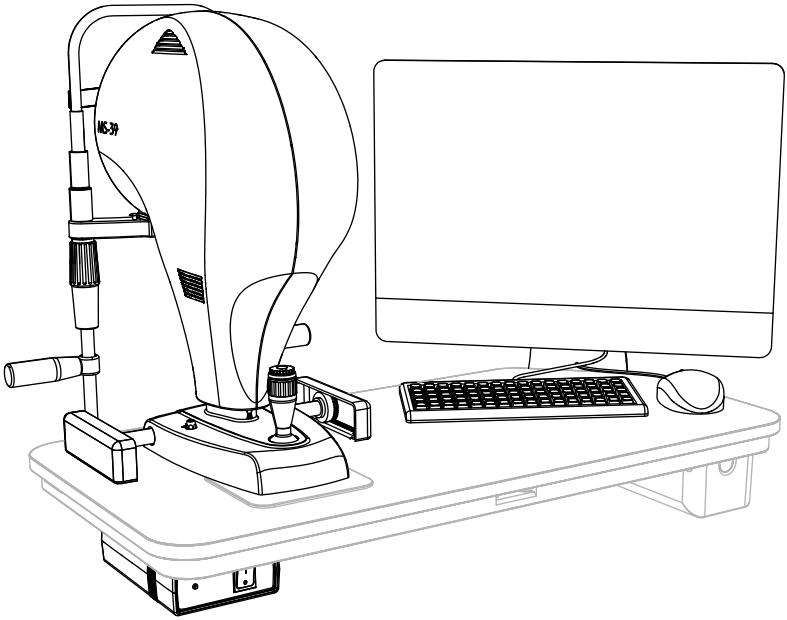
COSTRUZIONE STRUMENTI OFTALMICI



AS-OCT

INSTRUCTIONS FOR USE

MS-39

COSTRUZIONE STRUMENTI OFTALMICI

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MS-39IFUENGCSO0001032025

CE 0051

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.

Trademarks

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 0051	CE Marking (Directive 93/42/EEC) Identification number of the notified body (IMQ)
MD	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
	Class II device

1.2 GENERAL WARNINGS

THESE INSTRUCTIONS FOR USE REFER TO THE MS-39 DEVICE (HEREINAFTER "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.

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 support service does not cover damage resulting from inadequate packaging of the device when sent back to an authorised Service Centre.

Check for potential damage to the device caused by transport/storage prior to its use.

It is forbidden to reproduce, in full or in part, texts or images contained in these instructions for use without the written authorisation 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 (to the extent applicable)
- 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.
- UNI EN ISO 19980 - Ophthalmic instruments - Corneal topographers

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 compliance of the device with EU Directive 93/42/EEC as amended by 2007/47/EC 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 technical operations on the device that are not indicated or described in these 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

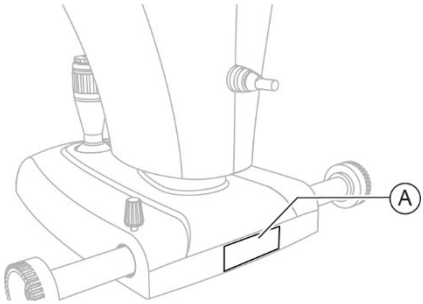

Fig. 1 - Data plate position

Pos	Description
A	Device data plate

Fig. 2 - Device data plate

2.2.3 POWER SUPPLY UNIT DATA PLATE

Fig. 3 - PSP2405 power supply unit data plate

2.3 INTENDED USE

Medical device used in ophthalmological diagnostics to carry out the analysis of the anterior segment of the eye and total ocular biometry. It combines corneal topography with a Placido disk, OCT-based anterior segment tomography and biometry in a single structure.

The device has been designed for the screening, acquisition and processing of 25 clear, high-resolution sectional images over a diameter of 16 mm.

The device provides pachymetry data, lift, curvature and power information for both corneal surfaces.

Additional examinations enable the accurate measurement of the pupil diameter in scotopic, mesopic and photopic conditions and in dynamic mode, and their integration with the corneal map.

Based on the pachymetric map and corneal altimetric data, the device enables intrastromal ring segment planning for the correction of refractive defects and some forms of keratoconus.

The device allows to perform glaucoma screening and provides the measurement of iridocorneal angles and pachymetry. These values, together with the most common IOP correction formulas, are useful to diagnose several pathologies that may depend on the conformation of the anterior chamber.

The device has no known contraindications.

The main features of the device are listed below.

Corneal topography and tomography of the anterior segment

The device provides information on pachymetry, lift, curvature and dioptric power of both corneal surfaces over a diameter of 10 mm.
All biometric measurements of the anterior chamber are calculated starting from 25 sections of the cornea over a diameter of 16 mm.
In addition to clinical diagnostics of the anterior segment, the most common fields of application are refractive and cataract surgery.

Pupillography

The pupillography module is completely integrated with the topography and enables the user to:

- Perform pupillometry measurements in scotopic light conditions in order to evaluate the maximum pupil extension and eye area dimensions to set for a treatment.
- Perform the pupillometry measurement in scotopic light conditions.
- Perform the pupillometry measurement in mesopic light conditions.
- Perform the pupillometry measurement in photopic light conditions.
- Perform the dynamic pupillometry measurement starting from 400 lux and turning off the light source so that the pupil dilates to its maximal extension.
- Evaluate pupil decentralisation with respect to the corneal vertex for each of the conditions described above and the pupil centre drift during dilation.

Meibography

The device allows for analysis of the Meibomian glands using a non-invasive method. The meibography is performed through infrared illumination that enhances contrast, magnifying the anatomic structure of the glands without causing any discomfort to the patient.

Analysis of the tear film

The device's Placido disk enables advanced tear film analysis and the evaluation of the NI-BUT (Non-Invasive Break-up Time).

IOL calculation module

An IOL calculation module based on the Ray-Tracing Technique is available which, regardless of the clinical status of the cornea, provides the values of the spherical and toric power of the intraocular lens. This enables the planning of corneal corrective surgery for refractive defects, both photoablative and by means of intraocular lens implants.

Corneal aberrometry

The device enables the analysis of corneal aberrations. It is possible to select the anterior, posterior or total corneal section for different pupil diameters. The OPD/WFE map and visual simulations (PSF, MTF and image convolution) can help understand and explain the patient's visual discomfort.

Glaucoma screening

The device enables glaucoma screening and provides measurements of the iridocorneal angles, AOD, TISA and corneal pachymetry. Together with the most common IOP correction formulas, these values are useful in diagnosing several diseases which may depend on the shape of the anterior chamber.

Keratoconus screening

An efficient keratoconus screening system, clinically validated, provides an indication of the risk of ectasia, underlining the cases with greater possibility of complications.

Dry Eye Report

The Dry Eye Report provides an overall evaluation of the patient's clinical conditions, aimed at diagnosing tear film dysfunctions. The evaluation is based on:

- Ocular Surface Disease Index (OSDI)
- eye redness analysis (combining other devices)
- Meibomian glands analysis
- Tear meniscus analysis (combining other devices)
- NI-BUT.

Ocular biometry
Ocular biometry includes:

- Image of the eye sections
- Measurement of the axial length of the eye (AL)
- Anterior chamber depth measurement (ACD)
- Aqueous depth measurement (AD)
- Crystalline lens thickness measurement (LT)
- Central corneal thickness measurement (CCT).

The table of contents indices include:

- (⌀) Pupil diameter + Pupil centre
- W-W Diameter of the cornea + (α) - Limbus centre.

The keratometric indices include:

- SimK
- Kflat
- Ksteep
- Kavg
- Cyl.

The topographical maps include:

- Axial map
- Keratoscopic image.

Biometry of the crystalline lens
In order to more accurately determine the ELEP and refine the intraocular lens calculation, the device offers an acquisition mode to measure the crystalline lens thickness, its distance from the cornea and its equator.

Export

Through the application software, the device is capable of performing the function of data export/plug-in to other medical devices. This function can be useful, for example, for calculating a laser ablation model for corneal refractive surgery.

Additional device features with the application software

Together with the application software, the device allows for:

- guided manual acquisition
- management of patient data and the possibility of personalizing research and statistics
- measurement and visualisation of the sagittal and tangential curvature of the cornea, both for the anterior and posterior surfaces
- map visualisation: pachymetry, refractive power (anterior, posterior and total), altimetry (anterior and posterior) and depth of the anterior chamber; epithelial map
- map summaries
- analysis of anterior segment aberrations
- analysis of the differential maps
- advanced ring editing system, which permits the modification of the position of the edges in order to provide proper reconstruction, even on distorted surfaces.
- availability of the following maps: sagittal curvature map, tangential curvature map, lift, refractive power, Gaussian curvature map, corneal pachymetry.
- screens and summaries that allow the customisation of the device depending on the user's needs:
    - four map summary
    - single map screen
    - keratoconus summary
    - six map summary
    - advanced altimetry and Zernike summary
    - adjustable corneal wavefront analysis of the pupil. It includes maps of the most common aberrations
    - corneal wavefront analysis with optical quality summary referred to the anterior corneal section, with PSF, Spot Diagram, MTF and vision simulation for the analysed wavefront.
- devices for follow-up check, with differential maps with 2 or 3 elements
- devices for follow-up check, with comparison of up to 4 different maps

- a wide-ranging series of synthetic descriptors of the properties of the cornea, including:
    - Sim-K to simulate the measurement of a fixed-target ophthalmometer (for the anterior surface)
    - principal corneal meridians in the 3 mm, 5 mm and 7 mm zones
    - flatter and steeper hemi-meridians in the 3 mm, 5 mm and 7 mm zones
    - peripheral degrees
    - pupil decentralisation, pupil diameter, and corneal diameter size
    - keratorefractive indices calculated in the pupil area for an assessment of the patient's visual quality
    - keratoconus screening index for diagnosis and follow-up
- Dry Eye Report

For the system requirements, read paragraph **“Personal Computer” on page 34.**

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.

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.

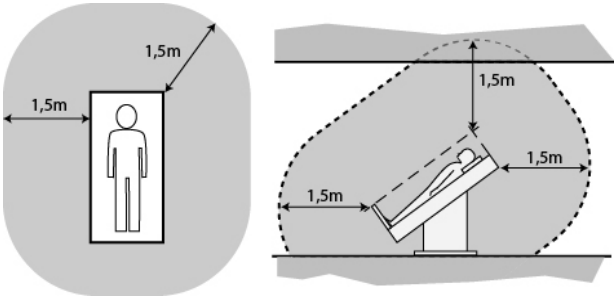

Fig. 4 - Patient area

2.4 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification according to EU Medical Device Regulation 2017/745 (MDR)	Class IIa

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%

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.

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic 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.
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

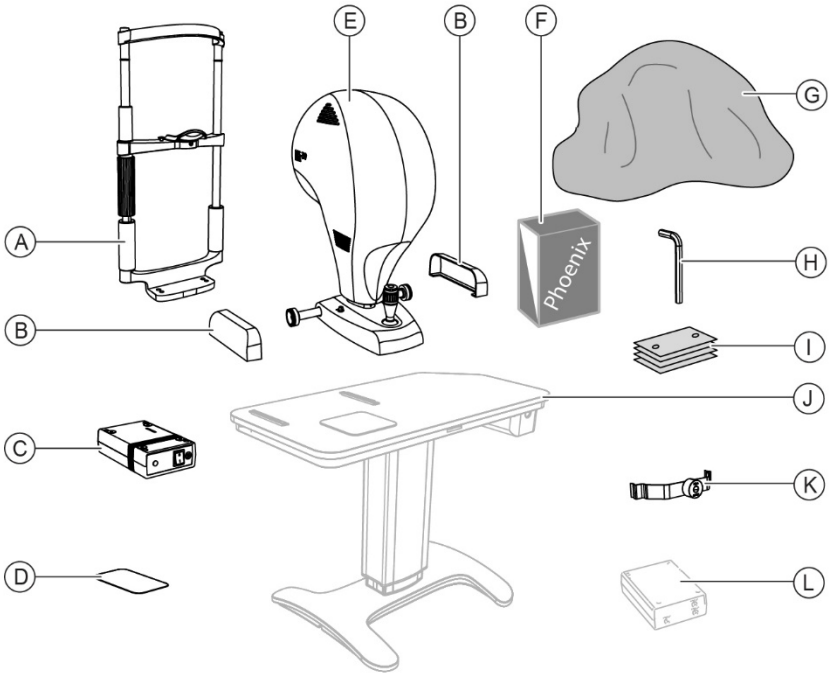

Fig. 5 - Supply description

Pos	Name		Description
A	Chin rest with adjustable chin cup		Adjustable height. Adjustable distance between chin and forehead. Adjustable chin cup.
B	Wheel cover		Protection against accidental crushing of fingers.
C	Power supply unit		A cable is provided with the power supply unit.
D	Sticker pad	Optional (*)	Sticker for right/left identification.
E	MS-39 device		Consisting of an image acquisition unit, a USB cable for connection to the PC and a connector on the base for connection to the power supply unit.
F	Personal Computer and application Software		Application software for image acquisition and device management.
G	Dust cover		Place on the device when not in use to protect it from dust.
H	Hexagon wrench with screws		
I	Package of chin cup papers		Papers to be placed on the chin cup of the chin rest.
J	Ophthalmic table	Optional	Table top with one or two columns and electronic adjustment of height. Drawer and auxiliary sockets with cable guide.
K	Calibration tool		Accessory equipped with sphere (radius 8 mm).
L	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices in the patient area.

Optional: accessory not provided with the basic supply.
Accessories marked with (*) are essential for the proper functioning of the device.

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

3.1.1 MS-39 DEVICE

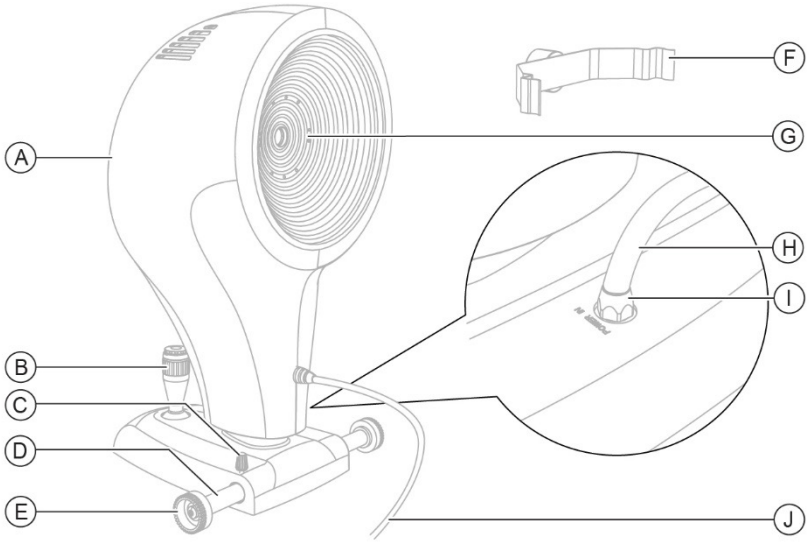

Fig. 6 - MS-39 device

Pos	Description
A	MS-39 device
B	Joystick
C	Device locking knob
D	Sliding rod
E	Cogwheels
F	Calibration tool
G	Shooting channel
H	Device power supply cable
I	Connector
J	USB connection cable between device and PC

3.1.2 POWER SUPPLY UNIT

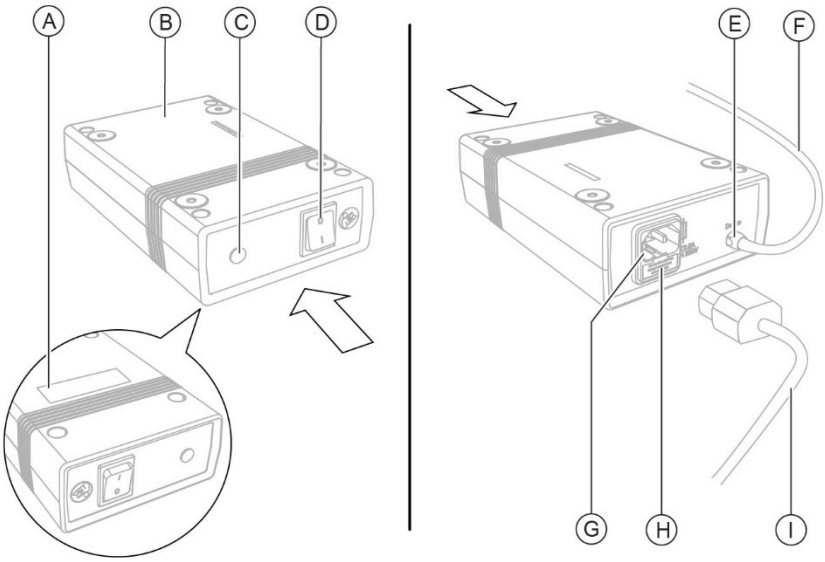

Fig. 7 - Power supply unit

Pos	Description
A	Data plate
B	Power supply unit
C	Power supply status control light
D	ON/OFF switch
E	Device out connector
F	Device power supply cable
G	Power grid connector
H	Fuse box
I	Power supply cable from electric network

3.1.3 CHIN REST

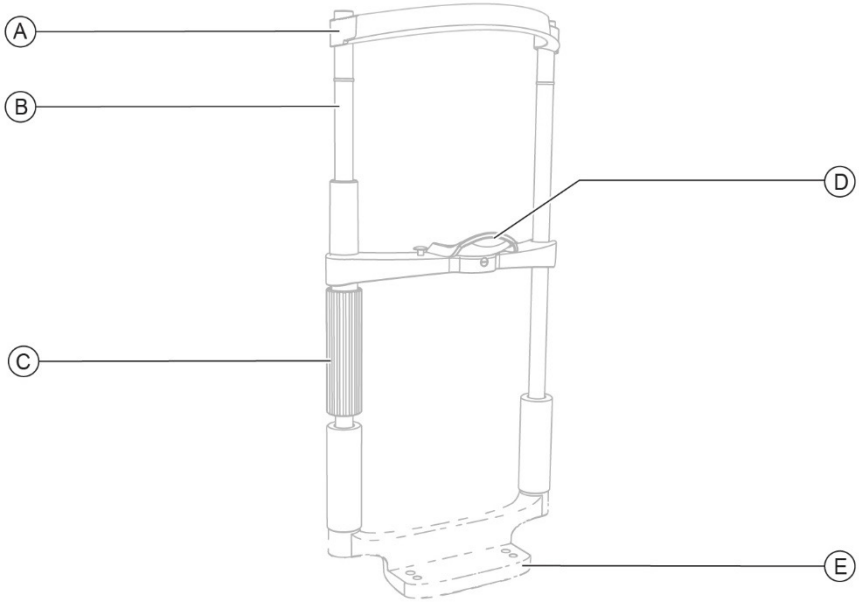

Fig. 8 - Chin rest

Pos	Description
A	Forehead rest
B	Chin rest structure
C	Chin cup adjustment knob
D	Adjustable chin cup
E	Chin rest support (*)

(*) The chin rest support may vary depending on the table top where the chin rest will be installed.

3.1.4 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. 9 - One-column table

Read the instructions for use of the ophthalmic table.

3.1.5 PERSONAL COMPUTER

The device must be used in combination with a PC.
Minimum system requirements:

- CPU: i5 quad core (2.5 GHz)
- RAM: 8 GB
- Video Card: 1 GB RAM (not-shared) resolution 1920 x 1080 pixels
- Operating system: Windows 11 (64 bit)

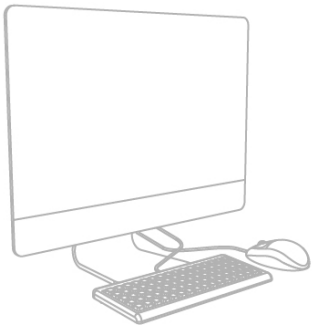

Fig. 10 - Personal Computer

The PC must comply with Directive IEC 62368-1 Information technology equipment - Safety - Part 1: General requirements.
If the PC is 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”.

It is possible to connect other accessories to the PC (printer, modem, scanner, etc.) through 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”.

3.2 TECHNICAL DATA

Technical data	Value
Data transfer	USB 3.0
Power supply	External power supply unit 24 VCC In: 100-240 VAC - 50/60 Hz - 2 A Out: 24 VDC 4 A
Network cable	with C14 socket
Dimensions (Height x Length x Depth)	505 x 315 x 251 mm
Weight	10.4 kg
Chin rest stroke	70 mm ±1
Minimum height of the chin cup from the work surface	23 cm
Base movement (x, y, z)	105 x 110 x 30 mm
Working distance	74 millimetres

Light sources

Technical data	Value
Placido Disk	LED @635 nm
OCT	SLED @845 nm
Pupillography	LED @950 nm *(central wavelength)

Topography

Technical data	Value
Placido Disk	22 rings
Measured points	31,232 (anterior surface) 25,600 (posterior surface)
Topographic covering	ø 10 mm
Measurement accuracy	Class A complying with the UNI EN ISO 19980 standard

Section

Technical data	Value
Image field	16 mm x 9 mm (in air)
Axial resolution	5 µm (in air) 3.6 µm (in tissue)
Transverse resolution	35 µm (in air)
Image resolution	Keratoscopy (640x480) + 25 radial scans over transverse field of 16 mm (1024 A-scan) - Section: over 16 mm (1600 A-scan); over 8 mm (800 A-scan)

4 DEVICE USE

4.1 HOW TO INSTALL THE DEVICE

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

1 Place the ophthalmic table in the room. The table must be lifted by two people.
2 If present, lock the table wheels. Lower the brake lever.
3 Place the power supply unit under the table top. Screw the screws into the four holes.

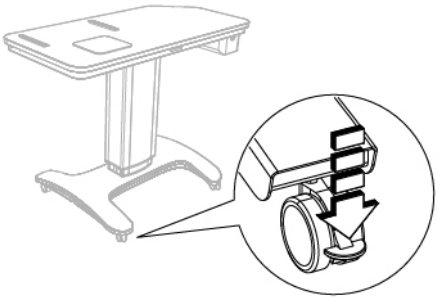

Fig. 11 - Table placement

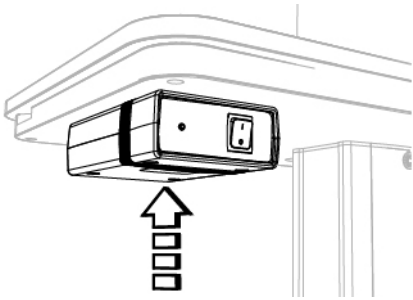

Fig. 12 - Power supply unit placement

4 Check the position of the sticker with respect to the central axis (A).

5 Remove the protective film. Place the sticker pad between the two cogged wheels and the sliding plate.

While placing the sticker pad (sticker for right/left identification) on the table top, observe the specified distances.

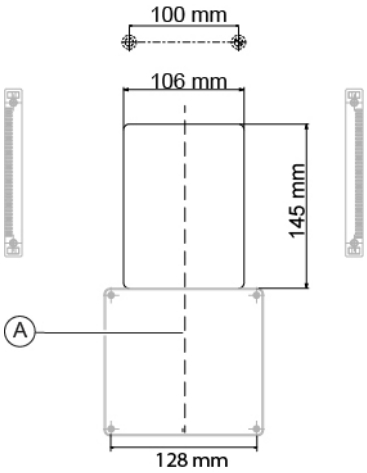

Fig. 13 - Distances

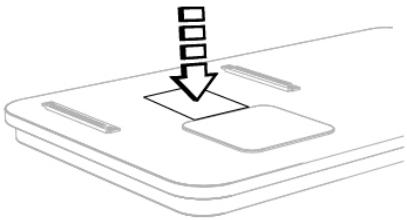

Fig. 14 - Positioning the sticker pad

6 Place the device on the table top and correctly align the cogwheels on the cogged guides.

7 Fasten the two wheel covers to the cogged guides on the table top.

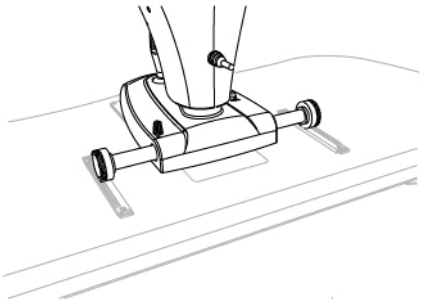

Fig. 15 - Placement of the device

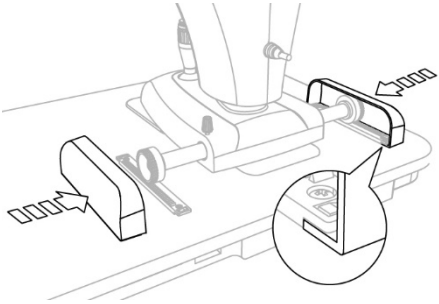

Fig. 16 - Placement of wheel covers

8 Install the chin rest. Beneath the table top, there are two screws to fasten the chin rest support to the table top.

9 Complete the electrical connections between the different components.

The chin rest must be installed so that the eye-level indicator (A) is placed at a height of 380 mm from the table top.

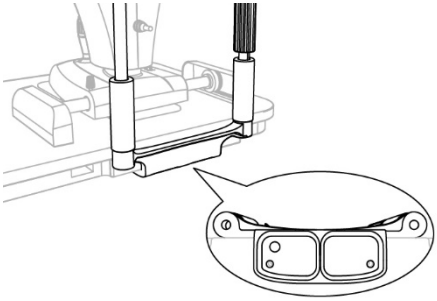

Fig. 17 - Placement of the chin rest

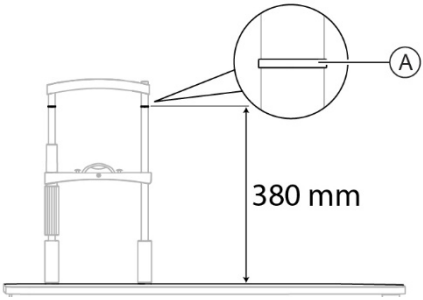

Fig. 18 - Correct height of the eye-level indicator

4.2 HOW TO CONNECT THE DEVICE

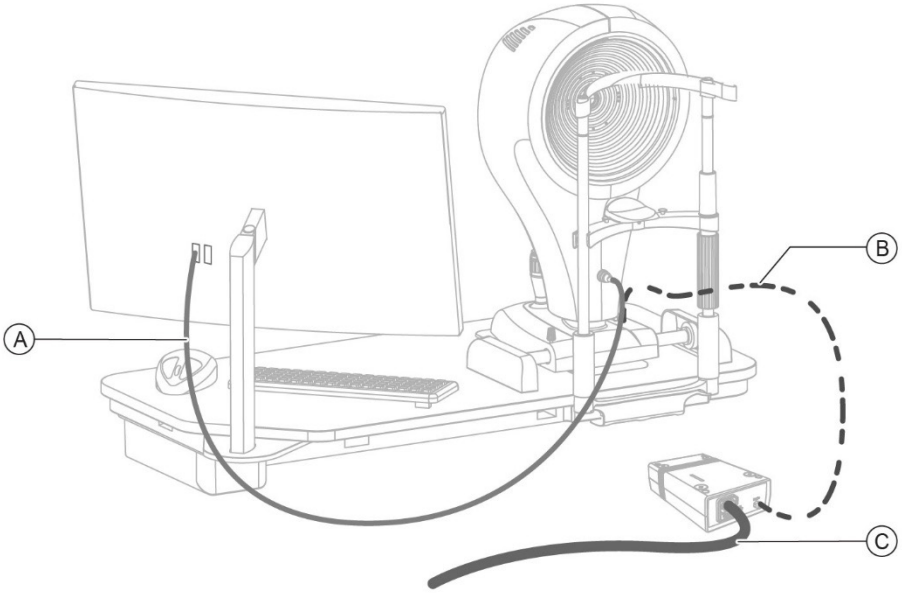

Fig. 19 - Device connection

Pos	Name
A	USB connection cable between device and PC
B	Power supply cable for the connection of the power supply unit to the device
C	Power supply cable to connect the electric table to the power supply unit

To connect the table base to the electric network, read the instructions for use of the table or ophthalmic unit.

4.3 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.

4.4 HOW TO TURN ON THE DEVICE

Before using the device, read the instructions in the Phoenix application software handbook.

1 Turn on the PC.
2 Press the power switch of the power supply unit to turn it ON.
3 Start the Phoenix application software.
4 Wait until the main screen of the application software is displayed.
5 When powering the device for the first time or after a long period of non-use, calibration will be required. Follow the instructions given in paragraph **“How to calibrate the device” on page. 43**.

4.4.1 HOW TO CALIBRATE THE DEVICE

Calibration must be performed when powering the device for the first time or after a long period of non-use.
The procedure should be carried out in a dark room, to simulate the environmental conditions of a standard acquisition procedure.

Follow the instructions given in the Phoenix application software handbook concerning the device calibration.

The procedure must be carried out with the utmost care. It is important to check the stability of the device before starting the procedure.
Calibration is essential to obtaining precise measurements.

1 Make sure that the calibration tool is clean and undamaged. If needed, clean it using a soft cloth.

Do not use solvents or thinners to clean the calibration tool.

2 Place the calibration tool on the chin rest.
3 Check that the sphere of the calibration tool is aligned with the shooting channel.

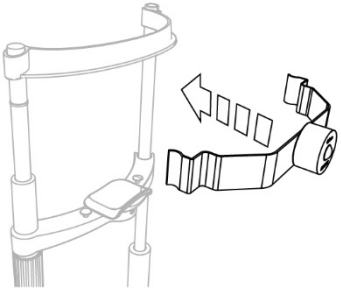

Fig. 20 - Placement of the calibration tool on the chin rest

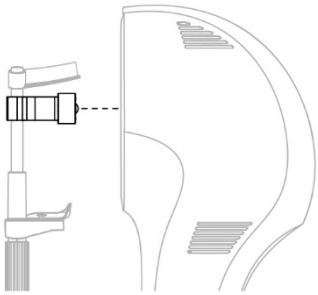

Fig. 21 - Alignment of the calibration tool with the device

4 Start the Phoenix application software.
5 Click the device icon.
6 Click the calibration button.
7 A window will appear on the screen, showing the calibration procedure in two steps. Carefully follow the instructions provided.
8 If the calibration procedure has been performed correctly, a confirmation message will appear on-screen.
9 After completing the calibration, it will be necessary to perform a check to ascertain calibration of the device using the calibration tool (sphere radius 8 mm).
10 Press the NEW PATIENT button, enter the personal data, confirm, and then select the CORNEAL TOPOGRAPHY exam.
11 Press CTRL+T on the keyboard to start Test Eye.
12 Press the space bar to start acquisition mode.
13 Once the image has been acquired, press the EXIT button and process the acquired exam.
14 From the SETTINGS panel, select the unit of measurement for curvature in millimetres.
15 Check the correspondence with the reference sphere value on the anterior tangential curvature map.

The radius measured on the anterior tangential curvature map must be 8 ± 0.03 mm.

16 If the measurements are not deemed reliable, repeat the entire calibration procedure.

If the device is found to be non-calibrated, the application software will display a warning message. Repeat the calibration process.

4.4.2 HOW TO TEST THE CALIBRATION

Close attention must be paid while performing the entire procedure. Check the device stability prior to starting the procedure.

To check that the device is calibrated correctly, follow the steps below:

1 Make sure that the calibration tool is clean and undamaged. If needed, clean it using a soft cloth.

Do not use solvents or thinners to clean the calibration tool.

2 Place the calibration tool on the chin rest.
3 Click the device icon in the top right corner of the main screen of the Phoenix application software and select “Calibration Check”.
4 Start the calibration check procedure.
5 At the end of the calibration check procedure, the result of the calibration check will appear on the display:
a) Calibration check successful.
b) Calibration check failed.
6 If the calibration check is successful, the button will be green, otherwise it will be yellow. If the calibration check fails, perform a new device calibration procedure.

The date of the last check is shown above the “Calibration Check” button. Calibration checks last 30 days. The calibration check is not mandatory in order to use the device. Perform calibration checks once every month to obtain accurate measurements.

7 If the calibration check has not been performed for more than 30 days, a warning notification will appear on the main screen of the software. Click the blue “Calibration Check” link. A new calibration check procedure will start.

4.4.3 HOW TO CREATE A NEW PATIENT

1 Click NEW PATIENT and enter their personal data. If the patient is already present in the database, you can automatically search for their surname by typing it into the command prompt.
2 A new examination will be created automatically.
3 Select the examination to be performed.
4 The image acquisition screen will open. Now it will be possible to proceed with the image acquisition.

4.4.4 HOW TO CREATE A NEW EXAMINATION

1 Click NEW EXAMINATION.
2 Select the examination to be performed.
3 The image acquisition screen will open. Now it will be possible to proceed with the image acquisition.

4.5 HOW TO ADJUST THE CHIN CUP

1 Ask the patient to sit down.
2 Move the chin cup left or right. The chosen position will determine the position of the eye to be examined.

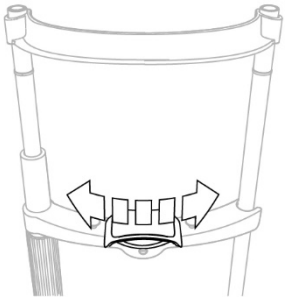

Fig. 22 - Chin cup positioning

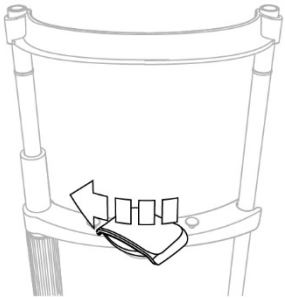

Fig. 23 - Chin cup positioning for left eye

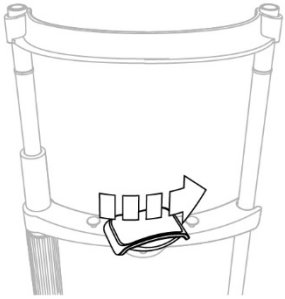

Fig. 24 - Chin cup positioning for right eye

3 Show the patient how to position their face against the chin cup and forehead rest

4 Check that the eye is correctly positioned in relation to the shooting channel.

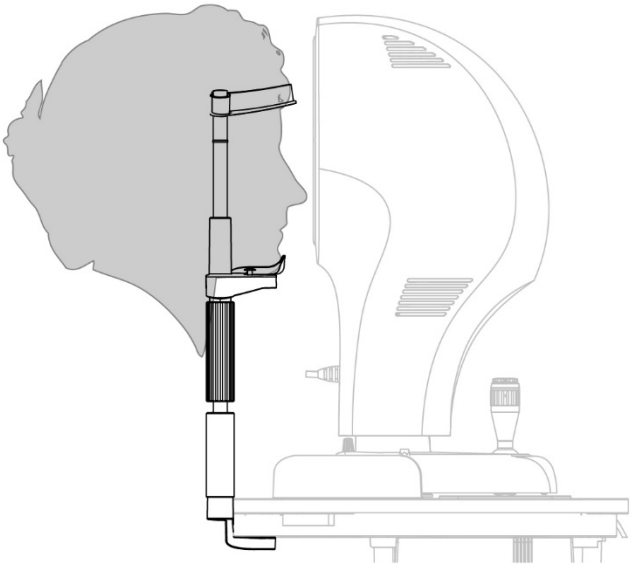

Fig. 25 - Patient position on the chin rest

5 Raise or lower the chin cup by rotating the knob.
6 Begin acquiring images as directed in paragraph **“How to acquire an image” on page 50.**

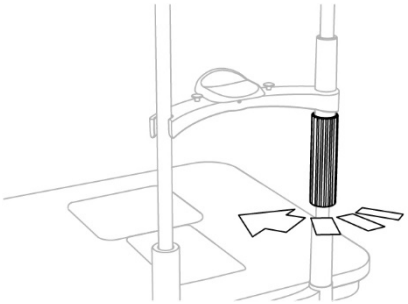

Fig. 26 - Knob rotation

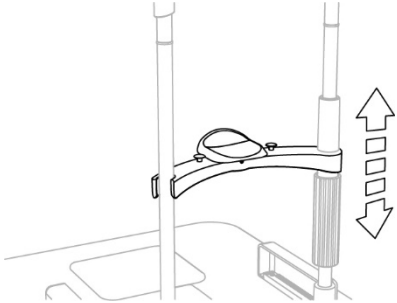

Fig. 27 - Chin cup placement

7 At the end of the acquisition procedure, ask the patient to lift their face from the chin cup and forehead rest.
8 Move the chin cup in the opposite direction to that chosen before.
9 Show the patient how to position their face against the chin cup and forehead rest
10 Check that the eye to be examined is correctly positioned in relation to the shooting channel.
11 Begin acquiring images as directed in paragraph **“How to acquire an image” on page 50.**

4.6 HOW TO ACQUIRE AN IMAGE

1 Rotate the joystick and align the device with the patient's eye.
2 Move the device towards the eye. Keep the reflection of the corneal vertex centred in both images.
3 Perform small movements with the joystick to obtain the best image alignment.

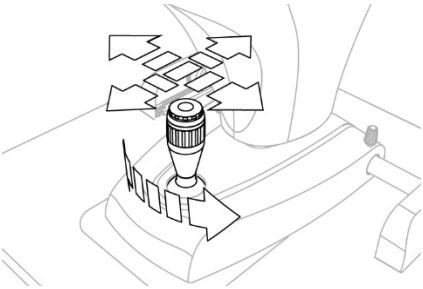

Fig. 28 - Placement of the device

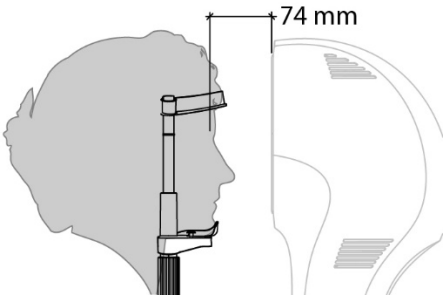

Fig. 29 - Distance from the patient

4 Press the joystick button to acquire the topographic image. The image will be saved in the gallery.
To acquire a tomographic image, turn the knob on the joystick and adjust the scanning axis of the tomographic section. Press the joystick button to perform the acquisition.

5 Double click on the acquired image to process and visualise it on the computer screen.

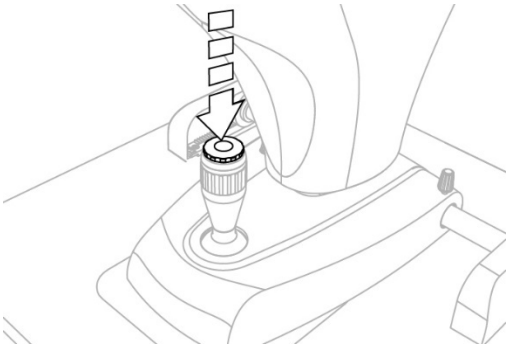

Fig. 30 - Image acquisition

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

4.7 HOW TO REPLACE CHIN CUP PAPERS

At the end of each examination, always remove the chin cup paper, so that there is always a new sheet, to ensure hygiene 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 pack of chin cup papers
3 Replace the plastic rivets in the holes of the pack and in the holes of the chin cup.

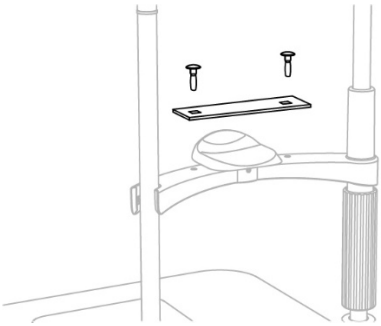

Fig. 31 - Changing the chin cup papers

To order the spare part, see the part number in the **"List of spare parts and accessories" on page 60.**

4.8 HOW TO TURN OFF THE DEVICE

CAUTION
Do not turn off the computer and do not disconnect the connection cable between the computer and the device when the program is in use.

1 Lock the device. Turn the locking knob.
2 Exit the Phoenix application software. Turn off the computer.
3 Press the power switch of the power supply unit to turn it OFF.
4 Place the dust cover on the device to prevent dust accumulation.

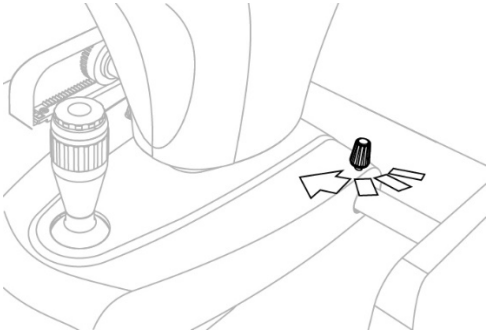

Fig. 32 - Locking the device

5 ORDINARY MAINTENANCE

5.1 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 not indicated in the instructions for use.

In the case of damage or malfunction or for any maintenance operations not indicated in the instructions for use, contact an authorised Service Centre or the device Manufacturer.

5.2 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.

5.3 REPLACING THE FUSES

DANGER

Danger of electric shock. Do not touch the accessible contacts of the connectors. When replacing the fuses, do not touch the accessible contacts of the fuse drawer and the patient at the same time.

CAUTION

Danger of material damage. Before replacing the fuses, disconnect the plug from the socket. Only use fuses with technical specifications matching those on the fuse identification plate. The fuse compartment is located below the electricity input of the device.

1 Disconnect the power supply cable from the electric network.
2 Pull out the fuse drawer (A) on the rear of the power supply unit.
3 Remove the fuses (B) from the fuse drawer (A).
4 Replace the fuses. Check that the rating of the new fuses is compatible with that of the electric network, as indicated on the data plate of the power supply unit.
5 Connect the power supply cable to the mains.

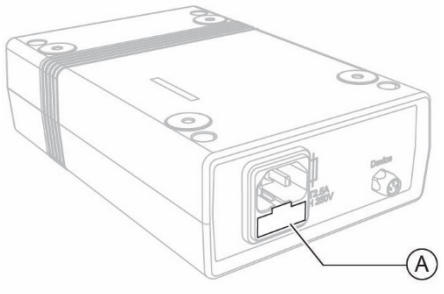

Fig. 33 - Remove the fuse drawer

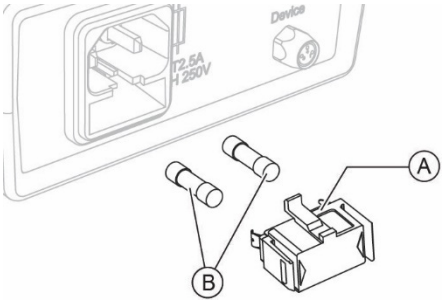

Fig. 34 - Remove the fuses

5.4 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.

5.4.1 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.

5.4.2 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.

5.4.3 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 for protection 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 57.**

5.4.4 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 57.**

5.4.5 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.

5.5 DEVICE EXCURSION CHECK

Check that the base sliding rod is well cleaned. Move the device base all the way to the right and all the way to the left, back and forth. Check that the device performs all movements completely.

5.6 DEVICE CALIBRATION TEST

Check the calibration every 30 days to obtain accurate measurements. Check the calibration as indicated in paragraph **“How to test the calibration” on page 45**.

5.7 DEVICE CALIBRATION

Perform the device calibration periodically in order to ensure accurate measurements. Follow the calibration instructions given in paragraph **“How to calibrate the device” on page 43.**

5.8 LIST OF SPARE PARTS AND ACCESSORIES

Code	Description
30010071D3F	Power supply cable
101013-20	Isolation transformer 230V/230V. 800 VA (maximum load) power supply cable
4014020	Chin cup paper pack (50 pieces)
4013090	Dust cover
100710803	Multicoloured table top
100710-00	Electric support with one column for table top
33071095	Power supply cable for electric support (95 cm)
100278900	Power supply unit PSP2405 24 VDC 4A
300409315	Power supply cable 1.5 m
300409350	Power supply cable 5 m
103111200	Calibration set for corneal maps (Calibration tool)
100270700	Chin rest with adjustable chin cup
3020150	USB 3.0 cable 5 m

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

5.9 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	Power cable not connected to the power supply unit.	Connect the power supply cable of the device to the power supply unit. 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.
The PC does not start	Power cable not connected to the power supply unit.	Connect the power supply cable to the power supply unit. Press the button of the power supply unit to turn it ON. Replace the PC.	Ensure that the electric system of the room is working correctly.
The operating system of the PC does not start	Hard Disk failure. Corrupted operating system.	Replace the Hard Disk. Reinstall the operating system. Replace the PC	Ensure that the new PC meets to the minimum requirements of the device.

Issue	Cause	Solution	Note
The Phoenix application software does not start	Hard Disk failure. The anti-virus software is preventing the start of the Phoenix application software. Corrupted operating system. The Phoenix application software does not work properly.	Replace the Hard Disk. Check the anti-virus software settings. Reinstall the operating system. Reinstall the Phoenix application software.	Contact Technical Assistance. The installation of the Phoenix application software requires administrator privileges.
The Phoenix application software does not work properly	The connection cable between the device and PC does not work properly. The anti-virus software interferes with the drivers of the Phoenix application software. The Phoenix application software is installed as local user.	Unplug and then re-plug the connection cable between the device and the PC. Replace the connection cable between the device and the PC. Uninstall the anti-virus software. Reinstall the Phoenix application software with administrator privileges.	The installation of the Phoenix application software requires administrator privileges.

Issue	Cause	Solution	Note
The PC mouse does not work	Connection cable with the PC disconnected. The power switch of the mouse is OFF. The mouse batteries are exhausted (only for wireless mouse).	Check that the mouse connection cable is properly inserted into the USB port. Turn on the mouse by switching the power switch to ON. Replace the mouse batteries (only for wireless mouse).	Check whether there are any device conflicts in the PC control panel.
The PC keyboard does not work	Connection cable with the PC disconnected. The power switch of the keyboard is switched to OFF. The keyboard batteries are exhausted (only for wireless keyboard).	Check that the keyboard connection cable is properly inserted into the USB port. Turn on the keyboard by switching the power switch to ON. Replace the keyboard batteries (only for wireless keyboard).	Check whether there are any device conflicts in the PC control panel.

Issue	Cause	Solution	Note
The images can't be saved in the database	The database is not connected to the Phoenix application software. No network connection. The USB cable is faulty.	Check that the correct path to the "phoenix.mdb" file is specified on the database setup screen. Refresh the connection to the database file. Check that the network connection is working. Replace the USB cable.	Regularly check the connection to the data network.
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.	
Poor image quality from the Placido disk	The tear film is not well distributed on the cornea surface (dry eye).	Ask the patient to close and open their eyes.	

Issue	Cause	Solution	Note
Unfocused image from the Placido disk	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.
Failed recognition of the left/right part of the eye by the device	The black sticker has not been affixed to the device base. The position detector does not work.	Affix the black sticker to the device base.	Some colours and materials of the table top do not reflect the infrared light. Move a white paper below the device base to check the operation of the position detector.
Device movement difficulties (forward, back, left, right)	The joystick's plastic protection was not removed from the base during installation. The device locking knob is tight. The sliding rod is dirty.	Remove the joystick's plastic protection from the base. Loosen the device locking knob. Clean the sliding rod.	Before beginning the examination, check that the device locking knob is loosened.

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