

Specular Microscope EM-2

Instructions for Use and Maintenance



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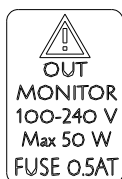
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1. INTRODUCTION

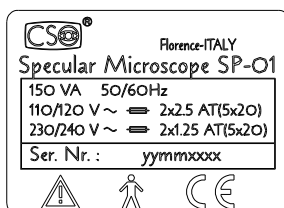
Thank you for having purchased EM-2 by bon Optic

All bon Optic products are manufactured to rigorous safety standards. In particular, the SP 01 specular microscope is a high-performance instrument. In order to use it efficiently and in complete safety we recommend reading this manual carefully before beginning installation and heeding all the safety warnings provided herein and on the instrument labels. Even technicians who have already used this type of instrument should verify their knowledge of the instructions contained in this manual. Keep this manual near the instrument for handy reference during use

2. GENERAL SAFETY PRECAUTIONS



Monitor Socket Data Plate

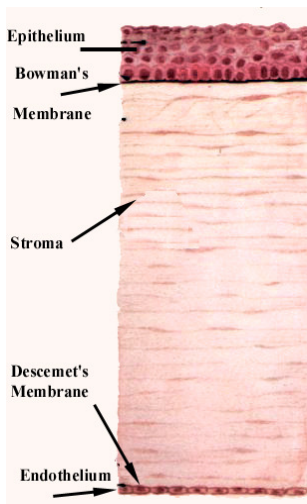


Instrument Data Plate

- Check that your line voltage is the same as that reported on the instrument data plate. Should the values differ, contact your customer service or the manufacturer (see INSTALLATION section). Your electrical system must comply with CEI/IEC standards for electrical systems for medical use. In case of doubt, contact your installation and maintenance service.
- Never use multiple plugs, adapters, or extension cords to connect the instrument plug to the line socket.
- When unplugging the instrument from line power supply, even under emergency conditions, grasp the plug and never the cord; never pull the cord to disconnect the plug.
- Never touch the power cord with wet hands. Check frequently that the cord is so placed as not to be stepped on or crushed by weights. Never knot the cord.
- A damaged power cord can cause fires or electrical shocks. Check frequently that the instrument power cord is in good condition. If it becomes necessary to replace the power cord originally supplied with the instrument, contact your supplier.
- Do not perform any repairs or maintenance work on the instrument or the electrical system beyond what is explained in this manual.
- Do not use the instrument near water and be careful not to spill liquids on any part of it. Avoid damp and dusty locations and locations subject to brusque changes in temperature and humidity.
- Disconnect the instrument from the line power supply before cleaning and/or disinfecting.
- ***The instrument neither generates nor receives electromagnetic interference when used in proximity to other devices; no preventive or corrective measures need therefore be taken.***
- ***The standard version instrument contains non-medical accessories (LCD monitor, keyboard, and mouse). The resulting system is tested in accordance with international standards EN 60601-1 "Medical Electrical Equipment. PART 1: General Requirements for Safety" and EN 60601-1-1 "Collateral Standard: Safety Requirements for Medical Electrical Systems" and is fully compliant with these standards. Note that the standard version instrument can be connected to other***

instruments, medical electrical and not; bon Optic cannot test the compliance of all possible system configurations

- *Any additional accessories (printer, scanner, CD reader, etc..) connected to the analog or digital interfaces must be certified in accordance with the standards listed below:
For the United States of America:
UL 1950 for ITE devices.
UL 2601-1 for medical electrical devices.
For Europe:
EN 60950 for ITE devices.
EN 60601-1 for medical electrical devices;*
- *Once all the equipment making up the system has been connected and assembled, check that the resulting medical electrical system complies to the requirements set by EN 60601-1-1 "Collateral Standard: Safety Requirements for Medical Electrical Systems."*
- *Should the leakage current values exceed the limits set by standard EN 60601-1-1, additional safety measures must be adopted as suggested by the standard itself. In this case, we recommend powering the entire system through a safety insulating transformer.*



3. BRIEF DESCRIPTION OF THE INSTRUMENT – USES

The endothelium is the deep layer of the cornea, in a young subject about 5 micrometers in thickness and possessing about 300,000 hexagonal cells.

The endothelium is important for correct corneal function; for this reason, analysis of the endothelium is of fundamental importance for diagnosis of the health of the eye.

The most important characteristic of endothelial cells is their lack of reproductive capacity; age, surgical treatment, and use of contact lenses are factor influencing their quantity and form.

As already mentioned, the cells composing the endothelium, which are hexagonal in children and younger people, do not reproduce and their form and quantity influence the health of the cornea. At birth, the endothelium contains about 4000 cells/mm²; with time, the number decreases and the structure of the layer accordingly changes.

The bon Optic specular microscope permits obtaining electronic photographs of the patient's endothelium with no instrument contact with the patient. The acquired endothelium image can then be mathematically processed to display clinically-useful endothelial parameters relative to the cells, including: cell number and density, form, surface area, mean area, standard deviation, coefficient of variation, percentage of cells of different forms, histogram of cell area distribution, pachimetric datum.

The bon Optic specular microscope permits performing:

- Non-invasive examination of the endothelial tissue.
- Automatic focusing of the endothelial layer of the cornea.

Automatic search for cell borders and broad-based statistical analysis of the data.

The bon Optic specular microscope is an indispensable aid in diagnosing corneal health.

It is extremely useful in pre- and post-transplant examinations, after cataract surgery, and for analysis of trauma damage to the cornea.

Since the examinations performed with the bon Optic specular microscope are totally non-invasive with no patient contact,:

- there is no risk of transmission of infectious diseases.
- the examination is absolutely painless and does not require use of any local anesthetics.

The instrument is composed of:

the SPECULAR MICROSCOPE as such, designed and built by bon Optic, and the user accessories listed below:

1. 15.1" LCD monitor (50 W max. power requirement);
2. Keyboard;
3. Mouse.

AUXILIARY and ACCESSORY DEVICES:

4. Commercially-available ink jet color printer compliant with international standard EN 60950.
5. 230V-230V insulating transformer (leakage current limiter) for use in operating rooms, compliant with international safety standard EN 60742.
6. Wooden table top and motor-driven telescopic column workstation, Schumo AG brand, a medical electrical device compliant with international standard EN 60601-1, purchased from bon Optic and not modified;

3.1. ACCESSORIES

The instrument is supplied complete with the accessories listed below.

- a protective cover
- one set of socket wrenches
- one package of chin rest papers
- two fuses
- this instruction manual.

4. OPERATING CONDITIONS

As long as the specular microscope remains in its original packing it may be exposed to the environmental conditions listed below, for a maximum of 15 weeks during shipping and warehousing, without suffering damage:

*Temperature between -10 °C and +60 °C;
atmospheric pressure between 500 hPa and 1060 hPa;
relative humidity between 10% and 90%.*

Ambient conditions for operation are:

*Temperature between +15 °C and +30 °C;
atmospheric pressure between 700 hPa and 1060 hPa;
relative humidity between 30% and 75%.*

Attention!

- Before examining any patient, clean the forehead rest and the chin rest with a clean cloth. Before each examination, remove the top strip of paper from the chin rest pack. If necessary, clean the forehead rest and the chin rest with a cloth dampened with alcohol.

5. END-OF-LIFE DISPOSAL ENVIRONMENTAL CONSIDERATION

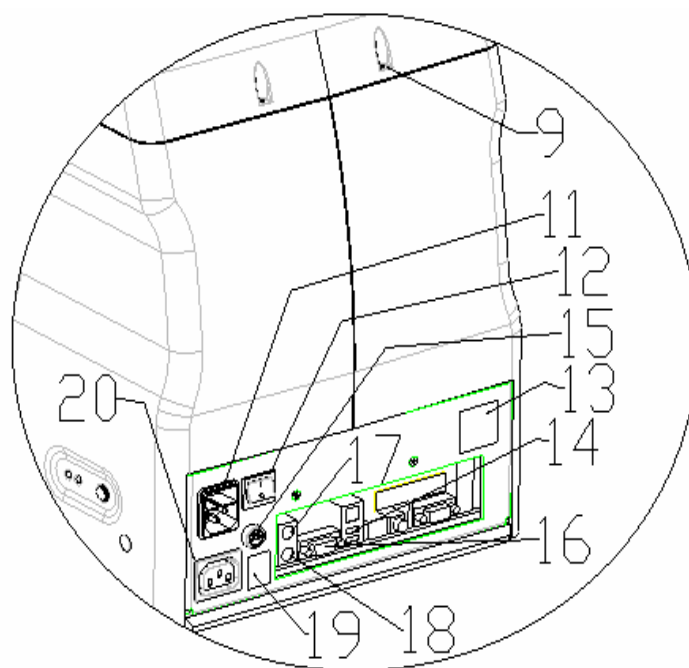
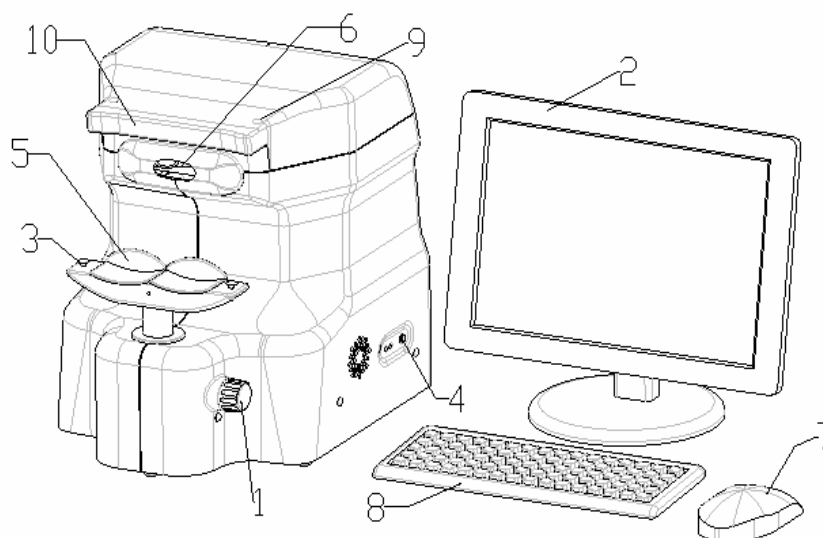


The symbol in the margin indicates that the end-of-life instrument must not be disposed of as normal waste. The various materials of which the instrument is made, as well as the packing materials, must be separated for disposal by type and in accordance with local laws and waste recycling regulations.

Dispose of the instrument and its packing in accordance with local regulations governing disposal and recycling of the various different materials of which the instrument is made.

6. LEGEND

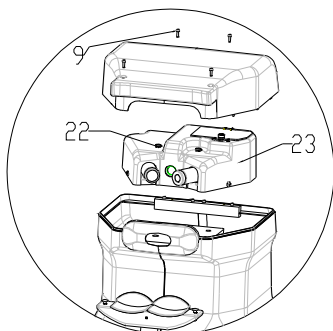
1. Chin rest height adjustment knob.
2. LCD monitor.
3. Paper-holder pins on chin rest.
4. Instrument computer ON pushbutton.
5. Chin rest.
6. Optical unit.
7. Mouse.
8. Keyboard.
9. Instrument head assembly screws.
10. Forehead rest.
11. Power socket with fuse holder compartment and voltage changer.
12. Main switch.
13. Data plate.
14. USB socket (printer connector).
15. Monitor fuse 0.5A T.
16. Monitor connector socket.
17. Mouse connector socket.
18. Keyboard connector socket.
19. Monitor outlet socket data plate.
20. Monitor power socket (max. output 50W).
21. Optical unit lock screws (see pag. 25).
22. Lamp door screws.
23. Optical head unit.
24. Optical head power connector.
25. Firewire signal connector.
26. Lamp maintenance door (see pag. 25).
27. Flash lamp (see pag. 25).
28. 12V 30W halogen projector lamp (see pag. 25).
29. Antivibration plate.
30. Videocamera driver cable



7. INSTALLATION

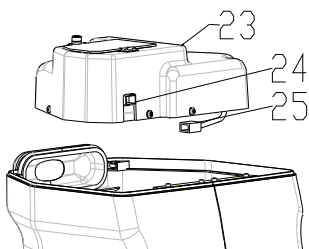
The instrument as supplied is packed for best withstanding standard shipping and warehousing conditions. Should you notice defects attributable to shipping when unpacking the instrument, contact your installation service.

7.1. UNPACKAGE THE INSTRUMENT AND REASSEMBLING THE OPTICAL HEAD (23)



For reasons of mechanical safety, the instrument is shipped with the optical head disassembled and separately packed. Unpack the instrument and proceed as described below to reassemble.

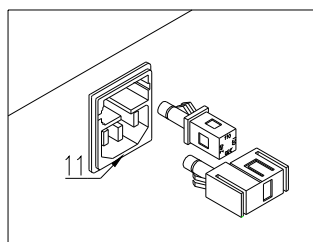
- 1) Loosen screws (9) and remove the optical head casing.
- 2) Take off the antivibration plate (29);
- 3) Connect the power cable (24) and the signal cable (25) to the optical head.
- 4) Insert the optical head in the instrument and lock in place by tightening the lock screws (21).
- 5) Reassemble the optical head casing and lock in place by tightening screws (9).



Place the instrument on a stable surface close to the monitor and keyboard to create an ergonomically-sound and comfortable workstation layout.

No software installation is required since the necessary software is pre-installed on the built-in instrument PC.

7.2. CONNECTING THE INSTRUMENT



Connect the instrument to the::

- monitor, using the VGA video cable (16) and the power cord (20). **Warning ! Maximum admissible monitor power is 50 W.**
- keyboard (socket 18).
- mouse (socket 17).
- power supply. Before connecting, check the setting of the voltage changer on the power socket (11), which must be set to the voltage at which the instrument will be used. If necessary, extract the relative cells and rotate until the correct voltage value appears in the window.
- printer (if used), using the parallel port or USB socket (14) (recommended).

7.3. PRECAUTIONS



Respect the precautions explained below for correct use of the instrument.



In order to guarantee that the instrument always operates correctly, perform maintenance as described in this manual. Before using the instrument, check that the fixation point and the instrument flash system operate correctly.



Take special care when examining children and subjects with



occluded corneas. It may be impossible to acquire images of the epithelium of the corneas of these subjects.



Always check that the patient's chin is correctly positioned on the chin rest and his forehead is firmly placed against the forehead rest.



There are endothelia which could be acquired with a certain difficulties, and can give ambiguous result. These can be: irregular corneas, recently-treated patients (3-4 days), patients suffering from keratoconus.



Check that the patient's eye is not obstructed by the lid or lashes, and that there are no teardrops on the eye surface, lids, or lashes. If necessary, help the patient open his eyelids fully or dry his eyes before beginning examination.



Acquisition is not possible if the patient is wearing contact lenses or intra-ocular lenses.

The result analysis must be done by a medicine doctor specialist.

8. INSTRUCTIONS FOR USE

8.1. LAUNCHING THE SOFTWARE

All the software required for using the BON OPTIC specular microscope is pre-installed on the instrument's built-in computer. This PC does not support installation of other types of software. *In order not to jeopardize the instrument performance level and/or correct operation, do not install software for other uses on this PC.* Press button (4) to switch on the instrument. After the operating system has booted, double-click the "ANKAA" desktop icon to launch the software.

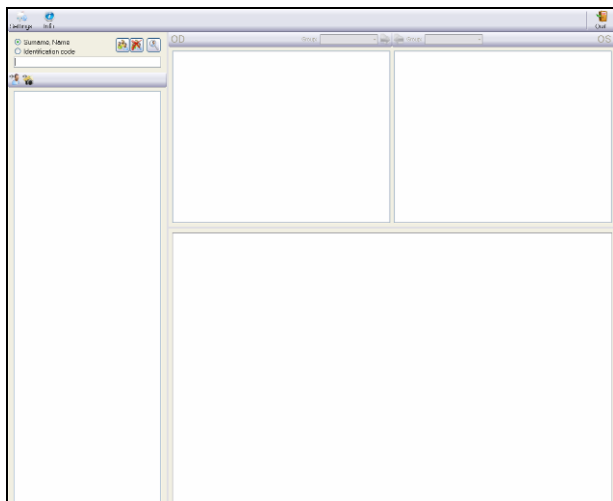


Fig. 1 – Main window

8.2. THE MAIN WINDOW

When the software is launched, the screen will display the main window shown in figure 1.

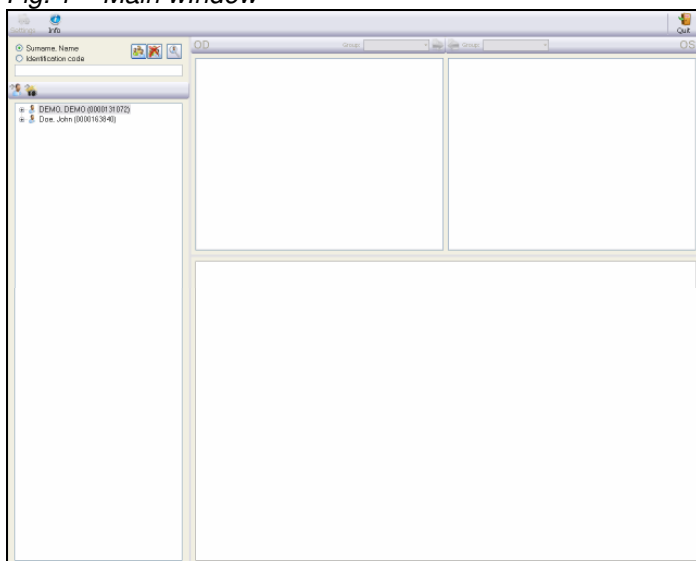




Fig. 2 – Patient list

The top of the window contains some commands which will be described below.

On the left is the LIST PATIENTS, which is accessed by pressing the  button.

With the  button is emptied textbooks patients.

8.3. TOOLBAR BUTTONS SUMMARY











BUTTON	KEYBOARD SHORTCUT	ICON	FUNCTION
Settings	-		Opens the general settings and database settings panel.
New Patient	-		Allows the user to create a new patient.
New Exam	-		Allows the user to create a new examination.
Capture	Space bar		Accesses the CAPTURE screen.
Info	-		Displays general information on software and database versions.
Esc	-		Closes the program.
Open patient list	-		Open the patient list
Empty patient list	-		Empty the patient list
Extended examination	-		Open window for extended examination

Fig. 3 – Main Window Commands

8.4. SETTINGS



Fig. 4 – Settings

To access system settings, empty the patients list, if open, and then click .

In this section, the user may change:

- the language used by the software
- the pathology groups to be attributed to the single examinations
- the database configurations
- the DICOM configurations.

8.4.1 LANGUAGE

The first screen allows the user to select the language used by the software (Fig. 4).

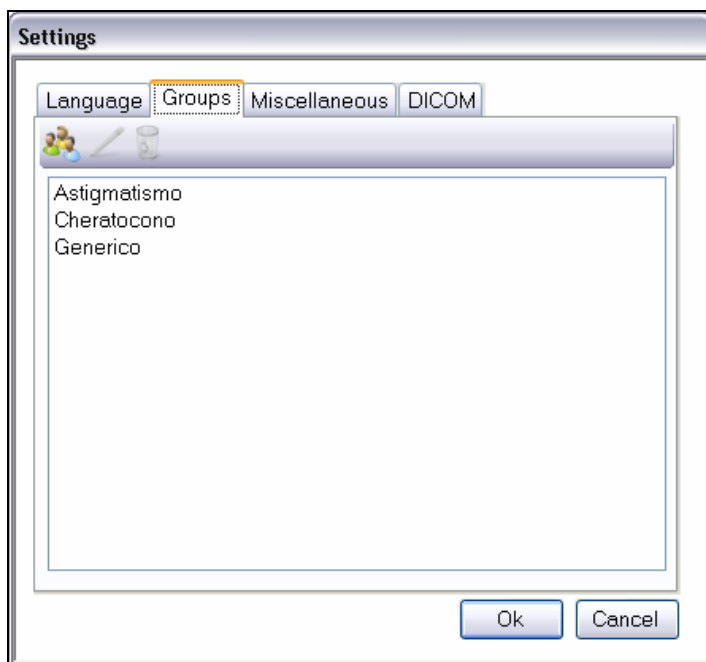





Fig. 5 - Groups

8.4.2 GROUPS

Select the GROUPS menu to manage the pathology groups to be assigned to each examination, distinguishing between right eye and left eye (OD/OS) (Fig. 5).

Click the  button to create a new group.

Click the  button to edit a pre-existing group.


The  button allows the user to delete a group. This function is applicable only if the group selected has not been matched with any examination currently in the database.

8.4.3 MISCELLANEOUS

The MISCELLANEOUS menu is composed of 4 sections:

Database

Click the  button to select the reference database file path, **phoenix.mdb**.

Use the  button to locate the file path of the **root.cso** file, which indicates the folder containing the images.

Patient Management

Select the *(External) Patient ID issuer* box to automatically assign a new ID code every time a patient is created. It is also possible to obtain the code from an external database, using the PMS mode. If the Patient ID box is deselected, it will be possible to insert the ID code each time a new patient is created.

Reminder

Selecting the four options in this section enables display of alarm and confirmation messages.

Performance

This section allows the user to select the number of examinations displayed at any

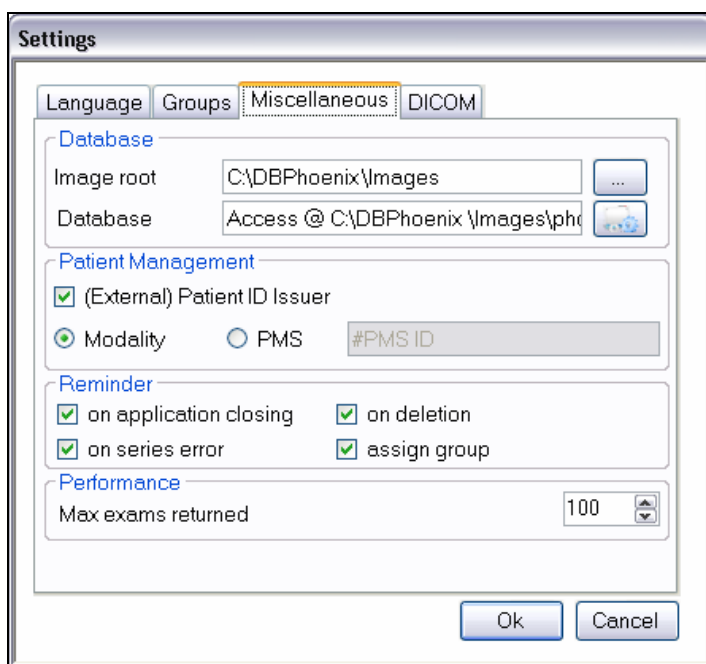


Fig. 6 - Miscellaneous

one time in the patients list. In the Figure 6 example: 100 examinations.

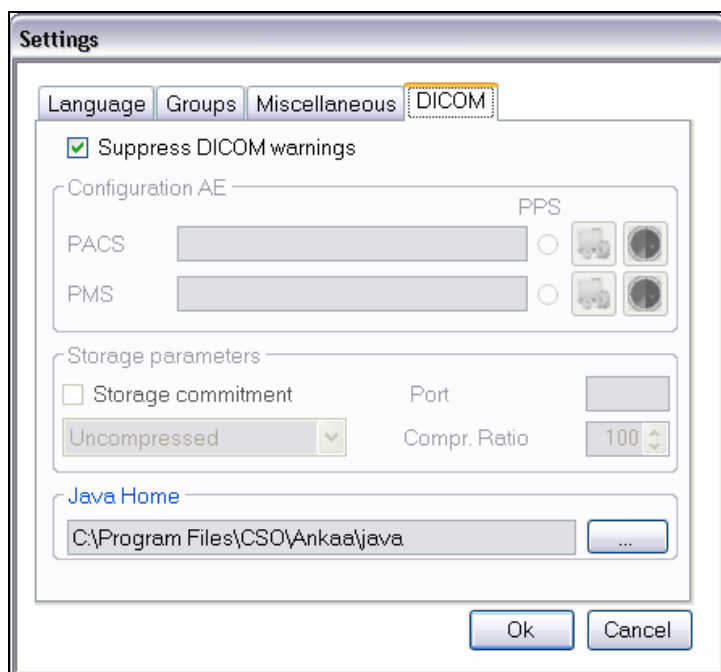


Fig. 7 – DICOM

8.4.4 DICOM

If the **Suppress DICOM warnings** box is selected, the menus and alarm messages referred to DICOM management will not be displayed.

Deselecting this box allows the user to manage the PACS and PMS configurations needed for DICOM data transfer.

For explanations about DICOM, see the relative section below.

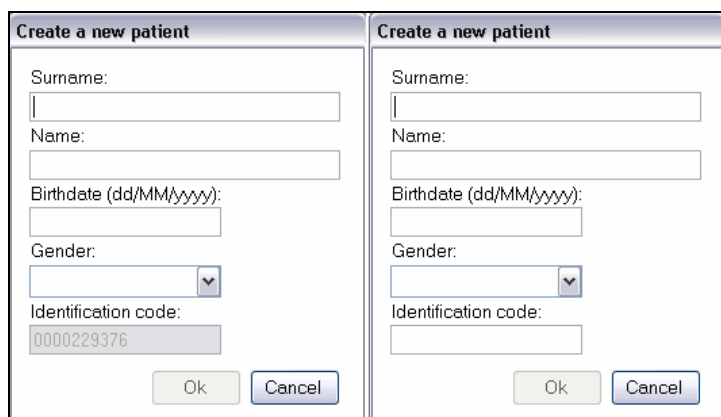


Fig. 8 – Create new patient

8.5. Patient Management

8.5.1 CREATING A NEW PATIENT

To create a new patient, click the



icon (see Fig. 1).

The new patient personal data entry window will open (Fig. 8).

Type in the last name, first name, and date of birth; indicate gender.

In the right-hand window, enter the identification code if the Patient ID box has been deselected (Figure 6).

Click OK after all the required personal data has been entered.

8.5.2 CREATING A NEW EXAMINATION

After a new patient is created, an examination will be created automatically and the capture screen will open.

To create an examination for a patient already in the archive, select the patient


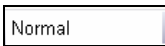






and click the button.

A new examination will be created and the capture screen will open.

8.6 CAPTURE

8.6.1 CAPTURE WINDOW COMMANDS

BUTTON	KEYBOARD SHORTCUT	ICON	FUNCTION
TK	-		Allows the user to select the correction to be applied for different corneal thicknesses.
Sensitivity	-		Allows the user to select the video camera sensitivity threshold (High, Normal, Low) for working with opaque, normal, and highly reflective corneas, respectively.
FMC	-		Allows the user to enable the correct capture procedure for corneas with very large curvature radiuses.
Capture	Space Bar		Enabled when the patient is correctly positioned. Allows the user to capture the image.
Home Position	-		Returns the optical head to the "rest" position.
Esc	Esc		Exits the capture window.

Follow the procedure outlined below to acquire an image. Position the patient's chin on the chin rest. The chin rest automatically detects correct placement for right eye (OD) or left eye (OS) capture.

Left eye capture

Position the patient's head on the RIGHT SIDE of the chin rest; check that the patient's forehead rests correctly on the forehead rest. If the patient is correctly positioned the reflection of the cornea will fall within the green square.

Right eye capture

Position the patient's head on the LEFT SIDE of the chin rest; check that the patient's forehead rests correctly on the forehead rest. If the patient is correctly positioned the reflection of the cornea will fall within the green square.

The capture mode is automatic.

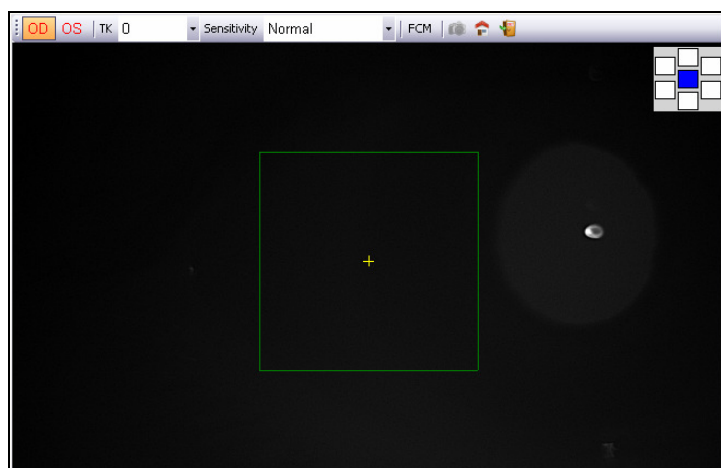





Fig. 9 – Incorrect patient positioning

Select the patient and click the  icon to create a new examination and access the capture screen. If the patient has not been closed, capture may continue using the same examination. In this case the "new exam" icon  will be replaced by the  icon.

A green square delimiting the instrument scanning quadrant, with a center cross-hair, will appear. In the LIVE mode, the instrument positions itself to capture the endothelium in the central corneal area. To capture the endothelium in a peripheral area, click the icon of the desired area:

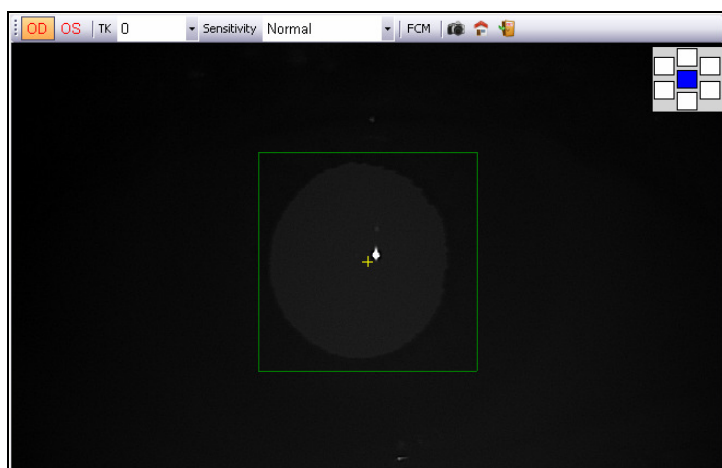
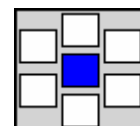


Fig.10 – Correct patient positioning




Now position the patient's head on the right side of the chin rest to capture the left eye or, vice-versa, on the left side to capture the right eye.

Check that the patient's chin is solidly positioned on the chin rest and the forehead on the forehead rest.


If the patient is not correctly positioned, the reflection will fall outside of the green square



and the  icon will be disabled Fig. 9. Move the patient's head, if necessary changing chin rest elevation, until the reflection of the eye falls within the scanning quadrant as shown in Fig. 10.

Ensure that the patient always looks directly at the fixation point inside the instrument and does not close the eye during the examination. The reflection of the eye in the scanning quadrant must be in focus. Use the ↑ and ↓ keyboard arrows to optimize focus.



To start the examination, click the  capture button or press the SPACE BAR. The instrument will automatically capture the image of the endothelium and, at the end of this operation, display it in the gallery. The preview will be visible in the foreground with the ruler at the top.
(Fig. 11)

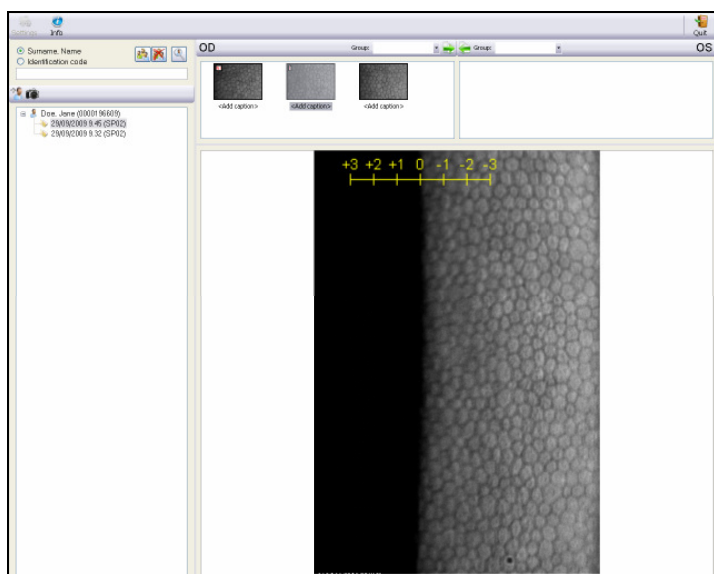


Fig. 11 – Gallery image

To view the preview of another image, simply select it.

Double-click the gallery image to proceed with processing.

8.7 ANONYMOUS CAPTURE

This new capture mode permits capturing and processing an image without attributing it to any patient.

To access this mode, empty the patients list

and click the  toolbar button.

Following capture, the instrument automatically accesses the processing screen. Fig.12

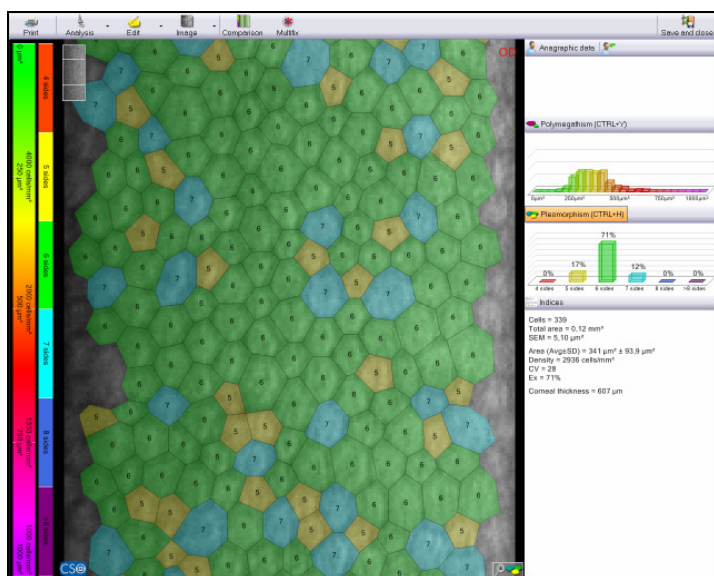



Fig. 12 – Anonymous capture

It is always possible to create a new patient to which to assign the image After processing has been completed and any operations of interest have been carried out. Simply click the

 button to open the “create new patient” screen. After the data has been saved, the patient will be visible in the gallery.

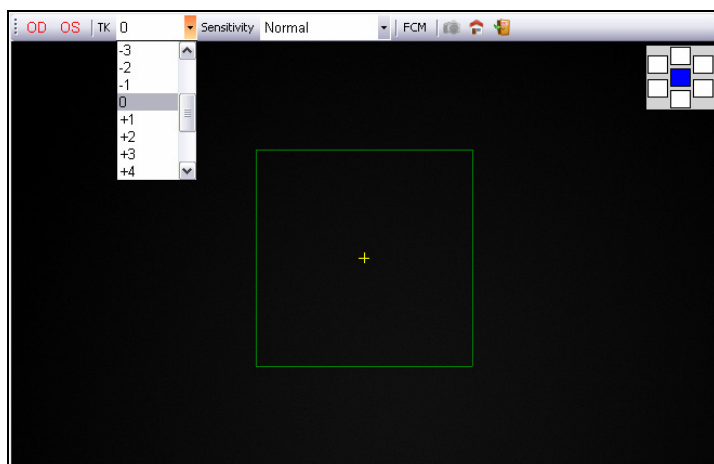


Fig. 13 – Corrections menu

8.8 CAPTURING CORNEAS WITH DIFFERENT THICKNESSES

A new cursor has been added to regulate the quality of capture of corneas with differing thicknesses. This cursor contains various values from -5 to +5 with a default 0 position at the center. In general, if the patient is correctly positioned and the cornea is normal, the cursor may be left in the 0 position.

The effect produced by thicker-than-normal corneas is to yield images that are not perfectly in focus on the left-hand side. In this case, move the cursor to the positive values to obtain images in better focus.

The effect produced by thinner-than-normal corneas is to yield images that are not perfectly in focus on the right-hand side. In this case, move the cursor to the negative values to improve capture.

8.8.1 EXAMPLES

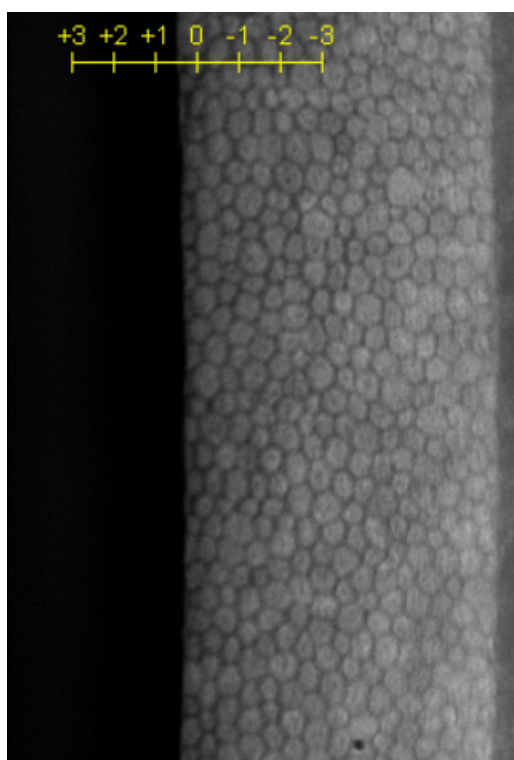


Fig. 14 – Focused image

To aid in understanding the correct correction value to be used, an indicative scale is displayed over the preview image.

In order for the pachymetric datum supplied by the instrument to be reliable, the image must be perfectly focused and the left edge of the captured image must correspond to the "0" value on the scale at the top of the screen (Figure 14).

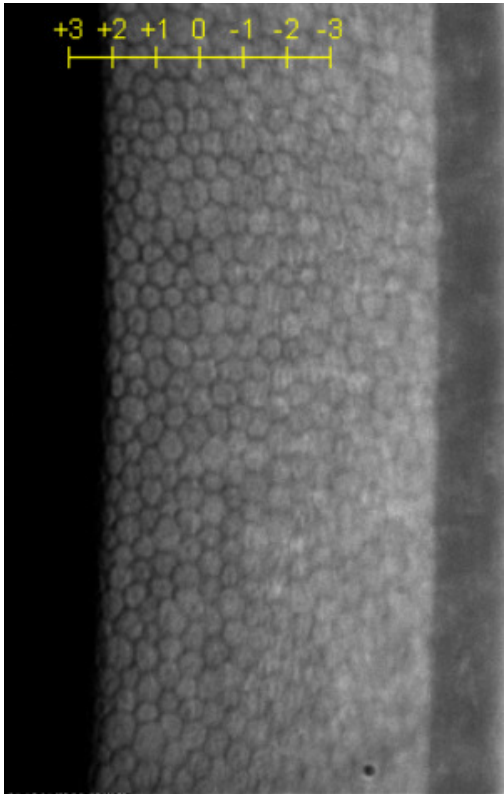


Fig. 15 – Positive correction

If the left edge of the image corresponds to a positive value, repeat capture after setting the cursor to the corresponding scale value. In the example (Figure 15), repeat the capture with the thickness value set to “+2.”

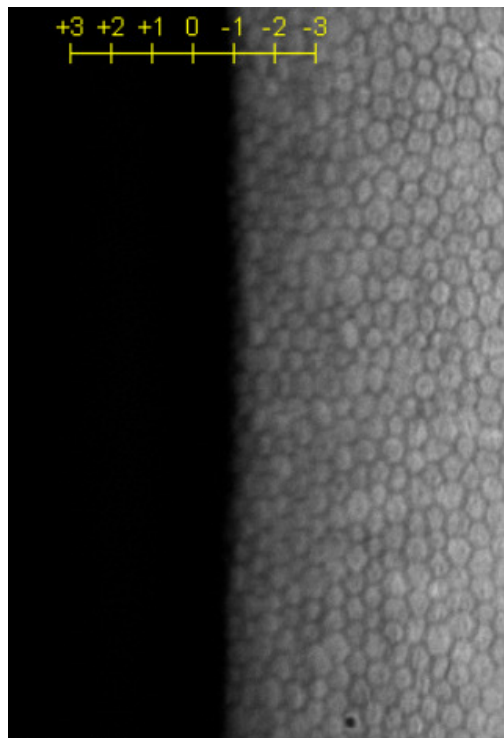
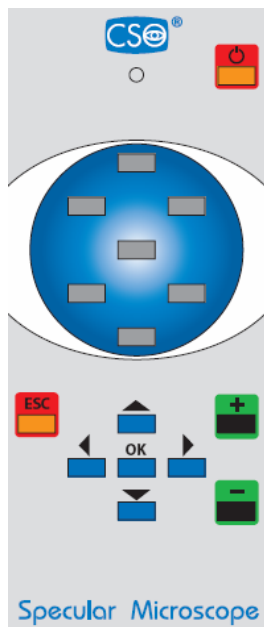


Fig. 16 – Negative correction

If the left edge of the image corresponds to a negative value, repeat capture after setting the cursor to the corresponding scale value. In the example (Figure 16), repeat the capture with the thickness value set to “-1.”

8.9 REMOTE CONTROL

The new SP-02 is equipped with an infrared remote control for greater operator convenience when using the instrument.



The remote can be used to:

- switch off the instrument.
- align and focus the corneal reflection before beginning capture.
- select the area of the cornea to capture.
- start capture.
- introduce correction for corneal thickness before capture.

8.10 THE REMOTE CONTROL KEY FUNCTIONS

KEY	FUNCTION
	Exits the "specular microscope" software.
	ESC function, for canceling a command or exiting the "specular microscope" program.
	Increases the capture index for thicker corneas.
	Decreases the capture index for thinner corneas.
	Allows the user to move the optical head: <ul style="list-style-type: none"> - to the right and left for centering the corneal reflection. - forward and backward for fine-focusing the corneal reflection. The OK key starts capture. Pressing the OK key from the main page opens the patients list.
	Allows the user to select the corneal area to be captured: <ul style="list-style-type: none"> - center area - 6 peripheral areas corresponding to the clock-dial positions 12, 2, 4, 6, 8, 10.

8.11 USING THE REMOTE CONTROL FOR IMAGE CAPTURE

Follow the procedure outlined below when using the remote control for image capture. Position the patient's head on the chin rest, which automatically detects the right eye (OD) or the left eye (OS).

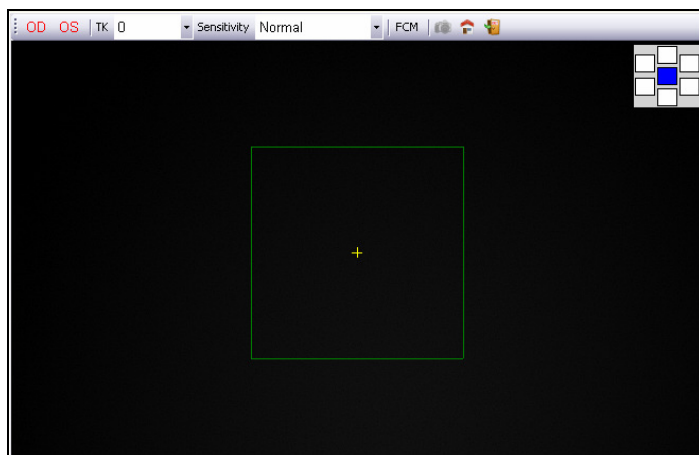


Fig. 17 – Capture window

Click the “capture” button on the main screen to access the capture screen.

In the LIVE mode, the instrument positions itself to capture the endothelium in the center area of the cornea. To capture the endothelium in a peripheral area, press the remote control key corresponding to the area of interest:

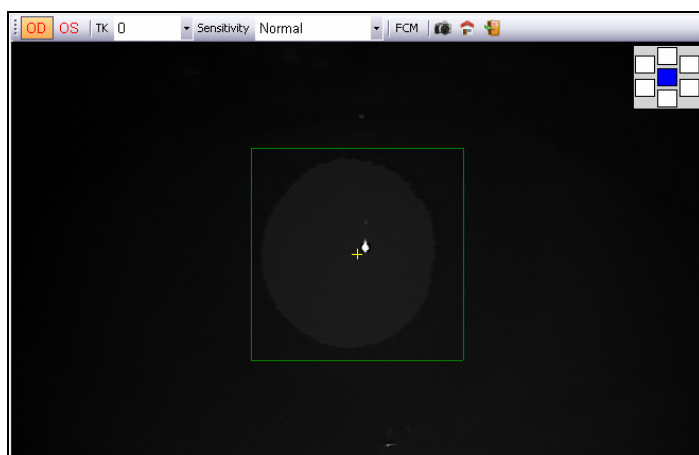
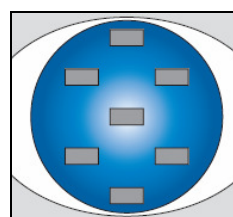


Fig. 18 – Correct patient positioning

Position the patient's head on the **RIGHT SIDE** of the chin rest. Check that the patient's forehead is correctly resting on the forehead rest. If the patient is correctly positioned, the reflection of the cornea will be centered in the green square. (Fig. 18).

Position the patient's head on the **LEFT SIDE** of the chin rest. Check that the patient's forehead is correctly resting on the forehead rest. If the patient is correctly positioned, the reflection of the cornea will be centered in the green square.

Check that the patient's chin and forehead are correctly and snugly positioned; ensure that the patient looks directly and steadily at the fixation point, with his eye fully open.

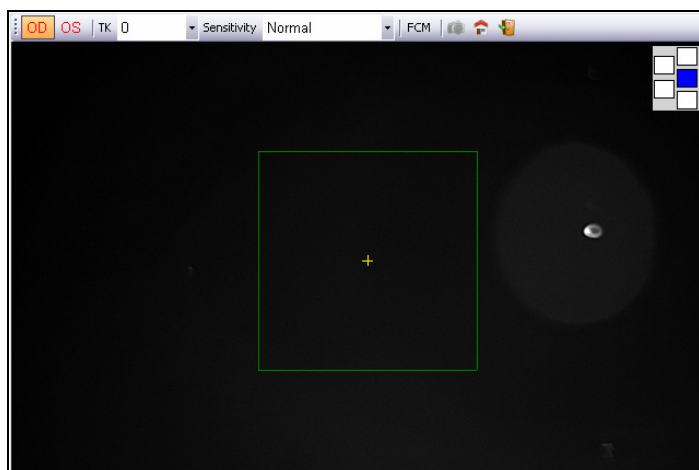
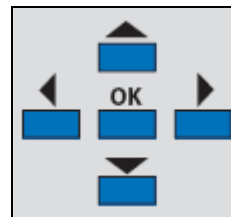


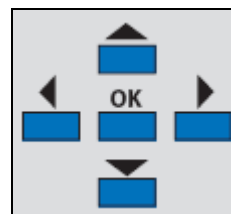
Fig. 19 – Incorrect patient positioning

Check that the reflection of the cornea shown on the screen falls within the scanning quadrant and that it is perfectly focused. If necessary, use the remote control arrow keys to adjust the reflection and to change chin rest height.

If the reflection does not fall within the scanning quadrant, the “capture” button is not enabled. (Fig. 19).



To begin the examination, press the OK key on the remote



or press the SPACE BAR. The instrument will automatically capture the image of the endothelium and, at the end of this operation, display it in the gallery.

8.11.1 EXAMPLES

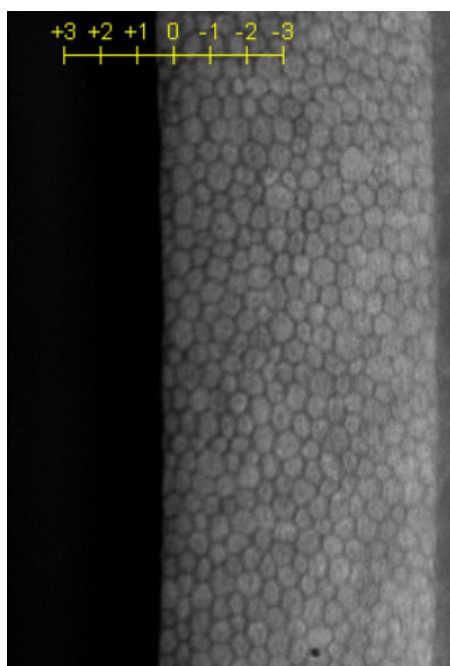


Fig. 20 – Focused image

In order for the pachymetric datum supplied by the instrument to be reliable, the image must be perfectly focused and the left edge of the captured image must correspond to the “0” value on the scale at the top of the screen (Fig. 20).

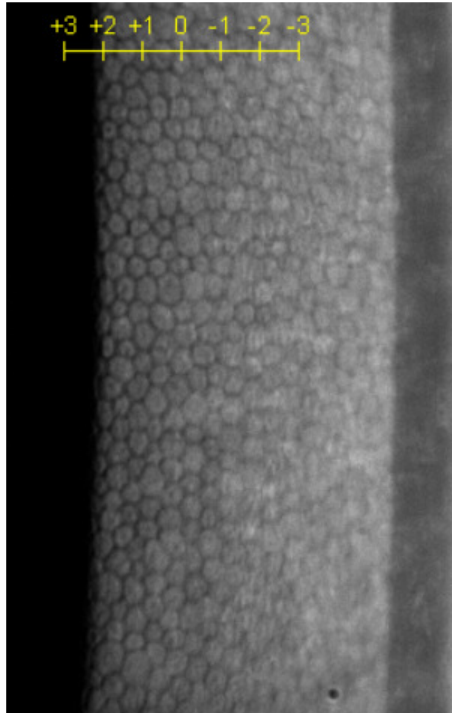


Fig. 21 – Positive correction

If the left edge of the image corresponds to a positive value, repeat capture after setting the cursor to the corresponding scale value (Fig. 21). In the example, repeat the capture after setting



the thickness value to “+2” using the remote control key.

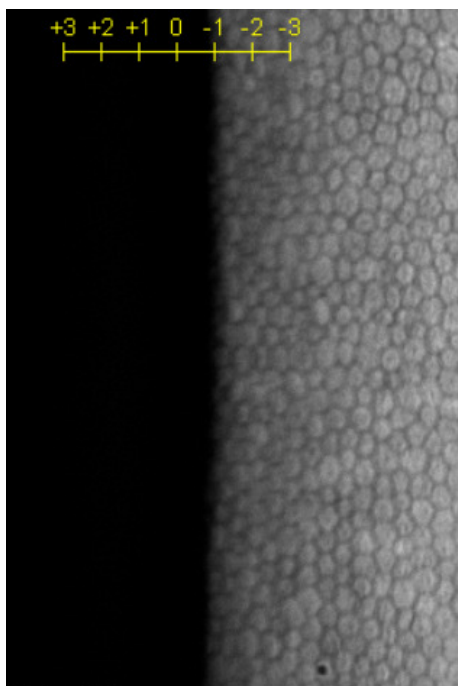


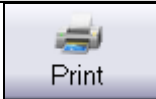
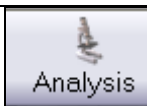







Fig. 22 – Negative correction

If the left edge of the image corresponds to a negative value, repeat capture after setting the after setting the cursor to the corresponding scale value. In the Figure 22 example, repeat the capture after setting the thickness value to “-1”



using the remote control key.

8.12.1 TOOLBAR BUTTONS AT THE TOP OF THE SCREEN

BUTTON	FUNCTION
 Print	Prints the processed image.
 Analysis	Shows the processed image after editing.
 Edit	Allows the user edit the cells.
 Image	Modifies the image display parameters.
 Comparison	Allows the user to compare two processed images.
 Multifix	Shows all the processed images referred to different areas of the endothelium in a single screen.
 Save and close	Saves and closes processing.
 Polymegathism (CTRL+Y)	Presents polymegathism processing results.
 Pleomorphism (CTRL+H)	Presents pleomorphism processing results.

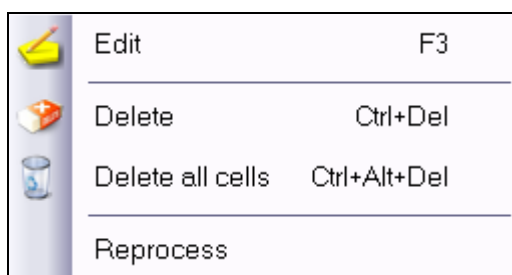


Fig. 24 – Editing Menu

8.12.2 EDITING SELECTED CELLS

To access the cell modification functions, click



the button or open the menu (Fig.24) and select Edit .

To view all the areas of the endothelium, scroll the image with the up ↑ and down ↓ keyboard arrows or hold down the left mouse key and drag the image. The figure on the upper left

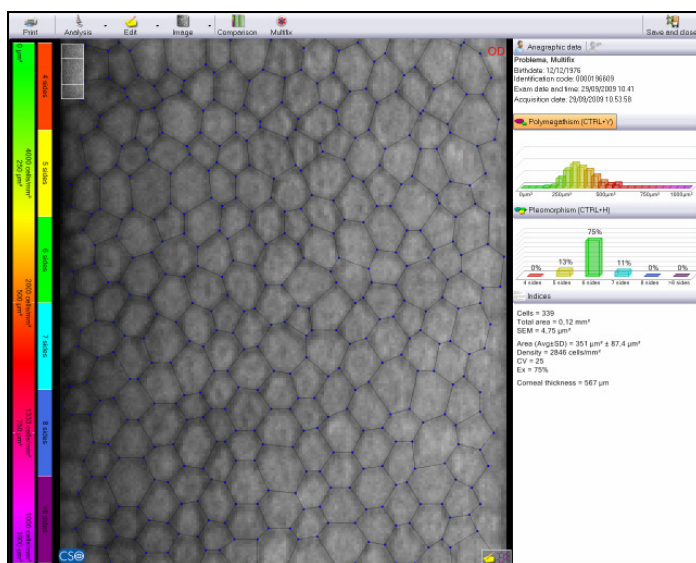
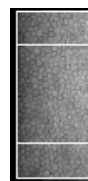


Fig. 25 – Edit cells



indicates the portion analyzed.

To add a point to a border in the image, simply left-click. Holding down the right mouse key selects and the point closest to the cursor and highlights it with a red dot. In this case, it may be deleted by pressing the CANC keyboard key.

When a point remains isolated and is not part of a complete cell, it will be displayed in yellow. (Fig. 25).

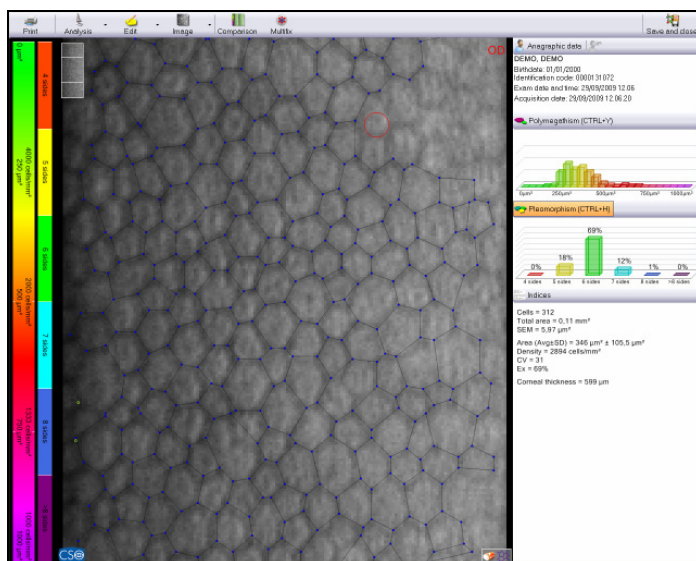


Fig. 26 – Delete cells

8.13 DELETING CELLS

Open the Edit menu and select Delete. Hold down the left mouse key to display a circular red cursor. As this cursor is moved over the image it deletes all the cells it touches (Fig.26).

To delete all the cells, select Delete all cells.

To re-edit the cells, click Reprocess.

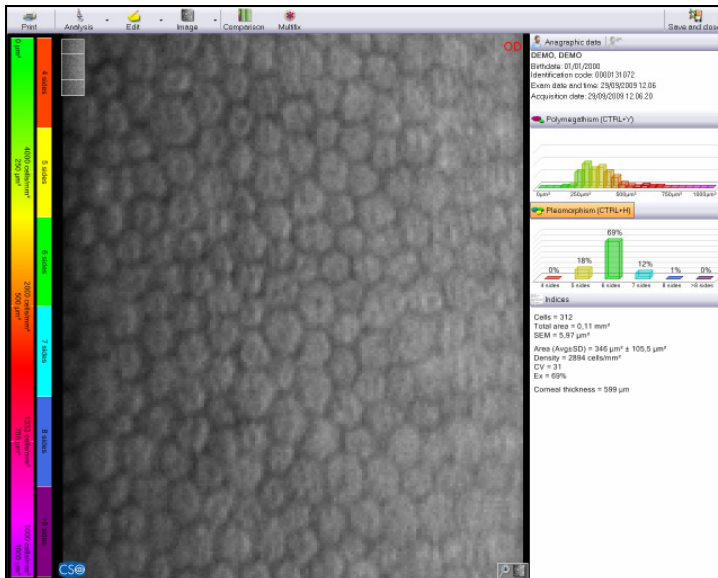


Fig. 27 – Image of endothelium

8.14 EDITING IMAGE PARAMETERS



Click the **Image** button to display the unprocessed image of the endothelium in the foreground.

To return to the processed image, click the



Analysis button.

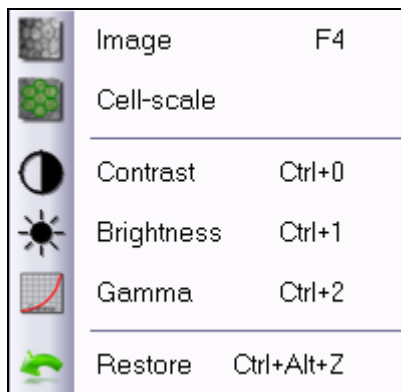


Fig. 28 – Image menu

Clicking the arrow at the side of the image button opens a menu (Fig. 28).

The **Image** function corresponds to the function described at the start of this section. (Fig.27).

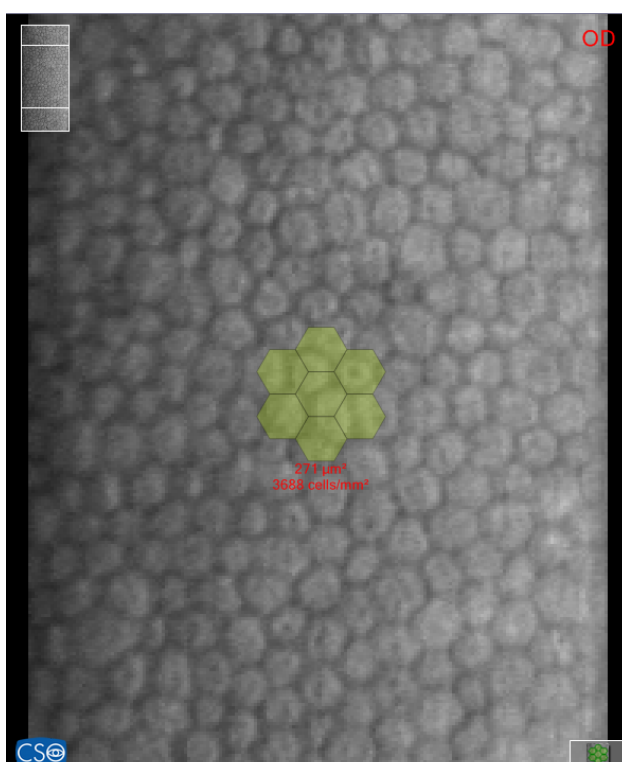
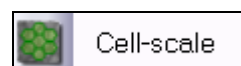


Fig. 29 – Scale



Cell-scale shows the density and cell mean cell area scale.

Scrolling with the mouse wheel, if available, displays all the dimensions and the color reported in the scale at the side (Fig. 29).



Fig. 30 – Image parameters

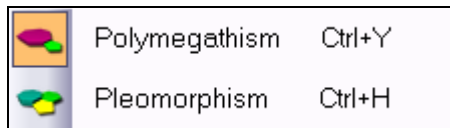


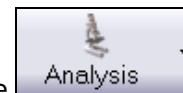
Fig. 31 – Analysis menu

The Figure 30 functions allow the user to change the contrast, the brightness, and the correction range applicable to the captured image.

To eliminate any modifications made, select



8.15 PROCESSING



Click the Analysis button to process an image. Two types of processing modes will be presented:

- Pleomorphism: image by number of sides per cell. (Fig.32).

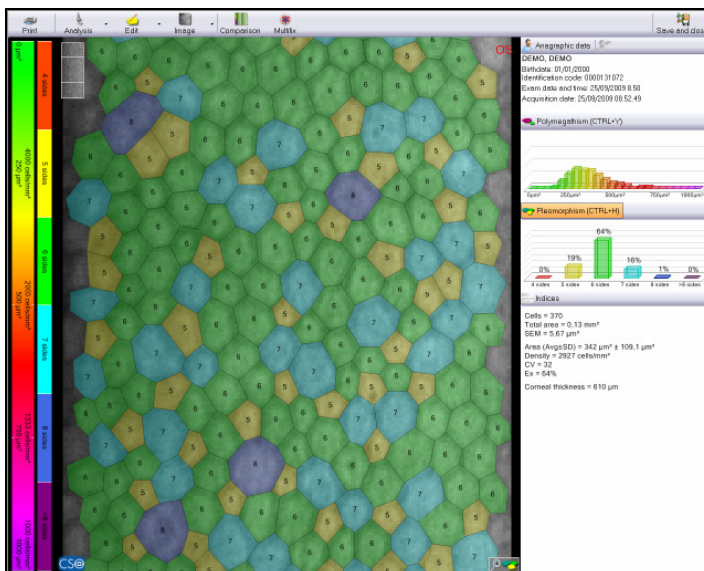
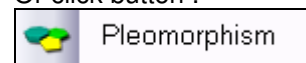


Fig. 32 – Pleomorphism

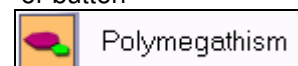
- Polymegathism: image displayed by surface area of each cell. (Fig.33).

To access the two processing types, open the pull-down menu from the Analysis button and select the desired item (Fig. 31).

Or click button :



or button



displayed on the right-hand side of the screen above the relative diagrams.

The reference scales for polymegathism and for pleomorphism are shown on the left-hand side of the screen.

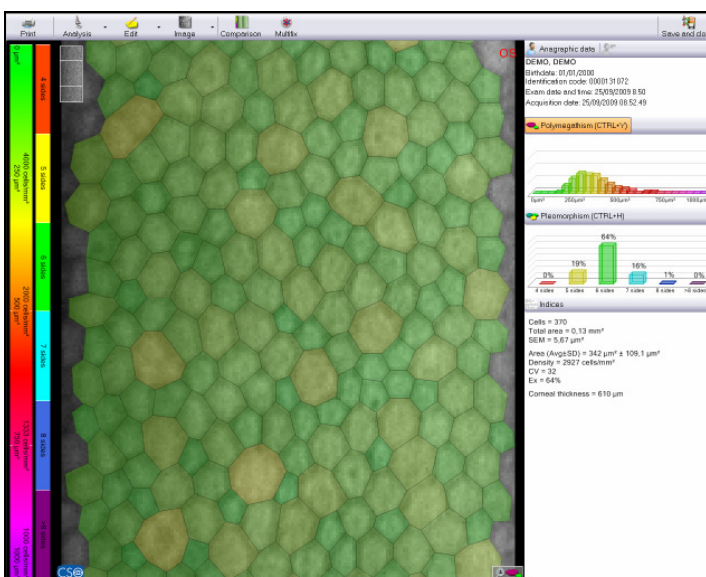


Fig. 33 - Polymegathism

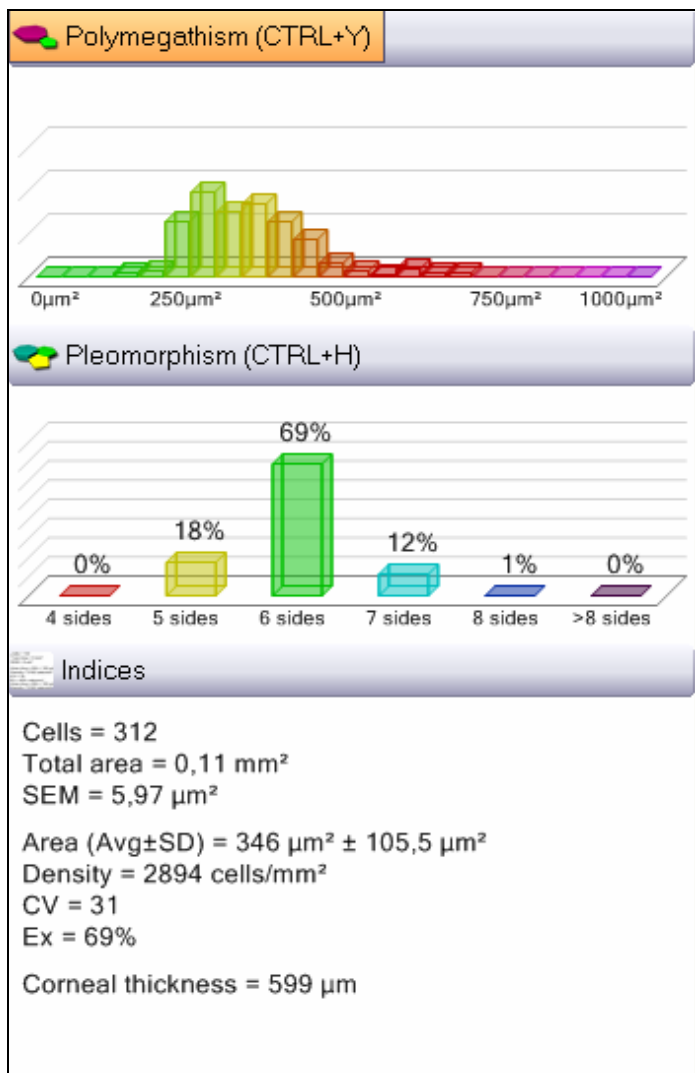


Fig. 34 – Analysis results

8.16 ANALYSIS RESULTS

The processing window on the right-hand side of the screen displays the graphs and numerical results.

The POLYMEGATHISM graph presents the number of cells with surfaces within the highlighted intervals.

The PLEOMORPHISM graph presents the percentages of cells having like numbers of sides, corresponding to the scale.

Cells : the number of cells counted for processing.

Total area : the area of the endothelium surface processed.

SEM (Standard Error of the Mean): evaluates the reliability of the measurement by comparing sample variability (standard deviation of the area) with the number of elements measured:

$$\text{SEM} = \frac{\text{Deviazione Standard Area}}{\sqrt{\text{Numero celle}}}$$

Area (Avg \pm SD) : average cell surface area with uncertainty given by standard deviation.

Density : density is given in cells per square millimeter [cell/mm^2]. An indicative normal value for a young male is 2500-3000 cells/ mm^2 .

CV (Coefficient of Variation): cell morphology is expressed using the Coefficient of Variation (CV), which is the ratio between the observed standard deviation and the arithmetic mean of all the cells examined. With reference to the Matsuda-Schultz index, an average value is less than 35.

$$\text{CV} = \frac{\text{Deviazione Standard Area}}{\text{Area media}}$$


Ex (hexagonality index): the ratio between the hexagonal (6-sided) cells and the total highlighted cells.


Thickness: indicative pachymetric datum

relative to the part of the cornea captured during the examination. The accuracy of corneal thickness measurement is strictly correlated with the quality of the captured image and for this reason the datum must be considered only indicative and approximate.

8.17 COMPARISON

The system allows the user to compare two captures. This function is especially useful for monitoring a patient's progress or the evolution of a pathology, or for comparing the pre- and post-treatment condition of the cornea. To access the COMPARISON function from the

main window, click the  button on the toolbar.

Accessing the COMPARISON function opens the window shown in Fig. 35. Click the  button at the top to select images of different examinations. Once the examination is selected, the relative gallery images will appear. Double-click an image to be compared with the starting image, shown on the top right. Only two images may be compared at a time. Click OK to confirm.

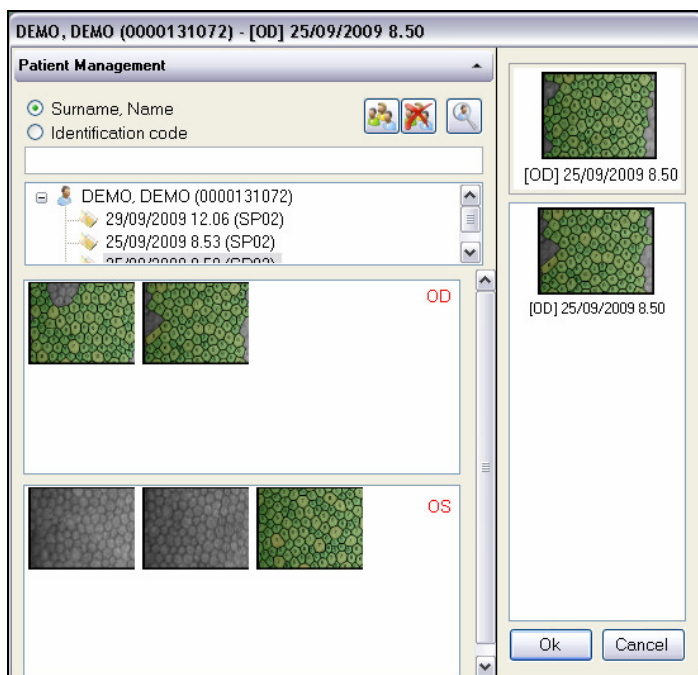


Fig. 35 – Selecting images for comparison

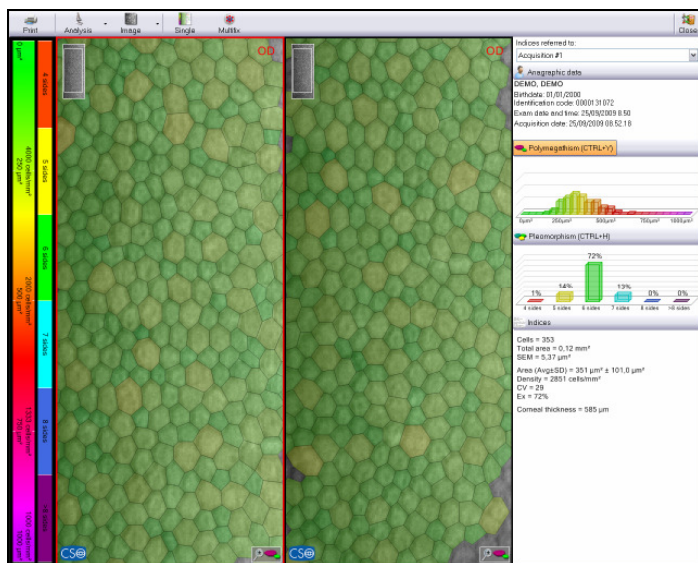


Fig. 36 – Image Comparison

A screen comparing the two processed images will open. The numerical values and the graphs on the right of the screen refer to the image highlighted by a red square. To select the other image, simply click on the image or open the menu on the top right,

Indices referred to:
Acquisition #1

and select the other image.

In this case as well, there are two possible analysis types: POLYMEGATHISM and POLYMORPHISM.

8.18 OVERALL COMPARISON OF ALL THE CORNEAL AREAS (Multifix)

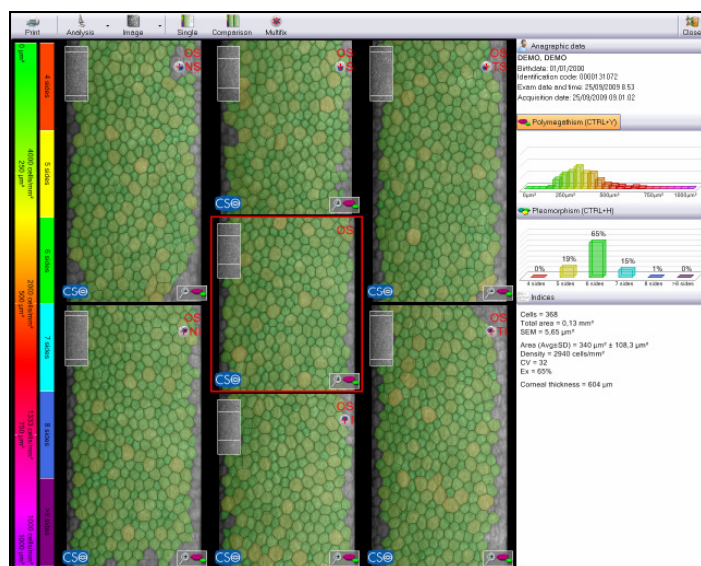



Fig. 37 – Multifix

When images of all the seven possible corneal areas are captured (one central plus six peripheral images), they may all be displayed in a useful summary format called “Multifix.” This function is active even when the acquisitions do not cover all the possible areas.



Click the  button in the processing window.

A new screen will display all the images referred to different areas of the endothelium.


OS or OD is indicated at the top of each image, as is the reference to the area of the endothelium photographed:

- ST: superior temporal
- IT: inferior temporal
- S: superior
- I: inferior
- SN: superior nasal
- IN: inferior nasal

The graphs and numerical values referred to the selected area are shown on the right-hand side of the screen, highlighted with a red square.

Fig. 38 – Patient search


8.19 OPENING A PATIENT FILE IN THE ARCHIVE

To open the patients list, click the  button. To find a particular patient, type the first letter/s of the last name in the command line. (Fig. 38). Only the patients whose last names begin with the letter/s entered will be displayed.

The ID code may also be used to find a patient. Select the ID code box and type the number in the command line.

Fig. 39 – Advanced search

8.20 ADVANCED SEARCH

Click the  button to run an advanced search. Figure 38 shows all search criteria selected; it is also possible to use only one criterion. Select the box of interest:

- GROUPS: select this option to view all the current groups. Select the groups that correspond to the search criterion.
- EXAM DATE: enter two dates delimiting the period of interest. In the Figure 38 example, all examinations conducted in the period 11 Nov 2006 to 01 September 2009 will be displayed.
- GENDER: select Male or Female.
- BIRTHDATE: as in the case of the Exam Date filter, enter two dates. All the patients whose birth dates fall in the period so delimited will be displayed.
- ACCESSION NUMBER: type in the examination accession number.
- PATIENT'S AGE: in this case as well, enter two values. The search will return all the patients whose age falls in the interval delimited by the two numbers.
- INSTRUMENT: leave "Specular Microscope" selected.
- LATERALITY: this menu opens only in the case of a search by group, to allow the user to select one of the two eyes as search criterion.

Click Search to start the search.

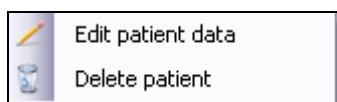


Fig. 40 – Edit, delete patient

8.21 PATIENT MENU OPTIONS

Select a patient and right-click. A menu opens. (Fig. 40).

EDIT PATIENT DATA: allows the user to edit the personal patient data.

DELETE PATIENT: permanently deletes the patient, as well as all the attached examinations and images, from the archive.

The software requests confirmation before deleting all the patient data.

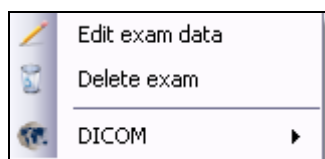


Fig. 41 – Edit, delete examination

8.22 EXAMINATIONS MENU OPTIONS

Select an examination and right-click. A menu opens. (Fig. 41).

 A dialog box titled 'Edit exam data'. It contains a date field with 'giovedì 24 settembre 2009' and a time field with '17.46.42'. Below these are three text input fields: 'Referring Physician's Name' (empty), 'Accession Number' (containing '090924174642'), and 'Identification code' (containing '090924174642'). At the bottom right are 'Ok' and 'Cancel' buttons.

Fig. 42 – Examination data editing screen

EDIT EXAM DATA: opens the screen shown in (Fig. 42) for editing the examination date, entering or changing the referring physician and/or the accession number for advanced searches.

EDIT EXAM: permanently deletes the selected examination and all the associated images. The program requests confirmation before proceeding with deletion.

DICOM: accesses the DICOM standard functions.

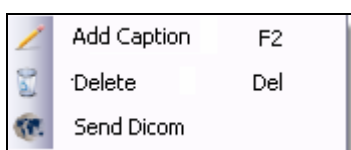


Fig. 43 – Image management menu

8.23 IMAGES MENU OPTIONS

Select a gallery image and right-click to open the menu shown in Fig. 43.

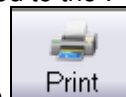
ADD CAPTION: adds a short description, shown in the gallery, for each image.

DELETE: permanently deletes an image from the gallery. The program requests confirmation before proceeding with deletion.

SEND DICOM: allows the user to send an image in DICOM standard protocol.

8.24 PRINTING

Printing is possible only if a printer has been connected to the PC.



Click the **Print** button on the processing screen to open the window shown in Figure 44.

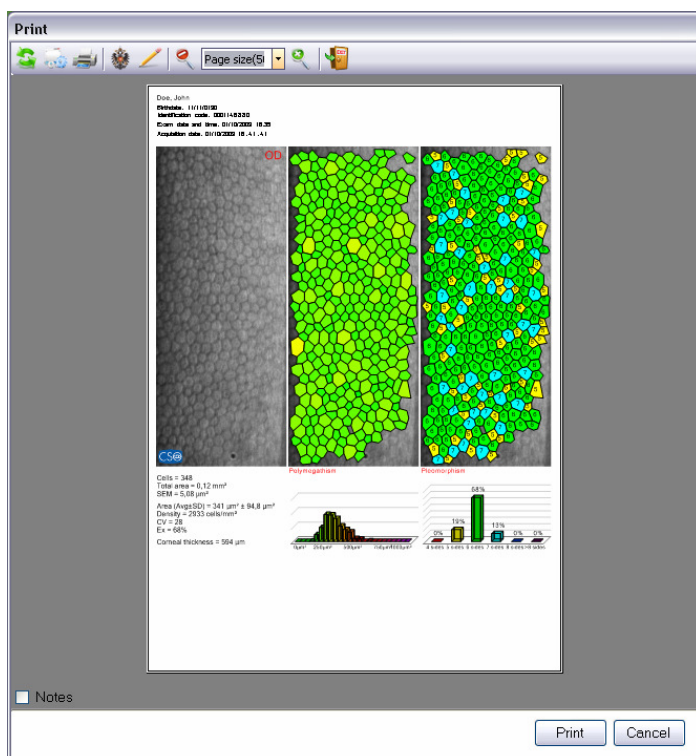


Fig. 44 – Print window



- **UPDATE:** allows the user to update the modifications in the print options and view them immediately in a video preview.

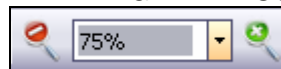


- **SETTINGS:** allows the user to change the print settings.



- **PRINTER:** allows the user to select the printer to be used and the relative properties.

- **ENLARGE – REDUCE PREVIEW:**



SHOW/HIDE HEADING: shows or hides the heading (if used) and relative logo.



- **ESC:** exits the printing screen.



- **EDIT COMPANY DATA:** opens the window shown in Figure 45. This function allows the user to insert the logo that will be displayed



on the printout by clicking and inserting company data by filling in the relative fields. Click OK to confirm.

Fig. 45 – Edit company data

To print after having viewed the preview, click **PRINT**.

8.25 DICOM

DICOM is a medical computer standard, adopted by many health agencies and hospitals in all parts of the world, which permits medical operators to exchange images and other information via computer systems adopting this standard.

Deselect the “Suppress DICOM WARNING” box to show any errors that do not interfere with image capture.

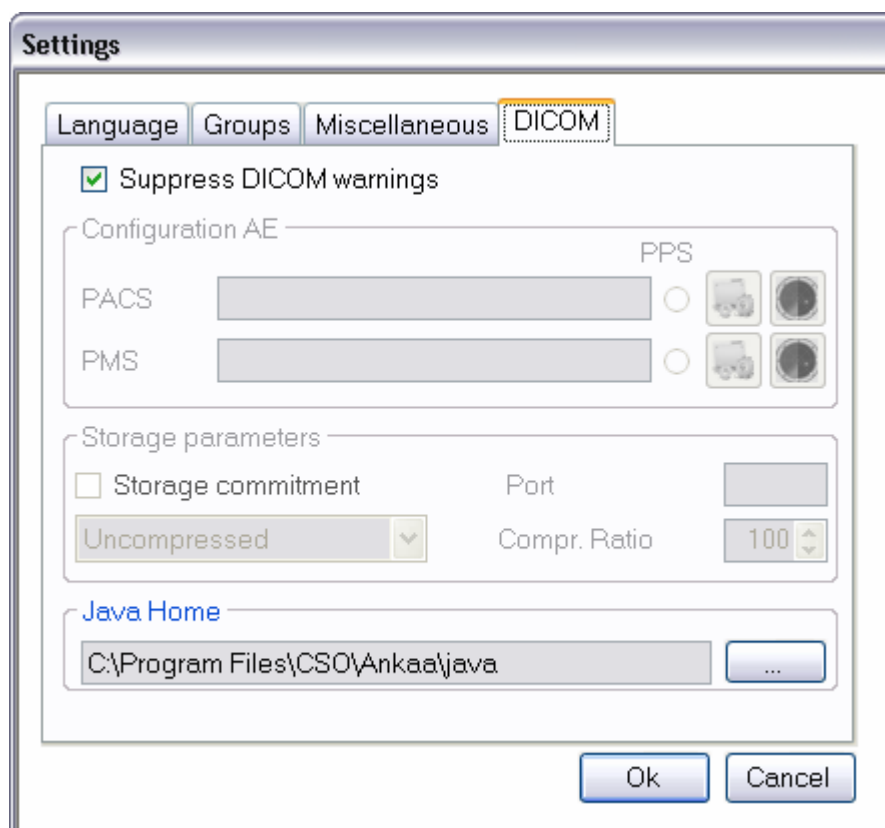


Fig. 46 – DICOM standard

If DICOM is instead selected, the remaining menus must be used.



Click the  PACS or PMS button to open the following windows:

This window allows the user to identify the PACS system that will receive his information or the PMS system from which information may be requested.

- In the relative fields, enter:
- Title: PACS/PMS ID.
- Host: PACS/PMS IP address.
- Port: PC port to which PACS/PMS is referred.
- Timeout(s): maximum waiting time before disconnecting a call.
- Limit: for PMS configuration only, identifies the maximum number of exams that may be received. If the field is left blank, any number of exams may be received.

Click [OK] to save the settings as entered; otherwise click [Cancel].

Click [Ping] to initiate a call to the PACS/PMS system.

The user may specify several data storage options as save parameters:

- Storage commitment: select this box to receive a computer receipt for the data sent. Enter the receiving PC in the Port field.
- Uncompressed/Lossless/Lossy: select this box to select the type of compression used for sending, in a 5% to 100% ratio by 5% steps. The files are sent in the original, if you select uncompressed format.

9. OPERATING FEATURES

The SP 02 Specular Microscope is the product of extensive research conducted in collaboration with highly-accredited professionals in order to ensure the very best in technological innovations, quality, and design.

The system incorporates a number of innovative solutions and therefore offers several features that make it unique. Let us mention a few:

- 1) There is no photosensor or linear sensor on the return light path. The image capture procedure is managed and implemented by the software to guarantee greater reliability (through reduction in the number of electronic components), lower production cost, and greater operational versatility.
- 2) The CCD digital camera ensures high-contrast, high-quality images.
- 3) The patient and exam files and captured images are stored in a relational database to permit working with the acquired data at any time following the examination.
- 4) The system supports data exchange via other applications in Intranet/Internet environments: the message format is XML and the SOAP protocol is used.
- 5) Future system expansions could include remote diagnostics and automated examination with no need of operator assistance.
- 6) The cell-count software is completely automatic and processes parameters that are not always supplied by other systems.

Software Features

The software can evaluate all the relevant data offered by the endothelial analysis, including the following cell size variability summary data (polymegathism):

- Number of cells in the area measured
- Cell density
- Mean cell area
- Standard deviation of the analyzed cells
- Coefficient of Variation
- Standard error of the mean (SEM)
- Histogram of cell size distribution

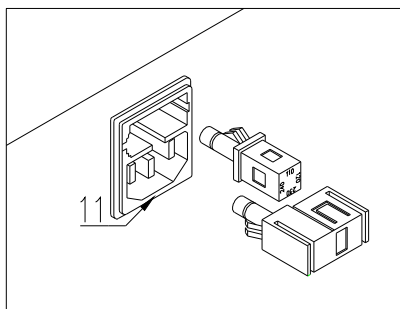
and the following cell morphology summary data:

- Hexagonal deviation (percentage of hexagonal cells)
- Form factor
- Histogram of cell form distribution.

The images are of excellent quality and cell count is fully automatic, although manual editing operations can be performed when necessary. This system permits automatically counting up to 400 cells with a single capture: the high number of cells analyzed permits obtaining statistically-relevant and extremely repeatable data. The endothelial data analyses and the images can be saved in an archive together with the patient's personal data. This archive may be integrated with the bon software solutions for Corneal Topography and the Digital Slit Lamp.



10 ROUTINE MAINTENANCE



Replacing the line fuses

The repairs illustrated below must all be performed only with the power cord disconnected from the line power socket. For any type of trouble requiring repairs different from those described below, contact your installation service.

34
Replacing the line fuses

10.1 REPLACING THE LINE FUSES

To replace the line fuses:

The line fuses are located on the rear of the transformer inside the socket/voltage changer unit (11).

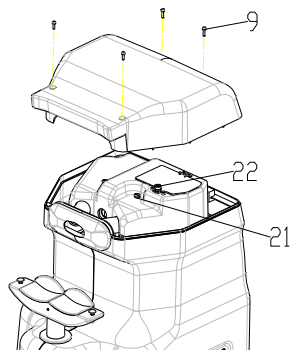
Before proceeding with replacement, disconnect power by unplugging the instrument power cord from the line socket.

Extract the voltage selector and remove the unserviceable fuses.
Replace the fuses with new fuses compatible with the line voltage supply, as

reported on the data plate (13).

Replace the voltage changer unit.

Reconnect the plug to the line socket.



10.2 REPLACING THE MONITOR FUSE

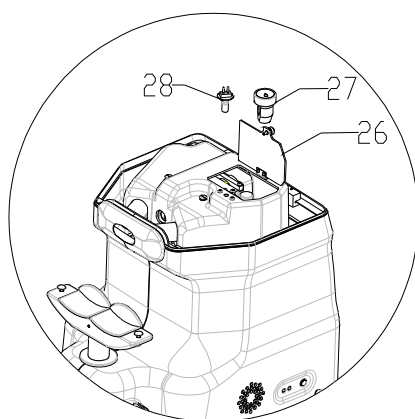
The fuse is located in the fuse holder (15).

Before proceeding with replacement, disconnect power by unplugging the power cord from the line socket.

Rotate the fuse holder lock ring in the direction indicated and remove the unserviceable fuse.

Replace the fuse with a good 0.315A fuse. Refer to the data plate (19).

Replace the fuse holder lock ring and tighten (turning in the opposite direction). Reconnect the plug to the line socket.



10.3 REPLACING THE HALOGEN (28) AND/OR FLASH (27) LAMP

To replace the lamps:

Before proceeding with replacement, disconnect power by unplugging the power cord from the line socket.

□ Unscrew the screws (9) and extract the optical head casing.

□ Unscrew screw (22) and open the lamp access door.

□ Replace the lamp: (28) 12V 30W halogen lamp, code 3008011230A, or flash

lamp, code 30080801010.

□ Close the access door (26) and tighten the screw (22).

□ Replace the optical head casing and lock by tightening screws (9).

□ Reconnect the plug to the line socket.

10.4 PROTECTING THE INSTRUMENT FROM DUST

When the instrument is not in use, it should be covered with the plastic cover supplied as standard equipment to protect it from dust. Any dust that may accumulate on the instrument should be periodically removed using a very soft cloth or a rubber ball air blower.

11. TECHNICAL DESCRIPTION

Photographic method:	Non-contact		
Photographic field:	0.54 mm x 0.27 mm		
Measurement accuracy:	±10 µm		
Video camera:	CCD video camera		
Flash:	bon flash tube		
Illumination for focusing:	12V 30W PG 22 alogen lamp		
Line voltage:	100V-120V ac ±10% 60 Hz 230V-240V ac ±10% 50 Hz		
Fuses:	<i>Line socket unit</i>	5x20 mm	100/120V ⇒ 2x 2.5AT 230/240V ⇒ 2x 1.25AT
	<i>Monitor:</i>	5x20 mm	1x 0.315AT
Power requirement:	150 VA		
Weight (instrument alone):	18 Kg circa		
Size:	420 mm (H) x 280 mm (L) x 380 mm (P)		

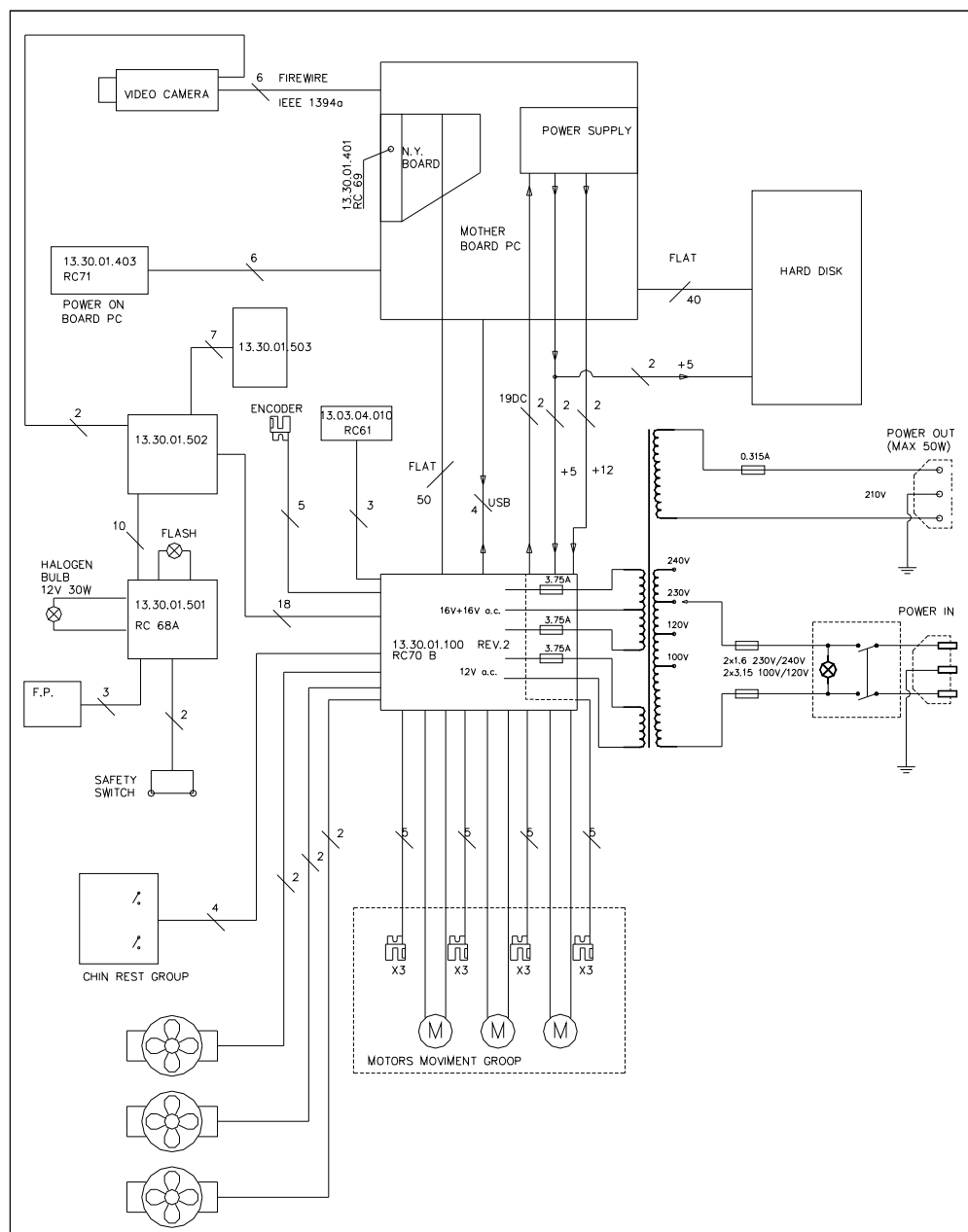
11.1 CLASSIFICATION ACCORDING TO EN 60601 STANDARD

Type of protection against direct and indirect contacts:	Class I
Level of protection against direct and indirect contacts:	Type B
Level of protection against humidity:	Common devices (no protection against water infiltration)
Method of sterilization:	Disinfection of equipment
Level of protection in proximity to inflammable anesthetics and/or detergents:	No protection
Use conditions:	Continuous service
Level of electrical connection between instrument and patient:	Device with applied parts

11.2 FUNCTION BLOCK DIAGRAM

On request, the manufacturer will supply diagrams, components lists, and detailed technical instructions for use only by authorized personnel with prior training in maintenance and calibration.

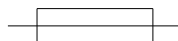
bon Optic hereby declares that all the components making up their instruments are covered by insurance and full warranty for 24 (twenty-four) months.



11.3 DATA PLATE SYMBOLS



Read the instructions carefully



Fuse



Type B protection against direct and indirect contacts



Mark of compliance with relevant standards

12. LIABILITY

CSO srl assumes responsibility for instrument compliance with European Directive 93/42/EEC and therefore for its performance, safety, and reliability.

CSO srl would like to point out that all the components of the devices it produces are covered by insurance and full warranty for 24 (twenty-four) months.

CSO srl nevertheless declines said responsibility if:

- installation and start-up are not performed in compliance with the instructions and precautions set forth in this manual.
- the instrument is used in ways not in accordance with the instructions and precautions set forth in this manual.
- accessories and/or spare parts not supplied or recommended by **CSO srl** are used.
- repairs and safety checks are not performed only by competent, qualified, and suitably-trained personnel authorized by **CSO srl**.
- the electrical system of the instrument installation site does not comply with CEI standards and the pertinent laws and regulations in force.

CSO srl also declines any and all responsibility for direct or indirect consequences or damage to persons and/or things deriving from improper use of the instrument and/or from erroneous clinical evaluation of information derived from its use.

13. WARRANTY AND TECHNICAL ASSISTANCE

CSO srl guarantees this product for a period of 24 months from date of invoice. This warranty includes *replacement, at CSO, of components and materials as well as relative labor. Shipping costs are at the customer's expense.*

Parts subject to wear and/or deterioration during normal use (for example, lamps and fuses) and parts damaged by improper use or inadequate maintenance are not covered by warranty.

CONDITIONS NOT INCLUDED UNDER WARRANTY

- Repair of damages caused by natural catastrophes, mechanical shock (dropping, crushing, etc.), defects in the user's electrical system, negligence, improper use, and/or maintenance/repairs performed using non-original materials and/or by persons not authorized by **CSO srl**
- Any type of improper use or use not specifically intended by the manufacturer.

CSO srl declines responsibility for any interruption or inefficiency in service due to causes or circumstances beyond their control. The customer shall in no case have any right to compensation for damages suffered as a consequence of the unavailability of the instrument.

To request technical assistance with maintenance, contact a technical assistance center or directly contact:

CSO srl
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50010 Badia a Settimo - Scandicci , Florence ITALY

14. CERTIFICATES / STATEMENTS OF COMPLIANCE

CSO srl - Costruzione Strumenti Oftalmici with headquarters in Via Degli Stagnacci 12/e – 50010 – Badia a Settimo – Florence – Italy, manufacturers of the medical electrical system denominated

SP/02 Specular Microscope

in the persons of its legal representatives Sergio Mura and Giuseppe Matteuzzi,
who assume full personal liability for the following,

HEREBY CERTIFY

that the above-mentioned product complies fully with the following EU Directive, including the latest amendments, and with the relative national implementing legislation:

DIRECTIVE 93/42/EEC “MEDICAL DEVICES ” of 14 June 1993

that the following harmonized standards were applied:

- ☐ **EN 60601-1 “Medical Electrical Equipment – Part 1: General Requirements For Safety,” as amended, corresponding to Italian standard CEI 62-5 – 1991 edition – record no. 1445.**
- ☐ **EN 60601-1-2 “Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility,” corresponding to Italian standard CEI 62-50 – 2001 edition.**
- ☐ **EN 60601-1-1 “Medical Electrical Equipment – Collateral Standard: Safety Requirements for Medical Electrical Systems,” as amended, corresponding to Italian standard CEI 62-51 – 1994 edition – Record no. 2308.**
- ☐ **UNI EN ISO 15004 “Ophthalmic instruments. Fundamental Requirements and Test Methods.” 2000 edition.**

that the product is a Class I device as per Annex IX of the above-cited Directive.

that the instrument is marketed with the  mark.

that the complete reports of the tests carried out on a random sample from series production and the rest of the technical and quality assurance documentation (as called for by Annex VII of Directive 93/42/EEC) are kept in the CSO srl Technical Office files.

Signature of Legal Representative

15. REFERENCE STANDARDS

The following reference standards were applied in design, production, and testing of the product:

EU Directives

- . □ **DIRECTIVE 93/42/EEC “MEDICAL DEVICES ” of 14 June 1993.**
- . □ **DIRECTIVE 2002/96/EC “Waste Electrical and Electronic Equipment (WEEE).”**

Standards concerning Quality Management Systems

- . □ **UNI EN ISO 9001:2000 “Quality Management Systems – Requirements.”**
- . □ **UNI EN ISO 13485:2004 “Medical Devices – Quality Management Systems - Clinical Requirements for Regulatory Compliance.**

Technical Standards

- . □ **EN 60601-1 “MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY” as amended, corresponding to Italian standard CEI 62-5 – 1991 edition – record no. 1445.**
- . □ **EN 60601-1-2 “MEDICAL ELECTRICAL EQUIPMENT – Collateral Standard: Electromagnetic Compatibility,” corresponding to Italian standard CEI 62-50 – 2001 edition.**
- . □ **EN 60601-1-1 “MEDICAL ELECTRICAL EQUIPMENT – Collateral Standard: Safety Requirements for Medical Electrical Systems,” as amended, corresponding to Italian standard CEI 62-51 – 1994 edition – Record no. 2308.**
- . □ **UNI EN ISO 15004 “Ophthalmic instruments. Fundamental Requirements and Test Methods.” 2000 edition.**
- . □ **UNI EN ISO 14971:2004 “Risk Management for Medical Devices.”**

The registered trademarks are property of the respective trademark owners.

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