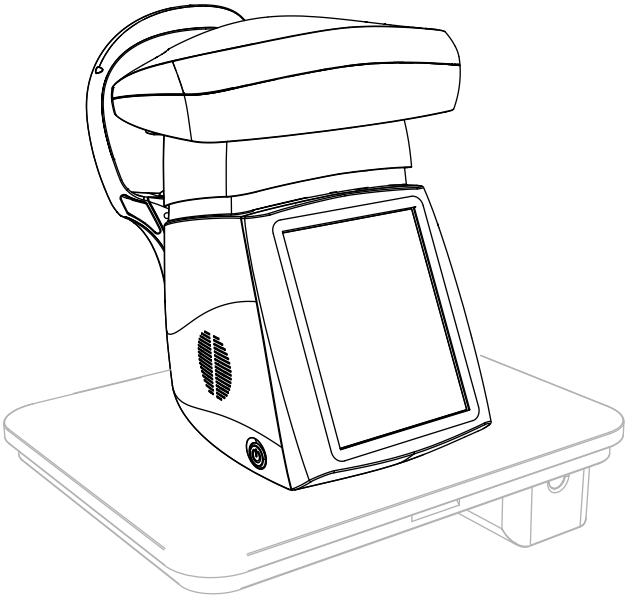
COSTRUZIONE STRUMENTI OFTALMICI



Endothelial microscope

INSTRUCTIONS FOR USE

PERSEUS

COSTRUZIONE STRUMENTI OFTALMICI

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PERSEUSIFUENGCSO0103032024

Colour inside

ENG

1 INTRODUCTION

The device is the result of extensive research, conducted with experts to ensure the product's technical innovation, quality and design.
The device can be used easily thanks to the guided manual acquisition and the electronic control of all its functions.

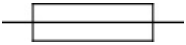
1.1 SYMBOLS

The following symbols may be displayed in the instructions for use, on the package or on the device:

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 Marking (EU Regulation 2017/745)

	Medical device
	Waste disposal in compliance with Directives 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 OPERATING INSTRUCTIONS REFER TO THE PERSEUS DEVICE (HEREINAFTER REFERRED TO AS "DEVICE").

THE ORIGINAL TEXT IS IN ITALIAN.

Before using the device or after a long period of non-use, carefully read these instructions for use. Follow the directions provided in the instructions for use and 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.

Always keep these instructions for use in an accessible and nearby place. If you decide to sell this device to a new user, remember to 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.

Before using the device, check for damage that may have resulted from transport or improper storage.

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

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

1.3 REFERENCE REGULATIONS

1.3.1 EU DIRECTIVES

- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices
- Directive 2012/19/EU on waste of electric and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

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

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

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

1.4 WARRANTY

The Manufacturer is responsible for the device conformity to Regulation (EU) 2017/745 of 5 April 2017 for:

- performance
- safety and reliability
- CE marking

The Manufacturer rejects all responsibility for:

- installation and start-up that is not carried out in compliance with the directions and precautions reported in the instructions for use
- use that fails to comply with the instructions for use or precautions reported in the instructions for use
- use of accessories or spare parts not provided or suggested by the Manufacturer
- repairs and safety checks not carried out by expert, qualified and trained personnel authorised by the Manufacturer
- failure of the electrical system of the premises where the device is installed to comply with the technical standards, laws and regulations in force in the country where the device is installed
- direct or indirect consequences or damage to objects or persons caused by the misuse of the device or erroneous clinical analysis originating from its use

The Manufacturer guarantees the device for 24 months after the invoice date. The warranty covers the replacement by the Manufacturer or an authorised Service Centre of components and materials and the corresponding labour. Shipping and transport costs are to be paid by the customer.

The warranty does not cover:

- repairs of malfunctions caused by natural disasters, mechanical shocks (falls, collisions, etc.), electrical system defects, negligence, misuse, maintenance or repairs carried out with non-original materials
- any other misuse or use not intended by the Manufacturer
- damage caused by service failings or inefficiencies due to causes or circumstances out of the Manufacturer's control
- wear and/or deterioration of parts due to normal use and parts that might break due to misuse or maintenance carried out by personnel not authorised by the Manufacturer.

To request maintenance interventions or obtain technical information about the device, contact an authorised Service Centre or the device Manufacturer directly.

The customer will not be refunded for damage caused by device downtime.

1.5 MANUFACTURER IDENTIFICATION

C.S.O. SRL
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50018 - Scandicci (FI) - ITALY
phone: +39-055-722191 - fax +39-055-721557
cso@csoitalia.it
www.csoitalia.it

2 SAFETY

2.1 SAFETY WARNINGS

DANGER
Danger of electric shock. Do not let water fall on the device. Do not immerse the device in water or other liquids.

DANGER
Danger of electric shock. If the power supply cables are damaged, they must be replaced by an authorised Service Centre to prevent any risk.

DANGER
Danger of electric shock. Unplug the power supply cable from the power socket before disinfecting or cleaning the device and before any maintenance operation.

DANGER
Danger of electric shock. Do not touch the power supply cables with wet hands.

DANGER
Danger of electric shock. Do not allow the power supply cables to come into contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

CAUTION
Do not use the device if visibly damaged. Periodically inspect the device and connection cables to check for signs of damage.

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

CAUTION
Danger of falling device. Do not leave loose cables, as they might be of obstacle or danger for the patient or operator.

CAUTION
Danger of tripping and falling. Do not leave the power supply or connection cables loose in places where people may walk.

CAUTION
If you notice a strange odour or smoke coming out of the device or if it becomes hot, turn it off immediately. Do not continue to use a damaged device or damaged component. Danger of injuries.

CAUTION
The electric network must have a residual-current device (IΔn=30mA) and 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 variations in temperature and humidity.

It is forbidden to use extension cables not authorised by the device Manufacturer.

It is forbidden to use the device outdoors.

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

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

2.2.2 DEVICE DATA PLATE

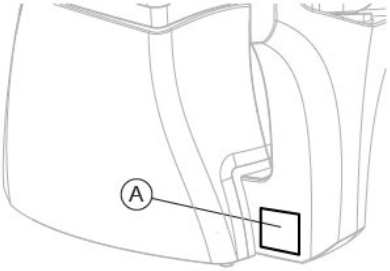


Fig. 1 - Data plate position

Pos	Description
A	Device data plate

Fig. 2 - Data plate

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, capture and digital processing of the image of the corneal endothelium in the ophthalmic procedure.
The device makes it possible, without any contact with the patient, to obtain a mapping of endothelial cells and a series of parameters to establish the health status of the cornea.
The endothelial image makes it possible to display cell-related parameters, including: cell number and density, shape, area, mean area, standard deviation, coefficient of variance, percentage of cells of various shapes, histogram of area size distribution, pachymetry data.
Endothelial microscopy is essential in the diagnosis of many corneal dystrophies and degenerations, in the pre and post-operative assessment of cataract surgery and corneal transplants.
Cell density, pleomorphism and polymegathism values, as well as pachymetry data, are calculated automatically. When it is necessary to carry out evaluations on peripheral areas of the cornea, the device is equipped with a set of fixation targets suitable for the purpose.
The device performs:

- non-invasive exam of the endothelial tissue,
- automatic focusing of the endothelial layer,
- automatic research of the cells' barycentres,
- 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 data interchange between other applications in the Intranet/Internet environment.
The device has no known contraindications.

Exam of the endothelial tissue

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

Feature of the integrated application software

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

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

The device is autonomous in its operation and, when necessary, can be integrated with Phoenix application software in order to extend the functionality of the device.

Do not install different application software in order not to impair the proper 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 only be used by specialist practitioners and sector operators (such as optometrists), within the limits of the laws and regulations for the exercise of the profession.

Read the instructions for the use of the application software.

Other accessories (printer, modem, scanner, etc.) can be connected to the device via the analogue or digital interfaces.

The accessories (printer, modem, scanner, etc.) must be installed outside the patient area.

The accessories must comply with Directive IEC 62368-1 Information technology equipment - Safety - Part 1: General requirements.
If the accessories are installed in the patient area, it is also necessary to install an isolation transformer compliant with Directive IEC 60601-1 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

Patient area: any volume in which a patient with applied parts may intentionally or unintentionally come into contact with other electromedical devices or electromedical systems, masses or foreign masses, or other people in contact with these elements.

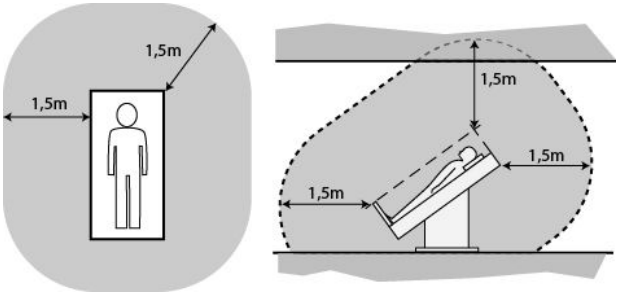


Fig. 3 - Patient area

2.4 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification in compliance with annexe VIII of Regulation (EU) 2017/745	Class I

2.5 ELECTROMEDICAL DEVICE CLASSIFICATION

Classification in compliance with technical specification IEC 60601-1

Technical data	Value
Type of protection against direct and indirect contacts	Class I
Applied parts	Type B
Degree of protection against humidity	IP20 (no protection against infiltration by liquids)
Sterilisation or disinfection method	This device can be disinfected
Degree of protection in the presence of anaesthetics or flammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous operation

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
	Bump	10g duration 6ms

CAUTION
Danger of damage to the device. During transport and storage, the device may be exposed to the environmental conditions described, only if kept in the original package.

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

Instructions for the correct disposal of the device pursuant to European Directives 2012/19/EU and 2011/65/EU regarding the reduction of the use of dangerous substances in electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device must not be disposed of with urban waste. The device may be delivered to designated separate collection centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents potential negative consequences for the environment and health caused by improper disposal and allows the materials it is made of to be recycled so as to attain significant savings in energy and resources. The data plate of the device displays the symbol of the crossed-out wheeled bin. The crossed-out wheeled bin symbol indicates the obligation to collect and dispose of electrical and electronic equipment separately at the end of their useful life.

The user must consider the potentially dangerous effects for the environment and human health arising from the improper disposal of the whole device or its parts.

Should the user wish to dispose of the device at the end of its useful life, the Manufacturer facilitates its potential reuse and recovery and the recycling of the materials contained therein. This prevents the release of hazardous substances into the environment and promotes the conservation of natural resources. Before disposing of the device, it is crucial to take into consideration European and national regulations, which prescribe the following:

- not to dispose of it as urban waste, but separate its parts, seeking advice from a firm specialised in the disposal of electrical/electronic equipment or the local administration in charge of 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 as the new device, the Distributor or Manufacturer is legally required to collect the old device.
- if the user decides to dispose of a used device placed on the market after 13 August 2005, the Distributor or Manufacturer is legally required to collect it.
- the Manufacturer takes care, by joining the appropriate technological waste disposal consortium, of the treatment and recycling of the used device collected, bearing any costs.

The Manufacturer is available to provide the user with information regarding the dangerous substances contained in the device, the recycling of these substances and the potential reuse of the used device.
Strict administrative sanctions for those failing to comply are provided for by law.
For specific information about disposal in countries other than Italy, contact your local Dealer.

2.8 MANUFACTURER DECLARATIONS

2.8.1 ELECTROMAGNETIC COMPATIBILITY

The device is subject to specific requirements regarding electromagnetic compatibility (EMC). The following factors may cause electromagnetic interference:

- Portable and mobile radio frequency (RF) communication devices located in the vicinity of the device.
- Other products installed near or connected to the device.
- Accessories, cables and spare parts not specified in the instructions for use and not sold by CSO as spare parts.

When using the device, certain precautions must be taken to respect EMC, including:

- Observe the instructions for use.
- Follow the restrictions and instructions in this section.

Restrictions on essential performance

The device provides the following essential performance: accuracy of measurement. If the acquisition is damaged due to electromagnetic interference, the image will not meet the quality threshold and the application software will warn the user with a message.

Danger from electromagnetic radiation

CAUTION
Using the device in the vicinity of other devices or connected to other devices not described in the instructions for use (e.g. in combination with an ophthalmic table) may cause interference with the functioning of the device.
Should it be necessary to use the device with other devices not described in the instructions for use, all devices must be monitored to ensure correct functioning.

CAUTION
Do not use portable high-frequency (HF) communication equipment (such as antenna cable and external antennas) and do not place equipment cables within a 30 cm (12 inches) radius around the device. Otherwise, a deterioration in the performance of the device can be expected.

CAUTION
The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could lead to increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CAUTION
Portable radio frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) must be used at a distance of no less than 30 cm (12 inches) from any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

Environmental conditions for intended use

The device is intended for use in professional healthcare facilities as regards electromagnetic compatibility. These are in particular hospitals and doctors' surgeries, including those connected to the public electricity network (e.g. in residential areas), and opticians' and optometrists' premises.
The device is not intended for operation in the following environments:

- Home healthcare (e.g. residential accommodation, nursing homes)
- Outdoor environments
- In vehicles (for example, cars, trains, ships, planes)
- Other special environments (for example military facilities, heavy industry, medical treatment or diagnostic facilities with high-powered devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and magnetic resonance devices)

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	Assembly 1	The device uses radio frequency energy only for its internal functioning. The device's electromagnetic emissions are very low and should not cause interference with nearby electronic devices.
Radio frequency emission. CISPR 11	Class B	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.
Harmonic emissions. IEC 61000-3-2	Class A	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.
Limitation of voltage changes, voltage fluctuations and flicker. IEC 61000-3-3	Compliant	The device may be used in all environments, including domestic ones. The device can be connected directly to a low-voltage electric network like that of residential buildings.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge. IEC 61000-4-2	±6 kV in contact. ±8 kV in air	±6 kV in contact. ±8 kV in air	The floors must be made of wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Temporary/rapid sequences of electrical pulses. IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines	±2 kV for power supply lines. Not applicable	The mains power supply must be that of a typical commercial or hospital environment.
Impulse. IEC 61000-4-5	±1 kV differential mode. ±2 kV common mode	±1 kV differential mode. ±2 kV common mode	The mains power supply must be that of a typical commercial or hospital environment.
Voltage dips. Brief disruptions and variations in voltage 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	The mains power supply must be that of a typical commercial or hospital environment. If the device user requires continued operation during power outages and voltage dips, the device must be powered by an uninterrupted power supply or battery.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Magnetic field at mains frequency (50/60Hz). IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency must have the same levels as a typical commercial or hospital environment.
RF conducted IEC 61000-4-6 RF radiated 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)

(1) Portable and mobile RF communication equipment must be used no closer to any part of the device, including cables, than the recommended separation distance (d) 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: maximum output power rating of the transmitter in watts (W), according to the transmitter Manufacturer.
d: recommended distance in metres (m) at which portable radio frequency (RF) devices can be used.
The field strength emitted by fixed RF transmitters, as determined by an electromagnetic site survey, must 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. The exposed electromagnetic environment may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

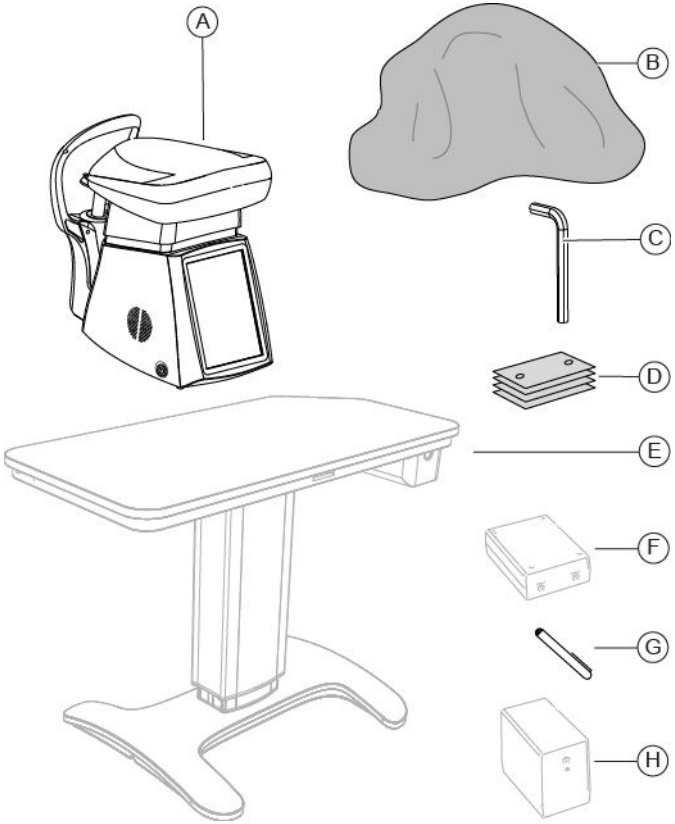


Fig. 4 - Supply description

Pos	Name		Description
A	PERSEUS device		Consisting of a camera unit equipped with a micro-camera for image capture and an adjustable chin strap. Integrated application software for image capture and device management.
B	Dust cover		Place on the device when not in use to protect it from dust.
C	Power supply cable hexagon wrench		
D	Package of chin cup papers		
E	Ophthalmic table	Optional	Table top with one or two columns and electronic adjustment of height. Drawer and auxiliary sockets with cable guide.
F	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices 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 damage due to current surges.

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

3.1.1 PERSEUS DEVICE

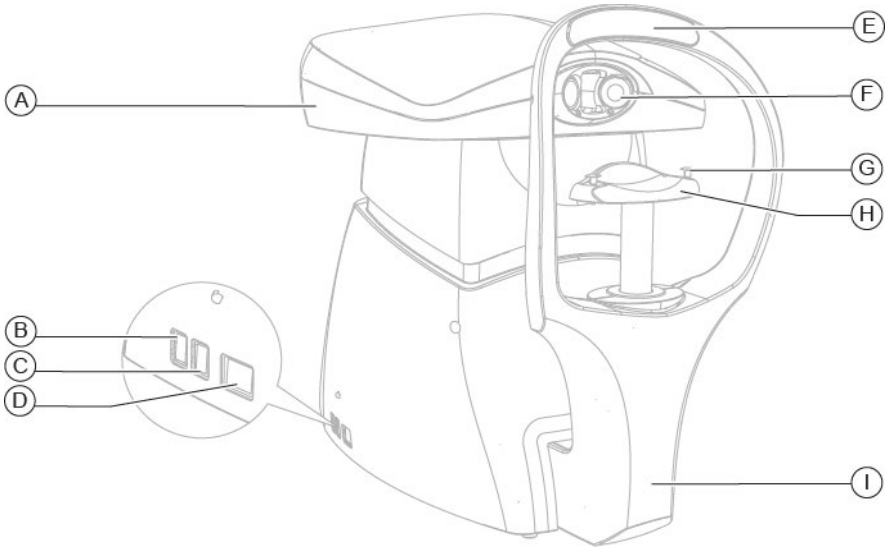


Fig. 5 - PERSEUS device

Pos	Description
A	PERSEUS device with moving head
B	USB port
C	USB port
D	Ethernet port
E	Forehead rest
F	Optical unit
G	Chin cup paper stop pins
H	Chin cup
I	Chin rest integrated with the device

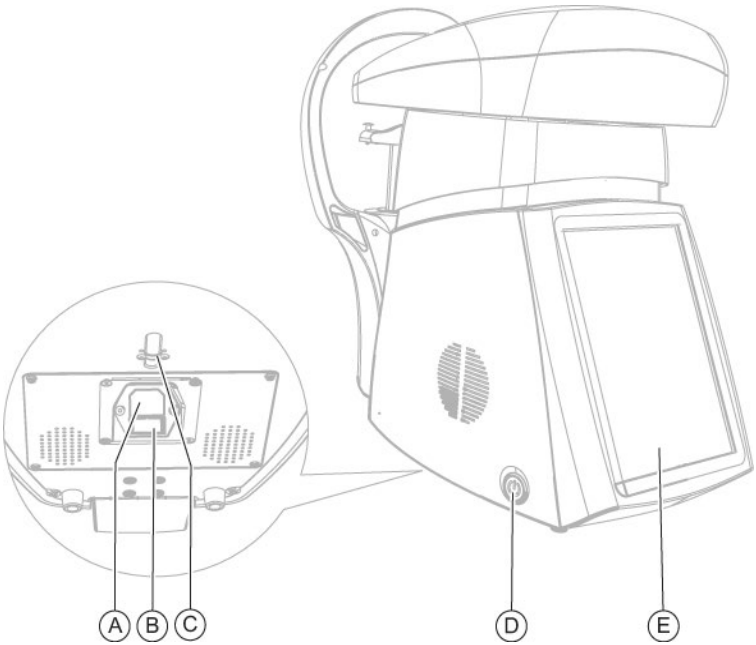


Fig. 6 - PERSEUS device

Pos	Description
A	Power socket
B	Fuse box
C	Cable lock with screws
D	ON/OFF button
E	Touch screen

3.1.2 OPHTHALMIC TABLE

Different table models are available based on the customer's choice. The table is composed of a table top on which the cogged wheels for the device compartment are installed. The table has one or two motorised telescopic columns that permit the height adjustment of the table top.

Fig. 7 - Ophthalmic table

Read the instructions for use of the ophthalmic table.

3.2 TECHNICAL DATA

Technical data	Value
Acquisition	Non-contact
Photographic field	0.54 mm x 0.27 mm
Video camera	CCD
Focusing illumination	LED
Magnification factor	180x
Pachymetric measurement	0.4 to 0.75 mm in steps of 0.01 mm
Fixation target	Internal LED
Monitor	10.4" touch screen
Size	437 x 328 x 448 mm
Weight	15 kg

4 INTEGRATED APPLICATION SOFTWARE DESCRIPTION

The device includes application software that makes it autonomous in its operation. Captured data and images are displayed on the screen. Manual editing is also possible. The endothelial data analysis and images can be saved in an archive together with the patient's master data and shared on the network.

4.1 START SCREEN

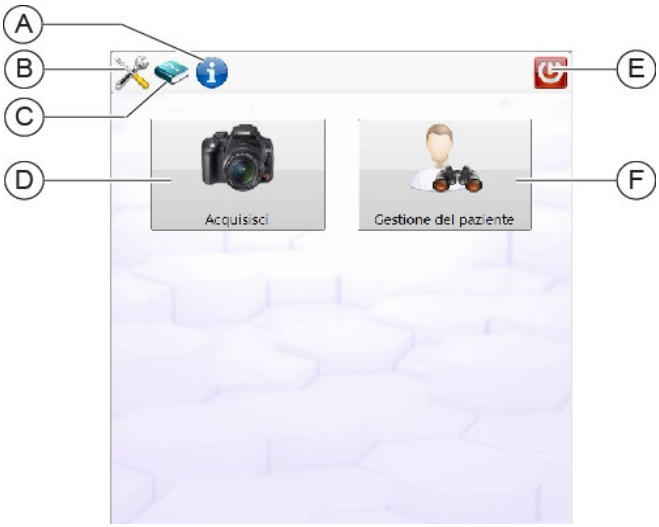


Fig. 8 - Loading screen

Pos	Description
A	About the application software
B	Settings
C	"Instructions for use" manual
D	Fast image capture
E	Application software shutdown
F	Patient data management

4.2 PATIENT SEARCH SCREEN

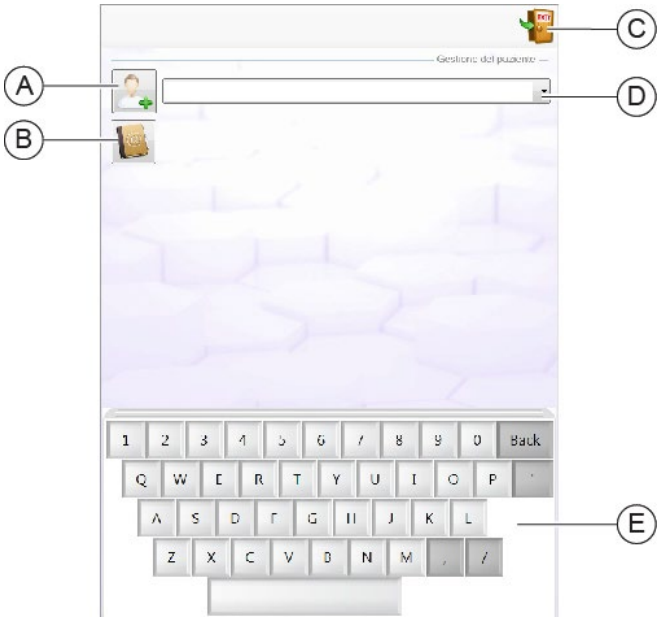


Fig. 9 - Patient search screen

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

Fig. 10 - New patient data registration

Pos	Description
F	New patient data entry

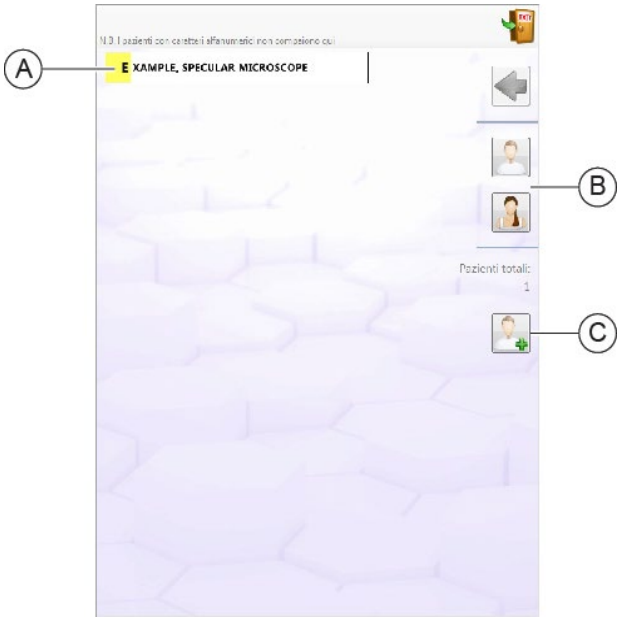


Fig. 11 - Archive

Pos	Description
A	Alphabetical list of patients
B	Patient search by gender
C	New patient registration

4.3 IMAGE CAPTURE SCREEN

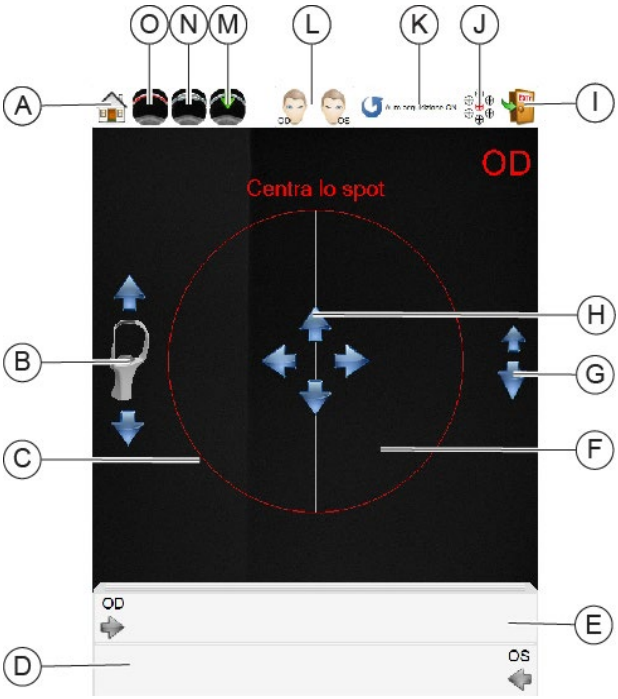


Fig. 12 - Image capture screen

Pos	Description	Pos	Description
A	Return of device head to home position	**I**	Return to main menu
B	Chin rest height adjustment	**J**	Fixation target selection
C	Image capture area	**K**	Automatic capture ON/OFF
D	Left eye image gallery	**L**	RE/LE capture laterality
E	Right eye image gallery	**M**	Manual capture mode
F	Corneal reflection area (when displayed)	**N**	Corneal transplant operation mode
G	Corneal reflection focusing	**O**	Flat cornea operation mode
H	Directional arrows for the corneal reflection centring		

4.4 EXAM MANAGEMENT SCREEN

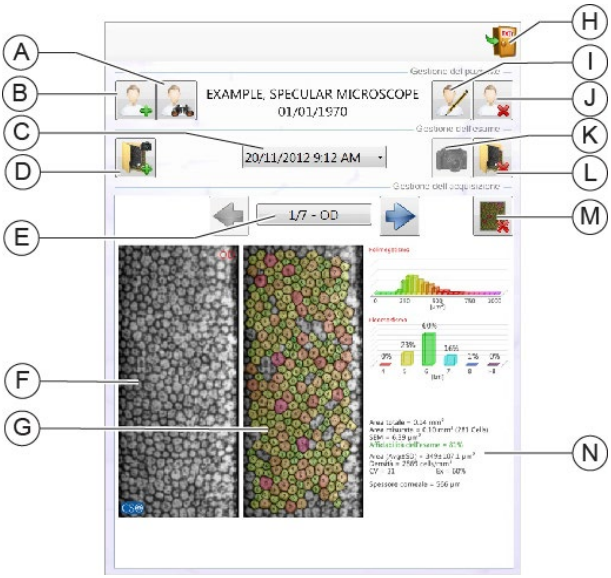


Fig. 13 - Exam management screen

Pos	Description
A	Patients database. Back to the PATIENT MANAGEMENT screen
B	New patient data entry
C	Patient's exam search by date and time
D	New exam folder. Each folder contains one or more captures.
E	Navigation of the data acquired during the exam relating to the active exams folder.
F	Captured image
G	Processed image
H	Return to the IMAGE ACQUISITION screen
I	Modification of patient data
J	Patient deletion
K	Image capture (only active if the folder is created on the same day of the exam)
L	Exam deletion
M	Image deletion
N	Acquisition summary

4.5 ACQUIRED DATA SCREEN

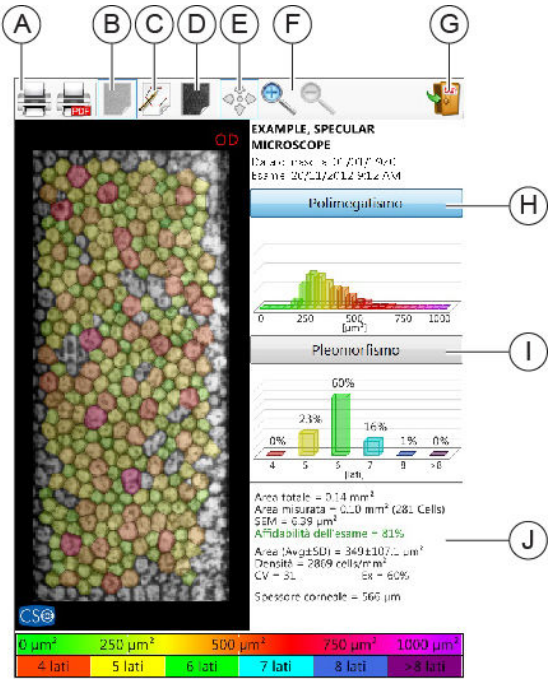


Fig. 14 - Acquired data screen

Pos	Description
A	Acquired data print
B	Elaborated image display
C	Manual editing of processed cells (only perform manual editing when automatic segmentation is not satisfactory)
D	View of the original non-processed image
E	Shift mode (only active when the image does not fit completely into the frame)
F	Image magnification or reduction
G	Exit the screen
H	Polymegathism mode
I	Pleomorphism mode
J	Statistical summary

4.5.1 MODIFICATION TOOLS

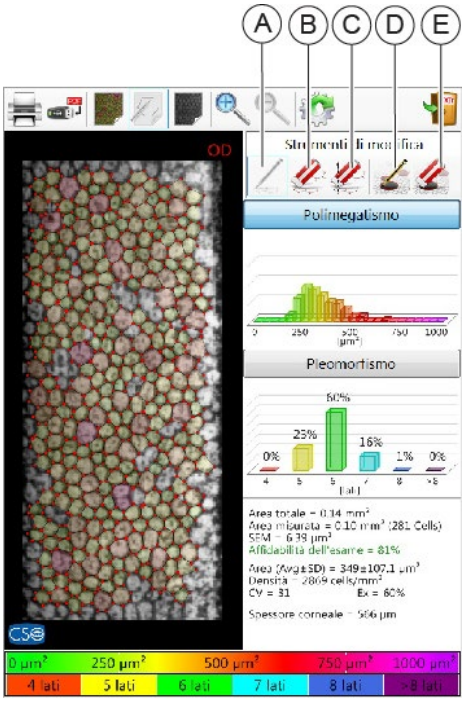


Fig. 15 - Modification tools

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

4.6 SETTINGS SCREEN

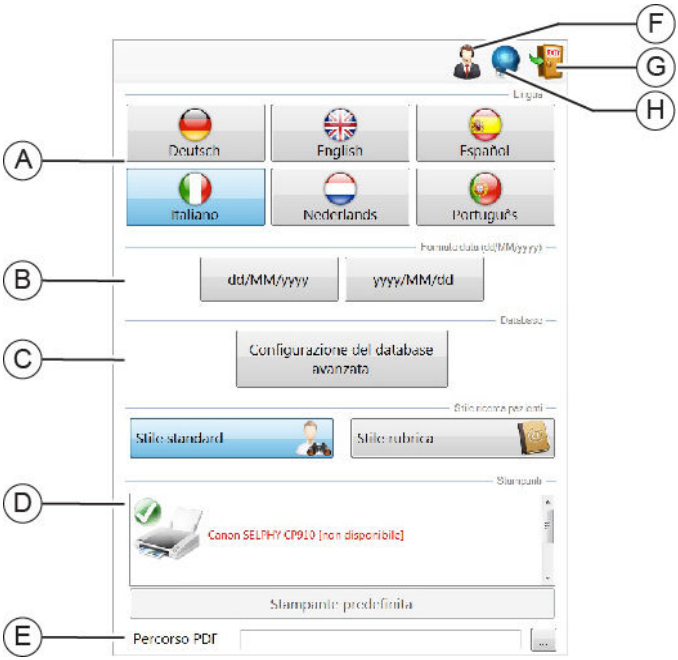


Fig. 16 - Settings screen

Pos	Description
A	Language setting
B	Date setting
C	Image archiving pathway
D	List of Printers
E	PDF print path
F	Link to technical assistance
G	Return to the start screen
H	Net setting

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, lock the table wheels. Lower the brake lever.

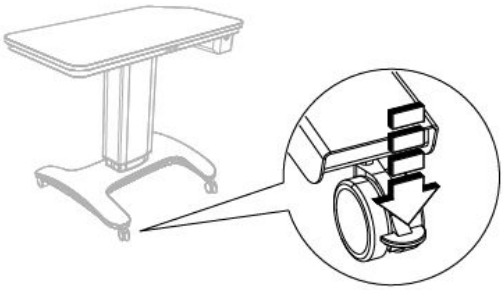


Fig. 17 - Table placement

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

Fig. 18 - Horizontal position

4 Connect the power socket to the device.

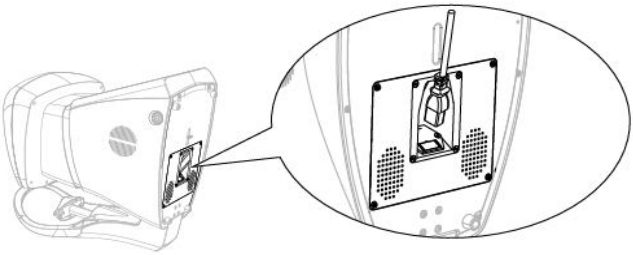


Fig. 19 - Power supply cable connection

5 Fasten the power cable to the device base with the locking clamp (A).

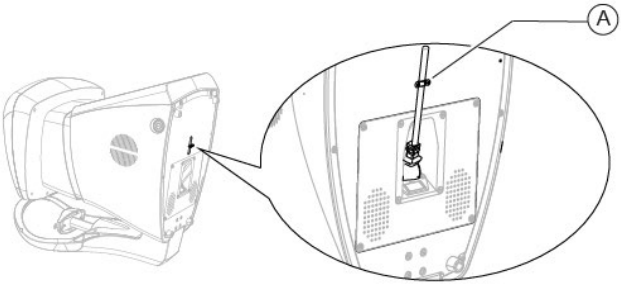


Fig. 20 - Fastening of the power supply cable

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

7 Connect the device to the power socket.

Fig. 21 - Vertical positioning of the device

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

5.1 HOW TO ARRANGE THE ELECTRIC CABLES

CAUTION
Danger of falling device. Do not leave loose cables, as they might be of obstacle or danger for the patient or operator.

CAUTION
Danger of tripping and falling. Do not leave the power supply or connection cables loose in places where people may walk.

DANGER
Danger of electric shock. Do not allow the power supply cables to come into contact with sharp edges or cutting parts. Always fix the power supply cables in place with ties.

It is forbidden to use extension cables not authorised by the device Manufacturer.

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

The power socket on the lower part of the column of the ophthalmic table is used to connect to the electric network. One of the power sockets at the top of the lifting column is dedicated to the power supply unit of the device.

5.2 HOW TO TURN ON THE DEVICE

1 Press the device ON/OFF button.

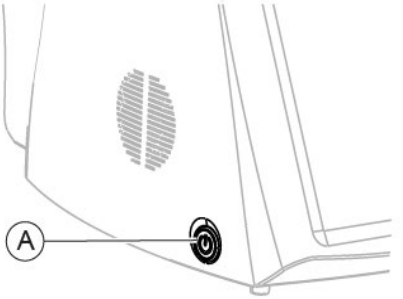


Fig. 22 - Device ON/OFF button

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

3 From the start-up screen, it is possible to access the application software information, the settings (B), view the user manual (C), choose the image capture mode (D) and (F) or shut down the device (E).

Fig. 23 - Loading screen

It is possible to choose between two image acquisition modes:

- Quick acquisition (D). Immediately starts the image acquisition without patient's data registration request. After the exam, it is still possible to enter the patient's data, although it is not compulsory. This mode is recommended if results are to be printed quickly and the printed image needs to be attached to the medical records of the patient.
- Patient management (F). Starts the registration of a new patient or allows searching and/or editing the data of a patient in the database. This mode is recommended when it is necessary to save the exam to the database before the image acquisition.

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

5.3 HOW TO CONNECT THE DEVICE TO THE PRINTER

The integrated application software is provided with already installed drivers that recognise the majority of printer brands. The connection procedure may require Technical Assistance support if the drivers in the device do not recognise the printer. The possible connection procedures are described below.

If the customer has purchased a printer recommended by the Manufacturer or owns a printer recognized by the standard drivers of the integrated operating system.

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

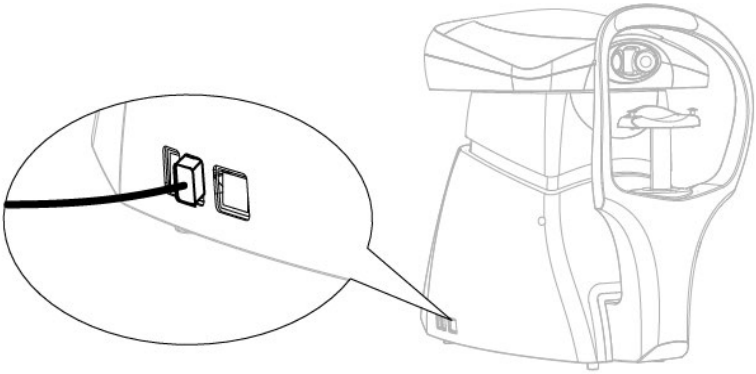


Fig. 24 - Connecting the printer USB cable to the device

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

1 Contact Technical Assistance for the printer driver installation. If the drivers are provided on CD, connect an external CD drive to proceed.
2 Contact the PERSEUS device manufacturer for further assistance when installing an unsupported printer.

For the installation procedure, contact the printer Technical Assistance service. The installation requires access to the instrument as administrator, which is only possible with the support of Technical Assistance.

In case of installation problems contact your printer dealer immediately.

Below is the list of printers recognized by the device.

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

5.4 HOW TO CONNECT THE DEVICE TO A LOCAL NETWORK

The device can be connected to a network to access the shared remote database.
In addition, some advanced functions are only available when using the device from a networked PC workstation, such as: exporting patients to file, generating pdf exam reports, producing DICOM output, assigning groups to exams and adding comments to acquisitions, setting advanced printing parameters and other extra features.

The device automatically logs in to Windows as a stand-alone local user. The shared database on the network must be located in a folder accessible without entering network credentials.
If the local network is managed by an ActiveDirectory system, it is necessary to ensure that the folder containing the database is accessible for reading and writing by a non-authenticated network user.

1 Access the SETTINGS screen.
2 Connect the device to the local network via an Ethernet cable.

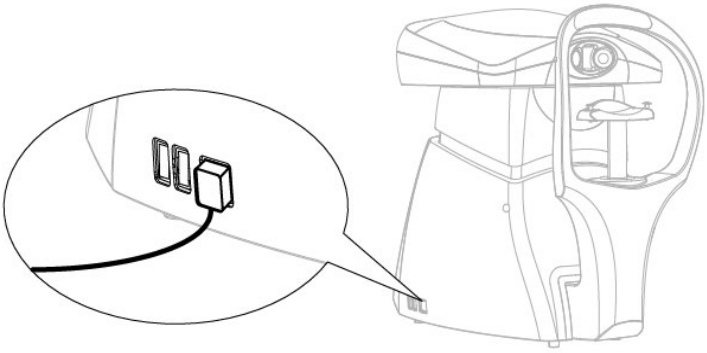


Fig. 25 - Connection between device and Ethernet cable

3 Touch the network button (A). The network parameter screen appears.

4 Specify all network parameters (IP, Subnet mask, Gateway, DNS) based on the local network parameters. If this information is not known, please contact your network administrator and ask for support.

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

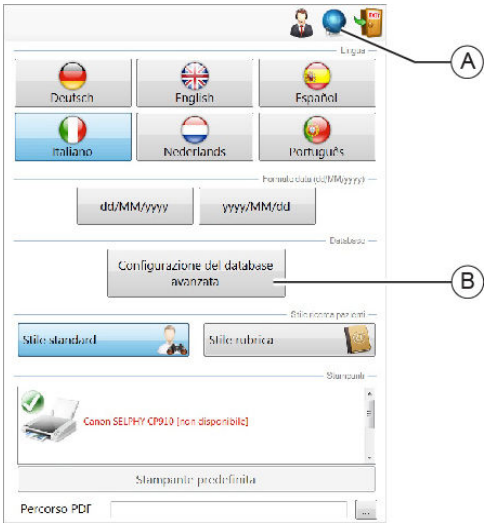


Fig. 26 - Ethernet cable connection

Fig. 27 - Network parameters

Device management through the PHOENIX application software

Using a PC workstation with PHOENIX application software installed, it is possible to process the images acquired by the device. In particular, it is possible to perform a mosaic reconstruction of the images in the database.

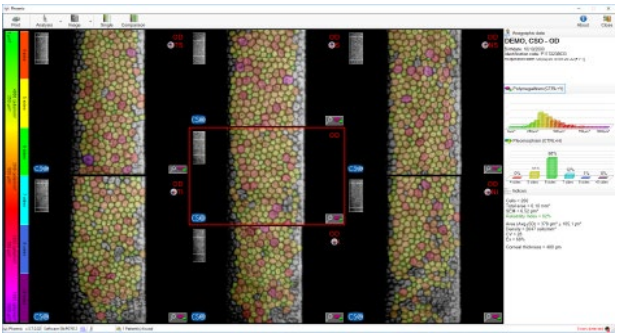


Fig. 28 - Mosaic mode screen on the PHOENIX application software

5.5 HOW TO CHOOSE THE ACQUISITION MODE

When starting the device, it is possible to perform quick acquisition or access the patient's exam management.

Fig. 29 - Loading screen

Quick capture mode (A)

1 On the start screen, select QUICK ACQUISITION.
2 The acquisition screen appears on the screen. For the image acquisition follow the instructions of the **“How to acquire an image” on page 54** paragraph.
3 When exiting acquisition mode, you will be asked to associate the exam with a patient (if already registered), to register a new patient, or to delete the acquired data.

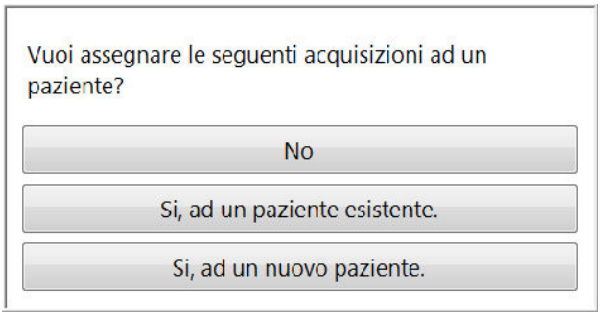


Fig. 30 - Data archiving request

Patient management mode (B)

1 On the start screen, select PATIENT MANAGEMENT.
2 The patient search screen appears.
3 Proceed with the patient search, if already in the archive, otherwise proceed with a new registration.

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). Matches will be shown in the drop-down menu (B). If there is only one match, it will be automatically selected without need to complete the insertion.

2 Alternatively, touch the button (A) to directly access the patient's folder.

Fig. 31 - Patient search screen

3 The list of names will appear on the screen (D). If necessary, the search can be filtered by selecting the gender of the patient (B).

4 If the patient does not appear in the archive, it will be necessary to make a new entry by pressing the button (F).

Fig. 32 - Searching for a patient in the archive

5.7 HOW TO MAKE 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 entry and complete the registration.

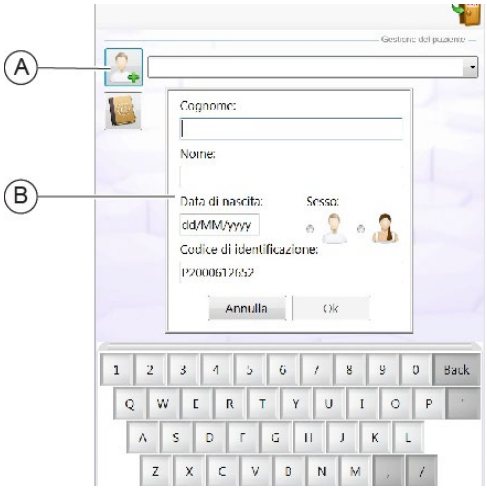


Fig. 33 - New patient data registration

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 records 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).

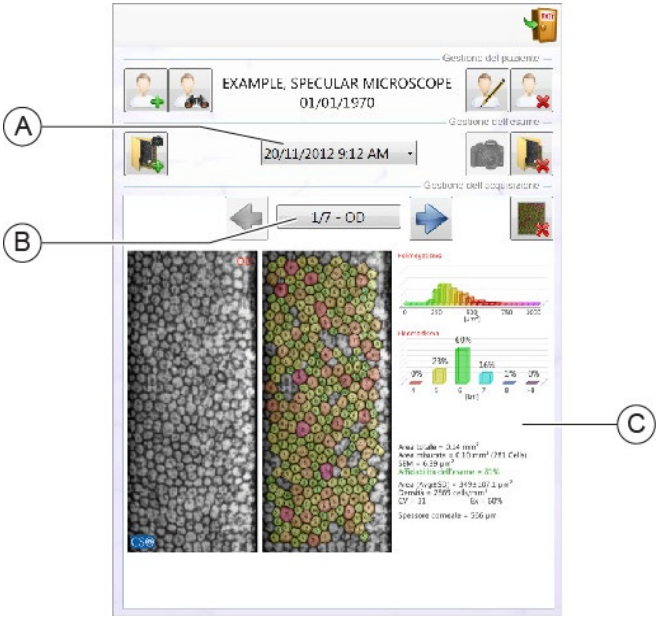


Fig. 34 - Exam management screen

5.9 HOW TO ACQUIRE AN IMAGE

Acquiring the endothelium image is an automated procedure, but it requires high precision in positioning the patient correctly and ensuring that he or she remains still during the exam.
If the acquisition fails, repeat the exam two or three times. Invite the patient to remain perfectly still, ignore the green light during acquisition and keep their gaze on the orange fixation point.

CAUTION
Care must be taken when examining children or patients with insufficiently transparent corneas. Image acquisition may not be possible.

There are endothelial cells whose acquisition could present considerable difficulties and could give rise to contradictory results. This may occur in patients with irregularly shaped corneas, in patients with recently medicated and/or operated eyes, in patients with corneal ectasia, keratoconus.
In the presence of intraocular lenses, the acquisition should be carried out in manual mode, taking the appropriate precautions.

1 Ask the patient to sit down.
2 Show the patient how to position their face against the chin cup and forehead rest
3 Check that the eye is correctly positioned in relation to the shooting channel.
4 Select the OS (left eye) or OD (right eye) icons to choose the laterality of the eye for image acquisition. The acquisition mode is similar for both the right and left eye.

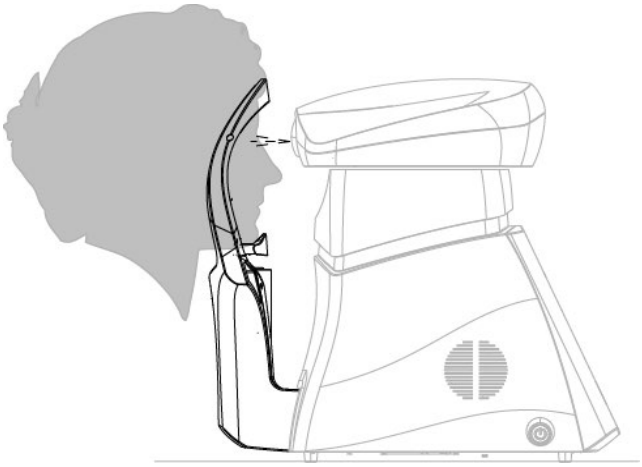


Fig. 35 - Patient position on the chin rest

Take care that the patient's eye is wide open and that the tear film on the surface of the eye 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 reflex should be positioned within 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 reflex (E) is in focus and positioned within the circle (C) it will turn green. A start acquisition message will be displayed.

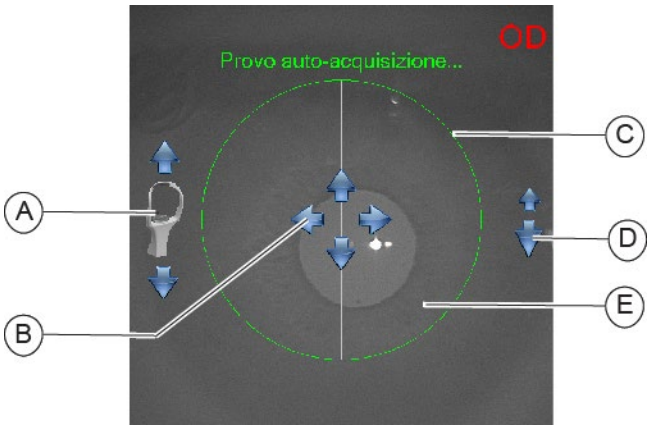


Fig. 36 - Eye centring

If the shape of the corneal reflex is oval (vertically or horizontally) or if its intensity is too weak, the device will not allow acquisition. This can occur if the patient's eye is out of focus. Correct the distance and focus accordingly.

9 When the circle turns green, the acquisition will start automatically. If the acquisition does not start automatically, a message will appear informing the user to touch the inside of the green circle to start the acquisition.

10 During processing, check the centring accuracy box (A). If the spot should fall outside the circle, the exam may not achieve sufficient quality. The total acquisition time is about 3 seconds.

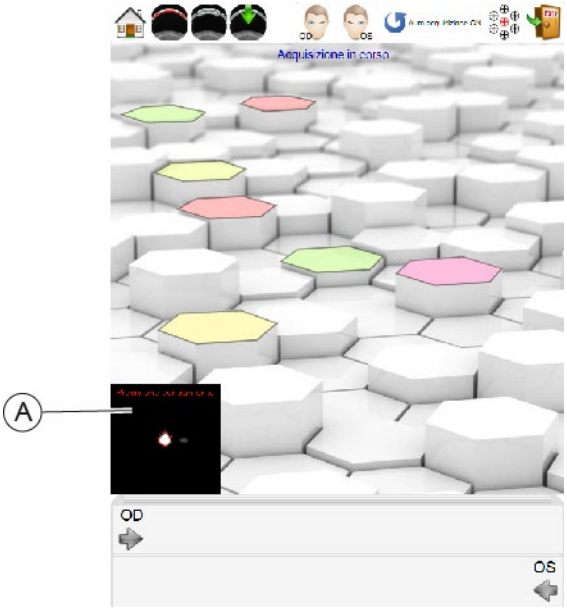


Fig. 37 - Acquisition in progress

For the management of images in the database, refer to the instructions for use of the application software.

5.9.1 TROUBLESHOOTING DURING IMAGE ACQUISITION

It is possible that, during acquisition, the image quality may not be satisfactory for the purpose of the exam. Certain steps can be taken before declaring that the patient's endothelium cannot be examined.

Problem	Solution
The corneal reflex is not visible on the screen or is out of view.	The patient's eye is not positioned at a suitable height. Use the chin rest controls to adjust the height. Raise or lower the chin rest while looking at the patient and the image on the screen. If the corneal reflex is outside the red circle, use the left/right arrows to centre the image within it.
The circle turns green, but as soon as the acquisition starts you get the messages 'No spot found!' or 'Target lost'.	The corneal reflex is not correctly focused, so as soon as the IR illumination is lowered for acquisition, the corneal reflex is lost. Adjust the focus of the image using the controls on the right-hand side of the screen.
The corneal reflex is inside the circle, but the circle does not turn green.	The corneal reflex is not correctly focused, so as soon as the IR illumination is lowered for acquisition, the corneal reflex is lost. Adjust the focus of the image using the controls on the right-hand side of the screen.
The patient has an intraocular lens IOL implanted and two or more corneal reflexes are visible.	Only one reflection is correct, the other is created by the IOL and must be ignored. Tap on the correct reflection to start acquisition. If the reflections are too close together, the tracking algorithm could fail. Try changing fixation points to make the reflections more distant and try again.
The corneal reflex is correctly centred and the patient is still, but you get the message 'Target lost' or the quality of the exam 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 made by the instrument will be longer to ensure 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 still be centred manually using the on-screen controls, if the patient remains sufficiently still. When the reflection is properly centred, touch the MANUAL ACQUISITION icon to start the process.

5.10 HOW TO CHANGE FIXATION POINTS

By changing the fixation point, it will be possible to access different areas of the cornea to observe the health of the corneal endothelium.

1 Touch the fixation icon (A). The graphic menu for choosing the fixation point appears.

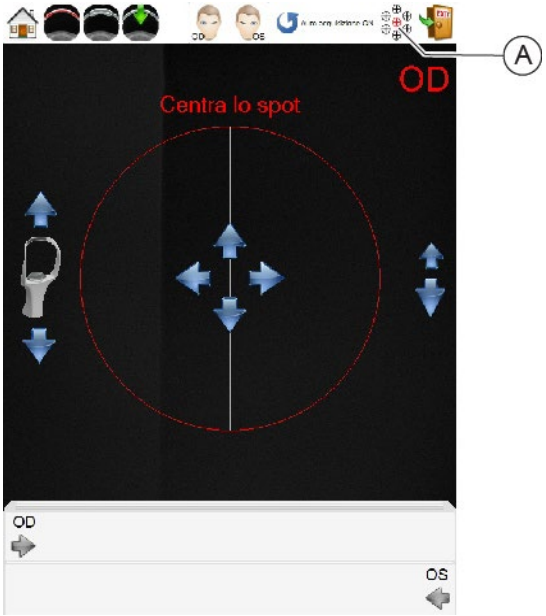


Fig. 38 - Fixation points

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

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

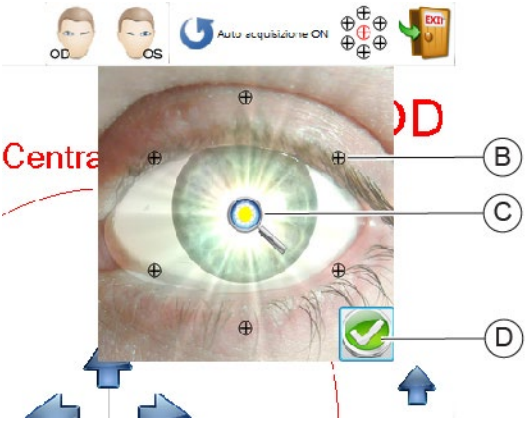


Fig. 39 - Fixation points

4 Proceed with the acquisition.

5 After acquisition, the fixation point will automatically return to the central position.

5.11 HOW TO ANALYSE THE ACQUIRED DATA

1 Once the acquisition has been completed, the ACQUISITION DATA screen will open with the Polymegatism data (B), the Pleomorphism data (C) and the statistical summary (D). It is now possible to analyse the examination data.

2 Press the EXIT button (A) to return to the acquisition screen and start a new exam.

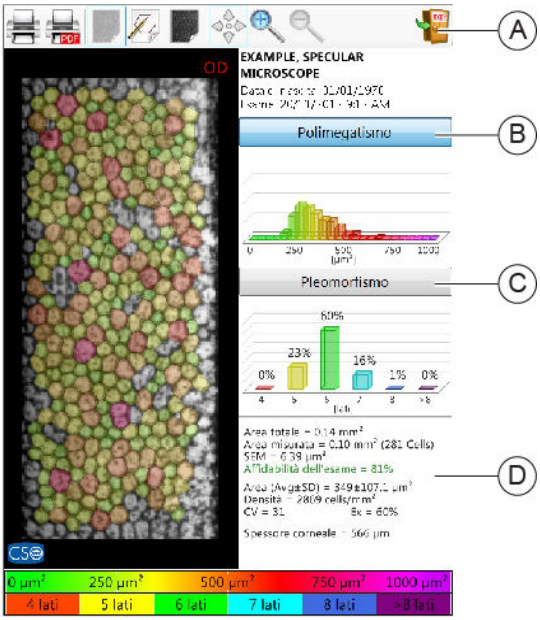


Fig. 40 - Acquired data screen

The following data will be displayed after each acquisition:

- The original image, with the overlay of the cells segmented automatically by the processing algorithms. The colours of the cells are relative to the Polymegatism and Pleomorphism scales and can be changed from one to the other by touching the respective on-screen buttons.
- Simple visual graphs showing statistical distributions for both Polymegatism and Pleomorphism.
- Textual statistical indications including cell area, density, corneal thickness, reliability of the exam etc. Please refer to the acquisition summary section of this manual for a detailed explanation of statistical data.

Polymegathism graph

The graph shows the amount of area occupied by cells of the same size. To understand the colouration of the cells in relation to their area and the resulting estimated health status, refer to the Polymegathism scale at the bottom edge of the screen. See graph for distribution according to the area of the cells examined.

Pleomorphism graph

The graph shows the percentage of cells with a given number of sides. To understand the colouration of the cells in relation to their number of sides and the resulting estimated health status, refer to the Pleomorphism scale at the bottom edge of the screen. See the graph for the distribution according to the number of sides of the cells examined.

Statistical summary

The statistical summary is based on automatic or manual cell segmentation. Below is a description of the values present.

Value	Description
Total area	Total endothelium surface, processed and non-processed.
Measured area	Processed surface with the total number of segmented cells.

Value	Description
Guttae area / total area (if available*)	Percentage of surface area affected by guttae compared to total surface area.
SEM (Standard error of the mean)	Evaluation of the reliability of the cell mean area calculation. It divides the standard deviation of the cell area by the square root of the number of cell samples.
Exam reliability	Reliability percentage. Green if the value is above 50%, yellow from 30% to 50%, red if below 30%. In the latter case, the reliability of the exam is insufficient to extract clinically valid numerical data and must be repeated.
AVG±SD	Average cell surface together with the uncertainty value given by the standard deviation.
Density	Cell density per square millimetre. An indicative value for an adult man is 2500-3000 cells/mm^2
Functional density (if available*)	In the presence of guttae, this parameter indicates the actual cell density after excluding the guttae-affected surface from the calculation.
CV (Coefficient of variation)	Coefficient of the ratio of standard deviation of the cell area to arithmetic mean of that area. With reference to the Matsuda-Schultz index, an average value should be below 35.
Ex (Hexagonality Index)	Ratio of number of hexagonal cells (with six sides) to total number of segmented cells.
Corneal thickness	Indicative pachymetric data relative to the portion of the cornea scanned during acquisition. The accuracy of corneal thickness is strictly dependent on the quality of the acquisition and other uncontrollable variables, so this figure should be regarded as indicative and approximate.

* Items only available after manually adding the guttae-affected surface to the image.

5.12 HOW TO MANUALLY MODIFY THE CELLS

When enabled in the acquisition summary, manual cell editing makes visible a number of tools for optimising cell segmentation. This function should be used to:

- Modify cells where segmentation appears to be inaccurate.
- Add cells where the automatic segmentation failed to detect them correctly.
- Delete non-existing cells wrongly detected by automatic segmentation.
- Add or remove guttae, which cannot be automatically detected by the segmentation algorithms.

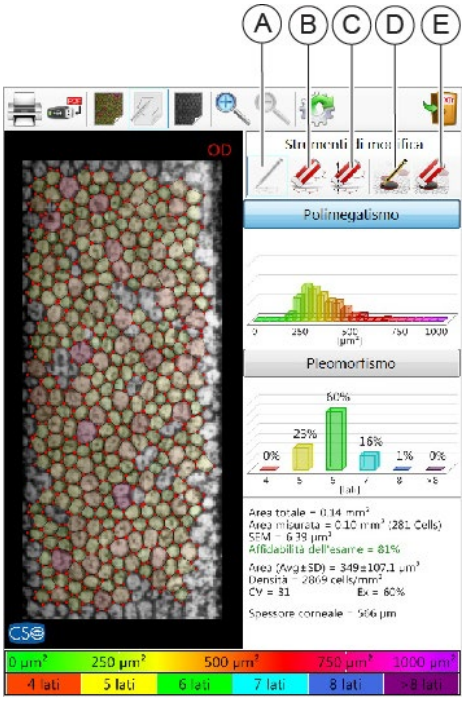


Fig. 41 - Modification tools

To add new cells (A)

1 Zoom in on the image before proceeding for better accuracy.
2 Touch the cell vertexes. Edges will be automatically drawn as soon as consistent cell shapes are detected by the new vertexes.

To delete the vertexes (B)

1 Zoom in on the image before proceeding for better accuracy.
2 Touch the false vertexes that you want to exclude from the process algorithms.

To delete the cells with area selection (C)

Select a rectangle on the image by touching and dragging with your finger. All the vertexes included in this rectangle will be deleted.

To add the guttae (D)

Use your finger or a touchscreen pen to draw circular shapes corresponding to the guttae on the image. The surface affected by guttae becomes marked with a dark shadow.

To delete the last guttae (E)

Touch the button to remove the last guttae from the list of those entered. It is not possible to choose which guttae to remove: the last one entered will be deleted.

5.13 HOW PRINT 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 that the printer path is as indicated in "**How to connect the device to the printer" on page 43**.

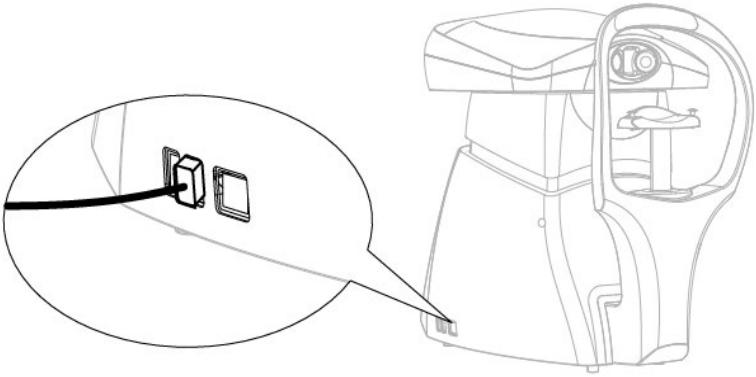


Fig. 42 - Connection to the printer

2 Touch the button (A) to start printing.

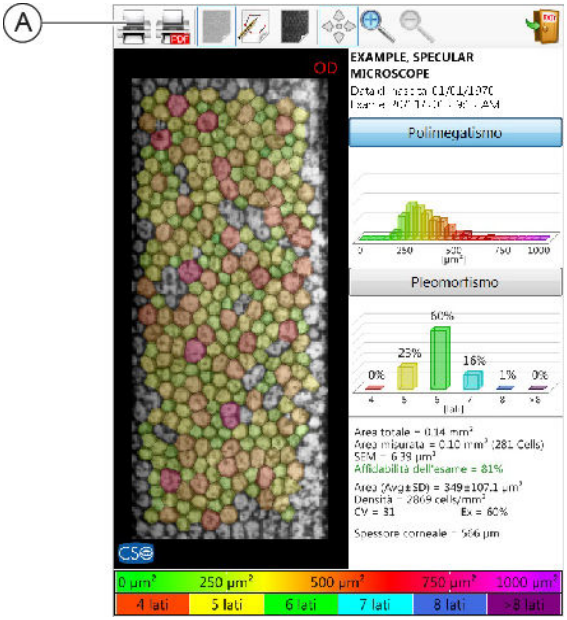


Fig. 43 - Paper print start button (A)

5.14 HOW TO PRINT TO PDF

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

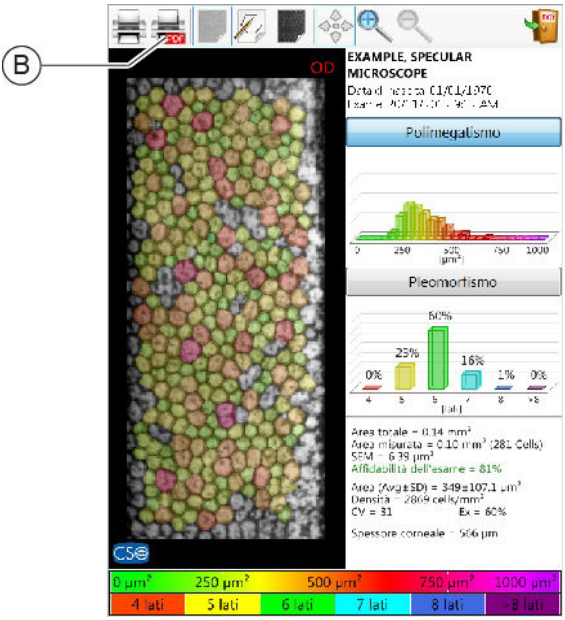


Fig. 44 - PDF print button activation (B)

2 Connect a memory stick to the device.

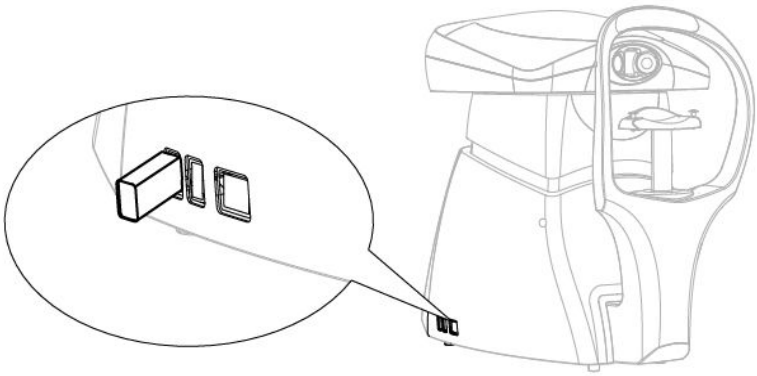


Fig. 45 - Memory stick connection

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

5.15 HOW TO REPLACE CHIN CUP PAPERS

At the end of each exam remove the chin cup paper and clean the forehead rest so that everything is always perfectly clean and ready for the next patient.

This device is provided with a package of chin cup papers. After using the last chin cup paper, replace the pack.

1 Extract the two plastic rivets.
2 Position the new package of chin cup papers.
3 Replace the plastic rivets in the holes of the pack and in the holes of the chin cup.

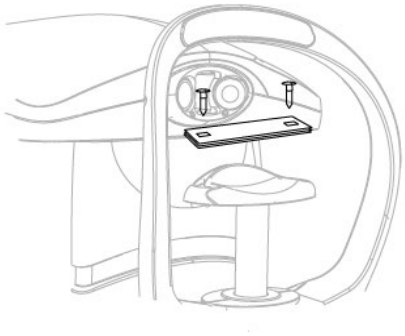


Fig. 46 - Replacing chin cup papers

To order the spare part, see the part number in the **“List of spare parts and accessories” on page 78.**

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 dust cover on the device to prevent dust accumulation.

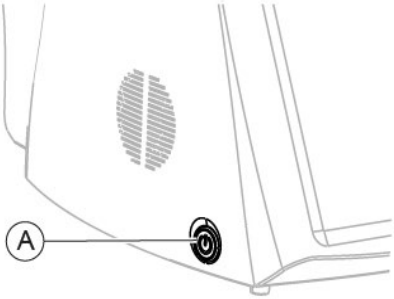


Fig. 47 - Device ON/OFF button

6 ORDINARY MAINTENANCE

6.1 SAFETY WARNINGS

DANGER

Danger of electric shock. Unplug the power supply cable from the power socket before disinfecting or cleaning the device and before any maintenance operation.

CAUTION

The device does not contain any parts requiring user intervention. Do not remove any parts of the device.

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

In the event of faults or malfunctions and for all maintenance work not indicated in the instructions for use, please contact the authorised service centre or the manufacturer of the device.

6.2 ELECTRICAL SAFETY CHECK

DANGER

Electrical danger due to age and wear.

The electrical safety of the device may decrease with age and wear.

Follow and comply with the regulations in force in the country of use regarding electrical tests on devices.

Otherwise, have an electrical safety test performed at least once a year in accordance with IEC 62353 by the manufacturer or a qualified technician. Follow the procedure indicated in the technical manual issued by the manufacturer.

Record and keep evidence of the tests and measurements taken during tests.

The test ends with a device operation test. This operation must be performed by a person familiar with the device application.

6.3 CLEANING AND DISINFECTION

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

CAUTION
A correct cleaning and disinfection procedure, together with appropriate operating procedures, is essential to preventing the spread of infections or cross contamination.

CAUTION
Danger of material damage. 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 must be carried out regularly.

Device parts that do not come into direct contact with the patient must be cleaned at least once a day.
Device parts that do come into direct contact with the patient must be thoroughly cleaned and disinfected after each use.

This section describes the procedures to be carried out during use and maintenance in order to ensure proper cleaning and disinfection of the device and its accessories.

6.3.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION
Danger of material damage. 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 damage caused by using disinfectant products not indicated in this manual.

The choice of the most suitable product and procedures for the cleaning and disinfection of the device must take into account both the sensitivity of the device to specific substances and the effectiveness of the product.
For the cleaning and disinfection procedures, use products approved by the FDA or EC for medical devices or medical-surgical devices.
Use the products as listed below, divided by category:

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

For information about the use of the chosen product, follow the instructions provided by the manufacturer.

6.3.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

CAUTION
The device supplied is not sterile and must not be sterilised prior to use.

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

6.3.3 DEVICE CLEANING

CAUTION
Carefully follow the cleaning instructions described in this section in order to avoid damage to the device and its accessories.

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

The device must be regularly cleaned.

The device is provided with a cover 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 cleaning solution.

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

6.3.4 CLEANING THE APPLIED PARTS

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

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

1 Turn off the device and unplug it from the power socket.
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 cleaning products, read paragraph **“Recommended products for cleaning and disinfection” on page 74.**

6.3.5 CLEANING THE OPTICAL COMPONENTS

CAUTION
Danger of material damage. 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.

6.4 NETWORK FUSE 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 value of the new fuses is compatible with the mains voltage used, as stated on the nameplate.
5 Connect the power supply cable to the mains.

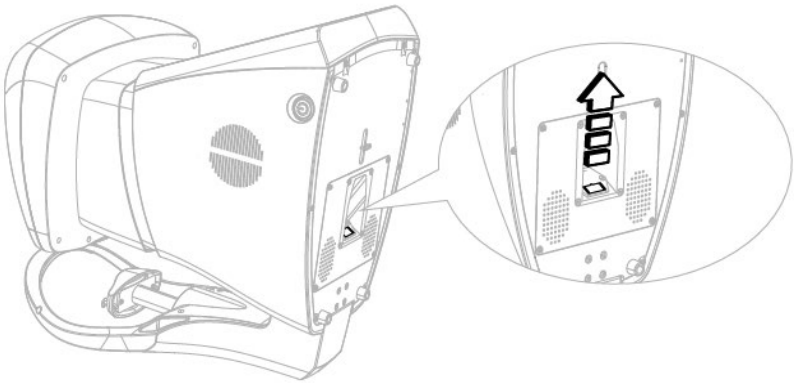


Fig. 48 - Network fuses replacement

6.5 LIST OF SPARE PARTS AND ACCESSORIES

Code	Description
3001007ID3F	Power supply cable
10101300	Isolation transformer 230V/230V. 800 VA (maximum load) power supply cable
4014020	Chin cup paper pack (50 pieces)
4013095	Dust cover
10070524	Table top 45x90 mm
10070521	Table top 45x60 mm
10070144	Electric support with one column for table top (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 local Dealer.

6.6 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	The power supply cable is not connected properly.	Correctly connect the power cable of the device to the power supply socket. Press the ON button of the device.	If the device is powered through the table, check the connection of the table to the electric network. Check the operation of the table fuses. Check the operation of the device fuses.
The application software does not start	Hard Disk failure. Corrupted operating system. The application software does not work properly.	Replace the Hard Disk. Reinstall the operating system. Reinstall the application software.	Contact Technical Assistance. The installation of the application software needs administrator privileges.
The touch screen does not work	Dust and grease on the touch screen. The application software does not work properly.	Clean the touch screen with a soft cloth. Restart the device.	The touchscreen may be defective. Contact the Technical Service Centre.

Issue	Cause	Solution	Note
Images cannot be saved in the device's internal/external database	The database is not connected to the software. No network connection. The Ethernet cable is faulty.	Check that the correct path to the file is specified in the database configuration screen. Refresh the connection to the database file. Check that the network connection is working. Replace the Ethernet cable.	Check the data network connections regularly.
Failed image acquisition	The patient moved or closed their eyes during the acquisition.	Ask the patient to keep their eyes open, look at the fixation light and not move their eyes.	See paragraph **"Troubleshooting during image acquisition" on page 58**.
Failed image focusing	Presence of dust or grease on the optical parts of the device.	Clean the optical parts of the device with a soft cloth.	Make sure the patient does not touch the optical parts.
Failure of the device to recognise the eye	Presence of dust or grease on the optical parts of the device.	Clean the optical parts of the device with a soft cloth.	Make sure the patient does not touch the optical parts.

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