

# 입찰규격서

관세분류번호	품목번호	품목 및 규격	수량	단위
HSK NO.	ITEM NO.	DESCRIPTION	UNIT	Q`TY
9018.19-8000	A26290.01	범용유발성응답용자극장치	SET	1

## A. 특징 :

1. One platform for all tests
2. Modular Concept
3. ABR system

## B. 사양 :

### 1. Hardware

#### a. Standards

- 1) Safety : IEC60601-1, Class I, Type BF and IEC 60601-1-1, Class I, Type BF
- 2) EMC : IEC 60601-1-2

#### b. Preamplifier

- 1) Two channels standard : Cable Collector (4 electrodes). Standard 50 cm.
- 2) Gain: 80 dB/60 dB
- 3) Frequency response: 0.5 - 5,000 Hz
- 4) CMR Ratio: Minimum > 118 dB. Typical 130 dB <100 Hz
- 5) Radio Frequency Immunity: Typically 25 dB improvement over previous available designs
- 6) Max input offset voltage: 2,5 V
- 7) Input impedance: 10 MΩ / 170 pF

#### c. Impedance check

- 1) Measurement frequency : 33 Hz rectangle (Selectable for each individual electrode)
- 2) Measuring Current: 19 μA
- 3) Ranges: 0.5 kΩ - 25 kΩ

#### d. Dimensions and weight

- 1) Dimensions ; (L x W x H) 28 x 32 x 5.5 cm
- 2) Weight: 2.5 kg

### 2. Software

#### a. PC requirements

- 1) Operating System: Windows 7 or 10
- 2) Processor: Pentium III, 650 MHz or better.
- 3) RAM: 256 MB better. Hard disk: 500 MB better
- 4) USB Port: 2.0 or lower

#### b. OtoAccess database (integration with EMR system)

- 1) Database: SQL
- 2) Data format: XML

#### c. Available Test

- 1) ABR
- 2) TEOAE
- 3) DPOAE

신청부서 : 이비인후과

의료기기 안전관리 책임자 : 최영운 (인)

### 3. ABR Spec

#### a. Stimulus

- 1) Rate: 0.1 – 80.1 per sec
- 2) Masking : White noise (+30 dB to -40 dB relative to stimulus presented in peSPL.)
- 3) Transducer : Ear-Tone ABR insert phone
- 4) Intensity : 20 – 135.5 dB peSPL, (-10 – 100 dB nHL) in 1 dB steps
- 5) Polarity : Condensation, Rarefaction, Alternating
- 6) Type
  - a) Click : 100  $\mu$ s (200 Hz -11 kHz)
  - b) Tone Burst Frequency : 500, 750, 1000, 1500, 2000, 3000, and 4000 Hz.  
Envelopes: Blackman, Gaussian, Hanning, Hamming, Bartlett, Rectangle, and manual rise/plateau/fall.
  - c) NB CE-Chirp® LS Frequency : 500, 1000, 2000 and 4000 Hz
  - d) Broad Band CE-Chirp® LS : 200Hz -11 kHz

#### b. Recording

- 1) Analysis time: -150 ms prior to stimuli and up to 1050 ms (license dependant).
- 2) A/D resolution: 16 bit.
- 3) Sampling frequency : 30 kHz
- 4) Artifact Reject System : Standard voltage based system
- 5) Rejection Levles : Manual 0.2 - 640  $\mu$ V input with 0.1 uV steps.
- 6) Dots per trace: 450 displayed.
- 7) Filters
  - a) Low Pass Filter : None or 17 – 12000 Hz, depending on the measurement type  
33 taps FIR Filter without wave peak latency displacement
  - b) High Pass Filter : 0.83 Hz to 500 Hz depending on the measurement type.
  - c) DSP Low Pass Filter : 100, 300, 750, 1 k, 1.5 k, 2 k, 3 k, 4 k, 5 k, 7.5 kHz
  - d) DSP High Pass Filter : 0.5, 1.0, 3.3, 10, 33, 100 Hz
  - e) Anti aliasing Filter : Analog 5 kHz, 24 dB / octave

### 4. DPOAE Spec

#### a. Stimulus

- 1) Frequency Range: 500-8000 Hz.
- 2) Frequency Step: 25 Hz.
- 3) Intensity : 30-70 dB SPL
- 4) Intensity Step: 1 dB SPL.
- 5) Transducer: Dedicated DPOAE/TEOAE probe

#### b. Recording

- 1) Analysis time: Minimum 2 sec to unlimited test time
- 2) A/D Resolution: 16 bit, 3.7 Hz resolution
- 3) Sampling frequency : 30 kHz
- 4) Artifact Reject System: Adjustable: -30 to 30 dB SPL or off. Applicable during testing.
- 5) SNR Criteria: Adjustable

#### c. Auto protocols

- 1) Preprogrammed tests. Additional tests preprogrammable by user.
- 2) Checkmark indication for S/N R passed

#### d. OAE probe

- 1) Dimensions : (W x D x H) 12 x 26 x 11 mm

### 5. TEOAE Spec

#### a. Stimulus

- 1) Type : Click Non-linear

- 2) Intensity : 30-90 dB SPL.
- 3) Intensity Step: 1 dB SPL.
- 4) Bandwidth: 500 Hz – 5500 Hz
- 5) Transducer: Dedicated DPOAE/TEOAE probe (Accuracy: 0.5 dB).
- b. Recording:
  - 1) Analysis time: 5 seconds to 30 minutes
  - 2) Sampling frequency : 30 kHz
  - 3) A/D Resolution: 16 bit, 3.7 Hz resolution.
  - 4) Artifact Reject System: 0 to +60 dB SPL or off. Applicable during testing.
  - 5) SNR Criteria: Adjustable between 5 and 25 dB.
- c. Auto protocols
  - 1) Preprogrammed tests. Additional tests preprogrammable by user.
  - 2) Checkmark indication for SNR passed
- d. OAE probe
  - 1) Dimensions : (W x D x H) 12 x 26 x 11 mm

#### C. 구성 :

- 1. Preamplifier
- 2. Cable collector USB cable
- 3. ABR Insert ear phones w/foam tips
- 4. ETB Electrode cables
- 5. PEG15 Set of 25 single use pre-gelled electrodes
- 6. 20 pcs. of Infant eartip ( 2X10)
- 7. Skin scrub accessory  
(Alcohol pads, Gauze swab, SPG15 NuePrep gel)
- 8. Cable (Power Cable, USB cable)
- 9. OtoAccess Software
- 10. Installation CD
- 11. Laptop computer or Desktop computer

#### D. 비고 :

- 1 공급자는 설치완료일로부터 3년 무상보증한다.
- 2 장비의 설치와 작동 및 교육은 무상으로(사용자와 협의) 제공하여야 한다.
- 3 공급자에 의해 제품의 설치, 테스트 및 시험작동이 이루어져야 한다.
- 4 사용자의 교육요청 시 국내 교육을 실시 하여야 한다.
- 5 무상보증기간 종료 전 병원 측의 장비 최종 점검 요청에 협조하여야 한다.
- 6 공급자는 장비의 안전성을 위하여 병원측의 예방점검 요청에 적극 협조하여야 한다
- 7 사양 및 구성에 표기 된 명칭과 기능이 각 제조사에서 사용하는 명칭 또는 기능과 상이하더라도 그 기능이 동등 또는 대체 가능하거나 그 이상일 경우에는 인정한다(단, 기종이 바뀔 수 있는 주기능이 아닌 보조 기능에 한한다.)