Ultrasound Biometric Scanner

PIROP

General Specification

Ophthalmic scanner:

A scan / B scan / Pachymetry

July 2017 / ***Ver. 16.***

CE 1011

CONTENS:

Software version information

This System Specifications applies to PIROP scanner with software version ≥ 01.24f.

Select ***Menu ->Setup -. Info*** for details on what software version is installed on your PIROP scanner

1. General properties:

- PIROP - State-of-the-art ultrasonic Ophthalmic scanner for Pachymetry and Ocular Biometry (A+ P+ B scan).
- Three operation modes:
  1. ***A-SCAN*** - Ocular Lens biometrics. Digital 'A-scan' tool for ophthalmology, biometry and lens power calculation for intra-ocular implants.
  2. ***B-SCAN*** - Digital 'B-scan' tool for ophthalmology, imaging of interior of an eyeball, retina, optical nerve ..
  3. ***P-scan - PACHYMETER*** - Ocular Cornea Thickness Biometrics. Ultrasonic pachymeter (cornea thickness biometrics) that uses a very high sampling frequency - 400 MHz - a significant increase in measurement accuracy.

- Quick Start (about 3 sec)
- Ergonomically and lightweight design: compact casing with Color LCD, Touch Screen and built-in Printer
- Easy and intuitive operation via **touch screen –** modern**,** user friendly Graphical Interface
- Functional **knob** (gain control, review results, cine etc.)
- Colour LCD panoramic 16:9 screen, size 7", 800 x 480 pixels
- Adjusting the monitor brightness
- Composite-video output PAL (option) - external optional video monitor 10" - 32" (or more)
- Probe operating frequency: 12 /15/ 20 MHz
- Run/Freeze: Foot Switch or touch screen activated
- Built-in internal calendar & clock (date and time)
- Entering a patient and operator data using the touch screen keyboard
- Internal patient's database
- Ability to choose up to 10 different user profiles (operators)
- Integrated internal memory for archive
- Storing measurement results and ultrasound images on internal memory and on USB memory stick (Pen drive).
- The possibility of printing the results of measurement on the built-in small thermal printer

- The possibility to print on the supplied printer the measurement results of the images from the archive (USB memory)
- Ready to use also in transport suitcase
- Probe holders
- Footswitch
- Trolley – option
- Easy firmware software upgrade via a USB memory
- Possibility of introducing changes according to specific user diagnosis requirements .

2. A-Scan application:

- Complete and quick biometry :
  - eye axial length /AXL/,
  - anterior chamber depth /AC/,
  - lens thickness /LENS/,
  - vitreous length /VITR/
- Calculation of the arithmetic mean of AXL, AC, LENS, VITR measurements
- Calculation of the standard deviation for AXL measurements
- Two Automatic modes of work, each with 10 measurements
- Measurements using individual zone velocities
- Adjustable velocities for each segment and pseudophakic materials - setting range: 300 to 3000 m/s (depending on the part of the eye)
- Automatic control of measurement scatters (with manual correction)
- Measurement Range:
  - AXL: 15 mm to 40 mm
  - AC: 1,8 mm to 6 mm
  - LENS: 1,5 mm to 6,5 mm
- Measurements of all eye types:
  - Normal,
  - Cataract,
  - Dense Cataract,
  - Silicone Oil Vitreous,
  - Aphakic,
  - Pseudoaphakic /PMMA,
  - Pseudophakic / Acrylate,
  - Pseudophakic / Silicone
- IOL power calculation - six formulas:

- SRK II,
- SRK T,
- Holladay,
- Hoffer-Q,
- Binkhorst II,
- Haggis

➢ Post refractive formulas :

- Double-K SRKT,
- Latkany / Flat-K SRKT/,
- Latkany /avg-K SRKT/,
- Masket

➢ Inputting IOL data (ranges): A-Constant (110 to125), SF value (3,50 to 5,25), Keratometry K values (5.00 to 14.99 mm; 15.00 to 67,99 D) , Target refraction TA (-9.99 to +9.99 D), AC value (1,5 to 7,0 mm), AXL value (14.00 to 45,00 mm).

➢ IOL power calculation comparison:

- simultaneous display four IOL power calculation results for different lenses and calculation methods selected by the user.
- comparison the IOL power calculation results for a given lens with all the formulas available in the PIROP scanner.

➢ Contact and immersion methods
➢ Immersion shell for probe OA12
➢ Probe frequency – 12 MHz
➢ Probe with central light beam for correct eye positioning (internal red LED)
➢ Memory of 20 scans with measurements for further analysis
➢ Automatic control of measurement scatters with manual correction
➢ Possibility to repeat selected measurements
➢ Easy review and sort post-operative results
➢ Entering parameters of artificial lenses – 10 types for each user
➢ Lens Database
➢ Automatically or Manually optimize Lens Constants for formulas.
➢ Customizable for 10 users, 10 profiles for each.
➢ Automatic TGC adjustment, GAIN adjustment (up to 110 dB)
➢ Range of scan: 40 mm
➢ Clinical resolution 0.1 mm
➢ Electronic resolution –/+ 0.01 mm
➢ Adjusting and test via attached calibrator.

3. B-Scan application:

- Display modes :
  - B,
  - B+A, (CV mode: B-Scan with simultaneous selectable vector A-Scan)
  - B+B
- Probe frequency - 12 MHz /15 MHz ; focused transducer
- Clinical resolution (axial) 0.12 mm
- Clinical resolution (lateral) 0.3 mm
- Scanning method: Sector
- Scanning angle 55°
- Scan depth: 20 - 60 mm (5 steps)
- Scan refresh rate - 12 frame / sec
- CV vector in Run and Freeze modes
- Automatic TGC adjustment
- Gain/dynamics up to 110dB
- 256 Levels Gray scale
- Dynamic Range Correction
- Image processing (sharp, smooth, brightness etc.)
- Four image memory B (cache memory) independent for right and left eyes
- Cache memory markers
- Measurements/calculations and annotations on snapshot playback
- Zoom function (x2) in Run and Freeze modes
- Controlling position the Zoom ROI
- Digital Gain Correction in Freeze mode
- Cine memory - Cineloop function (about 6 second) independent for left/right eyes
- 2 distances measurements with ultrasound velocity correction
- Axial distance measurement with ultrasound velocity correction
- Area measurement- draw method
- Angle measurement
- Comments entered by the user (4 text comment lines)
- Pointers (arrows)
- Sound velocity correction (adjustment range from 1400 to 2000 m/s)
- User setup for B-mode (Gain, CV on/off, Range, Display mode)
- Self test in B-mode for checking the probe and software algorithm
- Composite video output for video printer

4. P-scan (Pachymeter) application:

- Quick measurements of thickness for all corneal types
- Measurement of thickness at arbitrarily selected points of the corneal surface
- Automatic and manual measurements
- Calculation of the mean; standard deviation of the measured thickness
- Ability for rejecting uncorrected measurements
- Sophisticated algorithms for the accuracy improvement
- Very high frequency for measuring purpose- 400 MHz sampling rate
- High averaging ratio - 512 automatic measurements cycles.
- Intra-ocular pressure (IOP) calculations with measuring and/or manual correction
- Five IOP correction formulas : (Kohlhas/Shah, Herndon/ Doughty, Whitacre et al., Ehlers et al., custom - own)
- BIAS percentage deviation of the measured thickness from 60% to 130%
- 20 MHz operating frequency of the probe
- Direct contact probe
- Digital receiver 12 bit
- Default sound velocity - 1640 m/s (adjustment range from 1400 to 2000 m/s)
- Measurement range from 220 µm to 1100 µm
- Measuring accuracy < ± 2 µm
- Resolution 1 µm
- Nine maps of corneal thickness with the number of points: 1, 5, 9, 13, 21, 25, 1 MULTI, 5 MULTI, 9 MULTI
- Test Function for automatic checking the correctness of operation (without using external phantoms or patterns)

5. System setup :

- Selection of operator / user - operator name
- Date and time setting
- Brightness setting
- Application choice : P-scan, A-scan, B-scan
- User setup for B, P and A mode
- Ultrasonic velocity setting
- Eye type setup (mode, ultrasound velocities V_{AC}, V_L, V_V)
- Keratometry K1 and K2 edition

- Technique setup
- Parameters for post-refractive calculation
- IOL setup (lens, formula)
- Lens setup (name, type, const A, ACD,SF)
- Range in B-mode
- IOP formula selection
- Choice map in pachymeter application
- Measurement mode in P-scan
- BIAS setup
- Choice delay values

6. Archive:

- Build-in thermal printer to print measurement results in P and A application
- External video printer (print in gray scale)
- Printed values: screenshot, results of measurements, patient name, operator name, date and time.
- Images and measurements can be stored in build-in Internal memory (screenshot).
- Patients folders
- Apart from the image itself archive file contains full information of the measurement, image parameters, patient data etc.
- Internal memory to save images and measurements in all applications
  - Image file: BMP (24bit) formats 800 x 480 resolution (up to 8000 images)
  - Possibility to display images from internal memory
  - Possibility to delete selected image in internal memory
  - Possibility to export data from internal to external USB memory to display saved images on any PC computer
  - Possibility to print report from saved images on supplied thermal printer

7. Ultrasound probe :

- Dedicated sector probe OB 12, scanning angle 55°, for B-scan application
- Dedicated solid OA 12 i OP 20 probes for A-scan i P-scan applications
- Probe operating frequency :
  - A-scan: (OA 12) 12MHz
  - B-scan: (OB 12) 12/15 MHz
  - P-scan: (OP 20) 20 MHz

8. Dimensions and weight :

- Dimensions: 290 x 205 x 85 mm
- Weight (with built-in printer): 1.4 kg
- Overall weight (with transport suitcase) : ~ 2.6 kg

9. Supply :

- PIROP External AC/DC adaptor : input : 100 - 230 V AC /50-60hz/ 0.7A
  output : +12V DC / 2 A
- Power consumption (12 DC supply) - ca 11 W

10. Environmental conditions:

- Temperature : 10°- 40 °C
- Relative humidity : 30% - 85%

11. Electrical safety standards:

- Medical device **class IIa** comply with Medical Device Directive 93/42 EEC
- Scanner complies with requirements for **Class II** devices of EN/IEC 60601-1
- Medical Device Directive 93/42 EEC
- EMC Directive 89/336/EEC
- Electromagnetic Compatibility EN 60601-1-2
- Electrical Safety EN 60601

12. Approvals :

- CE marking

13. Acoustic safety standards:

- Acoustic safety : EN 60601-2-37 : 2007

All the probes foreseen to be used with Echo-Son systems PIROP meet the requirements of the Thermal Index TI and the Mechanical Index MI published by the Food and Drug Administration - USA and the International Electro-technical Commission IEC – International Standard 1157.

14. Liquid Ingress Protection:

- Scanner, printer, charger :

  IPX0 - (ordinary equipment without protection against ingress of water)

- Probes (position of the probe during the patient's examination):
  - ✓ OA 12 (A-Scan) - **IPX1 –** dripping water (vertically falling drops) shall have no harmful effect
  - ✓ OB 12 (B-Scan) - **IPX1 –** dripping water (vertically falling drops) shall have no harmful effect
  - ✓ OP 20 (P -scan) - **IPX3 –** water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect.

- Position of the cleaning and disinfection of the probe.:
  IPX1 – do not submerge the probe in any liquid deeper than shown in Fig *1 permissible level of submersion*

Fig 1