



BIOLINE
PORTABLE BIOMETER
INSTALLATION AND OPERATING MANUAL

OPTIKON 2000 S.p.A.

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OPTIKON 2000 SpA is an ISO 9001 and ISO 13485 certified company which manufactures surgical and diagnostic devices for ophthalmology.

Its products are manufactured to satisfy the requirements of 93/42/EEC Medical Devices Directive.

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1 DISCLAIMER

OPTIKON 2000 S.p.A. requires the user of this system to carefully read specific warnings found in this manual. It is responsibility of the user to provide its personnel with a thorough understanding of the equipment operation before use. In no event shall OPTIKON 2000 S.p.A. be liable for any injury, incidental or consequential damages incurred by the purchaser, users or patients as a result of operation of the product.

Use of this system is a matter of professional medical judgment in all cases. OPTIKON 2000 S.p.A. is not responsible for any clinical problem resulting from mishandling this equipment and makes no medical recommendations.

OPTIKON 2000 S.p.A. declares to be liable for safety, reliability and performance only if:

- upgrades, calibrations, repairs are carried out by OPTIKON 2000 S.P.A. authorized personnel;
- the system is used in accordance with its instructions for use;
- the mains electric installation to which the system is connected complies with the IEC Safety Regulations.

IMPORTANT NOTICE

Every effort has been made to have all the illustrations and information accurately represent the product and its operation as it actually was at the time this operation manual was printed. Changes in some items may be made during the life of this manual, so that we may effectively continue to meet the requirements of users. On occasion, these changes may be made without notice.

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2 LIMITED WARRANTY CONDITIONS

All OPTIKON 2000 S.P.A. equipment and accessories sold and installed in the European Union are guaranteed against defective workmanship and material faults for ONE YEAR, from the date of the invoice. Warranty on consumable materials is limited to the first use

Please, inquire with your local Optikon Distributor for warranty conditions in countries outside the European Union.

All items under warranty will be repaired or replaced free of charge.

Warranty includes the research of causes of the faults, reparation of the defect and a final inspection of the unit, or part(s).

This warranty does not cover the results of misuse, accident, abuse and tampering or alteration done by anyone other than personnel authorized by OPTIKON 2000 S.p.A.

OPTIKON 2000 S.P.A. reserves the right to ascertain, in case of faults, whether or not the equipment and/or its accessories have been altered, tampered with, in any way, or have been damaged by improper use.

OPTIKON 2000 S.P.A. also reserves the right to modify the equipment and/or its accessories whenever operating techniques necessitate modification(s).

No warranty will be recognized if serial number of the equipment and/or accessories attributed by OPTIKON 2000 S.P.A. is missing, tampered and/or not clearly readable.

Warranty does not include expenses for return shipment of equipment and accessories: all expenses for transport, packing etc. are to be borne by the purchaser.

In case of an expressly requested intervention of our technicians, all travel and hotel expenses will be debited to the client.

OPTIKON 2000 S.P.A. cannot be held liable for damages caused by transportation. If this is the case, the customer should apply at once to the carrier that handled the consignment.

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3 WARNINGS

The following warnings will help the user to operate the BIOLINE OPTIKON 2000 biometer correctly, resulting in safe use, free from any problems.

General

- All the medical personnel working with the instrument must read and understand the instructions provided in this manual before the system is used. If your instrument does not behave in the way described in this manual, do not attempt to use it.
- The use of this system is in any event subject to professional medical opinion. Optikon 2000 s.p.a. cannot be held responsible for any problems of a medical nature resulting from incorrect use of this instrument, and nor does it make any recommendations of a medical nature.

Environmental

- Do not install the instrument close to sources of heat or expose it to direct sunlight or high temperatures.
- Do not install the instrument in such a way that the ventilation slots are obstructed.
- The system must never be used in the presence of inflammable anaesthetics, inflammable disinfectants, or other substances which may cause fires or explosions.
- The use of flammable anaesthetics (N₂O, O₂), should be avoided unless they are removed by a gas aspiration system.
- Do not dispose of the BIOLINE unit as unsorted municipal waste. Collect it separately according to the local laws/regulations on disposal of waste electrical and electronic equipment.

Electrical

- The BIOLINE instrument is provided with thermal protection (with ptc) against overheating and against any internal short circuits. Consequently no fuses need to be replaced.
- In order to reduce the risk of electric shock, do not remove the cover of the instrument or the mains adaptor. Employ qualified technical personnel to carry out maintenance and repairs.

- The standard AC-DC adaptor must be used exclusively to supply the instrument.

Ordinary maintenance

- Do not sterilise the probe in hot air or in a chemical autoclave.
- Do not use solvents or alcohol to clean the exterior of the instrument.
- The probe (and the relating packaging) is not supplied as sterile and must be disinfected before it is applied to the cornea.

Precautions relating to the normal use of the instrument










- Gently apply the probe to the moist cornea, avoiding changing its normal geometric arrangement.
- If you are in doubt about the accuracy of the measurement carry out a calibration test on the probe and in the event of a negative result or incorrect functioning, do not use the instrument and seek technical assistance.
- Thermal prints tend to deteriorate in time. For long-lasting storage it is advisable to keep a photocopy of the print.
- Turn off the instrument at the switch when not in use

4 SYMBOLS

Table shown below reports some symbols approved by I.E.C. and their meaning. When there is not enough room, they are frequently used on medical equipment to enable an easy and fast communication of information and warnings. Sometimes two or more symbols may be assembled to obtain a special meaning.

These symbols are used on the BIOLINE label. Before starting to use the unit, you should familiarize yourself with them and their definitions shown in the table.

SYMBOLS PUBLISHED BY THE IEC

SYMBOL	DESCRIPTION
	ALTERNATING CURRENT
	DIRECT CURRENT
	PROTECTIVE EARTH (GROUND)
	ATTENTION CONSULT ACCOMPANYING DOCUMENTATION
	OPEN (POWER DISCONNECTED FROM THE MAINS)
	CLOSED (POWER CONNECTION FROM MAINS)
	TYPE B APPLIED TO THE PATIENT (BODY)
	TYPE BF FLOATING PART APPLIED TO THE PATIENT (BODY-FLOATING)
	SEPARATE COLLECTION OF WASTE ELECTRICAL/ELECTRONIC EQUIPMENT

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5 GENERAL INFORMATION

The piezoelectric effect in natural crystals was observed for the first time by Pierre and Jacques Curie in 1880. They showed that certain types of crystals (quartz, tourmaline), when deformed by mechanical causes, generate an internal electric field. Vice versa when an electric field is applied to these crystals, mechanical distortion of the material occurs. Some ceramics, treated in an appropriate way using a polarisation process, acquire the piezoelectric properties of natural crystals. These ceramics, obtained using up-to-date technology, are defined as piezoelectric. The BIOLINE probe contains a piezoelectric ceramic which, when stressed with an electrical impulse “vibrates” at the frequency of 10 megahertz (10 million oscillations per second). This movement of the ceramic transducer generates an extremely low energy ultrasound wave which crosses the cornea, aqueous humor and any other objects or tissues found along the signal propagation pathway. The ultrasound wave partly crosses the obstacles and is partly reflected by the latter towards the source (namely the actual transducer). It takes this reflected energy a certain amount of time to turn towards the transducer and this time is proportional to the distance from the obstacle. The measurement of this time and the experimental knowledge of the speed of the echo, allow the distance from the object (the retina for example) from the emitter (probe tip) to be mathematically calculated. The characteristics of the return echo are then processed by a fast microprocessor which detects its reliability for measuring purposes (automatic acquisition).

5.1 SYSTEM DESCRIPTION

The portable BIOLINE - OPTIKON 2000 Biometer – is a portable microprocessor-based instrument for measuring the axial length of the eye and for calculating the intraocular lens appropriate for restoring emmetropia, after removing the cataract.

Reliability, versatility, accuracy and simplicity, together with an attractive and functional design, make this a unique instrument among the various models available on the world market.

The principal functions are activated by a few dedicated keys. All the other parameters can be changed by using the four lateral arrows. Presentation of the echo in real time allows the operator to line up the probe easily even in the most difficult cases. In order to carry out the measurements more easily it is possible to select signalling with voice synthesis of standard deviation, in addition to traditional signalling with acoustic tones. Finally the internal thermal printer provides an accurate recording of the measurements taken as well as the parameters relating to the selection of the intraocular lens.

5.2 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATIONS
Manufacturer:.....	OPTIKON 2000 S.p.A. via del Casale di Settebagni, 13 00138 Rome - Italy
Model:.....	BIOLINE
Regulatory compliance:	93/42/EEC Medical Devices Directive (MDD)
Technical standards:	EN 60601-1 ; EN 60601-1-1 ; EN 60601-1-2 ; EN 60601-2-2
ENVIRONMENTAL SPECS	
Storage:	temp range -10°C to +70°C, humidity 10-100% (non condensing)
Operation:.....	temp range +10°C to +40°C, humidity 30-75%.
ELECTRICAL SPECS	
Input voltage:	100/120 or 220/240 Volt AC
Frequency:.....	50/60 Hz
Power consumption:	24 Watt Max
Line fuses	N.A.
Supplier protection:.....	automatic thermal switch
Instrument protection:.....	automatic thermal switch

PARAMETER
SPECIFICATIONS

TECHNICAL SPECIFICATIONS

Probe: piezoelectric with fixing light, which can be assembled on tonometric slide

Frequency: approx. 10 MHz

Clinical accuracy: 0.1 mm.

Resolution: 0.06 mm.

Field of measurement: 18-36 mm.

Screen: Liquid crystals 240x128 dots.

Speed of presentation: 20 frames per second.

Printer: 40 columns - 320 dots, thermal.

Modes of measurement: Automatic and manual.

Measurements in the memory: up to 5 with indication of average and standard deviation

Echo amplification: Manual in 7 levels or Self-regulation

Calculation formula: SRKII , Haigis, Holladay, Gernet, SRK/T

Lens memory: Up to 15 lenses, with relating storable parameters

Acoustic signalling: Sound or voice synthesis, selectable

Outputs

For computer: RS232, with 9 pin connector.

For the optional footswitch, with 2 way jack

Acoustic Output Parameters according to IEC/EN/DIN 61157 standard

See page 5-4

Acoustic Output Parameters according to IEC/EN/DIN 61157

Manufacturer: Optikon 2000 SpA

Device: Bioline (ref.141002)

Transducer: Biometry probe, 10 MHz (ref.143001)

Parameter	Unit	Mode A
Maximum Power	[mW]	0.003 ± 0.001
Peak negative acoustic pressure [p]	[MPa]	1.3 ± 0.14
Output beam intensity [I_{OB}]	[mW/cm ²]	0.006 ± 0.001
Spatial peak temporal average intensity [I_{SPTA}]	[mW/cm ²]	0.2 ± 0.04
Focal length [f_p]	[mm]	22.6
Pulse beam width (6 dB, parallel) [$w_{pb6} \parallel$]	[mm]	0.75
Pulse beam width (6 dB, orthogonal) [$w_{pb6} \perp$]	[mm]	0.82
Pulse repetition rate [prf]	Hz	20
Scan repetition rate [srr]	Hz	---
Output Beam Dimensions	[mm]	3.1
	[mm]	3.4
Arithmetic-mean acoustic working frequency [f_{awf}]	[MHz]	10.8
Transducer to transducer output face distance [t_t]	[mm]	---
Transducer standoff distance [t_s]	[mm]	Contact
Power up fraction		100 %
Acoustical initialization fraction		100 %
Power up mode		Default
Initialization mode		Default
Freeze output		Yes
Modes included		---
Control settings		---

EQUIPMENT CLASSIFICATION ACCORDING TO IEC 601-1

Type of protection against
electrical discharge: Class II

Degree of protection against electric shock
U/S: type BF

Degree of protection against
harmful ingress of water: IPX1

Degree of safety of application
in the presence of a flammable
anaesthetic mixture: not applicable

DIMENSIONS

Height: 15 cm
Width: 23 cm
Depth: 29 cm
Weight: 2.2 Kg

NOTE:

- 1) Weight and dimensions shown are approximate.
- 2) Specifications are subject to change without notice.

5.3 CIRCUIT DIAGRAMS

OPTIKON 2000 S.p.A. will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are repairable.

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6 INSTALLATION

6.1 INTRODUCTION

This section details the recommended procedure for installing and checking the operational functions of the BIOLINE unit.

The operational checks, however, which are performed after the system installation to verify equipment operation, must be performed exactly as indicated and should not be regarded as recommended practice or encouragement for any diagnostic procedures.

To bring your biometer in operation, a series of cable, footswitch and probe connections must be made.

Follow the installation and operating instructions carefully in a step by step manner and, within a short time, you will have gained all the knowledge needed for successful operation of your biometer.

6.2 UNPACKING AND INSPECTION

This unit has been packaged to minimize the risk of damage in shipment. Unwrap the package and examine the components. Handle all components with care during unpacking. Use caution cutting the wrapping to ensure that the cut does not penetrate the packing and damage the components. If external or internal shipping damage is discovered, notify the carrier (mail, railways or forwarding agents) and Optikon 2000 as soon as possible. Check the contents against the packing list and notify Optikon 2000 immediately of any discrepancies.

6.3 INSTALLATION PROCEDURE

NOTE

The operator is responsible for cleaning and disinfecting probes and reusable accessories

The following procedure should be observed to install the system:

Position the instrument in a comfortable way.

Insert the footswitch jack (optional) in the rear panel.

Insert the AC/DC adaptor in the 220 volt socket and the 12 volt connector in the rear panel.

Connect the biometry probe to the front panel.

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7 EQUIPMENT OPERATION

7.1 EQUIPMENT LAYOUT



FRONT PANEL (FIG.1)

1) LIQUID CRYSTAL DISPLAY (LCD)

Flat screen for presenting graphics and measurements. This screen has the characteristic of being fully legible in solar light as well as in poorly lit surroundings, thanks to backlighting. For maximum performance, position the instrument facing the observer. Adjust the contrast and brightness to the best possible setting.

2) CLEAR KEY

On the measurement page, by pressing the CLEAR button once, the graphic displayed is cancelled and the relating measurement cleared. To cancel all five measurements in the memory press the CLEAR key a second time. Make sure that all the measurements have been cancelled before starting with a new patient (eye).

3) A-SCAN KEY

Displays the measurement acquisition page with the relating A-SCAN graphic. In the course of acquisition this same key alternately starts and ends the acquisition.

4) IOL KEY

Displays the page for calculating the intraocular lens, with results which also relate to correction with spectacles or contact lenses. On the calculation page it selects the 2 principal lenses alternately.

5) D-BASE KEY

Not active in this version. Prepares any interface with an external computer for patient archiving.

6) SET KEY

Displays the page for setting up the instrument. On this page all the settings for the lens constants and the biometric examination can be cancelled, and the language for printing the user guide can be selected.

7) PRINT KEY

Sends the printer the results of the biometry and the IOL calculation.

8) ON LED

This indicator signals the presence of supply voltage when the rear switch is in the ON position.

9) POINT/ ENTER Key

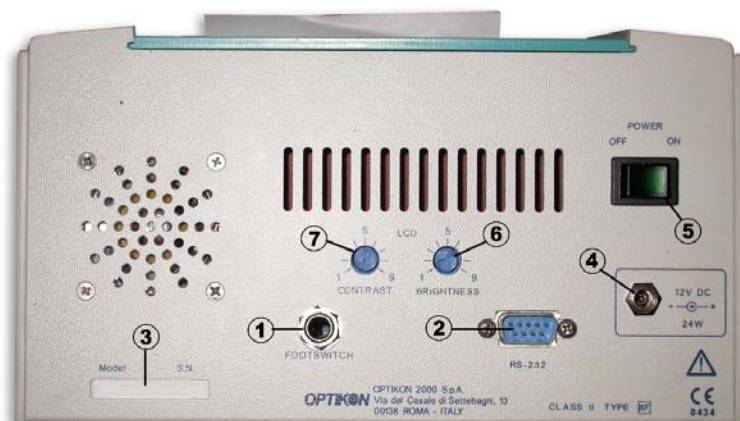
Press this key to confirm and close the selection of parameters indicated on the screen.

10) PROBE SOCKET

Input for the biometry probe connector.

11) ARROW KEYS

These are general use keys for changing and entering data. In general, the vertical arrows are used to select a parameter from those displayed on the screen; the horizontal arrows, on the other hand, are generally used to change the value of the parameter selected.

**REAR PANEL (FIG.2)****1) FOOTSWITCH SOCKET**

Input for the footswitch connector (optional). The footswitch closes down and reactivates the biometric measurement on the acquisition page (in a similar way to the A-SCAN key).

2) RS232 CONNECTOR

Socket for possible connection to a computer (not supported by the current version of the programme).

3) PLATE

Shows the data on the instrument plate and the serial number.

4) SUPPLY INPUT

Input socket (low voltage) for connection to the feeder model 142001/142002 or to another source with equivalent characteristics.

5) MAIN SWITCH

Activates and deactivates the instrument supply (display of the symbol "O" indicates the off position).

6) BRIGHTNESS CONTROL

This small potentiometer allows the back lighting of the screen to be adjusted from 1 to 9. Adjust to achieve good screen visibility.

7) LCD CONTRAST

This small potentiometer allows the screen contrast to be adjusted in an optimum way, depending on the visual angle of the screen.

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8 OPERATION

8.1 AUTOTEST SESSION

Turn on the instrument using the switch at the back. The instrument automatically carries out certain tests, then records the following information on the screen:

- **SELF TEST:** Shows the result of the system test (normally Passed otherwise the error code ERR.XXX).
- **PRINTER:** Indicates whether the printer is connected (Ready or Absent)
- **PC-LINK:** Indicates whether the connection via RS232 to the personal computer has been found (Ready or Absent).
One of the sessions indicated in the line at the bottom of the screen can be selected from this page: A-SCAN - IOL -HELP. A simple command memo can be printed by pressing the PRINT key or the paper can be pushed forward by pressing the key "Arrow up" (useful for loading a new roll).

NOTE:

If the self test identifies an error in the memory, a warning message is displayed, before you proceed to cancel the whole memory:

"DELETE ALL DATA IN MEMORY?: YES". Press the Enter key. The data on the intraocular lenses must then be re-entered by the operator.

8.2 A-SCAN MEASURING SESSION

In the A-scan session, the display shows either the parameters for selecting the operating mode or the results of the individual biometry. In addition the average of a maximum number of five biometries and the resulting standard deviation is indicated in large figures.

It is possible to bring up each of the 5 measurements taken and the relating graphs, by pressing the left and right arrow keys.

The keys lined up under the display allow the most frequently used functions to be activated.

The A-scan session page provides the following information:

- The moving A-SCAN graphic allows the operator to check that the probe is correctly lined up during the examination. After the image is automatically frozen the A-scan graphic helps to evaluate the quality and accuracy of the measurement. Two arrow-shaped symbols known as markers indicate the base of the corneal peak and that of the retina respectively, from which the axial length of the eye is calculated.
- The length of the anterior chamber (AC) the thickness of the lens (LNS) and the axial length (AXL).
- If the mode is manual (MODE = MAN.GATE) or the eye is aphakic, only the axial length AXL is indicated. All the measurements are in millimetres.
- The average of the measurements stored (up to 5). This is indicated in larger figures; under the average axial length the number of averaged measurements (AVG = nSamples with n from 1 to 5) is indicated. It is advisable to take from three to five measurements per patient. The accuracy of the measurements is deduced from the standard deviation (indicated as +-x.xx in small figures, to the right of the average). The standard deviation can be indicated vocally if the mode PRMT:VOX is selected.
The standard deviation of a series of accurate measurements must not exceed +/-0.3 mm. It is possible to increase the accuracy of the average by taking new measurements. If 5 measurements have already been taken (maximum number), the new measurement automatically replaces the worst of those in the memory.

8.3 A-SCAN KEY FUNCTIONS

In order to simplify the use of the instrument very few keys have been used. Some of these are reserved for the most frequent operations. In the A-scan session the keys have the following functions:

- **CLEAR** Clears the A-scan graphic and the measurement displayed on the screen. By pressing the CLEAR key again all the measurements in the memory are cleared; the latter operation generally precedes the examination of the other eye or that of a new patient.

NOTE: It is possible to recover measurements cancelled by mistake. To do this turn the instrument off immediately after any cancellation and then turn it back on.

- **ASCAN...** Starts or interrupts the acquisition of the A-scan. The same function can be carried out using the optional footswitch. The two modes are indicated

by the following wording on the screen: RUN X and STOP X respectively, with X from 1 to 5

Activation starts up a series of 5 measurements interspersed by a brief pause. After the acquisition of the fifth measurement a dual tone indicates that the series of measurements has been completed.

- **ARROWS** <— and —>: The 5 memories available for biometric measurements are brought up in succession. (The measurement is automatically saved when it is taken).
- **IOL**: Forwards to the lens calculation session. The axial length obtained from the average of the measurements (indicated by AVG) is automatically sent on to the calculation page.
- **SET**: Allows certain configuration parameters to be reset. The configuration menu allows either cancellation of all the data stored about the lenses, or selection of the language (English or Italian) for any printing out of the rapid user guide.
- **D-BASE**: Forwards to the archiving session if the connection with an external personal computer is present (via port RS232). If the connection is not present, the autotest page is displayed.
- **PRINT**: Starts up the printing of the graph and the biometry results. If several measurements are displayed the one closest to the average is displayed and sent to be printed.

8.4 SETTING UP THE A-SCAN EXAMINATION

The operating parameters (EYE, MODE, GAIN, PRMT) indicated at the bottom left of the screen, can be displayed one at a time and modified as follows:

1. Press the ENTER key or the vertical arrows; in this way one parameter for the input is displayed.
2. Now press the up-down arrows again to move to the desired parameter. Use the left-right arrows to change the value of the parameter.
3. Finally press the Enter key to close the input and return to operating mode.

The parameters of the A-SCAN session are as follows:

- **EYE** : Specify OS-REF, OD-REF, OS, OD, to indicate, respectively, reference Left Eye and reference Right Eye, Left Eye (principal), Right Eye (principal). The selection of a reference eye prior to examining the

principal one, allows the axial measurement of this eye to be retained, even after the double CLEAR . At the time of printing, the measurement of the reference eye is indicated together with the axial measurement and the A-Scan graph of the principal eye.

- **MODE** : Defines the conditions for acquiring the measurement
- **APHAKIC** : Enables automatic acquisition for an aphakic eye. If peaks are revealed in the lens zone the message "MODE ERR" (mode error) is indicated.
- **PHAKIC** : Enables automatic acquisition with non-cataractic lens.
- **CATAR.** : Enables automatic acquisition with normal or cataractic eye.
- **PS.PHAK.:** Enables automatic acquisition in the case of an artificial lens
- **WB.CATA.:** For immersion examination (without direct contact between probe and cornea). Enables automatic acquisition in the case of a normal or cataractic lens
- **MAN.GATE:** Mode with manual acquisition via A-SCAN or footswitch key. In any event an automatic procedure for identifying the type of eye (phakic or aphakic) is active for the correct calculation of axial length. If the A-scan is frozen it is possible to measure the axial length relating to peaks other than the one indicated by the marker (small arrow at the base of the peak). To move the marker to another peak, display EXAM = "MAN.GATE" (vertical, then horizontal arrows) then press the key → . The marker moves to the next peak and the measurements AXL and AVG will be updated as a result. Finally press Enter to confirm the measurement indicated and return to operating mode.

NOTE: AFTER ACQUIRING THE A-SCAN IN ONE OF THE AUTOMATIC MODES, IT IS HOWEVER POSSIBLE TO MOVE TO "MAN.GATE" MODE IF YOU NEED TO SELECT A DIFFERENT RETINAL PEAK.

- **GAIN.:** Selects the level of echo amplification; from MIN (minimum) to MAX (maximum) in seven levels. "MED/HIGH" or "MED." are the values normally recommended. There is also the option "GAIN = AUTOSSET" which allows automatic adaptation of the amplification to optimum level.
- **PRMT.:** Selects the acoustic signalling mode: BEEP for tone signalling, VOX for voice signalling of the standard deviation.

8.5 IOL CALCULATION SESSION

This session allows the power of the intraocular lens, spectacles or contact lens to be calculated after having specified the two keratometric constants K1 and K2. The axial length is sent directly from the A-scan session. The type of lens can be selected from a group of 15 lenses distinguished from one another by their respective serial number.

The following three values are associated with each lens:

1. ACD : length of the anterior chamber (used in the theoretical formulae).
2. A: Constant A (used in the SRK formula).
3. SF: Surgeon Factor (constant used in the HOLLADAY formula). If SF = -9.99 the value of SF is taken from the constant A of the lens. Specify -9.99 if SF is not known.

The aforementioned constants can be changed and remain stored with the relating lens. The result of the calculation is a table with 5 values, power and refraction, graded in half diopters. The powers of the contact lens (CONTACT) and the spectacles (APHAKIC) are also indicated.

An alternative method of inserting the keratometric constants K1, K2 is available in the form of corneal radius of curvature (in mm), rather than dioptres. In order to select the format of these values, enter on the preset page by pressing the SET key.

Use the arrow at the bottom in order to move to the last row " K READINGS UNITS:"; select using the horizontal "DIOPTERS" arrows for dioptres or "RADIUS MM" for corneal radius of curvature.

Press the Enter key to finish.

On the IOL calculation page, the two rows at the bottom will indicate K1 ,K2 for the dioptre format or R1, R2 for the radius of curvature format, depending on the previous selection.

NOTE: THE MEMORY OF THE LENSES, THE RELATING CONSTANTS AND THE SETTING OF THE A-SCAN, IS SUPPLIED BY AN INTERNAL 3.6 VOLT LITHIUM BATTERY, LASTING FOR APPROXIMATELY TEN YEARS. IF THE BATTERY RUNS DOWN THIS WILL NOT PREJUDICE THE EXAMINATION PROCEDURE OR ITS ACCURACY.

8.6 FUNCTION OF THE KEYS IN THE IOL CALCULATION

- **A-SCAN:** Returns to the A-Scan session.
- **PRINT:** Sends the results of the IOL calculation for printing
- **IOL:** Selects one of the two principal lenses, alternately. This key allows the immediate recalculation of the power-refraction table for the lenses normally used, referred to as principal lenses. To select the two principal lenses from among the 15 available ones, simply:
 - 1) Display the "IOL" field (using the up-down arrows)
 - 2) Bring up the desired lens (right-left arrows)
 - 3) Press the IOL key to store the first principal lens.

Repeat the above for the second lens and end by pressing Enter.

- **D-BASE:** Forwards to the archiving session if there is a connection with an external personal computer (via port R5232). If there is no connection, the autotest page is displayed.

NOTE: THE AFOREMENTIONED KEYS ONLY WORK IF NO FIELD IS DISPLAYED. IN ORDER TO TERMINATE THE INPUT FROM A DISPLAYED FIELD, PRESS THE ENTER KEY.

8.7 SETTING UP THE IOL CALCULATION

In order to change the parameters (type of lens, constants A, ACD, SF K1, K2, AXL, power PW and refraction RF), use the group of keys on the right of the screen.

First of all select the parameter to be changed (up – down arrows), then use the right- left arrows respectively in order to increase - decrease the value displayed. Press Enter to confirm the value.

If the value is a number with an integer part and a decimal part the cursor moves to the decimal part. Use the keys <-- and --> again to change the decimal figures and end with Enter, or move to another parameter requiring a change.

Prolonged pressure on the keys <-- and --> produces a rapid increase and decrease in the number displayed.

If the input of one parameter is closed (using the Enter key), the PW-RF table is recalculated.

8.8 PROBE TEST

It is possible to carry out a test to check the functioning of the probe and the accuracy of the biometric measurement. To this end a small tube of transparent plastic 149001 is supplied on which the value of the measurement test is indicated in millimetres together with the tolerance (+/-0.1mm.)

N.B.:

The tube material (plexiglas) is subject, like all materials, to thermal expansion. Consequently the value indicated on the tube refers to a tube surrounding temperature of between 20 °C. and 25 °C. For values of below 20°C, 0.1mm must be subtracted from the nominal value indicated on the label. For values higher than 25°C, 0.1 mm must be added to the nominal value indicated on the label.

E.g.: If the value indicated on the label is 20.8 mm and the surrounding temperature is higher than 25 °C., the reference value becomes 20.9 mm. Taking into account the tolerance of +/- 0.1 mm, we should expect an indication on the instrument of between $20.9+0.1=21.0$ mm and $20.9-0.1=20.8$ mm.

Under no circumstances must the temperature of the tube exceed 30°C because in this circumstance the attenuation of the signal does not allow automatic acquisition. The recommendation is therefore to place the tube on a flat surface without handling it or holding it back with the fingers for the strict time required for the measurement.

The procedure to be followed is as indicated below:

- 1) Enter the A-SCAN session (by pressing the A-SCAN key).
- 2) Cancel all the measurements (by pressing CLEAR twice)
- 3) Select the amplification GAIN=MED-HIGH
- 4) Select the aphakic mode MODEAPHAKIC
- 5) Place a drop of ultrasound gel on the surface of the probe and smooth it out on the tube.
- 6) Activate acquisition by pressing the A-SCAN key or footswitch

If the alignment is correct you will obtain an echo of maximum width with the consequent automatic acquisition of the measurement. If the width of the echo was not sufficient for "autofreeze", try to set GAIN= HIGH and if possible MAX. Check that AXL (or AVG in the event of several consecutive measurements) complies with the tube reference value.

At the end of the test reset MODE and GAIN in the normal way.

8.9 SHUT DOWN PROCEDURE

NOTE:

If the equipment is not being used for an extended period, the following procedure should be observed:

- 1) Depress the "POWER" switch to the "OFF" position to switch off the control console.
- 2) Refer to the chapter "Cleaning, sterilisation and maintenance".

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9 CLEANING, STERILISATION AND MAINTENANCE

The medical personnel must take the responsibility to keep existing instruments and equipment functioning properly. The following simple steps serve as practical guidelines in establishing your care and maintenance program.

9.1 CLEANING

9.1.1 UNIT

- 1) Periodically clean the touch screen LCD with soft dusting cloth dampened with distilled water. If necessary use only neutral detergent.
- 2) Do not use alcohol, solvents, or abrasives on the control console.

9.1.2 ACCESSORIES

Treat the accessories as indicated above

9.2 STERILISATION

9.2.1 UNIT

The console and footswitch do not need to be sterilised. For cleaning please refer to the indications given in the relevant instructions for use.

9.3 MAINTENANCE

9.3.1 UNIT

- 1) The BIOMETER should be stored in a clean and dry environment at room temperature.

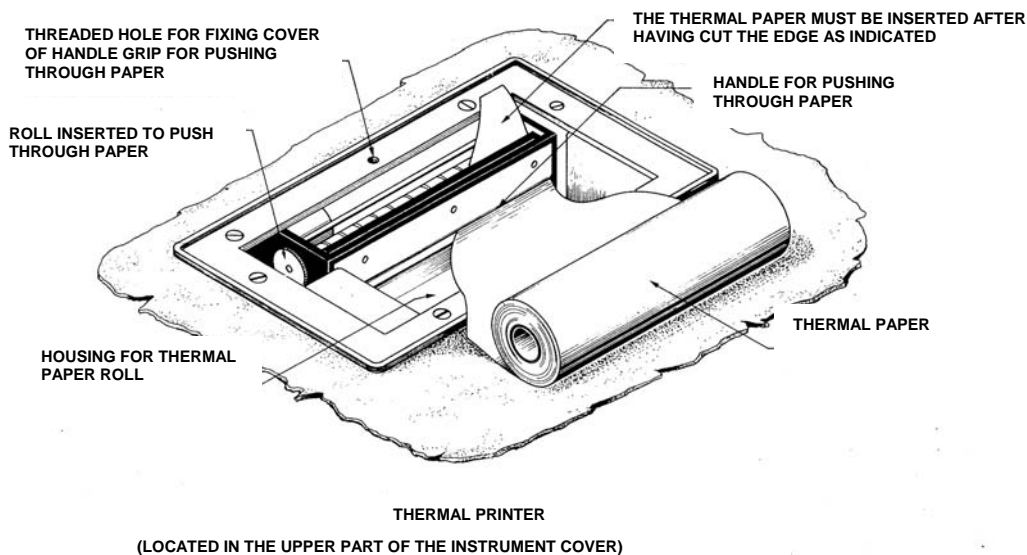
NOTE:

To maintain system safety, the compliance to EN60601-1 leakage current limits should be tested at least once a year. Please, inquire with the Bioengineering Department in your clinic or with your local Optikon Distributor/Service Center.

9.3.2 ACCESSORIES

- 1) Avoid dropping or mishandling probes and accessories. It is critical that these components be handled with outmost care and inspected thoroughly after each use for any damage or wear.
- 2) Place the probes in the appropriate holder after each use. Avoid propping up the probe on the table: if it falls over the point could be damaged, putting it out of use.
- 3) Place the protective caps on the probes when not in use for long periods.

9.3.3 REPLACEMENT OF THE PRINTER PAPER



THERMAL PRINTER (FIG.3)

A red strip on the edge of the print indicates that the roll will soon run out (approximately 1.5 metres remaining). To load a new roll of thermal paper, follow the procedure indicated below:

- 1) Turn off the machine and cut off any excess paper.
- 2) Remove the panel-paper cutter.
- 3) Take out the empty roll.
- 4) Insert one edge of the new roll in the internal slot, as indicated in fig. 3.
- 5) Switch on the instrument and press the UP arrow key to push the paper forwards, until it comes out of the upper part. You can also push the paper through when the instrument is switched off, by rotating the relevant roll (fig. 3).
- 6) Insert the roll in the appropriate compartment; close the panel-paper cutter, after having pushed the paper out of the appropriate slot.

NOTE: If the instrument is not being used for a long period of time, it is advisable to pull through a few centimetres of paper manually prior to use.

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10 TROUBLESHOOTING GUIDE

PROBLEM	INTERVENTION
The instrument cannot be switched on (the green "ON" light is out)	Push the rear supply connector firmly into place. Check the socket and the rear switch
The screen is too dark or too light and is not legible	Adjust the contrast using the rear blue "LCD" handle
After the autotest the following message appears: "RAM ERROR RECOVERY- DELETE ALL DATA IN MEMORY?"	Electrostatic discharge or interference caused by electronic equipment has damaged the memory. Switch off or move the equipment away; or the internal battery has run out. See chapter 2-3
DURING MEASURING...	
The instrument does not respond to keyboard commands	<ol style="list-style-type: none"> 1) The instrument is awaiting inputs relating to a selected field: press Enter 2) The printer is in operation; wait until the printing is completed
The instrument is not freezing	Make sure that the mode selected is correct and that the A-scan key has been pressed to start off the acquisition
The instrument finds it difficult to freeze	During the examination check the message displayed in the top left of the screen. Increase or decrease the GAIN. If GAIN = AUTOSET select MED/HIGH.
The average axial measurement (large figures) seems unreliable	Make sure that you have pressed the CLEAR key twice prior to the series of measurements. Check the ACD, LNS and AL reliability of each measurement in the memory.

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