- 3) Respiration: Impedance method (1 to 200 breaths per minute range)
- 4) Cardiac Output: Thermodilution, calculated and estimated Fick
- 5) Invasive pressure: 4 channels with means (-98 to 350 mmHg range)
- 6) Non-invasive pressure: Automatic and manual modes (Oscillometric)
- 7) Pulse Oximetry: Saturation range 0 to 100% (accuracy 90 to 100%, 1.5%)

7. Integrated Electronics Box (IEB)

- 1) 56.6K baud fax modem for remote support
- 2) Uninterruptible Power Supply (UPS)

8. Cardiac Stimulator

- 1) Current : 0.1 to 25mA
- 2) S1 Range : 180 to 9990 ms
- 3) S1 -S7
- 4) Coupling interval: 30 to 9990 ms

9. Accessories and Cables / Operating SVC manuals

10. Physical specifications (W x D x H, weight) in cm and Kg

- 1) Controller: 20 x 48 x 43, 15
- 2) Workstation: 114 x 76 x 75, 65 or similar
- 3) 20"LCD: 47 x 22 x 47.9

○ Consist of

1. EP Recording System ----- 1EA

- 1) Electrophysiology software
- 2) Modem communication software
- 3) Automatic RF ablation and stimulus detection
- 4) RF window
- 5) Digitize and store selected fluoroscopy image with patient electrograms
- 6) Multiple caliper display and beat to beat function
- 7) Shortcut and icon function key
- 8) User-defined protocols

- 9) Backup and restore capability
- 10) Analog In and Analog Output
- 11) Audible Indicators (240V)

2. EP Recording System Main Controller ----- 1EA

- 1) Intel 2.0 GHz Quad-core or Better
- 2) 16 GB RAM
- 3) 2 x 500 GB in Raid 1 Hard Drive
- 4) DVD RW Drive
- 5) SDHC CARD Drive
- 6) Optical Scroll Mouse
- 7) Windows 7 Ultimate®
- 8) Microsoft Office professional 2010

3. Amplifier, 128 Channels ----- 1EA

4. Cardiolmage Fluoroscopy Image Management Module Interface ----- 1EA

5. Integrated FFR Module Interface (Software)

6. Patient Data Module(PDM) ----- 1Set

- 1) PDM MODULE with 12 SL ECG with ST Sagment analysis
- 2) SpO2, NIBP
- 3) Up to 4 Invasive Blood Pressure
- 4) Cardiac Output & Defib Sync
- 5) PDM Basestation w/power supply, EXPORT
- 6) Cables & accessories

7. Integrated Electronics Box (IEB) ----- 1Set

8. 65" Workstation Desk ----- 1EA

9. Laser Printer ----- 1EA

10. Flat-Panel Monitor ----- 3EA

11. Cardiac Stimulator ----- 1Set

12 Accessories and Cables

- 1) Disposable BP Transducer ----- 1Box
- 2) BP Transducer cable ----- 2EA
- 3) BP transducer holder ----- 1EA
- 4) NIBP and SpO2 Accessories KIT ----- 1Set
- 5) Operator and Service Manual ----- 1Set
- 6) ECG leadwire and Cable ----- 1Set

○ Remarks

1. Warranty : 검수완료(합격)일로부터 3년 종료 월 말일까지
2. The equipments should be installed by contractor.