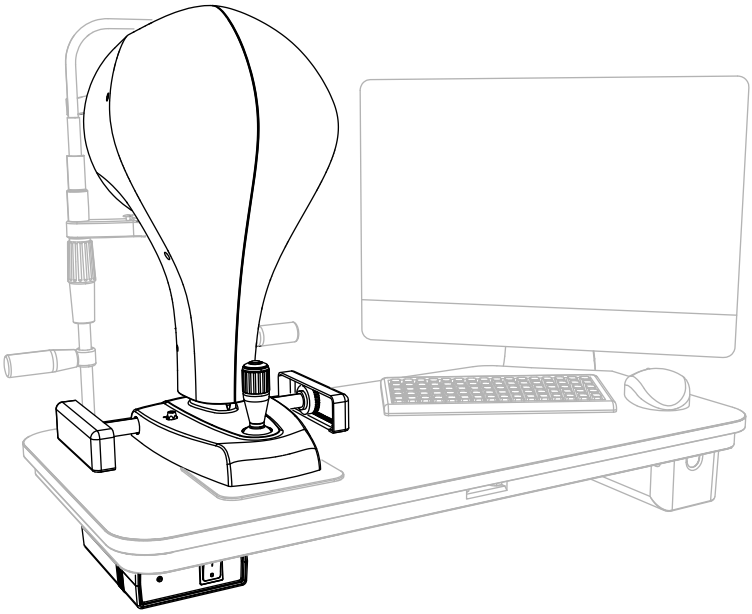
CSO® COSTRUZIONE STRUMENTI OFTALMICI



Corneal Topograph/Tomograph

sirius +

INSTRUCTIONS FOR USE

CSO®
COSTRUZIONE STRUMENTI OFTALMICI

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IFU327EN00 - 01/2021

CE 0051

EN

1 INTRODUCTION

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

1.1 SYMBOLS

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

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

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

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part
	Class II device

1.2 GENERAL WARNINGS

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

THE ORIGINAL TEXT IS IN ITALIAN.

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

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

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

Verify the presence of damage signs on the device caused by the transport/storage, before using the device.

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

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

1.3 NORMATIVE REFERENCES

1.3.1 COMMUNITY DIRECTIVES

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

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1: 2005 + A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EC 60601-1-2:2014 Edition 4 - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- UNI EN ISO 15004-1:2009 Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic devices
- UNI EN ISO 15004-2:2007 Ophthalmic Instruments. Fundamental requirements and test methods - Part 2: Light hazard protection.
- UNI CEI EN ISO 14971:2012 Medical devices. Application of risk management to medical devices.
- UNI EN ISO 19980:2012 - Ophthalmic instruments - Corneal topographs

1.3.3 QUALITY MANAGEMENT SYSTEMS STANDARDS

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

1.4 WARRANTY

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

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

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

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

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

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

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

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

1.5 MANUFACTURER IDENTIFICATION

CSO S.r.l.
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
Electric shock danger. Do not let water fall on the device. Do not immerse the device in water or other liquids.

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

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

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

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

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

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

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

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

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

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

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

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

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

It is forbidden to use the device outdoors.

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

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE MEDICAL DEVICES LIST

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

2.2.2 DEVICE DATA PLATE

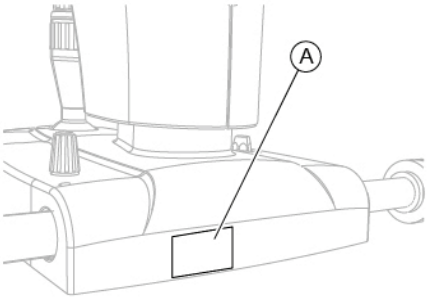

Fig 1 - Data plate position

Pos	Description
A	Device data plate

Fig 2 - Device data plate

2.2.3 POWER SUPPLY UNIT DATA PLATE

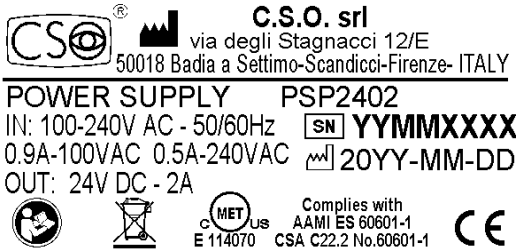

Fig 3 - Power supply unit PSP2402 data plate

2.3 INTENDED USE

Sirius+ is a medical device used for diagnosis in ophthalmology. The device combines optical reflection topography with Placido's disk to the Sheimpflug tomography of the anterior segment.

The device has been designed for the capture and the elaboration of 25 images of the cornea section and of the anterior chamber.

The device provides information on pachymetry, elevation, curvature and dioptric power of both corneal surfaces over a diameter of 12 mm and biometric measures of the anterior chamber.

Thanks to two video cameras, you can film "live" the cornea and the anterior chamber of the eye and visualize them on the computer screen.

In addition to the clinical diagnostic, the most common fields of application are the refractive and cataract surgery.

An accurate measurement of the pupil diameter in scotopic, mesopic and photopic conditions in a dynamic way and their integration with the corneal map allow the photo-ablative surgery planning and the follow-up.

On the basis of the pachymetry map and corneal elevation data, the device allows the intrastromal rings system planning, for the correction of refractive defects and some forms of keratoconus.

Corneal topography

The device provides information on pachymetry, elevation, curvature and refractive power of both corneal surfaces over a diameter of 12 mm.

Pupillography

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

- follow the pupillometry measurement in scotopic light condition in order to evaluate the maximal pupil extension and the optic zone dimension that has to be set for a treatment.
- Perform the pupillometry measurement in scotopic light conditions (0.04 lux).
- Perform the pupillometry measurement in mesopic light condition (4 lux).
- Perform the pupillometry measurement in photopic light condition (50 lux).
- Perform the dynamic pupillometry measurement, starting form 400 lux and turning off the luminous source so that the pupil dilates to its maximal extension.
- Evaluate the pupillary decentralization with respect to the corneal vertex for each of the conditions described above and the pupillary centre deviation during the dilatation.

Meibography

The device allows to analyse the Meibomian glands in a non-invasive method. The meibography is performed through the infrared illumination which enhance the contrast, magnifying the anatomic structure of the glands without causing any discomfort to the patient.

An additional negative lens is provided with the device. Magnetically apply the lens to the device in order to increase the image shooting range.

Analysis of the tear film

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

Videokeratoscopy

Sirius+ has a white light source which aids with the capturing of colour images or videos and a cobalt blue light source for the analysis of corneal surface, fluorescein staining and rigid contact lenses fitting. The accessory yellow filter, which is attached to the device magnetically, enhances the visualization of the image when stained with fluorescein.
The accessory negative lens supplied with the device increases the magnification of the visual field allowing for the analysis of tear meniscus height and conjunctival or limbar hyperemia.
The accessory diffuser filter supplied with the device, which is attached to the Placido disk magnetically, allows for the analysis of the lipid layer interference pattern.

Corneal aberrometry

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

IOL calculation module

It is available an IOL calculation module based on Ray-Tracing techniques which, regardless of the clinical status of the cornea, provides the values of the spherical and toric power of the intraocular lens. This allows the planning of the surgery for refractive defects by means of intraocular lens implants.

Glaucoma screening

The device allows the glaucoma screening and gives the measurement of iridocorneal angles and corneal pachymetry. These values, and the most common IOP correction formulas are useful to diagnose some diseases which can be due to the conformation of the anterior chamber.

Keratoconus screening

An efficient keratoconus screening system, clinically validated, provides suggestions on the ectasia risk underlining the cases which have a greater possibility of complications.

Module for contact lenses application.

The module for the application of contact lenses application allows to perform the simulation of rigid contact lenses thanks to a wide database of models and international manufacturers.

Dry Eye Report

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

- Ocular Surface Disease Index (OSDI)
- Analysis of the redness of the eye
- Analysis of Meibomian glands
- Tear meniscus analysis
- NiBUT.

More features of the device with the application software

The device, with the application software allows:

- Guided manual capture
- Management of the patients' data and possibility to personalize researches and statistics
- Advanced editing system of the rings which allows to modify the position of the edges in order to provide a proper reconstruction even on distorted surfaces.

- Availability of the following maps: sagittal curvature map, tangential curvature map, elevation, refractive power, Gaussian curvature map, corneal thickness.
- Screens and summaries which allow to personalize the device depending on the user:
    - Four maps summary
    - Single map screen
    - Keratoconus summary
    - Six maps summary
    - Advanced altimetry and Zernike summary
    - Corneal wavefront analysis with setting of the pupil, it includes the maps of the most common aberrations
    - Corneal wavefront analysis with summary of visual quality referred to the anterior corneal face with PSF, Spot Diagram, MTF and vision simulation for the analysed wavefront
- Autofit for the research of the best contact lens based on the altimetric elevation measure of the cornea, on a database of more than 50.000 lenses
- Possibility to personalize the contact lens and to simulate its application
- Tools for the follow-up control with differential maps with 2 or 3 elements
- Tools for the follow-up control with comparison between 4 different maps
- A wide series of concise descriptors of the features of the cornea, such as:
    - Sim-K to simulate the measurement of an ophthalmoscope with fixed targets (for the anterior surface)
    - Principal corneal meridians in the zones of 3 mm, 5 mm and 7 mm
    - flatter and steeper hemimeridians in the zones of 3 mm, 5 mm and 7 mm
    - Peripheral degrees
    - Pupil decentralization, pupil diameter, and corneal diameter size

- Keratorefractive indices calculated in the pupil area for an evaluation of the patient's visual quality
- Keratoconus screening index for diagnosis and follow-up

- Dry Eye Report

For system requirements read paragraph "**Personal Computer" at page 29**.

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

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

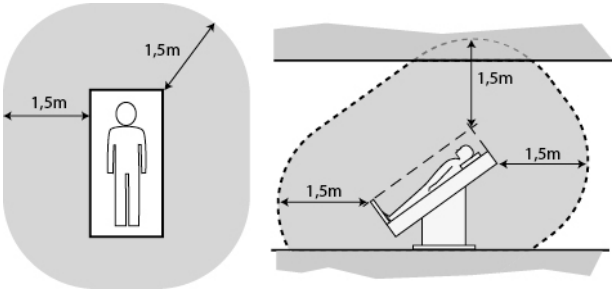

Fig 4 - Patient area

2.4 MEDICAL DEVICES CLASSIFICATION

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

2.5 MEDICAL ELECTRICAL DEVICES CLASSIFICATION

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

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

2.6 ENVIRONMENTAL CONDITIONS

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

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

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

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

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

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

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

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

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

2.8 MANUFACTURER DECLARATIONS

2.8.1 ELECTROMAGNETIC EMISSIONS

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

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

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

Immunity test	IEC 60601-1-2 test level	Conformity level	Electromagnetic environment
RF conduced IEC 61000-4-6 **RF conduced IEC 61000-4-3**	3 Vrms from 150kHz to 80 MHz 3 V/m from 80 MHz to 2.5 GHz	3 Vrms 3 V/m	(1)

(1) Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
d=1,167*sqrt (P)
d=1,167*sqrt (P) 80 MHz to 800 MHz
d=2,333*sqrt (P) 800 MHz to 2.5 GHz
P: is the maximum output power rating of the transmitter in watts (W) according to the transmitter Manufacturer.
d: is the recommended distance in metres (m) at which the portable radio frequency (RF) appliances can be used.
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

(Un) is the AC mains voltage prior to application of the test level.
At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

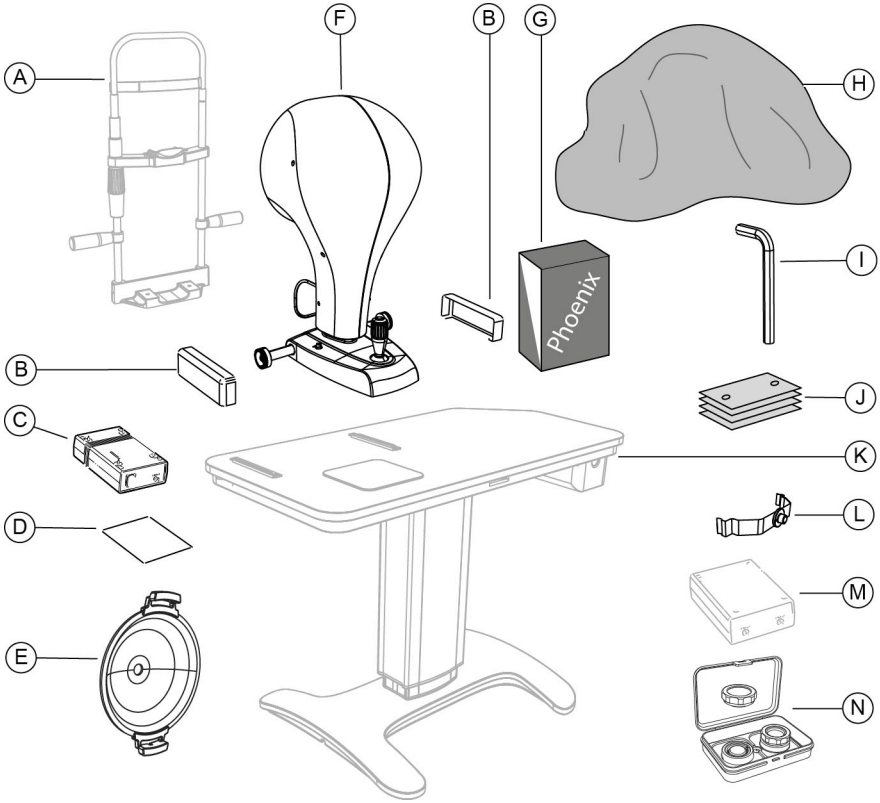

Fig 5 - Supply description

Optional: accessory not provided with the basic supply.

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

Pos	Denomination		Description
A	Chin rest with adjustable chin cup	Optional	Adjustable height. Adjustable distance between chin and forehead. Adjustable chin cup
B	Wheel cover carter		Protection against accidental hand crushing.
C	Power supply unit		A cable is provided with the power supply unit.
D	Sticker pad		Sticker for right/left identification.
E	Diffuser filter		To be applied magnetically to the device for the analysis of the lipid layer interference pattern.
F	Device sirius+		Composed by a camera unit equipped with one or several micro video cameras for capturing the images. USB cable compatible with the device for the connection between power supply unit and computer.
G	Application software		Application software for image capture and device management.
H	Protective cover		Place on the device when it is not in use to protect it from dust.
I	Hex wrench with screws		
J	Package of chin cup papers		Papers to be placed on the chin cup of the chin rest.
K	Ophthalmic table	Optional	Adjustable electric support surface with one or two columns. Drawer and auxiliary sockets with fairlead.
L	Calibration tool		8 mm radius calibration sphere.
M	Isolation transformer	Optional	230V/230V for the use of the non-electromedical appliances in the patient area.
N	Kit of additional lenses		Yellow filter for Fluorescein exam + negative lens for Meibography.

3.1.1 DEVICE SIRIUS+

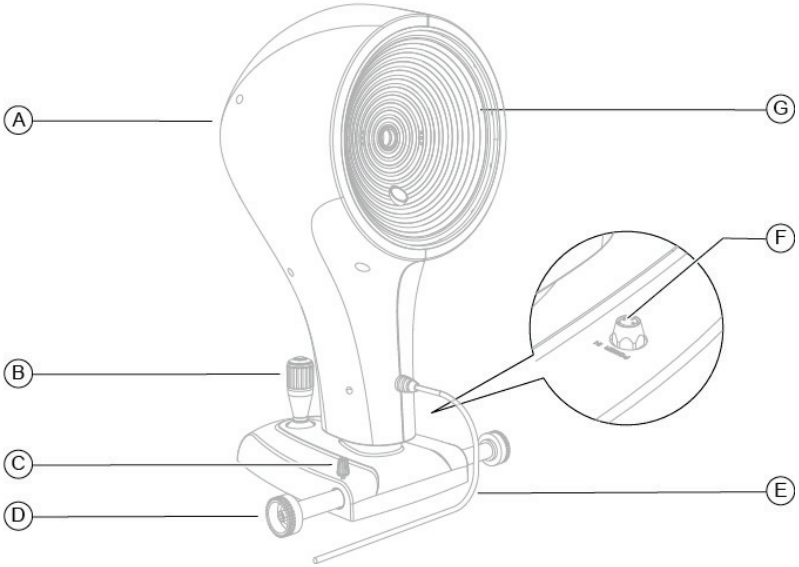

Fig 6 - Device sirius+

Pos	Description
A	Device sirius+
B	Joystick
C	Device blocking knob
D	Cogged wheels
E	Connection cable between device and power supply unit
F	Connection cable between device and computer
G	Shooting channel

3.1.2 POWER SUPPLY UNIT

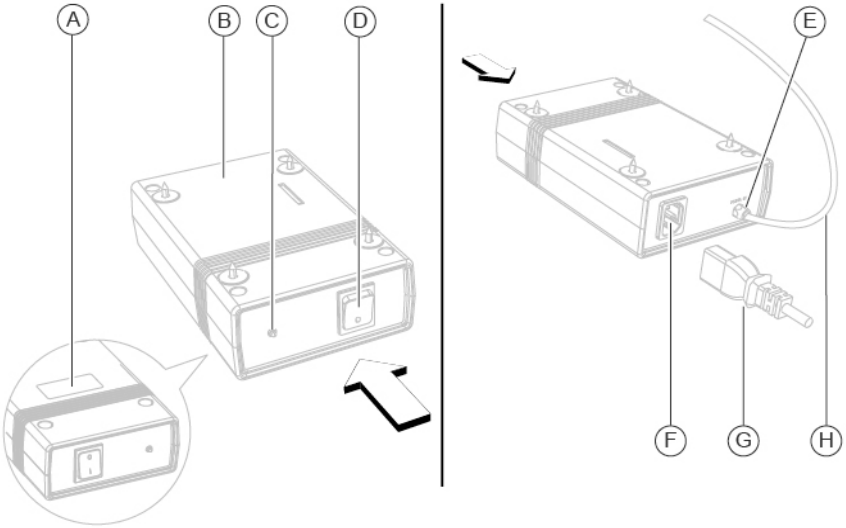

Fig 7 - Power supply unit

Pos	Description
A	Data plate
B	Power supply unit
C	Power supply status control light
D	ON/OFF switch
E	Power supply out connector
F	Power supply mains connector
G	Power supply cable
H	Device power cable

3.1.3 CHIN REST

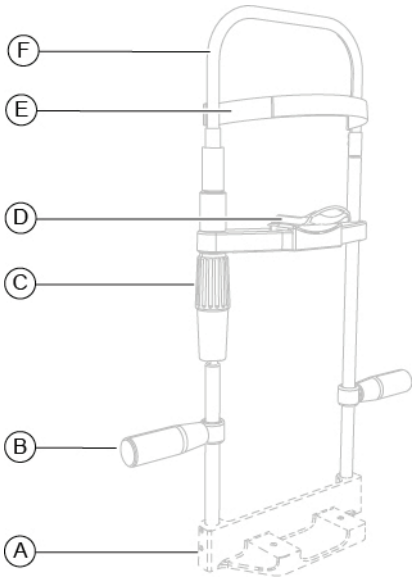

Fig 8 - Chin rest

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

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

3.1.4 OPHTHALMIC TABLE

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

Fig 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 and the application software Phoenix.
Minimum system requirements

- PC: 4 GB RAM - Video Card 1 GB RAM (not shared) resolution 1280 x 960 pixels or higher
- Operating system: Windows 7 (32/64 bit), Windows 8 (64 bit) and Windows 10 (64 bit).

Read the instructions for use of the application software.

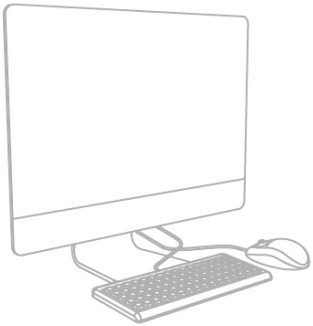

Fig 10 - Personal Computer

The PC must be compliant to the norm IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements.
If the PC is installed in the patient area it is necessary to install an insulating transformer compliant with the directive IEC 60601-1:2005 + A1:2012- "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 analogical or digital interfaces.
The accessories (printer, modem, scanner, etc) must be installed outside the patient area.

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

3.2 TECHNICAL DATA

Technical data	Value
Data transfer	USB 3.0
Mains power	External power supply unit 24 VCC. In: 100-240Vac - 50/60Hz - 0.9-05A Out: 24Vdc - 40W
Net cable	with C14 socket
Dimensions (Height x Length x Depth)	515 x 315 x 255 mm
Weight	7 kg
Chin rest stroke	70 mm ±1
Minimum height of the chin cup from the working plan	24 cm
Base movement (x, y, z)	105 x 110 x 30 mm
Working distance	74 mm

Light sources

Technical data	Value
Placido	LED @400 - 700 nm
Scheimpflug	LED @475 nm UV-free
Pupillography	LED @940 nm
Lighting for Fluorescein exam	LED @470 nm
Auxiliary lighting	LED @400 - 700 nm

Topography

Technical data	Value
Placido's Disk	22 rings
Measured points	From 41932 to 150832 (anterior surface) From 41932 to 145200 (posterior surface)
Topographic covering	12 mm
Dioptric range	from 1D to 100D
Accuracy	Class A according to UNI EN ISO 19980-2012

Accessories

Technical data	Value
Light diffuser filter for auxiliary illumination	Magnetic, light diffuser filter
Yellow barrier filter	Magnetic, 530 nm filter
Additional lens	Magnetic, -6D lens
Calibration tool	Calibration sphere, r 8 mm

4 DEVICE USE

4.1 HOW TO INSTALL THE DEVICE

CAUTION
Danger of device falling down. 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, block the table wheels. Lower the lever of the brake.
3 Place the power supply unit under the table top. Fasten the screws to the four holes.

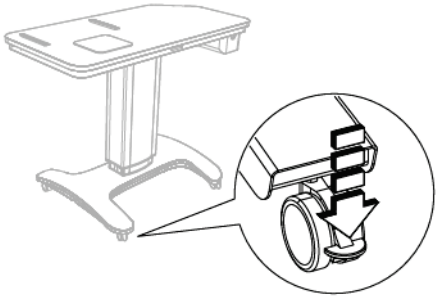

Fig 11 - Table placement

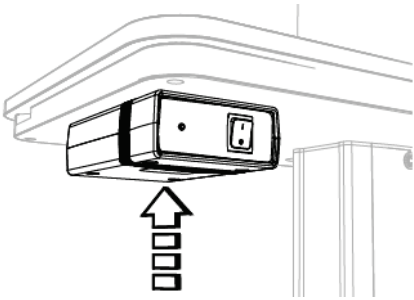

Fig 12 - Power supply unit placement

4 Verify the sticker position respectively to the central axis (A).

5 Remove the protection film. Place the sticker pad between the two cogged wheels and the scrolling plate.

Respect the indicated distances while placing the sticker pad (for right/left identification) on the table top.

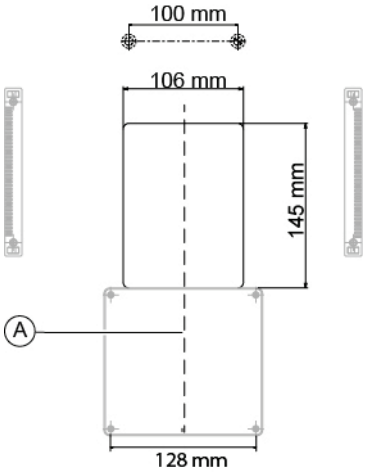

Fig 13 – Distances

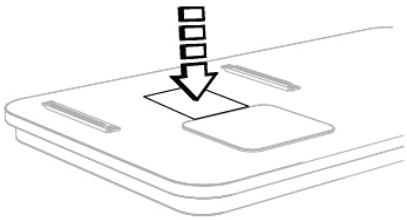

Fig 14 – Placement of the sticker pad

6 Remove the joystick protection (A) placed under the device base.

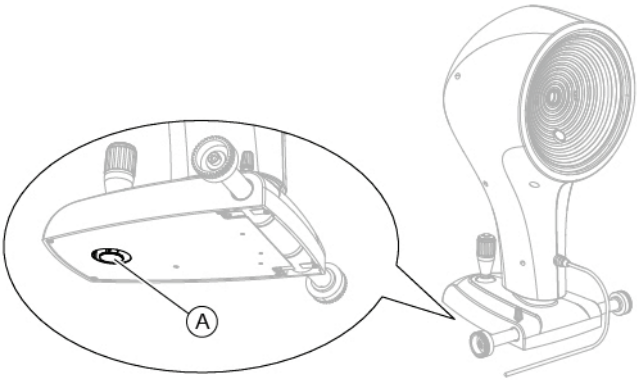

Fig 15 – Protection removal

7 Place the device on the table top and align the cogged wheels on the cogged guides.
8 Fasten the two wheel cover carters to the cogged wheels on the table top.

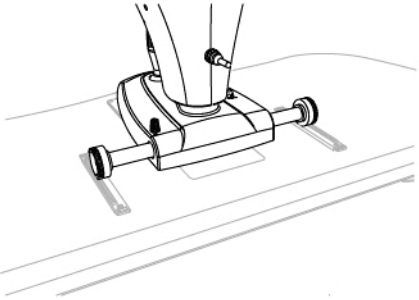

Fig 16 - Placement of the device

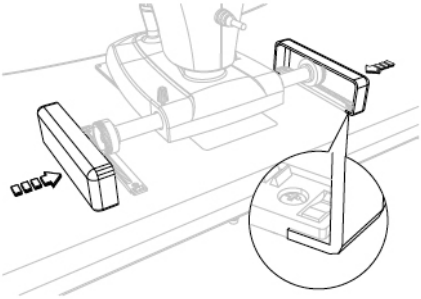

Fig 17 - Placement of wheel cover carters

9 Install the chin rest. Under the table top, there are two screws to block the chin rest support to the table top.

The chin rest shall be installed so that the eye level indicator (1) is placed at a height of 380 mm from the table top.

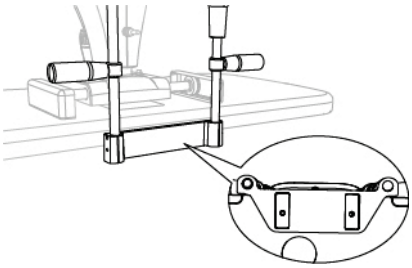

Fig 18 - Placement of the chin rest

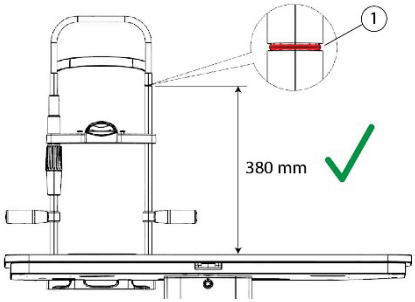

Fig 19 – Correct height of the eye level indicator

10 If the eye level indicator does not reach the required height, adjust the chin rest.

11 Loosen the 4 locking grub screws placed on the chin rest support.

12 Slide the chin rest rods until reaching the required height of 380 mm. Tighten the previously loosened locking grub screws.

The chin rest rods shall be adjusted upwards no more than 18 mm.

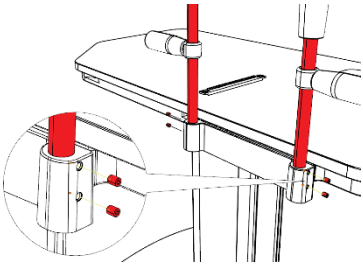

Fig 20 – Loosening the chin rest grub screws

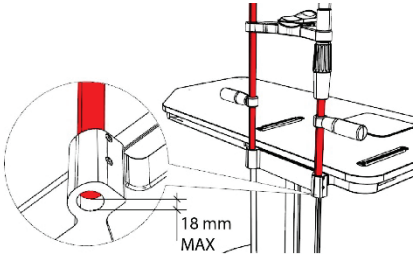

Fig 21 – Maximum height for rods adjustment

13 Carry out the electrical connection between the several components.

4.2 HOW TO CONNECT THE DEVICE

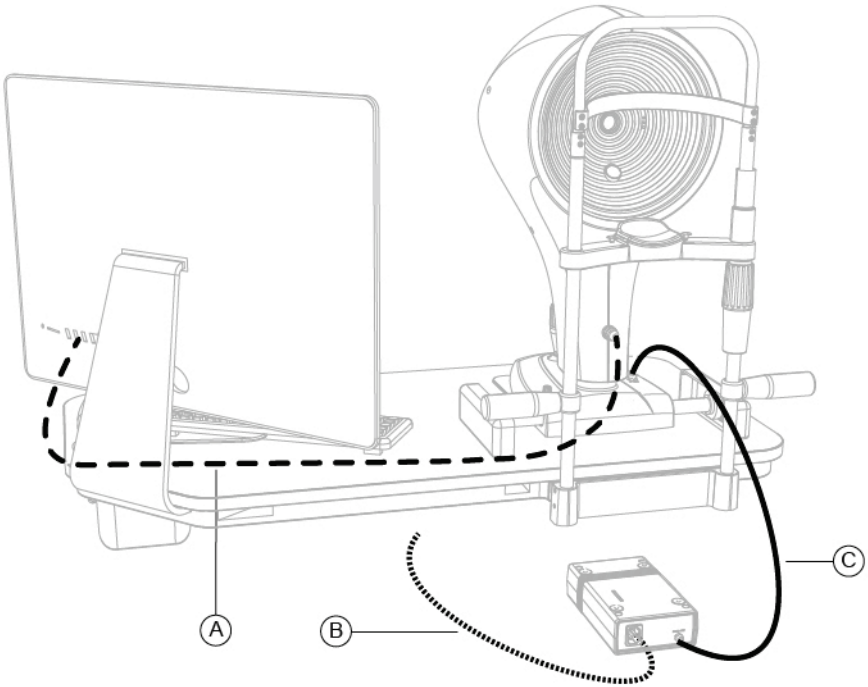

Fig 22 - Device connection

Pos	Denomination
A	3.0 USB connection cable between device and PC
B	Power cable for the connection of the electric table to the power supply
C	Cable for the connection between the power supply unit and the device

To power the table basement, read instructions for use of the table or of the ophthalmic unit.

4.3 HOW TO PLACE ELECTRIC CABLES

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

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

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

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

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

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

4.4 HOW TO TURN ON THE DEVICE

Read the instructions for use before using the application software.

1 Press the activation switch of the power supply unit on ON.
2 Turn on the PC.
3 Launch the Phoenix application software.
4 Wait until the main screen of the application software is shown.
5 If this is the first time you're starting the device, or after a long period of inactivity, calibration shall be performed. Follow the instructions given in paragraph **"How to perform device calibration" on page 39.**

4.4.1 HOW TO PERFORM DEVICE CALIBRATION

Calibration shall be performed when starting the device for the first time or after a long period of inactivity of the latter.
The procedure shall be carried out in a dark room so as to simulate the environmental conditions of a standard capture procedure.

Follow the instructions about calibrating the device sirius+ which are given in the Phoenix application software handbook.

Particular attention shall be paid while performing such procedure. It is important to check device stability before starting with the procedure.
The calibration is essential to obtain precise measurements.

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

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

2 Place the calibration tool on the chin rest.

3 Make sure the sphere is aligned with the shooting channel.

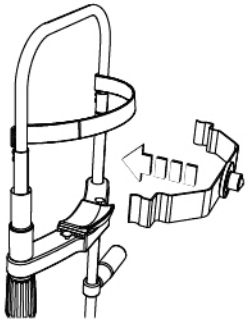

Fig 23 - Placement of the calibration tool on the chin rest

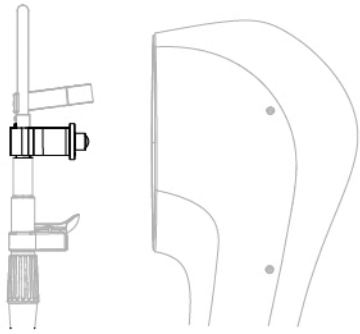

Fig 24 – Alignment of the calibration tool with the device

4 Open the SETTINGS menu of the application software.
5 Click on the calibration button.
6 Perform curvature calibration.
7 A window will appear on the screen, showing the calibration procedure. Carefully follow the given instructions.
8 Align the red cross with the centre of Placido's rings reflected on the sphere (8 mm radius).
9 Place the device at the correct distance from the sphere. The correct distance is such that the white arc, corresponding to the reflection of the blue slit on the sphere surface, touches the red horizontal line displayed on the upper part of the screen.
10 Lock the device by using the device locking knob placed on its base.
11 Carry out image acquisition of the sphere placed on the calibration tool.
12 If the calibration procedure is performed correctly, a confirmation message will be shown on the screen.
13 If not, repeat the whole calibration procedure.

14 After performing calibration, an examination shall be carried out by means of the calibration tool (8 mm sphere radius), in order to check proper calibration of the device.
15 Click on the button NEW PATIENT, enter their personal data, then confirm and choose the CORNEAL TOPOGRAPHY examination.
16 After capturing the image, press the EXIT button and process the captured examination.
17 On the OPTIONS panel, select the curvature's unit of measurement in millimetres.
18 Check the value of the reference sphere corresponds to that on the anterior tangential curvature map.
19 If the elaborated measures are not considered reliable, repeat the whole calibration procedure.

In case the device is not properly calibrated. Repeat the calibration procedure.

4.4.2 HOW TO CREATE A NEW PATIENT

1 Click on NEW PATIENT and enter his personal data. If the patient is already present in the database, you can automatically search the surname in the surname command line.
2 A new examination will be created automatically.
3 Select the examination to be performed.
4 The image capture screen will open. Now it will be possible to capture the image.

4.4.3 HOW TO CREATE A NEW EXAMINATION

1 Click on the button NEW EXAMINATION.
2 Select the examination to be performed.
3 The image capture screen will open. Now it will be possible to capture the image.

4.5 HOW TO ADJUST THE CHIN CUP

1 Inform the patient to take a seat.
2 Move the chin cup left or right. The chosen position will identify the position of the eye to be tested.

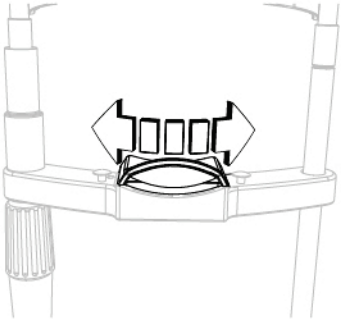

Fig 25 - Adjusting the chin cup

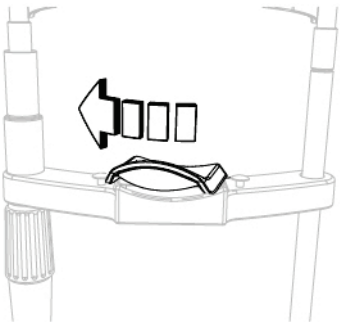

Fig 26 – Chin cup orientation for left eye

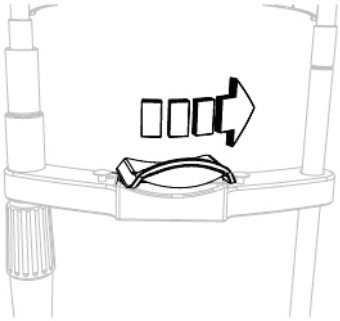

Fig 27 – Chin cup orientation for right eye

3 Ask the patient to put the chin on the chin cup and the forehead against the forehead rest.

4 Check the eye is correctly placed respectively to the shooting channel.

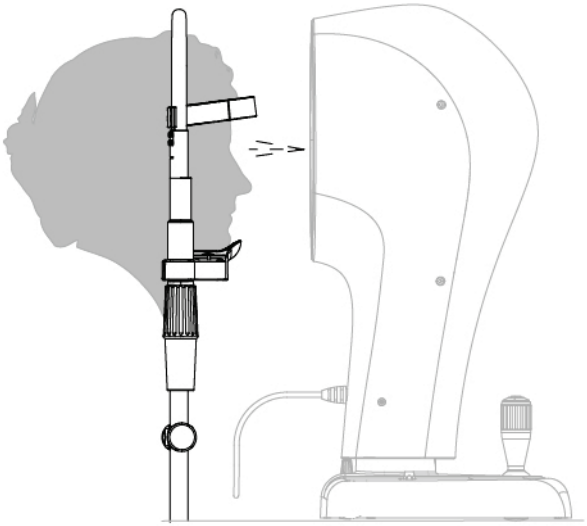

Fig 28 - Patient position on the chin rest

5 Lift or lower the chin cup by rotating the knob.

6 Start capturing images as indicated in the paragraph **“How to capture the image” on page 45.**

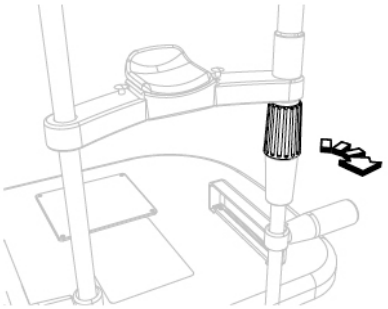

Fig 29 - Knob rotation

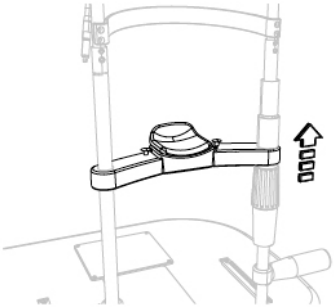

Fig 30 - Chin cup placement

7 At the end of the acquisition procedure, ask the patient to lift their face up.

8 Move the chin cup in the opposite direction to that chosen before.

9 Ask the patient to put the chin on the chin cup and the forehead against the forehead rest.

10 Check the eye to be tested is correctly placed respectively to the shooting channel.

11 Start capturing images as indicated in paragraph **"How to capture the image" on page 45.**

4.6 HOW TO CAPTURE THE IMAGE

1 Turn the joystick and align the device with the patient's eye.
2 Move towards the eye with the tool. Keep centred the reflection of the corneal vertex in both the images.
3 Perform some micro movements with the joystick for the best image alignment.

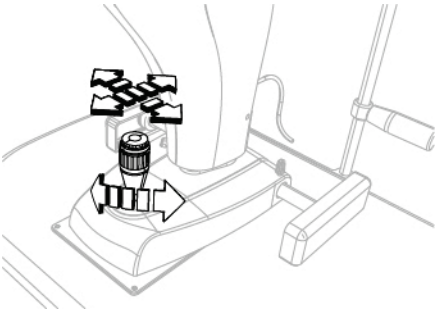

Fig 31 - Placement of the device

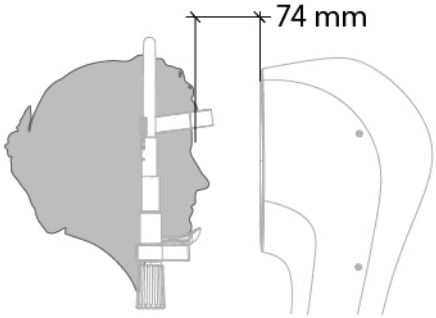

Fig 32 - Distance from the patient

4 Press the joystick button to capture the image. The image will be saved in the gallery.
5 Double click on the captured image to process and visualize on the computer screen.

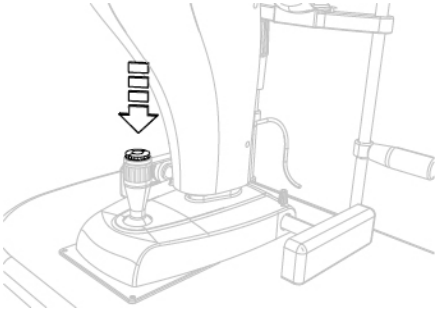

Fig 33 - Image acquisition

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

4.7 HOW TO REPLACE CHIN CUP PAPERS

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

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

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

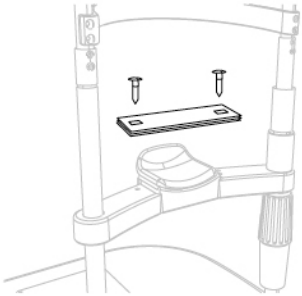

Fig 34 - Changing chin cup papers

To order a spare part, read the code indicated on the spare parts and accessories list on **page 53.**

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 Immobilize the device. Turn the locking knob.
2 Exit the images management systems program. Turn off the computer.
3 Press the activation switch of the power supply unit on OFF.
4 Place the protective cover on the device to prevent dust to fall on the device.

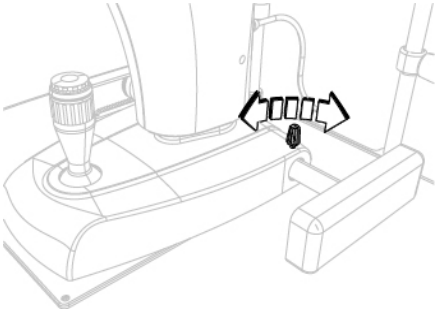

Fig 35 - Blocking the device

5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

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

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

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

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

5.2 CLEANING AND DISINFECTION

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

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

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

Cleaning and disinfection procedures shall be regularly carried out.

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

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

5.2.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

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

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

Follow the products listed below, divided by category:

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

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

5.2.2 CLASSIFICATION OF THE DEVICE FOR HYGIENE AND SAFETY

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

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

5.2.3 DEVICE CLEANING

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

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

The device shall be regularly cleaned.

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

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

For more information about suitable cleansing products, read the **“Recommended products for cleaning and disinfection” paragraph on page 49.**

5.2.4 CLEANING THE APPLIED PARTS

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

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

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

For more information about suitable cleansing products, read the **"Recommended products for cleaning and disinfection" paragraph on page 49.**

5.2.5 CLEANING THE OPTICAL COMPONENTS

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

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

5.3 DEVICE CALIBRATION

Perform device calibration periodically, in order to ensure accurate measurements. Follow the calibration instructions given in paragraph **"How to perform device calibration" on page 39.**

5.4 SPARE PARTS AND ACCESSORIES LIST

Code	Description
30010071D3F	Power supply cable
10101300	Insulating transformer 230V/230V. Power supply cable 800 VA (maximum load)
4014020	Package of chin cup papers (50 pieces)
4013095	Protective cover
10070144	Electric table top with one column (230 V, 50 Hz)
33071095	Power supply cable for electric support (95 cm)
103103900	PSP2402 input 100-240 V AC 50/60 Hz max 0,9 A output 24 VDC 2 A
100130201	Calibration tool
100130700	Chin rest with adjustable chin cup
963107100	Kit with additional lenses (yellow filter for Fluorescein exam + negative lens for Meibography)
103107105	Diffuser filter

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

5.5 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device does not switch ON	Power cable not connected to the power supply unit	Connect the power cable of the device to the power supply unit Press the ON/OFF button on the device.	If the device is powered trough the auxiliary power supply of the table, check the connection of the table to the power line. Check the functioning of the table fuses.
The PC does not start	Power cable not connected to the power supply unit	Connect the power cable to the power supply unit. Press the button of the power supply unit on ON. Replace the PC.	Make sure the power outlet of the room works properly.
PC Operating system does not start	Hard Disk failure. Spoiled operating system	Replace the Hard Disk. Reinstall the operating system. Replace the PC.	Make sure the New PC features are equivalent to those required by the device.
The application software Phoenix does not start	Hard Disk failure. The anti-virus software impedes the starting of the application software Phoenix. Spoiled operating system The application software Phoenix does not work properly.	Replace the Hard Disk. Check the settings of the anti-virus software. Reinstall the operating system. Reinstall the Phoenix application software.	Contact the Technical Service Centre. The installation of the application software Phoenix needs the administrator privileges.

Issue	Cause	Solution	Note
The application software Phoenix does not work properly	The connection cable between device and PC does not work properly. The anti-virus software interferes with the drivers of the application software Phoenix. The application software Phoenix is installed as local user	Unplug and plug in again the connection cable between device and PC. Replace the connection cable between device and PC. Uninstall the anti-virus software. Reinstall the Phoenix application software.	The installation of the application software Phoenix needs the administrator privileges.
The mouse of the PC does not work	Connection cable with the PC disconnected. Mouse switch in position OFF. The mouse batteries are down (only for wireless mouse)	Check that the mouse connection cable properly fit in USB port. Switch the mouse button in position ON. Replace mouse batteries (only for wireless mouse).	From the control panel of the PC, check that there are no devices conflicts.
The keyboard of the PC does not work	Connection cable with the PC disconnected. Keyboard switch in position OFF. The keyboard batteries are down (only for wireless keyboard)	Check that the keyboard connection cable properly fit in USB port. Switch the keyboard button in position ON. Replace keyboard batteries (only for wireless keyboard).	From the control panel of the PC, check that there are no devices conflicts.

Issue	Cause	Solution	Note
The images can't be saved in the database	The database is not connected to the application software Phoenix. Power connection absent. The USB cable does not work	Check the correct path to the "database.db3" file is specified in the configuration window of the database. Restore the connection to the database file. Check the functioning of the net connection. Replace the USB cable.	Regularly verify the connections with the data net.
Failed image capture	The patient moved or closed the eyes during the capture	Ask the patient to keep the eyes open, look the fixation light and not to move the eyes.	
Poor image quality from Placido's disk	The tear film is not well distributed on the cornea surface (dry eye)	Ask the patient to close and open the eyes.	
Failed image focus from Placido's disk	Presence of dust of grease on the optical parts of the device.	Clean the surface of optical parts with a soft cloth.	Make sure the patient does not touch the optical parts.
Device movement difficulties (ahead, back, left, right)	The joystick plastic protection has not been removed from the base during the installation. Device blocking knob is fastened	Remove the joystick plastic protection from the base. Loosen the device blocking knob.	Before starting the exam check that the device blocking knob is loosened.

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