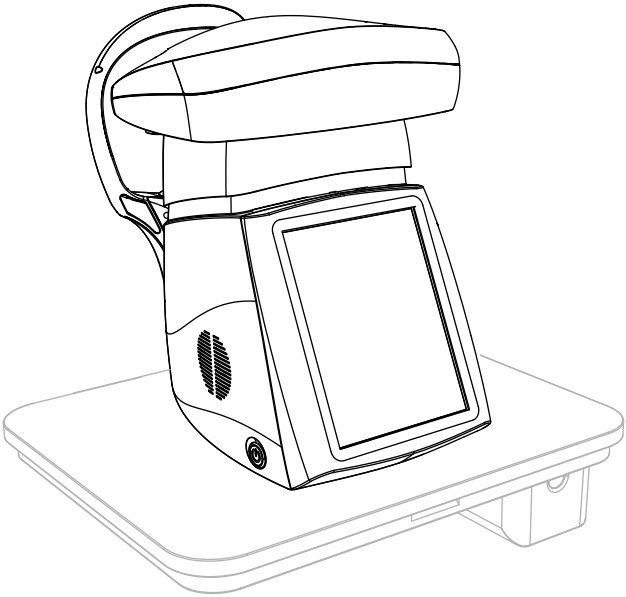
COSTRUZIONE STRUMENTI OFTALMICI



PERSEUS

Endothelial microscope

INSTRUCTIONS FOR USE

COSTRUZIONE STRUMENTI OFTALMICI

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EN

Colour inside

CE 0051

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1 INTRODUCTION

The device is the result of a long research period, conducted by experts to give the product technical innovation, quality and design.
The device can be easily used thanks to the guided manual capture and the electronic control of all the functions of the device.

1.1 SYMBOLS

Within the instructions for use, on the package or on the device, there can be the following symbols:

Symbol	Meaning
	Caution
	Danger of electric shock
	Read the instructions for use
	General obligation
	Note. Useful information for the user
	General prohibition sign
	Manufacturer
CE 0051	CE Marking (Directive 93/42/EEC). Identification number of the notified body (IMQ).

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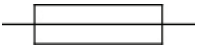
Waste disposal in compliance with the Directive 2012/19/EU (WEEE), and 2011/65/EU (RoHS II)

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part
	Fuse

1.2 GENERAL WARNINGS

THESE INSTRUCTIONS FOR USE REFER TO THE DEVICE PERSEUS ("DEVICE" FROM NOW ON).

THE ORIGINAL TEXT IS IN ITALIAN.

Before using the device or if you don't use it since a long time, read these instructions carefully. Read the instructions given in the instruction manual and reported on the device.

The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Keep this manual close by for future consultation. If you should decide to sell this appliance to other people, remember to also include these instructions, complete and readable.

Keep the original box and packaging, as the free-of-charge service does not cover any damage resulting from inadequate packaging of the product when this is sent back to an Authorized Service Centre.

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Before using the device check that there is no sign of damages due to transport or an incorrect storage.

It is forbidden to reproduce, totally or partially, texts or images contained in these instructions for use without the written authorization of the Manufacturer.

The Manufacturer reserves himself the right to modify the contents of the instructions for use, without notice.

1.3 NORMATIVE REFERENCES

1.3.1 COMMUNITY DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and integrations concerning medical devices
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1: 2005 + A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EC 60601-1-2:2014 Edition 4 - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- UNI EN ISO 15004-1:2009- “Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all Ophthalmic devices”.
- UNI EN ISO 15004-2:2007- “Ophthalmic Instruments. Fundamental requirements and test methods - Part 2: Light hazard protection”.
- UNI CEI EN ISO 14971:2012 - Medical devices. Application of risk management to medical devices.

1.3.3 QUALITY MANAGEMENT SYSTEMS STANDARDS

- UNI CEI EN ISO 13485:2016 - Medical devices. Quality management systems - Requirements for regulatory purposes”.

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1.4 WARRANTY

The Manufacturer is responsible for the device conformity to the Community directive 93/42/EEC as amended by the 2007/47/EC for:

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

- installation and activation not activated in conformity to the indications and the precautions reported in the instructions for use
- use not in compliance with the instructions for use and precautions reported in the instructions for use
- use of accessories or spare parts not provided or suggested by the Manufacturer
- repairs and safety controls not effectuated by expert, qualified, trained and personnel authorized by the Manufacturer
- electrical system of the space where the device is installed not in compliance with the technical standards, the laws and regulations in effect in the country of installation of the device
- direct or indirect consequences or damages to objects or persons, originating from the improper use of the device or erroneous clinical analysis originating from its use

The Manufacturer guarantees the device for 24 months after invoicing. The Warranty includes the substitution, at the Manufacturer's or an Authorized Service Centre, of components and materials and the relative labour. The shipping and transport fees are to be paid by the client.
The warranty does not cover:

- repairs of faults originating from natural disasters, mechanical shocks (fall, hit, etc), electrical system faults, negligence, improper use, maintenance or reparations carried out with non-original materials
- any other improper use or not intended by the Manufacturer
- damages caused by service lack or inefficiency, originating by causes or circumstances out of the Manufacturers control

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- the parts subject to usage and/or deterioration originating from the normal use and those that might be broken because of an improper use or maintenance carried out by personnel non-authorized by the Manufacturer.

To ask maintenance interventions or to have technical information about the device, address to an Authorized Service Centre or directly to the device Manufacturer.

The client will not be refunded for damages originating from the device halt.

1.5 MANUFACTURER IDENTIFICATION

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2 SAFETY

2.1 SAFETY WARNINGS

DANGER
Electric shock danger. Do not let water fall on the device. Do not immerse the device in water or other liquids.

DANGER
Electric shock danger. If the power cables are damaged, they must be replaced in an Authorized Service Centre to prevent any risk.

DANGER
Electric shock danger. Unplug the power cable from the mains socket before disinfecting the device and before any maintenance operation.

CAUTION
Do not use the device if visibly damaged. Periodically inspect the device and the connection cables to verify if there are damage signs.

CAUTION
Always keep the device out of the reach of children.

CAUTION
Danger of device falling down. Do not leave free cables which can represent an obstacle or a danger for the patient or the operator.

CAUTION
Danger of stumbling and falling. Do not let the power cord or the connection cables free in a place where people could walk.

CAUTION
Electric shock risk. Do not touch the power supply cables with wet hands.

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CAUTION
Electric shock risk. Do not leave the power supply cables in contact with sharp corners or objects. Collect and attach always the power supply cables.

CAUTION
If you notice a wired odour or smoke coming out of the device or if it emanates heat, turn it off immediately. Do not keep using a damaged product or a damaged part. Danger of injuries.

CAUTION
The electrical net must have a Residual-Current Circuit Breaker (IΔn=30mA) Thermal-Magnetic Circuit Breaker (Vn=230V) to protect the device. Place the device in such a way that the power socket is easily accessible.

It is forbidden to carry out any technical operation on the device that is not recalled or described in the instructions for use.

It is forbidden to place the device in humid, dusty places or environments subject to sudden temperature and humidity variations.

It is forbidden to use any extension cable not authorized by the manufacturer.

It is forbidden to use the device outdoors.

The device does not generate and does not receive any electromagnetic interference if it is placed near other electrical appliances. No preventive or corrective actions are required.

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2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE MEDICAL DEVICES LIST

The device registration data can be verified on the Italian Ministry of Health website at this page:
Ministero della Salute - Ricerca dispositivi

2.2.2 DEVICE DATA PLATE

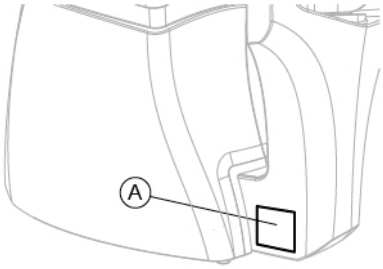

Fig 1 - Data plate position

Pos	Description
A	Device data plate

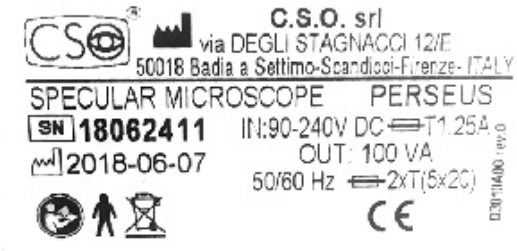

Fig 2 - Data plate

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2.3 INTENDED USE

Perseus is a medical device for the analysis of the corneal endothelium.
The device is a specular microscope designed for the screening, the capture and the elaboration of a digital image of the corneal endothelium in the ophthalmic procedure.
The device allows, without any contact with the patient, to obtain a mapping of the endothelial cells and a series of parameters to establish what is the corneal medical condition.
The endothelium image allows to visualize the cells parameters, including: cells number and density, cells shape, surface, average area, standard deviation, coefficient of variation, cells percentage of various shape, areas dimension distribution histogram, pachymetric data.
Endothelial microscopy is essential in the diagnosis of many corneal dystrophies and degeneration, in the pre and post-operative assessment of cataract surgery and corneal transplants.
Cell density, pleomorphism and poimegatism values, as well as pachymetric data are calculated automatically. If it is necessary to make evaluations on the peripheral areas of the cornea, the device is equipped with a set of fixation targets suitable for this purpose.
The device performs:

- non-invasive exam of the endothelial tissue,
- automatic focus of the endothelial layer,
- automatic research of the cells' barycentre,
- statistical analysis based on the collected data.

The device has an integrated application software that manages and realizes the capture of data and images that can be visualized through the touch screen. The digital CCD camera allows to obtain well contrasted images of good quality.
The system allows the data interchange between other applications in the Intranet/Internet environment.

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Exam of the endothelial tissue

It is possible to automatically count up to 400 cells with a single acquisition. The examination allows to obtain a mapping of the endothelial bed and a series of indicators based on the shape and size of the cells comparing more images at the same time.

Feature of the integrated application software.

The integrate application software of the device can evaluate all the significant data obtained with the endothelial analysis: such as:

- cells number in the measured area,
- cells density,
- average cells area,
- standard deviation of the analysed cells,
- coefficient of variation
- average error of the mean,
- cells dimensions occurrences histogram.
- hexagonal deviation (percentage of hexagonal cells).
- shape factor.

The device works autonomously and, when necessary, it can be integrated with the Phoenix application software to increase the device functionalities.

Do not install other application softwares to avoid impairing the correct functioning of the device.

Do not use writing pens or other sharp devices. For the touch screens use your fingers or the specific pens.

The device must be only used by specialist practitioners and operators (such as optometrists), within the limits of the law and the regulations for the exercise of the profession.

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Read the instructions for use of the application software.

It is possible to connect other accessories to the device (printer, modem, scanner, etc) through the analogical or digital interfaces.
The accessories (printer, modem, scanner, etc) must be installed outside the patient area.

The accessories must be compliant to the norm IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements.
If the accessories are installed in the patient area it is necessary to install an insulating transformer compliant with the directive IEC 60601-1:2005 + A1:2102 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

Patient area: any volume in which intentional or unintentional contact can occur between patient and parts of the system or between patient and other persons touching parts of the system.

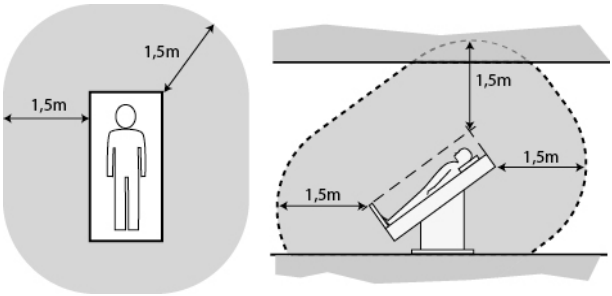

Fig 3 - Patient area

2.4 MEDICAL DEVICES CLASSIFICATION

Technical data	Value
Classification in compliance with the attached IX to the Directive 93/42/EEC and successive modifications	Class I

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2.5 MEDICAL ELECTRICAL DEVICES CLASSIFICATION

Classification complying with the standard EN 60601-1:2005 + A1:2012

Technical data	Value
Type of protection against the direct and indirect contacts	Class I
Applied parts	Type B
Protection degree against humidity	IP20 (no protection against liquid infiltration)
Sterilization or disinfection method	This device can be disinfected
Protection degree in presence of anaesthetics or inflammable detergents	No protection
Electrical connection degree between device and patient	Appliances with applied part on the patient
Use conditions	Continuous functioning

2.6 ENVIRONMENTAL CONDITIONS

Phase	Technical data	Min	Max
Transport	Temperature	-40°C	+70°C
	Atmospheric pressure	500 hPa	1060 hPa
	Relative humidity	10%	95%
Storage	Temperature	-10°C	+55°C
	Atmospheric pressure	700 hPa	1060 hPa
	Relative humidity	10%	95%
Use	Temperature	+10°C	+35°C
	Atmospheric pressure	800 hPa	1060 hPa
	Relative humidity	30%	90%

Phase	Technical data	Min
Vibration	Sinusoidal	10 Hz to 500 Hz, 0.5g
	Shock	30g duration 6ms
	Bumb	10g duration 6ms

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CAUTION
Danger of device damages. During transport and storage, the device can be exposed to the environmental conditions for a maximum period of 15 weeks, only if kept in the original packaging.

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

Instruction for disposal of product correctly according to European Directive 2012/19/EU, and 2011/65/EU about the reduction of use of dangerous substances in the electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device must not be disposed of as urban waste. The device can be delivered to the appropriate separate waste collection centres set up by municipal administrations or to retailers that offer this service. Separately disposing of an electrical device prevents possible negative consequences for the environment and health, caused by its improper disposal, and lets the materials it is made of to be recycled so as to achieve significant savings of energy and resources. On the label of the device there is the symbol of the of the crossed-out wheeled bin. The graphic symbol of the crossed-out wheeled bin, indicates the obligation to collect and dispose separately the electrical and electronic equipment at the end of their useful life.

The user has to consider the effects potentially dangerous for the environment and the human health originating from an improper disposal of the whole device or its parts.

In case the user wishes to dispose of the device used at the end of its useful life, the Manufacturer facilitates the possibility of its reuse and the recovery and recycling of the materials contained therein. This to prevent the release of hazardous substances into the environment and to promote conservation of natural resources. Before disposing of the device, it is necessary to take into consideration the European and national regulations that order what follows:

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- not to dispose as urban waste but collect it separately and address to a firm specialized in the disposal of electrical and electronic equipment or to the local administration in charge for waste collection.
- in the event that a new device is purchased from the same Manufacturer to replace an old one placed on the market before 13 August 2005, equivalent and with the same functions of the new device, the Distributor or Manufacturer are legally required to collect the old device.
- if the user decides to dispose a used device, put on the market after the 13th August 2005, the Distributor or the Manufacturer have to collect it.
- the Manufacturer takes care, by joining a consortium for the technological devices waste, of the treatment and the recycling of the used device by paying its costs.

The Manufacturer is available to give the user all the information about the dangerous substances contained in the device, and on the recycling modalities of those substances and about the possibility of a reuse of the used device.
Strict sanctions for transgressors are provided for by law.
For specific information about the disposal in other countries than Italy, contact the local Dealer.

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2.8 MANUFACTURER DECLARATIONS

2.8.1 ELECTROMAGNETIC EMISSIONS

The device is designed to be used in a room with the following electromagnetic characteristics:

Emission test	Compliance	Electromagnetic environment
Radio frequency emission. CISPR 11	Group 1	The device uses radio frequency energy only for its inner functioning. The radio frequency emissions of the device are very low and should not cause interferences with the near appliances.
Radio frequency emission. CISPR 11	Class B	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.
Harmonic emissions. IEC 61000-3-2	Class A	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.
Limitation of voltage changes, voltage fluctuations and flicker. IEC 61000-3-3	Compliant	The device can be used in all the environments, included the domestic environment. The device can be connected directly to a low-voltage power supply net as there is in the housing units.

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Immunity test	IEC 60601-1-2 test level	Conformity level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV contact. ±8 kV air	±6 kV contact. ±8 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/burst. IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	±2 kV for power supply lines. Non-applicable	Mains power quality shall be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode	±1 kV differential mode. ±2 kV common mode	Mains power quality shall be that of a typical commercial or hospital environment.
Voltage dips. Short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% Un for 0.5 cycles. 40% Un for 5 cycles. 70% Un for 25 cycles. <5% Un for 5 s	<5% Un for 0.5 cycles. 40% Un for 5 cycles. 70% Un for 25 cycles. <5% Un for 5 s	Mains power quality shall be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterrupted power supply or battery.
Power frequency (50/60Hz) magnetic fields. IEC 61000-4-8	3 A/m	3 A/m	Power frequency of the magnetic fields should be that of a typical commercial or hospital environment.
RF conduced IEC 61000-4-6 **RF conduced IEC 61000-4-3**	3 Vrms from 150kHz to 80 MHz 3 V/m from 80 MHz to 2.5 GHz	3 Vrms 3 V/m	(1)

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(1) Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

d=1,167*sqrt (P)

d=1,167*sqrt (P) 80 MHz to 800 MHz

d=2,333*sqrt (P) 800 MHz to 2.5 GHz

P: is the maximum output power rating of the transmitter in watts (W) according to the transmitter Manufacturer.

d: is the recommended distance in metres (m) at which the portable radio frequency (RF) appliances can be used.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

(Un) is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

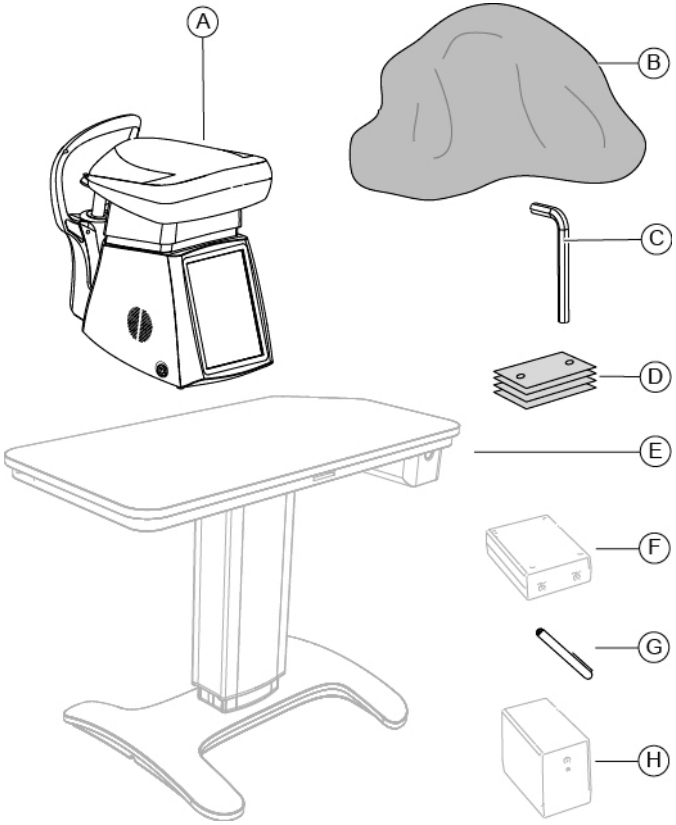

Fig 4 - Supply description

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Pos	Denomination		Description
A	Device PERSEUS		Composed by a camera unit equipped with micro video camera for capturing the images and an adjustable chin rest. Integrated application software for image capture and device management.
B	Protective cover		Place on the device when it is not in use to protect it from dust.
C	Hex wrench for power supply cable		
D	Package of chin cup papers		
E	Ophthalmic table	Optional	Adjustable electric support surface with one or two columns. Drawer and auxiliary sockets with fairlead.
F	Isolation transformer	Optional	230V/230V for the use of the non-electromedical appliances in the patient area.
G	Touch screen pen		
H	Uninterruptible power supply	Optional	It provides emergency power to the device in the event of a blackout, thus avoiding damages due to current surges.

For the list of accessories and available models, contact the Manufacturer or the local Distributor.

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3.1.1 DEVICE PERSEUS

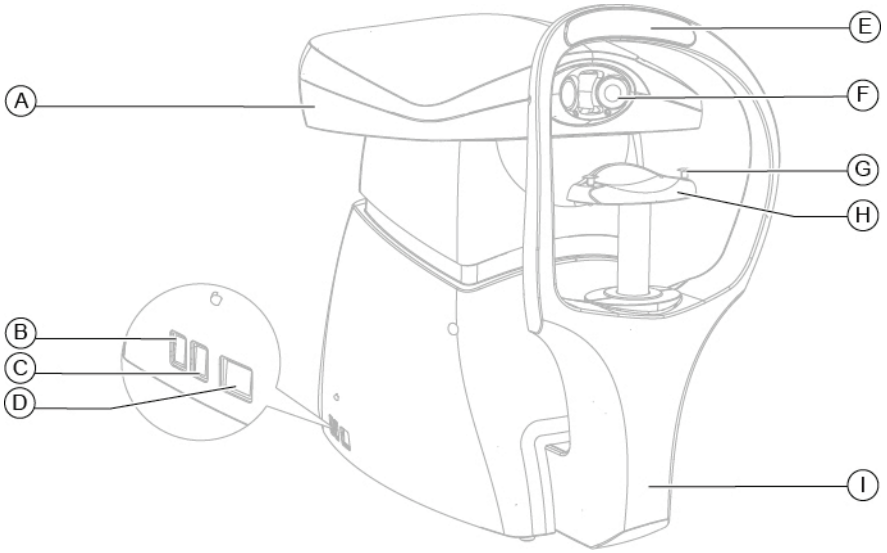

Fig 5 - Device PERSEUS

Pos	Description
A	Device PERSEUS with mobile head
B	USB port
C	USB port
D	Ethernet port
E	Forehead rest
F	Optical parts
G	Pins for paper for chin cup
H	Chin cup
I	Chin rest integrated with the device

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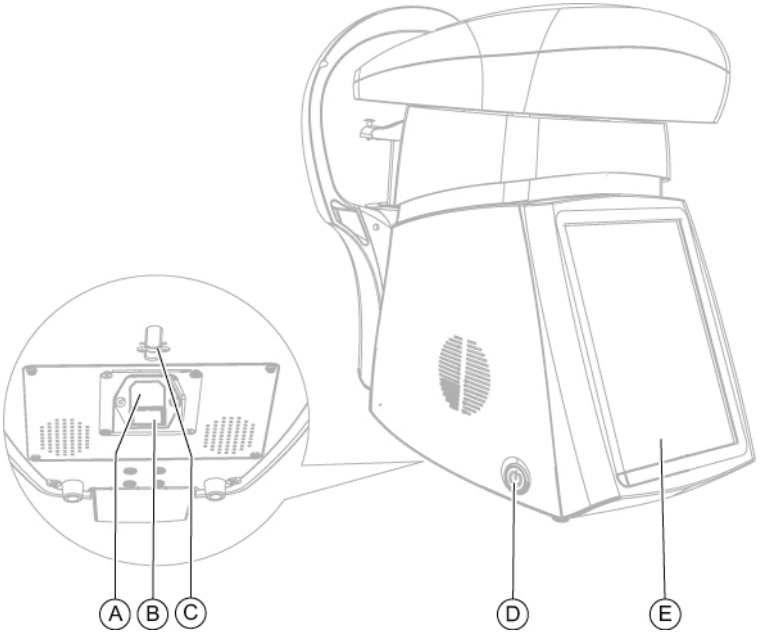

Fig 6 - Device PERSEUS

Pos	Description
A	Supply outlet
B	Fuses box
C	Cable block with screws
D	ON/OFF button
E	Touch screen

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3.1.2 OPHTHALMIC TABLE

Different table models are available accordingly to the client's choice. The electric table is composed by a support surface on which are installed the cogged guides for the device housing. The table has one or two telescopic columns, motorized, that allow to adjust the height of the support table top.

Fig 7 - Ophthalmic table

Read the instructions for use of the ophthalmic table.

3.2 TECHNICAL DATA

Technical data	Value
Acquisition	Not in contact
Photographic field	0,54 mm x 0,27 mm
Video camera	CCD
Focus lighting	LED
Magnification factor	180x
Pachymetry measurement	from 0.4 to 0.75 mm step 0.01 mm
Fixation target	Internal LED
Monitor	Touch screen 10.4"
Size	437 x 328 x 448 mm
Weight	15 kg

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4 INTEGRATED APPLICATION SOFTWARE DESCRIPTION

The device includes an application software that allows its autonomous functioning. The captured data and images are visualized on the screen. It is also possible to perform manual editing operations. The endothelial data analysis and the images can be saved in an archive with the patient's personal data and can be shared on the net.

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4.1 LOADING SCREEN

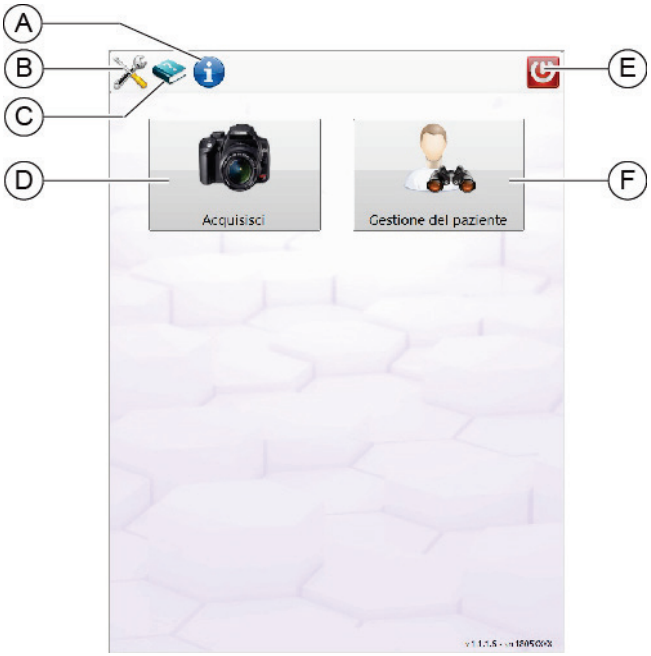

Fig 8 - Loading screen

Pos	Description
A	Features of the application software
B	Settings
C	Manual "Instructions for use"
D	Fast image capture
E	Application software stop
F	Patient's data management

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4.2 PATIENT SEARCH SCREEN

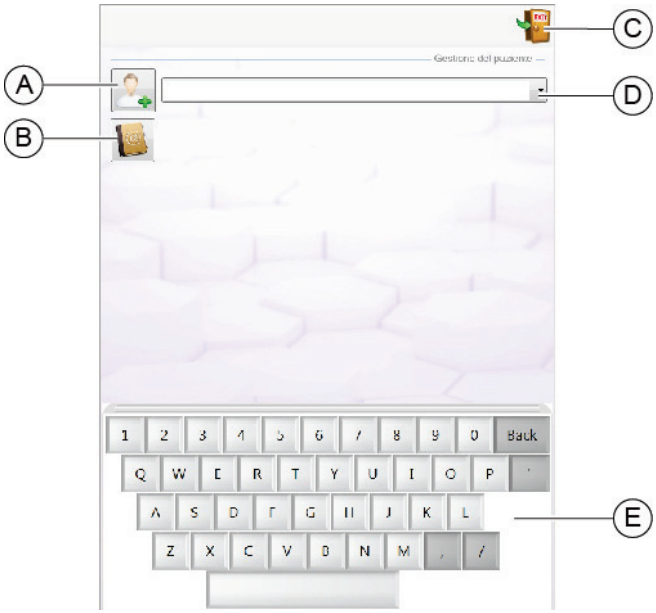

Fig 9 - Patient search screen

Pos	Description
A	New patient registration
B	Patients archive
C	Exit the screen
D	Research by name
E	Keypad

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Fig 10 - New patient data registration

Pos	**Description**
F	New patient data addition

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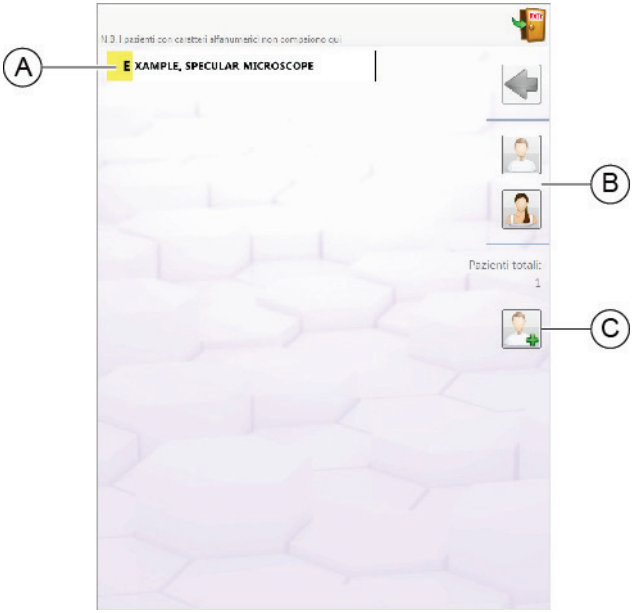

Fig 11 - Archive

Pos	Description
A	Alphabetically ordered patients list
B	Patient research by sex
C	New patient registration

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4.3 IMAGE CAPTURE SCREEN

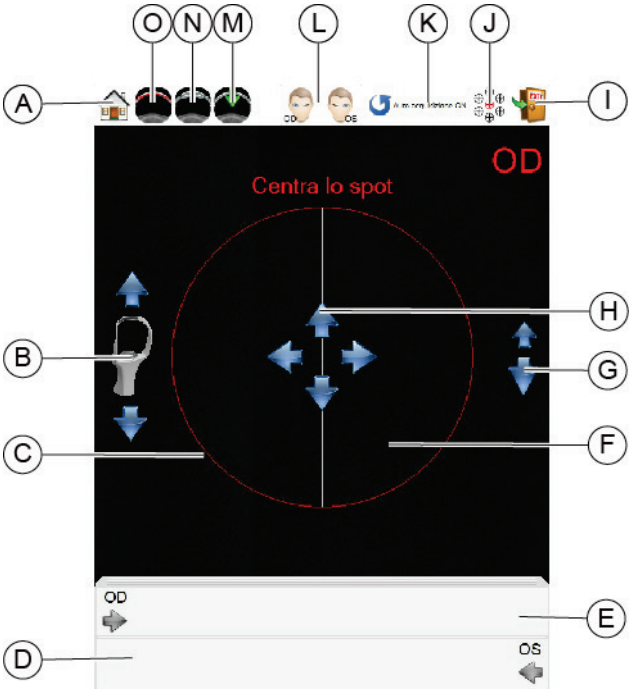

Fig 12 - Image capture screen

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Pos	Description
A	The device head returns in the home position
B	Chin rest height adjustment
C	Image capture area
D	Left eye images gallery
E	Right eye images gallery
F	Corneal reflection area (when visualized)
G	Corneal reflection focusing
H	Directional arrows for the corneal reflection centring
I	Go back to the main menu
J	Fixation target selection
K	Automatic capture ON/OFF
L	OD/OS capture laterality
M	Manual capture mode
N	Corneal transplant functioning mode
O	Flat cornea functioning mode

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4.4 EXAMS MANAGEMENT SCREEN

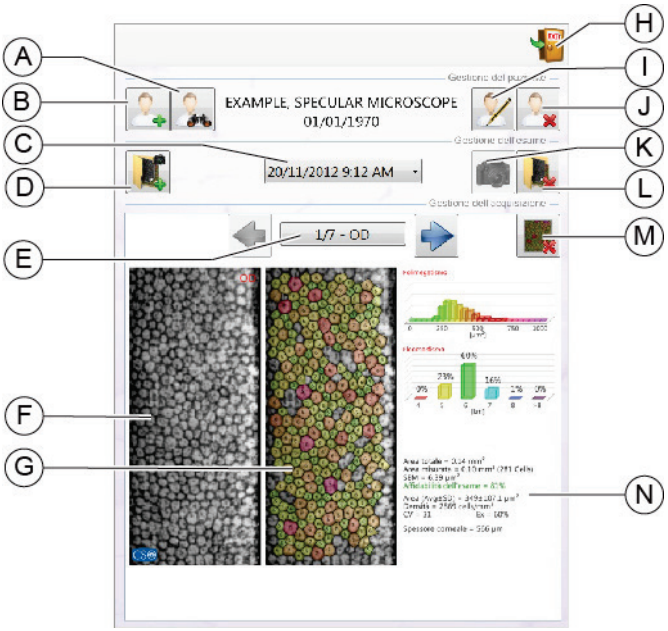

Fig 13 - Exams management screen

Pos	Description
A	Patients database. Go back to the screen PATIENT MANAGEMENT
B	New patient data addition
C	Patient's exams research by date and hour
D	New folder exams. Each folder contains one or more captures.
E	Surfing between the acquired data during the exam related to the active exams folder.
F	Captured image
G	Elaborated image
H	Go back to the screen IMAGE CAPTURE
I	Patient's data modification
J	Patient's deletion
K	Image capture (active only if the folder is created in the same day of the exam)
L	Exam deletion
M	Image deletion
N	Acquisition summary

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4.5 ACQUIRED DATA SCREEN

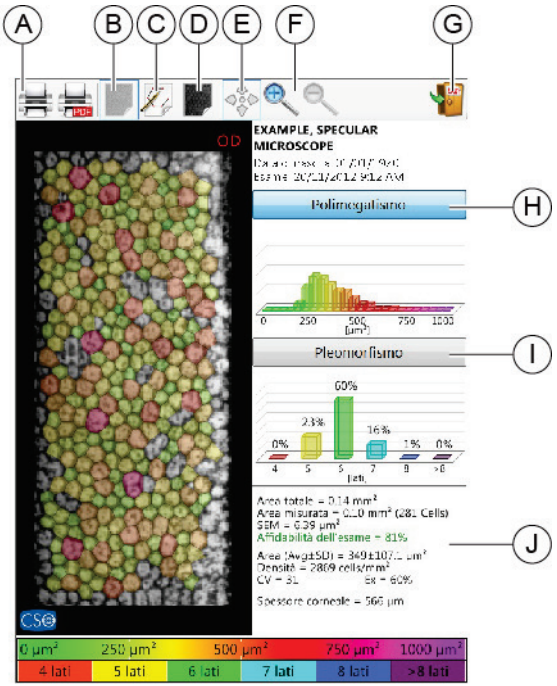

Fig 14 - Acquired data screen

Pos	Description
A	Acquired data print
B	Elaborated image visualization
C	Processed cells manual modification (perform the manual modification only when the automatic segmentation is not satisfying)
D	Original not elaborated image visualization
E	Displacement mode (active only when the image doesn't fit completely in the frame)
F	Image magnification or reduction
G	Exit the screen
H	Polymegathism mode
I	Pleomorphism mode
J	Statistical summary

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4.5.1 MODIFICATION TOOLS

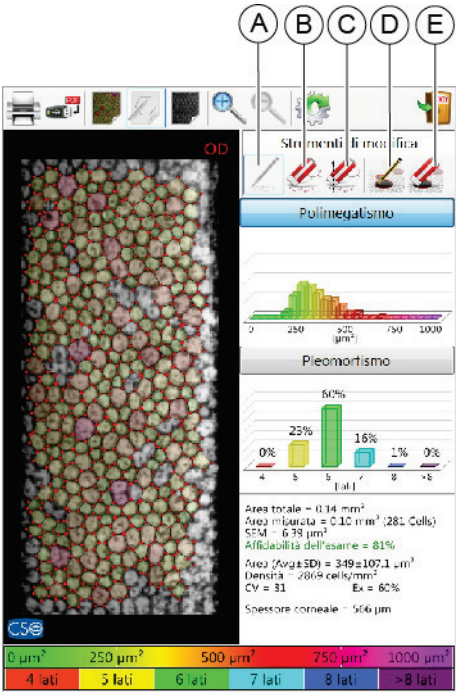

Fig 15 - Modification tools

Pos	Description
A	New cells definition
B	Vertex deletion
C	Cells deletion with area selection
D	Guttae area definition
E	Guttae area deletion

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4.6 SETTINGS SCREEN

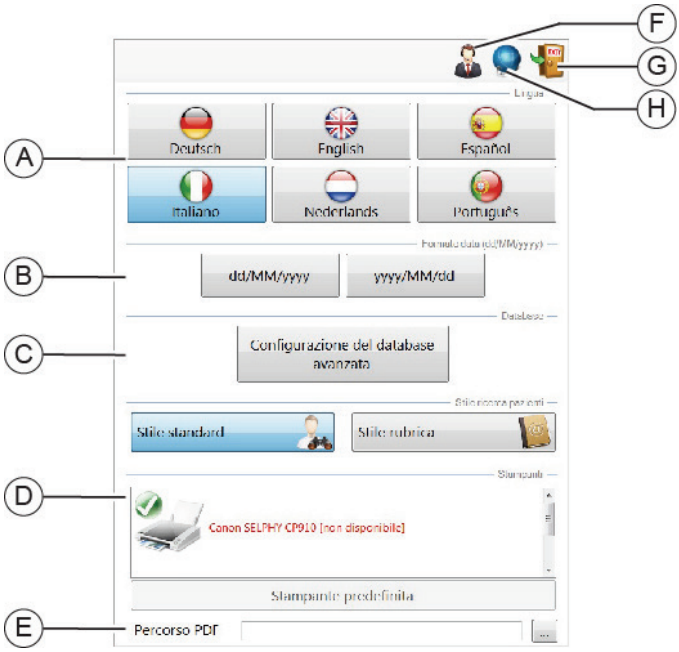

Fig 16 - Settings screen

Pos	Description
A	Language setting
B	Date setting
C	Images filing path
D	Printers list
E	PDF print path
F	Connection to the technical assistance
G	Go back to the loading screen
H	Net setting

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5 DEVICE USE

5.1 HOW TO INSTALL THE DEVICE

Never grab or lift the device by its head during the installation procedure.

1 Place the electric table in the work environment. The table must be lifted by two people.

2 If present, block the table wheels. Lower the lever of the brake.

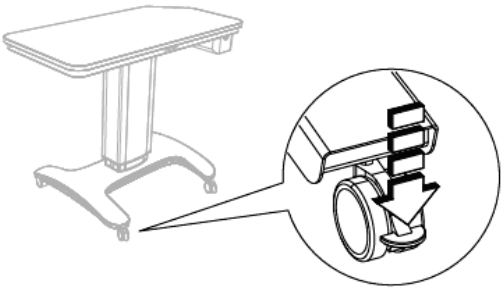

Fig 17 - Table placement

3 Place the device on the support table top in the horizontal position on the chin rest side.

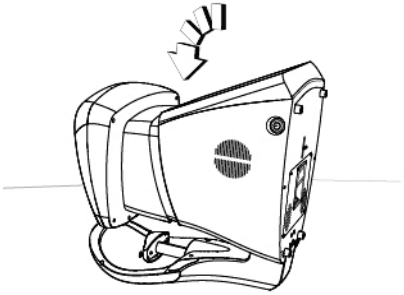

Fig 18 - Horizontal position

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4 Connect the mains socket with the device.

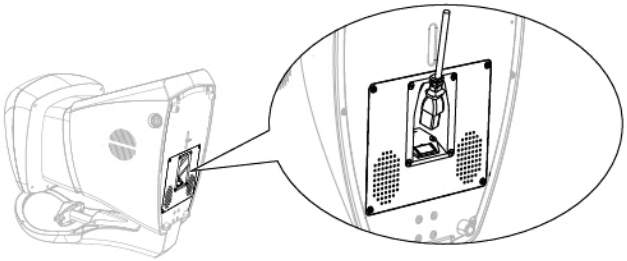

Fig 19 - Power supply cable connection

5 Block the power cable to the device base with the blocking clamp (A).

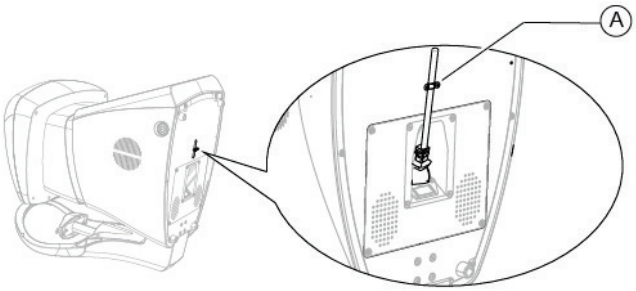

Fig 20 - Power supply cable blocking

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6 Lift the device and place it in the vertical position on the support table top.

7 Connect the device to the mains socket.

Fig 21 - Vertical placement of the device

CAUTION

Danger of device falling down. The ophthalmic table must be installed on a horizontal and stable surface.

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5.1 HOW TO PLACE ELECTRIC CABLES

CAUTION
Danger of device falling down. Do not leave free cables which can represent an obstacle or a danger for the patient or the operator.

CAUTION
Danger of stumbling and falling. Do not let the power cord or the connection cables free in a place where people could walk.

CAUTION
Electric shock risk. Do not leave the power supply cables in contact with sharp corners or objects. Collect and attach always the power supply cables.

It is forbidden to use any extension cable not authorized by the manufacturer.

For the proper placement of electrical cables and connection to the elevation column, read instructions for use of ophthalmic tables or of ophthalmic units. The instruction manual can also be downloaded from the website www.csoitalia.it.

The power socket is on the lower part of the column of the ophthalmic table and it has to be used for the connection to the mains power. One of the power sockets on the upper part of the elevation column is dedicated to the device power supply unit.

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5.2 HOW TO TURN ON THE DEVICE

1 Press the device ON/OFF button.

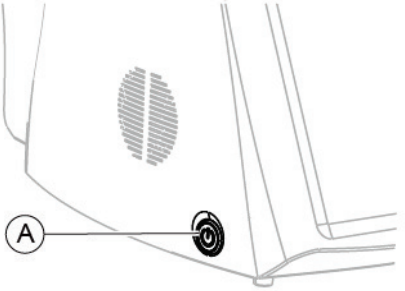

Fig 22 - Device ON/OFF button

2 The application software will start after a few seconds. Wait until the loading screen of the software is shown.

3 From the loading screen you can access the application software information, access the settings (B), consult the instruction manual (C), choose the image capture mode (D) and (F) or stop the device (E).

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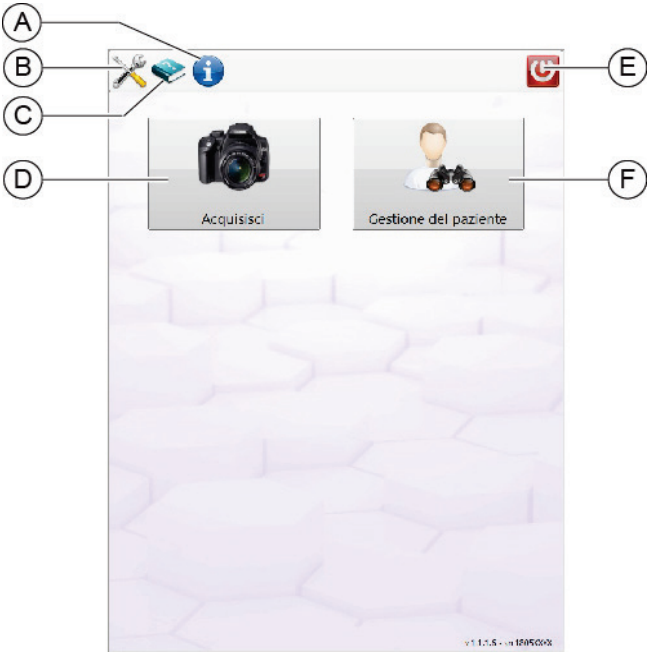

Fig 23 - Loading screen

It is possible to choose between two image capture modes:

- Quick capture (D). Immediately starts the image capture without the patient's data registration request. After the exam it is always possible to insert the patient's data, but it is not mandatory. This mode is recommended if you need to quickly print the results and then attach the printed image to the patient's medical records.
- Patient management (F). Launches the registration of a new patient or allows for research and/or modification of the data of a patient already present in the database. This mode is recommended if you need to save the image on the database before capturing the image.

Do not use writing pens or other sharp devices. For the touch screens use your fingers or the specific pens.

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5.3 HOW TO CONNECT THE DEVICE TO THE PRINTER

The integrated application software is provided with already installed drivers to recognize the majority of printer brands. The connection procedure might require the technical support assistance whether the driver in the device does not recognize the printer. Here follow the possible connection procedures.

If the customer has purchased a printer recommended by the Manufacturer or if he owns a printer which is recognized by the integrated operating system.

1 Connect the printer USB cable to the device.
2 Enter the screen SETTINGS.
3 In the detected printers list, choose your own printer as active.

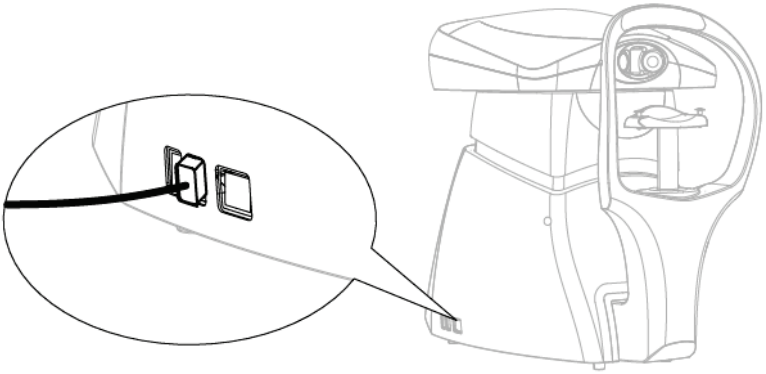

Fig 24 - Connecting the printer USB cable to the device.

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If the customer owns a printer which is not recognized by the standard drivers of the integrated operating system.

1 Contact the technical support for the printer driver installation. If the drivers are provided on CD, connect an external player to proceed.
2 Contact the Manufacturer of the device PERSEUS to obtain further assistance during the installation of a non-supported printer.

For the installation procedure, contact the printer technical support. The installation requires the access to the instrument administrator mode, that can be activated only with the technical support assistance.

If you have problems with the installation, contact the printer Dealer immediately.

Here follows the list of printers recognized by the device.

- Brother
- Canon
- Epson
- Gestetner
- HP
- Infotec
- Konica
- Kyocera
- Lanier
- Lexmark
- NRG
- Oki Data
- Ricoh
- Savin
- Toshiba

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5.4 HOW TO CONNECT THE DEVICE TO A LOCAL NET

The device can be connected in the net co access to the shared remote database.
Moreover, some advanced functions are available only using the device from a PC connected to the net, E.G: patients export on file. exams report generation oh pdf, DICOM output production, exams groups attribution and adding comment to the captures, setting advanced print parameters and other extra features.

The device performs the Windows log-in automatically like a stand-alone local user. the database shared on the net has to be localized in a folder accessible without inserting the net log-in information.
If the local net is managed by an ActiveDirectory system, you need to make sure that the folder containing the database is accessible in read and write modes by a non-authenticated net user.

1 Access the screen SETTINGS.
2 Connect the device to the local net by means of an Ethernet cable.

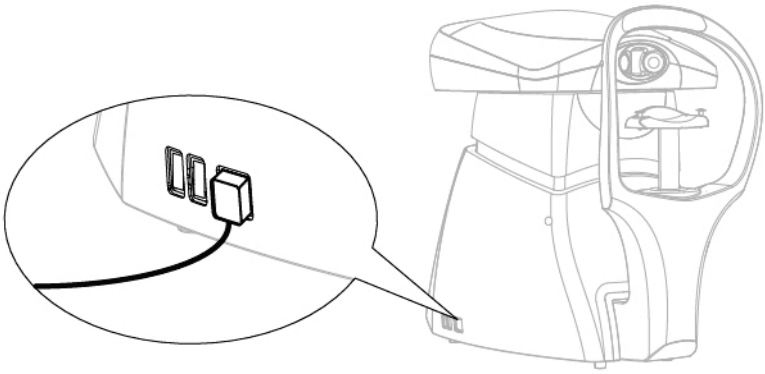

Fig 25 - Connection between device and Ethernet cable

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3 Touch the net button (A). The net parameters screen will open.

4 Specify all the net parameters (IP, Subnet mask, Gateway, DNS) based on the local net parameters. If you don't have this information, contact the net administrator and ask for support.

5 Set a valid path couple (B) for the Database file (.mdb) and the root image folder.

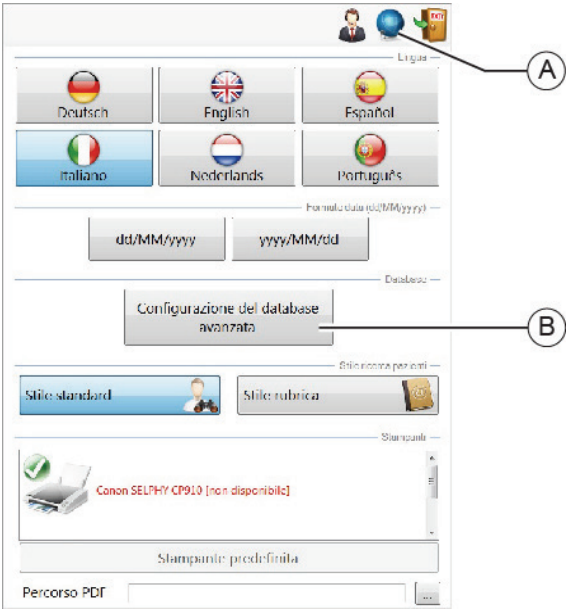

Fig 26 - Ethernet cable connection

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Fig 27 - Net parameters

Device management through PHOENIX application software

It is possible to elaborate the images captured by the device with a PC where the application software PHOENIX is installed. In particular, it is possible to do a mosaic reconstruction of the images in the database.

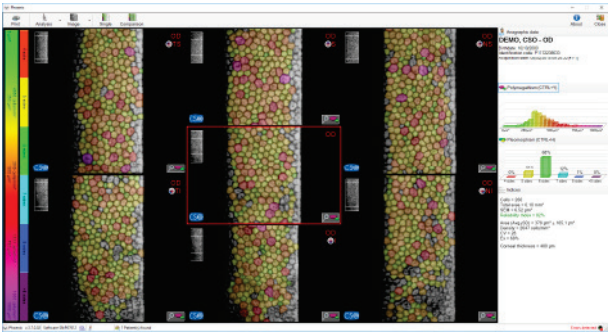

Fig 28 - Mosaic mode screen on the PHOENIX application software

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5.5 HOW TO CHOOSE BETWEEN THE IMAGE CAPTURE MODES

At the device start-up you can perform the quick capture or access to the patient's exams management.

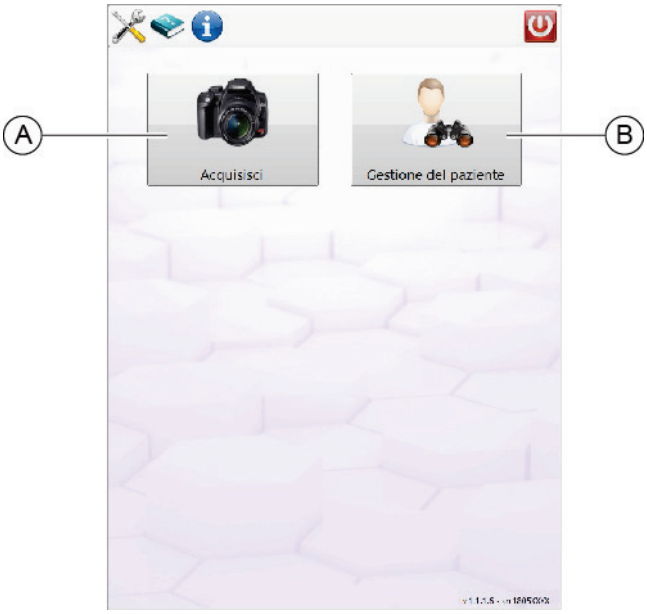

Fig 29 - Loading screen

Quick capture mode (A)

1 On the launching screen choose QUICK CAPTURE.
2 On the screen will appear the capture screen. To capture images, read paragraph **How to capture the image at page 53**.
3 When you exit the capture mode, you'll need to associate the exam to a patient if already registered, insert the data to register a new patient, or delete the acquired data.

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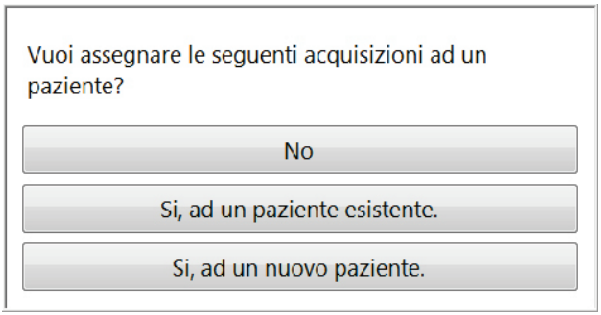

Fig 30 - Data storage request

Patient management mode (B)

1 On the launching screen choose PATIENT'S MANAGEMENT.
2 Patient search screen will appear
3 Proceed with the patient search, if already in the archive, otherwise proceed with a new registration.

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5.6 HOW TO SEARCH A PATIENT IN THE ARCHIVE

1 To search and update the previously acquired data, write the patient's name with the keypad on the screen (C): The correspondences will be shown in the drop-down menu (B). If there is only one correspondence, it will be automatically selected without completing the insertion.

2 Alternatively, touch the button (A) to access the patients archive directly.

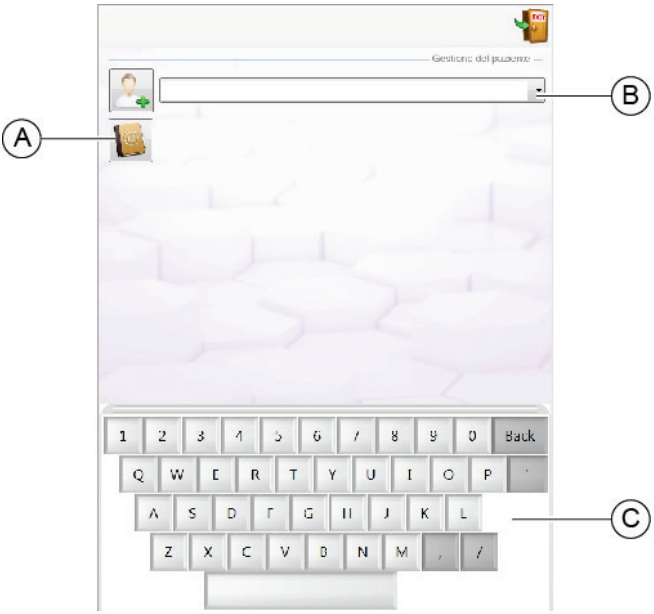

Fig 31 - Patient search screen

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3 The names list will appear on the screen (D). If necessary, you can filter the research by selecting the patient's sex (B).

4 If the patient is not in the archive you need to do a new registration by touching the button (F).

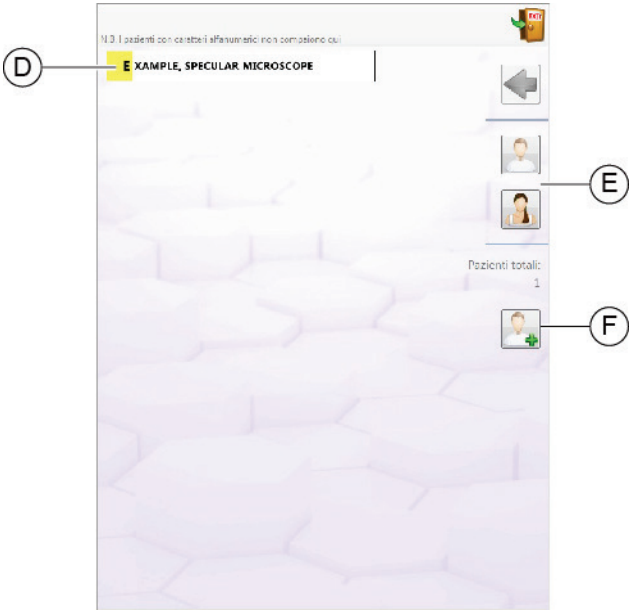

Fig 32 - Searching for a patient in the archive

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5.7 HOW TO DO A NEW REGISTRATION

1 Touch the button (A) to open the new patient registration tab (B).
2 Insert the patient's data filling the form in all its parts.
3 Touch OK co confirm the data insertion and complete the registration.

Fig 33 - New patient data registration

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5.8 HOW TO SEARCH AN EXAM IN THE ARCHIVE

1 Select the patient's folder. Now you can consult the exams, perform a new acquisition, delete an existing one, delete the whole patient record and more. Every folder in the drop-down menu (A) is identified by creation date and hour. When a folder is selected, only the acquisitions related to that folder will be shown in the lower part of the summary.

2 Use the right and left arrows to search the patient's exams (B). Each folder is identified by a sequential number and its laterality (right eye and left eye) The image is shown in the lower section.

3 Touch the button between the two arrows to load the acquisition summary (C).

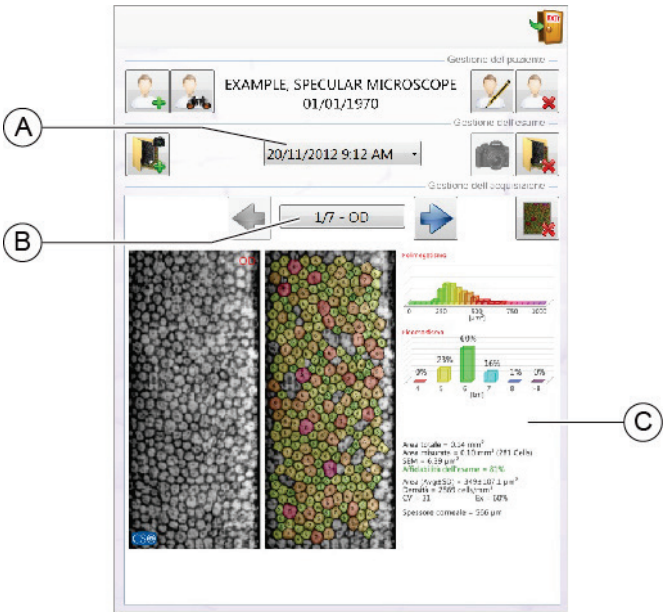

Fig 34 - Exams management screen

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5.9 HOW TO CAPTURE THE IMAGE

The endothelium image capture is an automatized procedure that requires high precision in the patient's position who has to stay perfectly still during the exam.
In case of capture failure repeat the exam two or three times. Tell the patient to stay completely still, to ignore the green light during the capture and to keep the eyes on the orange fixation point.

CAUTION
Keep attention if you need to examine children or patients whose cornea is not transparent enough. The image capture might be not possible.

There are endothelial cells for which the acquisition could be very difficult and could give contradictory results. This could happen for patients whose cornea has an irregular shape, for patients whose eyes have been recently and/or operated, for patients suffering from corneal ectasia, keratoconus.
If there are intraocular lenses, the acquisition has to be effectuated in manual mode with appropriate precautions.

1 Inform the patient to take a seat.
2 Ask the patient to put the chin on the chin cup and the forehead against the forehead rest.
3 Verify the correct eyes position respectively to the shooting channel.
4 Select the icon OS or OD to choose the eye laterality for capturing the images. The capture mode is similar for the right eye and the left eye.

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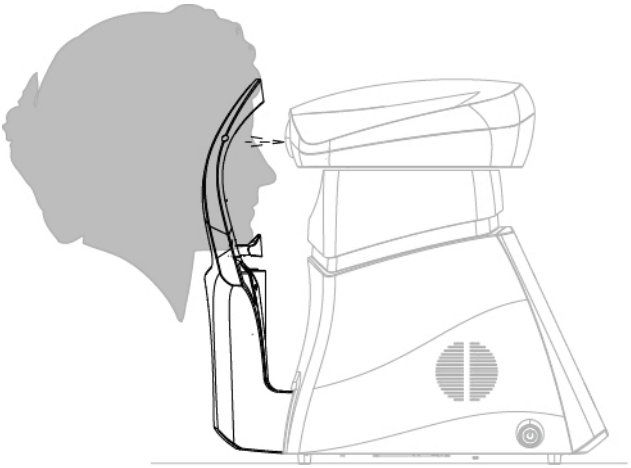

Fig 35 - Patient position on the chin rest

Make sure that the patient's eye is well open and the tear film on the eye surface is well distributed. If necessary, help the patient to open the eye in such way that the eyelid or the eyelashes do not interfere with the measure.

5 Lower or lift the chin rest (A) to centre the corneal reflection. The corneal reflection has to be placed in the red circle.

6 Use the directional arrows (B) to perform horizontal movements to centre the corneal reflection, if necessary.

7 If necessary, adjust the focus of the corneal reflection using the arrows on the screen right (D).

8 When the corneal reflection (E) will be focused and placed inside the circle (C), the circle will become green. The message of capture beginning visualized.

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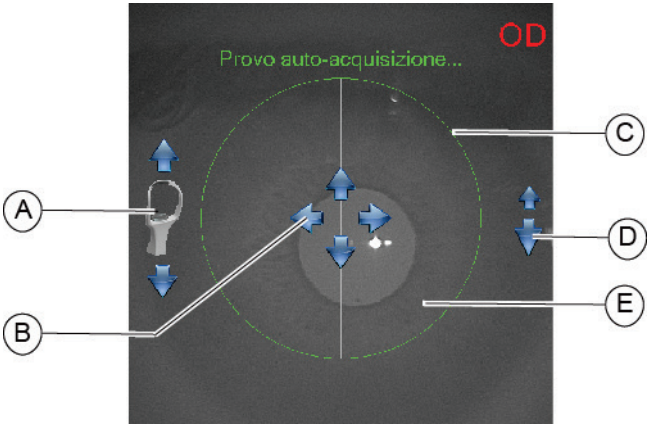

Fig 36 - Eye centring

If the corneal reflection shape will be oval (vertically or horizontally) or if its intensity is too faint, the device won't allow the capture. This can happen if the patient's eye is not in focus. Correct the distance and the focus.

9 When the circle becomes green the acquisition will start automatically. If the acquisition does not start automatically, a message will be shown to inform the user that he/she has to touch the inside of the green circle to start the acquisition.

10 During the elaboration check the centring precision box (A). If the spot is outside the circle, the exam could not reach a sufficient quality. The total acquisition time is 3 seconds circa.

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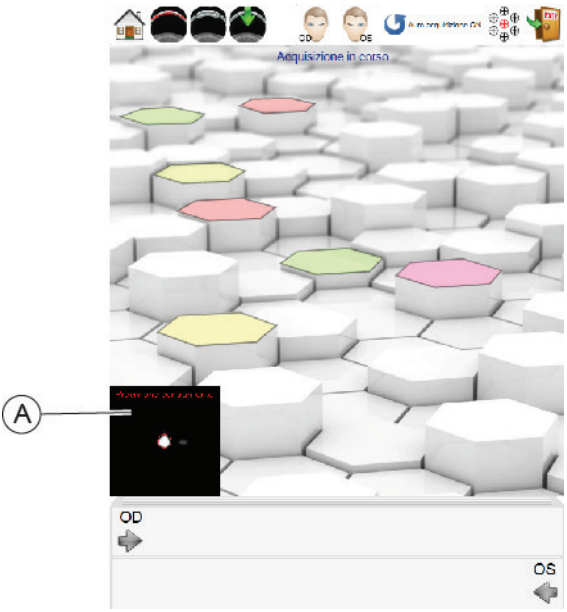

Fig 37 - Acquisition in progress

Refer to the application software instructions for the image managing in the database.

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5.9.1 TROUBLESHOOTING WHILE CAPTURING THE IMAGE

It is possible that, during the acquisition, the image quality is not sufficient for the exam purposes. Some precautions can be adopted before declaring the patient's endothelium cannot be examined.

Problem	Solution
The corneal reflection in not visible on the screen or is out of the field.	The patient's eye is not at a suitable height. Use the chin rest commands to adjust the height. Lift or lower the chin rest looking at the patient and the image on the screen. If the corneal reflection is outside the red circle, use the right/left arrows co centre the image within the circle
The circle becomes green, but as soon as the acquisition begins, you obtain the messages "No spot found"! or "Target lost".	The corneal reflection is not correctly focused, so, as soon as the IR illumination is reduced for the acquisition, the corneal reflection is lost. Adjust the image focus using the commands on the right side of the screen.
When the corneal reflection is inside the circle, but the circle does not become green.	The corneal reflection is not correctly focused, so, as soon as the IR illumination is reduced for the acquisition, the corneal reflection is lost. Adjust the image focus using the commands on the right side of the screen.
The patient has an implanted intraocular lens IOL and you can see two or more corneal reflections.	Only one reflection is the correct one, ignore the one created by the IOL. Touch the correct reflection to start the acquisition. If the reflections are too close to each other, the tracking algorithm might fail. Try to change the fixation points to put more space between the reflections and try again.
The corneal reflection is correctly centred am the patient stays still, but you obtain the message "Lost target" or the exam quality is low.	The patient might have a very flat cornea. Touch the FLAT CORNEA MODE on the upper menu and try a new acquisition. The movement performed by the tool will be longer to assure a greater scanning depth in the endothelium search path.
The corneal reflection is inside the circle, but the shape is irregular and the circle does not become green, or the acquisition fails upon starting.	Some diseases cause a deformed reflection that cannot be automatically detected by the system. This reflection can be manually centred using the screen commands, if the patient stays still. When the reflection is properly centred, touch the icon MANUAL ACQUISITION to start the process.

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5.10 HOW TO CHANGE FIXATION POINTS

Changing the fixation points it will be possible to access to the different areas of the cornea to observe the medical condition of the corneal endothelium.

1 Touch the fixation icon (A). The graphic menu for the fixation point choice will appear.

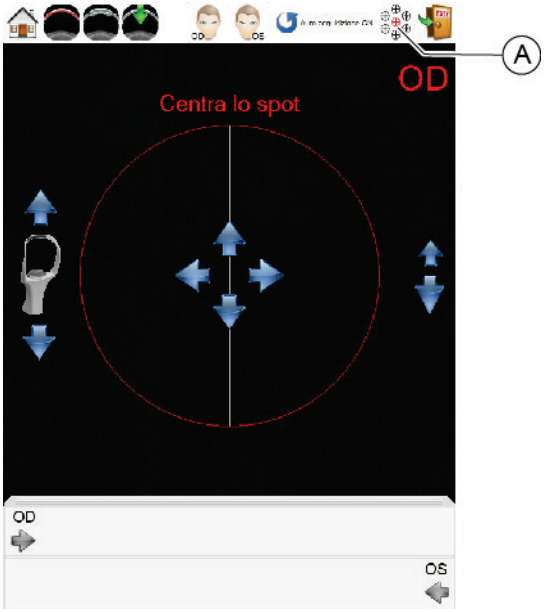

Fig 38 - Fixation points

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2 Touch on of the seven available fixation points (B) based on the cornea interest area. The area will be highlighted for each point of the magnification lens (C).

3 Touch the green flag symbol (D) to confirm the selected point.

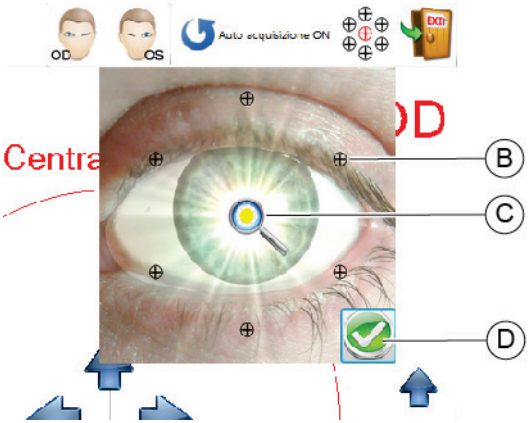

Fig 39 - Fixation points

4 Go on with the acquisition

5 After preforming the acquisition, the fixation point will automatically go back to the central position.

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5.11 HOW TO ANALYSE THE ACQUIRED DATA

1 Once the acquisition is done the ACQUISITION DATA screen will open with the Polymegathism data (B), the Pleomorphism data (C) and the statistical summary (D). Now it is possible to analyse the exam data.

2 Touch the button EXIT (A) to go back to the capture screen and start a new exam.

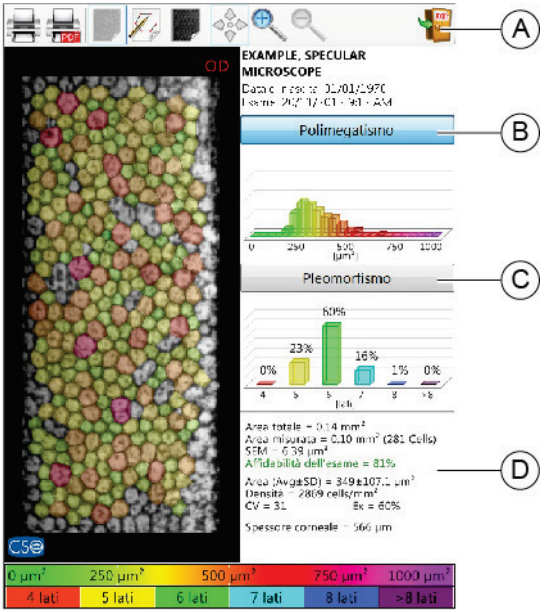

Fig 40 - Acquired data screen

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After each acquisition the following data will be shown:

- The original image, with the overlaying of the cells automatically segmented by the process algorithms. The cells colours are related to the Polymegathism and Polymorphism scales and can be changed from one to the other by touching the related buttons on the screen.
- Simple visual graphics showing the statistic distributions for Polymegathism and Pleomorphism.
- The textual statistic indications including cells area, density, corneal thickness, exam reliability, etc. Refer to the acquisition summary section of this manual for a detailed explanation of the statistical data.

Polymegathism graphic

The graphic shows the quantity of the areas occupied by cells of the same dimension. To understand the cells colouration in relation with their area and with the resulting esteemed medical condition, refer to the Polymegathism scale on the lower part of the screen. See the graphic for the distribution based on the area of the examined cells.

Pleomorphism graph

The graphic shows the percentage of cells having a certain number of sides. To understand the cells colouration in relation with their number of sides and with the resulting esteemed medical condition, refer to the Pleomorphism scale on the lower part of the screen. See the graphic for the distribution based on the number of sides of the examined cells.

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Statistical summary

The statistical summary is based on the automatic or manual cells modification. Here follows the description of the present values.

Value	Description
Total area	Total endothelium surface, processed and non-processed.
Measured area	Processed surface with the total number of segmented cells
Guttae area / total area (if available*)	Surface percentage affected by guttae in relation with the total surface
SEM (Standard error of the mean)	Evaluation of the reliability of the average cells area calculation Divides the standard deviation of the calls area with the square root of the number of cells samples.
Exam reliability	Reliability percentage. Green if the value is more than 50%, yellow from 30% to 50%, red if less than 30%. In this last case the exam reliability is insufficient to extract numerical data clinically valid and has to be repeated.
AVG±SD	Average cell surface united to the uncertainty value given by the standard deviation.
Density	Cells density for square millimetre. An indicative value for an adult man is 2500-3000 cells/mm^2
Functional density (if available*)	If there are guttae, this parameter indicates the actual cell density after excluding the surface affected by the guttae from the calculation.
CV (Coefficient of variation)	Calculation coefficient of the relationship between the cell area standard deviation and the arithmetic mean of that area. In reference to the Matsuda-Schultz index an average value should be less than 35.
Ex (Hexagonality Index)	Relationship between the hexagonal cells number (with six sides) and the total number of segmented cells.

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Value	Description
Corneal thickness	Approximate pachymetric data related to the part of cornea scanned during the capture. The accuracy of the corneal thickness depends on the quality of the acquisition and by other variables which can't be controlled, so this data has to be considered as approximate.

*Items available only after manually adding the surface affected by the guttae on the image.

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5.12 HOW TO MANUALLY MODIFY THE CELLS

When enabled in the acquisition summary, the manual modification of the cells makes visible a series of instruments to optimize the cells segmentation. This function has to be used for:

- Modify the cells where the segmentation seems inaccurate.
- Add cells where the automatic segmentation could not detect them correctly.
- Delete non existing cells erroneously detected by the automatic segmentation.
- Add or remove the guttae, which might be not detected automatically by the segmentation algorithms.

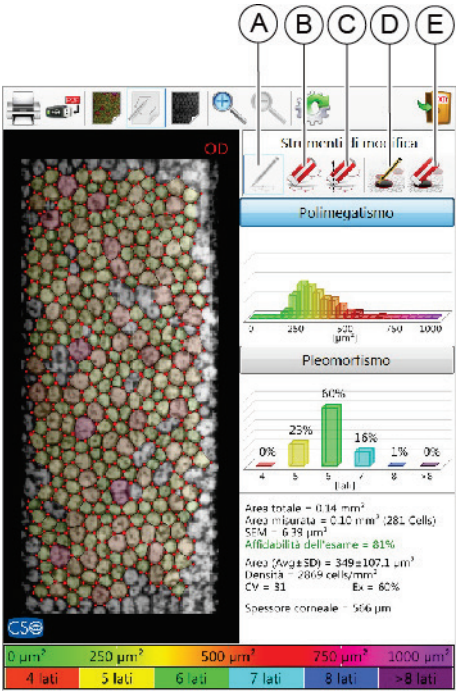

Fig 41 - Modification tools

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To add new cells (A)

1 Zoom the image before proceeding for a better precision.
2 Touch the cells vertexes. The borders will be automatically drawn as soon as consistent cells shapes will be detected by the new vertexes.

To delete the vertexes (B)

1 Zoom the image before proceeding for a better precision.
2 Touch the false vertexes that you want to keep out from the process algorithms.

To delete the cells with area selection (C)

Select a rectangle on the image by touching it ad drag it with the finger. All the vertexes included in this rectangle will be deleted.

To add the guttae (D)

Use a finger or a touch screen pen to draw circular shapes corresponding to the guttae on the image. Surface percentage affected by guttae is highlighted by a dark shade.

To delete the last guttae (E)

Touch the button to remove the last guttae from the list of the inserted ones. You cannot choose the guttae to be removed: the deleted one will be the last inserted one.

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5.13 HOW PRINT IN ON PAPER

1 Check that the device is connected to the printer. If necessary, connect the USB cable of the printer to the device and check the correct printer path as described in the paragraph **How to connect the device to the printer at page 42** .

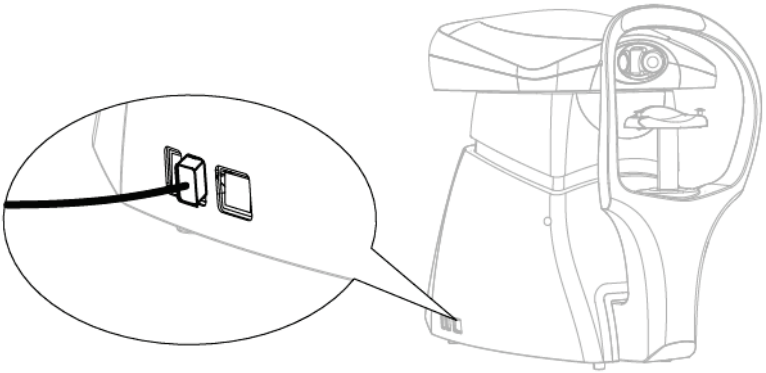

Fig 42 - Connection to the printer

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2 Touch the button (A) to launch the print.

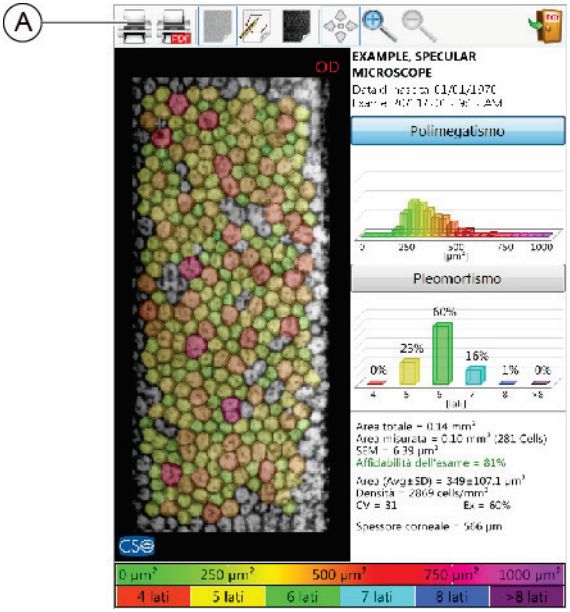

Fig 43 - Paper print start button (A)

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5.14 HOW PRINT IN PDF

1 Touch the button (B) to activate the PDF print.

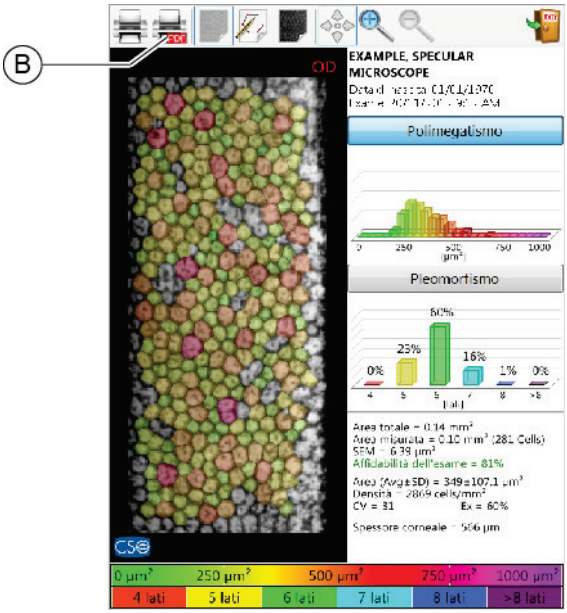

Fig 44 - PDF print button activation (B)

2 Connect a flash drive to the device

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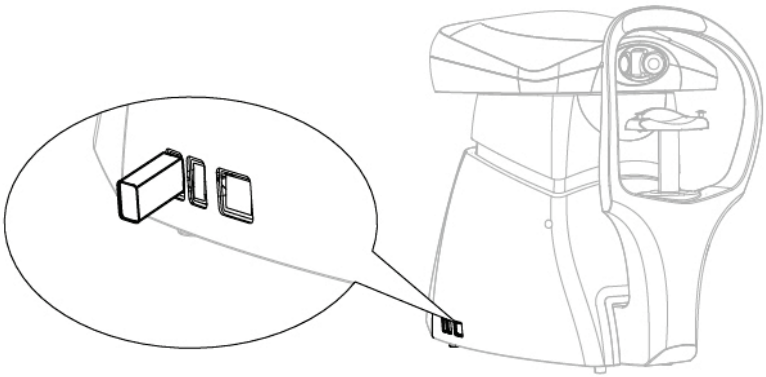

Fig 45 - Flash drive connection

3 Touch the button (B) to launch the PDF print.

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5.15 HOW TO REPLACE CHIN CUP PAPERS

At the end of each exam remove the chin cup paper and clean the forehead rest in order to always have a new and hygienic paper for the next patient.

This device is provided with a package of chin cup papers. When you use the last paper change the package.

1 Extract the two plastic rivets.
2 Place the new package of chin cup papers.
3 Insert the plastic rivets in the holes of the package and in the holes of the chin cup.

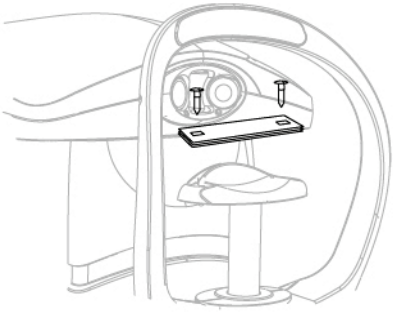

Fig 46 - Replacing chin cup papers

To order a spare part, read the code in the **Spare parts list on page 78.**

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5.16 HOW TO TURN OFF THE DEVICE

CAUTION
Do not disconnect the device connection cable when the program is in use.

1 Exit the device management systems program.
2 Press the device ON/OFF button.
3 Place the protective cover on the device to prevent dust to fall on the device.

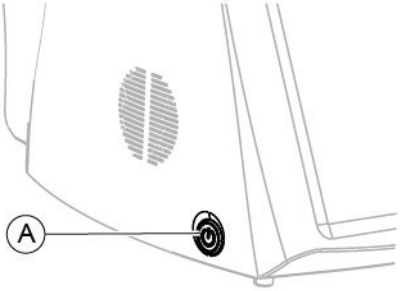

Fig 47 - Device ON/OFF button

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6 ORDINARY MAINTENANCE

6.1 SAFETY WARNINGS

DANGER

Electric shock danger. Unplug the power cable from the mains socket before disinfecting the device and before any maintenance operation.

CAUTION

The device does not contain any piece that requires the user's intervention. Do not dismantle any part of the device.

It is forbidden to carry out any maintenance operation on the device that is not recalled in the instructions for use.

In case of operational faults or malfunctions or for every maintenance operation not mentioned in the instructions for use, there is the obligation to address an authorized technical service centre of the device Manufacturer.

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6.2 CLEANING AND DISINFECTION

CAUTION
Carefully follow the instructions about cleaning and disinfection described in this manual, in order to avoid any damages to the device and the accessories.

CAUTION
A correct cleaning and disinfection procedure, together with appropriate operating procedures, are essential to prevent the spread of infections or cross-contaminations.

CAUTION
Danger of material damages. Do not use spray products.
Do not use excessively wet cloths, as they may drip.
If needed, use a damp and well wrung out cloth.
Make sure no liquid penetrates into the device.

Cleaning and disinfection procedures shall be regularly carried out.

Parts of the device that do not come into direct contact with the patient shall be cleaned at least once a day.
Parts of the device that do come into direct contact with the patient shall be thoroughly cleaned and disinfected after each application.

The current section described the procedures to be carried out during use and maintenance, in order ensure proper cleaning and disinfection of the device and its accessories.

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6.2.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION
Danger of material damages. Do not use solvents, acidic or basic solutions (pH <4,5 or >8,0), abrasive or caustic substances, chlorine-based and chlorine-derived products.
The Manufacturer is not liable for any damages caused by using disinfecting products which are not indicated in this manual.

The choice of the most suitable product and procedures for the cleaning and disinfection of the device takes into account both the sensitivity of the device to specific substances and the product's disinfecting effectiveness.
For cleaning and disinfection procedures, use medical products FDA or CE approved for medical devices or medical-surgical devices.
Follow the products listed below, divided by category:

Detergents	Use polyenzymatic solutions or neutral surfactant-based solutions.
Disinfectants and decontaminating products	Use surface-friendly disinfectants (containing or not containing aldehyde) or formaldehyde-free surface disinfectants-cleaners (i.e. Kohrsolin FF). Alternatively, you may use ethyl alcohol, 70% v/v alcohol or isopropyl alcohol.

For information about using the chosen product, please comply with the instructions provided by the manufacturer.

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6.2.2 CLASSIFICATION OF THE DEVICE FOR HYGIENE AND SAFETY

CAUTION
The device is supplied non-sterile and it shall not be sterilized prior to use.

This device is classified as “non-critical” since it is only used on healthy skin and therefore has a low infectious risk**.**
For devices classified as non-critical, regular cleaning is sufficient, or low-level disinfection.
However, in cases where the patient’s condition is transmissible by direct contact, or in case of accidental exposure to body fluids, the device shall be disinfected with a higher-level disinfectant after cleaning.

6.2.3 DEVICE CLEANING

CAUTION
Carefully follow the instructions about cleaning described in this paragraph, in order to avoid any damages to the device and the accessories.

CAUTION
Danger of material damages. Clean using a non-abrasive cloth to avoid damaging the surface.

The device shall be regularly cleaned.

The device is provided with a cover whose function is to protect it from dust, especially during periods of non-use.

Clean the outer parts of the device using a damp, non-abrasive cloth and a rinse-free cleansing solution.

For more information about suitable cleansing products, read the **“Recommended products for cleaning and disinfection” paragraph on page 74.**

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6.2.4 CLEANING THE APPLIED PARTS

CAUTION
Danger of material damages. Only use detergent and disinfecting products specifically approved for medical devices or medical-surgical devices.

Applied parts that come into direct contact with the patient during the examination shall be thoroughly cleaned after each use with a disinfectant approved for the purpose.

1 Turn off the device and unplug it from the electrical outlet.
2 Clean the applied parts using products suitable for surface disinfection (they may contain aldehyde).
Alternatively, use a non-abrasive cloth soaked in a solution of water, ethyl alcohol (70% maximum) or isopropyl alcohol.

For more information about suitable cleansing products, read the **"Recommended products for cleaning and disinfection" paragraph on page 74.**

6.2.5 CLEANING THE OPTICAL COMPONENTS

CAUTION
Danger of material damages. The device is equipped with optical components. The optical components of the device are precision and pressure sensitive parts. Clean using a non-abrasive cloth to avoid damaging the surface.

Clean the optical components carefully using a dry, non-abrasive, lint-free cloth.

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6.3 NETWORK FUSES REPLACEMENT

1 Place the device on the table top on the chin rest side.
2 Disconnect the power supply cable.
3 Pull out the fuse drawer.
4 Replace the fuses. Check that the new fuses value is compatible with the voltage of the used net. as written on the data plate.
5 Connect the power cable to the mains.

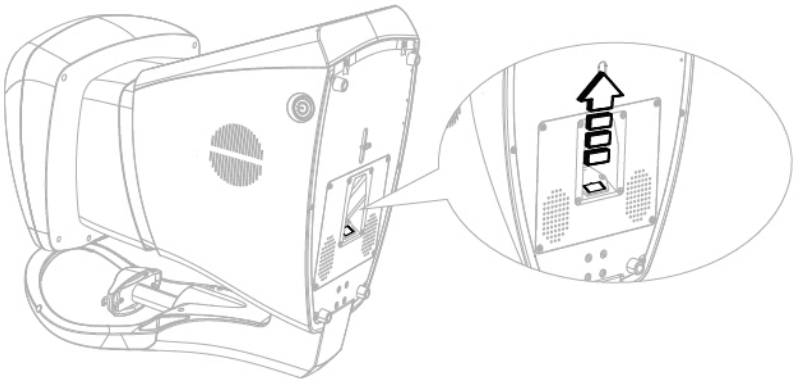

Fig 48 - Network fuses replacement

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6.4 SPARE PARTS AND ACCESSORIES LIST

Code	Description
3001007ID3F	Power supply cable
10101300	Insulating transformer 230V/230V. Power supply cable 800 VA (maximum load)
4014020	Package of chin cup papers (50 pieces)
4013095	Protective cover
10070524	Table top 45x90 mm
10070521	Table top 45x60 mm
10070144	Electric table top with one column (230 V, 50 Hz)
10090533	Touch screen pen
33071095	Power supply cable for electric support (95 cm)

For spare parts or accessories not included in the list, ask the Manufacturer or the local Dealer.

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6.5 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	Power cable not connected properly.	Correctly connect the device power cable to the mains socket. Press the ON/OFF button on the device.	If the device is powered trough the auxiliary power supply of the table, check the connection of the table to the power line. Check the functioning of the table fuses. Check the functioning of the device fuses.
The application software does not start	Hard Disk failure. Spoiled operating system The application software does not work properly.	Replace the Hard Disk. Reinstall the operating system. Reinstall the application software.	Contact the Technical Service Centre. The installation of the application software needs the administrator privileges.
The touch screen does not work	Presence of dust of grease on the touch screen. The application software does not work properly.	Clean the touch screen with a soft cloth. Restart the device.	Possible touch screen fault. Contact the Technical Service Centre.
The images can't be saved in the internal/external database of the device.	The database is not connected to the software. Power connection absent. The Ethernet cable does not work.	Verify that in the database configuration window is specified the correct path to the file. Restore the connection to the database file. Check the functioning of the net connection. Replace the Ethernet cable.	Regularly verify the connection to the data net.

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Issue	Cause	Solution	Note
Failed image capture	The patient moved or closed the eyes during the acquisition.	Ask the patient to keep the eyes open, look the fixation light and not to move the eyes.	Read paragraph **Troubleshooting during the image capture at page 57**.
Failed image focus	Presence of dust of grease on the optical parts of the device.	Clean the surface of optical parts with a soft cloth.	Make sure the patient does not touch the optical parts.
Missing acknowledgment of eye by the device	Presence of dust of grease on the optical parts of the device.	Clean the surface of optical parts with a soft cloth.	Make sure the patient does not touch the optical parts.

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