ECHOSON

PIROP

Ophthalmic Scanner

A scan / B scan / CCT-Pachymetry

USER
MANUAL
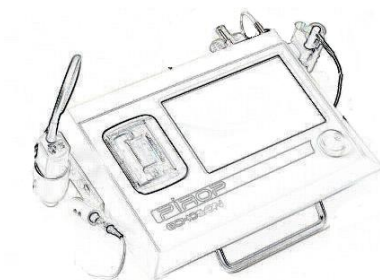
Version **PAB_33**

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RESPONSIBILITY ON THE MANUFACTURER PARTY

ECHO-SON S.A. is responsible for safety, reliability and performance of this equipment under the following conditions only:

- any repairs may only be made by persons authorized by manufacturer and have certified controlling and measurement equipment for electrical safety tests (in accordance with IEC-601-1) and for measurements of the power of emitted ultrasonic wave (IEC-601-1-2-37).

- the device should be connected to the mains in the manner specified by the manufacturer.

- this device have to be operated in accordance with User Manual

Software version information

- This User Manual applies to PIROP scanner with software version: from v. **01.39a.**

- Select **Menu -> Setup -> Info** for details on what software version is installed on your PIROP scanner (Version box). You can also read the software version in the Title screen (after turning the scanner on) – in the upper left corner of the screen.

> **U.M. version:**
> - **PIROP PAB 33**   (*PIROP_UserManual_PAB33_13.pdf*)
> - ✓ **Rev.13 ; 21.01.2022**

Warning

✓ **PIROP User Manual is designed for explanation of the features and functionality of the scanner and cannot be considered as a medical guide and does not provide clinical training.**

✓ *User of this equipment is asked to learn this manual carefully. Do not attempt to operate PIROP until you exactly understand all instructions and procedures in this User Manual. Ignoring this advice may cause failures or damage of the equipment and/or even can have influence on injuries of the human health.*

✓ *Echo-Son S.A. cannot be held liable for any damage or injury which results from a failure to follow, or incorrect use of, the instructions contained in this manual.*

✓ *Echo-Son preserve the right of revising the content in PIROP User Manual without any further notice.*

Examples of measurements used in this User's Manual are fictitious and do not in any way represent real patient.

According to the European Instruction 2002/96/EC and the Polish Law, referring to „waste electrical and electronic equipment", such scrap is not to be mixed with the home wastes. The user is obliged to deliver the worn out apparatus or its parts, at his own expense, to the manufacturer or to a place appointed for gathering such scrap.

Separate storage and recycling of such kind of worn out products contributes to preserve natural resources, secure human health and protect the natural environment.

For further information how to handle with worn out electrical and electronic devices, contact your local authorities, local recycling company or the manufacturer.

CONTENTS:

1. INTRODUCTION

1.1. APPLICATION

PIROP - state-of-the-art ophthalmic ultrasonic device for Biometry, Visualization and Pachymetry of eyeballs (A+B+P Scan).

Warning: This device is intended for healthcare professionals who are trained in A-scans, IOL power calculations, and/or B-scan and/or pachymetry measurements.

A-SCAN - Ocular Lens biometrics

The PIROP scanner in the A-scan mode provides a way to measure the axial length of the eyeball AXL, the depth of the anterior chamber (AC), the thickness of the lens (LENS) and the thickness of the vitreous body (VITR) using the OA 12 MHz probe. The applications used in the A-scan system provide a way to calculate the IOL power for the intraocular lens implants.

B-SCAN

PIROP scanner in B-scan mode enables the diagnosis of morphological changes of the eye structures and measurements. Ultrasound scanner also allows localization of foreign bodies, tumours, stroke and inflammation in the eye, and measurements of the various structures of the eye. Particularly valuable services gives the ultrasound scanner in case of the optical opacity of the eye structures and the evaluation of the retina, choroid, and optic nerve.

CCT- PACHYMETER (P-SCAN - Ocular Cornea biometrics

Up-to-date ultrasonic pachymeter used to measure the thickness of the eye's cornea (glaucoma screening and refractive surgery), with a very high sampling frequency –*400MHz* (a significant increase in measurement accuracy – ≤ *2 µm)*. Corneal pachymetry is an important test in the early detection of glaucoma (central corneal thickness CCT), and it help also surgeons by providing graphical surgical plans to eliminate corneal astigmatism..

Note : There are a lot of options in the PIROP versions:

- ➢ Only Pachymeter
- ➢ Only the A-scan
- ➢ Only the B-mode

or any combination of the **two** options listed above

Note: On the *mode selection Page, the mode keys in the background color are inactive. Active are those that correspond to the current PIROP scanner options (see chapter 9.7 – Unlocking Inactive Modes)*

PIROP user's interface based on touch screen technology makes operation easy and user-friendly. The touch screen can be also operated not only with fingers, but also using the enclosed stylus to keep it clean

1.2. TECHNICAL DATA

1.2.1. GENERAL PROPERIES

- ✓ Three operation modes: *A-scan ; B- scan ; Pachymeter*

- ✓ User-friendly and easy-to-use, intuitive operation via **touch screen** – modern user interface

- ✓ Ergonomically and lightweight design: compact casing with Color LCD, Touch Screen and built-in Printer

- ✓ Colour LCD panoramic 16:9 screen, size 7", 800 x 480 pixels

- ✓ Quick Start (about 3 sec)

- ✓ Probe operating frequency: 12 /15/ 20 MHz

- ✓ Composite-video output PAL - external videprinter or video monitor 10" - 32" (or more)

- ✓ Probe holders

- ✓ Run/Freeze: Foot Switch or touch screen activated

- ✓ Adjusting the monitor brightness

- ✓ Built-in internal calendar & clock (date and time)

- ✓ Entering a patient and operator data using the touch screen keyboard

- ✓ Support for an external barcode reader

- ✓ Possibility of connecting an external alphanumeric keyboard

- ✓ Voice messages

- ✓ 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 of printing the measurement report on the external (Wi-Fi or USB) printer – option

- ✓ The possibility of saving the measurement report as PDF file in USB memory (Format FAT 32)

- ✓ The possibility to print on the supplied printer the measurement results of the images from the archive

- ✓ Footswitch

- ✓ Ready to use also in transport suitcase

- ✓ Trolley – option

- ✓ Easy firmware software upgrade via a USB memory

- ✓ Possibility of introducing changes according to specific user diagnosis requirements .

1.2.2. A SCAN

- ✓ 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
- ✓ Sound signalling after taking the measurement
- ✓ 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)
- ✓ 4-Gate manual mode
- ✓ Measurement Range:
    - AXL: 15 mm to 40 mm   AC: 1,8 mm to 6 mm   LENS: 1,5 mm to 6,5 mm
- ✓ Measurement of all eye types:
  lens eyes (Normal, Cataract, Dense Cataract) ; eyes with artificial lenses pseudoaphakic (PMMA, Acrylate, Silicone) , and lens-free eyes (Aphakic)
- ✓ IOL six formulas:
    SRK II, SRK T, Holladay-1, Hoffer-Q, Binkhorst II, Haigis
- ✓ 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
- ✓ <u>Probe with central light beam</u> for correct eye positioning (internal red LED)
- ✓ Memory of 20 scans with measurements for further analysis
- ✓ 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: 45 mm on 2500 real measurement points
- ✓ Clinical resolution 0.1 mm
- ✓ Electronic resolution –/+ 0.01 mm
- ✓ Adjusting and test via attached calibrator.

1.2.3. B SCAN

- ✓ Display modes :
    - B,
    - B+A, (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
- ✓ TGC - zone gain adjustment in selected eye segments
- ✓ 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
- ✓ Angle measurement
- ✓ Area measurement- draw method
- ✓ 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 videoprinter.

1.2.4. CCT- PACHYMETER

- ✓ Quick measurements of thickness for all corneal types
    - measurement of thickness at arbitrarily selected points of the corneal surface
    - automatic and manual measurements
    - sound signalling after taking the measurement
    - calculation of the mean; standard deviation of the measured thickness
    - ability for rejecting uncorrected measurements
- ✓ Very high level of accuracy and repeatability of all measurements:
    - sophisticated algorithms for the accuracy improvement
    - very high frequency for measuring purpose- 400 MHz
    - 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%
- ✓ Two measurement ranges – SHORT: 220 ÷ 650 µm, LONG: 400 ÷ 1100 µm
- ✓ Setting the corneal velocity of ultrasounds
- ✓ Automatic TGC adjustment
- ✓ TEST function for automatic checking the correctness of operation (without using external phantoms or patterns)
- ✓ Result map and measurement parameters can be printed out using the connected l thermal process printer or stored in external USB memory (Pendrive).

SPECIFICATIONS:

- 20 MHz operating frequency of the probe
- 400 MHz sampling rate
- 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 defined maps of corneal thickness with the number of points:1, 5, 9, 13, 21, 25, 1 MULTI, 5 MULTI, 9 MULTI (central, paracentral, peripheral, parietal, mixed)
- digital receiver 12 bit

1.2.5. Electrical and mechanical parameters

- Medical device **class IIa** complies with **Medical Device** Directive 93/42 EEC
- Scanner complies with requirements for **Class II** devices of **EN/IEC 60601-1**
- Standards and norms: Medical Device Directive 93/42 EEC, EMC Directive 89/336/EEC, Electromagnetic Compatibility EN 60601-1-2, Electrical Safety IEC 601
- External power adapter: input: 100-234 VAC 1.2A ; output:+12V DC /3.3 A - *type ADP-40BW*
- device weight: 1,4 kg
- case with full equipment weight: 2.6 kg

- dimensions: 290 x 205 x 85 mm

1.2.6. 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. Chapter 2.3.1 - permissible level of submersion*

1.2.7. 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.

Declaration for ultrasound scanner PIROP : In all modes Thermal Index TI don't exceed the value 1,0 and Mechanical Index MI don't exceed the value 0,23.

1.2.8. Periods of device use

- The PIROP device can be stored in the warehouse from production for a period of 2 years
- Guaranteed shelf life of the PIROP ultrasound scanner from the first start-up - 10 years
- Average service life of the PIROP ultrasound scanner - 10 years

2. SAFETY

⚠ *WARNING* - describes precautions necessary to prevent injury or loss of life

⚠ *CAUTION* - describes precautions necessary to protect the products

2.1. GENERAL SAFETY PRECAUTIONS

The ultrasound scanner PIROP is specified as Class II equipment under EN 60601-1 standards (Safety and Medical Equipment).

⚠ *WARNINGS:*

➢ **Use devices that comply with IEC6060-1 in the patient environment. If any device that does not comply with IEC 60601-1 is to be used, use an isolating transformer or common protective grounding. Furthermore, all configurations shall comply with the system standard IEC 601-1-1.**

➢ The PIROP has to be disconnected from the USB devices (i.e. PC) during examination

➢ The equipment has no waterproof features. Do not use this equipment in any place with the possibility of water ingress. There is a risk of electric shock if any water is sprayed on or into the equipment.

➢ To avoid the electrical shock risk, all plugs, and power cord must always be completely dry and not damaged.

➢ This equipment is intended for medical diagnostics only. It must be operated by qualified scanning operator.

➢ Before using the probes, inspect the probes' faces, housings and cables. Do not use the probe, if the probe or cable have visible damages.

➢ Do not operate the system in the presence of flammable gasses or anaesthetics.

➢ If you have experienced any trouble with the equipment, switch it off immediately and contact ECHO-SON S.A. technical service.

➢ It is forbidden to carry out any repairs or modifications of the equipment, probes and accessories by unauthorized persons. ECHO-SON S.A do not take responsibility for any claims on its products, repaired or serviced by others as the manufacturer or authorized by him personnel

➢ Any repairs may only be made by persons authorized by manufacturer and have certified controlling and measurement equipment for electrical safety tests (in accordance with IEC-601-1) and for measurements of the power of emitted ultrasonic wave (IEC-601-1-2-37).

➢ Do not use this product on eyes when corneal integrity is compromised by infection or trauma.

➢ **Report any serious incident related to the device to the manufacturer and the competent authority in the country where the user resides.**

⚠ ➢ **WARNING:**

  Use only External AC/DC Adaptor for PIROP supplied by manufacturer

CAUTIONS :

  - **It is recommend to use special pointer to operate touch screen that is enclosed with scanner equipment. It is forbidden to use any sharp-ended items due to screen surface damage.**

- It is forbidden to use any detergents a specially particular including alcohols or dissolvent.

It is necessary to keep touch screen clear (dust and dirtiness may cause incorrect item operation).

To clean the screen use only dry, soft clout or specially destined confection. do not apply these agents directly on the screen. When the scanner is on you can turn on the blank screen to clear the touch screen (see Service mode chapter 4.7.4)

CAUTIONS :

- The ultrasound main unit, monitor and the probes must be kept and used in environment with temperature between 10^0C and 40^0C. Humidity should be between 30% and 85%.
- It is forbidden to use with ECHO-SON S.A. scanner probes from other manufacturers
- The equipment and the probes must be kept clean - especially any contact gel remaining must be removed. Keep device and keyboard clean, using simple detergents (for example: the same as for washing dishes).
- Always keep the equipment dry. Avoid transporting it quickly from cold to warm place, otherwise condensation of water drops may cause short circuits. In such case do not plug in the system, until the temperatures of the system and the environment will be equal.
- Although ultrasound system has been manufactured in compliance with existing EMI/EMC requirements, the use of the system in the presence of an electromagnetic field can cause disturbance of the ultrasound image. If this occurs often, ECHO-SON S.A. suggests to identify and remove the possible sources of the disturbances or move your system to other place

2.2. LABELS AND ICONS

B- type, basic unit of scanner

BF – type equipment – probes

Equipotential ground

Protective ground

Danger Voltage. Caution: To reduce the risk of electric shock, do not remove cover. Refer servicing to qualified service personnel.

See User Manual

I Mains power ON

O Mains power OFF

USB port

Do not throw worn out device to the home waste

Footswitch

2.3. HOW TO HANDLE THE ULTRASOUND PROBES

2.3.1. Care and use of probes

WARNINGS:

⚠

> To avoid the risk of electrical shock, before using the probes, inspect the probes face, housing and cable. **Never use damaged or faulty probes.**

> To maintain the required safety of the transducer, its plug must always be completely dry.

> Biometry and Pachymetry probes are fragile components which must not undergo rough use or handling; this can destroy or alter operation of the probe.

The ultrasound probes may be damaged or even destroyed when are improperly handled.

CAUTIONS: To avoid damage or destruction of the very delicate equipment, the following rules must be strictly followed:

- Do not expose the probes to shocks or strokes -ultrasound probe is easily damaged if knocked, dropped or excessively vibrated.

- **Always keep the probes in special holders attached to the scanner**

- Especially protect the front part of the probe against any damage

- Do not twist or stretch the probe cable - the correct way of winding the probe cable –see picture:

- Do not expose the probes to temperatures exceeding +50 degrees Centigrade and below - 20 degrees. If ultrasound probes were cooled below 0°C, keep them in the room temperature (about 20°C) approximately 2 hours before use. Noncompliance of foregoing notice may damage the probe.

- Do not expose the probes to the pressure different from atmospheric pressure

- Before each usage of the probe check if it's free from visible damages on the part which is in contact with patient's body, on the cover or cable

- Do not submerge the probe in any liquid deeper than shown in Fig 1. presenting acceptable level of immersion of the probe in the liquid .

Permissible level
of submersion

Fig. 1

- Do not allow for contact with inadequate gels or cleaning agents

- Do not wet or submerge the probe with liquids containing alcohol, ammonia, perhydrol, etc.

- Avoid the contact of the probe with solutions and gels containing mineral oil, olive oil, lanoline, polyethylene glycol, dimethylene silicone, derivatives of ethyl and methyl

2.3.2. Probe cleaning

Careful cleaning and disinfecting of the used probes prevents spreading of diseases. The User is responsible for the recommended anti infection procedures .

1. Remove gel from the probe after each use using soft cloth or a towel and by rinsing carefully with water
2. **The probe body and the cable should be washed with the solution of soft soap using soft brush, sponge or cloth**
3. Do not use detergents or aggressive cleaning agents
4. After washing wipe the probe with soft cloth moistened in clean possibly dematerialized water
5. Dry the probe with air or soft cloth

⚠ *WARNING :* Be sure to keep the probe plug dry all the times

2.3.3. Disinfection of the probes

After cleaning procedures as described above, it is possible to carry out the disinfection of the probe by submerging it as shown on Fig.1 in preparation for probes disinfection or by sprinkling it with this solution

Useful preparations for probes disinfection:

- AOSEPT PLUS – manufacturer: Ciba Vision,
- BIOTRUE – manufacturer: Baush & Lomb,
- BOSTON SIMPLUS – manufacturer: Baush & Lomb,
- OCTENISEP – manufacture SCHÜLKE & MAYR GmbH
- EYEYE B5 Conditioner –manufacture Barnaux Healthcare

⚠ *WARNING :*

1. *The remains of bactericidal agent rinse with clean, possibly distilled water*.
2. *Always use the disinfected diagnostic probes.*

GAS STERILISATION - CAUTION : It is not recommended to use gas sterilization

2.3.4. Emission of ultrasound waves

Even if it is known, that ultrasound waves do not cause significantly changes in the mammal tissues, the user of the ultrasound device has to consider eventual possibilities of incidental biological effects, which can appear. Therefore, you should limit the time of examination to a minimum

2.3.5. Calibration of OB probe

When replacing the OB probe, in order to adapt the PIROP scanner to its mechanical properties, must be carried out once the process of calibration. Failure to do so may result in difficulties with normal starting motion of sensor, or noise in the image B-mode in the initial phase of the probe work.

To initiate the calibration process for OB probe, click in **Menu** screen *Service* key, and then in **Service** screen *Self-test B-mode* key. The B-mode self-test screen appears. Press *Start* button to start B-mode self-test. OB probe starts automatically and for a few seconds the calibration process is proceeding. The completion of calibration is signaled by the message: "Self-test OK" . Press *Start* button again to repeat calibration procedure or **Exit** menu button to returns to normal operating mode.

3. INSTALLATION

3.1. EQUIPMENT OF PIROP

The basic set includes:

1. Ultrasound scanner with built-in 7" color display, a touch screen and graphic thermal printer
2. Specialized ultrasound diagnostic probes:
   - OP 20 MHz ultrasound probe (options with Pachymeter)
   - OA 12 MHz ultrasound probe (options with A-Scan) with central light beam for correct eye positioning (internal red LED)
   - OB 12 MHz ultrasound probe (options with B-Mode)
3. Power supply adapter AC 100- 240v/50..60HZ – 12V DC/2A - type GE24I12
4. Footswitch
5. Probe holder
6. Immersion attachment (only with A-scan probe)
7. Axial length test piece (only with A-scan mode)
8. Printer paper roll
9. Flash memory (Pen Drive) connected to USB slot
10. Pointer (stylus) with a hanger
11. Protective case
12. Operation manual of PIROP
13. External - WIFI or USB Printer - option

3.2. INSTALLING AND CONNECTING THE SCANNER

3.2.1. Elements of the PIROP set
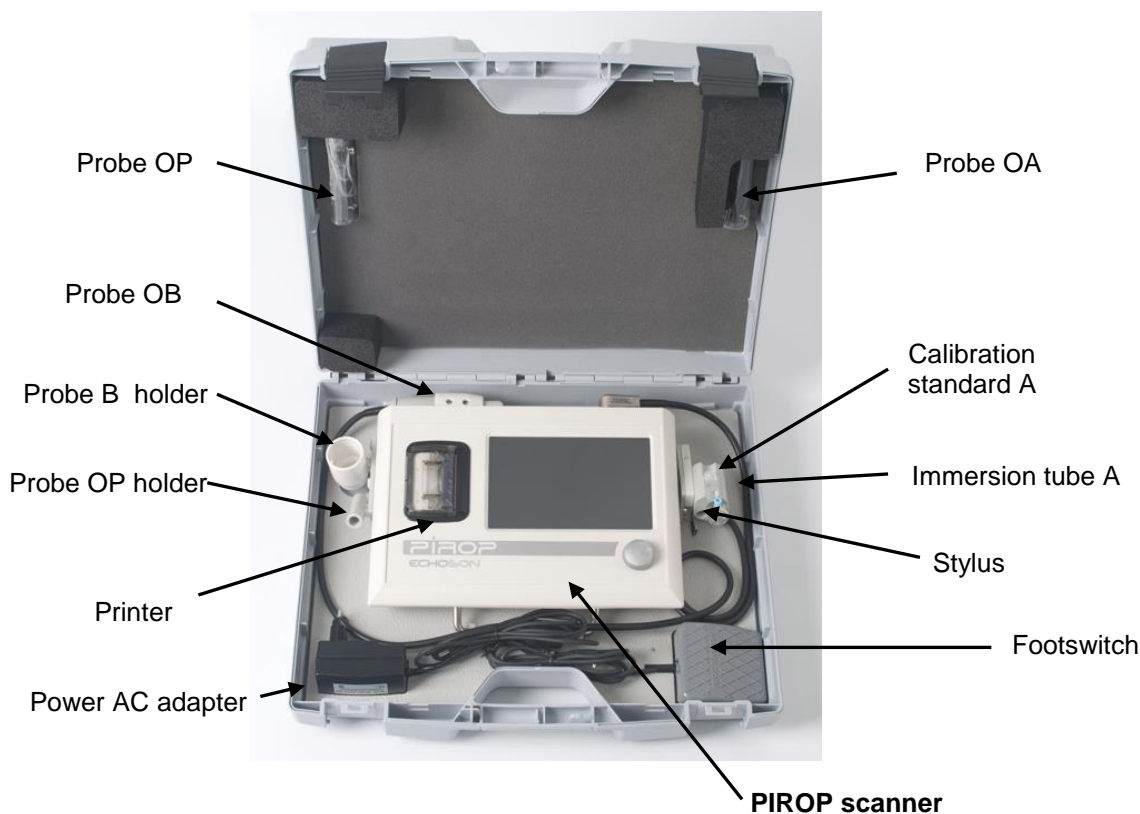
3.2.2. Rear panel of the device - description of outlets

Probe P socket   Probe A socket   Video output   USB Pendrive socket   USB socket to PC   Power switch

Footswitch socket   Probe B socket   Printer socket   Power AC adapter socket
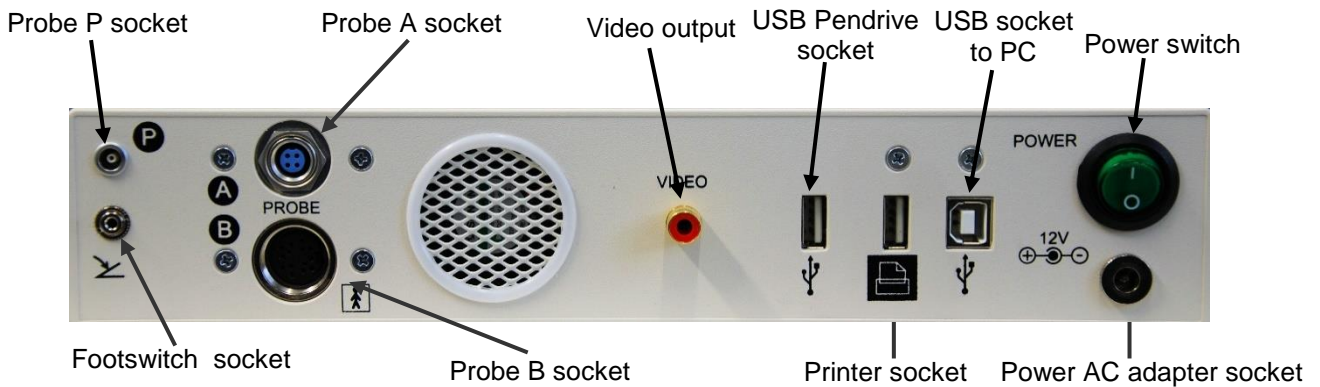
3.2.3. Probe connections

A probe

The biometry OA-probe socket is located on the back panel. Before inserting the connector rotate it slightly to find the good position and then inserting the connector and screw on the knurled ring of the plug clockwise to secure.

Specific probe holder for the biometry probe with immersion tube holder and special element for testing, are on the right side of the front panel. Turn the holder to the vertical until reach the <u>fixing</u> point (latch lock). Check the stability of the probe holder

B probe

The OB-probe socket is located on the back wall. Inserting the connector and screw on the knurled ring of the plug clockwise to secure.

Specific probe holder is located on the left hand size of front panel.

P probe

The pachymetry OP-probe socket is located on the back wall. The biometry OP probe is equipped with a push-pull type connector with a locking system. To connect the probe insert the plug as far as it goes. Pull the connector body to disconnect the probe (do not pull the cable).

Specific probe holder for the pachymeter straight probe is located on the left hand size of front panel.

3.2.4. Diagram of connecting components
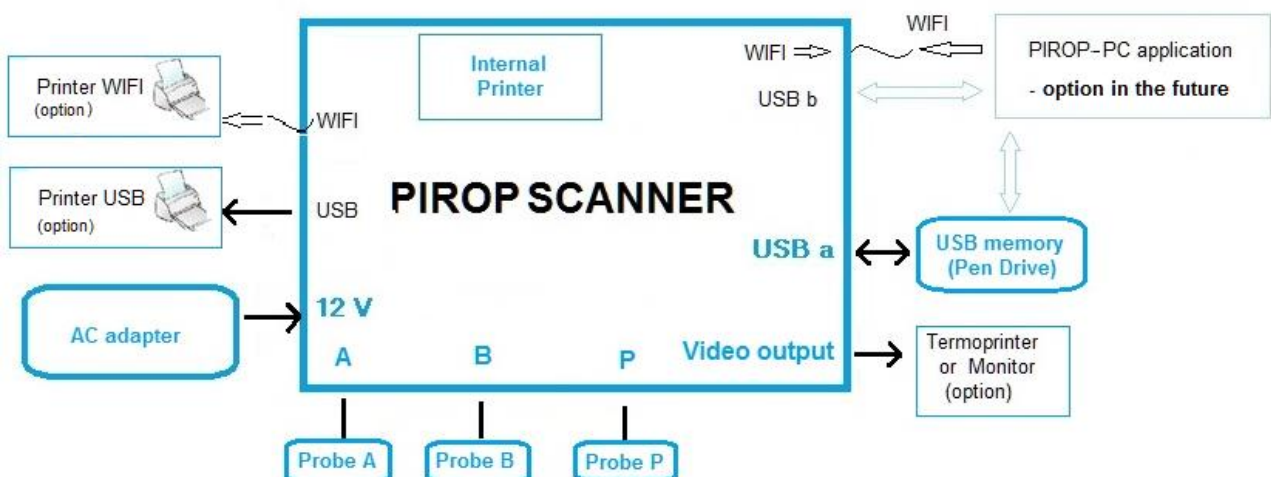
3.2.5. PIROP setup to operate in case

2. Connect probes and place them in appropriate holders

1.Take holder for A-probe up - latch lock

3. Connect the footswitch

4. Connect the Power AC adapter
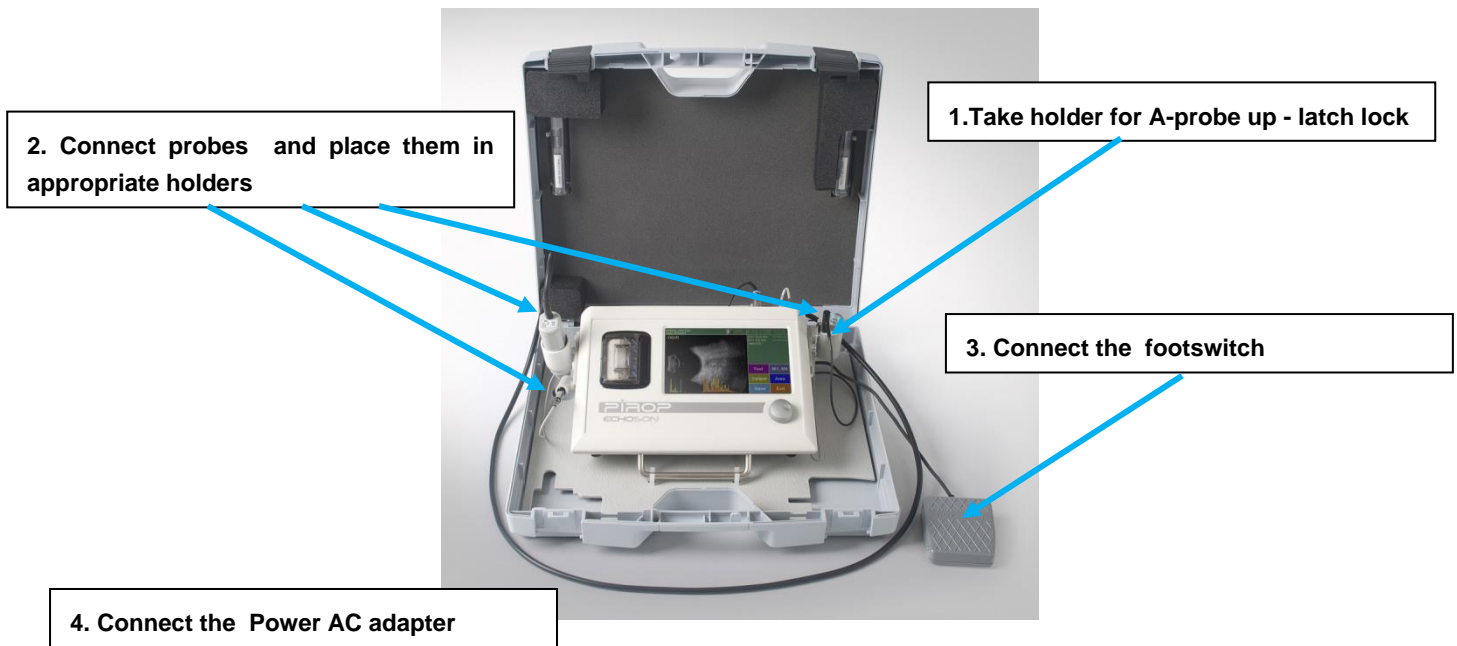
3.2.6. Assembling the trolley (option)

1. Turn the holder OA to the vertical until reach the fixing point
2. Place the device on a trolley and slide down to fix
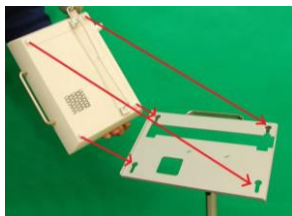
a)

b)

3. Adjust the scanner position.

4. GENERAL OPERATION OF THE SCANNER

4.1. TURNING ON THE SCANNER

⚠ **CAUTION:**

***Use only external AC Adaptor for PIROP supplied by manufacturer**. Scanner may be damaged if used with an AC adapter other than that provided.*

Before switching the power on, check:
- condition of the adapter
- condition of the screen and casing of the scanner
- condition of all connection cables
- condition of the spot face of probes
- condition of the printer

Check whether all components are connected according to the instruction of installation (Section 3).

⚠ **CAUTION:**

Do not turn on the power supply if any damages, cracks or other abnormalities are found.

Plug the power AC adapter cable into the power socket on the rear wall of the scanner. Start the device with the **POWER** button on the back of the housing. (pos. **I**)

WARNING:

Do not power the scanner on and off quickly. After turning off the power wait for at least a few seconds before turning it on again. Turning the scanner on and off in a very short period of time can cause malfunction or damage of the device.

After the power is switched on correctly, the scanner will:

- signal it with a sound

- display the title page on the screen

⚠ **CAUTION:**

If the scanner still does not start properly or any symptoms of improper operation are detected, immediately turn off the scanner and try to contact the manufacturer's service.

Note:

In order to maintenance of hygiene, it is recommended to wash the probe before each use of the scanner, as well as between examination of consecutive patients. (see 2,3,2 and 2.3.3)

4.2. TURNING OFF THE SCANNER

The scanner is switched off with the mains switch located on the rear panel (pos. **O**).

The turned-off scanner stores data of all operators and has its internal clock and calendar active.

4.3. TITLE PAGE – Mode screen

After turning the scanner on, a title screen is displayed with the information:
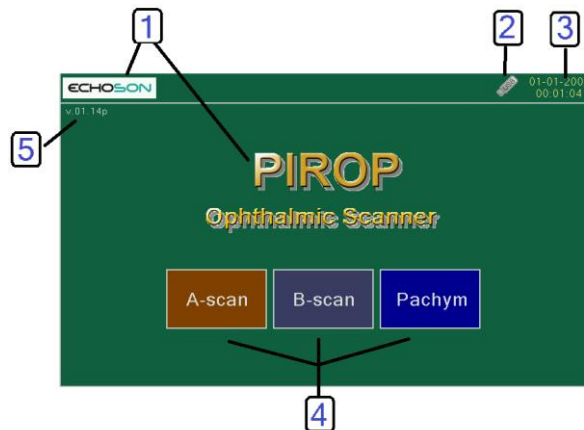
1. Scanner name and company name
2. USB drive icon (becomes active when the USB memory is inserted to the corresponding socket)
3. Date and Time
4. Three menu keys: to selection **A-scan** mode, **B-scan** mode and **Pachymeter** mode
5. Software version

PIROP system uses a **touch screen** user interface. All buttons on the screen are activated by using a **stylus**
or at **a finger** press**.** The stylus provided with the system is the recommended tool to use when
touching the screen to make selections.

Note:
1. *Mode keys in the background color are inactive. Active are those that correspond to the current PIROP scanner options*
2. *Inactive mode of operation can be activated using the service window. Please contact your scanner supplier to unlock inactive modes. (see Chapter 9.7 **– Unlocking Inactive Modes**)*
3. *By using a virtual alphanumeric keyboard displayed on the touch screen, any text can be entered. Optionally, via one of the USB ports, it is possible to connect an external alphanumeric keyboard*

4.4. GENERAL MENU SCREEN

After pressing the MODE key on the title page the main menu window appears on the screen.
Also switching to the menu window of the device takes place always after pushing the ***MENU*** button.
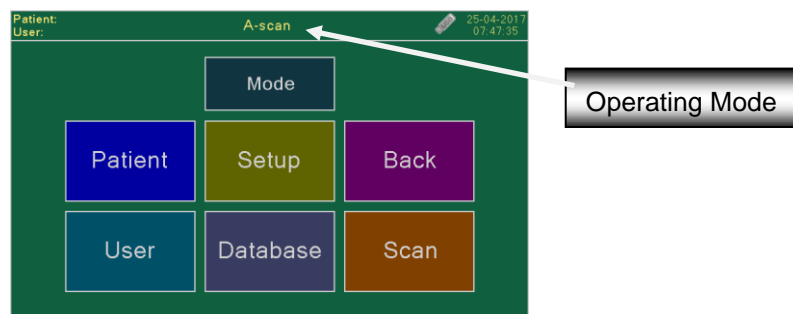
**The same functional buttons are available in all modes in the Menu window. In relation to work
mode, which is described in the page heading menu, using particular buttons may activate different
pages or functions specific for a given mode.**.

The following buttons appears on the general Menu screen:

1. *Mode* - open the Mode Screen (Title page) for selection operating mode (chap. 4.3)
2. *Patient -* open the Patient Screen for the entrance of **new** patient's data and **editing** those already existing (chap. 4.6)
3. *User -* open User Screen for the selection of Physician (user) from the scanner's memory and editing the operator setup function. (chap. 4.5)
4. *Setup -* go to the Setup Screen: adjustment of the LCD display, setting the Time and Date, choose the menu language, open the Settings and Info screens etc. (chap. 4.7)
5. *Database –* open Patient's List Screen allows the use of internal database of patient data (chap. 8.2).
6. *Scan -* Going to the new **diagnostic window** for a given work mode
7. *Back -* return to the previous page.

    Note: After performing e.g. the biometry you can go to the **Menu screen** *to change some parameters in the* **User** *and* **Patient** *windows. Then you can use the* **Back** *button to return to the measure screen, keeping the measurements. Introducing a new patient, changing the user, or changing global parameters, such as the type of eye, causes the* **Back** *button to become* <u>inactive</u>*. Pressing the* **Scan** *key always initiates the* <u>new</u> *scan (biometry).*

4.5. USER DATA SCREEN

When the scanner is used by more than one person, each user (physician) can enter a set of properties for each mode <u>as personal profile</u>. The system allows to store and select up to ten (**10**) users) different user profiles The profile is permanently stored in memory also after the scanner is switched off. User profiles allow for user identification and selection of a particular IOL formula and associated constants. The profile is selected automatically when corresponding user is entered.

Pressing the *User* button in the MENU window opens the **User Screen** with the Operation List.
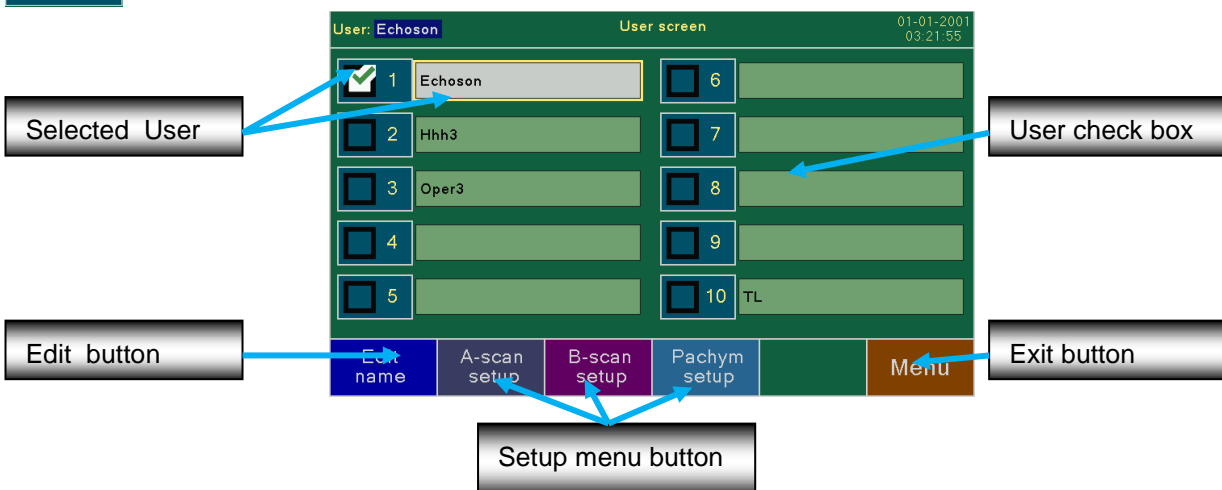
1. *Edit name* - open the edit screen for the entrance of **new** user's name –see chapter 4.5.1
2. *A-scan setup –* open a setup screen for the selected user to enter specific settings for biometry mode (A-scan) *- see chapter 5*.5
3. *B-scan setup –* open a setup screen for the selected user to enter specific settings for B- mode - *see chapter 6.4*

4. **Pachym. setup** – open a setup screen for the selected user to enter specific settings for pachymetry mode (P-scan) - *see chapter* 7.4

5. **Menu -** return to the main Menu page with selected user.

You can select a specific user (operator) via the touch screen checking the appropriate box on User Screen. You can confirm the selection and exit the window by pressing **Menu**. Operator's data will be displayed in the upper part of the main screen.

4.5.1. EDITING OPERATOR'S NAME

Pressing the **Edit** menu button opens a page to edit user information in the previously selected field. If the selected field was empty - you can add the new user to the list.

A virtual keyboard appears on the display allowing to enter data. (max. 27 characters):

- **Clear** button – deletes data field
- **Back** button – deletes the last entered character
- **Alt -** allows entering **special** characters for **each language.**
- **Shift** (when pushed, changes color) - changes small / capital letters
- **Exit** menu button - exiting the user information editing and approving the changes.

In this mode the first letter of name is capitalized automatically.

The entered username will be displayed with label *User* in the upper part of the main screen.

Note: iIf the username is longer than 20 characters, the label is one-letter "u:"

By using a virtual alphanumeric keyboard displayed on the touch screen, any text can be entered. Optionally, via one of the USB ports, it is possible to connect an <u>external alphanumeric keyboard</u>. When the external keyboard is connected, the small keypad icon in info field is appeared.

4.6. PATIENT DATA SCREEN

Press **Menu** key to open Main Menu windows. Pushing buttons **Patient** opens a page for entering or editing patient's information. Such data will be later included in the printout or save measurement results.
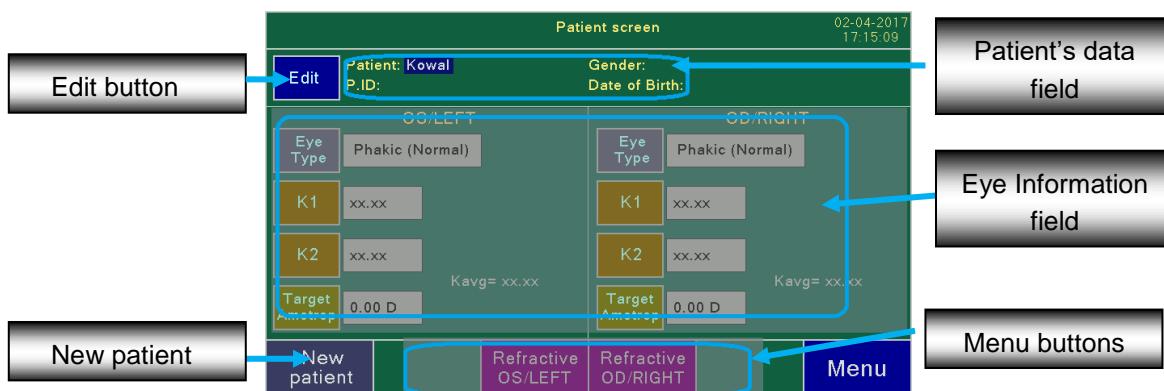
1. **New patient** button - open the edit screen for the entrance of **new** user's name –*see chapter 4.6.1*
2. **Edit** button allows entering patient information and does not cause the deletion of previous measurements - *see chapter 4.6.1*

3. **Patient's data field** - current patient data : Name , identification number P.ID number , Gender and Birth date.

4. **Eye Information field** - information about the patient's right and left eye. This field is different for each mode of operation:
    -   In **A –scan** mode – the parameters of the patient's eye can be entered (e.g. keratometry values) - see chapter 5.4
    -   In **P –scan** mode – the intraocular pressure and the calculation of the adjusted intraocular pressure can be entered - see chapter 7.3

5. **Menu buttons** - additional control keys different for each mode of operation:
    -   In **A –scan** mode – **Refractive OS/Left** and **Refractive OD/Right** buttons open the page to enter more patient information used for post refractive calculation - see chapter 5.4.4
    -   In **P –scan** mode the **IOP** button opens the page where the intraocular pressure and the calculation of the adjusted intraocular pressure are entered - see chapter 7.3.1

6. **Menu** button -   return to the main Menu page.

4.6.1. PATIENT DATA ENTRY

Using alphanumerical keyboard enter patient name and other patient data (PId , date of birth and gender). Such data will be later included in the printout of measurement results. Patient data are not stored after switching the scanner off.

New patient menu button allows entering new patient information- also <u>deletes</u> any previous data and all performed measurement .

Note: *Entering new information clears the memory of the measurement results of the last patient.*

Patient **Edit** button allows entering patient information and does not cause the deletion of previous measurements.

Using alphanumerical virtual QWERTY keyboard enter patient **Name** (max. 22 characters) and the patient **P.ID** (max. 22 characters), **Date of Birth** and **Gender**:

➢   **Name** menu button – selection field Name for editing

➢   **P.ID** menu button – selection field P.ID for editing

➢   **Date of Birth** menu button - open the screen with numeric virtual keyboard to entering date of birth.

➢   **Gender** menu button – open the screen to gender selection

➢   **Get From Database –** get Patient's data from internal Database (*see chapter 4.6.2*)

➢   **Exit** menu button - exiting the patient information editing and approving the changes.

➢   **Clear** button – deletes data field

➢   **Back** button – deletes the last entered character

➢   **Shift** (when pushed, changes color) - changes small / capital letters

➢   **Alt**- - allows entering **special** characters for each language.

The entered patient's data will be displayed in the upper part of the main screen.

The patient's data is not stored after the scanner is powered off.

By using a virtual alphanumeric keyboard displayed on the touch screen, any text can be entered. Optionally, via one of the USB ports, it is possible to connect an external alphanumeric keyboard. When the external keyboard is connected, the small keypad icon in info field is appeared.
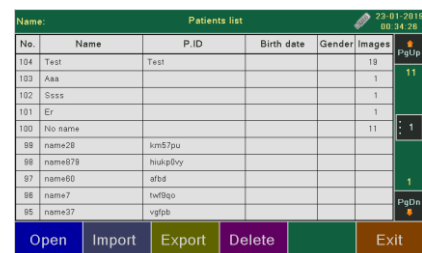
To enter the PID number, you can also use an external barcode reader (e.g. *Metrologic Instruments MS9540 Voyager CG Bar Code Scanner*), that can be connected to service USB port of the scanner. When the barcode reader is connected, the small keypad icon in info field is appeared. Before scanning the bar code, first open the patient data window and the PID field to be edited. After loading the code, the system will automatically enter the read code into the open PID field

4.6.2. GETTING PATIENT INFORMATION FROM DATABASE

PIROP scanner allows the use of **internal database** of patient data, created successively by user by using *Save* function or by importing from special file via USB memory (See chapter 8.2). In the new scanner factory installed database of patients data is empty.

 After opening Main menu window, select the new patient option using the key *Patient new-* a page for entering patient's information is opened. Press *Get From Database* menu key - the full list of patients stored in database is displayed on the screen (*Patient List* window). The patient list can be displayed alphabetically by name or starting from the last record. The display method is selected on the *Options* screen in the tab *Patient list* - options *Name alphabetically* or *Nevest first* (chapter 4.7.5)

Each patient is assigned a unique *record of the patient*, which is automatically created when the first image is recorded for the patient (*see chapter 8.2.1*)

In particular columns the following information are displayed: record number *(No);* patient's name *(Name);* patient's number *(PiD); Birth date, Gender* and the number of saved images *(Images).*

 By pressing arrows menu keys you can scroll up/ down the pages in the database (only when the number of patients exceeds ten). An additional key on the bar allows you to change the number of pages you can move one time: 1, 5 or 10.

Number of patients is additionally displayed on the scroll bar.

To download patient information from database:
- **Select** the individual patient in the database (different colour of the background), by pointing with the use of finger or by stylus, or using the *Knob*
- Press *Get* menu key or press *Knob* key - new patient data (Name and PID) from the selected record will be downloaded.
- Downloaded patient's Name will be displayed at the top of the screen.

Exit key – the output from the database without download data from the database.

Note: To manage internal Database e.g. to import a Patient List from external USB memory, see 8.2.

4.7. SCANNER SETTINGS - SETUP SCREEN

Setup

The first time a new system is powered up it is important to configure it with your local information (date, time, etc.). Select **Setup** button from the menu screen – Setup Screen appears:

1. **Brightness** field – for the adjustment of the LCD display (*see 4.7.1*)
2. **Date** field **-** setting the Date (*see 4.7.2*)
3. **Time** field **-** setting the Time (*see 4.7.2*)
4. **Language** field –selection of menu language.
5. **Volume** field **-** setting the volume of the measurement final beep (optional – *4.7.3*)
6. **Service** **-** service function menu (*4.7.4*)
7. **Option** **-** for edition additional properties (*4.7.5*)
8. **Info -** displays detailed information on the scanner and system *(4.7.6)*
9. **Hospital Name -** editing the name of the medical facility (it is used in printed reports - *4.7.7*)
10. **Menu** button – exit from Setup window.
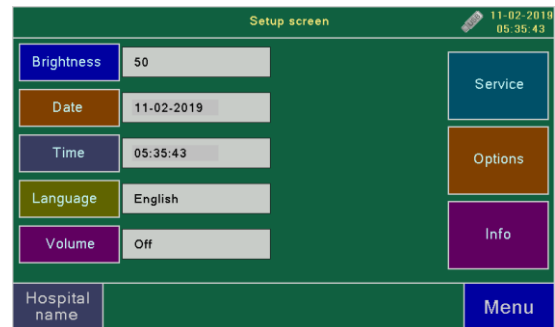
4.7.1. DISPLAY BRIGHTNESS ADJUSTMENT

Pressing the **Setup** button in the MENU window opens the settings window. Press the **Brightness** button to

Brightness

to open the *Brightness Screen* to set the display brightness providing the best comfort of work in current lighting conditions. By checking the appropriate box you can choose the brightness from 0 to 100% in ten steps – selected value is displayed also in the Brightness box on Setup page. The set brightness level is stored after the scanner is switched off.

4.7.2. SETTING THE DATE AND TIME

Buttons "**Date**" and "**Time**" on the settings window set the date and time, respectively (the device has its

Date

Time

own internal battery-powered clock system). Pressing buttons "**Date**" or "**Time**" opens a page for editing date and time. The date and time are set with a virtual numerical keyboard. The new date and time become current after pressing **SET** button. If there is no new modification of time or date **Exit** button exits the modification window without any changes.
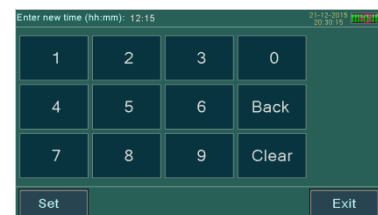
4.7.3. VOLUME ADJUSTMENT

Optional, after installing an additional speaker in the scanner (requires hardware changes), voice messages informing about situations requiring attention and the beep at the end of a series of automatic measurements in P-mode, A-mode and calibration in A-mode is added. The voice messages can be turning on/off on Option screen (see 4.7.5).
The volume of additional sound can be set on the settingspage. Press the **Volume** button to to open the *Volume Screen* to set the volume of the measurement final beep.. By checking the appropriate box you can

choose the volume from 40 to 120% in nine steps – selecting *off* box switches the sound off. The set volume level is stored after the scanner is switched off.

4.7.4. SERVICE MODE

Pressing the **Setup** button in the MENU window opens the settings window. Press the **Service** button to to open the *Service* window.
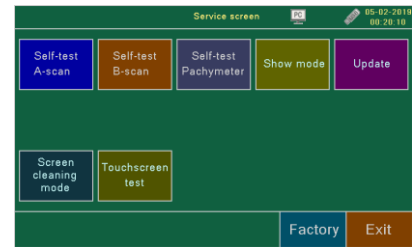
1. **Sefl_test A-mode** – A-mode self test is used to check the software algorithm. To star A-mode self test press **Start** menu button. Special A-mode window appears on the screen. The test procedure should end up after about 2 seconds. If all internal electronic systems work correctly, the message *"Self - test OK* " should appear on the screen. If self-test error occurred, please contact with manufacturer or distributor. You can repeat test procedure again by pressing the **Start** button on the screen.

2. **Sefl_test B-mode** - B-mode self test is used to check the probe and software algorithm. You can use B-mode self test every time when the OB probe is replaced. To star B-mode self test press **Start** menu button. Special B-mode window appears on the screen. At the beginning of **Self test** procedure, the probe test procedure is performed**.** The progress bar on the screen is displayed. The probe test procedure should end up after about 30 seconds

   Note : Probe should be treated with care and stored safely. If any abnormality appears when working with the probe or any probe malfunction is identified, you can perform a probe test procedure. Also, it is recommended to carry out the probe test procedure, when a other probe (e.g. after servicing) to the scanner is connected. If the problem with probe still exists, please contact with manufactures technical service department or authorized by him personnel.

   If all internal electronic systems work correctly, the message *" Self - test OK* " should appear on the screen. If self-test Error occurred (*Probe Error* or *T/R Error* etc.) , please contact with manufacturer or distributor

3. **Sefl_test Pachymeter** –- Pachymeter- mode self test is used to check the probe and software algorithm. You can use Pachymeter self test every time when the OP probe is replaced. To star Pachymeter self test press **Start** menu button.
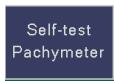
   SENSITIVITY – the sensitivity of the probe is tested. When the test is performed, the probe ought to be dry and clean and ought not to touch any object. The message "OK" is displayed when the test result is positive. If the probe is disconnected, the message "No Probe!" is displayed. (No Probe!)

   The message "Weak Probe!" is displayed when the test result is negative. (Weak Probe!). Make sure the probe is clean. If the probe is clean and the repeated sensitivity tests give the same result, it means the probe has lost its sensitivity and the manufacturer's service should be contacted.

   ACCURACY – the internal test of the measurement accuracy is performed. Independent of the measurement system, artificially created echo signals (at an interval corresponding to the thickness of 492 μm) are measured. The probe is not used in this test. The positive result (the measurement result are within the tolerance limits) indicates good performance of the scanner and the message "OK" is

displayed. The message "*Bad Accuracy*" is displayed when the result is negative. Several repeated accuracy tests ought to be performed by pressing the **Retry** button. If the negative result occurs again, the manufacturer's service should be contacted.

Note:

➤ *The pachymeter tests ought to be performed each time the scanner is switched on.*

➤ *A user can always perform calibration by pressing the **Test** button in the P-scan window menu.*

4. **Show mode** button – use to enable the display of images from a USB flash memory drives with a folder
PIROP2 / Demo2 - slideshow in Demo mode ; the display time one image approximately three seconds.
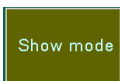
5. *Update* button - Pressing this button in the Service window opens the *Update screen.* Software update procedure in PIROP scanner is performed through USB port with use of USB memory (Pen Drive). Files are placed in the folders: *PIROP2 / Update2.* and *PIROP2/Graph2*

6. **Screen cleaning mode** - turn on (on 10 sec) the blank screen to clear the touch screen (you can clear the touch screen when the scanner is on)
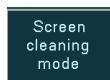
7. **Touch screen test** - turn on the special screen to test the correct operation of the touch screen. The test consists of pressing the touch screen successively at five selected points to automatically determine the accuracy of the screen calibration
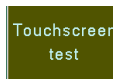
4.7.5. OPTIONS SCREEN
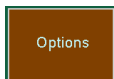
Pressing the **Setup** button in the MENU window opens the settings window. Press the **Options** button to to open the *Options screen*.
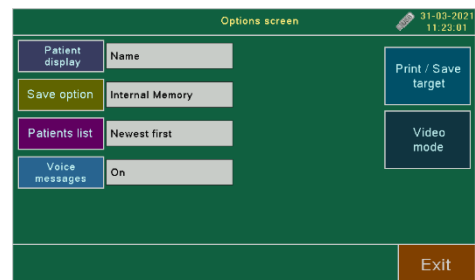
1. **Patient display** - selection of information displayed on the screen: patient's name or PID

2. **Save option** - the ability to save images (**Save** menu key) only to internal memory, or simultaneously to internal memory and external USB memory or only to external memory USB – see chapter 8.2.1.

Note: *Save PDF report* menu key will always save PDF file on external USB memory*.*

3. **Patients list** - opening the window with the possibility of choosing the way of displaying the patient database - alphabetical sorting (**Name alphabetically**) or by date of entry (**Nevest first** - last entry at the beginning) – see chapter 8.2.2

4. **Voice messages** – (option) turning on / off voice messages (voice adviser), informing about situations requiring attention, for example: „ *No probe" ; „Out of range" ,"High standard deviation, correction necessary*" etc. (see also chapter 4.7.3 – *Volume adjustment*)

5. **Print/Save target** – (option) - opening the window with the possibility of choosing the type of printer (*Print* button) and memory (*Save* button) – see chapter 8.3

6. **Video mode** - (only for the HDMI output option) displaying a new window for selecting HDMI and Video output parameters - see chapter 4.7.8

4.7.6. INFO SCREEN

Info
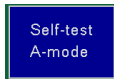
Pressing the *Setup* button in the MENU window opens the settings window. Press the *Info* button to to open the *System info* window. It displays <u>detailed information</u> on the scanner and system, including:
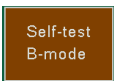
✓ software versions, unit number etc. (*Versions* field)

✓ level of power voltage etc for servicing purposes (*Power supply* fields)

✓ temperature inside the housing, brightness etc. (*System* field)
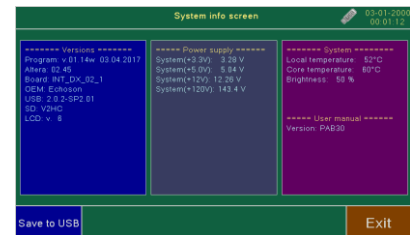
Save to USB button saves System Info screen on connected USB memory (pen-drive) in the BMP format file (*PIROP2/ _SYSINFO.bmp*).

4.7.7. ENTERING HOSPITAL NAME

Hospital name menu key on the *Setup screen* allows you to edit the name of the medical unit in which

Hospital name

the PIROP scanner is used. After pressing the *Hospital name* button a virtual keyboard appears on the display allowing to enter data (see description of entering data in chapter 4.5.1 – Entering Operator's name). The Hospital name (max. 52 characters) is <u>not displayed</u> on the scanner screen. It is placed only on all printouts on external and internal printer and in the exam reports in a pdf files.

5. BIOMETRY (A-SCAN)

5.1. PURPOSE

The PIROP scanner in the A-scan function provides a way to measure the axial length of the eyeball (**AXL)**, the depth of the anterior chamber (**AC**), the thickness of the lens (**LENS**) and the thickness of the vitreous body (**VITR**) using the OA 12 MHz probe with a light beam. The applications used in the A-scan system provide a way to calculate the **IOL** power for the intraocular lens implants.

.
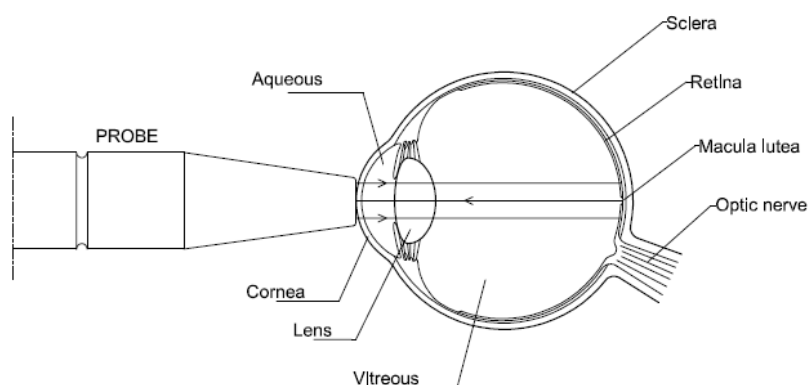
Through the alignment of the ultrasound probe opposite the patient's eye and the contact of its probe with the cornea direct or indirect through the liquid distance (contact or immersion techniques), the scanner performs measurements of the eye and store the results.

On the basis of the measurement of the axial length of the eye AXL and using the appropriate formula for calculations (available are SRK-II, HOLLADAY-1, HOFFER-Q, BINKHORST-II, HAIGIS) and the curvatures K1 and K2 (measured using a keratometer) and the parameters of the lens implant, the required IOL power is calculated. Using the HAIGIS formula, the depth of the anterior chamber AC and the AXL are used for calculations.

5.2. BRIEF DESCRIPTION THE A-SCAN PROCEDURE

1. Activation A-scan mode and perform calibration – *see chapter 5.3*
2. Check and set if necessary on the User page in the tab **A-Setup**: default parameters e.g. gain, selected technique, eye type setup (mode ,velocity etc., lens setup and IOL setup – *see chapter 5.5*
3. In   Patient page enter **patient** data, select the patient's eye type, edit parameters for IOL calculation – *see chapter 5.4*
4. Press **Scan** button on Menu page to open A-scan biometry window and make measurements: select the right or left eye to measured; select the measurement mode; adjust the gain by rotating the knob etc. - *see chapter 5.8*
5. Editing the results if necessary - *see chapter 5.8.6 and 5.8.7*
6. Use **IOL** power calculation - *see chapter 5.9*
7. Use **Prin**t or **Save** function for archiving measurements and calculations -*see chapter 5.10 and 5.11*

5.3. ACTIVATION A-SCAN MODE
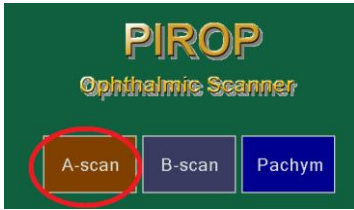
The selection of A-scan biometry application is possible from directly from **Title** page (Mode page) or from the level of the **Menu** window by pressing the **Mode** key. Pressing the **A-Scan** button on the Mode select page (see chapter 4.3) opens the Menu page for A-scan mode - the scanner is intended for examination in A-scan biometry.

The following buttons appears on the general Menu screen:

1. **Mode** - open the Mode Screen (Title page) for selection operating mode (chapter 4.3)
2. **Patient -** open the Patient Screen (chapter 5.4)
3. **User -** open User Settings Screen (chapter 5.5)
4. **Setup -** go to the Setup Screen: adjustment of the LCD display, setting the Time and Date, choose the menu language, open the Settings and Info screens etc. (chapter 4.7)
5. **Database –** open internal database of patient's exams (chapter 8)
6. **Scan -** Going to the Measurement A-scan screen (chapter 5.8)
7. **Back -** return to the previous page
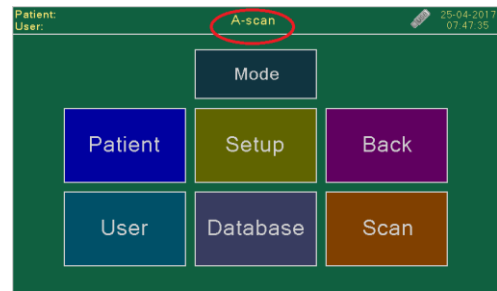
*Note: After performing e.g. the biometry you can go to the **Menu screen** to change some parameters in the **User** and **Patient** windows. Then you can use the **Back** button to return to the measure screen, keeping the measurements. Introducing a new patient, changing the user, or changing global parameters, such as the type of eye, causes the **Back** button to become <u>inactive</u>. Pressing the **Scan** key always initiates the <u>new</u> scan (biometry).*

5.4. PATIENT DATA FOR A-SCAN

Pushing buttons **Patient** in the **MENU** window opens a page for entering or editing patient's information.
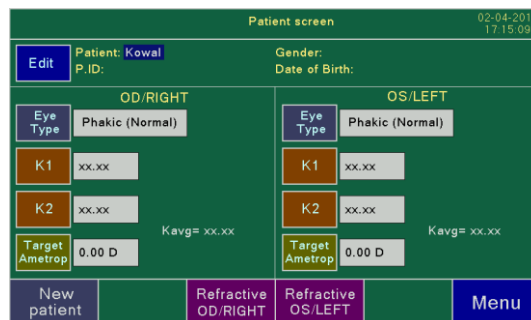
Using **New patient** menu button enter patient data Name.P.ID,Gender and Date of Birth– see chapter 4.6.1. In **Eye Information field** - the parameters of the patient's right (OD) and left (OS) eye can be entered e.g. keratometry values)**.**

*Note: Always start a new patient by first activating **New patient** key. Entering the new patient's data restores the default values*

5.4.1. EYE TYPE SELECTION

The *Eye Type* button leads to the page where the parameters of the patient's eye type can be selected. (The eye type can be select also by pressing the *Eye Type* button in A-scan screen in RUN mode see chapter 5.8).The page contains check box for the selection of the following eye types:

- Normal
- Cataract
- Dense Cataract
- Silicone Oil
- Aphakic
- Pseudo Acryl
- Pseudo PMMA
- Pseudo Silicone
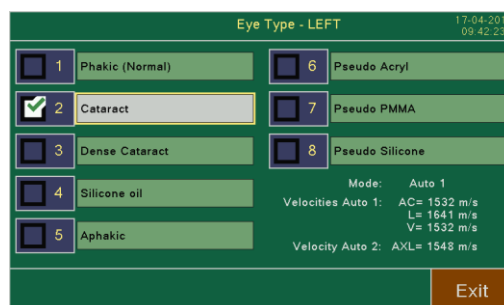
The selection of the eye type automatically sets the measurement method for the currently selected eye:

Auto 1 – Normal, Cataract, Silicon Oil,

Auto 2 – Dense Cataract, Pseudo Acryl, Pseudo PMMA, Pseudo Silicon

Auto – APHAKIC

The measurement mode can be forced manually after pressing the *MODE* button in A-scan screen (RUN mode see chapter 5.8). For example, a change from Auto 1 mode to Auto 2 mode is recommended in difficult cases (a multitude of echoes behind the anterior chamber).

In addition, for the selected eye type for each method, the parameters related to the speed of the ultrasound are displayed on the screen.

All velocities and standard measurement mode for each type of eye can be changed in the **User** window in the *A-setup* tab - after pressing the *Eye type setup* button (*see chapter 5.5.2*)

5.4.2. KERATOMETRY K1 AND K2 EDITION

For each eye two keratometry values (coefficients of refractive power of the cornea) can be entered: K1 and K2. Pressing buttons *K1* and *K2* opens the page where you can enter keratometry values for the currently selected eye (left or right) using the numeric pad. If the entered values is bigger or equal to 15, it is assumed as a diopters value. If it is smaller than 15, it is assumed as a value in millimeters. After entering both values the average **Kavg** calculation is performed and displayed.

If the parameters K1 or K2 have not been entered yet, their value is displayed as **xx.xx**
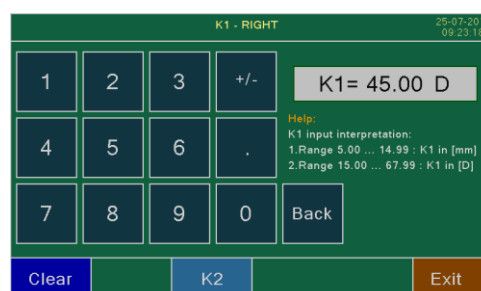
5.4.3. ENTERING TARGET AMETROPIA VALUES

Pressing button *Tam* (*Target Ametropia)* opens the page where you can enter *Target Ametropia* value for the currently selected eye. The user has the choice to type in his own value for any particular patient, but for the next selected patient it will default back to the value entered in the **User** screen in the *A-setup* tab (chapter 5.5.1). Acceptable range is -9.99 D to +9.99 D.

5.4.4. PARAMETERS FOR POST- REFRACTIVE CALCULATION

By default the *Eye Information field* in Patient screen enables to enter classical Keratometry measurements. By pressing the menu keys : *Refractive OS/LEFT* or *Refractive OD/RIGHT* you can open field to enter more patient information used for post refractive calculation **(**See **Appendix-A: IOL formulas):**
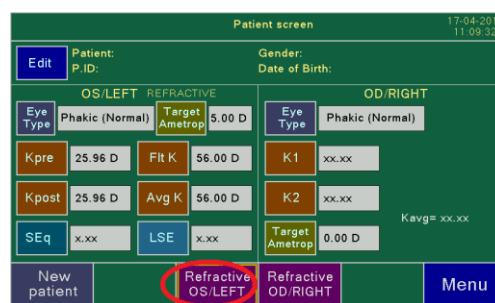
- ➢ **K-pre**, **K-post,** - pre-op and post-op refractions **-** parameters referring to refractive power of the cornea for the calculation using *Double-K SKR/T* formula for an eye after a LASIK or PRK operation. If the parameters has not been entered yet, its value is displayed as **xx.xx**.

- ➢ **Flt K, Avg K** parameters referring to refractive power of the cornea for the calculation using post refractive *Latkany* formulas: *Flt-K SKR/T* and *Avg_K SKR/T*.

- ➢ **SEq –** prerefractive surgery myopic pre-LASIK spherical equivalent - parameter is used in the IOL calculation using the *Latkany* methods. Pressing the *SEq* button opens the page where the coefficient SEq can be entered for the currently selected eye (left or right), using the numeric pad. The value is in diopters. If the parameter has not been entered yet, its value is displayed as **xx.xx**.

- ➢ **LSE –** vertex distance corrected laser vision correction spherical equivalent - *LSE* key follows to the page, where using the numeric keypad, you can enter a factor LSE, used in the calculation of the IOL by *MDF-Masket* method. The value in diopters. If the parameter has not been entered yet, its value is displayed as xx.xx.

Note: After performing e.g. the biometry you can go to the **Menu screen** *to change some parameters in the* **Patient** *windows. Then you can use the* **Back** *button to return to the measure screen, keeping the measurements. Introducing a new patient, or changing global parameters, such as the type of eye, causes the* **Back** *button to become <u>inactive</u>. Pressing the* **Scan** *key always initiates the <u>new</u> scan (biometry).*

5.5. USER SETTINGS FOR A- SCAN

Pressing the *User* button in the **MENU** window opens the **User Screen** with the Operation List.

Each user can enter a set of properties as personal profile.

Press *A-scan setup* menu button - **A-setup** window for given user appears on the screen.

*Note: After performing e.g. the biometry you can go to the* **Menu screen** *to change some parameters in the* **User's** *windows. Then you can use the* **Back** *button to return to the measure screen, keeping the measurements. Changing the user causes the* **Back** *button to become <u>inactive</u>. Pressing the* **Scan** *key always initiates the <u>new</u> scan (biometry).*

5.5.1. ENTER A-SCAN PARAMETERS

➢ **Gain A-mode Contact** – tap the gain field- a window with numeric pad opens that allows you to enter a new default Gain setting of the receiver in A-scan Contact method. The allowable range is 40-100 with a system default of 68-78

➢ **Gain A-mode Immersion -** tap the gain field- a window with numeric pad opens that allows you to enter a new default Gain setting for Immersion method. The allowable range is 40-100 with a system default of 68-76.

➢ **Technique** - select the desired technique: *Immersion* or *Contact*. In the <u>Contact</u> technique the OA probe is placed directly on the patient's cornea. In the <u>Immersion</u> technique, an immersion tube (Shell) containing the OA probe is placed on the patient's eye and filled with solution between the probe and the cornea.- there is an offset on the display between the peak from the probe tip and the peak from the cornea. The default technique is Contact.

➢ **Increment** – Selection 0.25 or 0.5 D increments nine different powers in IOL Power

➢ **Target Ametropia** - tap the Target Ametropia button- a window with numeric pad opens that allows you to enter a new default Target Ametropia setting. The default for target ametropia is 0.00.D (acceptable range is -9.99D to +9.99D). The entered value of TAM is treated as default value in the patient window (see chapter 5.4.3)

➢ **Processing -** select the desired Processing: P0, P1 or P2. Pressing the *Processing* button opens the page where the level of processing can be selected. The Processing function is active in RUN mode when the probe operates (see chapter 5.8.5)

➢ **Algorithm –** select the algorithm of A-scan: Basic or Advanced. The choice of the Advanced algorithm makes it possible to control the Standard Deviation (SD) level (**A - scan SD level**) - see chapter 5.8.7 (Note)
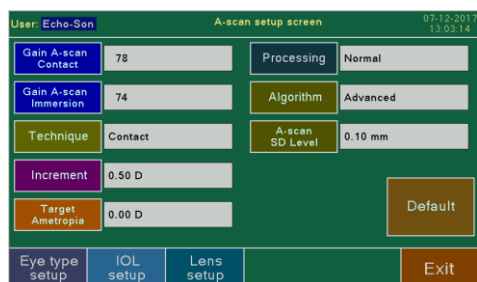
By pressing the *Default* button and then *Set default* button it is possible to set the standard default values for all of the above parameters.

5.5.2. EYE TYPE SETUP – MEASURENT MODE AND VELOCITIES

Pressing the *Eye Type Setup* menu button on **A-setup** window opens a page *Eye type setup screen* to edit all velocities and standard measurement mode for <u>each type</u> of eye. Using this page you can **change the sonic velocity** required for the calculation in the A-scan biometry and IOL power calculation. The page contains list of the following eye types:

➢ Normal
➢ Cataract
➢ Dense Cataract
➢ Silicone Oil Type 1
➢ Aphakic
➢ Pseudo Acryl
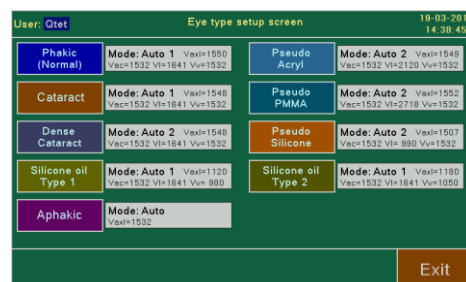
> ➢ Pseudo PMMA
> ➢ Pseudo Silicone
> ➢ Silicone Oil Type 2

For every type of eye, the following data is stored:

1. *Mode* : **Auto** (default for Aphakic eye), **Auto 1** (default for Normal and Cataract eyes) , **Auto 2** (default for all other eyes) and **Manual.** The measurement mode can be forced also manually after pressing the *MODE* button in A-scan screen (See the description of the modes in the chapter 5.8.4).

2. *Ultrasound Velocities*:

   - V_{AC} - Anterior Chamber depth ultrasound velocity: **1532 m/s** by default

   - V_L **-** Lens ultrasound velocity: **1641 m/s** by default for Normal, Cataract, Dense Cataract and Silicone Oil ; **2120 m/s** by default for Pseudo Acryl ; **2718 m/s** by default for Pseudo PMMA; **990 m/s** by default for Pseudo Silicon

   - V_V **-** Vitreous body ultrasound velocity: **1532 m/s** by default ; Silicon oil propagation speed in case of silicone filled eyes (Silicon oil eye type 1 or type 2) default is **980 m/s** (Type1) or **1050 m/s** (Type2).

Table 1- *Determination of the eye structure*

Eye structure		Velocity [m/s]
Cornea		1640
Anterior chamber	V_{AC}	1532
Vitreous body	V_v	1532
Normal lens	V_L	1641
Cataract lens	V_L	1641
Dense Cataract lens	V_L	1641
Acrylic lens	V_L	2120
PMMA lens	V_L	2718
Silicon lens	V_L	990
Silicon oil	V_V	980 (Type1) or 1050 (Type 2)

   - **Vaxl** - Average ultrasound velocity for measurement Axial Length in Auto 2 mode and Manual mode. Default Axial Length Average Velocity values for ultrasound waves propagating for eyes: Normal, Cataract , Dense Cataract and Silicon Oil – see Table 2 below.

Table 2 - Default Axial Length *Average Ultrasound Velocity values (V_{axl})*

-

Eye type	Default V_{axl} *(Average velocity)*
Normal	**1550** m/s
Cataract	**1548** m/s
Dens cataract	**1548** m/s
Silicone Oil	**1120** m/s (Type1) or **1180** M/S (Type 2)
Acryl pseudofakia	See Table 3
PMMA pseudofakia	See Table 4
Silicone pseudofakia	See Table 5

Average velocity values Vaxl are set by <u>default for an eye with pseudofakia</u> for the following thicknesses of pseudofakic lenses:

- Thickness of the acrylic lens = 0.8 mm
- Thickness of the PMMA lens = 0.7 mm
- Thickness of the Silicone lens = 0.9 mm

In order to measure an eye with a pseudofakic lens that has different thickness, the mean velocity V_{axl} should be set according to the table:

Table 3 - *Average Velocity values V_{axl} for Pseudo Acryl eye type*

Acryl lens thickness [mm]	Average velocity [m/s]
0,7	1547
0,8 (default)	**1549**
0,9	1551
1,0	1553
1,1	1554
1,2	1556

Table 4 - *Average Velocity values V_{axl} for Pseudo PMMA eye type*

PMMA lens thickness [mm]	Average velocity [m/s]
0,5	1549
0,6	1551
0,7 (default)	**1552**
0,8	1557
0,9	1560
1,0	1563

Table 5 - *Average Velocity values V_{axl} for Pseudo Silicone eye type*

Silicone lens thickness [mm]	Average velocity [m/s]
0,8	1510
0,9 (default)	**1507**
1,0	1505
1,1	1502
1,2	1499
1,3	1496

You can modified all parameters for each type of eye by pressing the corresponding box with the type name. The special **Edit** page appears on the screen with a list of parameters that can be changed.
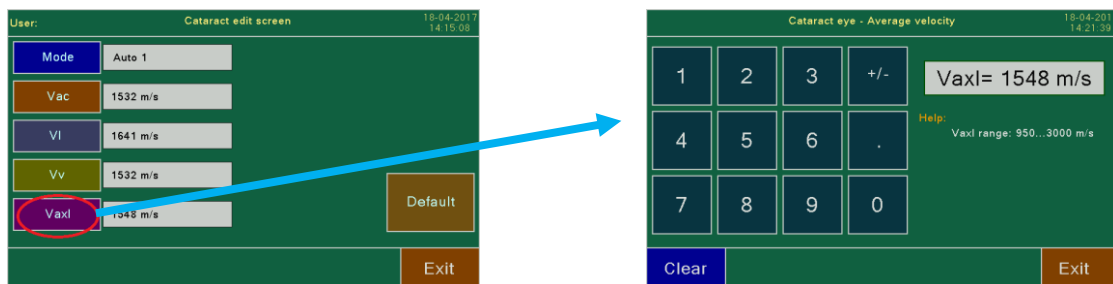
Tap inside the field of parameter you want modify. On the new screen enter a desired value using the numeric keypad or using selection menu.

Note:

1. If the entered value is outside the approved range, the change of the parameter will not take place.
2. For Pseudo Acryl, Pseudo PMMA and Pseudo Silicone eyes V_{AXL} is selecting from a tables (see Table 3, Table 4 and Table5)

WARNING!

➢ ***The change of the speed of the respective structures of the eye must accept the examiner, because it is a parameter that affects the measured results of the eyeball length.***

➢ ***It is very important to verify that the correct default velocities are displayed prior to measuring Axial lengths and corneal thickness.***

| Default | Pressing the ***Default*** button and then ***Set default*** button default values of ultrasound velocity and standard method for selected eye types can be restored. One column shows the current velocity |

values and the other one shows the defaults. Pressing the ***Set default*** menu key causes the default values to become the current values. The ***Exit*** button leaves the values unchanged.

The selected eye type, mode, method and all sound velocities are displayed on the Measurement A-scan screen (see 5.6).

5.5.3. IOL SETUP

Pressing the ***IOL setup*** button in the **A-setup** window opens the *Formula reflectiv* screen **-** for selection the

formula for IOL calculation and type of lens for **four** different Lens settings: *Lens 1..:Lens 4*.

For each Lens settings you can choose: one from ten defined lenses (**Lens type** area)**,** one from six IOL formulas: SRK-II, SRK/T, HOLLADAY-1, HOFFER-Q, BINKHORST-II and HAIGIS (**Formula IOL** area), and one from four postoperative formulas: Double-K SKR/T, LATKANY Flt-K SKR/T, LATKANY Avr-K SKR/T and mdf-MASKET (**Formula Refractive** area).

To change any of the setting, select the appropriate field - a new selection window will be displayed on the screen.

*Note: For more information about IOL formulas see **Appendix-A : IOL Formulas***

Each settings in *Lens 1..Lens 4* can also be changed on the *IOL Calculation* page. The *IOL calculation screen* is divided into four parts with 4 IOLs result tables: *Lens 1, Lens 2, Lens 3, Lens 4* - calculations concerning the lens type, selected by the user in the ***IOL Setup*** menu. If such number of lens has no selection, it part of the table remains empty, but *Lens 1* cannot be empty.
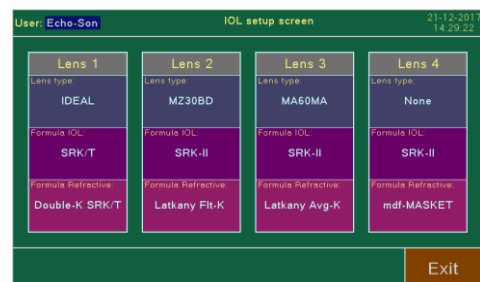
5.5.4. LENS SETUP

Pressing the *Lens setup* button in the **A-setup** window opens the **Lenses list screen** for setting

parameters for any of the ten stored lenses on the selected User. Thus, a part or the whole set of the lenses that are intended for the given user can be changed.

➢ *Edit name* – editing the lens name. Pressing the *Edit name* button opens the page where the selected lens name can be changed using the QWERTY alphanumeric pad.

➢ *Edit parameters*– editing the lens parameters. Pressing this button opens the page where for the

selected lens parameters can be changed. The parameters assigned to the selected lens are used during the calculation of IOL formulas. Pressing buttons *A, ACD* or *SF* edits the corresponding parameter using the numeric pad.

The *TYPE* button switches between the lens types – **Posterior** or **Anterior.**
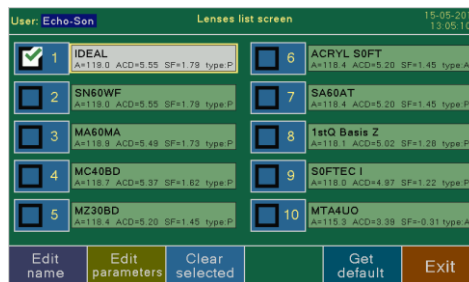
Description of lens parameters

- **const A** – Used for the calculation of the implant power using the methods SRK II, HAIGIS and SRK-T. The values from the range: 110.00 ÷ 125.00.

- **const ACD** – (*Anterior Chamber Depth*). Used for the calculation of the implant power using the HOFFER-Q, BINKHORST II method The values from the range 0.30 ÷ 9.05.

- **const SF** – (*Surgeon Factor*). Used for the calculation of the implant power using the HOLLADAY method. The values from the range: -3.50 ÷ 5.25.

- If a parameter has been changed, pressing the *Exit* button saves the changes and returns you to the **Lenses list screen** page. If a value for the new parameter is not entered, pressing the *Exit* button returns you to the previous page leaving the previous parameter values unchanged.
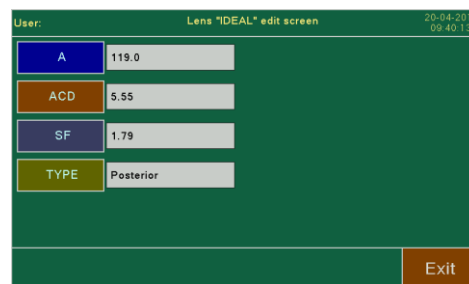
   WARNING :

   1. *If the const ACD value is not given by the manufacturer of the lens (on the package or in the information leaflet), the scanner calculates it automatically after the const A value is entered according to the formula: const ACD=[(const A* 0.5663) – 65.600 +3.595]/ 0.9704; – look at* **Appendix – B: Lens Constant Conversion Table**

   2. *If the const SF value is not given by the manufacturer of the lens (on the package or in the information leaflet), the scanner calculates it automatically after the const A value is entered according to the formula: const SF = (const A* 0.5663) – 65.60; - look at* **Appendix – B: Lens Constant Conversion Table**

3. *The erroneously given values for the lens or the selection of the inappropriate lens result in errors in the calculation of the implant power IOL.*

➢ *Clear selected*– removes the selected lens from the list for the assigned user (Lens 1 always has to be defined – default as an "IDEAL")

➢ *Get Default* – It allows you to fill the whole list (ten lenses) with standard lenses: pressing the *Set default* menu key causes the default values to become the current values. The *Exit* button leaves the values unchanged.

Get default
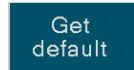
5.6. CALIBRATION A-SCAN MODE

Pressing the *Scan* button on the **Menu** page first time opens the page for testing the scanner and probe A. Calibration is performed to control the performance of the scanner and the probe.

A user can always perform calibration by pressing the *Calibration* button in the A-scan window menu.

A user can skip the testing procedure by pressing the *Exit* button. After it is pressed, the page with the main A-scan menu opens.

⚠ Note: **The tests ought to be performed each time the scanner is switched on.**

Calibration procedure:

1. Inspect the probe of the calibration standard and the tip of the probe visually (cleanness)

2. Make sure the velocity is displayed properly, i.e. 1532 m/s in the top right corner of the screen

3. To make a contact use a small amount of gel and place the probe perpendicularly to the calibration standard, alternativy befor placing it to the calibration standard insert the probe tip into demineralized wather.

4. Place the A-mode probe perpendicularly on the top of the calibration cylinder.

5. Try to provide steady probe position.

6. Press the *Start* button in the device or press the foot switch.

7. Wait until set of 10 measurement will be automatically collected

8. Measurement result **15 mm** ± 0.15 mm should be displayed on the screen.

9. If a measurement is outside the aforementioned tolerance limits, the measurement should be repeated (*Repeat* button or press the foot switch again) slightly correcting alignment of the probe and if necessary increase the pressure of the probe until the proper result is obtained (A higher result indicates that the probe is not aligned perpendicularly to the probe of the standard).

10. After calibration is completed, the standard and the probe face should be wiped gently.
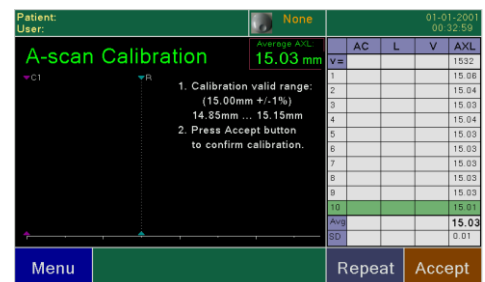
Notes:

1. *Perform the calibration test at an ambient temperature from 20ºC to 25ºC*

2. *If you cannot obtain the proper result during calibration, you should contact the manufacturer.*

3. *You can start the examination of the patient when you leave the calibration process by pressing the Accept button.*

5.7. MEASUREMENT A-SCAN SCREEN

Pressing the *Scan* button in the **MENU** window opens the **Biometry Screen** (Measurement A-scan screen)

Pressing the *Scan* button on the **MENU** page for the first time opens the Calibration page for testing the scanner and probe A. . –see chapter 5.6

If the probe is disconnected, the message "**No Probe**!" is displayed

A user can skip the calibration procedure by pressing the *Exit* button. After it is pressed, the main Measurement A-scan screen opens.

The A-scan application screen contains the following information:
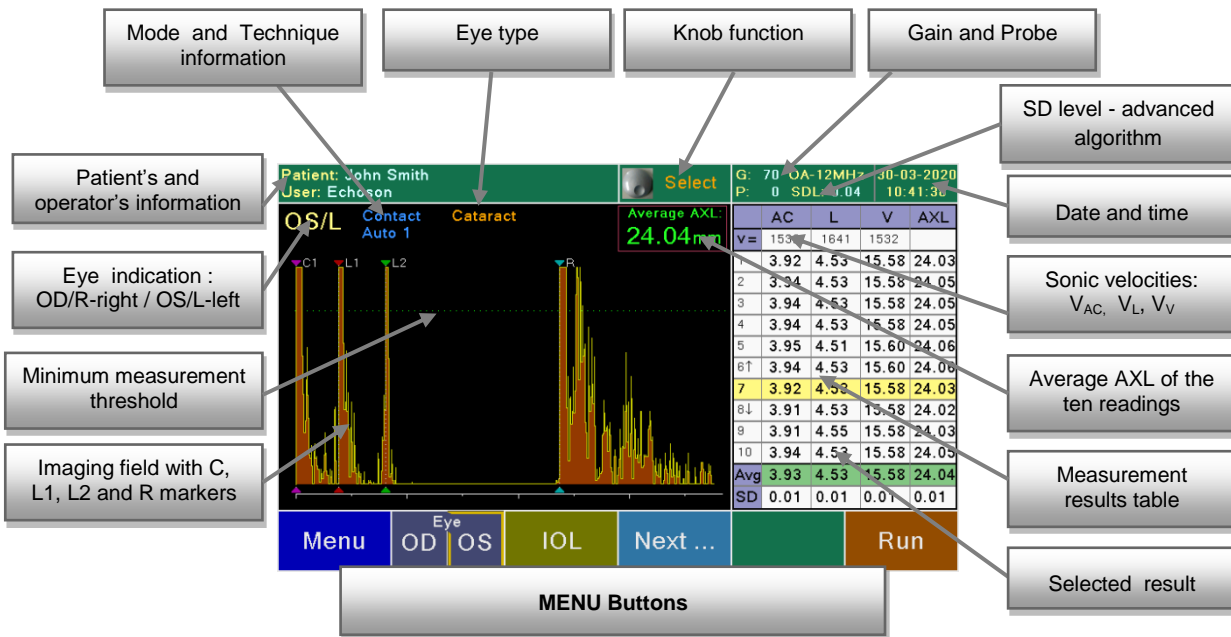
The knob allows the user to:

During acquisition:

- *Gain* - adjust the default gain

On a frozen image (pressing the Knob calls up the vertical menu for selecting the knob function):

- *Select* the previous or next line in the result table.

- **Corr X -** adjust the position of a selected marker (L1 ,L2 or R) when the Marker screen is selected.

*Note: After performing e.g. the biometry you can go to the **Menu screen** to change some parameters in the **User** and **Patient** windows. Then you can use the **Back** button to return to the measure screen, keeping the measurements. Introducing a new patient, changing the user, or changing global parameters, such as the type of eye, causes the **Back** button to become inactive. Pressing the **Scan** key always initiates the new scan (biometry).*
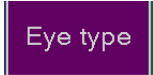
5.8. BIOMETRICAL MEASUREMENTS PROCEDURE

5.8.1. EYE SELECTION

The eye selection is done by pressing the menu button **OD** or **OS.** The selected menu button is marked with
an edging. The description of the sected eye is displayed in the upper left corner of the screen.
By default the scanner responds by reporting the right eye.

The scanner has two sets of memories: for the right and the left eyes. Make sure the parameters of the
measurement displayed and the ultrasound velocity values displayed on the screen are compliant with the
user's intentions.

Additionally in A-scan screen in RUN mode the eye type can be select by pressing the **Eye
Type** button (see chapter 5.4.1)

5.8.2. ACQUISITION IN BIOMETRY MODE

The probe face shall be applied perpendicular to the eye along the visual axis.
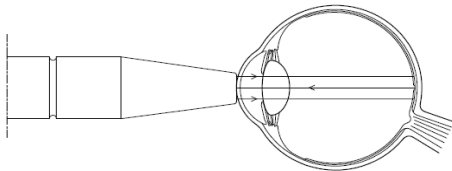
__Proper__ placement of probe In the eye axis
– perpendicular to the rear wall
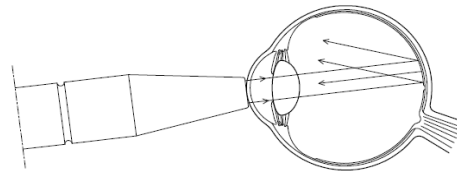
__Improper__ placement of probe
– not perpendicular to the rear wall

The measurement is initiated using the **Run** button or the **footswitch.** The screen will display the signal
received by the probe. The cornea should be anaesthetized.

- After starting acquisition using **Run** button on the screen or by briefly pressing the **footswitch**, the
  scanner immediately enters the **measurements** mode - starts searching for characteristic signals in the
  wave, corresponding with borders of measured structures. After fulfillment of measuring conditions the
  device will take 10 measurements.

- After starting acquisition by pressing and holding the **footswitch,** scanner enters **Prescan** mode -
  echogram is displayed on the screen, but automatic measurement collection is off. Inscription "*Prescan*"
  is displayed on the screen. Adjust the Gain and align the probe to obtain clear and equal amplitudes C1,
  L1, L2, R. All echoes should exceed the minimum measurement threshold (green dotted line) and the
  echo from the R retina should be perpendicular to the base line. A strong S sclera echo should also be
  obtained above the minimum threshold at a distance of approximately 1,5 mm after the echo from the R
  retina. After fulfillment of above mentioned conditions release the footswitch, the scanner will take 10
  measurements.

After starting the measurement, the scanner starts searching for characteristic signals (peaks) in the wave,
corresponding with borders of measured structures Found points are marked with numbered vertical white
lines–cursors C1, L1, L2, R (see 5.8.4). When all needed points are found by the scanner and marked with
cursors, the measurement is calculated and result is entered in the table. The scanner will take ten
measurements. After all measurements have been performed, the process is stopped (Freeze mode).

Measurement procedure can be stopped at any time by pressing the *Freeze* key. By using foot operated switch you can activate the **Prescan** mode (measuring off). In the auto modes, the stop and the restart initiate the measurement of the series from the beginning. In Freeze mode it is recommended to review all measurements and, if necessary, make a adjustment (see 5.8.16).

5.8.3. SELECTION OF THE MEASUREMENT TECHNIQUE

Technique

Pressing the *Technique* menu button selects the desired technique: *Immersion* or *Contact.*.

In the **Contact** technique the OA probe is placed directly, smoothly on the patient's cornea. The contact must be very light, no hard pressure on the cornea.

In the **Immersion** technique, an immersion tube (Shell) containing the OA probe is placed on the patient's eye and filled with solution between the probe and the cornea.- there is an offset on the display between the peak from the probe tip and the peak from the cornea. The shell must be placed directly on the sclera over the limbus.

 In Immersion mode the software criteria looks for C1 (anterior cornea). All other criteria for amplitude threshold and peak locations are the same as for the contact modes.

Note: Ensure the technique is selected as indicated in the upper left corner of the Measure Screen.

The default technique for the user is selected on the User Settings for A-scan page – *see chapter 5.5.1.*

5.8.4. MEASUREMENT MODE SELECTION

The selection of an eye type automatically sets the measurement mode for the given eye (independently for the left and the right eyes. Default settings are: for Aphakic eye **– Auto** mode ; for Normal and Cataract eyes - **Auto 1** mode and for all other eyes – **Auto2** mode. User can be change default mode on the Eye Setup Screen (*chapter 5.5.2*)

Mode

The measurement mode can be forced also manually after pressing the *MODE* button in A-scan screen. Pressing the *Mode* button opens the page where the measurement mode can be selected. Aphakic eye method is fixed (Auto). For other types you can choose between : **Auto 1, Auto 2** and **Manual**.

5.8.4.1. Auto 1 Measurement Algorithm

In the **Auto1** mode, if the software criteria for range and amplitude of peaks is met (C1,L1,L2 and R), the system will automatically obtain a series of ten (10) reading, whose results are inserted into a table. After the measurements have been performed, the process is paused.

After stopping the measurement procedure or collecting whole 10-result series automatically calculated:
- the average axial length of the eyeball AXL
- the standard deviation for AXL measurements
- the average length of the anterior chamber AC
- the average lens thickness L
- the average length of the vitreous body V

Auto 1 mode

Normal eye

V_{AC} - 1532 m/s
V_L - 1641 m/s
V_V - 1532 m/s

AXL= AC+L+V

OD/R Contact Phakic (Normal)   Average AXL
Auto 1   23.73 mm

	AC	L	V	AXL
V=	1532	1641	1532	
1↓	3.78	4.50	15.40	23.68
2	3.65	4.61	15.44	23.70
3	3.68	4.61	15.43	23.72
4	3.68	4.63	15.43	23.73
5	3.66	4.63	15.41	23.70
6	3.68	4.58	15.50	23.76
7↑	3.69	4.58	15.49	23.76
8	3.71	4.58	15.49	23.77
9	3.57	4.56	15.63	23.76
10	3.62	4.53	15.63	23.77
Avg	3.67	4.58	15.48	23.73
SD	0.05	0.04	0.08	0.03
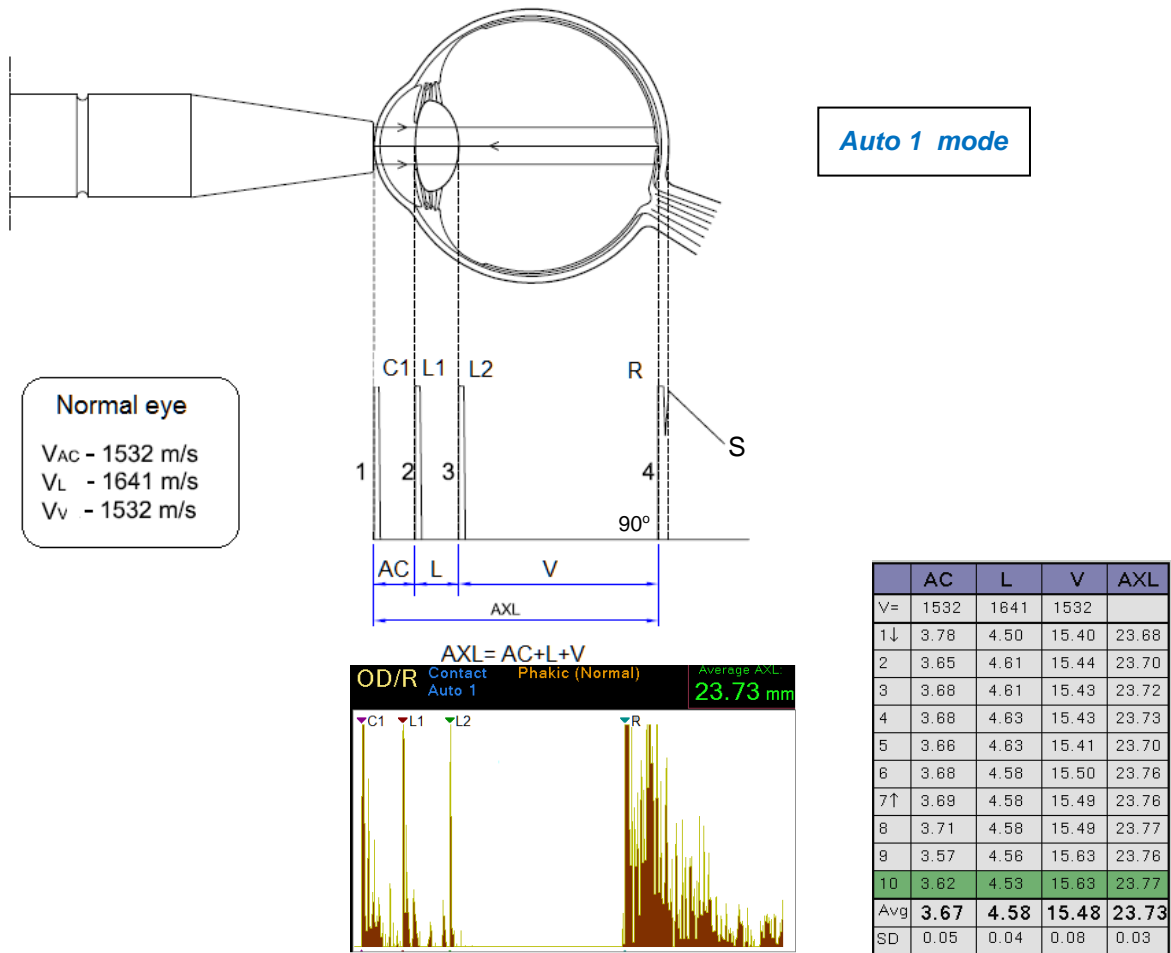
Note: Each of the ten measured axial lengths of the eyeball AXL is a sum of measurements of three segments of the eye: AC, L, V. Each of the segments is calculated considering separate ultrasound velocity values: V_{AC}, V_L, V_V.

The values are by default set to: V_{AC} = 1532 m/s, V_L = 1641 m/s, V_V = 1532 m/s for the Normal eye

The values V_{AC}, V_L, V_V can be changed by a user on **A-setup** window (*chapter 5.5.2*)

5.8.4.2. Auto 2   Measurement Algorithm

If the scanner is in the **Auto 2** mode, it performs a series of quick **10** measurements provided that the appropriate criteria for the location and value of C1, L1 and R are met. The measurements results are automatically inserted in the table. After the measurements have been performed, the process is paused.

In **Auto 2 (**or **Auto** for APHAKIC eye) - 10 measurements one by one are performed to calculate:

- the average axial length of the eyeball AXL

- the standard deviation for AXL measurements

- the average length of the anterior chamber AC

Note: Each of the ten measured axial lengths of the eyeball AXL is a result of the measurement of the cornea-retina segment with velocity V_{AXL} dependent on the eye type. Additionally (does not apply to the APHAKIC eye), the length of the anterior chamber AC is measured considering the ultrasound velocity V_{AC}

The values are by default set to: V_{AC} = 1532 m/s , V_{AXL}= 1550 m/s for the Normal eye.

The V_{AC} and V_{AX} velocity values for each eye type can be changed by a user on **A-setup** window (*chapter 5.5.2*)

Auto 2 mode

Normal eye
V_{AC} - 1532 m/s
V_{AXL} - 1550 m/s

	AC	L	V	AXL
V=	1532			1550
1	3.00			22.94
2	3.00			22.94
3	3.00			22.94
4	3.00			22.94
5	3.00			22.94
6	3.00			22.94
7	3.00			22.94
8	3.00			22.94
9	3.00			22.94
10	3.00			22.94
Avg	3.00			22.94
SD				
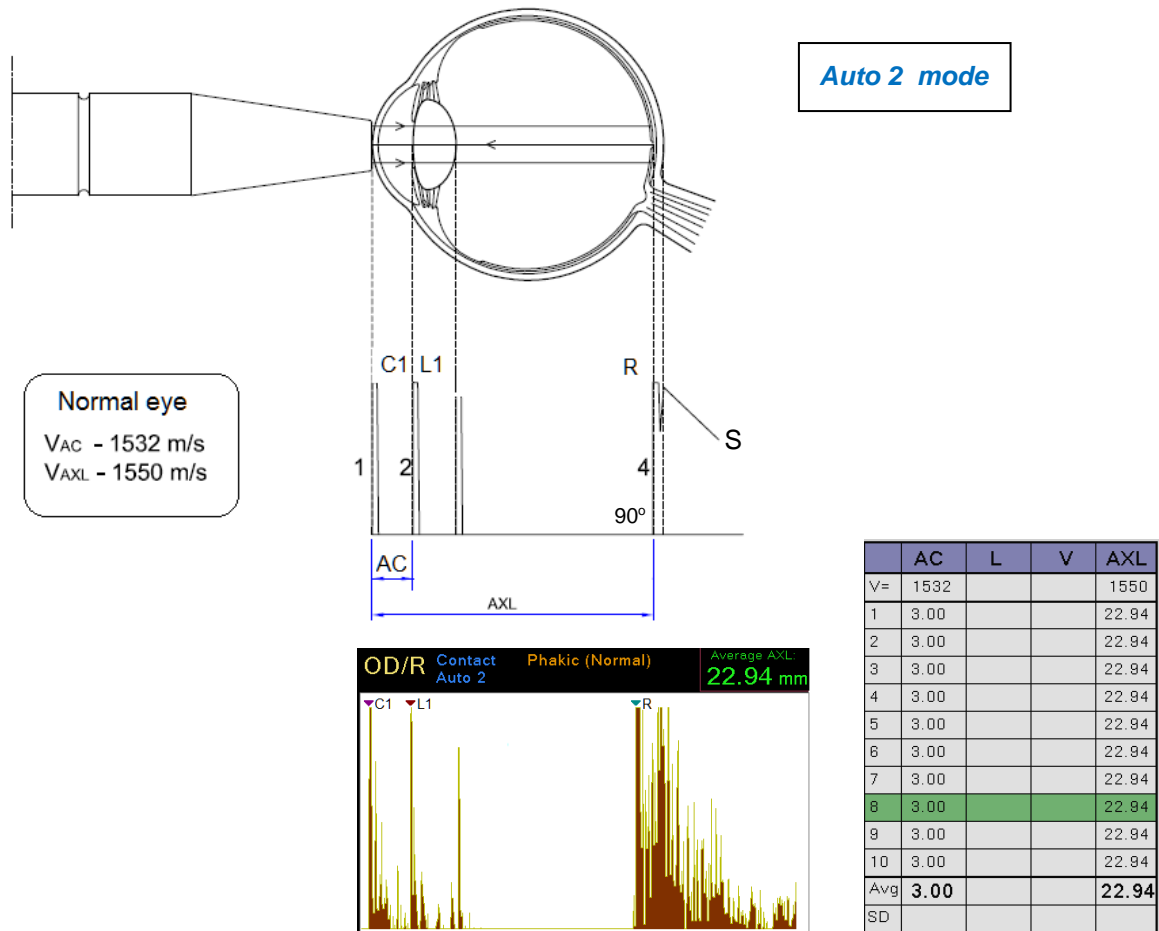
5.8.4.3. Manual Measurement

If the **Manual** mode, the scanner stops after taking a measurement. The measurement result is approved either by pressing the *Freeze* button or the footswitch.

The program set the four markers automatically. If the correct echoes criteria are not found, the appropriate markers will not be set. The user must then set the markers manually or take a measurement again.
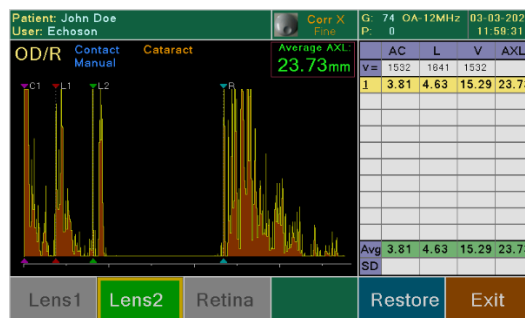
5.8.5. GAIN ADJUSTMENT

Adjust scanner gain using the *Knob* in order to better suit the signal for the purpose of detecting required structures. The current amplification value. is displayed on the upper screen bar **G:xx.** Initially, the gain is set in the USER menu (see chapter 5.5.1).
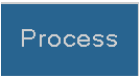
By default scanner is set to gain 78 for contact method, and 74 for immersion method.

Note: Gain value should be adjusted individually for each patient.

Should it prove during examination that the amplitude of monitored echoes (signed by letters: c, l, v) **is too low**, while the probe is perpendicular to tissue surface, gradually increase gain (turning the knob to the right) in order to allow automatic measurement. In the event that **echoes on peaks are too saturated**, or in the event that additional strong echoes occur that might affect correctness of automatic measurement, reduce gain turning the knob to the left.

5.8.6. PROCESSING ADJUSTMENT

Use the Processing function to adjust the gray scale to help reduce noise in the image. The Postprocessing function is active on a motion image when the probe operates (*RUN* mode).

Process   To select the level of processing click the *Process* menu button on the screen. Pressing the *Process* button opens the page where the level of processing can be selected: P0, P1 or P2.

The current processing status is displayed on the information bar   *P:x* .

The default processing level for the user is selected on the User Settings for A-scan page – *see 5.5.1.*

5.8.7. RESULT TABLE CALCULATION

The scanner performs a series of 10 measurements, results of which are saved in the table. After completion of measurements the scanner automatically stops.

Measurement procedure can be stopped at any time by pressing the *Freeze* key or using foot operated switch which starts and stops the scanner alternately. Stopping and starting the scanner again restarts the series measurement.

After stopping the measurement procedure or collecting whole 10-result series, a diagram of the last in series measurement is displayed. In addition, at the bottom rows of the table the average arithmetic values **Avg** and standard deviation **SD** in measurement series are displayed.

To display diagrams for other measurement results in the series use the **Knob**

Select   (function *Select*) or, use the **stylus** to point to the appropriate field in the table. Currently a diagram is displayed for which measurements are marked in *green* color.

	AC	L	V	AXL
V=	1532	1641	1532	
1	3.02	5.01	15.00	23.02
2	3.02	5.01	15.00	23.02
3	3.02	5.01	15.00	23.02
4	3.02	5.01	15.00	23.02
5	3.09	5.01	14.85	22.94
6	3.02	5.01	15.00	23.02
7	3.02	5.09	15.00	23.10
8	3.02	5.01	15.00	23.02
9	3.02	5.01	15.00	23.02
10	3.02	5.01	15.00	23.02
Avg	3.03	5.01	14.98	23.02
SD	0.02	0.03	0.05	0.04

In addition, two **arrows** ↑ and ↓ next to the measurement number are displayed. They indicate the largest and shortest axial length data (AXL) respectively.

Select   If the result of any measurement deviates too much from the rest, due to any interference, user can exclude the result from the collection of results used in calculation of the average value and standard deviation. Significant drop in standard deviation value with exclusion of the

3	3.78	4.56	15.38	23.73
4	3.81	4.51	15.37	23.69
5↓	3.77	4.55	15.32	23.63
6	2.62	5.79	15.29	23.70
7	3.78	4.61	15.32	23.72
8	3.78	4.61	15.32	23.72
9	3.80	4.61	15.34	23.75
10	3.83	4.59	15.24	23.67

measurement should assure the user that such exclusion is justified. Press the *Knob* (or *Select* menu button in **Next** menu) to exclude given result from the IOL calculation. Excluded results are marked with red cross.. Press *Knob* again to include the result to corresponding collection of results. Each time the data is deleted and the deletion is undone, the average (Avg) and standard deviation (SD) are recalculated.

Run selected

When the excluded measurement (marked with *red* cross) is highlighted (*green* backlight), additional button **Run selected** appears on the menu bar. By pressing the **Run selected** button the selected result <u>will be erased</u> and the scanner will go into Run mode for one measurement to get the <u>new</u> reading.

Note:

1. ***Standard algoritm for standard deviation SD of AXL measurement exceeding level set in Setup/Options window (default 0.15 mm), a message in red is displayed on the screen and a roice warning is being played , advising adjustment of results by repeating measurements or excluding results deviating excessively from the average.*** *The warning level is displayed in the information bar: SDW=x.xx*

2. ***The choice of the Advanced algorithm (chapter 5.5.1) makes it possible to control the Standard Deviation (SD) level - the entered limit value for SD is displayed in the information bar: SDL = x.xx***

3. *The automatic functions of the scanner have been developed to facilitate the examination and **never replace the evaluation of the examining physician**.*

4. *All the results from the 10 measurements should be evaluated carefully by the examining physician. In the case of doubts, the measurements should be repeated and the erroneous results (extremes) should be rejected. Only when the results **are approved by the examining physician**, can the appropriate formula for the calculation of the IOL implant power be selected.*

5.8.8. MANUAL MARKERS CORRECTION

If you decide that automatic measurement on a given picture requires correction (e.g. If one of the peaks were outside the normal software range), you can go to the manual marker mode (**4-Gate** manual mode). This function is used to eliminate the influence of extraneous echoes.

Next ...

Select the **Next** menu button and then **Marker** button – the new screen for manually correction will then be displayed. Using the **Knob** and menu button you can set one position

Corr X

markers C1 (**Cornea** button in immersion only), L1 (**Lens1** button), L2 (**Lens2** button)

and R (**Retina** button).

Turn **Knob** and move each marker to left or to right side of respective echoes. You can select two function for Knob: **Fine** - it allows to precisely move the marker (by one pixel) or **Coarse** - it allows you to move the marker faster (by 10 pixels).
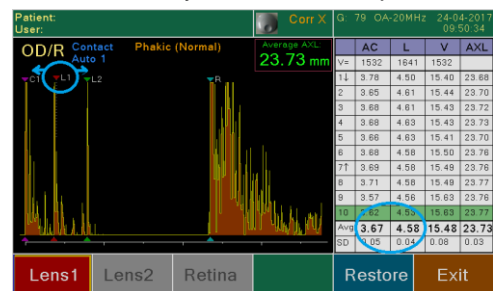
Note   Pressing the Knob calls up the vertical menu for selecting the knob function.

When each marker is moved, the system automatically <u>recalculates</u> the all distances this scan. The modified measurement is marked with an <u>underlined</u> measurement number. The SD (Standard Deviation) and Avg (Average) values are also recalculated. Using **Restore** menu button to restore previous position all markers.

5.9. IOL CALCULATION

IOL

Select the *IOL* menu button once the series of measurement is achieved- the **IOL calculation** screen will then be displayed

The default values necessary for the calculation are results of biometrical measurements and the parameters entered in the menus of the patient's and user's data. The calculation can also be performed without measurements because the values necessary for the calculation can be entered manually (5.9.3)

Note : make sure keratometry values have been filled in the Patient Screen (for standard or Post refractive surgery cases)

If all the data needed for the calculation have been defined and measured before entering the IOL Calculation page – the eye data has been entered on the patient's page, the lens data has been entered on the user's page and the biometrical measurements of the eye have been performed, the calculation results appear in the table. Otherwise, the table remains empty.

The IOL Calculation screen can be used by the operator to perform IOL power calculations using four different user selectable IOL/Formula combinations. The table is divided into four parts: Lens 1, Lens 2, Lens 3, lens 4 - calculations concerning the lens type, selected by the user in the USER menu (*A-setup: chapter 5.5.3.*) If such number of lens has no selection, it part of the table remains empty.

When entering the IOL page, at the beginning the data from the Patient menu (*chapter 5.4*), the User menu (chapter 5.5) and the results of real biometrical measurements are binding.

Each part of the table contains lens data that is part of the calculation and the calculation results:

Emme (Emmetropia) – the calculated implant power

IOL – the suggested implant power;   **REF** – refraction

The calculation result takes into consideration the value of **Target Ametropia.**

IOLs can be increment by steps of 0.25 or 0.5 - default values you can change in User screen – see chapter 5.5.1.

5.9.1. EYE SELECTION IN IOL

Press the *OD/R* or *OS/L* fieldswitch to select the right or left eye for which the IOL calculation is to be performer. Each time the button is pressed, the eye indication in right corner of the screen the switch changes between **OD/R** (right eye) and **OS/L** (left eye).

The scanner has two sets of memories: for the right and the left eyes. Make sure the results of biometrical measurements and the parameters entered in the menus of the patient's and user's data. are compliant with the user's intentions.

5.9.2. LENSES SELECTION

The default Lens type will be displayed upon opening the IOLs calculation Screen. They has been entered on the user's page on IOL Setup screen - see chapter 5.5.3. It is still possible to choose different Lens in each of the 4 tables. Just you can <u>tap</u> the box with the name of the lens for a given table - the Lenses selection screen is displayed.

5.9.3. MANUALLY IOL PARAMETERS ENTER

The AXL and AC average values are brought forward from the scan screen. The user may also manually enter the AXL and AC values along with Tam, K1 and K2 to perform IOL power calculations. Press **Manual correction** menu button to open new menu to enter parameters to IOL calculation:

- **TAM** button (*Target ametropia)* - opens the page where you can enter *Target Ametropia* value for the currently selected eye. (acceptable range is -9.99D to +9.99D)..

- **Average AXL** - opens the page where you can enter the average axial length of the eyeball AXL

- **Average AC** - opens the page where you can enter the average length of the anterior chamber AC (parameter used in the Haigis formula)

- **K1** and **K2** buttons **-** opens the page where you can enter keratometry values (coefficients of refractive power of the cornea) for the currently selected eye (left or right) using the numeric pad. (*see chapter 5.4.2*). After entering both values the average **Kavg** calculation is performed and displayed.

Note: *You can enter only classical keratometry measurements K1 and K2.. For Post Refractive formulas you can enter only TAM and AXL values. To enter the parameters for post refractive calculation should be used the patient's page – see chapter 5.4.4.*

5.9.4. IOL FORMULAS SELECTION

The table values are calculated using the specified IOL formula. The default Formulas for each table will be displayed upon opening the IOLs calculation Screen. They has been entered on the user's page on IOL Setup screen - see chapter 5.5.3. It is still possible to choose different Formulas in each of the 4 tables. Just you can tap the box with the name of the formula for a given table - the Formulas selection screen is displayed. You can use the **Set to all 4** menu button to set the selected formula for all four lenses.

You can choose one from **6 IOL formulas**:
1. **SRK-II,**
2. **SRK/T,**
3. **HOLLADAY-1,**
4. **HOFFER-Q,**

5. **BINKHORST-II**

6. **HAIGIS**

and/or one from **4 postoperative (LASIK,PRK) formulas**:

1. **Double-K SKR/T,**

2. **LATKANY Flattest-K SKR/T,**

3. **LATKANY Average-K SKR/T**

4. **mdf-MASKET**

For more information about IOL formulas please refer to the *Appendix A – IOL FORMULAS*

Note: Depending on the measured axial length of the examined eye, preferable methods for the calculation of the implant power are recommended:

Avr AXL < 22	formula HOFFER-Q
22.0 ≤ Avr AXL < 24.5	any formula
24.5 ≤ Avr AXL < 26.0	formula HOLLADAY-1
Avr AXL ≥ 26	formula SRK/T

5.9.5. COMPARISON OF VARIOUS FORMULAS

The *Formulas Comparison* button opens the page where a comparison of the results of IOL calculations according to all the available formulas in the PIROP scanner is possible. If the current formula is the postoperative formula (post-LASIK or post-PRK), the results of the postoperative calculations are displayed. If not, the preoperative results are displayed.

The table shows the results of calculations for which all the necessary data has been measured and entered (e.g. in the Patient menu). Otherwise, the table shows empty spaces.

5.9.6. COMPARISON IOL FOR ALL LENSES FROM DATABASE

The main IOL calculation screen allows the user to view up to 4 lens models with the corresponding full IOL calculation. It is also possible to display a table with IOL calculations for all 10 lenses from the database at the same time. To do this, press the *Formulas Comparison* key on the main IOL calculation screen (see chapter 5.9.5), and than press the *Lenses Comparison* menu key - the new table screen to be displayed. This table allows the user to view all lens models from his lens database (up to **10** names) with the corresponding IOL calculation (the calculated implant powers *Emme*, the suggested implant powers *IOL* and refractions *REF*).

The table values are calculated using the current IOL formula. It is possible to choose different Formula - you can tap the box with the name of the formula - the Formulas selection screen is displayed.

5.10. PRINTING IN A-SCAN MODE

Printing on internal thermal printer are available for each scan performed and for the IOL powers calculation table (see chapter 8.1).

Print To print A-scan with Result table calculation touch the **Next** button on Measure screen and then press **Print** menu button. To print table of IOL calculation touch the **Print** button on IOL calculation screen.

Printing in A-scan mode are also available by using optional external videoprinter connected to video port, or the optional external laser printer, which is connected to PIROP via USB or an ad hoc wireless Network (*see chapter 8.3*).

5.11. SAVING IN A-SCAN MODE

Saving are available for each scan performed and for the IOL powers calculation table (see chapter 8.2).

Save To save A-scan with Result table calculation touch the **Next** button on Measure screen and then press **Save** menu button. To save table of IOL calculation touch the **Save** button on IOL calculation screen. (chapter 8) . There is the ability to save images only to internal memory or simultaneously to internal and external USB memory (see chapter 4.7.5).

PIROP scanner with factory mounted special printer adapter (see chapter 8.3) allows you to save a measurement report as a **PDF file** in the external memory connected to the USB port. Depending on the current screen various reports can be saved as PDF file: A-scan / Biometry Report, A-scan /IOL Report , A-scan / Lenses comparison, A-scan / Formulas comparison

Save PDF report To save reports as PDF file on a connected external USB memory, touch the **Next** button on Measure screen and then press **Save PDF report** key on the screen menu.

When you create and save a PDF report, an appropriate message is displayed on the screen (*more about writing a PDF report file - chapter 8.4)*

6. B - SCAN

6.1. PURPOSE

General B-Scan application is intended for a basic ultrasound examination in B-mode. B-scan ultrasonography is an important adjuvant for the clinical assessment of various ocular and orbital diseases. PIROP scanner in B-Mode enables the diagnosis of morphological changes of the eye structures and measurements. Ultrasound scanner also allows localization of foreign bodies, tumors, stroke and inflammation in the eye, and measurements of the various structures of the eye. Particularly valuable services gives the ultrasound scanner in case of the optical opacity of the eye structures and the evaluation of the retina, choroid, and optic nerve.

6.2. ACTIVATION B-SCAN MODE

The selection of B-scan biometry application is possible from directly from **Title** page (Mode page) or from the level of the **Menu** window by pressing the *Mode* key. Pressing the *B-Scan* button on the Mode select page (see chapter 4.3) opens the Menu page for A-scan mode - the scanner is intended for examination in B-scan mode.

The following buttons appears on the general Menu screen:
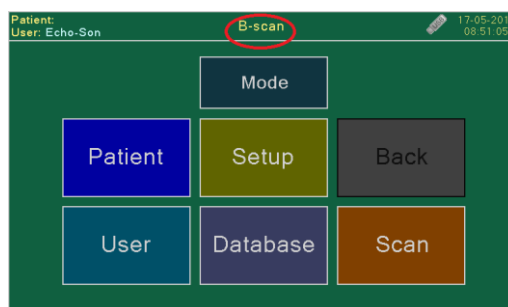
1. *Mode* - open the Mode Screen (Title page) for selection operating mode (chapter 4.3)
2. *Patient* - open the Patient Screen (chapter 6.4)
3. *User* - open User Settings Screen (chapter 6.5)
4. *Setup* - go to the Setup Screen: adjustment of the LCD display, setting the Time and Date, choose the menu language, open the Settings and Info screens etc. (chapter 4.7)
5. *Database* – open internal database of patient's exams (chapter 8)
6. *Scan* - Going to the Measurement B-scan screen (chapter 6.7)
7. *Back* - return to the previous page

Notes:

- *After performing e.g. the B scanning you can go to the* **Menu screen** *to change some parameters in the* **User** *and* **Patient** *windows. Then you can use the* **Back** *button to left the menu screen and* keep *the B image. Introducing a new patient, changing the user, or changing global parameters, such as the type of eye, causes the* **Back** *button to become* inactive. *Pressing the* **Scan** *key always initiates the* new *scan.*

- *At any time in B-scan you can use* **B-mode self test** *check the probe and software algorithm. You can use B-mode self test also every time when the OB probe is replaced - see chapter 4.7.4*

6.3. PATIENT DATA FOR B-SCAN

Patient

Pushing buttons *Patient* in the **MENU** window opens a page for entering or editing patient's information. Using *New patient* menu button enter patient data Name.P.ID, Gender and Date of Birth– see chapter 4.6.1.

*Note: Always start a new patient by first activating **New patient** key.*

6.4. USER SETTINGS FOR B- SCAN

Pressing the *User* button in the **MENU** window opens the **User Screen** with the Operation List.

User

Each user can enter a set of properties as personal profile.

Press *B-scan setup* menu button - **B-setup** window for given user appears on the screen.

| Edit name | A-scan setup | B-scan setup | Pachym setup |

6.4.1. ENTER B-SCAN PARAMETERS

➢ **Gain B-mode** – tap the gain field- a window with numeric pad opens that allows you to enter a new default Gain setting of the receiver in B-scan. The allowable range is 40-100 with a system default of 50

➢ **Range** - select the default range of the scan. Tapping the Range field - a window with list of possible ranges opens that allows you to select a new default Range setting. The allowable ranges are 2,3,4,5,6 cm with a system default of 4 cm. In B Run mode Range is switched alternately by pressing the *Range* key.

➢ **CV on/off -** turn on/off vector -A mode. Tapping this field opens a selection window for allowing you to select a new default state of the CV vector. In B Run mode CV state is switched alternately by pressing the *CV* menu key

➢ **Display CV -** For B-scan with A-Vector CV, you can choose to display waveform A on the B image (option B+A) or decrease B image and display waveform A-scan below image B (B / A option)

➢ **Eye mark -** Turning on / off the display of the eye mark (for graphically represent the probe position during the exam)

➢ **Print -** normal or negative

➢ **Processing -** P0 – logarithmic, P1 – linear, P2 – logarithmic "S"
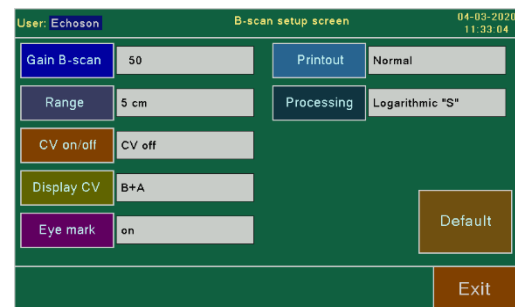
Default

By pressing the *Default* button it is possible to set the standard default values for all four of the above parameters.

*Note: After performing e.g. the B scanning you can go to the **Menu screen** to change some parameters in the **User** windows. Then you can use the **Back** button to left the menu screen and <u>keep</u> the B image. Introducing a new patient or changing the user, causes the **Back** button to become <u>inactive</u>. Pressing the **Scan** key always initiates the <u>new</u> scan).*

6.5. B-SCAN SCREEN

Pressing the *Scan* button in the **MENU** window opens the **B scan Screen.**

The B-scan application screen contains the following information:
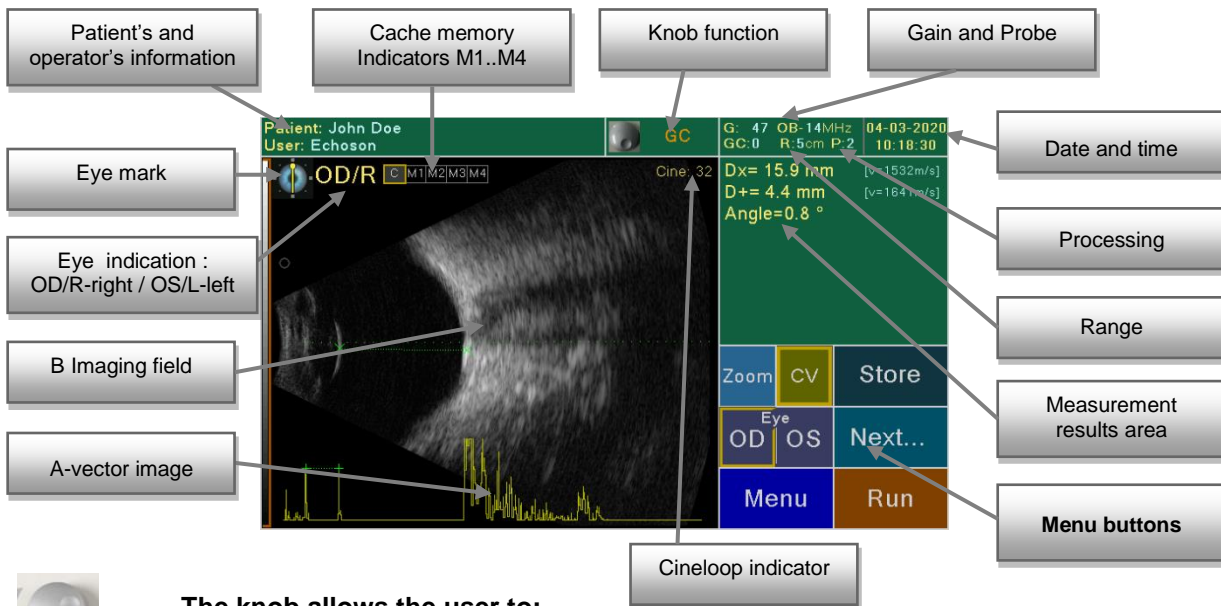
The knob allows the user to:

During acquisition:

- *Gain* - adjust the gain

- *DR* - adjust the display range (*DR* menu key)

- *CV -* positioning of the A-vector (CV) on the B Image in Run mode

On a frozen image:

- *GC* – digital Gain Correction in Freeze mode.(*ch.6.7.2*)

- **Cine -** rewinding the cine memory. (*chap. 6.9*)

- *CV -*. positioning of the A-vector (CV) on the B Image in Freeze mode (*ch.6.6.6*)

- *Corr X* , *Corr Y* - precise positioning of the measurement cursors in distance measurement. (*ch.6.7.4)*

- *Rotate* - Rotate the markers (arrows) in their setting mode (*ch.6.7.8.)*

- *Fine, Coarse* – moving the cursors in Distance CV measurement (*chap. 6.7.5*)

By pressing the Knob button you call up additional, **vertical selection menus**. The options from such menu are selected by the knob. You must confirm selection by pressing the knob button.

The vertical selection menu switches off automatically.

6.6. RUN B-MODE - Scanning

The **RUN** mode – (acquisition – information collecting mode) is used during examination of a patient to display the appropriate cross-sections of examined organs on the screen.

To display the acquisition screen for B-mode press the *Run* button in the B-mode window.

If the probe is disconnected, the message "*No Probe*!" is displayed.

After entry to the scanning probe B is automatically activated and starts working in B + A or B Mode (see chapter 6.4.1 CV on/off option). All previously displayed measurements and text will be deleted.

Previously set parameters: patient and user data, range, gain, the choice of the eye, are displayed at the top of the screen.

The scanning process is used at the stage of examination of the patient, to obtain the relevant sections of the examined eye, on the screen in real time. The result is the appearance of the image sector on the display. Define the scan direction facilitates fact that the upper part of the scan picture corresponds to the location of the tag on the probe housing.

In the case of **B+A** mode, under the sector is plotted waveform type A, of the signal from the selected line (CV vector), symbolized by the dotted line in the image of the sector (see 6.6.6).

In the RUN mode, it is possible to store four different images in cache (Snapshot, Slides Memory): **M1..M4** (see chapter 6.8).

During the examination the **Cineloop** value is increasing - by default, the loop value is 0 when accessing the examination screen (see chapter 6.9)

During the scan, can be performed temporary **gain** control and **range** changes. These settings are not saved and after switching off and restarting the scanner or when you change the user number, return to the values set in the USER menu.

6.6.1. GAIN ADJUSTMENT

The amplification adjustment of all received echoes allows setting the brightness of the entire image.

Use control **knob** to select the desired gain level. Turning the knob to the right will cause the gain to be increased and turning it to left will result in the gain reduction. During the adjustment process screen brightness will change. The current amplification value is displayed on the information bar in the upper part of the screen **G:xx.**

6.6.2. TGC - ZONE GAIN ADJUSTMENT IN SELECTED EYE SEGMENTS

Individual gain adjustment in five zones and on 6 cm scope in six zones.
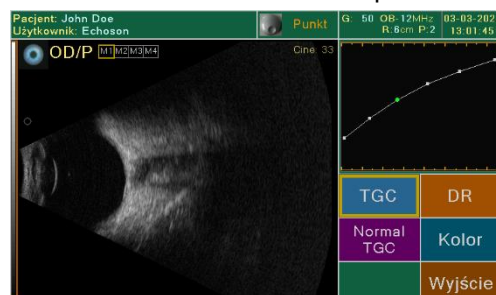
Next... **TGC** The zone gain adjustment is selected in the "Run" mode by pressing the More key and then by pressing the TGC key. The TGC curve with adjustment points will be displayed in the top right-hand field of the screen. Pressing the knob changes the adjustment zone (the default curve is reported the third zone). After selected a zone, turning the knob to the right will increase the gain in that zone, turning it to the left will decrease the gain. Press the knob button again to change the adjustment zone.

The default TGC curve will be restored after selecting the Norma & TGC key. **Normal TGC**

6.6.3. CHANGING THE RANGE

This function allows changing the penetration depth of an examined area. This can be changed only in the acquisition mode (RUN). The number of images (frames) per second will be automatically optimized in

Range relation to the changed examination range. The allowable ranges are 20, 30, 40, 50, 60 mm with a system default of 40 mm. To change the depth of an examination, use the *Range* key. The selected examination depth will be displayed in the information bar (**R:x cm**). Changing the range automatically sets the optimal operating frequency of the probe from 12 to 15 MHz.

6.6.4. ZOOMING THE IMAGE

Zoom To change the image size, use the *Zoom menu* key.

Activating the zoom function in *RUN* or *FREEZE* mode causes an image to be enlarged by two times (200% of original size). The information *Zoom x2* will be displayed in the upper left corner of the screen. In order to see which part of the original image is being enlarged on the screen, in the upper right corner of the screen there is a small information window displayed - the frame implies the enlarged area. Moving the frame you can be quickly change the large-scale image.

Press the *Zoom off* key to return to original image size.

Note: In B + B mode Zoom function is not available

6.6.5. B+B MODE

B+B By pressing the *B+B* key the two images B side by side are displayed - changes the single image display mode (Single) to B+B two-screen display mode (Dual)).

Scan 1/2 In operation of the probe, one sector B corresponding to the eye, is drawn. Second sector at this time is frozen. To change scan area (*Scan 1* or *Scan 2*) use the *Scan1/2* menu button. The name of the field currently in use is displayed in green. For each scan, a separate Cine memory is assigned.

OD/OS Press the *OD/OS* switch to select the right **OD/R** or left **OS/L** eye for which the B-scan imaging is to be performer.

B-scan Select the *B-scan* key to change B+B two-screen display mode to single mode.

Note: In B + B mode in Freeze mode not all functions are available

6.6.6. DISPLAY RANGE

The B-scan image is displayed in 256 gray scales within the range of the echo intensity (50 dB). Wide dynamic range are effective for observation of delicate changes in the organization.

The range of the echo intensity can be changed as necessary. You can eliminate unnecessary echo such as imaginary images which are caused by the reflection and/or refraction of ultrasound beams.

Press the **Next..** key and than **DR** menu button - the new dynamic range selection window will be displayed on the screen. The display range can be selected among 10, 20, 30, 40, and 50 dB.

The dynamic range is depicted a special brown line next to gray bar. You can set the range relative to the gray scale to display clearly low or medium or high intensity echoes. The position of the line can be modified by using the **Knob.** First select the **DR** function from vertical selection menu. Adjustment is possible when a display range value other than 50 dB is selected.

6.6.7. B+A MODE - VECTOR CV WAVEFORM

In the case of B+A mode, under the sector is plotted waveform type A, of the signal from the selected line, symbolized by the dotted line in the image of the sector.

Press the **CV** key - the cursor line (**C**ross **V**ector Line CV) and the A-scan waveform its line position are displayed on the Image field. The A-scan waveform in the cursor line is displayed at real time. In User B-setup window you can select a Display mode for B-scan and A-Vector CV. You can choose to display waveform A on the B image or decrease B image and display waveform A-scan below image B (see chapter 6.4.1)

The position of the CV line can be modified if necessary. To move the cursor line up and down use the **Knob.** First select the **CV** function from vertical selection menu. A desired line we can choose both, during operation of the probe B (Run mode) , as well as on the picture frozen () Freeze mode).

To leave alone B-mode on the scanner screen, press the **CV** key again.

Note: In B + B mode in Freeze and Run modes CV vector is not available

6.6.8. IMAGE PROCESSING

The image processing are function used to modify the viewed images by adjust the gray scale. The image processing function is active on a motion image when the probe operates (*RUN* mode).

Press the **Next..** key and than **Proces.** menu button - the new selection window will be displayed on the screen. It allows you to choose between two types of processing for modifying the grayscale: Logarithmic mode, Logarithmic mode "S" and Linear mode. This setting is not saved and after switching off and restarting the scanner return to the standard logarithmic processing.

The selected processing will be displayed in the information bar: **P0** – logarithmic and **P1** –linear.

6.6.9. COLOURING THE IMAGE

In B-mode it is possible to change colouring the ultrasound image. Normally, the image is displayed in the 256 bit greyscale map (i.e. monochromatic B&W image). Color post-processing allows to increase the ability

to distinguish the shades of grey, improves eye adaptation and reduces eye-strain of the person who conducts the examination.

The color function is active on a motion image when the probe operates (*RUN* mode).

Next... **Color**   In order to select the appropriate map for the image B, press the *Next.*. key and then *Color* menu button - the new selection window will be displayed on the screen.

You can select **Black & White** to produce the image in the greyscale mode, **Sepia** to produce the image in sepia colours, **Blue** to add the blurring effect in blue colour, or *Color* option for color scale.

The color selection is not memorized - after each new scan start, the PIROP activates a B&W scale.

Color Scale	
☑ 1	Black & White
☐ 2	Sephia
☐ 3	Blue
☐ 4	Color
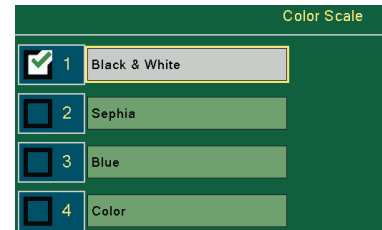
6.7. FREEZE B-MODE

Image generation hold (freezing) mode – FREEZE – corresponds to saving the image of an examined object and activating the measurement and archiving phase.

Freeze   After pressing the *Freeze*. key the image of the examined eye freezes, probe stop working and scanner goes to the measurements and remember phase. The function of the *Freeze*. key meets the foot switch.

The following functions are available in main menu FREEZE mode:

1. *CV* – on/off B+A mode (vector CV) – see chapter *6.6.6*
2. *OD/OS* - eye selection – see chapter *6.7.1*
3. *Zoom* - to change the image size - see chapter *6.6.3*
4. *Next* – go to the next menu (*see below*)
5. *Menu* - going to the MENU page - see chapter *6.2*
6. *Run* - restarts the scanning mode - operation of the probe
7. *GC- Knob –* Digital gain correction - *see chapter 6.7.2*
8. *Eye mark* selection - *see chapter 6.7.3*
9. *Store (Save, Save PDFreport, PRINT)*

The following functions are available in **Next** menu in FREEZE mode:

1. *Distance 2D* - entering the distance and angle measurement mode – *see chapter 6.7.4*
2. *Distance CV* - Measure the distance along the CV axis – *see chapter 6.7.5*
3. *Comment –* *(Text, Pointer)* - Introduction of descriptions and pointer on the screen – *see chapter 6.7.7 and 6.7.8*
4. *Area* - area measurement – *see chapter 6.7.6*
5. *Store* – open new archive menu: *Save -* storing the current image in internal memory; *Save PDF report* – storing the report as PDF file in USB memory - *see chapter 6.7.9.; Print* - printing in B-scan mode – *see chapter 6.7.10*
6. *Exit* - going to the previous menu.

In freeze mode you can used also **Cache** memory (see chapter 6.8) and **Cine** memory (see chapter 6.9)

Note: *In B + B mode in Freeze mode not all functions are available*

6.7.1. EYE SELECTION (RIGHT, LEFT)

The eye selection is done by pressing the menu button *OD* or *OS.* The selected menu button is marked with an edging. The description of the sected eye is displayed in the upper left corner of the screen. By default the scanner responds by reporting the right eye.

The scanner has two sets of memories: for the right and the left eyes. Make sure the parameters of the measurement displayed and the ultrasound velocity values displayed on the screen are compliant with the user's intentions.

Additionally in A-scan screen in RUN mode the eye type can be select by pressing the *Eye Type* button (see chapter 5.4.1).
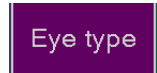
6.7.2. DIGITAL GAIN CORRECTION

After freezing the image is the ability to control gain of stored image in order to better display the observed structures. Adjustment is made using control **knob** when GC function is selected. Turning the knob to the right will cause the gain to be increased and turning it to left will result in the gain reduction. Digital Gain Correction in Freeze mode allows to change the gain in the range of from **-20** to **+20** dB. When you start a new scan, the digital gain automatically returns to 0. The current amplification value is displayed on the information bar in the upper part of the screen **GC:xx** (dB).

6.7.3. EYE - MARK SELECTION

The eye-mark is used to mark the probe position and to graphically represent the position of the eyeball during the exam. Eye-mark is displayed in the upper left corner of the image field when in *B-setup screen* option *Eye display* is turn on. (6.4.1)
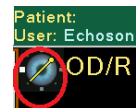
In the B/B mode, two independent eye marks can be selected for each image.

To select new eye-mark press the field *Eye mark* on the upper left corner touch screen in **Freeze** mode. The Eye-mark screen is displayed:

The probe mark - scanning plane indicator, consists of a long yellow bar and small circle. Using the *Knob* you can set direction (angle) of the probe on the eye mark. The B-scan probe is marked with the scanning direction-mark which indicates the direction of scanning. Placing the probe mark with small circle on the eye-mark should correspond to the location direction-mark of the probe during touching the eyelid.
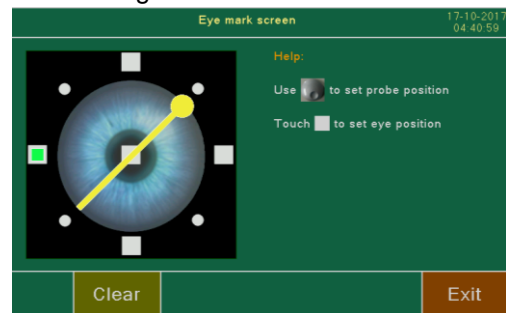
On the eye-mark the user may also indicate the five eyeball position during the exam (left, right, up, down and central).

After selecting the positon of indicators (probe-mark and eyeball mark) , lower the Eye-mark screen by pressing the *Exit* key . The eye-mark will be displayed on the main screen..

To turn off the both display indicators select the *Clear* key in *Eye-mark* window. To turn off the eye-mark display, use the option on the B-setup screen – User settings for B-mode (chapter 6.4.1).

6.7.4. DISTANCE 2D AND ANGLE MEASUREMENTS

In the B-scan application two independent distance measurements with two pairs of pointers/markers can

Distance 2D

be performed. To perform measurements in the frozen image mode press **Next** menu button than **Distance 2D** button – the distance measurement menu will appear on the screen:

- *Cursor x* key **–** activating the first pair of cursors **x**
- *Cursor +* key – activating the second pair of cursors **+**
- *Fix* key - selecting the cursor in the pair
- **Clear** key – deleting the measurement
- **Velocity** - changing ultrasonic velocity for a pair of cursors
- *Exit* key – returning to the previous menu and storing the measurements.
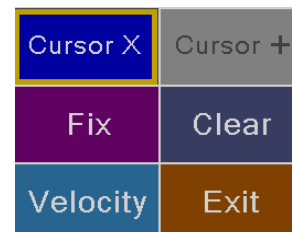
In order to perform the measurement of the first distance following the selection of the measurement menu press the *Cursor x* key (the selected key is highlighted in color).

Place the cursor over the desired location on the picture and click *Fix* menu button to freeze its position. Repeat this procedure to place the second cursor **x.** Both cursors **x** will be linked with a dotted line. In measurement field the value of distance **Dx = xx.x mm** will be displayed.

By indicating new locations on the screen it is possible to modify the locations of both cursors. Pressing the *Fix* key again to switch between **x** cursors to indicate new locations.

To perform the measurements of the second distance, press the *Cursor +* key (the selected key is highlighted in color) and repeat the previous steps. After indicating two **+** cursors, the second value of distance between the cursors **D+= xx.x mm** will be displayed. Depending on the active key, the relevant pair of cursors can be modified.

Corr Y

For precise positioning of the measurement cursors (x and +) in distance measurement you can use the Knob – function *Corr X* (move the cursors horizontally) and *Corr Y* (move the cursors vertically)

Using the *Velocity* key you can change ultrasonic velocity for the selected pair of cursors. You can choose to calculate distance: standard velocity (Vavg = 1550m/s), anterior chamber sonic velocity (Vac =1532m/s), lens sonic velocity (Vl =1641m/s), vitreous body sonic velocity (Vv=1532m/s), oil velocity (type1 980m/s or type2 1050m/s). To change other values, press *Vcustom* button – additional *Edit V$_c$* menu button appears on the screen.

In PIROP scanner it is possible to measure the angle between two surfaces, such as the anterior chamber angle. When both pairs of cursors are set additionally in the measurement field the **Angle** between lines of cursors pairs will be displayed.

Measurements are deleted with the measurement menu *Clear* key. They are also deleted when moving to the Run mode – scanning another image.

To archive the image along with the measurements in an internal memory, go to the main menu pushing the *Exit* key, and then use the *Save* key.

Note: Be sure to press the NEW Patient key before a new patient is examined and delete all the measurement data.

6.7.5. DISTANCE CV MEASUREMENT

The Distance CV measurement mode is intended to provide accurate distance measurements along the cross-vector line. To make a measurement, use *Distance CV* button go to the special measurement menu and to place the first cursor **D1** on the axis.

Note: Distance CV button is activated only when the CV line is displayed on the screen.

The next cursors **D2** activate when you press the *Fix* key. Also use the *Fix* key to switch between cursors.

The selected cursors can be moped to the desired location using the *Knob* function. By pressing the Knob button you call up additional, vertical selection menus. You can select two function for Knob: **Fine** - it allows to precisely move the cursor (by one pixel) or **Coarse** - it allows you to move the cursor faster (by 10 pixels).

The measurement value of the distance between the two cursors can be displayed on the screen: D= xx.xx mm. For the measurement is used the standard, average tissue velocities. Using the *Velocity* key you can change ultrasonic velocity. You can choose: standard velocity to calculate distance (Vavg = 1550m/s), anterior chamber sonic velocity (Vac =1532m/s), lens sonic velocity (Vl =1641m/s) or vitreous body sonic velocity (Vv=1532m/s) - see chapter 6.7.4. To change other values, press Vcustom button – additional *Edit* V_c menu button appears on the screen.

6.7.6. VOLUME, AREA AND PERIPHERY MEASURMENT BY ELLIPTICAL METHOD

The volume measurement mode allows you to obtain an approximate result by inscribing the ellipse into the outline of the measured object. It uses the previously made measurement along the **CV** axis described in the previous section. During this measurement, the **CV** axis should be placed on the symmetry axis of the object, cursor **D1** at the beginning of the object and cursor **D2** at the end. After pressing the **Volume** key, the contour of the ellipse appears, the position of which corresponds to the previously set cursors **D1** and **D2**. The shape of the ellipse and its thickness can be corrected with the **Knob**. The calculated volume corresponds to the volume of the virtual ellipsoid, which is created by rotating the drawn ellipse along the **CV** axis. The more the shape of the measured object is to the shape of this ellipsoid, the more accurate the measurement result. In the case of measuring the eyeball, it is assumed that its transverse dimension and height are very similar to each other.

The measurement field displays the length of the ellipse axis along the **CV** line: **D** (mm), **Periphery** of the ellipse (cm), **Area** of the ellipse (cm2) and **Volume** of the ellipsoid (cm3).

Pressing the **Knob** brings up an additional, vertical selection menu, from which you can choose two functions of the knob: **Fine** - precise contour correction (one pixel) or **Coarse** - faster correction (every 5 pixels).

6.7.7. MEASURING A SURFACE WITH A MULTIPOINT CONTRACT

Area function is used to calculate the surface area in the region of interest (ROI). To use the area calculation press *Next* menu button than *Area* button – the area measurement menu will appear on the screen.

For area measurement you manually define the points located on edges of ROI: use the stylus supplied with the scanner to indicate points on the screen – a filled dot will appear on the screen in indicated places. The indicated points will be automatically linked by lines, thus creating closed contours. Repeat as necessary to surround the area to be selected. Use the **Back** menu key to delete last point (e.g. for position correction). After marking the contour press the **Set** key. The scanner will automatically complete the gaps in the contour by linking the last and the first point. The results will be displayed in measurements field: **A = xxxx cm^2 .**

To perform the contour measurement again, delete the previous measurement pressing the **Clear** key and repeat steps.
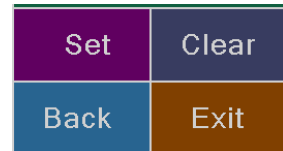
6.7.8. ENTERING COMMENTS

The description function accepts a brief comments of the pathology and identifies the eye that was scanned. You can edit **four** (Text 1..Text4) short (22 characters) descriptions that you can be placed anywhere on the image. To entering comments displayed on the image press **Next** menu key and then click **Comment** button.

Press the menu key **Text x** and then select description **x** (x= 1..4) from the list of ten (10) comments. Next you indicate the place on the screen where the inscription is to be placed. Any menu key leaves the comment positioning mode and confirms its position. By pressing the **Text x** key one more time you can enter the next text on the screen. After entering four texts, each next text replaces the earlier text with the indicated number.

Use the **Clear texts** menu key to remove the all entered texts from the screen. Switching to Run mode will always deletes all texts on the screen.

When a list of ten comments is displayed, it is possible to edit each list item (**Edit** menu button). **Get Default** button allows you to fill the whole list with standard descriptions: pressing the **Set default** menu key causes the default descriptions to become the current comments.

Note: A list of ten comments is shared by all users of the scanner.

6.7.9. ON SCREEN POINTERS

The scanner allows to highlight the points of interest in the image field by using special markers in the form of color arrows. The user can use 4 (*Pointer 1 ... Pointer 4*) independent arrows: each of them can be placed anywhere in the image field and oriented at any angle.

To entering pointers on the image press **Next** menu key and then click **Comment** button. Activate the marker number **x** by pressing the menu key **Pointer x** - a green marker (arrow) will be displayed on the screen. Point the location of the marker and then set the arrow direction by using **Knob** (Rotate function). Any menu key leaves the marker positioning mode and confirms its position.

The menu key **Clear pointers** deletes all markers from the screen..

6.7.10. SAVING IN B-SCAN MODE

Saving are available for each scan performed .
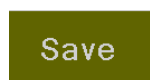
Save To save B-scan with Measurements touch the *Next* button on main freeze screen, then display the *Store* menu and press *Save* menu button. There is the ability to save images only to internal memory or simultaneously to internal memory and external USB memory (chapter 4.7.5)

PIROP scanner with   factory mounted special printer adapter (see chapter 8.3) allows you to save a B-mode report as a **PDF file** in the external memory connected to the USB port.

Save PDF report To save reports as PDF file on a connected external USB memory, touch the *Next* button main freeze screen, display the *Store* menu and then press *Save PDF report* key on the screen menu.

When you create and save a PDF report, an appropriate message is displayed on the screen (*more about writing a PDF report file - chapter 8.4)*

6.7.11. PRINTING IN B-SCAN MODE

Printing in B-mode are available <u>only</u> by using: <u>optional external</u> videoprinter connected to video port, or the <u>optional external</u> laser printer e.g LaserJet Pro M102w or HP LaserJet Pro M14-M17, which is connected to PIROP via USB or an ad hoc wireless Network (*see chapter 8.3*). To print B-scan screen on the optional videoprinter press the print button directly on the printer. To print B-scan screen on the optional external printer touch the *Next..* menu button, then touch the *Store* field and press *Print* button.

6.8. CACHE OPERATION (Snapshot Memory)

In the RUN mode, it is possible to store („ to freeze") five different images in cache (Snapshot, Slides Memory): in **C** – current image with Cine function and in four cache memory **M1..M4**.
In Freeze mode stored in cache images can be quickly restored on the full screen in order to perform measurements or analysis. Then, they can be printed and/or saved them in archives.
In the RUN mode when tapping (by finger or stylus) on the image area, the current ultrasound image in the next cache window is saved. A message "*Image captured into Mx memory*" appears on the screen.

M1 M2 M3 M4 When information bar *M1..M4* is displayed on the left corner of image screen, saved image can be displayed in sequence on the screen after <u>tapping on the image area..</u>

When viewing any image from the cache on the screen, the corresponding frame is specially highlighted in yellow.

Note: <u>*Only the display*</u> *the image obtained at the time of switching to FREEZE mode (**C**urrent image) allows you to use **Cine** memory.*

6.9. CINE MEMORY

PIROP scanner is equipped with an image memory module – **Cine**. The Cine function allows the user to review saved images. In Run mode a sequence of the last 64 frames is saved automatically.
When the probe is active and the scanner operates in RUN mode, the Cine memory always automatically saves <u>every</u> frame of an image (the images are stored into the CINE memory frame by frame based on time

sequence). A changeable indicator – successive number of saved image frame – is displayed on the screen (**C:xx** counter). By default, the loop value is 0 when accessing the examination screen. If a 64th image is saved, the next one will be saved under the number 0. Switching to RUN mode will always <u>reset</u> the memory counter.

Note: Every change of examination range, mode or toggling ZOOM function on/off or use freeze/run function, automatically deletes images saved in cine memory (reset the counter).

A sequence of images saved in cine memory in Run mode can be viewed frame by frame in **Freeze** mode. In the case of a shorter sequence, only saved images will be displayed in playback mode.

*Note: In Freeze mode <u>only the display</u> the image obtained at the time of switching to FREEZE mode **(Current image)** allows you to use Cine memory.*

Select the **Cine** function for the **Knob**. Use the **Knob** left to view a cine image with a lower number (rewinding the cine memory); rotate the **Knob** to the right to view the next image from the cine memory (higher image number). Number of currently viewed image is displayed on the upper right corner of the image area.

Pressing the box with the description of the knob function *Cine,* starts the continuous playback of the cine memory (**cine-loop**). Every use of the touch screen or knob stops continuous cine-loop.

7. CCT- PACHYMETRY (P-SCAN)

7.1. PURPOSE

As a Pachymeter, **PIROP** is a medical electronic device that measures and creates a map of the thickness of the cornea using ultrasounds. Corneal pachymetry is considered an important test in the early detection of glaukoma- the measurement of central corneal thickness (**CCT**) by pachymetry is an essential part of the contemporary glaucoma work-up.

The measurement is performed using an ultrasound probe that is placed in front of the patient's eye, which then touches the cornea and measures the time taken for the echo of the ultrasound impulse to return. The time is then automatically converted to the corneal thickness and displayed in an appropriate place on the map of the cornea. The map is displayed on the screen of the scanner.

The scanner calculates and corrects the value of **intraocular pressure** (IOP) that was entered manually, on the basis of the measured (or manually entered) value of the **central corneal thickness** (CCT).

The map of results and the parameters of the measurement can be printed on paper using a thermal printer connected to the scanner or stored in internal memory and USB memory.

7.2. ACTIVATION PACHYMETRY MODE
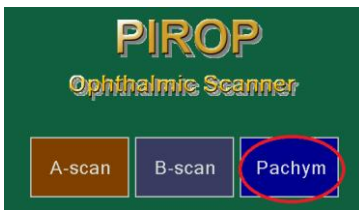
The selection of Pachymetry application is possible directly from **Title** page (Mode page) or from the level of the **Menu** window by pressing the *Mode* key. Pressing the *Pachym* button on the Mode select page (see chapter 4.3) opens the Menu page for P-scan mode - the scanner is intended for examination in Pachymetry.

The following buttons appears on the general Menu screen:

1. *Mode* - open the Mode Screen (Title page) for selection operating mode (chapter 4.3)
2. *Patient -* open the Patient Screen (chapter 7.4)
3. *User -* open User Settings Screen (chapter 7.5)
4. *Setup -* go to the Setup Screen: adjustment of the LCD display, setting the Time and Date, choose the menu language, open the Settings and Info screens etc. (chapter 4.7)
5. *Database –* open internal database of patient's exams *(chapter 8)*
6. *Scan -* Going to the Measurement P-scan screen (chapter 7.7)
7. *Back -* return to the previous page
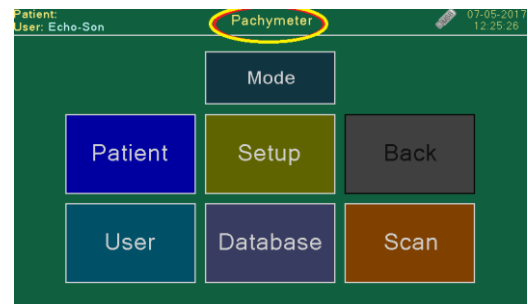
   Note: After performing e.g. the biometry you can go to the **Menu screen** *to change some parameters in the* **User** *and* **Patient** *windows. Then you can use the* **Back** *button to return to measure screen, keeping the measurements. Introducing a new patient, changing the user, and changing global parameters, such as the type of eye, causes the* **Back** *button to become* inactive*. Pressing the* **Scan** *key always initiates the* new *measurements.*

7.3. PATIENT DATA FOR PACHYMETER

Patient

Pushing buttons *Patient* in the **MENU** window opens a page for entering or editing patient's information.

Using *New patient* menu button enter patient data Name.P.ID,Gender and Date of Birth– see chapter 4.6.1.

In *Eye Information field* - the parameters of the patient's right (**OD**) and left (**OS**) eye can be entered e.g. IOP values)**.**

*Note: Always start a new patient by first activating **New patient** key. Entering the new patient's data restores the default values*

7.3.1. IOP CALCULATION

IOP

The *IOP* button opens the page where the intraocular pressure and the calculation of the adjusted intraocular pressure are entered. The button *OD/OS* selects an eye for which the calculations will be performed.

The *IOP* value determined with a Tonometer is entered using the numeric pad.

If the PIROP scanner has measured the central corneal thickness (**CCT**) for the given patient, the calculations results for **Adj** and **AIOP** are being displayed.

If no measurement has been performed, the **IOP** values entered manually are stored. The result of the AIOP calculations will appear after the central corneal pressure is determined and it will be displayed on the measurement page. It will also be placed on the printout if the printer is used.

The adjusted value is calculated according to the following formula:

Adj = (NORM – CCT) * COEF [mmHg]

AIOP = IOP + Adj

where:

- Adj [mmHg] - adjustment of the result of the measurement of the intraocular pressure IOP
- NORM [μm] - normative adjustment value (IOP adjustment for this value is zero)
- CCT [μm] - the result of the measurement of the central corneal thickness
- COEF [mmHg/μm] - pressure adjustment coefficient .
- IOP [mmHg] - the intraocular pressure measured using a Tonometer
- AIOP [mmHg] - adjusted intraocular pressure

The parameters *NORM* and COEF are defined individually by each of the 10 possible users by selecting an IOP formula in the USER menu. (see chapter 7.4.6)

7.3.2. IOP CALCULATION WITH CCT ENTERED MANUALLY

If a user wishes to calculate **AIOP** without measuring of the corneal thickness, e.g. basing on the results of

the previous measurements, the value of the central corneal thickness can be entered manually after the **CCT** button is pressed - any CCT value can be entered using the numeric pad to

calculate AIOP.

Pressing the appearing **IOP** button takes you back to the page where the IOP values can be entered.

The results of the AIOP calculations preceded with a heading with the time of the examination, the patient's data, the user, the measurement parameters and the formula used in the calculation, can be printed or saved in a memory.
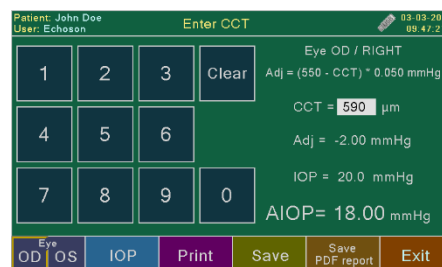
Leaving the page where the parameters of the IOP measurement can be entered using the Exit button clears the manually entered **CCT** value and restores the actual **CCT** value that has been measured.

*Note: After performing measurement you can go to the **Menu screen** to change some parameters in the **Patient** windows. Then you can use the **Back** button to return to the measure screen, keeping the measurements. Introducing a new patient causes the **Back** button to become underline inactive. Pressing the **Scan** key always initiates the underline new measurements.*

7.4. USER SETTINGS FOR PACHYMETER

Pressing the **User** button in the **MENU** window opens the **User Screen** with the Operation List.

Each user can enter a set of properties as personal profile.

Press **Pachym-setup** menu button – **P-setup** window for given user appears on the screen:

If any change has been made in the USER page, they are stored in the non-volatile memory - when the scanner is switched off and then switched on, it starts with the number and the parameters of the last user working with the scanner.
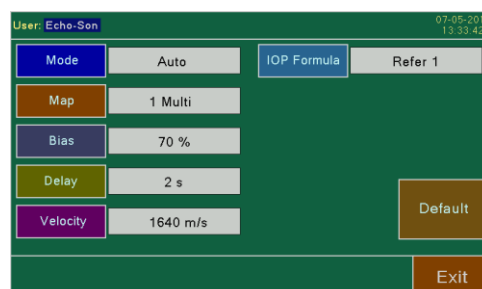
7.4.1. MEASUREMENT MODE

The **Mode** button switches between the following measurement modes: **Auto** or **Manual** (chapter 7.7.1):

✓ **Auto** – (the default mode) measurements are performed one by one through each point on the map according to their order without a stop at intervals set with the Delay parameter.

✓ **Manual** – measurements are performed one by one through each point on the map according to their order with a stop after each measurement. It requires pressing the **Cont** button or the foot button to measure the next point on the map. The measurement begins after the interval set with the DELAY parameter from the moment the **Cont** button is pressed.

7.4.2. MAP SIZE

Pressing the **Map** button the following map sizes can be selected: *1, 5, 9, 13, 21, 25* measurement points. Maps *1, 5* and *9* also have versions for measurements in the **Multi** mode. The selected map size will be displayed on the screen during measurements.

The default map is 1 MULTI.

7.4.3. BIAS SETUP

The *Bias field* is used for setting the percentage bias of the measurement results displayed on the map on the measurement page. (Bias parameter defines the correction value of the measured corneal thickness).

The **Bias** value is considered only when the **Bias** button is activated on the measurement page.

The new Bias value can be entered using the numeric pad. Pressing the **Exit** button saves the new value. If the entered value is outside the approved range (*60 ÷ 130%),* the change of the parameter will not take place and **xxx** will be displayed. Then, a new value can be entered or leave the page by pressing the **Exit** button with no change.

The default BIAS value is 70%.

7.4.4. DELAYED START OF MEASUREMENT

Press the **Delay** key to go to the page where you can enter, using numerical keyboard, the time of delay between starting the measurements (using the **Start** key or foot operated switch) and automatic starting of search for characteristic impulses in ultrasound wave. Delay offers time to correctly apply the probe to the eye surface, so as to prevent measuring of random signals.

Delay time is used also between **Auto** mode measurements, to give time for correctly placement of the probe on the next measure point. Each user can adjust the Delay according to their skill.

Time of delay setting range is 1 ÷ 9 seconds. Default time of delay is 2 seconds

7.4.5. EDITING ULTRASONIC VELOCITY

Pressing the **Velocity** field in the **P-setup** window opens numerical keyboard to enter the value of ultrasonic velocity in cornea tissue.

In the event of entering the value from outside of the permitted range (1400 ÷ 2000 m/s), the parameter value is not accepted. Default cornea velocity is 1640m/s.

7.4.6. CHOICE OF IOP FORMULA

Pressing the *Formula IOP* field in the **P-setup** window, each user can select one of seven predefined formulas for AIOP calculation or their own CUSTOM formulas:

REFER 1:   Adj = (550 - CCT) * 0.050 [mmHg]   Kohlhaas, Shah

REFER 2:   Adj = (578 - CCT) * 0.071 [mmHg]   Argus et al

REFER 3:   Adj = (545 - CCT) * 0.020 [mmHg]   Whitarce et al

REFER 4:   Adj = (545 - CCT) * 0.050 [mmHg]   Doughty

REFER 5:   Adj = (545 - CCT) * 0.071 [mmHg]   Ehlers

REFER 6:   Adj = (550 - CCT) * 0.0423 [mmHg]   Dresden

REFER 7:   Adj = (550 - CCT) * 0.0725 [mmHg]   Stodmeister

CUSTOM1;2;3: Adj = (NORM – CCT) * COEF [mmHg]

After the CUSTOM formulas is selected, the *Edit* button appears and pressing it opens the page where the **NORM** value and the **COEF** value (adjustment coefficient) can be edited.

The value is selected using the *Norm* and *Coef* buttons.

The *Exit* button saves the formulas and coefficients and returns you to the previous page.

The selected formula and coefficients of the CUSTOM formula are stored separately for each of the 10 users.

7.4.7. DEFAULT VALUES

 By pressing the *Default* button it is possible to set the standard default values for all of the parameters. One column shows the current parameters and the other one shows the defaults.

Pressing the *Set default* menu key causes the default values to become the current values. The *Exit* button leaves the values unchanged.

The DEFAULT values for each parameter are as follows:

Mode: Auto
MAP: 1 MULTI
Bias: 100%
Delay: 2 seconds
Velocity :   1640 m/s
IOP Formula: REFER 1

The default values in the CUSTOM formulas are:

	CUSTOM 1	CUSTOM 2	CUSTOM 3
NORM	550	550	550
COEF	0,045	0,060	0,028

7.5. TEST P-SCAN MODE

 A user can always perform calibration by pressing the *Test* button in the P-scan window menu or Service page from main menu (see chapter 4.7.4)

Note: The tests ought to be performed each time the scanner is switched on.

The tests are performed to control the performance of the scanner and the probe. Two function tests are performed automatically:

SENSITIVITY – the sensitivity of the probe is tested. When the test is performed, the probe ought to be dry and clean and ought not to touch any object. The message "*OK*" is displayed when the test result is positive.

If the probe is disconnected, the message "*No Probe!*" is displayed. The message "*Weak Probe!*" is displayed when the test result is negative.. Make sure the probe is clean. If the probe is clean and the repeated sensitity tests give the same result, it means the probe has lost its sensitivity and the manufacturer's service should be contacted.

ACCURACY – the internal test of the measurement accuracy is performed. Independent of the measurement system, artificially created echo signals (at an interval corresponding to the thickness of 490 µm) are measured. The probe is not used in this test. The positive result (the measurement result are within the tolerance limits) indicates good performance of the scanner and the message "*OK*" is displayed.

The message "*Bad Accuracy*" is displayed when the result is negative. Several repeated accuracy tests ought to be performed by pressing the *Retry* button. If the negative result occurs again, the manufacturer's service should be contacted.

7.6.   P-SCAN - THE MEASUREMENT SCREEN

Pressing the *Scan* button in the main P-scan **Menu** window opens the **Measurement Screen.**
The page displays a map of measurements, the basic parameters and button for the performance of the measurements.
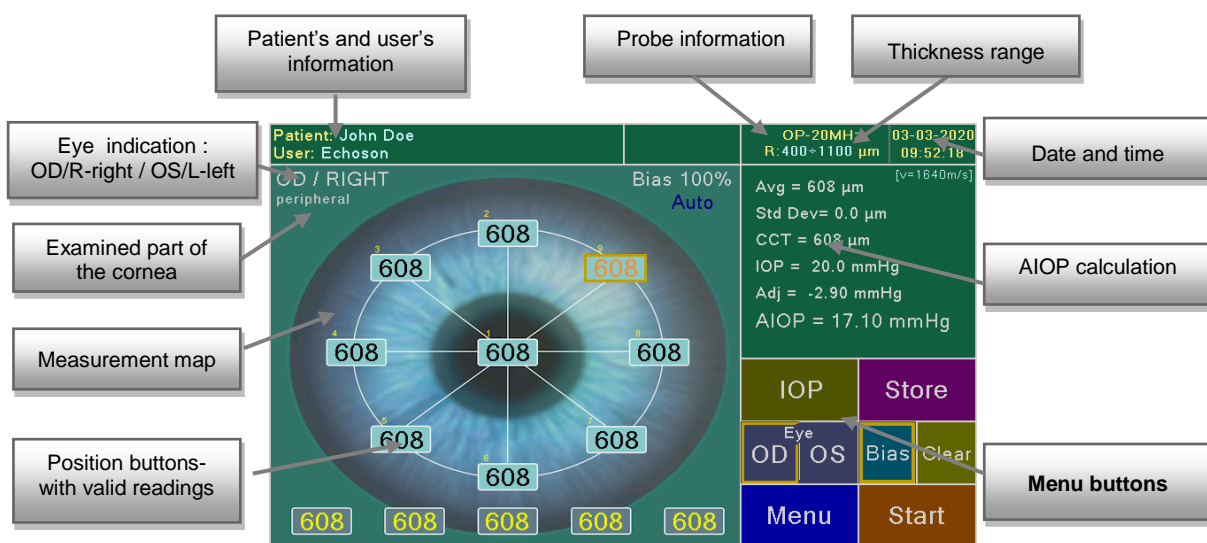
The map of measurements is composed of numbered fields, symbolically arranged in an oval, in which the measurement results are displayed. The fields also functions as buttons if we wish to enter the next measurement result into it, out of order.

A map of measurements is displayed with the number of points set using the **Map** parameter (chap. 7.4.2).
Each screen has up to 25 programmable locations positioned in the general topography of the eye.

- ✓ **Basic maps** - *Maps with 1, 5, 9, 13, 21, 25* measurement points - this maps allows for the user to obtain reading at each of up to 25 different points along the corneal surface

- ✓ **Multi maps**- *1 Multi, 5 Multi, 9 Multi maps* – this maps allows for the user to obtain series of several readings from each different points along the corneal surface. For *1 Multi* – series of 12 readings, for *5 Multi* or *9 Multi* – series of 5 readings. In the case of **Multi** maps, a set of measurements of a

series from the current measurement point is additionally displayed. The current measurement point is the last measured point or the point indicated by pressing.

Each reading which is obtained actually, consists of the average obtained from **512** individual measurements.

If no measurement was performed after the scanner was switched on or the parameters or the options affecting the calculation of results were changed after leaving this page i.e. Patient, Velocity, Map, the memory of measurements is cleared.

7.6.1. CHANGING THE RANGE

This function allows changing the penetration depth of an examined area.

Two measurement thickness ranges can be selected:

Range

Short: 220 ÷ 650 µm

Long: 400 ÷ 1110 µm

To change the depth of an examination, use the *Range* key. The selected examination depth will be displayed in the information bar *R:220-650 µm* or *R: 400-1100 µm*

Note   After the scanner is switched on, the Long range (400-1100 µm) is set as default.

7.6.2. EYE SELECTION

Eye
OD OS

The eye selection is done by pressing the menu button *OD* or *OS.* The selected menu button is marked with an edging. The description of the sected eye is displayed in the upper left corner of the screen. By default the scanner responds by reporting the right eye.

The scanner has two sets of memories: for the right and the left eyes. Make sure the parameters of the measurement displayed and the ultrasound velocity values displayed on the screen are compliant with the user's intentions.

Additionally in A-scan screen in RUN mode the eye type can be select by pressing the *Eye Type* button (see chapter 5.4.1).

Eye type
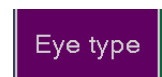
7.6.3. BIAS ACTIVATION

Bias

Menu

The display of results can be activated taking into consideration the previously selected bias in the USER menu by pressing the *Bias* button. Its activation the percentage bias value display on the screen. (see chapter 7.4.3)

7.6.4. OPEN MENU SCREEN

By using Menu button you can go to the **Menu screen** to change some parameters in the **User** and **Patient** windows. Then you can use the *Back* button to return to the measure screen, keeping the measurements. Introducing a new patient, changing the user, or changing global parameters, such as the type of eye, causes the *Back* button to become <u>inactive</u>. Pressing the *Scan* key always initiates the <u>new measurements</u>.

7.7.   P-SCAN - PERFORMANCE OF MEASUREMENTS

Start

  A cycle of measurements is initiated by pressing the *Start* button or the foot switch. The previous measurements are deleted and a <u>blue round</u> sign indicating the current measurement point will appear in point *No. 1* on the map. The contact probe should be placed perpendicularly to the spot on the eye symbolized by this sign.

When the measurements have not been performed yet, no measurement result is present in the memory of the map for the given eye.

If the probe is disconnected, the message "No Probe!" is displayed.

Note: Remove the black protective probe cover before attempting to use the Pachymeter probe to obtain a measurement

After the time set using the Delay parameter, a double beep signal occurs and the measurement begins. If it is successful, the result is entered into the current point on the map. It is indicated by a single beep signal. The measurement process consists of a series of *512* separate measurements, lasting less than a second, from which the arithmetic mean is calculated and it becomes the final measurement result.

When the measurement results are already available, their arithmetic mean is displayed above the map. When the IOP parameter has been entered for the given eye, the result of the **AIOP** calculation appears after the CCT has been measured.

7.7.1. AUTO AND MANUAL MODE

In Pachym-Setup User page the *Mode* button switches between the following measurement modes: **Auto** or **Manual** *(see chapter 7.4.1) :*

- *Auto mode*: (the default mode) If the scanner is working in the Auto Mode, in the case of a correct measurement, the blue sign appears in another point after the result is entered into the current point on the map. Then, the probe ought to be moved to the new place on the eye. After the Delay time, a double beep signal occurs again and the measurement is performed for another point.
  The Auto mode is useful for users who move the probe skillfully in an appropriate order through the measurement points on the surface of the eye. The time devoted to the movement of the probe can be set with the Delay parameter in the user's menu (from 1 to 9 seconds).

- *Manual mode:*   In the Manual Mode, measurements are performed one by one through each point on the map according to their order with a stop after each measurement - the time between measurements is adjusted by the user on an ongoing basis. After each correctly measured point, the cycle of the measurement pauses and the measurement of the next point is performed after the *Cont* button or the foot switch is pressed and the Delay time passes. Using the *Clear* button, all the performed measurements can be cleared and the measurement can be performed from the beginning.

Cont

Clear

7.7.2. USING BASIC MAPS

 A cycle of the measurement consists in performing a series of measurements of the corneal thickness in places symbolically marked on the map of the measurement as measurement points - **maps with 1, 5, 9, 13, 21, 25 measurement points**. In order to perform a cycle of measurements efficiently, they should be performed in the order indicated by the numbering of the points The cycle ends after the last point with the highest number on the selected map (1, 5, 9, 13, 21, 25) is measured.
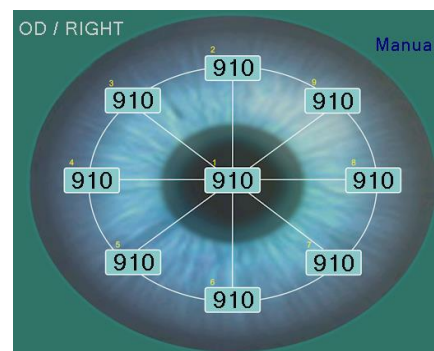
Short sound signals facilitate the proper alignment of the probe as their frequency increases when the signal reflected from rear membrane increases, which indicates better alignment of the probe.

 If no correct measurement is performed (no proper reflection) after 20 seconds of measurement attempts, the warning "*Error*!" will appear instead of the result and the cycle will stop. The absence of a correct measurement is most frequently caused by the wrong contact of the probe face with the eye or its diagonal alignment.
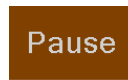
The cycle can be paused during the measurement without waiting for an error by pressing the **Pause** button or the foot switch. In order to continue the measurement in this case press the **Cont** button or the foot switch.

 The Delay time is recommended to last long enough for the probe to be correctly aligned on the eye when the double beep signal occurs. It will eliminate erroneous results when, for example, the scanner measures the thickness of a drop remaining on the probe or the liquid between the probe face and the eye.
The cycle of the measurement ends automatically when the last point on the map is measured correctly.

There is a possibility to measure or correct a single point. In the same way, measurements can be performed in an order that is different from the current point numbering. By pressing the field of the given point, the measurement is initiated like in the Manual mode and its result will be entered into the field.

7.7.3. USING MULTI MAPS

The Multi mode - **1 Multi, 5 Multi, 9 Multi maps-** differs from the basic mode because the measurement of each point on the map is performed several times in a quick series lasting approx. 0.1 seconds on maps 5 Multi and 9 Multi and 0.4 seconds on map 1 Multi. The arithmetic average of the results of this series as the result of the measurement is entered.

Each measurement of the Multi series is an arithmetic average of a series of 512 separate measurements.

In the **1 Multi** mode, a point is measured **12** times in a series, the results of each measurement are inserted in the table visible on bottom side of the screen and the arithmetic average of the multi series is displayed in the central field as the measurement result.
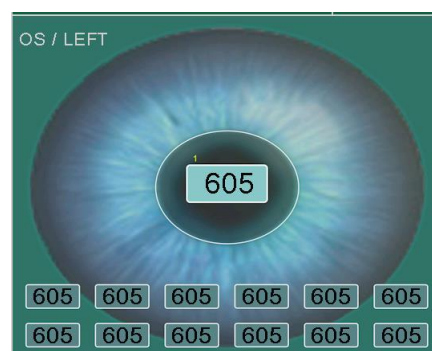
In modes **5 Multi** and **9 Multi**, each point on the map is measured **5** times in a series, the results of each measurement of the current point in the multi series is inserted into the table on the bottom side of the screen and the arithmetic average is placed on the map as a result of the point measurement. After the map measurements have been performed, components of the Multi series of measurements of this point can be obtained from the memory by pressing any point on this map. They are displayed in a table on the screen. Standard deviation (**Std Dev**.) is displayed on the screen and is the standard deviation of results in a series of Multi measurements.

If any result of the Multi measurements deviates significantly from the expected result according to the user, it can be <u>excluded</u> from the set from which the average is calculated by pressing the place where it is displayed (pressing the empty space can <u>restore</u> its validity). The average and the standard deviation are calculated on an ongoing basis. A significant decrease in the standard deviation during the selection of the results from the Multi series indicates removal of unreliable measurement results.

If the cycle of measurements of the Multi series is paused using the *Pause* button or due to an error, the measurement of the whole Multi series for the current point is repeated after the *Cont* button is pressed.
If a point on the map that has no result yet is pressed, a measurement of this point will start regardless of the automatic order.

7.7.4. <u>PRINTING IN P-SCAN MODE</u>

Store

Print

Printing on <u>internal thermal printer</u> are available for each measurement performed in P-mode (see chapter 8.1).To print P-scan with Result maps and AIOP calculation touch the *Storet* button on P-scan freeze screen and then press *Print* menu button. To print user or patient's settings for pachymetry touch the *Print* button on Patient's page or on User's P-Setup screen (see chapters 7.3 and 7.4)

Printing in P-scan mode are also available by using <u>optional external</u> <u>videoprinter</u> connected to video port, or the <u>optional external laser</u> printer, which is connected to PIROP via USB or an ad hoc wireless Network (*see chapter 8.3*).

7.7.5. <u>SAVING IN P-SCAN MODE</u>

Store

Save

Saving are available for each measurement performed .
To save P-scan screen with result table AIOP calculation, touch the *Store* button on P-scan freeze screen and then press *Save* menu button. There is the ability to save images only to internal memory or simultaneously to internal and external USB memory (chapter 4.7.5)

Save
PDF report

PIROP scanner with factory mounted special printer adapter (see chapter 8.3) allows you to save a P-mode report as a **PDF file** in the external memory connected to the USB port.
To save reports as PDF file on a connected external USB memory, touch the *Store* button main freeze screen, and then press *Save PDF report* key on the screen menu.

When you create and save a PDF report, an appropriate message is displayed on the screen (*more about writing a PDF report file - chapter 8.4)*

8. ARCHIVING

8.1. PRINTING RESULTS ON THE THERMAL PRINTER

In A-scan and Pachymeter the currently displayed screen with image or measurement results may be printed on the build-in thermal printer. ***Note:*** *In B-scan mode, the thermal printer is not available.*

It is the possibility also to print the measurement results from the archived images.

Print   Print is only possible in freeze mode. To print using the thermal printer, press the ***Print*** key on the ***Store*** screen menu. (*see chapters 5.10 and 7.7.4*)

The printout always includes: date and time of printing, number and name of operator(user) , name of patient (if entered), patient's ID, date of birth , Gender and black white screenshot containing images and measurements

Additionally in Pachymeter mode some of the parameters set on the user's screen are printed (range, BIAS, Velocity IOP refer etc.)
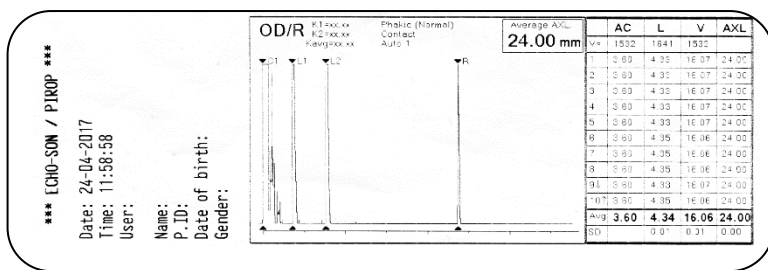
Sample prints on a thermal printer
in **A-scan** mode
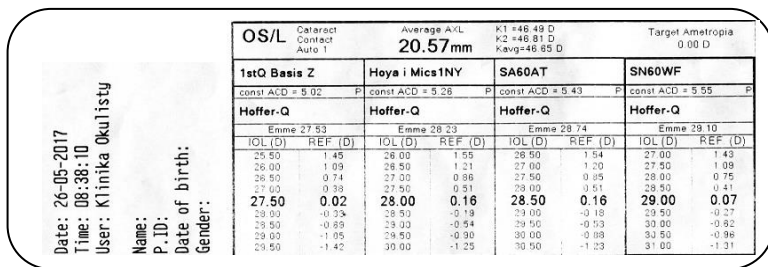
Sample print on a thermal printer
in **P-scan** mode
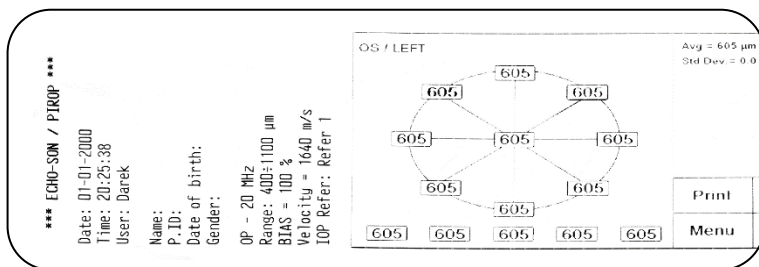
For the short period of sending information to the printer, the scanner becomes inactive. After the completion of printing, the scanner is ready to perform other operations.

The paper can be torn by cutting it along the edge of the housing gap, pulling it to oneself sidelong.

If despite starting the printing process the printer does not print, it may mean there is no paper- install a new roll of paper or check check if the paper is correctly inserted (*see **Chapter 9.2** – Replacing the printer paper*).

Note: If optional external printer is connected, there is an additional option to select printer (*see 8.3*).

8.2. ARCHIVE MANAGEMENT

8.2.1. IMAGE SAVING

Every image with the obtained measurement results can be stored only in the internal memory or simultaneously to internal and external USB memory or only to external USB memory (chapter 4.7.5)

In the internal database information about 960 of patients can be stored and for each of them about 64 pictures from exams. Internal memory capacity is about 5500 images. Exceeding the internal database capacity (number of stored records) is signaled by an appropriate messages.The number of stored images on a USB disk depends only on the capacity used external USB memory. Every exam is saved as the image file with 800 x 480 resolution.

To store image in internal and/or external memory press **SAVE** menu button on the touch screen. *(see chapters 5.11, 6.7.9 and 7.7.5)*

Save

In the memory an exact image of what you see, including patient information and the measurements result will be stored. While the image is being saved, the appropriate messages are displayed on the screen (e.g. *Saving image to database)*.

In the internal memory the image will be assigned to a particular patient folder as a next exam. When a particular patient was not in the database yet - automatically a new patent's record is created. If the patient's name is not entered, the images will be saved in a database record titled **No Name**. Maximum 64 exams can be stored in a one patient record.

When writing to the internal database (also with the option of simultaneous saving in USB memory), the default name for a saved image is created automatically - contains the number a particular patient in the database and a sequence number for a particular patient exam, preceded by an "P_ " prefix, e.g.

P_03_14 . BMP

Prefix P_	Patient's number in database	Examination sequence number (on a given patient)
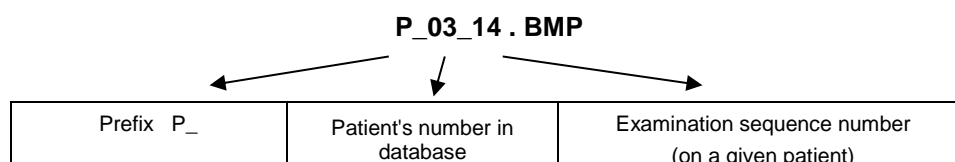
If you choose to **write to USB only** option (chapter 4.7.5), the internal database will not be updated. Then the default name of each saved to USB memory file is created automatically according to the following rule – it contains a prefix about the working mode (A-scan, B-scan or P-scan), date (year and month) and the

order number of the next file saving, for example:

A 1 8 C 0 0 0 2 . BMP

Prefix **A** –A-scan mode (respectively: B and P)	**18 -** 2018 year (last two digits of the year)	**C-** December (month in hex: 1..9, A, B, C)	**0002**- the next number image file (after reaching 9999 , starts from 1)
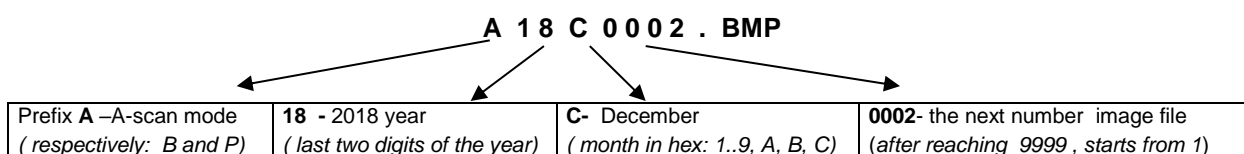
The option of writing to a USB flash drive only is recommended especially when using the optional PIROP-PC database software on an external computer. It enables both quick transfer of recorded images by means of a USB disk or automatic transfer using a direct connection with a USB cable to a computer. (see the PIROP-PC program manual)

8.2.2. REVIEWING PATIENT EXAMS
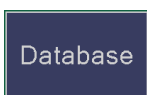
Database

By pressing the **Database** button in the main *Menu screen* you will go to database manager: the full list of patients stored in database is displayed on the screen (*Patient List* window). Each patient is assigned a unique *record of the patient*, which is automatically created when the first image is recorded for the patient (*see chapter 8.2.1*)

In particular columns the following information are displayed: record number (**No**); patient's name (**Name**); patient's number (**PiD**); **Birth date**, **Gender** and the number of saved images (**Images**).

The patient list can be displayed alphabetically by name or starting from the last record. The display method is selected on the *Options* screen in the tab **Patient list** - options **Name alphabetically** or **Nevest first** (chapter 4.7.5).

By pressing arrows menu keys **PgUp** and **PdDn** you can scroll up/ down the pages in the database (only when the number of patients exceeds ten).

An additional key on the bar allows you to change the number of pages you can move one time: 1, 5 or 10.

 Number of patients (up to 960) is additionally displayed on the scroll bar.

Patient List screen the following menu keys are available:

Open - open the *Patient Exams* window for the selected patient.

Import - import patient information from the USB memory (*see 8.2.3*)

Export - export patient information and results of exams to the USB memory (*see chapter 8.2.4*).

Delete - delete the selected patient information (*see 8.2.5*)

Exit - return to the previous *Menu* screen .

By pointing with the use of finger or by stylus, or using the **Knob** you can select the individual patient in the database (different colour of the background). Press the **Open** menu key or press **Knob** key. New screen - *Patient exams* window will be displayed. The exams list always starting from the last record.

In particular columns the following information are displayed:

- **No** - Examination sequence number;
- **Date** - Date of the study ;
- **Time** -Time of the study;
- **Eye** – Right or Left eye;
- **Type** – type of exam and measurement: A-scan, A-IOL, B-scan or P-scan
- **Image filename** - Image name - when you export it via USB.

Files are sorted according to date and time of exam.

Maximum 64 exams can be stored in the one patient record, but only 10 files are visible at the same time on the screen. Use two arrow keys **PgUp** and **PdDn** to scroll up/down the page – to display the data that do not fit in the current window.

On the *Patient Exams* screen the following menu keys are available:

- **Display -** display the selected exam
- **Export -** send selected exam (picture) or all exam to external USB memory
- **Delete -** delete the selected or all exams
- **Exit -** go back to the previous window (*Patient List* window)

With the stylus or finger or using the **Knob** select the exam you want to see – you can open selected (highlighted) file or send to external USB memory or delete.

The image from the selected exam will be displayed after pressing ***Display*** button. An image will appear on the screen, and examination sequence number on a given patient in the menu field.

Use the **<<<** and **>>>** menu buttons to display another saved exams for a given patient.
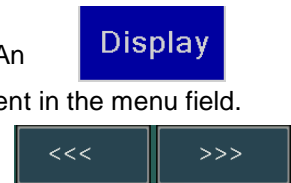
By pressing the ***Print*** button it is possible to print the measurement results from the archived images.

The ***Save PDF Report*** key allows you to save a measurement report as a PDF file to a USB memory (*see chapter 8.4*).

Return to the file manager window takes place after pressing the ***Exit*** key.

8.2.3. IMPORTING THE PATIENT LIST

PIROP scanner allows the use of **internal database** of patient data, created successively by user by using ***Save*** function or by importing from special file via USB memory. In the new scanner factory installed database of patients data is empty.

Using USB memory to import the patient information first you must create a special *Patients List* file: ***pirop2.dtb***.

You can create ***pirop2.dtb*** file manually, using e.g. *Notepad* - a standard Windows editor. The file structure is very simple: each row contains information about one patient: ***Name*** and *PID* separated by a comma (see the picture).
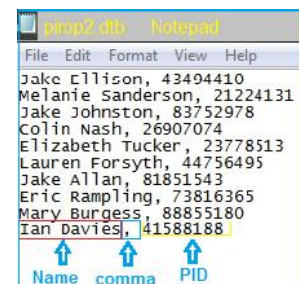
Created *List Patient* file should be saved under the name ***piropt2.dtb*** in folder ***Pirop2/*** USB memory.

 Important : during *Save As* operation, you can select Encoding option: *Unicode* and Save as type option: *All Files (see screenshot beside).*
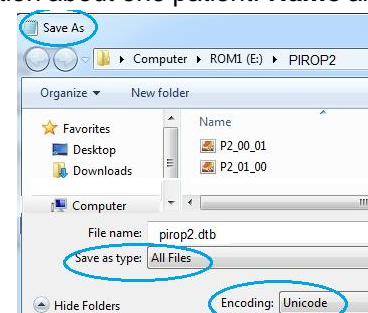
To import *Patient List* from external USB memory:

- In the main **Menu** *w*indow select the database option using the key ***Database.*** A list of all the patients stored in the database is displayed on the screen. No patient is selected (highlighted).

- Insert USB memory with the current ***pirop2.dtb*** file (in PIROP2/ folder), into the PIROP scanner. Wait until the small *Pen memory* icon appears at the top of the screen

- Press ***Import*** menu key. A new *Import Patient List* window appears on the screen.
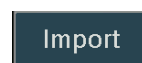
- To replace patient list press **Replace** button. *Note: this option deletes all previous data !*
- To append patient list press **Append** menu button.
- Windows with the new patient data (Name and PID) will be displayed on the screen.
- Press **Exit** button to return to the previous screen.

8.2.4. EXPORTING DATA TO THE USB MEMORY

Internal Memory has additional option - export function. The export function enables to export selected or all images from the Internal Memory to the External USB memory (Format FAT32). Files are exported to *PIROP2/* folder. The name of saved image is created automatically - contains the number of a particular patient in the database and a sequence number of a particular patient exam, preceded by an prefix "P_" (*see chapter 8.2.1*). The export archive file .bmp apart from the image itself, contains full information of the measurement, image parameters, patient data etc. The files can be opened in any image browser on the PC computer.

After exporting files it is possible to erase all Internal Memory data.

Exporting patient data from database to external USB Memory:
- Open memory manager from Menu Page by pressing **Database** button.
- Insert USB memory into the PIROP - check if external USB memory is connected (a USB pen drive icon should be lit in the information bar on the screen)
- Select the individual patient in the database (different colour of the background).
- Press **Export** Menu button. *Export patient screen* appears.
- Press **Exp. Sel.** *(export selected)* or **Exp. all** *(export all)* button to start exporting. The images from selected record or from all records will be exported to USB memory.

Exporting selected exam from database to external USB Memory:
- Open memory manager from Menu Page by pressing **Database** button.
- Insert USB memory into the PIROP - check if external USB memory is connected (a USB pen drive icon should be lit in the information bar on the screen)
- Select the patient in the database (different colour of the background).
- Press **Open** menu keys to open *Patient exams screen.*
- Select the exam in patient's record (different colour of the background).
- Press **Export** Menu button. *Export patient screen* appears.
- Press **Yes** button to start exporting. The image from selected exam will be exported to USB memory.
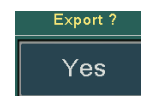
8.2.5. DELETING ARCHIVED FILES

Deleting patient data from database :
- Open *Patient List* window from Menu Page by pressing **Database** button.
- Select the patient in the database (with the stylus or finger or using the **Knob -** different colour of the background).
- Press **Delete** Menu button – a *Delete patient screen* appears.

- Press *Del.sel. (delete selected)* or *Del. all (delete all)* button to start deleting. The <u>selected</u> patient record or <u>all</u> patient records will be deleted.

Deleting selected exam from database :

- Open *Patient List* window from Menu Page by pressing *Patient Database* button.
- Select the individual patient in the database (different colour of the background).
- Press *Open* menu keys to open *Patient exams screen.*
- Select the exam in patient record (different colour of the background).
- Press *Delete* Menu button – a *Delete exam screen* appears.
- Press *Yes* button to start deleting. The selected exam in patient records will be deleted.

By pressing the *Exit* button, you will return from the file *Delete screen* to the previous menu

8.3. PRINTING ON THE EXTERNAL PRINTER (OPTION)

Optionally, it is possible to work with external <u>USB printers</u> (*HP LaserJet Pro M102*, *HP LaserJet Pro M14-M17* or most *Mobile Printers*) via USB connection*.* Connection to the external printers will be obtained by using the optionally <u>factory mounted special adapter</u>. A printer - internal and / or external, can be selected from the scanner settings window (see chapter 8.3.1).

Depending on the PIROP operation mode various reports printout can be received on external printer. (see chapter 8.3.4)

8.3.1. SELECTING THE PRINTERS

Press *Setup* menu button in *Menu window* than choose *Options* key. On the *Options* Screen press *Print/Save target* key to open *Print/Save target screen*:
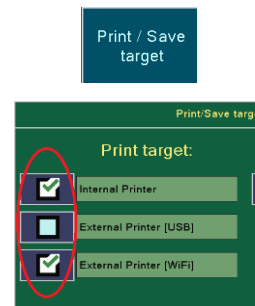
By checking the appropriate box you can choose different printer configurations : the <u>internal</u> built-in small thermal printer, <u>and/or</u> **one** of the options of <u>external</u> printers: external printer USB or external printer Wi-Fi.

8.3.2. CONNECTING THE EXTERNAL USB PRINTER

When the external USB printers: *HP LaserJet Pro M102 or HP LaserJet Pro M14-M17* is used, <u>pay attention</u> to the following information

⚠ *WARNING***:**

1. *Connection to the external printer via USB will be obtained by using the optionally <u>factory mounted special internal adapter</u>.*

2. *Only printers recommended by the manufacturer can be connected - the manufacturer installed drivers for the following printers: **LaserJet Pro M102, HP LaserJet Pro M14-M17;** each other printer must be approved by the manufacturer before connection.*

3. *Printers, as external devices directly connected to a power source, require a galvanic signal separation and/or control cables according to related standards - EN 60601-1 or EN 60950)*

4. ***All devices meeting IEC60950 must be kept outside the patient environment, as defined in IEC60601-1-1, unless it, according to IEC60601-1-1, is equipped with additional protective earth***

or extra isolating transformer. Non-medical equipment, according to IEC 60601-1, must be placed outside the patient environment.

5. *Echo-Son does not take any responsibility for safe operation, reliability and performance of the equipment if the printer connection caused the non-compliance of the system with IEC 60601-1-1 standard and with the relevant EN standard or other applicable national or international standard.*

Connect the external printer to the appropriate USB port on the scanner (**Printer socket**). Turn on the printer and PIROP scanner. Open the *Print/Save target screen* (chapter 8.3.1). Select field "*External Printer [USB]* " on the *Print/Save target screen* - the new window: *External Printer USB screen* appears on the screen. On the basis of the printer configuration data, select the printer language with the **Printer language protocol** key: **PCL** or **SPL**. *If there is no printer language data, you can change the language options after the failed connection and try to connect again.*
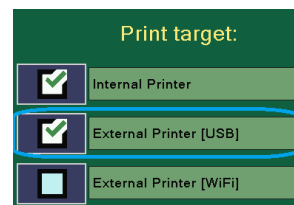
Press **Connect** menu key - wait for the connection. When the connection is made, in *Connection string* the full name of connecting printer should appear. In the field below the message "C*onnection OK* " appears.

Additional special icon on the information bar should appear. A <u>red cross</u> on the icon indicates that there is no connection with the printer.
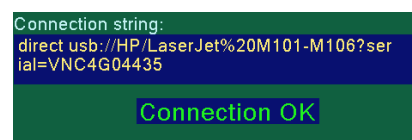
After getting the correct connection to the external USB printer, each time you turn on the PIROP scanner, it <u>automatically</u> starts the process of connecting to this printer. The successful completion of the automatic connection (usually takes a <u>several dozen seconds</u> after switching on) is indicated by the appearance of the connection icon on the screen.

8.3.3. REPORTS PRINOUT ON EXTERNAL PRINTER

To print reports on a connected external printer, press **Print** key on the screen menu. (*see chapters 5.10 , 6.7.10 and 7.7.4)*

Depending on the PIROP operation mode various reports printout can be received on external printer: A-scan / Biometry Report, A-scan /IOL Report , A-scan / Formulas comparison Report, B-scan Report and Pachymetry Report.

The report printout contains all the information from the scan screen: user and patient data, exam data, parameters of eye and lens, IOL calculation, measurements, image (screenshots) etc.

It is possible to print exam report saved in the archive. To print an image saved in the image archive, first display the image on the screen and then press the **Print** menu key.

If a full IOL calculation is performed for both eyes, pressing the **Print** button on the IOL calculation screen print an A-scan / IOL measurement report <u>for both eyes simultaneously</u>..

Note: *When using the WiFI printer, the time from the moment you press the Print button to print may take a few seconds - <u>wait patiently</u> and do not press the Print key again*.
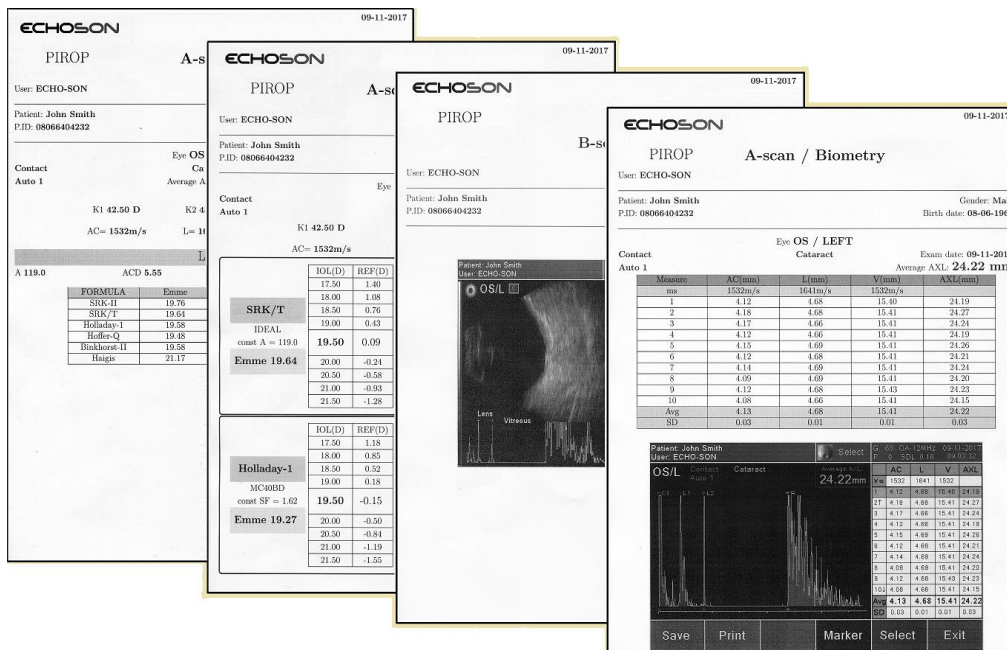
8.4. SAVING THE MEASUREMENT REPORT AS PDF FILE IN USB MEMORY (OPTION)

PIROP scanner with factory mounted special adapter (see chapter 8.3)) allows you to save a measurement report as a PDF file in the external memory connected to the USB port. Depending on the PIROP operation mode various reports can be stored as a PDF file (see chapter 8.3.4)

To save reports as PDF file on a connected external USB memory, press **Save PDF report** key on the screen menu. (*see chapters 5.11 , 6.7.9 and 7.7.5*)

When you create and save a PDF report, an appropriate message is displayed on the screen.

Depending on the PIROP operation mode various reports can be saved as PDF file: A-scan / Biometry Report, A-scan /IOL Report , A-scan / Formulas comparison Report, B-scan Report and Pachymetry Report.

The report file contains all the information from the scan screen: user and patient data, exam data, parameters of eye and lens, IOL calculation, measurements, image (screenshots) etc.

If a full IOL calculation is performed for both eyes, pressing the **Save PDF report** button save an A-scan / IOL measurement report for both eyes simultaneously

The default name of each saved PDF file is created automatically according to the following rule – it contains a prefix about the working mode (A-scan, B-scan or P-scan), date (year and month) and the order number of the next file saving, for example:

A 1 8 C 0 0 0 2 . PDF

Prefix **A** –A-scan mode (respectively: B and P)	**18 -** 2018 year (last two digits of the year)	**C-** December (month in hex: 1..9, A, B, C)	**0002**- the next file number of the PDF file(*after reaching 9999 , starts from 1*)
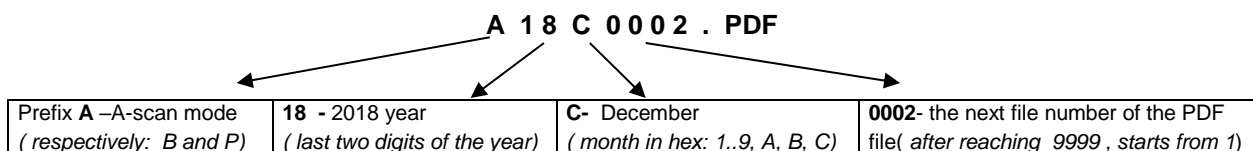
It is possible to create a PDF file for the exam image stored in the archive. To do this, first display the image from database on the screen and then press the **Save PDF report** menu key.

Note: Save PDF report menu key will always save PDF file on external USB memory*.*

9. MAINTENANCE

9.1. USER PREVENTIVE MAINTENANCE

1. No periodic or preventive maintenance is required for the system, transducer or accessories other then cleaning and disinfecting the transducer every use and checking calibration.
2. There is no internal components that require periodic testing.
3. All maintenance requirements are described in this document and in PIROP User Manual and Service Manual.

Action	Description	Period
Cleaning the LCD screen	To clean the screen use only dry, cotton, soft cloth or special cleaning agents dedicated for LCD screen.	Daily, or as necessary
Cleaning and disinfecting probes	A detailed description in the User Manual, point 2.3.2 and 2.3.3	Always before a new patient
Inspection of probes	the probe enclosure should be regularly checked: the front part that comes into contact with patients and the cable should be checked for any possible damage.	Daily
Visual check	Check all fitting and cables are properly connected. Check there are no signs of spilled liquids or cable damage.	Weekly
Calibration probe A (OA12) and P (OP20)	Calibration of the probe A (OA12) is described in point 5.6 and 4.7.4 of the User Manual Calibration of the probe P (OP20) is described in section 4.7.4 and 7.5 of the User Manual	The calibration in A-scan and P-scan modes ought to be performed each time the scanner is switched on
Calibration probe B (OB12)	Test of the probe B (OB12) is described in section 4.7.4 and 2.3.5 of the User Manual	The tests B probe ought to be performed each time the scanner is switched on

Contact Echo-son Technical Support for any maintenance questions.

9.2. TROUBLESHOOTING THE SCANNER

This section contains the information intended to aid the process of troubleshooting the operation of the PIROP ultrasound scanner. If a problem occurs which is not explained below or the presented remedies failed, contact the manufacturer's service department.

Problem	Possible remedy
The scanner does not turn on.	1. Connect an external power adapter. Check the connection state. Set the mains switch to OFF (**O**), wait 15 seconds and turn it ON again (**I**).
No reaction to the Print key – printer not print	1. Check if printer paper is setting correct. If the printer is short of paper, set a new printer paper roll. 1. Connect an external power adapter to charge the internal printer battery
Image quality deteriorated	1. Adjust the gain 2. Check the display brightness settings (4.7.1) 3. Position the scanner to achieve the proper observation angle. The perceived display significantly changes depending on the point of view!
The probe is not working – there is no ultrasound image	1. Check the connection state of the probe (screw the outlet down) 2. Check the condition of the probe end face, housing and connection cables. **DO NOT use damaged or faulty probes!** 3. Perform probe test procedure by use e.g. the **Self test** buttons in Service page (4.7.4)
The scanner does not recognize the connected probe	1. Check the connection of the probe and scanner (whether the probe is screwed down) 2. Switch the scanner off and on again.
The scanner switched to the suspended mode and does not react to screen keys.	1. Set the mains switch to "off" (**O**), wait 15 seconds and turn it on again (**I**). .
The scanner does not see the USB memory	1. Disconnect the USB memory, wait a few seconds and connect again. 2. Check another USB memory.

NOTE:
In the event of doubts or problems as to the interpretation of the PIROP scanner measurements, it is <u>*strongly required*</u> *to provide the service stored images with measurements in memory (Save button) and/or print results of measurements (Print button). None of the above documentation prevents effective/proper service activities and measurements for checking.*

9.3. REPLACING THE PRINTER PAPER

Printer prints on 2"- wide heat-sensitive paper with the diameter of a new roll of max. 33 cm. To install a new roll of paper, open the lid of the paper container **(1) -** place finger underneath indentation located at the top of the lid covering the printer, and gently lift up. If the previous roll has been used up, remove the remaining reel and throw it away. Place the new roll **(2)** in a way that the paper rolls out from the bottom to the centre of the printer. Then pull the end of paper sheet above the printer housing and close the lid, pushing down until it snaps **(3**). The paper should protrude from the gap.

Lid   Clamping roll   Roll of paper
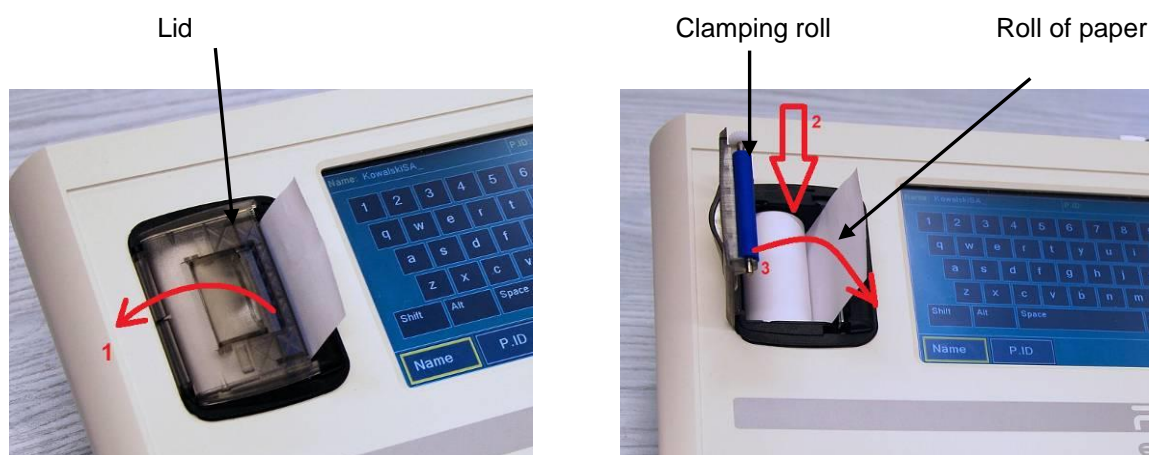
If there is any irregularity caused by jammed paper, do not use any tools to take it out; open the lid, take the paper out, cut the crumpled end off, possibly clean the clamping roll and install the paper properly.

Detailed specification of paper by the printer's manufacturer:

Type of paper: Roll of thermal paper (heat-sensitive surface on the outside of the roll)

Recommended type: 55 g/m² – 60 g/m² (KANZAN KF50 or MITSUBISHI PG5075)

Thickness of paper: 61 µm

Width of paper roll: 57 mm (± 0.5) = 2"

Maximum diameter of roll: Ø 33 mm

End of paper: not attached to the reel

Inner diameter of the reel: Ø 12 mm (± 1)

Reel structure: cardboard or plastic

9.4. SYSTEM MESSAGES

	MESSAGE	CAUSE
1.	**NO PROBE**	The probe in a given mode is not connected. Connect the corresponding probe.
2.	**No USB Memory detected**	The USB flash drive is not connected. Connect the USB flash drive
3.	**Saving image on the USB memory**	Saving the current image on the USB memory
4.	**Saving image to database**	Saving the current image on the internal memory
5.	**Current image restored**	Back from the Mx cache to the current screen (chap. 6.8)
6.	**Image captured into Mx memory**	Saving the current image to cache x (chap. 6.8)
7.	**Printing results on thermal printer**	For the short period of sending information to the printer, the scanner becomes inactive (chap 8.1)
8.	**Select patient !**	Select the patient record from the database (ch.8.2)
9.	**Select exam !** **No exams to export**	Select the exam record from the database (ch.8.2)
10.	**No 'pirop2.dtb' file !** **Bad 'pirop2.dtb' file !**	No patient data file on USB drive (ch.8.2.2)
11.	**Error! Out of range**	Bad parameters BIAS or Velocity in setting pachymetry mode (ch.7.4)
12.	**Lens 1 name cannot be empty**	Setting the lens name # 1 in Lens setup (ch.5.5.4)
13.	**Probe not detected !!! Check connection**	Self test in B- scan (chap. 4.7.4)
14.	**Choose lens and try again**	IOL screen (switch to formulas comparison –chap 5.9.5)
15.	**SD CARD ERROR!**	Problem with internal memory. Switch the scanner off and on again. If a problem occurs again contact the manufacturer's service department
16.	ERRORS: **- CRC ERROR in update files** **- Check if all files exists** **- No update files found** **- UPDATE2 folder not found** **- PIROP2 folder not found**	Messages during program update in service mode
17	**High Std Deviation!** **Correction necessary.**	Standard deviation SD of AVL measurement exceeding 0,15 mm – see ch.5.8.6

18.	**Saving report on USB memory**	Saving a measurement report as a PDF file in USB memory
19	**Maximum number of patients/ exams reached . Archive data**	The number of stored data has been exceeded in the internal database - the required archiving on an external medium and the deletion of data from the internal memory
11	**Modules update is required**	The software version for the printer module is not compatible with the main program - upgrade required
12.	**Module not responding !**	No communication with an additional external printer module. If the message repeats contact the manufacturer's service department

9.5. CLEANING THE SCANNER

1. To clean the scanner housing, wipe it with a soft cloth or a soft cloth soaked in a neutral detergent and wrung out. Then wipe with a dry and soft cloth.

   ⚠ *CAUTION: Never use an organic solvent !*

2. It is necessary to keep touch screen clear (dust and dirtiness may cause incorrect item operation). To clean the screen use only dry, soft clout or specially destined confection

   ⚠ *CAUTION:*

   - *It is recommend to use special pointer to operate touch screen that is enclosed with scanner equipment. It is forbidden to use any sharp-ended items due to screen surface damage.*
   - *It is forbidden to use any detergents a specially particular including alcohols or dissolvent*.

3. After repeated usage, the paper slot in the printer may be soiled with powdery paper. The paper container and the pressure roller should be cleaned

9.6. CLEANING PROBES

Careful cleaning and disinfection of the used probes prevents spreading of diseases. The User is responsible for the recommended anti infection procedures.

Cleaning and disinfection of probes are described in **chapters 2.3.2** and **2.3.3**

9.7. CALIBRATION

Calibration of OB probe – see **chapters 2.3.5** and **4.7.4**

Calibration of OA probe and A-scan mode – see **chapters 4.7.4** and **5.6**

Calibration of OP probe and P-scan mode – see **chapters 4.7.4** and **7.5**

Note:

- The calibration in A-scan and P-scan modes ought to be performed each time the scanner is switched on
- The tests B probe ought to be performed each time the scanner is switched on

9.8. UNLOCKING INACTIVE MODES

There are a lot of options in the PIROP versions:

- ➢ Only Pachymeter
- ➢ Only the A-scan
- ➢ Only the B-mode
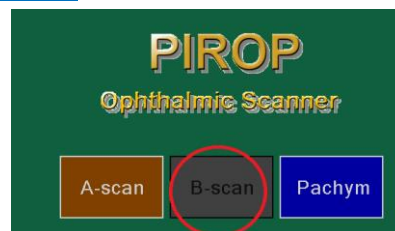
or any combination of the **two** options listed above. On the mode

selection Page, the mode keys in the background color are inactive. Active are those that correspond to the current PIROP scanner options

Inactive mode of operation can be activated using the service window. Unlocking inactive modes requires an activation key code.
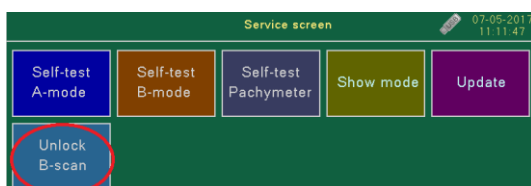
Please contact your scanner supplier for details on how to order this option and get an activation key code

10. APPENDIX A - IOL FORMULAS

10.1. IOL IN PIROP SCANNER

The page for the intraocular lens (IOL) calculation of the implant power is opened from the A-scan measurement page by pressing the IOL button All the data needed for the calculation should be defined and measured before entering the IOL Calculation page. The calculation can also be performed without measurements because the values necessary for the calculation can be entered manually.

The regression formulas are empiric formulas generated by averaging large numbers of postoperative clinical results.

Into the PIROP scanner the following types of IOL formulas are pre-programmed:

1. SRK-II (Sanders-Retzlaff_Kraftf formula);
2. SKR/T
3. HOLLADAY-1
4. HOFFER-Q
5. BINKHORST-II
6. HAIGIS

and the following types of Postoperative (LASIK, PRK) formulas:

7. Double-K SKR/T
8. LATKANY Flt-K SKR/T
9. LATKANY Avr-K SKR/T
10. mdf-MASKET

Depending on the measured axial length of the examined eye, preferable methods for the calculation of the implant power are recommended:

Avg AXL < 22	formula HOFFER-Q
22.0 ≤ Avg AXL < 24.5	any formula
24.5 ≤ Avg AXL < 26.0	formula HOLLADAY-1
Avg AXL ≥ 26	formula SRK/T

The average axial eye length – Avg AXL – (calculated from biometrical measurements), the mean value of coefficients K1, K2 – Avg K – (found in the patient's data) and the parameters for the current lens (const. A, ACD and F) are assumed for calculations.

The value of the calculated implant power is presented as Emmetropia (**Emm**).

The value of the suggested implant power for the selected lens, taking into consideration Target Ametropia (**TAM**), is displayed in the middle of the table highlighted in yellow

Note !

If the coefficients of the refractive power of the cornea K1 or K2 for the given eye have not been entered, the mean value: Avg K is displayed as xx.xx. The correct values should be entered on the page with the patient's data or are also temporarily available on IOL Calculation page

10.2. SRK-II FORMULAS

Description of the data for the calculation of the implant power using the SRK II method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const A - the parameter of the currently selected lens

K = Kavg

L = Average AXL

TAM = Target Ametropia

A = const A

EMM = Emmetropic power

REFR = Refraction

C = Correction with respect to original SRK formula where C = 0

if L < 20	then C = 3;
if 20 ≤ L < 21	then C = 2;
if 21 ≤ L < 22	then C = 1;
if 22 ≤ L < 24.5	then C = 0;
if L ≥ 24.5	then C = -0.5;

EMM = A - 2.5 * L - 0.9 * K + C;

    if EMM > 14 then:

        IOL = EMM - TAM *1.25

    else:

        IOL = EMM - TAM

    if IOL > 14 then:

        REFR = (EMM - IOL) / 1.25

    else:

        REFR = EMM - IOL

    If eye type is APHAKIC then:

        REFR = 80.4 - 1.65 * L - 0.7 * K

Note:
Calculation of the implant power using the SRK II method is not recommended when the axial length of the eyeball is smaller than 22 mm or bigger than 24.5 mm. In order to facilitate the selection of the appropriate formula and the comparison of the calculation results, it is recommended that the COMPARISON page is opened (see chapter 5.9.5).

10.3. SRK–T FORMULAS

Description of the data and formula for the calculation of the implant power using the SRK T method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const A - the parameter of the currently selected lens

K = Kavg

L = Average AXL

TAM = Target Ametropia

A = const A

EMM = Emmetropic power

REFR = Refraction

R –Corneal curvature in mm   R = 337.5 / K (K in Dioptres)

  if L > 24.2 then:

   Lcor = -3.446 + 1.716 * L - 0.0237 * L ²

  else:

   Lcor = L

  Cw = -5.40948 + 0.58412 * Lcor + 0.098 * K

  Hest = R - √(R ²- Cw ² /4)

  Lopt = L + 0.65696 - 0.02029 * L

  ACDest = Hest + 0.62467 * A - 68.74709 - 3.3357

EMM = (1336*1.336*R – 1336 * 0.3333*Lopt) / ((Lopt - ACDest) * (1.336*R - 0.3333*ACDest))

  P1 = 12 * (1.336 * R - 0.3333 * Lopt) + Lopt * R;

  P2 = 12 * (1.336 * R - 0.3333 * ACDest) + ACDest * R;

  P3 = 1336 * 1.336 * R - 1336 * 0.3333 * Lopt - 1.336 * TAM * P1;

  P4 = (Lopt - ACDest) *(1.336 * R - 0.3333 * ACDest - 0.001 * TAM * P2);

  IOL = P3 / P4;

  Lo = 0.97971 * L + 0.65696;

  S1 = Lo - ACDest;

  S2 = 1.336 * R - 0.3333 * ACDest;

  S3 = 1.336 * R - 0.3333 * Lo;

  S4 = 12 * S3 + Lo * R;

  S5 = 12 * S2 + ACDest * R;

REFR = (1336 * S3 – IOL * S1 * S2) / (1.336 * S4 - 0.001 * IOL * S1 * S5)

10.4. HOLLDAY-1 FORMULAS

Description of the data and formula for the calculation of the implant power using the HOLLADY-1 method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const SF - the parameter of the currently selected lens

K = Kavg

L = Average AXL

TAM = Target Ametropia

SF = const SF

EMM = Emmetropic power

REFR = Refraction

R –Corneal curvature in mm   R = 337.5 / K (K in Dioptres)

        if R < 7 then:

                Rag = 7

        else:

                Rag = R

AG = 12.5 * L / 23.45

    if AG > 13.50 then: AG = 13.50

CA = 0.56 + Rag - √ (Rag ² - AG ²/ 4) + SF

LC = L + 0.20

EMM = (1336 *(1.336 * R - 0.3333 * LC)) / ((LC - CA) * (1.336 * R - 0.3333 * CA))

P1 = 1336 *(1.336*R - 0.3333*LC - 0,001 * TAM * (16.032*R - 4*LC + LC*R))

P2 = (LC - CA) * (1.336*R - 0.3333*CA - 0,001 * TAM * (16.032*R - 4*CA + CA*R))

IOL = P1 / P2

P3 = 1336 *(1.336 * R - 0.3333 * LC) – IOL * (LC - CA) * (1.336 * R - 0.3333 * CA)

P4 = 1.336*(16.032*R - 4*LC + LC*R) - 0,001 * IOL*(LC-CA)*(16.032*R - 4*CA + CA*R)

REFR = P3 / P4

10.5. HOFFER-Q FORMULAS

Description of the data and formula for the calculation of the implant power using the HOFFER-QI method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power

- Const ACD - the parameter of the currently selected lens

K = Kavg

L = Average AXL

TAM = Target Ametropia

ACD = const ACD

EMM = Emmetropic power

REFR = Refraction

      if L < 18.50   then: L = 18.50

      if L > 31.00   then: L = 31.00

      if L ≤ 23 then:

        M = 1,   G = 28

      else:

        M = -1, G = 23.5

     T1 = tan(K * π / 180)

     T2 = tan(0.1 * (G - L) ² * π / 180)

     C = ACD + 0.3 * (L - 23.5) + T1 ² + 0.1 * M * (23.5 – L) ² * T2 - 0.99166

   EMM = 1336 / (L - C - 0.05) - (1.336/(1.336/K – 0,001 * (C + 0.05)))

   R = TAM / (1 - 0.012 * TAM)

   IOL = 1336 / (L - C - 0.05) - (1.336/((1.336/(K + R)) - 0,001 * (C + 0.05)))

    P = 1.336 / (1.336 / (1336 / (L - C - 0.05) - IOL) + 0,001*(C + 0.05)) - K

  REFR = P / (1+0.012 * P)

10.6. BINKHORST-II FORMULAS

Description of the data and formula for the calculation of the implant power using the BINKHORST-II method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const ACD- the parameter of the currently selected lens

K = Kavg

L = Average AXL

TAM = Target Ametropia

ACD = const ACD

EMM = Emmetropic power

REFR = Refraction

R –Corneal curvature in mm   R = 337.5 / K (K in Dioptres)

   LB = L + 0.1984

   LC = LB

if (LB > 26) then: LB = 26

   if type = Posterior then: CA = ACD * LB / 23.45

   if type = Anterior   then: CA = ACD

EMM = 1336*(1.336*R - 0.3333*LC) / (LC - CA)*(1.336*R - 0.3333*CA)

  P1 = 1336*(1.336*R - 0.3333*LC - 0.001* TAM * (16.032*R - 4*LC + LC*R))

  P2 = (LC - CA)*(1.336*R - 0.3333*CA - 0.001* TAM * (16.032*R - 4*CA + CA*R))

  IOL = P1 / P2

  P3 = 1336*(1.336*R - 0.3333*LC) - IOL*(LC - CA)*(1.336*R - 0.3333*CA)

  P4 = 1.336*(16.032*R - 4*LC + LC*R) - 0.001*IOL*(LC - CA)*(16.032*R - 4*CA + CA*R)

REFR = P3 / P4

10.7. HAIGIS FORMULAS

Description of the data and formula for the calculation of the implant power using the HAIGIS method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)

- Kavg - the average keratometry value of the coefficients of the refractive power of the cornea (by default, it is the average value of the coefficients K1 and K2 from the patient's data page)

- TAM (Target Ametropia) - correction of the target implant power

- Const A- the parameter of the currently selected lens

- Avg AC- the value of the average length of anterior chamber (by default, it is the result of the biometrical measurement)

K = Kavg

L = Average AXL

AC = Avg AC

TAM = Target Ametropia

A = const A

EMM = Emmetropic power

REFR = Refraction

R –Corneal curvature in mm   R = 337.5 / K (K in Dioptres)

      C = (1331.5 - 1000) / R

      A1 = 0.4

      A2 = 0.1

      A0 = 0.62467* A - 72.434

      D = A0 + A1 * AC + A2 * L

   EMM = 1336 / (L - D) - 1.336 / (1.336 / C – D / 1000)

       Z = C + TAM / (1 - TAM * 0.012)

     IOL = 1336 / (L - D) - 1.336 / (1.336 / Z – D / 1000)

     P = 1.336 / (D / 1000 - 1.336 / (IOL - (1336 / (L - D)))) - (331.5 / R)

   REFR = P / (1 + 0.012 * P)

10.8. DOUBLE-K SKRT/T FORMULAS

Description of the data and formula for the calculation of the implant power using the Double-K SRK/T method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kpre   - the preoperative value of the coefficients of the refractive power of the cornea (by default, it is the value of the coefficients Kpre from the patient's data page)
- Kpost   - the postoperative value of the coefficients of the refractive power of the cornea (by default, it is the value of the coefficients Kpost from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const A- the parameter of the currently selected lens

Kpre = K preoperative

Kpost = K postoperative

L = Average AXL

TAM = Target Ametropia

A = const A

EMM = Emmetropic power

REFR = Refraction

Rpre = 337.5 / Kpre

$\quad$ if L > 24.2 then:

$\quad\quad$ Lcor = -3.446 + 1.716 * L - 0.0237 * L ²

$\quad$ else:

$\quad\quad$ Lcor = L

$\quad$ Cw = -5.40948 + 0.58412 * Lcor + 0.098 * Kpre

$\quad$ Hest = Rpre - √(R ²- Cw ² /4)

$\quad$ Lopt = L + 0.65696 - 0.02029 * L

$\quad$ ACDest = Hest + 0.62467 * A - 68.74709 - 3.3357

$\quad$ Rpost = 337.5 / Kpost

EMM = (1336*1.336*Rpost – 1336*0.3333*Lopt) / ((Lopt - ACDest)*(1.336*Rpost - 0.3333*ACDest))

$\quad$ P1 = 12 * (1.336 * Rpost - 0.3333 * Lopt) + Lopt * Rpost;

$\quad$ P2 = 12 * (1.336 * Rpost - 0.3333 * ACDest) + ACDest * Rpost;

$\quad$ P3 = 1336 * 1.336 * Rpost - 1336 * 0.3333 * Lopt - 1.336 * TAM * P1;

$\quad$ P4 = (Lopt - ACDest) *(1.336 * Rpost - 0.3333 * ACDest - 0.001 * TAM * P2);

$\quad$ IOL = P3 / P4;

$\quad$ Lo = 0.97971 * L + 0.65696;

$\quad$ S1 = Lo - ACDest;

$\quad$ S2 = 1.336 * Rpost - 0.3333 * ACDest;

$\quad$ S3 = 1.336 * Rpost - 0.3333 * Lo;

$\quad$ S4 = 12 * S3 + Lo * Rpost;

$\quad$ S5 = 12 * S2 + ACDest * Rpost;

$\quad$ REFR = (1336 * S3 – IOL * S1 * S2) / (1.336 * S4 - 0.001 * IOL * S1 * S5)

10.9. LATKANY Flattest-K SKR/T FORMULAS

Description of the data and formula for the calculation of the implant power using the LATKANY Flattest-K SRK/T method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- FltK- the flattest value of the coefficients of the refractive power of the cornea (by default, it is the smallest value of the coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const A- the parameter of the currently selected lens
- SEq - prerefractive surgery myopic spherical equivalent (in diopters)

FltK = min(K1, K2)

L = Average AXL

TAM = Target Ametropia

A = const A

EMMpost = postoperative Emmetropic power

REFR = Refraction

R = 337.5 / FltK

    if L > 24.2 then:

      Lcor = -3.446 + 1.716 * L - 0.0237 * L ²

    else:

      Lcor = L

    Cw = -5.40948 + 0.58412 * Lcor + 0.098 * FltK

    Hest = R - √(R ²- Cw ² /4)

    Lopt = L + 0.65696 - 0.02029 * L

    ACDest = Hest + 0.62467 * A - 68.74709 - 3.3357

    EMM = (1336*1.336*R – 1336 * 0.3333*Lopt) / ((Lopt - ACDest) * (1.336*R - 0.3333*ACDest))

  EMMpost = EMM – (0.47 * SEq + 0.85)

    P1 = 12 * (1.336 * R - 0.3333 * Lopt) + Lopt * R;

    P2 = 12 * (1.336 * R - 0.3333 * ACDest) + ACDest * R;

    P3 = 1336 * 1.336 * R - 1336 * 0.3333 * Lopt - 1.336 * TAM * P1;

    P4 = (Lopt - ACDest) *(1.336 * R - 0.3333 * ACDest - 0.001 * TAM * P2);

    IOL = P3 / P4;

    IOLpost = IOL – (0.47 * SEq + 0.85)

    Lo = 0.97971 * L + 0.65696;

    S1 = Lo - ACDest;

    S2 = 1.336 * R - 0.3333 * ACDest;

    S3 = 1.336 * R - 0.3333 * Lo;

    S4 = 12 * S3 + Lo * R;

    S5 = 12 * S2 + ACDest * R;

  REFR = (1336 * S3 – IOLpost * S1 * S2) / (1.336 * S4 - 0.001 * IOLpost * S1 * S5);

10.10. LATKANY Average-K SKR/T FORMULAS

Description of the data and formula for the calculation of the implant power using the LATKANY Average-K SRK/T method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg   - the value of the average coefficients of the refractive power of the cornea (by default, it is the value of the average coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- Const A- the parameter of the currently selected lens
- SEq - prerefractive surgery myopic spherical equivalent (in diopters)

K = Kavg

L = Average AXL

TAM = Target Ametropia

A = const A

EMMpost = postoperative Emmetropic power

REFR = Refraction

R = 337.5 / FltK

    if L > 24.2 then:

      $Lcor = -3.446 + 1.716 * L - 0.0237 * L^2$

    else:

      Lcor = L

    Cw = -5.40948 + 0.58412 * Lcor + 0.098 * K

    $Hest = R - \sqrt{(R^2 - Cw^2 /4)}$

    Lopt = L + 0.65696 - 0.02029 * L

    ACDest = Hest + 0.62467 * A - 68.74709 - 3.3357

    EMM = (1336*1.336*R – 1336 * 0.3333*Lopt) / ((Lopt - ACDest) * (1.336*R - 0.3333*ACDest))

EMMpost = EMM – (0.46 * SEq + 0.21)

    P1 = 12 * (1.336 * R - 0.3333 * Lopt) + Lopt * R;

    P2 = 12 * (1.336 * R - 0.3333 * ACDest) + ACDest * R;

    P3 = 1336 * 1.336 * R - 1336 * 0.3333 * Lopt - 1.336 * TAM * P1;

    P4 = (Lopt - ACDest) *(1.336 * R - 0.3333 * ACDest - 0.001 * TAM * P2);

    IOL = P3 / P4;

    IOLpost = IOL – (0.46 * SEq + 0.21)

    Lo = 0.97971 * L + 0.65696;

    S1 = Lo - ACDest;

    S2 = 1.336 * R - 0.3333 * ACDest;

    S3 = 1.336 * R - 0.3333 * Lo;

    S4 = 12 * S3 + Lo * R;

    S5 = 12 * S2 + ACDest * R;

    REFR = (1336 * S3 – IOLpost * S1 * S2) / (1.336 * S4 - 0.001 * IOLpost * S1 * S5);

10.11. MASKET FORMULAS

Description of the data and formula for the calculation of the implant power using the MASKET method:

- Average AXL - the value of the average axial eye length (by default, it is the result of the biometrical measurement)
- Kavg   - the value of the average coefficients of the refractive power of the cornea (by default, it is the value of the average coefficients K1 and K2 from the patient's data page)
- TAM (Target Ametropia) - correction of the target implant power
- const ACD - the parameter of the currently selected lens
- const SF - the parameter of the currently selected lens
- LSE - The vertex distance corrected laser vision correction spherical equivalent (in diopters)

EMM = Emmetropia

EMMpost = postoperative Emmetropia

REFR = Refraction

EMM value is calculated according to the following formula:

For Avg AXL values less than 23 mm is used HOFFER-Q formula

For Avg AXL values greater than 23 mm is used HOLLADAY-1 formula.

(These formulas are described in other chapters.)

Then the result of the calculation is adjusted by the following formula:

EMMpost = EMM - (LSE * 0.4385) + 0.0295

The value of the refraction REFR is calculated based on the value EMMpost:

For Avg AXL values less than 23 mm according to the HOFFER-Q formula

For Avg AXL values greater than 23 mm according to the HOLLADAY-1 formula.

11. APPENDIX B - LENS CONSTANT CONVERSION TABLE

Corresponding values of the implant coefficients for IOL calculation
(see chapter 5.5.4)

A	ACD	SF	A	ACD	SF	A	ACD	SF
110,0	0,30	-3,31	114,0	2,63	-1,04	118,0	4,97	1,22
110,1	0,36	-3,25	114,1	2,69	-0,99	118,1	5,02	1,28
110,2	0,41	-3,19	114,2	2,75	-0,93	118,2	5,08	1,34
110,3	0,47	-3,14	114,3	2,81	-0,87	118,3	5,14	1,39
110,4	0,53	-3,08	114,4	2,86	-0,82	118,4	5,20	1,45
110,5	0,59	-3,02	114,5	2,92	-0,76	118,5	5,26	1,51
110,6	0,65	-2,97	114,6	2,98	-0,70	118,6	5,32	1,56
110,7	0,71	-2,91	114,7	3,04	-0,65	118,7	5,37	1,62
110,8	0,76	-2,85	114,8	3,10	-0,59	118,8	5,43	1,68
110,9	0,82	-2,80	114,9	3,16	-0,53	118,9	5,49	1,73
111,0	0,88	-2,74	115,0	3,21	-0,48	119,0	5,55	1,79
111,1	0,94	-2,68	115,1	3,27	-0,42	119,1	5,61	1,85
111,2	1,00	-2,63	115,2	3,33	-0,36	119,2	5,67	1,90
111,3	1,06	-2,57	115,3	3,39	-0,31	119,3	5,72	1,96
111,4	1,11	-2,51	115,4	3,45	-0,25	119,4	5,78	2,02
111,5	1,17	-2,46	115,5	3,51	-0,19	119,5	5,84	2,07
111,6	1,23	-2,40	115,6	3,56	-0,14	119,6	5,90	2,13
111,7	1,29	-2,34	115,7	3,62	-0,08	119,7	5,96	2,19
111,8	1,35	-2,29	115,8	3,68	-0,02	119,8	6,02	2,24
111,9	1,41	-2,23	115,9	3,74	0,03	119,9	6,07	2,30
112,0	1,46	-2,17	116,0	3,80	0,09	120,0	6,13	2,36
112,1	1,52	-2,12	116,1	3,86	0,15	120,1	6,19	2,41
112,2	1,58	-2,06	116,2	3,91	0,20	120,2	6,25	2,47
112,3	1,64	-2,00	116,3	3,97	0,26	120,3	6,31	2,53
112,4	1,70	-1,95	116,4	4,03	0,32	120,4	6,37	2,58
112,5	1,76	-1,89	116,5	4,09	0,37	120,5	6,42	2,64
112,6	1,81	-1,83	116,6	4,15	0,43	120,6	6,48	2,70
112,7	1,87	-1,78	116,7	4,21	0,49	120,7	6,54	2,75
112,8	1,93	-1,72	116,8	4,26	0,54	120,8	6,60	2,81
112,9	1,99	-1,66	116,9	4,32	0,60	120,9	6,66	2,87
113,0	2,05	-1,61	117,0	4,38	0,66	121,0	6,72	2,92
113,1	2,11	-1,55	117,1	4,44	0,71	121,1	6,77	2,98
113,2	2,16	-1,49	117,2	4,50	0,77	121,2	6,83	3,04
113,3	2,22	-1,44	117,3	4,56	0,83	121,3	6,89	3,09
113,4	2,28	-1,38	117,4	4,62	0,88	121,4	6,95	3,15
113,5	2,34	-1,32	117,5	4,67	0,94	121,5	7,01	3,21
113,6	2,40	-1,27	117,6	4,73	1,00	121,6	7,07	3,26
113,7	2,46	-1,21	117,7	4,79	1,05	121,7	7,12	3,32
113,8	2,51	-1,16	117,8	4,85	1,11	121,8	7,18	3,38
113,9	2,57	-1,10	117,9	4,91	1,17	121,9	7,24	3,43

A	ACD	SF	A	ACD	SF	A	ACD	SF
122,0	7,30	3,49	123,0	7,88	4,05	124,0	8,47	4,62
122,1	7,36	3,55	123,1	7,94	4,11	124,1	8,52	4,68
122,2	7,42	3,60	123,2	8,00	4,17	124,2	8,58	4,73
122,3	7,47	3,66	123,3	8,06	4,22	124,3	8,64	4,79
122,4	7,53	3,72	123,4	8,12	4,28	124,4	8,70	4,85
122,5	7,59	3,77	123,5	8,18	4,34	124,5	8,76	4,90
122,6	7,65	3,83	123,6	8,23	4,39	124,6	8,82	4,96
122,7	7,71	3,88	123,7	8,29	4,45	124,7	8,88	5,02
122,8	7,77	3,94	123,8	8,35	4,51	124,8	8,93	5,07
122,9	7,82	4,00	123,9	8,41	4,56	124,9	8,99	5,13
						125,0	9,05	5,19

A – constant [D]

ACD – Anterior Chamber Depth [mm]

SF- Surgeon Factor [mm]

(based on Jack T. Holladay, MD, MSEE, International Intraocular Lens & Implant Registry 2002 –special report , J Cataract Refract

Surg. 2002; 28: 154-156.)

12. APPENDIX C - ACOUSTIC OUTPUT

12.1. Acoustic output table

Transducer : OA12   **Operating mode : A-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non - scan		Non-scan	
					$A_{aprt}<=1$	$A_{aprt}>1$		
Maximum Index Value			0.06	--	a)	--	a)	a)
Associated Acoustic Parameters	$p_{r.,3}$	[MPa]	0.18					
	W_o	[mW]		--	#		#	#
	min. of [$W_3(z_1)$, $I_{TA.3}(z_1)$]					--		
	z_1	[cm]				--		
	z_{bp}	[cm]				--	#	
	z_{sp}	[cm]	2.5				#	
	$d_{eq}(z_{sp})$	[cm]					#	
	f_c	[MHz]	9.8	--	#	--	#	#
	Dim of A_{aprt} X	[cm]		--	#	--	#	#
	Y	[cm]		--	#	--	#	#
Other information	PD	[us]	0.35					
	PRF	[Hz]	50					
	p_r @ PII_{max} [MPa]		0.41					
	d_{eq} @ PII_{max}	[cm]					#	
	Focal FL_x	[cm]		--	#	--		
	Length FL_y	[cm]		--	#	--		
	$I_{PA.3}$ @ MI_{max} [W/cm^2]		6.14					
Operating Control Conditions	Sample Volume Position		--					
	Focus		--					
	Depth		--					
	PRF		--					

a) this index is not required for this operating mode

b) this probe is not intended for transcranial or neonatal cephalic uses

#) no data are reported for this operating condition since the global maximum index is not reported for the reason listed

Transducer : OB12   **Operating mode : B-mode**

Index Label		MI	TIS			TIB	TIC
			Scan	Non - scan		Non-scan	
				$A_{aprt}<=1$	$A_{aprt}>1$		
Maximum Index Value		0.19	a)	--	--	a)	a)
Associated Acoustic Parameters	$p_{r.,3}$ [MPa]	0.61					
	W_o [mW]		#	--		#	#
	min. of $[W_3(z_1), I_{TA.3}(z_1)]$				--		
	z_1 [cm]				--		
	z_{bp} [cm]				--	#	
	z_{sp} [cm]	1.8				#	
	$d_{eq}(z_{sp})$ [cm]					#	
	f_c [MHz]	10.5	#	--	--	#	#
	Dim of A_{aprt} X [cm]		#	--	--	#	#
	Y [cm]		#	--	--	#	#
Other information	PD [us]	0.4					
	PRF [Hz]	8.5					
	p_r @ PII_{max} [MPa]	1.16					
	d_{eq} @ PII_{max} [cm]					#	
	Focal Length FL_x [cm]		#	--	--		
	FL_y [cm]		#	--	--		
	$I_{PA.3}$ @ MI_{max} [W/cm^2]	30.31					
Operating Control Conditions	Sample Volume Position	--					
	Focus	--					
	Depth	--					
	PRF	--					

a) this index is not required for this operating mode

b) this probe is not intended for transcranial or neonatal cephalic uses

#) no data are reported for this operating condition since the global maximum index is not reported for the reason listed

Transducer : OP20 **Operating mode : A-mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non - scan		Non-scan	
					$A_{aprt}\leq 1$	$A_{aprt}>1$		
Maximum Index Value			0.04	--	a)	--	a)	a)
Associated Acoustic Parameters	$p_{r.,3}$	[MPa]	0.18					
	W_o	[mW]		--	#		#	#
	min. of $[W_3(z_1), I_{TA.3}(z_1)]$					--		
	z_1	[cm]				--		
	z_{bp}	[cm]				--	#	
	z_{sp}	[cm]	0.01				#	
	$d_{eq}(z_{sp})$	[cm]					#	
	f_c	[MHz]	22	--	#	--	#	#
	Dim of A_{aprt} X	[cm]		--	#	--	#	#
	Y	[cm]		--	#	--	#	#
Other information	PD	[us]	0.15					
	PRF	[Hz]	8600					
	p_r @ PII_{max} [MPa]		0.18					
	d_{eq} @ PII_{max}	[cm]					#	
	Focal Length FL$_x$	[cm]		--	#	--		
	FL$_y$	[cm]		--	#	--		
	$I_{PA.3}$ @ MI_{max} [W/cm^2]		2.57					
Operating Control Conditions	Sample Volume Position		--					
	Focus		--					
	Depth		--					
	PRF		--					

a) this index is not required for this operating mode

b) this probe is not intended for transcranial or neonatal cephalic uses

#) no data are reported for this operating condition since the global maximum index is not reported for the reason listed

12.2. Acoustic output definitions

Symbol	Term	Reference
A_{aprt}	= -12dB OUTPUT BEAM AREA	IEC 62359, 3.25
d_{eq}	= EQUIVALENT BEAM DIAMETER	IEC 62359, 3.22
f_{awf}	= ACOUSTIC WORKING FREQUENCY	IEC 62359, 3.2
$I_{pa,\alpha}$	= ATTENUATED PULSE-AVERAGE INTENSITY	IEC 62359, 3.5
I_{pi}	= PULSE-INTENSITY INTEGRAL	IEC 62359, 3.32
$I_{pi,\alpha}$	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359, 3.6
I_{spta}	= SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.38
$I_{ta,\alpha}(z)$	= ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.8
MI	= MECHANICAL INDEX	IEC 62359, 3.23
P	= OUTPUT POWER	IEC 62359, 3.27
P_{α}	= ATTENUATED OUTPUT POWER	IEC 62359, 3.3
$P_{r,\alpha}$	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.4
P_r	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.28
prr	= PULSE REPETITION RATE	IEC 62359, 3.34
TI	= THERMAL INDEX	IEC 62359, 3.41
TIB	= BONE THERMAL INDEX	IEC 62359, 3.11
TIC	= CRANIAL-BONE THERMAL INDEX	IEC 62359, 3.15
TIS	= SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.37
t_d	= PULSE DURATION	IEC 62359, 3.31
X, Y	= -12dB OUTPUT BEAM DIMENSIONS	IEC 62359, 3.26
z_b	= DEPTH FOR BONE THERMAL INDEX	IEC 62359, 3.17
z_{bp}	= BREAK-POINT DEPTH	IEC 62359, 3.13
z_s	= DEPTH FOR SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.18

12.3. Table for global acoustic output data

Probe	MI	$I_{SPTA.3}$ [mW/cm2]	$I_{SPPA.3}$ [W/cm2]
OA12	0.06	0.11	6.14
OB12	0.19	0.10	30.31
OP20	0.04	3.32	2.57

Table for acoustic limits required by regulations (for ophthalmic application).

Standard / Regulation	MI	TI	$I_{SPTA.3}$ [mW/cm2]	$I_{SPPA.3}$ [W/cm2]
O.D.S (Output Display Standard)	0.23	--	720	--
FDA 510 (Track1)	0.23	--	17	28
FDA 510 (Track3)	0.23	< 1.0	50	28

13. Warranty

ECHO-SON S.A. warrants its products to be free from defects in materials and workmanship for a period of 24 months from the date of original shipment from its works under normal use and service.

The Manufacturer's obligation under this warranty is limited to substantive repairing or replacing, at its own option, any defective of its products, under the following conditions:

1. Any product or its part shall be unpacked, installed and operated adequately to the Manufacturer's "User Manual".

2. If the product or its part is found to be defective, the user should contact the Manufacturer as soon as possible and inform in detail about the founded defect or defects.

3. The defective product/part shall be send to the Manufacturer for necessary tests and repairs. The shipment is to be prepaid by the proprietor.

4. If the product/part will show any defects in materials or workmanship it will be repaired by the Manufacturer   within 7 days and returned to the proprietor on costs of ECHO-SON S.A. One week period does not apply to the time necessary for Customs clearance (in and out), and shipments.

5. Product/part returned as defective during the warranty period and subsequently found by ECHO-SON S.A. to meet all specifications (fault-free) in effect time of manufacture, will be subject to retesting and shipment charges.

6. The warranty terms shall not apply to the product/part which in Echo-Son S.A. judgement, has been subject to misuse, abuse, neglect, or improper installation or maintenance, unauthorised repair, modifications or alterations of the product.

7. The mechanical convex (sector) probes stroked or dropped which show trace(s), on the inner surface of the transducers cover are not covered by the manufacturer's warranty. The array (electronic) probes with such defects, are not covered by the warranty as well. The Manufacturer can only assure a replacement on additionally agreed payment conditions.

8. ECHO-SON S.A. is not liable for any other costs as mentioned: par 4, any losses or claims, such as last profits, loss of equipment, loss of data, costs of substitutes, claims by third parties, or otherwise.

9. ECHO-SON S.A. declares its help and assistance in introduction, use and maintenance of its products.

10. ECHO-SON S.A. obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution of parts or accessories not approved by ECHO-SON or repaired by anyone than a ECHO-SON authorized representative.

11. Allowable fault (defective) pixels on the LCD display are defined and limited by the standard ISO-13406-2 (class II of the product)