



PACLINE
PORTABLE PACHYMETER

***Installation and
operating manual***

OPTIKON 2000 S.p.A.

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WARNINGS



The following warnings will aid the user to provide adequate safeguards to assure safe, troublefree performance:

1. ALL MEDICAL PERSONNEL SHOULD READ AND UNDERSTAND THE INSTRUCTIONS IN THIS MANUAL BEFORE THE SYSTEM IS USED. DO NOT ATTEMPT TO USE THE SYSTEM IF IT FAILS TO PERFORM AS SET OUT IN THE OPERATION PROCEDURES, IN THIS MANUAL.
2. 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 INSTRUMENT AND MAKES NO MEDICAL RECOMMENDATIONS.
3. THE SYSTEM SHOULD NEVER BE USED IN THE PRESENCE OF FLAMMABLE ANAESTHETICS, DISINFECTING AGENTS, CLEANING AGENTS, ETC., DUE TO POSSIBLE FIRES OR EXPLOSION.
4. THE PACHYMETER PROBE IS DELIVERED **NOT STERILIZED** AND IT IS **NOT DISINFECTED**. THE PROBE MUST BE DISINFECTED OR STERILIZED BY THE USER BEFORE EVERY USE.
5. DO NOT SUBJECT THE PROBE TO HOT AIR STERILIZATION, CHEMCLAVE OR AUTOCLAVE. GAS STERILIZATION UP TO 60°C CAN BE TOLERATED BY THE PROBE.
6. THE PROBE HANDPIECE MUST BE HANDLED WITH CARE. FALLS AND SHOCKS CAN EASILY CAUSE PERMANENT DAMAGE TO THE TRANSDUCER.

7. FOR OPERATING SAFETY, DO NOT INSTALL THE SYSTEM IN A LOCATION WHERE IT WILL BE EXPOSED TO HEATING EQUIPMENT OR RADIATORS, DIRECT SUNLIGHT, AND ANY OTHER SOURCE OF HIGH TEMPERATURES.
8. NON SOTTOPORRE LA SONDA A STERILIZZAZIONE AD ARIA CALDA O ADAUTOCLAVE CHIMICA.
9. OPTIKON 2000 GUARANTEES ELECTRICAL SAFETY ONLY WHEN THE CONSOLE IS CONNECTED TO THE ORIGINAL AC/DC ADAPTER.
10. DO NOT OPEN THE CONSOLE ENCLOSURES. THERE ARE NO USER ACCESSIBLE PARTS INSIDE THE INSTRUMENT. INTERNAL DEVICES MUST BE SERVICED BY QUALIFIED SERVICE PERSONNEL.
11. TURN OFF THE MAIN POWER SWITCH WHENEVER THE INSTRUMENT IS NOT IN USE.

1.1 SYSTEM DESCRIPTION

The Optikon 2000 Pacline is an advanced, microprocessor based, portable unit, for the measurement of the thickness of the cornea .

The measurement technique is not dangerous for the patient, as it is based on small ultrasounds pulses, emitted by the probe piezo transducer.

The Optikon 2000 Pacline operates with time saving semplicity and it is very easy to use, nevertheless we strongly recommend to read this manual to get the best performances from the instrument. After that, the short instruction summary printed by the instrument (pushing the HELP key), will be clear enough to operate, in most of the cases, without consulting this guide.

1.2 BASIC PACKAGE

The Pacline basic package includes:

- 1 Pachymeter console
- 1 Solid tip probe, 20 Mhz
- 1 AC-DC adapter
- 1 Transportation bag.
- 1 User manual
- 2 Rolls of thermal paper

If physical damage is found on any parts, immediately notify the damage to the carrier and to Optikon 2000 Sales office for replacement.

KEEP UP TO DATE!

Registration form is on the last page of this manual. Mail or fax this completed form today to receive new product data and new literature when issued.

1.3 INSTALLATION

The following procedure should be observed to install the system:

- 1) Place Pacline pachymeter on a secure plane. The handle of the instrument can be pulled outward at the sides and rotated to be used as an adjustable support ; orientate the console in a convenient position.
- 2) Check that the voltage supply indicated on the AC-DC adapter corresponds to the value used in your country, then insert the connector to the rear panel (12V).
- 3) Connect the optional footswitch
- 4) Fix the adhesive probe support in a comfortable position (We suggest the external side of the console handler)
- 5) Insert the probe connector into the PACLINE front panel .



2.1 PACLINE PACHYMETER OPERATION

THE AUTO-PRIMING AUTO-CHECK PAGE

Depress "POWER" switch, located on the rear panel to turn ON the instrument.

The PACLINE performs an automatic priming and check of the instrument connections and resources, then it reports the current status on the screen:

SELF TEST: This is the hardware check test report (if no fault is found: Passed, otherwise the error code ERR XXX is reported).

PRINTER: Reports if the printer has been recognized (Ready or Absent)

PC-LINK: Reports if a connection to a personal computer is detected on the RS232 rear panel connector (Ready or Absent)

In Test page, the following keys can be used:

CLEAR: enters the pachymetry operating page

SAVE: enters the parameters setting page

PRINT: prints a summary of the main instructions

UP arrow: advances the printer paper

In the parameters setting page, it is possible to reset all the parameters and the programmed maps. The reset operation can be required in case of upgrade of the internal program, (to be done from technical personnel).

2.2 PACHYMETER OPERATING PAGE

This screen page contains all the informations and settings required to make the corneal map thickness examination.

This means to acquire, each one of the points indicated by a cursor, on the map.

The screen is subdivided in three areas: on the left ,the map pattern is displayed, in the middle the echoes from the probe with the position number, and on the right the operating parameters and the average thickness (AVG) in micron followed by the standard deviation.

When entering the operative page, the PACLINE starts automatically the acquisition phase, without the need of a "start " footswitch.

The message "SEARCH" flashes on the LCD screen indicating the instrument is ready to measure.

The probe can be placed now on the cornea waiting for autofreeze.

A short sound prompts the measure is ready.

A short pause of two seconds follows, allowing the operator to evaluate the result, to save it and to move the probe on the next point.

When all the map points are acquired, two consecutive tones alert the end of the examination and the cursor resets to first map position.

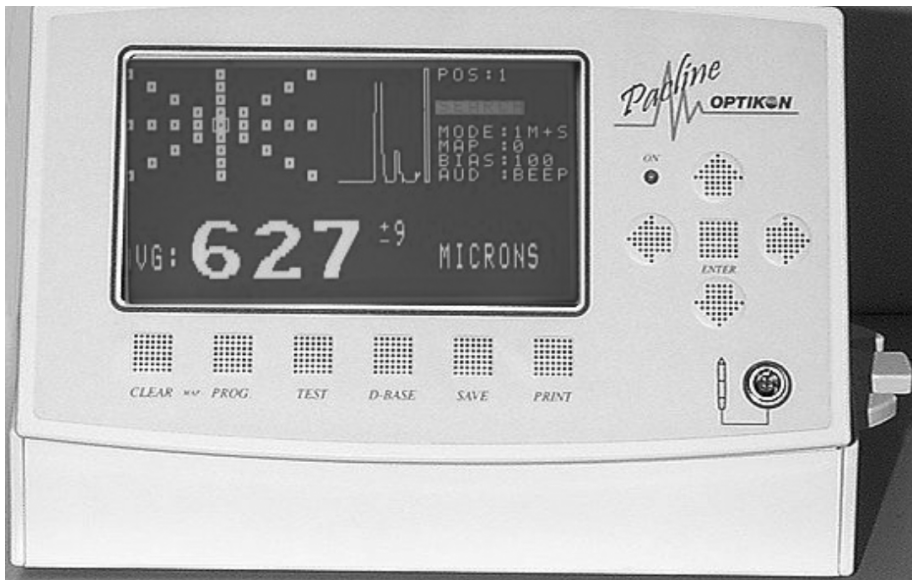


FIG.1 FRONT PANEL

Keyboard functions in the operative page:

- CLEAR:** cancels all the points of the map (for a new examination)
- PROG:** enters the map programming page (see chapter 3.1)
- TEST:** enters the probe testing page (see chapter 4.1)
- SAVE:** save the actual AVG measure; the cursor steps on the next point.
- PRINT:** makes a printout of the map with thickness scaled by the bias factor
- LEFT/RIGHT arrows:** move the cursor on the map, decrementing/incrementing the position number. The AVG and echoes relative to that position are displayed.
When a parameter is pointed out, the horizontal arrows work in a different mode: they change the parameter value, not the position on the map.
- UP/DOWN arrows:** select the parameter field (MODE, MAP, BIAS, AUDIO) to be changed.
- ENTER:** confirms the value of the parameter pointed out on the screen and returns to acquisition mode. On the contrary, if none of the parameters is selected, the ENTER key selects a parameter.
- FOOTSWITCH:** works as the SAVE key.

2.3 SETTING THE OPERATING PARAMETERS

The operating parameters allow to personalize the procedure for different needs and examination techniques . The operating parameters should be set once for all or can be changed before a new patient. To change a parameter, press UP or DOWN arrows and repeat until the desired parameter field is reached. The selected field is displayed in reverse mode (dark background). Then push the RIGHT or LEFT arrow to change the parameter value, conforming to your requirements. Finally push the ENTER key to end the selection.

The following is a list of the available parameters settings:

MODE= Acquisition mode

Three modes available:

1M- - : manual saving on 1 Measure

The operator can save manually the measure in memory, pushing the SAVE key (or the footswitch).

In this case, the relative box on the map is filled and the map pointer steps to the successive position.

1M+S: Autosaving mode. Autofreezes on 1 Measure

Then, SAVE operation is accomplished automatically without the operator intervention.

2M+S: Averaging mode

Two measure are required on the same point to make the automatic average.

If the two measure are reasonably dose (+/- 10 microns), the save operation occurs automatically after the second acquisition, otherwise another measure is required.

MAP= Map Number

Standard maps (from 0 to 3) and programmable maps (from 4 to 13) can be selected.

The map display is composed of standard position markers (+) and programmed points markers (square box). The box is filled when the relative measure has been saved.

BIAS= Scaling factor for the printout.

All the saved thickness are percentually scaled by the bias value.

The bias value affects only the printed out thickness, not the values displayed on the screen.

The bias value can be incremented or decremented in steps of 1 (%).

AUDIO= Acoustical prompting

At autofreeze, it is possible to activate sound prompting as well as vocal prompting.

Change to VOX for the speech of the thickness or select BEEP for acoustical tones.

3.1 MAPS PROGRAMMING

This page of the screen allows to built custom maps. Ten maps are available for programming, ranging from number 4 to 13. Push the key Program to enter the programming page. The first map available (among the unprogrammed ones) is automatically displayed, then the PROGRAM MENU is prompted indicating the keys to be used:

KEY name	Action
CLEAR:	Cancels all the programmed points (displayed as empty boxes).
ENTER:	programs the point indicated by the cursor, draws a box in the map.
LEFT/RIGHT arrows:	move the cursor back/forward in the map area.
PROG:	Terminates the map programming session, returning to acquisition mode.

Use the Left/right arrows to move the square cursor over the first desired point of the map, then press ENTER. Repeat, as above, for all the other points.

In case of mistake, the map must be cleared (CLEAR) and reprogrammed from the first point.

It is important to program the points respecting the measurement sequence .

If nothing happens pushing "PROG", this means that the displayed map is not programmable (number 0 to 3 are fixed maps); in this case, select a different map number.

4.1 PROBE TEST

In the operating page, the autofreezing can be checked by using the tester supplied with the probe.

Wet the probe tip, then insert the tip in the cavity and softly touch the black membrane; move gently the probe until autofreezing occurs.

The measurements can be saved on the map as well as printed.

The supplied tester is not useful to test the instrument calibration.

To test probe efficiency and instrument calibration use a glass full of water.

Softly touch the water surface with the tip, push the TEST key when ready, avoid moving the probe during the test phase.

If test is unsuccessful, try to modify the probe inclination and press TEST key again.

If Test is passed, the PACLINE prompts the message "PROBE OK" on the screen and a series of measurements starts, followed by some "beeps".

During the test, probe echoes are displayed on the screen.

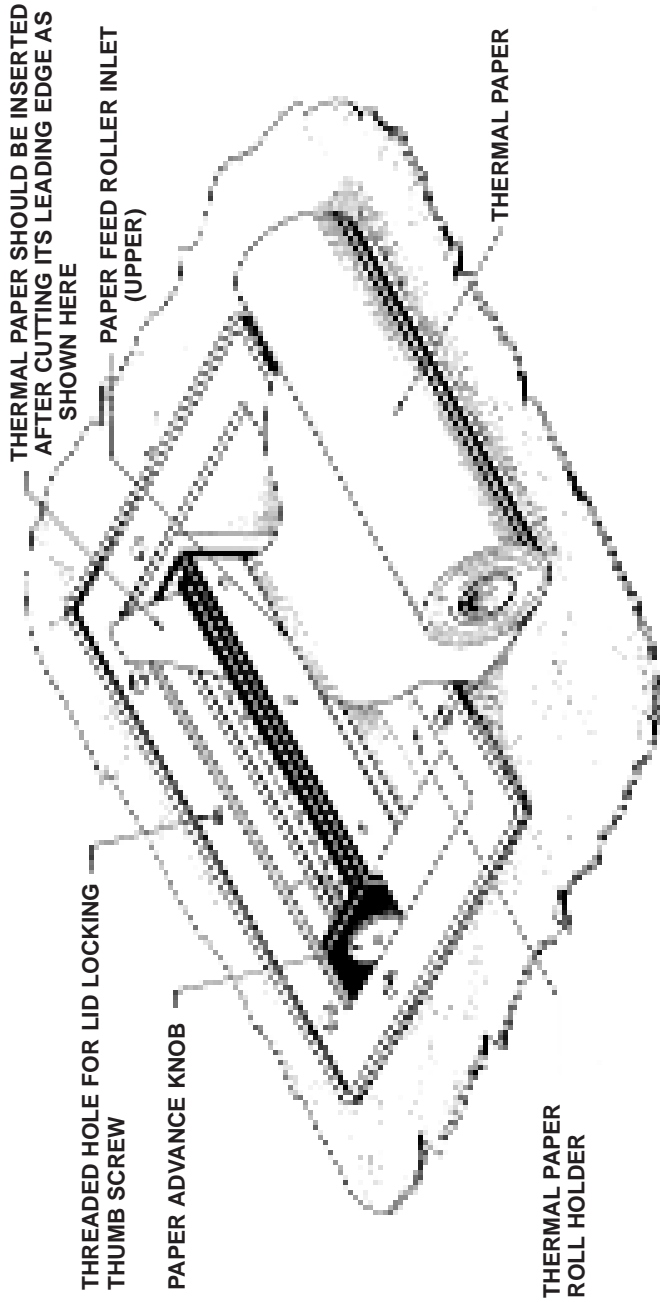
Test takes few seconds to be completed, then some statistical results are provided (MIN, MAX, AVG). The displayed AVG value should match the Test value, printed either on the probe box or in the attached probe instructions.

Press TEST key to repeat the test or any other key to exit the Test mode.

5.1 PAPER REPLACEMENT

A pale pink line appearing on the thermal paper indicates that the internal printer is running out of paper. To load a new roll of thermal paper, proceed as follow:

- 1) Turn the instrument on, thus entering the opening page.
- 2) Remove the lid that conceals the paper receptacle (on the upper cover of the instrument).
- 3) Insert the edge of the paper roll in the printer slit (see the drawing on the next page).
- 4) Depress the UP arrow to advance paper until it goes through the printer and comes out approximately five centimeters (2").
- 5) Place the paper roll in its receptacle and drive the paper lead through the slit of the paper receptacle lid.
- 6) Close the paper receptacle with its lid.



6.1 TECHNICAL SPECIFICATIONS

Automatic acquisition modes:

- Manual saving mode
- Autosaving mode
- Averaging and autosaving mode
- Test mode



Map programming:

Number of stored maps : 14
Number of map points : 33 max

POWER SUPPLY	13.5V de , +/- 10%, 25 WATT
SIZE	6" x 9" x 11"
WEIGHT	2.2 Kg (5lbs)
PROBE	20 Mhz, solid tip probe
CLINICAL ACCURACY	10 micron
INSTRUMENT RESOLUTION	0.5 micron
MEASUREMENT RANGE	0.28 - 1.0 mm
COMPUTER INTERFACE	RS232, 9 PIN CONNECTOR
PRINTER thermal	40 columns, 320 dot
SCREEN	LCD display, 240 x 128 dots
INTERNAL BATTERY	3.6V, lithium , 10 years lifetime

7.1 PACLINE REGISTRATION FORM

OPTIKON 2000 S.p.A. maintains a mailing list of people interested in our products and new product developments. If you wish to be placed in our mailing list, please complete the registration form below and mail or fax it to us. This form is for information and registration only, it does not obligate you to order.

OPTIKON 2000 BIOLINE REGISTRATION FORM

**MAIL TO: OPTIKON 2000 S.p.A.
VIA DEL CASALE DI SETTEBAGNI, 13
00138 ROME (ITALY)**
or send by fax: + 39 06 8888388

NAME

ORGANIZATION OR OFFICE LOCATION

ADRESS

CITY **STATE** **ZIP**

COUNTRY **TEL**

SIGNATURE

