

의료장비 일반 사양서

문서번호 : 영의26-0909호

신청부서		안과	신청수량	1 set	
장비명	국문	전안부 촬영장치	도입구분	분류	A28090.01[1]
	영문	Anterior Segment Imaging Device		사유	신규

I. General Specification

The specifications below are basically similar or superior specifications.

A. Features :

- The system shall be an advanced ophthalmic imaging device capable of non-contact and non-invasive examination and analysis of the cornea and anterior ocular surface.
- The system shall provide corneal topography measurement and analysis using Placido disk technology or equivalent technology.
- The system shall be capable of evaluating corneal parameters including curvature and other corneal topographic data.
- The system shall provide one or more additional ophthalmic examination functions, including pupil measurement, meibomian gland imaging, tear film analysis, or dry eye assessment.
- The system shall support automated image acquisition and/or analysis functions to improve examination efficiency and reproducibility.
- The system shall provide dedicated software for image acquisition, analysis, storage, and review.
- The system shall support digital data management and provide connectivity for hospital information systems or image management systems, where applicable.

B. Specifications :

Imaging System

- The system shall be based on a corneal topography or anterior segment imaging system using one of the following technologies:
 - Placido Disk-based imaging system or
 - Placido Disk-based anterior segment imaging system with integrated ocular surface analysis.
- The system shall support one or more of the following acquisition modes:
 - Single-shot imaging
 - Multi-shot imaging
 - Video acquisition
 - Automated image acquisition or Automated image acquisition.

Optical System

- The system shall use LED-based illumination.
- The illumination system shall include one or more of the following light sources:
 - White LED and Blue LED or White LED, Blue LED, and Infrared LED.
- The working distance shall be suitable for non-contact anterior segment examination and shall meet either of the following requirements:
 - Approximately 74mm or 60mm to 90mm

Corneal Topography

- The system shall provide corneal topography measurement and analysis.
- The system shall be capable of measuring or analyzing one or more of the following parameters:
 - Corneal curvature
 - Corneal topographic data
 - Simulated keratometry (Sim-K)
 - Corneal elevation
 - Corneal irregularity or index analysis.
- The system shall provide measurement coverage or analysis capability meeting either of the following requirements:
 - Placido disk-based topographic measurement with 24 rings or
 - Equivalent or superior corneal topography analysis.
- The dioptric measurement range shall meet either of the following requirements:
 - 1 D to 100 D or
 - equivalent or wider measurement range.

Anterior Segment and Additional Analysis

- The system shall provide one or more of the following functions:
 - Pupillometry and Meibography or
 - Pupil measurement and/or meibomian gland imaging.
- The system may provide additional functions including one or more of the following:
 - Contact lens fitting simulation
 - Corneal aberration analysis



Zernike polynomial analysis
Dynamic pupillometry
Fluorescein stimulation

Dry Eye and Ocular Surface Analysis

1. The proposed system shall provide one or more ocular surface or dry eye examination functions.
2. The system shall support one or more of the following functions, where applicable:
 - Non-invasive tear break-up time (NIBUT) measurement
 - Tear film analysis
 - Tear lipid layer analysis
 - Interferometry
 - Tear meniscus height measurement
 - Meibomian gland imaging
 - 3D meibography
 - Blink analysis
3. The system shall be capable of performing non-contact examinations without fluorescein dye, where applicable.

Measurement and Analysis

1. The system shall provide automated or semi-automated measurement and analysis functions.
2. The system shall provide measurement accuracy and performance appropriate for clinical corneal topography examinations.
3. The system shall support standard ophthalmic data management and reporting functions.

Data Management and Connectivity

1. The system shall provide data transfer capability through USB or equivalent interface.
2. The system shall support DICOM connectivity or equivalent standard ophthalmic data integration.
3. The system shall be capable of storing and reviewing acquired examination data.

Computer System

1. The proposed system shall include a computer system or shall be compatible with a computer system meeting the manufacturer's recommended minimum requirements.
 - Minimum 4 GB RAM, 1 GB dedicated video memory, minimum resolution of 1024 × 768 pixels, and USB 3.0 Type-A interface or
- Computer system supplied by the manufacturer and fully compatible with the proposed device.

II. Consist of : (A Model or B Model)

A - Model :

- | | |
|---|-------|
| 1. Main Unit(ANTARES+) | 1 set |
| 2. Computer System | 1ea |
| 3. Instrument Table | 1ea |
| 4. Operating/Service Manual | 1bk |
| 5. Light diffuser filter for auxiliary illumination, magnetic lock light diffuser filter (optional) | |

B - Model :

- | | |
|-----------------------------|-------|
| 1. Main Unit(ES-600) | 1 set |
| 2. Computer System | 1ea |
| 3. Instrument Table | 1ea |
| 4. Operating/Service Manual | 1bk |



III. 특기사항

1. 무상하지보증기간 : 3년
2. 한국식약처 의료기기 수입품목허가증 사본 제출