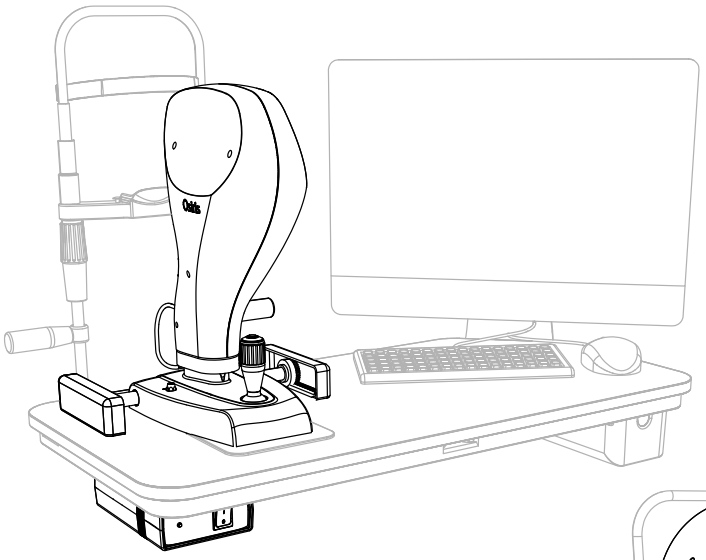
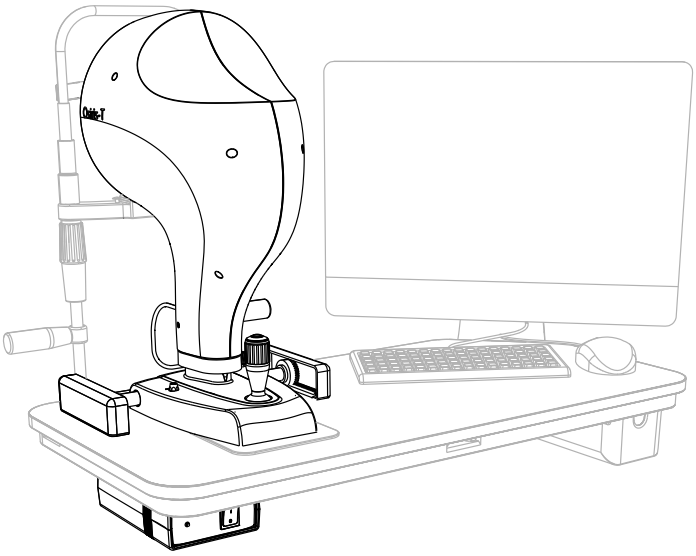
COSTRUZIONE STRUMENTI OFTALMICI





Aberrometer and Topo-aberrometer

SERVICE MANUAL

Osiris and Osiris-T

COSTRUZIONE STRUMENTI OFTALMICI

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CE 0051

EN

TABLE OF CONTENTS

1 INTRODUCTION

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

1.1.1 SYMBOLS

Within the instructions for Technical service, on the package or on the device, there might be the following symbols:

Symbol	Meaning
	Caution
	Danger of electric shock
	Components sensitive to electrostatic discharges (ESD)
	Read instructions
	General obligation
	Note. Useful information for the user
	General prohibition sign
	Manufacturer
	CE Marking (Directive 93/42/EEC). Identification number of the notified body (IMQ).
	Waste disposal in compliance with Directives 2012/19/EU (WEEE) and 2011/65/EU (RoHS II)

1.1.2 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part
	Class II device

1.2 GENERAL WARNINGS

THE INSTRUCTIONS GIVEN IN THIS TECHNICAL SUPPORT MANUAL REFER TO THE DEVICES OSIRIS AND OSIRIS-T ("DEVICE" FROM NOW ON).
THE ORIGINAL TEXT IS IN ENGLISH.

Within the technical support manual, the paragraphs dedicated to one or another device are marked with Osiris or Osiris-T.
When not specified the paragraph is valid for all the devices and models.

Before using the device or if you haven't been using it since a long time, read these instructions carefully. Follow the directions provided in the instructions for use and reported on the device.

Keep this manual close by for future consultation.

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

Verify any potential damage to the device caused by transport/storage prior to using the device.

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

The Manufacturer reserves himself the right to modify the contents of these instructions without notice.

1.3 NORMATIVE REFERENCES

1.3.1 EU DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and additions concerning medical devices
- Directive 2012/19/EU on waste from 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 SYSTEM 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 compliance of the device with EU Directive 93/42/EEC as amended by 2007/47/EC for:

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

- installation and start-up operations which are not carried out in accordance with the indications and the precautions reported in this manual
- misuse contrary to the instructions and precautions set forth in this manual
- use of accessories or spare parts not provided or suggested by the Manufacturer
- repairs and safety controls 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 improper use 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 substitution by the Manufacturer or an authorised Service Centre of components and materials and the corresponding labour. Shipping and transport fees are to be paid by the client.
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
- the wearing out and/or deterioration of parts due to normal use and those 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 client will not be refunded for damage caused by device stoppage.

1.5 HOW TO REPORT MALFUNCTIONS TO THE MANUFACTURER

You shall report any operating malfunctions or faults of the device to the Manufacturer, C.S.O. Costruzione Strumenti Oftalmici SRL, by accessing the following link:
https://service.csoitalia.it/index.php.
Together with the malfunction or fault description, the following information shall also be sent:

- Client
- Device serial number
- Release of the application software currently in use
- Version of the Operating System installed on the PC
- LOG file: C:\ProgramData\P4Data\Logs
- LOG file: C:\ProgramData\P4Data\Diagnostic

1.6 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
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 shall 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.

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

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

CAUTION
Danger of falling device. Do not leave loose cables which may represent an obstacle or danger for the patient or operator.

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

CAUTION
Risk of electric shock. Do not touch the power supply cables with wet hands.

CAUTION
Risk of electric shock. Do not leave the power supply cables in contact with sharp edges or cutting parts. Always collect and fasten the power supply cables.

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

CAUTION
The power grid shall have a residual-current device (IΔn=30mA) and circuit breaker (Vn=230V) to protect the device. Place the device in such a way that the power socket is easily accessible.

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

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 any extension cable not authorised by the device Manufacturer.

It is forbidden to use the device outdoors.

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

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.

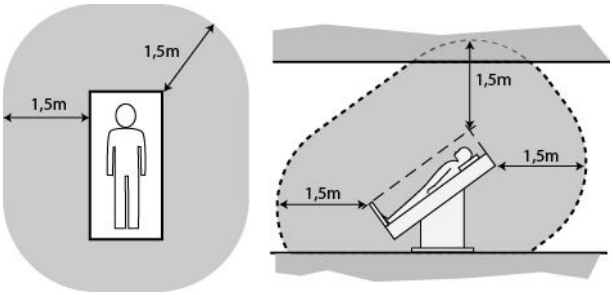


Fig 1 - Patient area

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

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

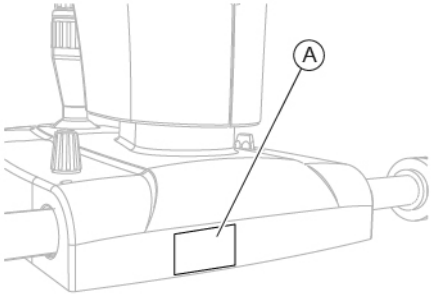


Fig 2 - Plates position

Pos	Description
A	Device data plate

Fig 3 - Device Osiris data plate

Fig 4 - Device Osiris-T data plate

2.2.3 POWER SUPPLY UNIT DATA PLATE

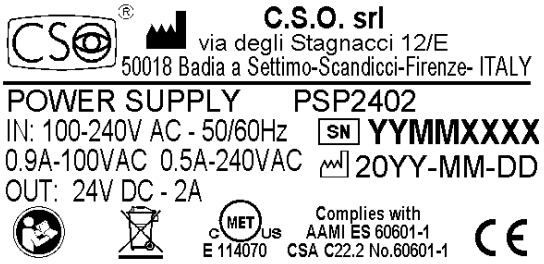


Fig. 5 - Power supply unit PSP2402 data plate

2.3 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification based on annexe IX of Directive 93/42/EEC and subsequent modifications	Class IIa

2.4 ELECTROMEDICAL DEVICE CLASSIFICATION

Classification based on the IEC 60601-1:2005 + A1:2012 technical standard

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 inflammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous functioning

2.5 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 for a maximum period of 15 weeks, if kept in the original package.

2.6 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 shall not be disposed of with urban waste. The device may be delivered to designated waste sorting 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 shall 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 it out, turning to a firm specialised in the disposal of electrical/electronic equipment or to 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 required to collect it.
- the Manufacturer provides for the processing and recycling of the used device, joining a technological waste consortium and paying for the corresponding 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 transgressors are provided for by law.
For specific information about disposal in countries other than Italy, contact your local Dealer.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

Device Osiris

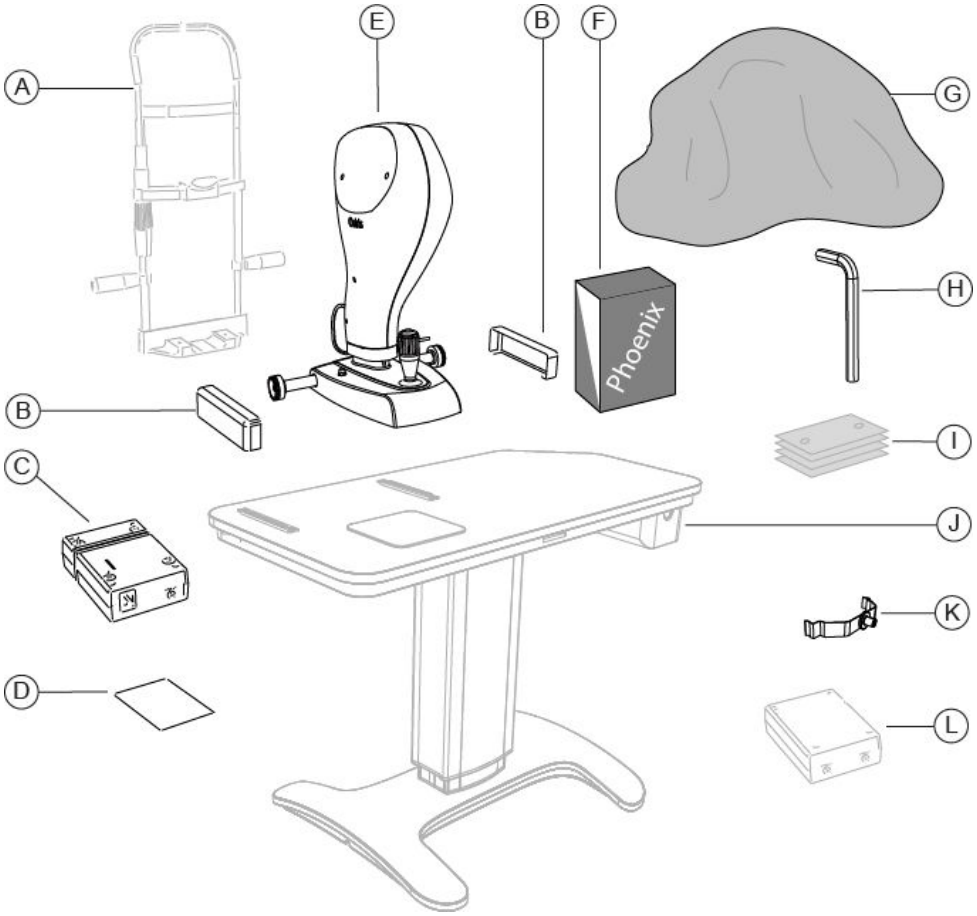


Fig 6 - Device Osiris supply description

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

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

Pos	Name		Description
A	Chin rest with adjustable chin cup	Optional (*)	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 pad for right/left position identification of the device.
E	Device Osiris		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	Application software		Application software for image acquisition and device management.
G	Dust cover	Optional	Place on the device when not in use to protect it from dust.
H	Hexagon wrench with screws	Optional	
I	Package of chin cup papers		
J	Ophthalmic table	Optional	Table top with one or two columns and electronic adjustment of height. Drawer and auxiliary sockets with cable guide.
K	Testing tool for calibration		Tool with reference value to perform calibration testing of the aberrometer section.
L	Isolation transformer	Optional	230V/230V for the use of the non-electromedical devices in the patient area.

Device Osiris-T

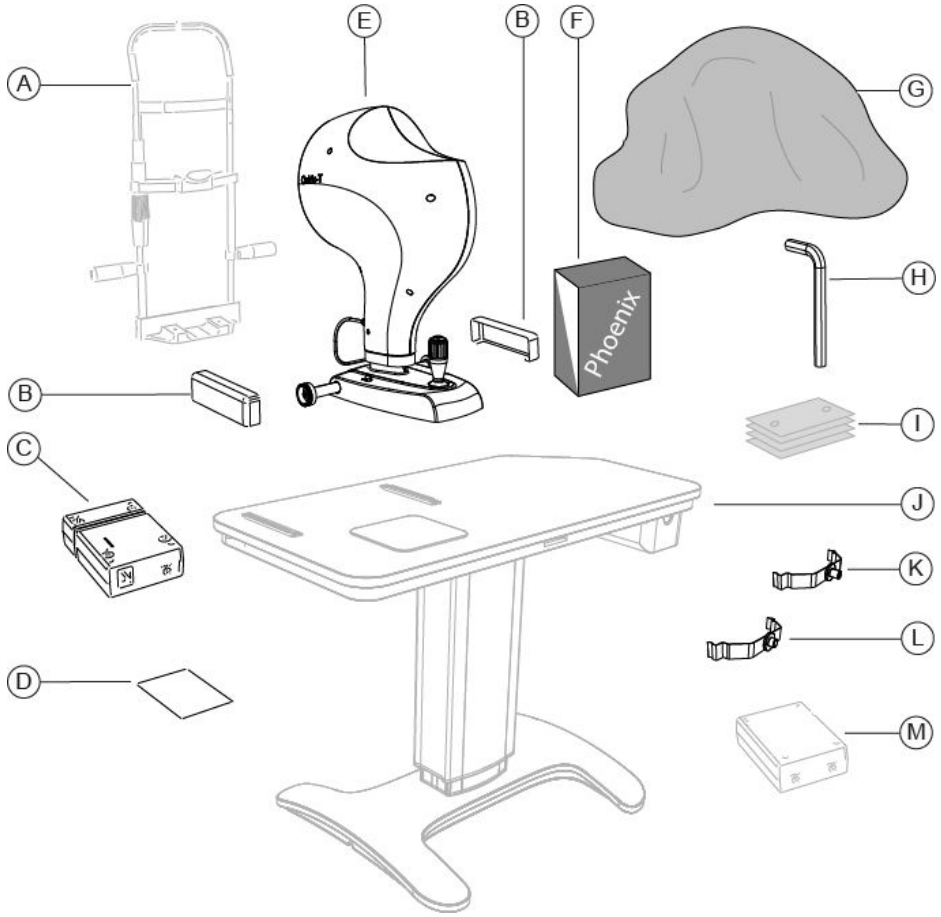


Fig. 7 - Device Osiris-T supply description

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

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

Pos	Name		Description
A	Chin rest with adjustable chin cup	Optional (*)	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		Sticker pad for right/left position identification of the device.
E	Device Osiris-T		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	Application software		Application software for image acquisition and device management.
G	Dust cover	Optional	Place on the device when not in use to protect it from dust.
H	Hexagon wrench with screws	Optional	
I	Package of chin cup papers		Papers to be placed on the chin cup of the chinrest.
J	Ophthalmic table	Optional	Table top with one or two columns and electronic adjustment of height. Drawer and auxiliary sockets with cable guide.
K	Testing tool for calibration		Tool with reference value to perform calibration testing of the aberrometer section.
L	Calibration tool		8 mm radius calibration sphere
M	Isolation transformer	Optional	230V/230V for the use of the non-electromedical devices in the patient area.

3.1.1 DEVICE OSIRIS

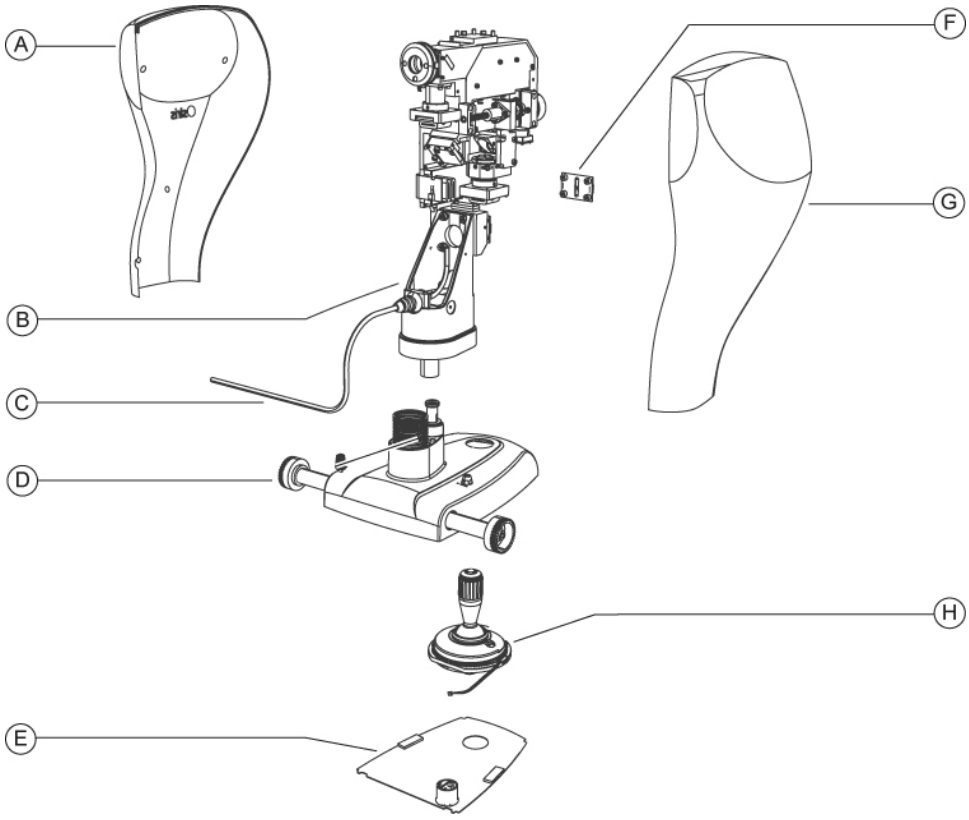


Fig 8 - Device Osiris

Pos	Description
A	Left protective shell
B	Structure assembly
C	USB 3.0 cable 2 m length with wireway
D	Complete base
E	Plate with left/right sensor
F	Opto-coupler board
G	Right protective shell
H	Joystick unit with button

3.1.2 DEVICE OSIRIS-T

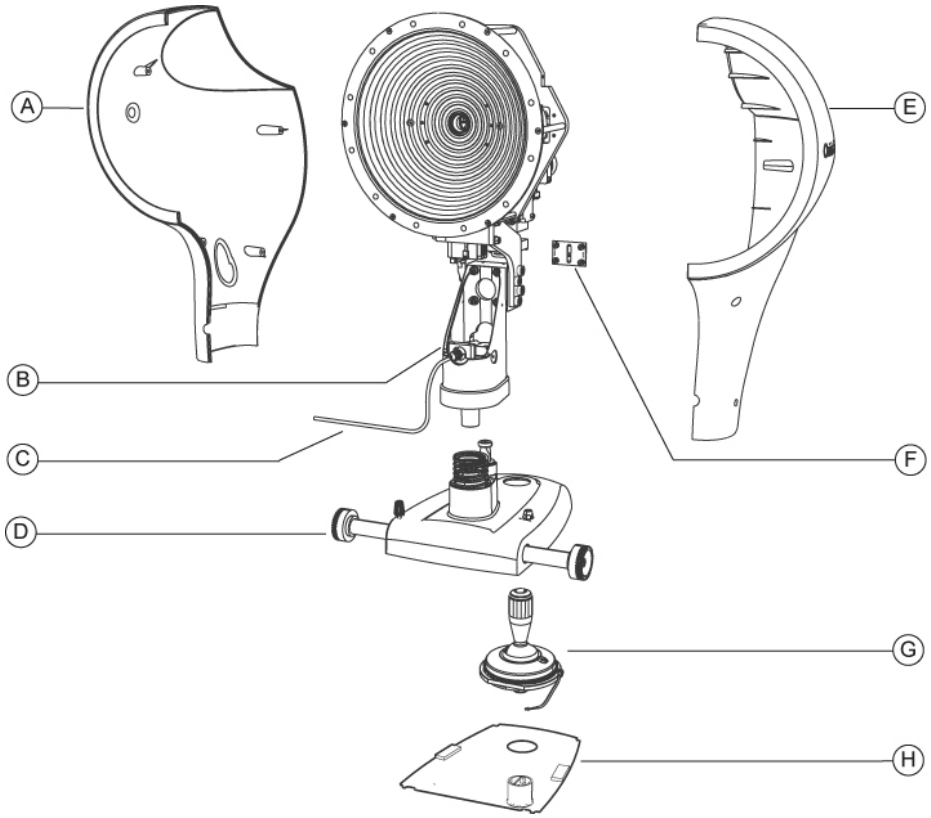


Fig. 9 - Device Osiris-T

Pos	Description
A	Left protective shell
B	Structure assembly
C	USB 3.0 cable 2 m length with wireway
D	Complete base
E	Right protective shell
F	Opto-coupler board
G	Joystick unit with button
H	Plate with left/right sensor

3.1.3 POWER SUPPLY UNIT

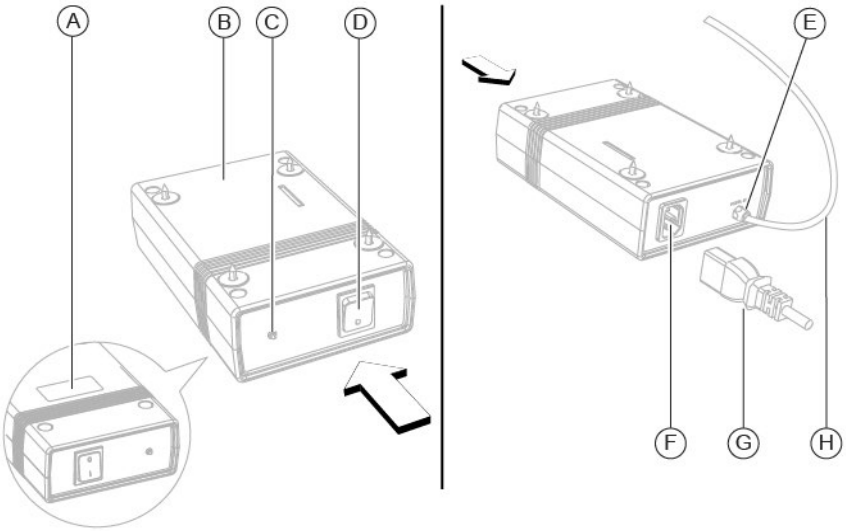


Fig 10 - Power supply unit

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

3.1.4 CHIN REST

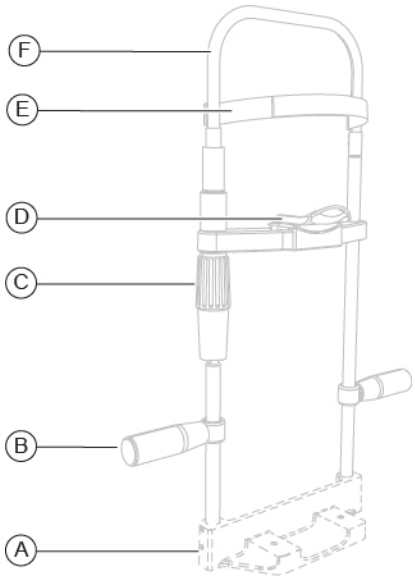


Fig 11 - Chin rest

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

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

3.1.5 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 guides 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 12 - One column table

Refer to the table manual.

3.1.6 PERSONAL COMPUTER

The device shall be used in combination with a PC and the Phoenix application software.

Read document "Minimum PC requirements" which is available for download on the website www.csoitalia.it in the section "Documents - Software download" (log-in including username and password required).
Read the instructions for use of the application software.

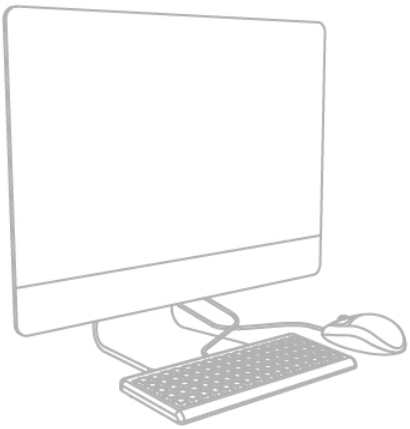


Fig. 13 - Personal Computer

The PC shall comply with standard 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 isolation transformer that complies with standard IEC 60601-1:2005 + A1:2012- "Electromedical 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.
Accessories (printer, modem, scanner, etc.) shall be installed outside the patient area.

The accessories shall comply with standard 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 isolation transformer compliant with the directive IEC 60601-1:2005 + A1:2012 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

3.2 TECHNICAL DATA

3.2.1 DEVICE OSIRIS

Technical data	Value
Data transfer	USB 3.0
Mains power	External power supply unit 24 VCC In: 100-240 VAC - 50/60 Hz - 0.9-0.5 A Out: 24 VDC - 40 W
Network cable	with C14 socket
Dimensions (Height x Length x Depth)	425 x 315 x 265 mm
Weight	5.8 kg
Chinrest stroke	70 mm ±1
Minimum height of the chin cup from the work surface	24 cm
Base movement (x, y, z)	105 x 110 x 30 mm
Working distance	78 mm

Light sources

Technical data	Value
Aberrometer	LED@850 nm
Auxiliary	LED @780 nm
Fixation	LED @450-650 nm

Aberrometry

Technical data	Value
Points measured at maximum pupil	45000
Spatial resolution	41 µm
Pupillary range	2-9 mm
Dioptric range	Sph from -15 D to +15 D Cyl ±10 D
Repeatability	0.05 D on test eyes

3.2.2 DEVICE OSIRIS-T

Technical data	Value
Data transfer	USB 3.0
Mains power	External power supply unit 24 VCC In: 100-240 VAC - 50/60 Hz - 0.9-0.5 A Out: 24 VDC - 40 W
Network cable	with C14 socket
Dimensions (Height x Length x Depth)	515 x 315 x 255 mm
Weight	7 kg
Chinrest stroke	70 mm ±1
Minimum height of the chin cup from the work surface	24 cm
Base movement (x, y, z)	105 x 110 x 30 mm
Working distance	74 mm

Light sources

Technical data	Value
Aberrometer	LED @850 nm
Pupillography	LED @780 nm
Fixation	LED @450-650 nm
Placido Disk	LED @635 nm

Aberrometry

Technical data	Value
Points measured at maximum pupil	45000
Spatial resolution	41 µm
Pupillary range	2-9 mm
Dioptric range	Sph from -15 D to +15 D Cyl ±10 D
Repeatability	0.05 D on test eyes

Topography

Technical data	Value
Placido Disk	22 rings
Measured points	5632
Topographic covering (on sphere 43 D)	ø 10 mm
Measurement accuracy	Class A complying with standard UNI EN ISO 19980-2012

4 DEVICE USE

4.1 HOW TO INSTALL THE DEVICE

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

1 Place the ophthalmic table in the room. The table shall be lifted by two people.
2 If present, fasten the table wheels. Lower the brake lever.
3 Install the cogged wheels, the scrolling plate and the sticker pad as indicated in paragraph **"How to install the accessories on the table** top**" on page 24.**
4 Place the power supply unit under the table top. Screw the screws into the four holes.

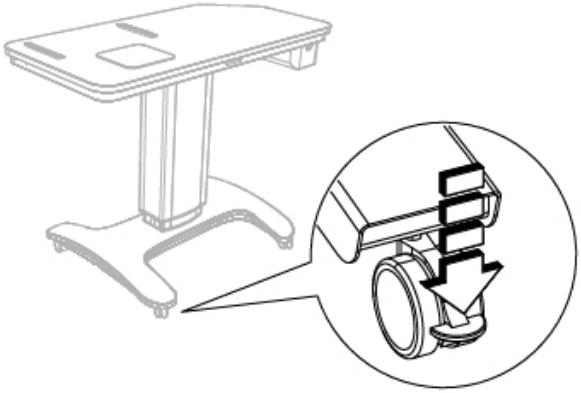


Fig 14 - Table placement

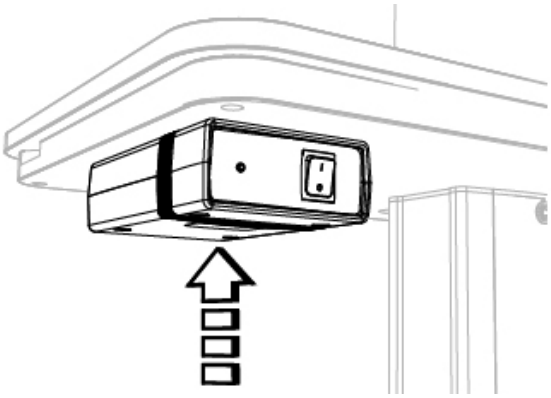


Fig 15 - Placement of the power supply unit

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

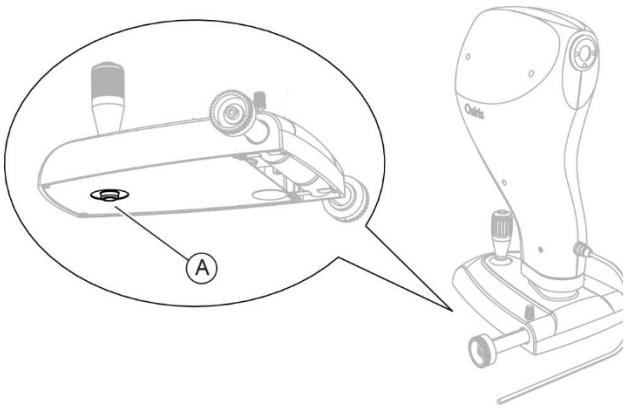


Fig 16 – Removing the protection on Osiris

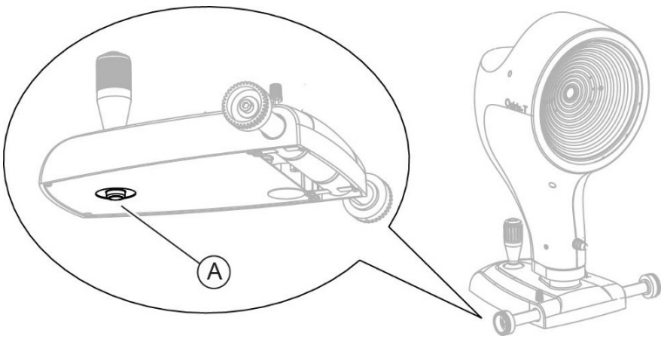


Fig 17 – Removing the protection on Osiris-T

6 Place the device on the table top and align the cogged wheels on the cogged guides.
7 Fasten the two wheel covers to the cogged guides on the table top.

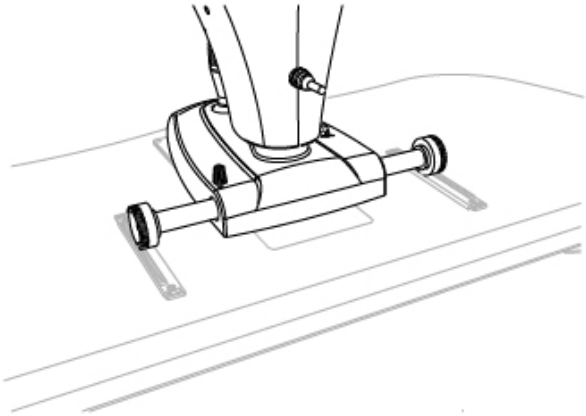


Fig 18 - Placing the device

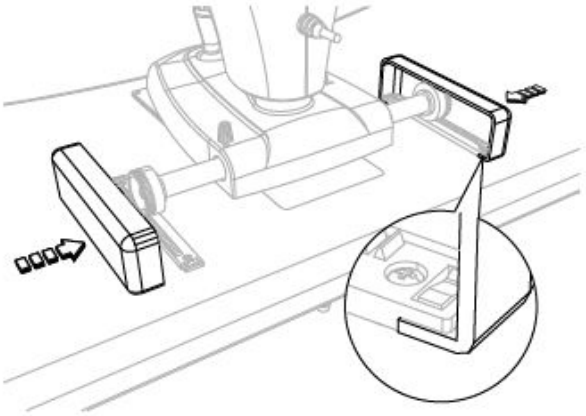


Fig. 19 - Placement of wheel covers

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

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

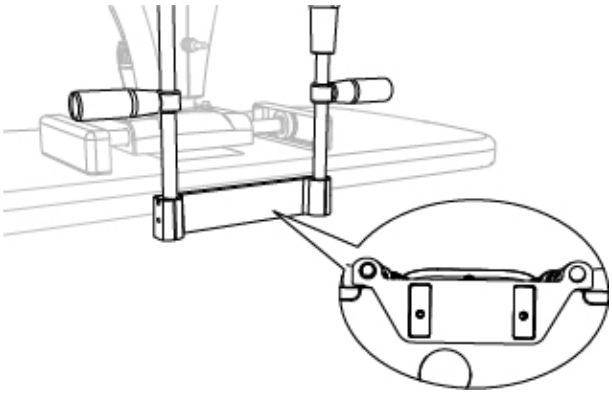


Fig. 20 - Placement of the chinrest

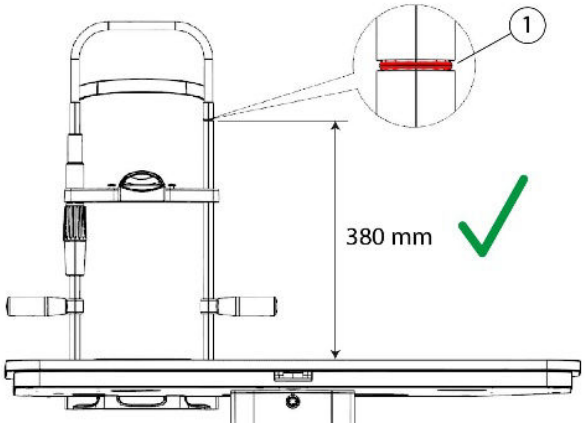


Fig. 21 – Correct height of the eye-level indicator

9 If the eye-level indicator does not reach the required height, adjust the chinrest.
10 Loosen the 4 locking grub screws placed on the chin rest support.
11 Slide the chinrest rods until the required height of 380 mm is reached. Tighten the previously loosened locking grub screws.

The chinrest rods shall be adjusted upwards by no more than 15 mm.

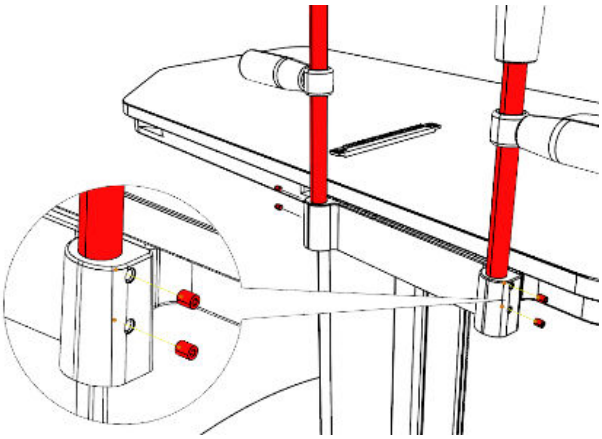


Fig. 22 – Loosening the chinrest grub screws

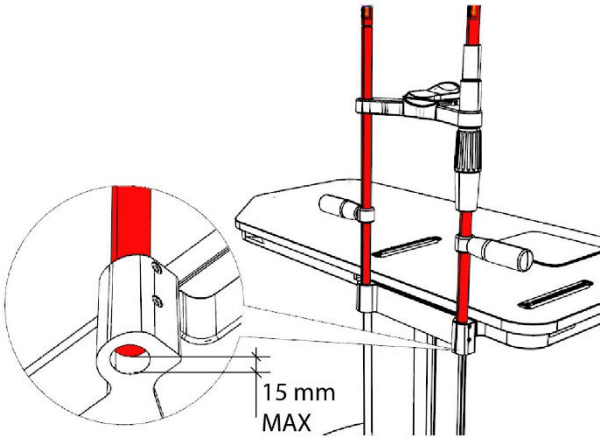


Fig. 23 – Maximum height for rod adjustment

12 Carry out the electrical connections between the different components.

4.2 HOW TO INSTALL THE ACCESSORIES ON THE TABLE TOP

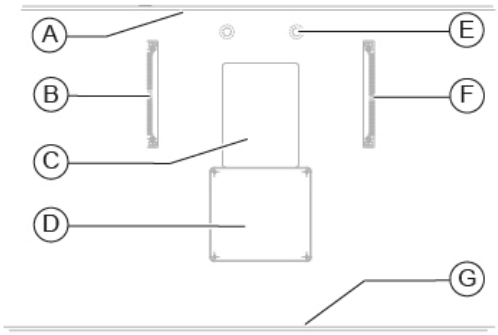


Fig 24 - Table top accessories

Pos	Description
A	Table top front side. Patient side
B	Left cogged guide
C	Sticker pad
D	Scrolling plate
E	Lower inserts for chin rest fixing
F	Right cogged guide
G	Table top rear side. Operator side

1 Install the right and left cogged guides on the table top with tapping screws Ø2.9x13.
2 Install the scrolling plate on the table top with tapping screws Ø2,2x2,9. As an alternative, apply the sticker plate (code 100710831).

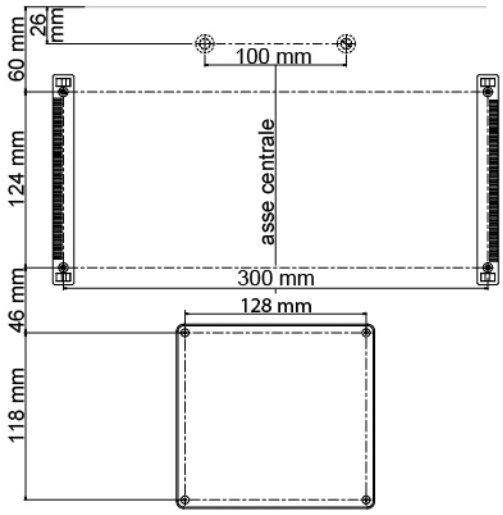


Fig 25 - Table placement

3 Clean the table surface accurately.
4 Verify the sticker pad position respectively to the central axis (A).
5 Remove the protective film. Place the sticker pad between the two cogged wheels and the scrolling plate.

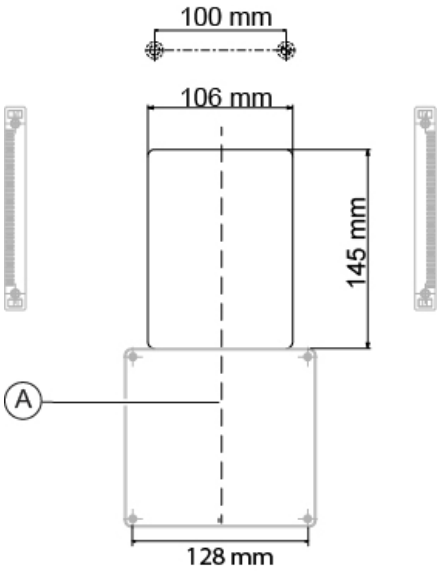


Fig. 26 – Sticker pad dimensions

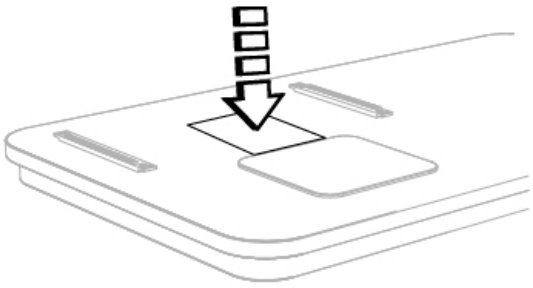


Fig. 27 – Placement of the sticker pad

4.3 HOW TO CONNECT THE DEVICE

Device Osiris

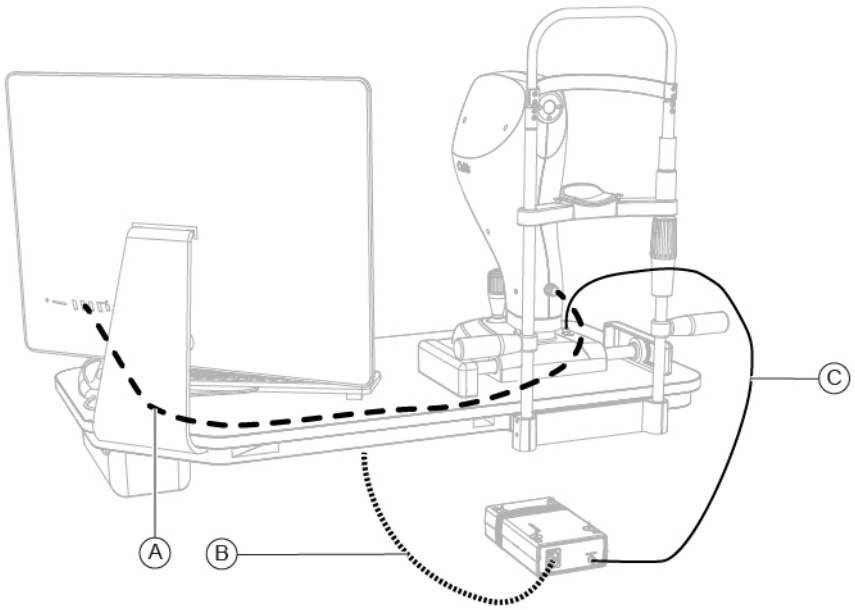


Fig 28 - Connecting the device Osiris

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

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

Device Osiris-T

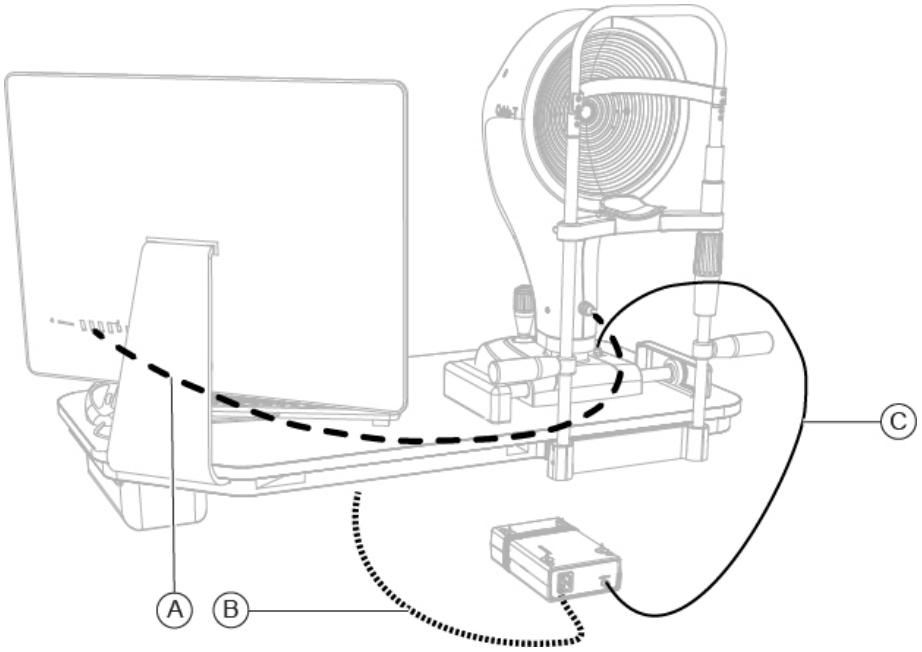


Fig. 29 - Connecting the device Osiris-T

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

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

4.4 HOW TO ARRANGE THE ELECTRIC CABLES

CAUTION
Danger of falling device. Do not leave loose cables which may represent an obstacle or danger for the patient or operator.

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

CAUTION
Risk of electric shock. Do not leave the power supply cables in contact with sharp edges or cutting parts. Always collect and fasten the power supply cables.

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

For the proper placement of electrical cables and 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 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.

4.5 PHOENIX APPLICATION SOFTWARE

4.5.1 INSTALLING THE PHOENIX APPLICATION SOFTWARE

The following procedure refers to installing the Phoenix application software on a Windows 10 operating system.

1 Turn the power switch of the power supply unit to ON.
2 Turn on the PC.
3 Make sure you have the required authorisations (administrator rights) before starting the installation procedure.
4 When active, temporarily disable all antivirus protections.
Start the installation of the Phoenix application software.
5 Start the Phoenix application software executable file (*Phoenix4_Setup.exe*) and wait for the installation procedure to start.
6 Select the language to be used during the installation procedure.

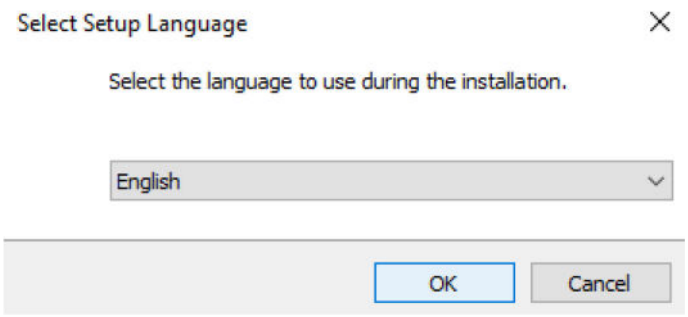


Fig. 30 - Select the language

7 Accept the License Agreement terms.
8 Click on *Next* to continue.
9 Select the file destination path for the software installation. It is recommended not to change the default displayed path.
10 Click on *Next* to continue.

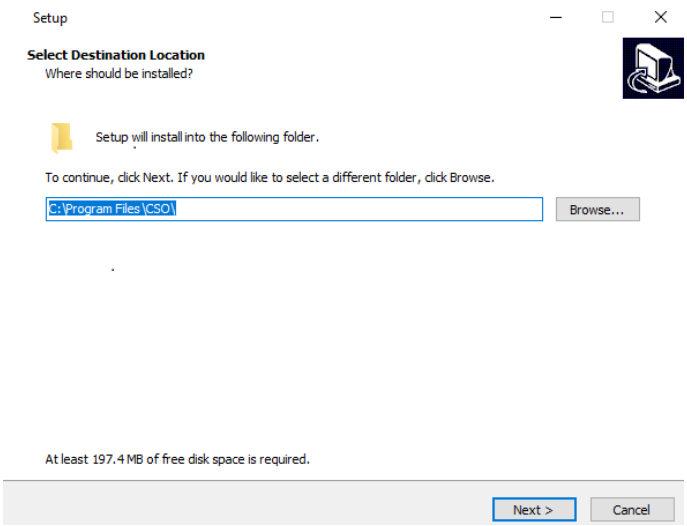


Fig. 31 - Select the destination path

11 Select the destination path of the software shortcuts. It is recommended not to change the default displayed path.

12 Click on *Next* to continue.

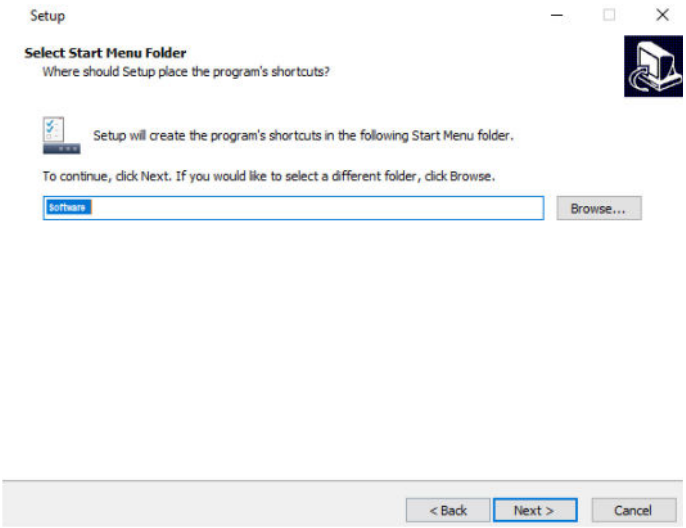


Fig. 32 - Select the destination path

13 Click on *Install* to start the installation procedure.

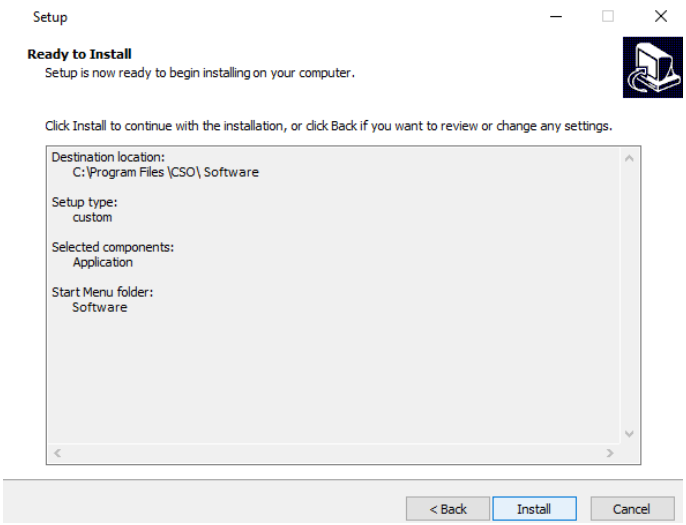


Fig. 33 - Start the installation

14 When the prompt pop-up appears on the screen, if you want to download the demo database, click on *Yes*.
An internet connection is required to download. Otherwise, the installation procedure ends.
The demo database is created in *C:\DBPhoenix*. If another *DBPhoenix* folder is already present in the path, the demo database will not be installed.

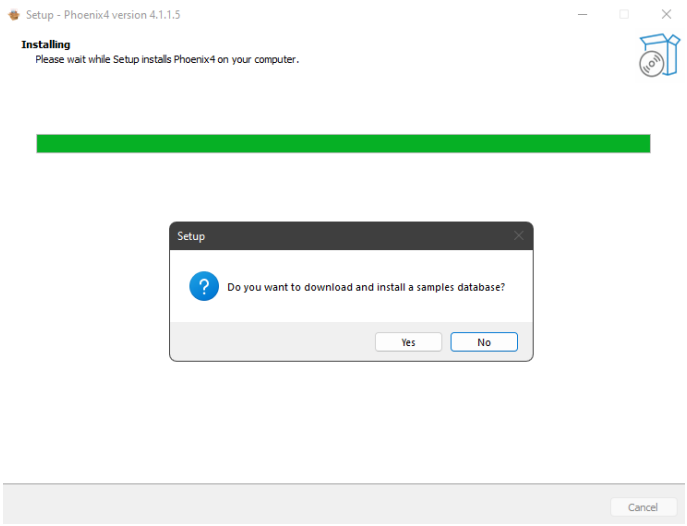


Fig. 34 - Download the demo database

15 Click on *Finish* to end the installation procedure. A shortcut icon appears on the desktop.

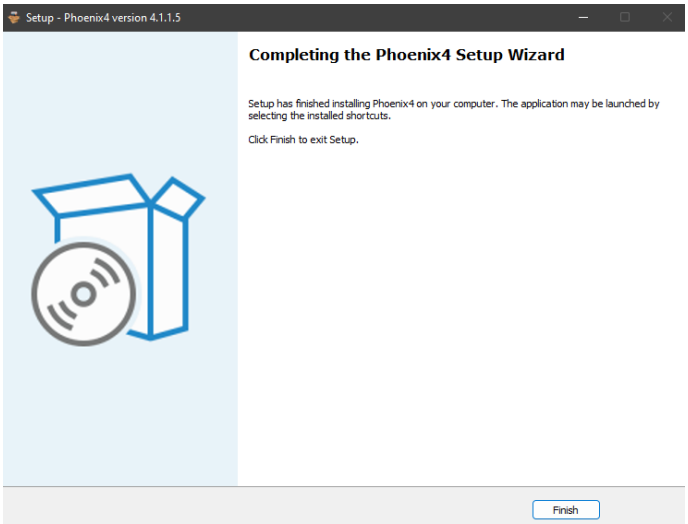


Fig. 35 - Complete the installation

16 Click on the shortcut icon to run the Phoenix application software.

The application software needs administrator privileges to run. If this requirement conflicts with the Company's security policy, contact the CSO Technical Assistance to consider possible solutions.

The first Phoenix application software run involves the update of the pre-requisites.

- If *Microsoft Visual C ++ 2008 Redistributable* or *Microsoft Visual C++ 2010 Redistributable* is not installed on the PC, the Microsoft License Agreement appears on the screen.
  - Check the box to accept the terms of the contract.
  - Click on *Install* and wait for the end of the procedure.

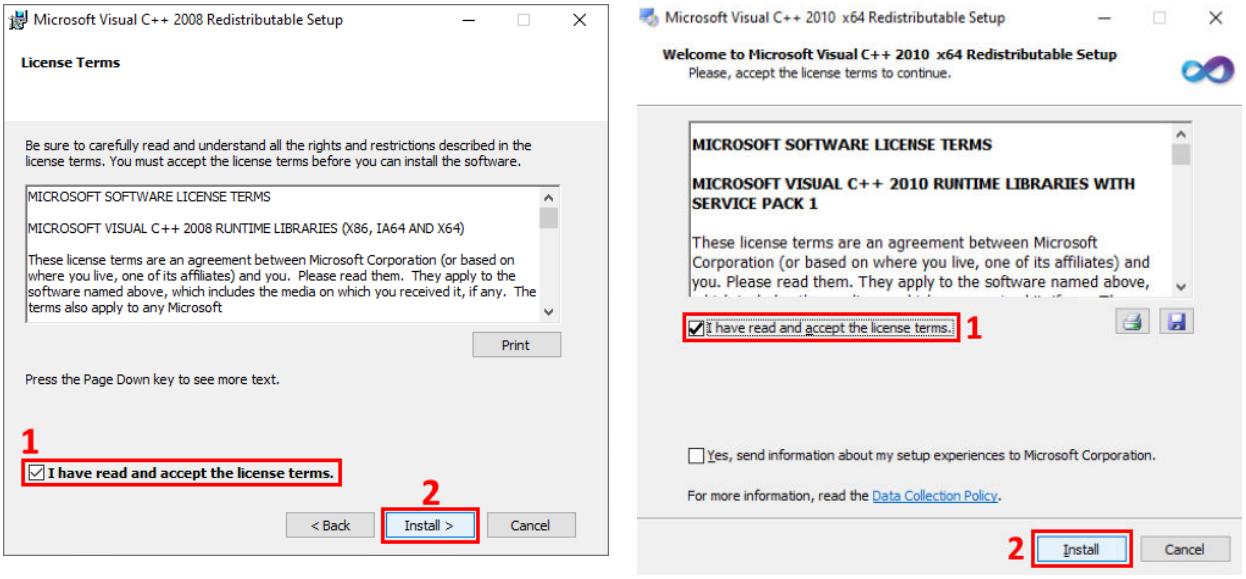


Fig. 36 - Microsoft License Agreement

- If the *Windows Security* window appears on the screen, it is necessary to install the Alkeria software.
  - Click on *Install* and wait for the end of the procedure.

Fig. 37 - *Windows Security* window

- If *Microsoft .NET 3.5 Framework* is not installed on the PC, the *Setup Wizard* window appears on the screen.
  - Click on *Next* and wait for the end of the procedure.

Fig. 38 - *Setup Wizard* window

- In case of first run, follow the procedure of **Activation and registration of the Phoenix application software on page 33.**
- At the end of the software activation and registration procedure, connect with the database through the database configuration window.
  - If a previous version of the application software is detected, a request of database conversion appears on the screen.
  - Otherwise, the software creates a new empty database.

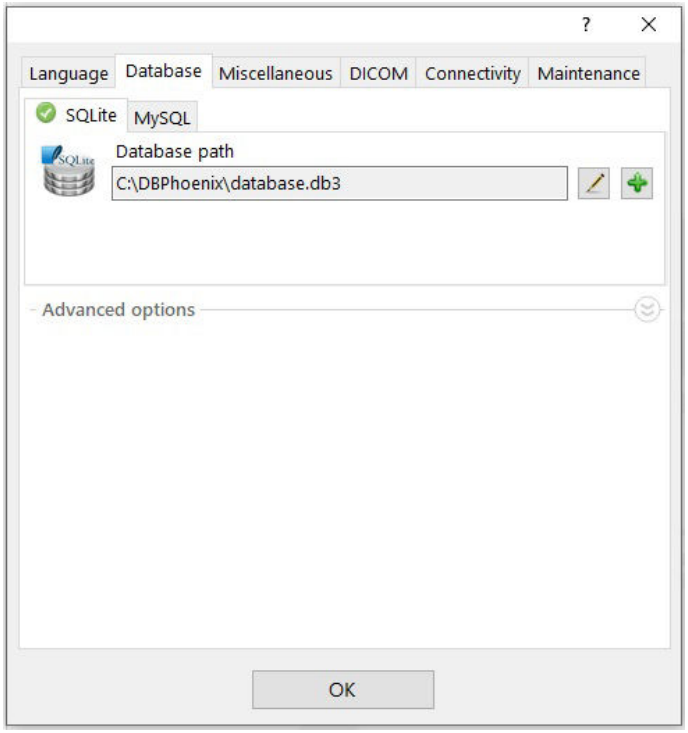


Fig. 39 - Database configuration

17 The Phoenix application software is now ready to be used. Please read the section *Managing patients and examinations* from the Phoenix application software handbook.

4.5.1.1 ACTIVATION AND REGISTRATION OF THE PHOENIX APPLICATION SOFTWARE

There are two license modules available.

- **DEFAULT**: includes the basic functionalities for all devices and pupillography functions.
- **Sirius IOL**: includes advanced topography, pupillography and IOL calculation functions.

1 Verify the device serial number.
For all devices released since 2016, the license is included into the device. Thus, the software is self-activated when the device is connected to the USB port. A popup appears on the upper part of the screen, showing the license type, the P-number and the device serial number.

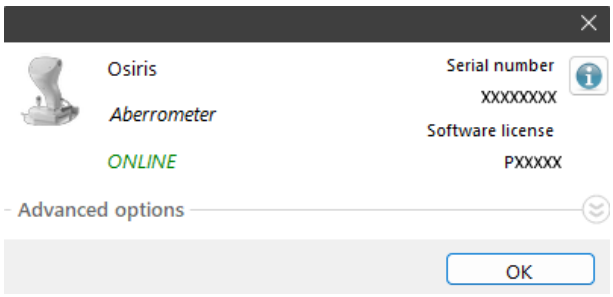


Fig. 40 - Popup window (Osiris)

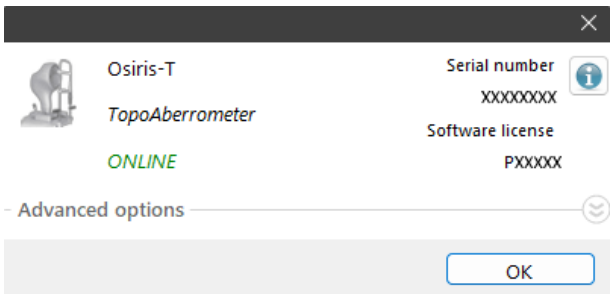


Fig. 41 - Popup window (Osiris-T)

When the device is disconnected from the USB port, the software license becomes inactive. Simply reconnect the device to the PC to reactivate the software license.

2 If the device is automatically detected by the software, it is not necessary to continue with the activation procedure.
Otherwise, proceed with the installation procedure as described below.
Follow the Offline procedure if the PC in not connected to the Internet, otherwise follow the Online procedure.

Activation procedure (Offline)

The activation form appears on the screen every time the Phoenix application software is launched.

1 Click on *Use free trial* to start the software in DEMO mode. This mode includes the same functions as the DEFAULT license, but can be run 60 times before preventing the software restart.
2 Otherwise, enter the 5-digit P-number. The P-number, which is the software license identifier, is placed on the device data plate or has been transmitted to the user by the Supplier.
3 Click on *Ok* to continue.

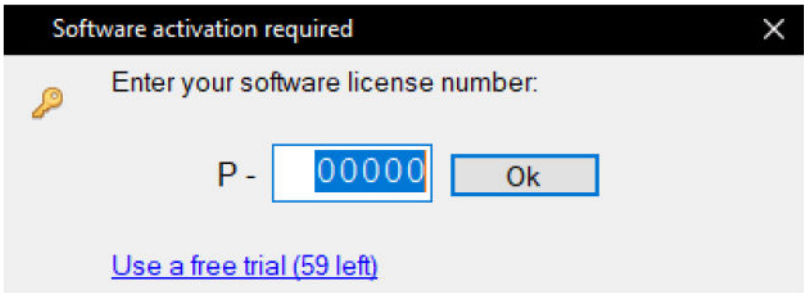


Fig. 42 - Enter the P-number

If the computer is not connected to the Internet, a 24-digit request code is produced.

4 Take note of the request code and send it to the Technical Assistance to request the activation code.

Click on *Copy* to take note of the request code. Send the request code as a text, not as an image or photo.

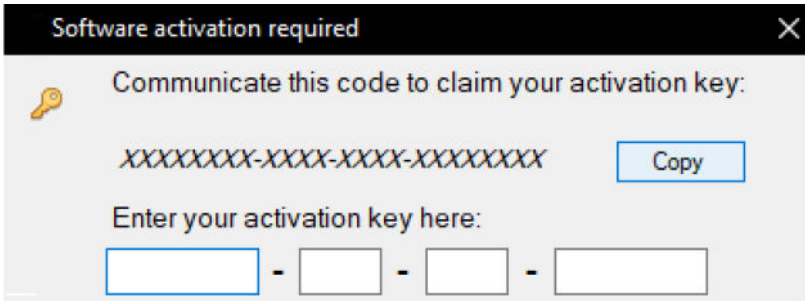


Fig. 43 - Take note of the request code

5 Wait for the activation code to be communicated. Input the activation code in the activation wizard.
The request code will be also displayed (in the lower part on the right) in this wizard, in the event it had not been recorded during the previous stage.

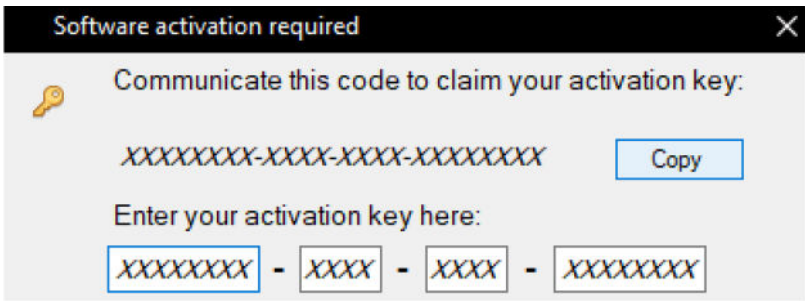


Fig. 44 - Enter the activation code

6 If the activation procedure fails, click on *Renew Request* to start a new activation request.

Activation procedure (Online)

1 Enter the 5-digit P-number. The P-number, which is the software license identifier, is placed on the device data plate or has been transmitted to the user by the Supplier.
2 Click on *Ok* to continue.

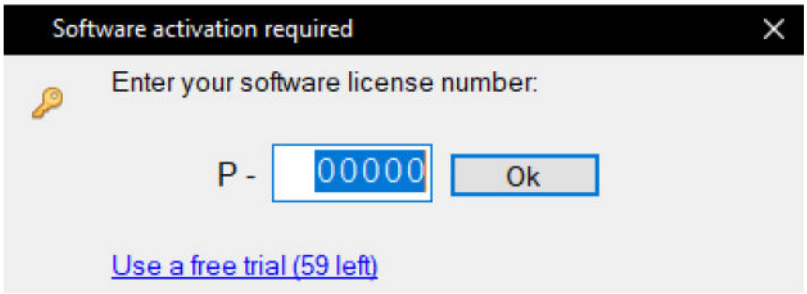


Fig. 45 - Enter the P-number

3 If the computer is connected to the Internet, the user receives an activation code. Input the activation code in the activation wizard.

4.5.2 INSTALLING THE REVIEW STATION

To install the Review Station, follow the procedure described in the paragraph **"Activation and registration of the Phoenix application software" on page 33.**

4.5.3 INSTALLING THE DEVICE IN A LOCAL NETWORK

The application software requires administrator privileges to run, only for the first use (activation and calibration).
If this requirement conflicts with the Company's security policy, contact the CSO Technical Assistance to consider possible solutions.

1. If the database was already created during a previous installation of the device, connect the device PC to the LAN network. Copy the *DBPhoenix* folder from the PC and paste it into the desired shared destination folder. Check that the database file and folder have full administrator read and write privileges for the users being enabled to sharing.
2. For each PC (and Review station) connected to the LAN network, connect to the database in the new location through the database configuration window.
3. Click on *Settings>Database>Edit Database path* and select the desired *database.db3* file from the new shared folder.
4. In the event of installation of an additional Review Station, if the database is already present on the server or in a relevant location, connect to the database through the database configuration window. Make sure you have read and write permissions for the new user.
5. For each PC, click on *Settings>Database>Edit Database path* and select the desired *database.db3* file from the shared folder.

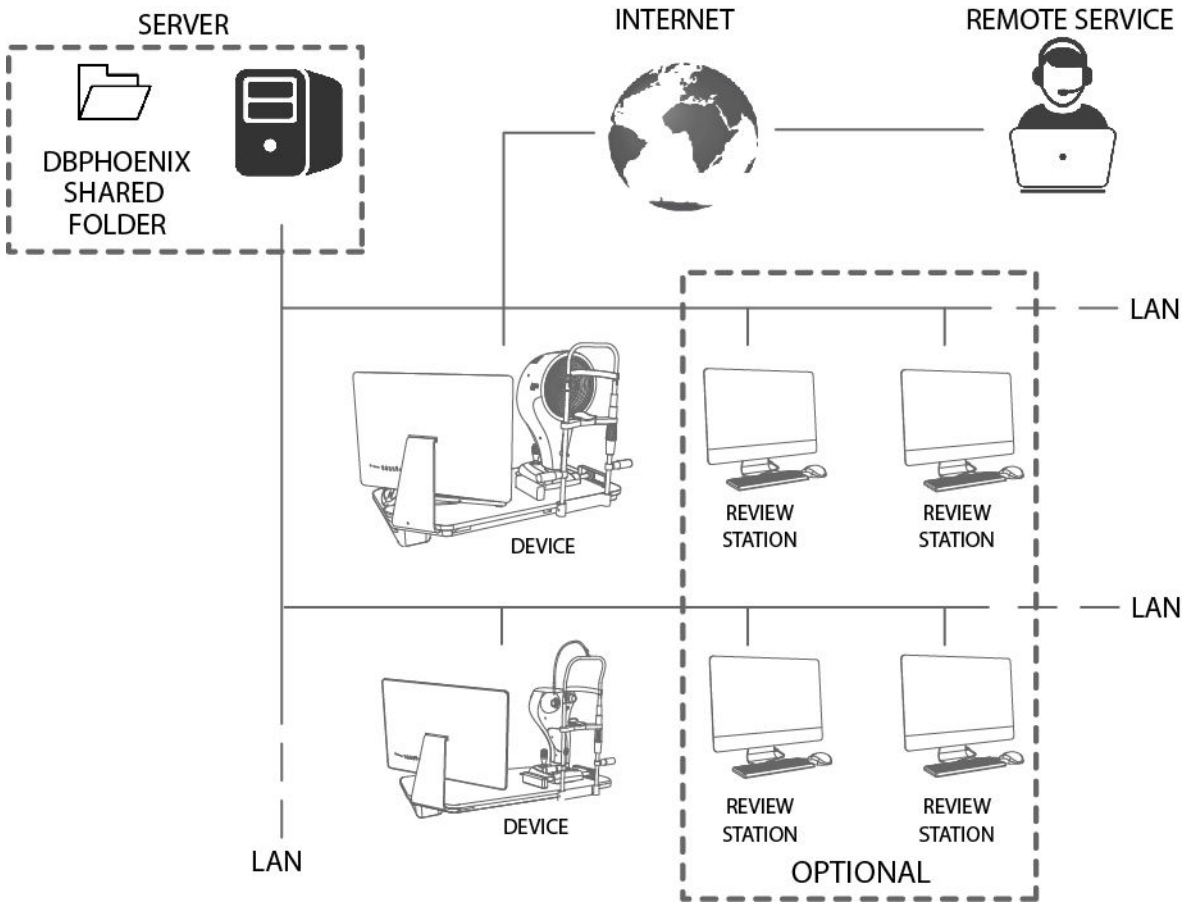


Fig. 46 - LAN path

4.5.4 DICOM ACTIVATION PROCEDURE

DICOM is a digital medical standard adopted by many health associations and hospitals from all over the world. It is used by healthcare operators to exchange images and other information through IT systems adopting such standard.

1 Click on *Settings* and select the DICOM tab.

2 Move the slider to *Enable DICOM connectivity* to enable the DICOM module.

3 From the *Configure* section, click on the settings icon to configure the DICOM general settings and available application entities.

Fig. 47 - Click on *Settings*

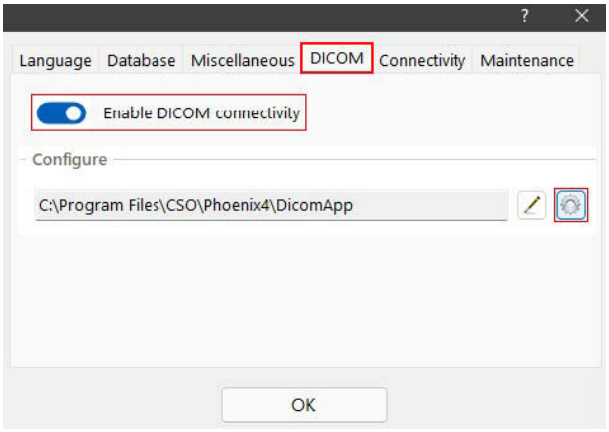


Fig. 48 - DICOM tab

From the configuration screen of the available *Application Entities*, you can set up:

- *PACS*: configuration parameters related to the *Picture Archiving and Communication System.*
- *PMS*: configuration parameters related to the *Practice Management System*. This entity is used by the DICOM module to retrieve the *Modality Worklist.*
- *PPS*: used to configure the entity in charge of the *Performed Procedure Step* service.
- *Local AE* and *Port*: local application entity name and port are used to authenticate the local installation into the customer's DICOM environment. The local port is used by a PC internal application. Make sure that this port is not blocked by the PC firewall and that is not already used by other local internal applications (on the PC where the Phoenix application software is installed).

4 In order to set up *PACS* and *PMS*, click on the related settings icon and fill in the requested fields (*AE Title, AE Host IP* or *Name, AE Port*).

5 Click on *Ok* to save the chosen configuration. Otherwise, click on *Cancel*.

6 To test each configuration, click on the related AE verification icon ( ).

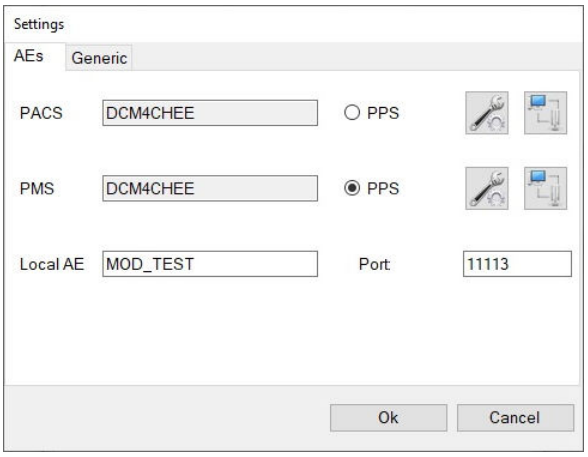


Fig. 49 - AE parameters

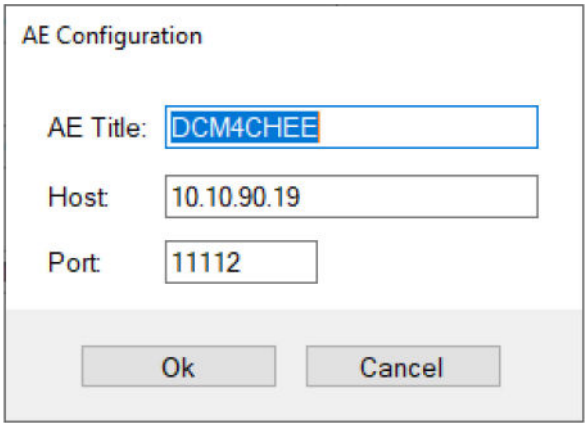


Fig. 50 - AE configuration

7 Click on *OK* to save the chosen settings. Otherwise, click on *Cancel*.

From the configuration screen of the DICOM general settings it is possible to configure:

- *Auto-Send mode*: configuration parameters of the examinations send mode to the *PACS.* There are 3 sending options available:
  - *Disabled*: the automatic send mode is disabled. The examination shall be manually sent by the user.
  - *Before entering into Exam*: the examination will be automatically sent after completing the acquisition phase.
  - *After exiting from Exam*: the examination will be automatically sent after ending the examination and after closing the related elaboration module.
- *Enable auto-send PDF*: all the PDF reports generated during the examination analysis phase will be automatically sent after ending the examination and after closing the related elaboration module.
- *Enable MPPS*: the *Modality Performed Procedure Step* messaging is enabled (please read the Conformance Statement document).
- *Filter search by contained modalities*: if the box is checked, the study search inside the *Import from PACS* window will be filtered based on the *OP, XC, OPT, OPM, AR, OT* parameters.
- *Filter MWL by Scheduled AE Title*: if the box is checked, the *Modality Worklist* will search only among the entries related to the title of the current application entity.
- *Send images as ImplicitVRLittleEndian*: if the box is checked, in order to send the images acquired during the examination, the *Implicit Value Representation Little Endian* mode will be used instead of the *JPEG Baseline* mode.
- *Max number of results*: setting of the maximum number of displayed results during a search.
- *Retrieve mode*: the examination retrieves the *SOP Class* used during the *Import from PACS* procedure. In case of *CMOVE*, the *PACS* entity shall be configured in order to properly send data to the current application entity.
- *IODs*: allows to configure the *Information Object Definition* to be used to archive the examination data that will be sent to the *PACS*. Each examination can support one or more *IOD*. Only examinations sent after setting the flag *Importable* to true can be imported later on into the application environment.

8 Configure the desired parameters.

9 Click on *Ok* to save the chosen configuration. Otherwise, click on *Cancel*.

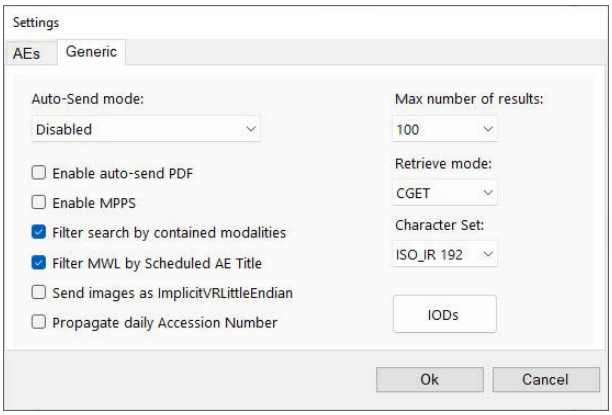


Fig. 51 - General settings

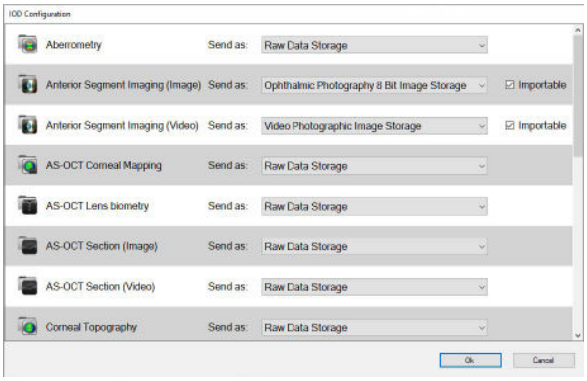


Fig. 52 - IODs

4.5.5 UPDATING THE PHOENIX APPLICATION SOFTWARE

Read the instructions for use before using the Phoenix application software.
The handbook can also be downloaded from the website www.csoitalia.it under the section "Documents - Software download" (registration required). or you may read the application software manual.

Before updating the Phoenix application software, uninstall the previous software version.

Before updating the Phoenix application software, please read the following table to check compatibility between the Phoenix application software and the operating system used with the device.

Before updating the Phoenix application software, make a backup of the patients archive currently used with the device. Follow the procedure described in paragraphs **"Import and export of examinations" on page 41** and **"Backup of the database archive and restoration of patient examinations" on page 41.**

Operating system	Versions of the Phoenix application software			
	3.7	**4.0.1.8**	**4.1.0.7**	**4.1.1.5**
Windows 7 Home Premium or Professional 32 bit with SPK1	X			
Windows 7 Home Premium or Professional 64 bit with SPK1	X			
Windows 8/8.1 Home or Pro 32 bit	X	X (*)	X (*)	X (*)
Windows 8/8.1 Home or Pro 64 bit	X	X (*)	X (*)	X (*)
Windows 10 Home or Pro 64 bit	X	X (*)	X (*)	X (*)
Windows 11 Home or Pro 64 bit			X (*)	X (*)

(*) Starting from version 4.0 of the Phoenix application software, the installation of *NET 4.0 Framework* is required.

When the PC is connected to the internet, the Phoenix application software periodically checks for new updates.

If the PC has an active internet connection, the user can find a green icon ( ) at the bottom right of the main screen of the Phoenix application software. A red icon ( ) appears next to the green icon to notify the user of the availability of a new software update.

1 Click on *Click here to download* to download the new software update.

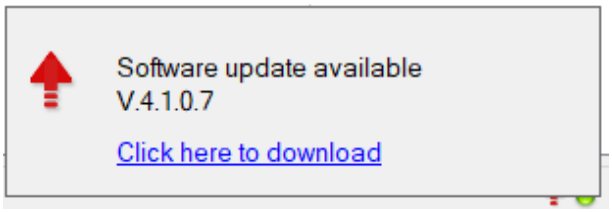


Fig. 53 - Download the update

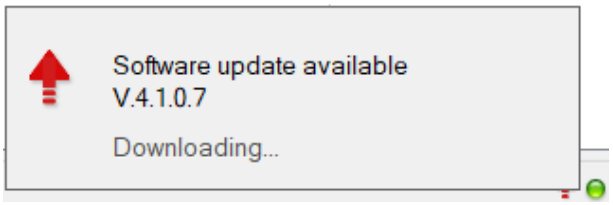


Fig. 54 - Download in progress

2 Once the download is complete, click on *Click here to install* to install the new software update.

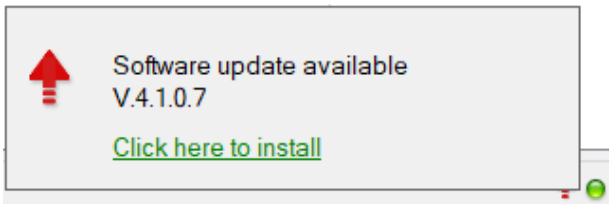


Fig. 55 - Install the update

3 Click on *Yes* to allow the Phoenix application software to close and start the update procedure.

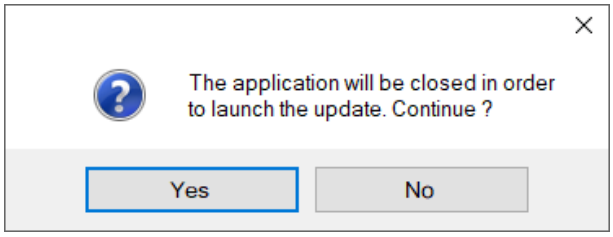


Fig. 56 - Confirm and start the update procedure

4 After the installation procedure is complete, restart the updated Phoenix application software.

4.5.6 IMPORT AND EXPORT OF EXAMINATIONS

1 To export an examination or patient record, right-click on the corresponding row in the *Patients/Examinations list*.

2 Click on the *Export patient* icon ( ).
Alternatively, select *Add patient*, then *Export patient* and click on *Export selected patient*.

3 To export multiple exams or patient records, select *Add patient*, then *Export patient* and click on *Export all patients actually in list*.

4 After selecting the destination path of the exported file, confirm to start the export. A file with the *.zc2* extension is created in the chosen destination folder.

5 To import an existing *.zcs* or *.zc2* file, select *Add patient* and click on the *Import patient* icon ( ).

4.5.7 BACKUP OF THE DATABASE ARCHIVE AND RESTORATION OF PATIENT EXAMINATIONS

1 To backup the databases archive of the patients' examinations, use third-parties applications for the management of backup files.
The backup default path is: C:\DBPhoenix.

4.6 STARTING THE DEVICE

Read the instructions for use before using the Phoenix application software.
The instruction manual can be downloaded from the website www.csoitalia.it or you may read the application software guide.

1 Turn the power switch of the power supply unit to ON.
2 Turn on the PC.
3 Launch the Phoenix application software.
4 Wait until the main screen of the application software is displayed.
5 Click on NEW PATIENT and enter the 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. A new examination will be created automatically.
6 Select the device to be used.
7 The image acquisition screen will open. Image acquisition can be now carried out.
8 If the device is started for the first time or after a long period of non-use, the device calibration shall be performed. Carry out the calibration as described in the paragraph **"Device calibration" on page 42.**

4.7 DEVICE CALIBRATION

Calibration shall be performed when powering up 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.

Close attention shall be paid while performing the procedure. It is important to check device stability before starting with the procedure.
calibration is essential to obtaining precise measurements.

The device calibration shall only be carried out by qualified and trained technical personnel.

Follow the instructions about calibrating the device Osiris and Osiris-T which are given in the Phoenix application software handbook.

4.7.1 CALIBRATION FOR THE ABERROMETER SECTION (OSIRIS AND OSIRIS-T)

To carry out the procedure described, only use the calibration testing tool of the aberrometric section supplied with the device. In case of loss of the the calibration testing tool of the aberrometric section, send the device to the Manufacturer to request a new calibration.

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

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

2 Place the testing tool for calibration on the chin rest.
3 Start the acquisition of a new examination.
4 Simultaneously press CTRL+T keys. "Test Eye" caption will be displayed on screen.
5 Make sure the sphere is aligned and properly focused with the shooting channel.

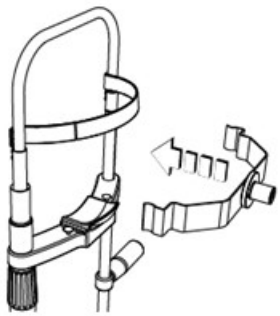


Fig 57 - Placing the calibration testing tool on the chin rest

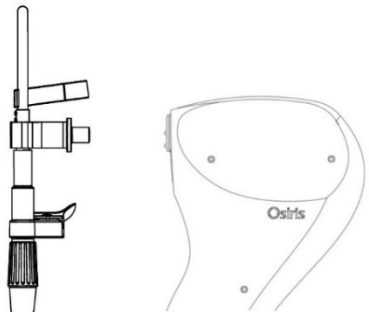


Fig 58 – Alignment of the calibration testing tool with the device Osiris

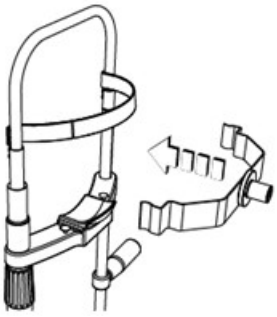


Fig 59 - Placing the calibration testing tool on the chin rest

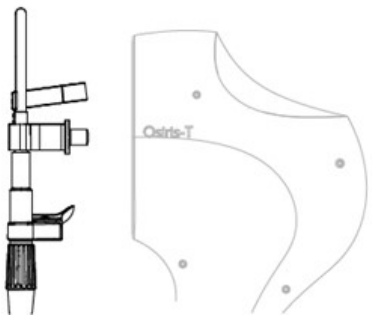


Fig 60 – Alignment of the calibration testing tool with the device Osiris-T

6 Push down the joystick button to perform an acquisition.
7 Check that the measured value for a diameter of 4mm@12.5mm corresponds to the value indicated on the calibration testing tool.

The benchmark value is specified on the back of the calibration testing tool. The measured value must correspond to the benchmark value, equal to ± 0.125 D.

8 If the elaborated measures are not considered as reliable, repeat the procedure.

4.7.2 CALIBRATION FOR THE TOPOGRAPHER SECTION (OSIRIS-T)

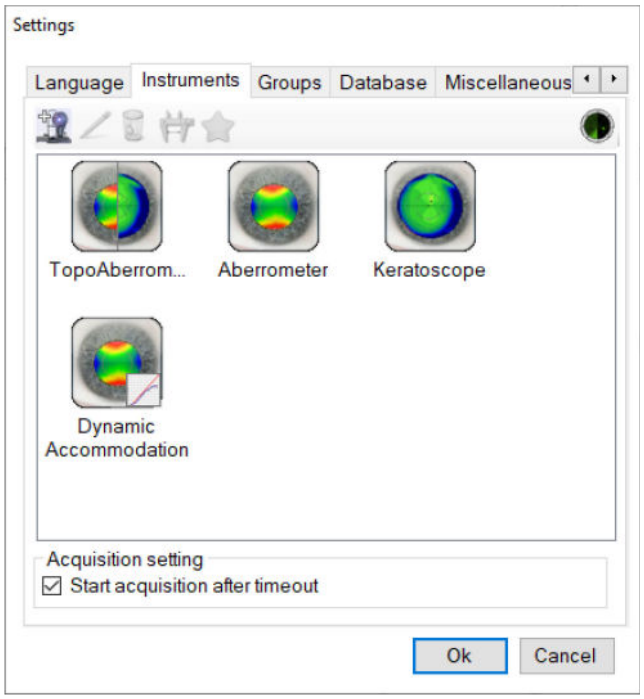


Fig 61 - Settings Window

1 Make sure that 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 chinrest.
3 Make sure the sphere is aligned with the shooting channel.

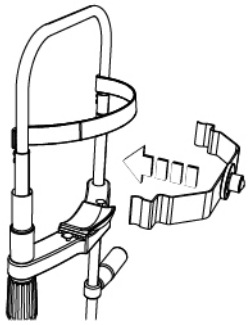


Fig. 62 - Placement of the calibration tool on the chinrest

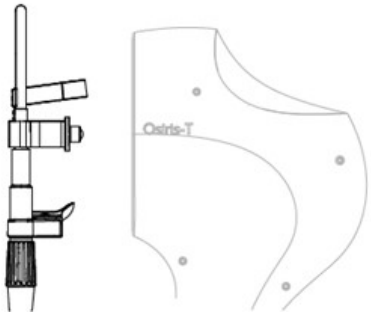


Fig 63 – Alignment of the calibration tool with the device Osiris-T

4 The patients list shall be emptied in order to access the configurations menu.
5 Open the CONFIGURATION menu of the application software.
6 Select the INSTRUMENTS panel.
7 Select the Topo-Aberrometer device.

8 Click on the calibration button  .

9 Perform curvature calibration.

Curvature calibration

1 A window will appear on-screen, displaying the calibration procedure. Carefully follow the instructions provided.
2 Carry out image acquisition of the sphere placed on the calibration tool (sphere radius 8 mm).
3 If the calibration procedure has been performed correctly, a confirmation message will appear on-screen.
4 If not, repeat the whole calibration procedure.

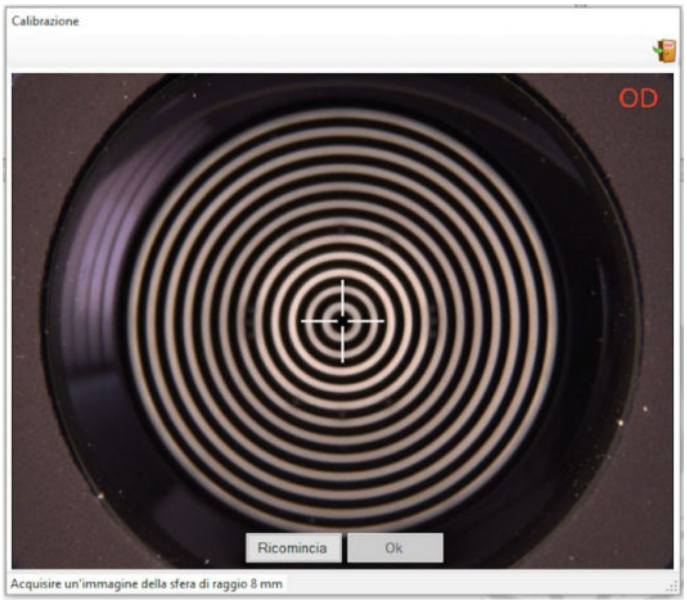


Fig 64 – Image of the 8 mm calibration sphere captured

Calibration verification

After performing calibration, an examination should be carried out using the calibration tool (8 mm sphere radius) in order to check proper calibration of the device.

1 Click on the button NEW PATIENT.
2 Enter personal data and confirm.
3 Choose the CORNEAL TOPOGRAPHY examination.
4 After acquiring the image, press the EXIT button and process the acquired examination.
5 On the OPTIONS panel, select the unit of measurement for curvature in millimetres.
6 Verify that the value corresponds to that of the reference sphere on the anterior tangential curvature map.

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

7 If the calculated measures are not considered reliable, repeat the entire calibration procedure.

If the device is not properly calibrated, the application software will display a warning message. Repeat the calibration procedure.
If the problem persists, after carrying out all the necessary operating and environmental checks, carry out the procedure described in the paragraph **"Replacement of the structural unit with** optical-electronic head**" on page 65** or contact the Manufacturer.

4.8 FUNCTIONAL TEST OF THE DEVICE

After installing the application software or the device, carry out a functional test of the device.

1 Make sure the device is on. Otherwise, turn the power switch of the power supply unit to ON.
2 Run the Phoenix application software and wait until the main screen of the application software is shown.
3 Acquire an image (use the calibration tool).
4 Check correct image acquisition.

Examination modes and image acquisition information can be found in the instructions for use of 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 part requiring user intervention. Do not remove any part of the device.

It is forbidden to carry out any maintenance operation on the device that is not recalled in this instruction manual.

In case of operational faults or malfunctions and for any operation not mentioned in this manual, there is the obligation to contact the device Manufacturer.

5.2 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 shall be routinely carried out.

Device parts that do not come into direct contact with the patient shall be cleaned at least once a day.
Device parts that do come into direct contact with the patient shall 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.

5.2.1 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 shall take into account both the sensitivity of the device to specific substances and the product's effectiveness.
For cleaning and disinfection procedures, use products approved by the FDA or CE for medical devices or medical-surgical devices.
Abide by the products 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.

5.2.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

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

This device is classified as "non-critical" since it only comes into contact with 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 the 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 cleaning instructions described in this section in order to avoid any 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 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 cleaning solution.

For more information about suitable cleansing products, read section **"Recommended products for cleaning and disinfection" on page 47.**

5.2.4 CLEANING THE APPLIED PARTS

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

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 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 cleansing products, read section **"Recommended products for cleaning and disinfection" on page 47.**

5.2.5 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.

5.3 DEVICE CALIBRATION

Device calibration shall be periodically carried out, in order to ensure accurate measurements. Follow the calibration instructions described in paragraph **"Device calibration" on page 42.**

6 CORRECTIVE MAINTENANCE

6.1 SAFETY WARNINGS

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

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

In case of operational faults or malfunctions and for any operation not mentioned in this manual, there is the obligation to contact the device Manufacturer.

Only use original spare parts to replace device components. The code is indicated within the **"Spare parts and accessories list" on page 82.**

Electrical safety tests shall be carried out in accordance with the EN60601-1 standard after any operation requiring electronic components to be replaced or protective shells to be removed from the device.

Should you encounter any problem which is not mentioned in the lists or procedures indicated within the following paragraphs, please ask for further information to the Manufacturer or the local Dealer.

Before replacing a component, make sure all tools and materials required for the installation are available.

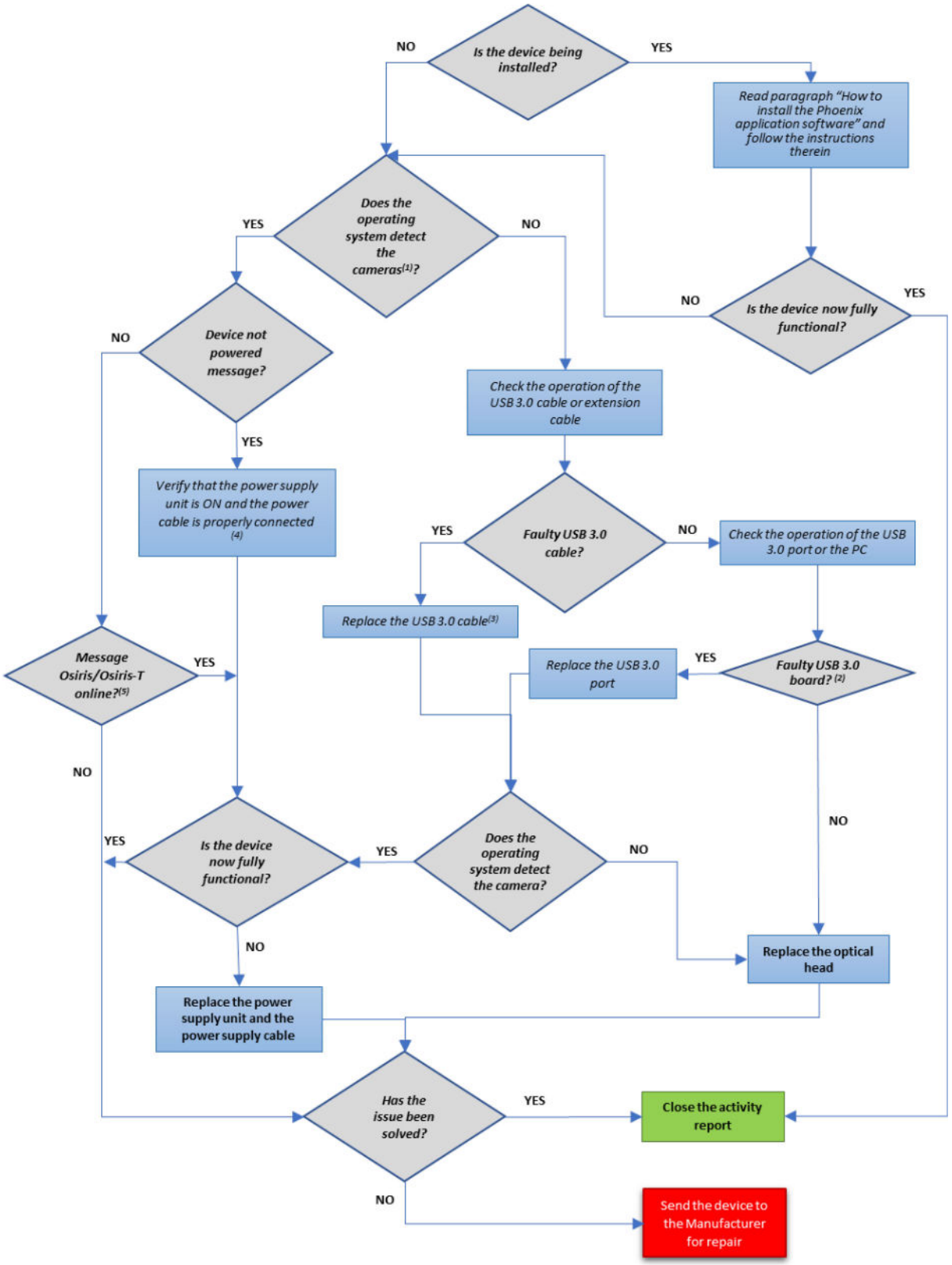
It is prohibited to use a powered screwdriver for any components' fixing or adjusting procedure.

6.2 FLOW CHARTS

Should the instructions given in the flow chart fail to solve the issue, please contact CSO Technical Support.

Only use original spare parts to replace device components. The code is indicated within the **"Spare parts and accessories list" on page 82.**

6.2.1 THE PHOENIX SOFTWARE CANNOT DETECT THE DEVICE



[1] *Access "Microsoft Windows>image acquisition devices" and check that the acquisition device (Dua414-AH SuperSpeed Camera) is correctly detected.*

[2] *Minimum functional requirement: USB 3.0 port with Texas Instruments or Intel chipset*

[3] *Use only cables and extensions supplied and certified by CSO*

[4] *See paragraph "**How to connect the** device" on page **26**.*

[5] *Restart the Phoenix application software.*

6.3 MESSAGES

ID	Message	Solution
PHOSI001	"Generic DB Exception"	Follow the path: Settings > Database. Check the database position and reconnect the .db3 file.
PHOSI002	"ALive has encountered an issue and will now close"	Check the operation of the USB 3.0 cable of the device and the USB 3.0 port of the PC. Restart your PC. If the problem persists: – Rename the folder C:\Users\"username"\AppData\Roaming\P4 to C:\Users\"username"\AppData\Roaming\P4_Old. – Rename the C:\Users\"username"\AppData\Local\CSO folder to C:\Users\"username"\AppData\Local\CSO_Old. Restart the Phoenix application software and check that the issue is resolved. **Note: this procedure will delete your user settings. Reset user settings manually.**
PHOSI003	"Phoenix has stopped working"	The Software cannot start and crashes before the first screen is displayed. Setting files are corrupt. Follow the troubleshooting steps described in Troubleshooting related to the error ID **PHOSI002**.
PHOSI004	"Database not accessible"	Allow the required authorisations (administrator privileges) in the folder "DBPhoenix".
PHOSI005	"Could not find a part of the path […]"	Database location is incorrect or Server is off. The software cannot detect the location of the pictures folder in the system file. Restore the path of the database pictures folder.
PHOSI006	"[…] Device appears unconnected…"	Check that the "MaestroUSB3 CSO Ed." drivers are properly installed on the PC: – Uninstall the "MaestroUSB3 CSO Ed." drivers. – Restart your PC. – Turn on the power supply unit. – Connect the device to the PC. – Launch the Phoenix application software. The drivers will be reinstalled automatically.

For any message of cases which are not included in the list, please ask the Manufacturer for information.
Contact the Technical support reporting the following data:

- Device Serial Number
- Detailed description of the issue and of the system behaviour
- Log files

If a message appears in the dialogue box, expand message details and paste message information in the e-mail. Follow the indications given in paragraph **"How to report malfunctions to the Manufacturer" on page 6.**

6.4 HOW TO DETECT AND SOLVE ISSUES (TROUBLESHOOTING)

ID	Issue	Solution
OSI001	The Phoenix application software does not start	Rename the folder C:\Users\"username"\AppData\Roaming\P4 to C:\Users\"username"\AppData\Roaming\P4_Old. Rename the C:\Users\"username"\AppData\Local\CSO folder to C:\Users\"username"\AppData\Local\CSO_Old. Restart the Phoenix application software and check that the issue is resolved. **Note: this procedure will delete your user settings. Reset user settings manually.**
OSI002	"Power supply not detected" message	The device power supply is off. Power cable disconnected or damaged. Faulty electronic control board. Turn on the power supply unit. Connect the power supply cable. Replace the opto-electronical head of the device.
OSI003	The Phoenix application software requires activation	USB 3.0 cable disconnected. USB 3.0 cable damaged. Replace the USB 3.0 cable with a certified CSO cable. If the problem persists, follow the instructions given in the paragraph **"Flow charts" on page 49.**
OSI004	The camera does not visualize the image in live (black screen)	USB 3.0 cable damaged. Replace the USB 3.0 cable with a certified CSO cable. If the problem persists, follow the instructions given in the paragraph **"Flow charts" on page 49.**
OSI005	The camera has problems. Red-blue blinking. Yellow image	Follow the procedure described in paragraph **"Replacement of the structural unit with optical-electronic head" on page 65.** If the problem persists, contact the Manufacturer.
OSI006	Error reading offset 0xF0F01104 in live	Problems with the USB 3.0 cable or the camera. Replace the USB 3.0 cable with a certified CSO cable. If the problem persists, follow the instructions given in the paragraph **"Flow charts" on page 49.**
OSI007	Tear film analysis stops during processing	Acquisition not valid. Repeat the image acquisition.
OSI008	"Connect to 2.0 USB port" message	The device has been connected to a 2.0 USB port. USB 3.0 cable damaged. USB 3.0 extension cable not certified by CSO. Replace the USB 3.0 cable with a certified CSO cable.
OSI009	"Calibration failed" message during the calibration procedure	Repeat the device calibration procedure. Follow the procedure described in paragraph **"Device calibration" on page 42.**
OSI010	The left/right position of the device is not detected when moving the base	Before replacing any of the following components, make sure the sticker pad is positioned correctly. Check that the sticker pad is a different colour than the colour of the table top. Replace one of the following components: – Plate with left/right sensor. Follow the procedure described in paragraph **"Replacement of the plate with left/right sensor" on page 68.** – Joystick unit. Follow the procedure described in paragraph **"Replacement of the joystick unit" on page 71.** – Complete base. Follow the procedure described in paragraph **"Replacement of the complete base" on page 74.**
OSI011	The Phoenix application software doesn't detect the device	See paragraph **"Flow charts" on page 49.**
OSI012	The image is out of focus or the device is not calibrated	Check the calibration of the device with the tool supplied (sphere radius 8 mm). Follow the procedure described in paragraph **"Device calibration" on page 42.**

ID	Issue	Solution
OSI013	The acquired image is not clear	Check the camera optical system is clean. Check the room lighting.
OSI014	Image is not displayed (black screen)	Check the cable connecting the PC to the device is plugged in. Check the optical system of the video camera.
OSI015	The calibration verification has failed or the value does not fall within the provided threshold	Send the device to the Manufacturer for repair.

6.4.1 REPLACEMENT OF PROTECTIVE SHELLS (OSIRIS)

Material and warnings:

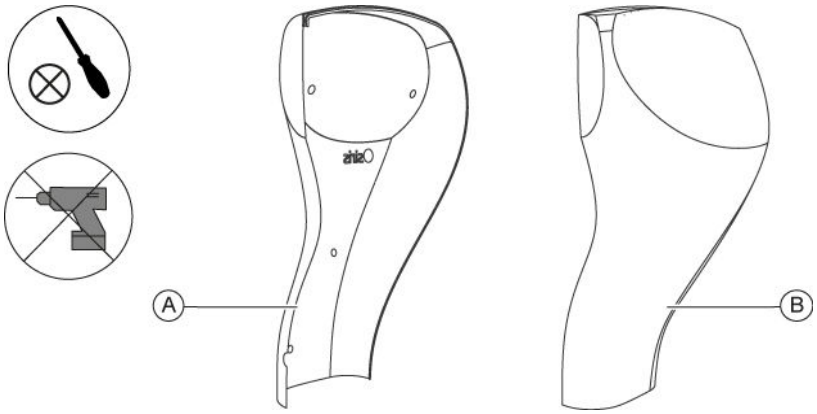


Fig 65 – Osiris protective shell

Pos	Description
A	Left protective shell for Osiris device (V0/AS3) – code 103103560S
B	Right protective shell for Osiris device (V0/AS3) – code 103103561S

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Dismantling procedure for the left and right protective shells:

1 Remove the four screws M3x6 (A) of the right protective shell.
2 Remove the right protective shell.

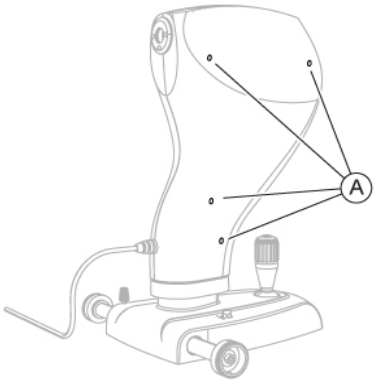


Fig 66 – Right shell

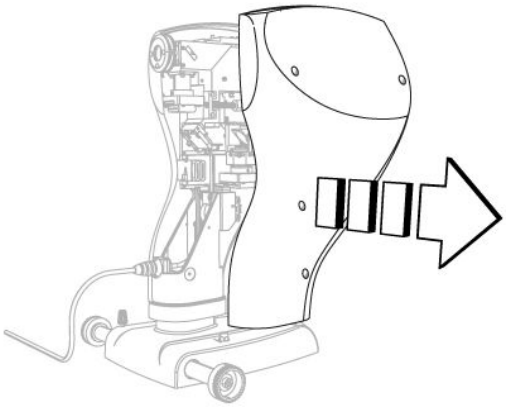


Fig 67 - Removing the right shell

3 Remove the three screws M3x6 (B) of the left protective shell. Remove the left protective shell.

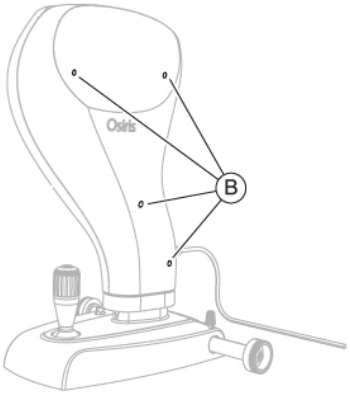


Fig 68 – Left shell

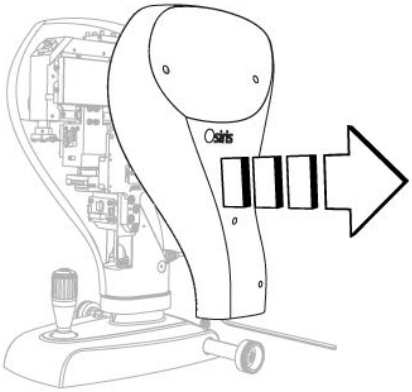


Fig 69 - Removing the left shell

Assembly procedure for the left and right protective shells:

1 Reinstall the left protective shell. Fasten the three screws M3x6 (B) of the left protective shell.

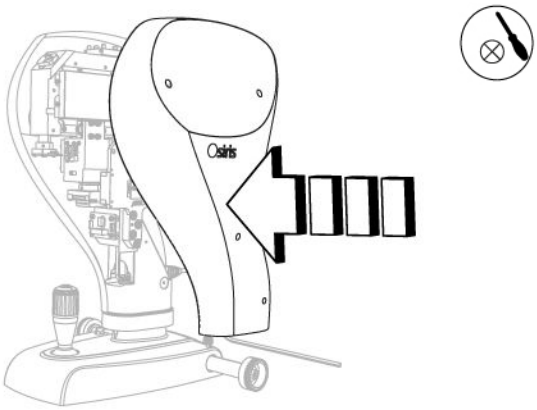


Fig 70 – Left shell

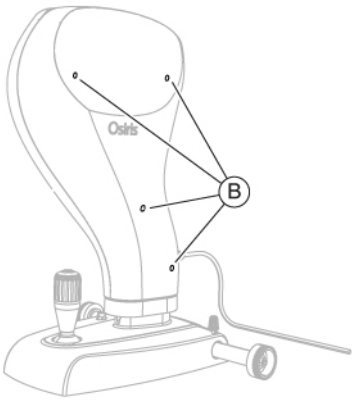


Fig 71 – Fixing the left shell

2 Reinstall the right protective shell.
3 Fasten the four screws M3x6 (A) of the right protective shell.

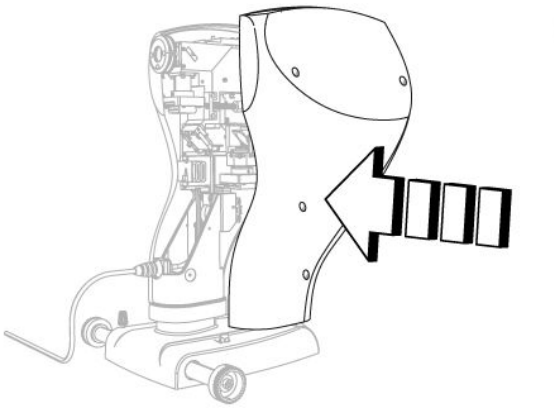


Fig 72 – Right shell

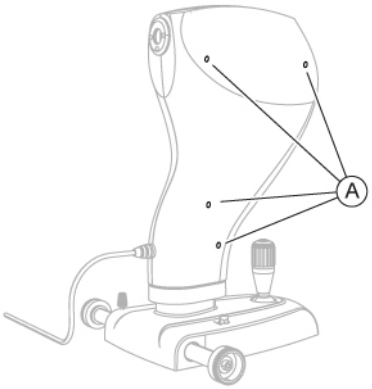


Fig 73 - Fixing the right shell

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.2 REPLACEMENT OF PROTECTIVE SHELLS (OSIRIS-T)

Material and warnings:

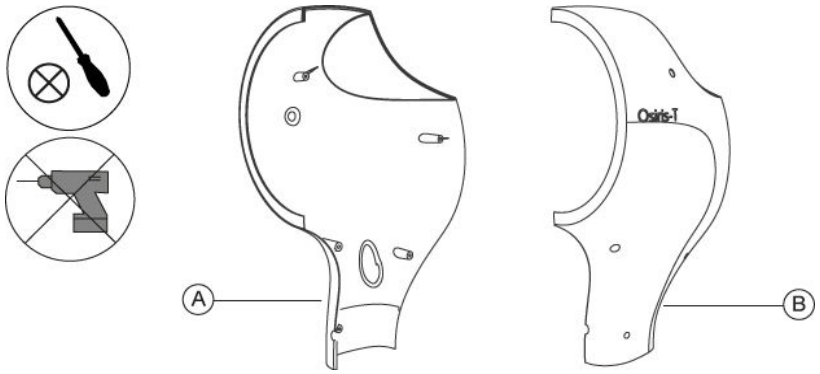


Fig 74 – Osiris-T protective shell

Pos	Description
A	Left protective shell for Osiris-T device (V0/AS3) – code 103102596S
B	Right protective shell for Osiris-T device (V0/AS3) – code 103102595S

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Dismantling procedure for the left and right protective shells:

1 Remove the five screws M3x8 (B) of the left protective shell. Remove the left protective shell.

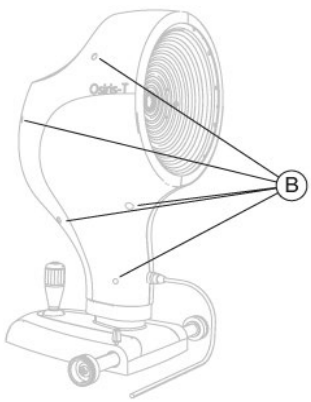


Fig 75 – Left shell

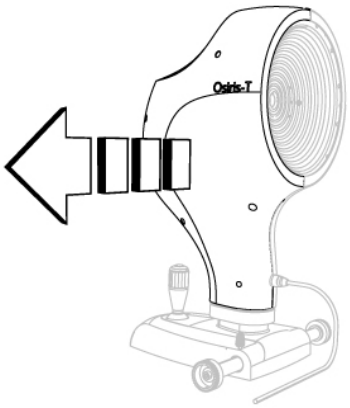


Fig 76 - Removing the left shell

2 Remove the five screws M3x8 (A) of the right protective shell.
3 Remove the right protective shell.

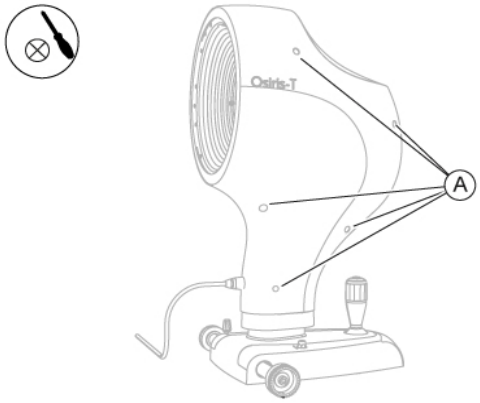


Fig 77 – Right shell

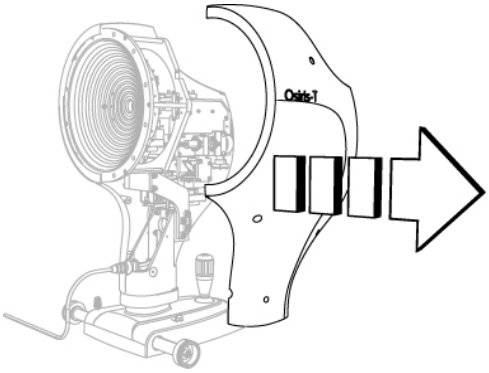


Fig 78 - Removing the right shell

Assembly procedure for the left and right protective shells:

1 Reinstall the right protective shell.
2 Tighten the five screws M3x8 (A) of the right protective shell.

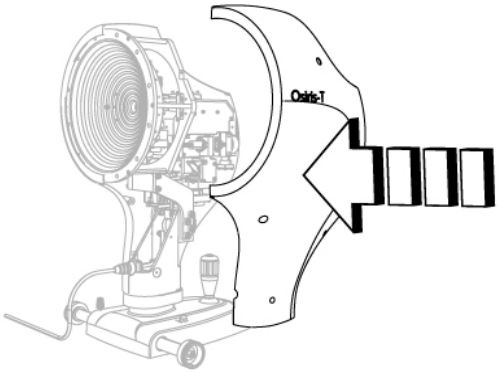


Fig 79 – Right shell

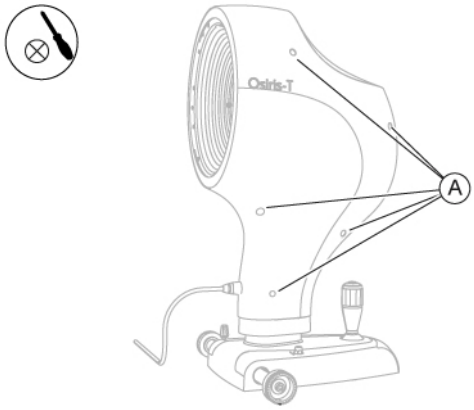


Fig 80 - Fixing the right shell

3 Reinstall the left protective shell. Tighten the five screws M3x8 (B) of the left protective shell.

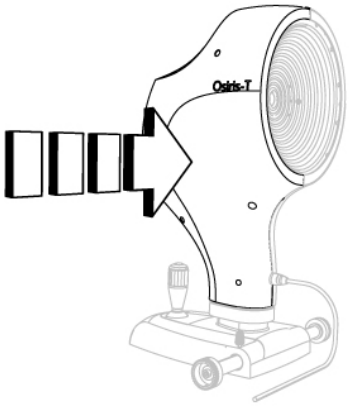


Fig 81 – Left shell

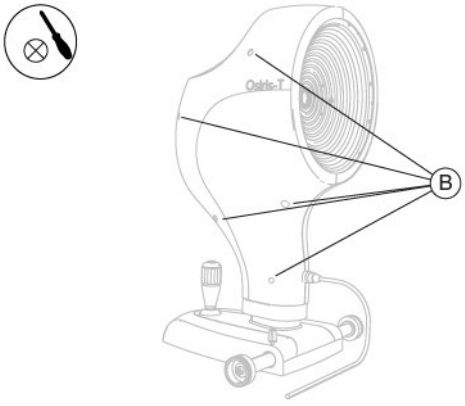


Fig 82 – Fixing the left shell

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.3 REPLACEMENT OF THE POWER SUPPLY UNIT

Material and warnings:

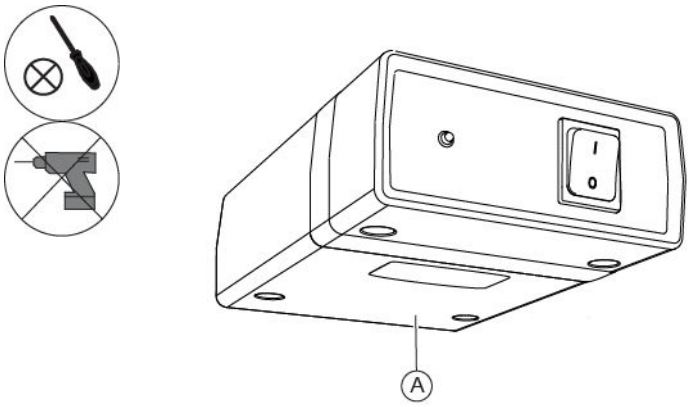


Fig. 83 - Power supply unit

Pos	Description	Code
A	Power supply unit (PSP2402)	103103900

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

The described procedure applies to power supply units installed under the table top.

Disassembling and assembling procedure for the power supply unit:

1 Turn off the device and the PC.
2 If present, fasten the table wheels. Lower the brake lever.
3 Disconnect the power cables on the power supply unit.
4 Loosen the screws on the four holes of the power supply unit.
5 Unscrew the four screws and remove the power supply unit.

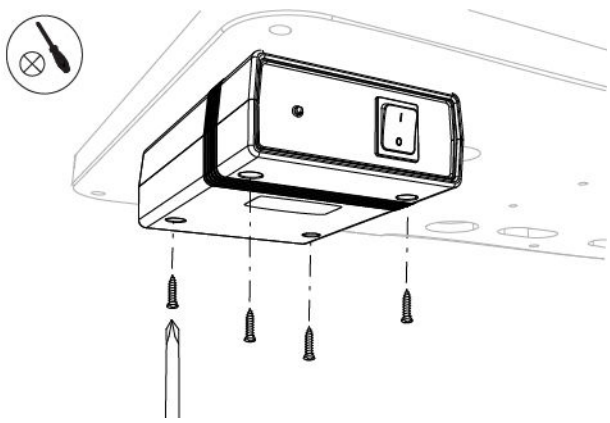


Fig. 84 - Unscrew the screws

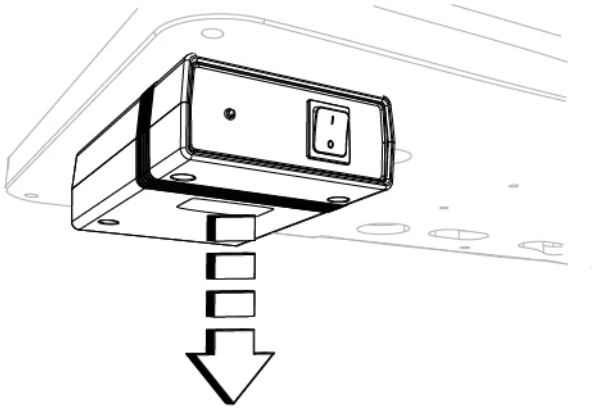


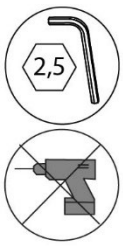
Fig. 85 - Remove the power supply unit

6 For assembly, follow the procedure in reverse order.

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.4 REPLACEMENT OF THE 3.0 USB CABLE

Material and warnings:



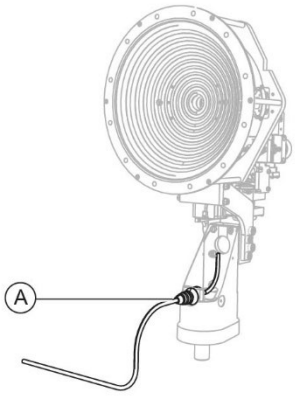


Fig. 86 – Osiris-T USB cable

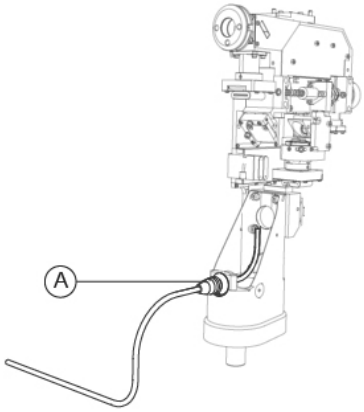


Fig. 87 - Osiris USB cable

Pos	Description
A	USB 3.0 cable 2 m length with cable retainer for device Osiris-T - code 3020804
A	USB 3.0 cable 2 m length with cable retainer for device Osiris - code 3020804

Before starting the replacement procedure, make sure the features of the new USB cable match with those of the used one.

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Disassembling procedure for the USB 3.0 cable:

1. Remove the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**
2. Remove the two cable ties (A).
3. Remove the two cable ties (B).

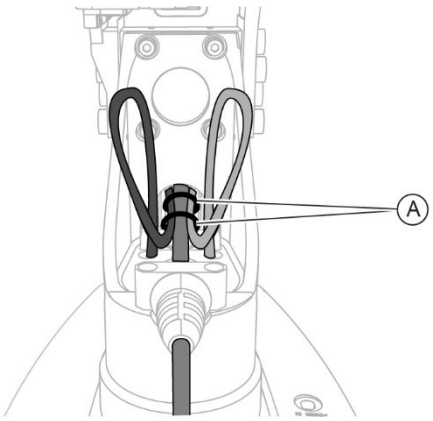


Fig. 88 - Remove the cable ties

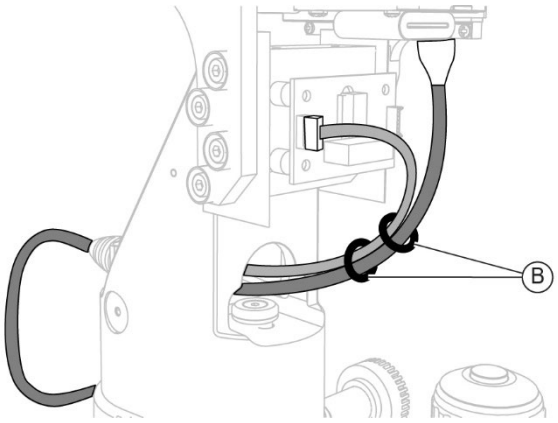


Fig 89 - Remove the cable ties (front)

4 Disconnect the USB 3.0 cable (C) from the socket on the Dual video Camera circuit board.
5 Remove the two screws (D) from the cable retainer (E).
6 Remove the cable retainer (E).
7 Remove the USB 3.0 cable (C).

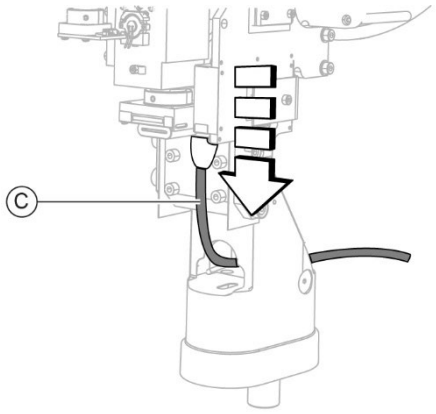


Fig. 90 - Disconnect the USB 3.0 cable (front)

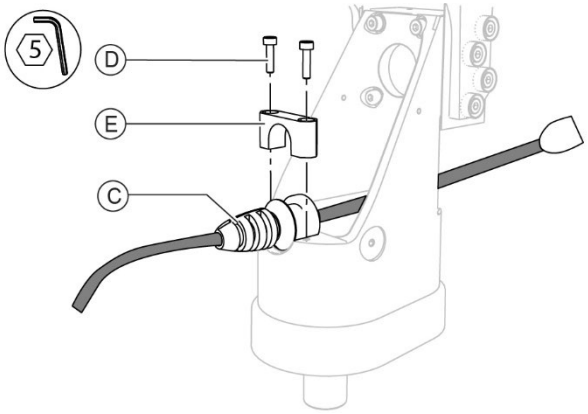


Fig. 91 – Remove the USB 3.0 cable

Assembling procedure for the USB 3.0 cable:

1 Place the USB 3.0 cable (C).
2 Place the cable retainer (E) on the USB 3.0 cable (C).
3 Screw in the two screws (D).
4 Connect the USB 3.0 cable (C) to the socket on the Dual video camera circuit board.

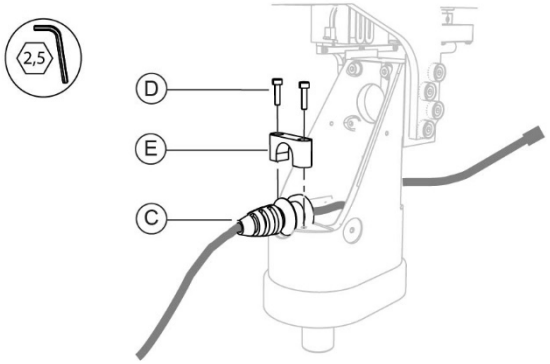


Fig. 92 - Place the USB 3.0 cable

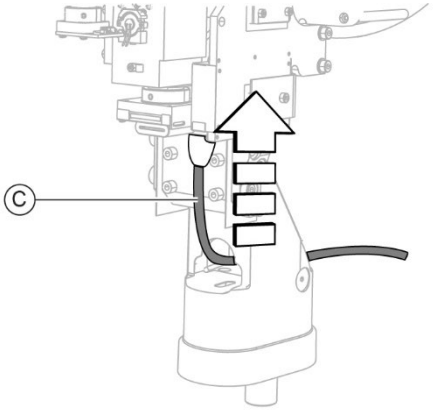


Fig. 93 - Connect the USB 3.0 cable

5 Place the two cable ties (B).
6 Place the two cable ties (A).

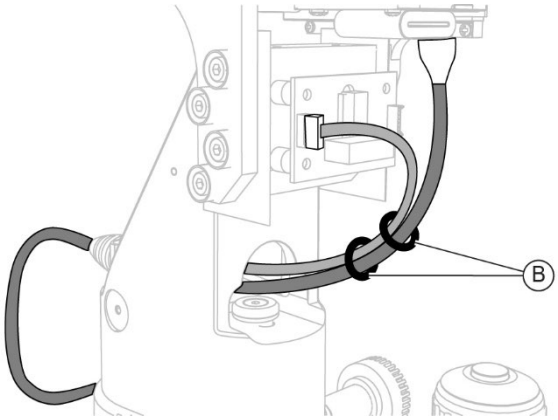


Fig. 94 - Place the cable ties (front)

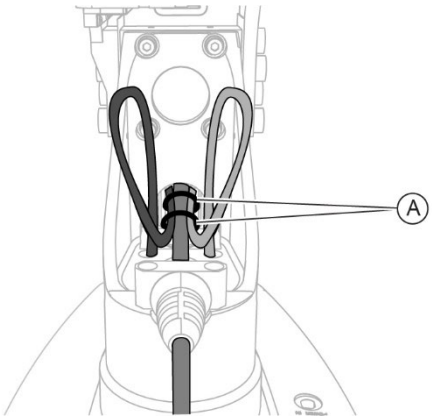


Fig. 95 - Place the cable ties

7 Reinstall the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.5 OPTO-COUPLER BOARD REPLACEMENT

Material and warnings:

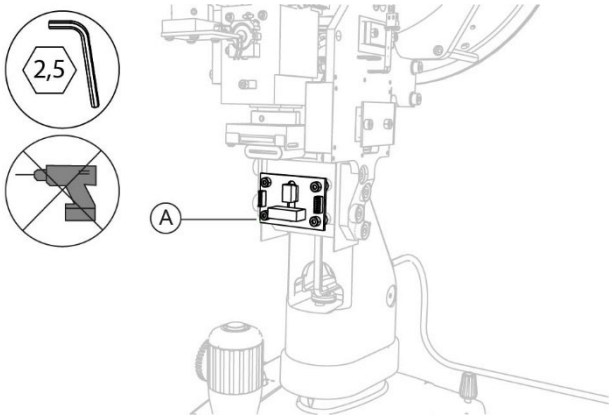


Fig 96 – Opto-coupler board

Pos	Description
A	Opto-coupler board– code 963103504

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Dismantling procedure for the opto-coupler board:

1 Remove the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**
2 Disconnect the connecting cable (B) from the J2 pin (A) of the opto-coupler board.
3 Disconnect the connecting cable (D) from the J1 pin (C) of the opto-coupler board.
4 Remove the screws (D) that secure the opto-coupler board.

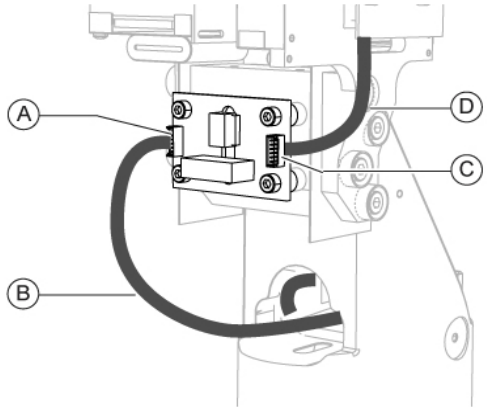


Fig 97 – Disconnect the cables from the opto-coupler board

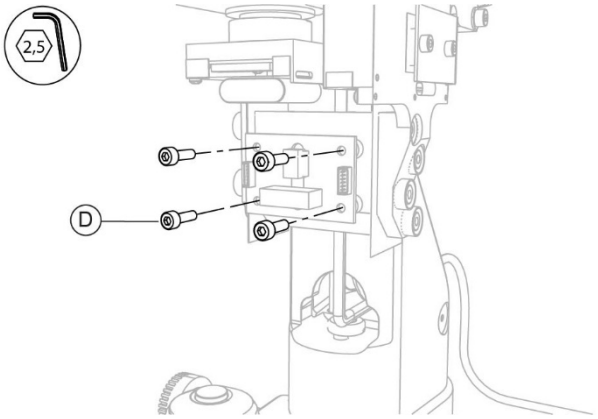


Fig 98 - Screws removal

5 Remove the opto-coupler board from its seat.

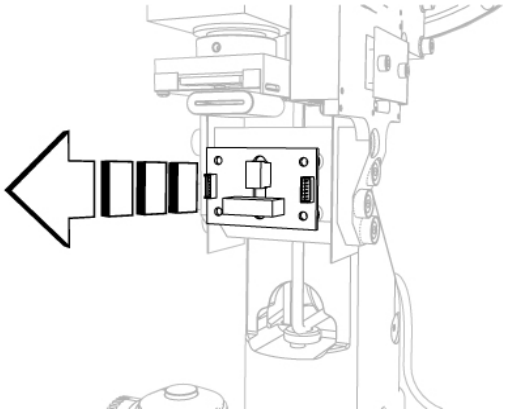


Fig 99 – Removing USB 3.0 cable

Assembling procedure for the opto-coupler board:

1 Place the board into its seat.

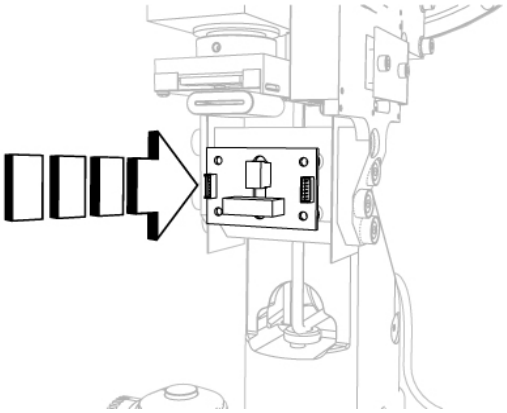


Fig 100 – Placing the opto-coupler board

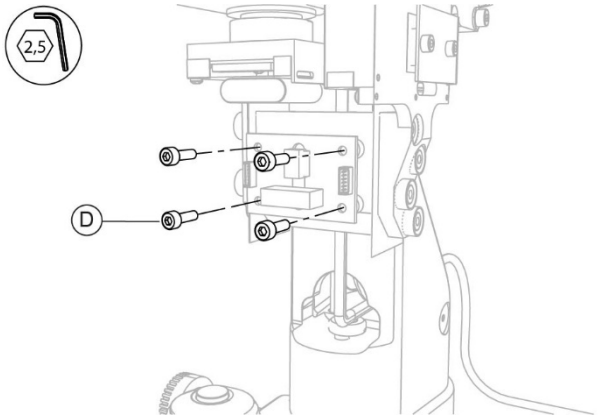


Fig 101 – Fastening the board screws

2 Fasten the screws (D) that secure the opto-coupler board.
3 Connect the connecting cable (B) into the J2 pin (A) of the board.
4 Connect the connecting cable (D) into the J1 pin (C) of the board.

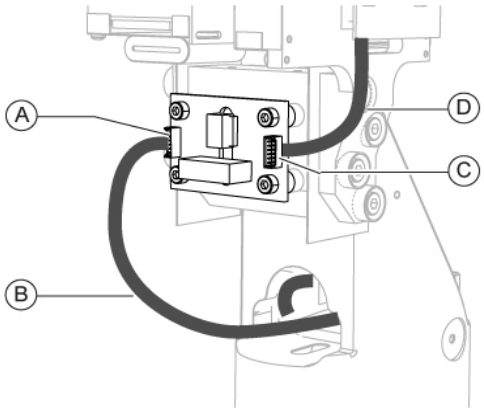


Fig 102 – Connecting cables on the board

5 Reinstall the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.6 REPLACEMENT OF THE STRUCTURAL UNIT WITH OPTICAL-ELECTRONIC HEAD

Material and warnings:

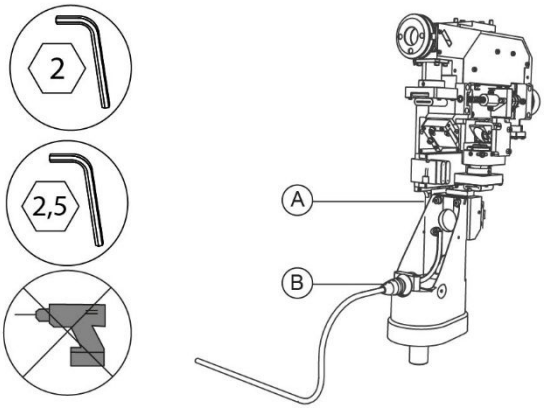


Fig 103 –Structural unit

Pos	Description
A	Structural unit with optical-electronic head.
B	USB 3.0 Cable 2 m length.

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Disassembling procedure for the structural unit:

1. Remove the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**
2. Remove the USB 3.0 cable as described in paragraph **"Replacement of the 3.0 USB** cable**" on page 60.**
3. Cut the cable tie (C) that connects the power supply cable (A) and the connecting cable (D) between the opto-coupler board and the sensor located on the plate.
4. Remove cable clamps (B) and (E).
5. Disconnect the connecting cable (D) from the J2 pin (F) of the opto-coupler board.

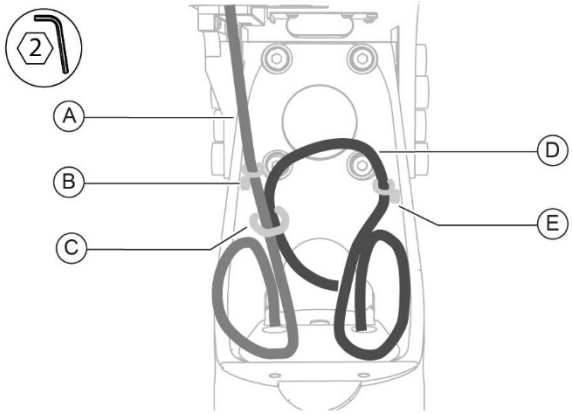


Fig 104 – Cables removal

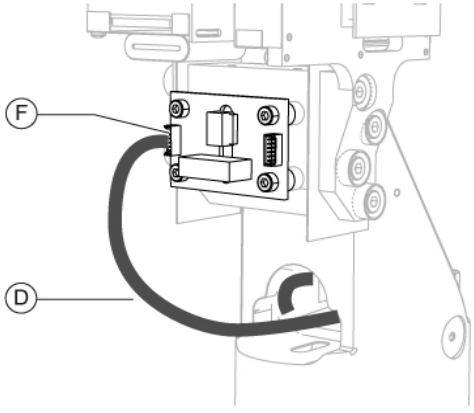


Fig 105 – Disconnect the cable (D) from the J2 pin

6 Cut the cable tie (G) and remove the duct tape (H).
7 Remove the screws (J) of the control board.
8 Remove the case (I) of the control board.
9 Disconnect the power supply cable (A) from the J17 pin (K) of the control board.

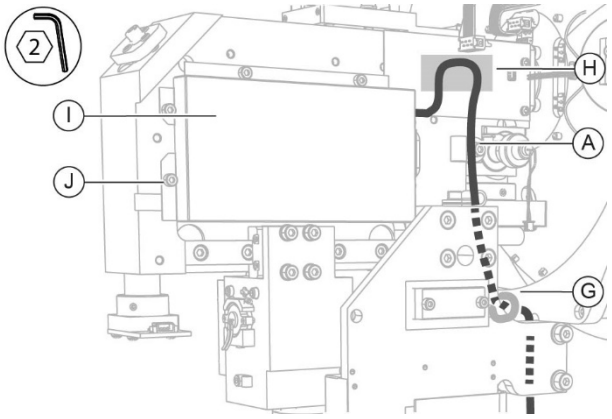


Fig 106 - Removing the board protective shell

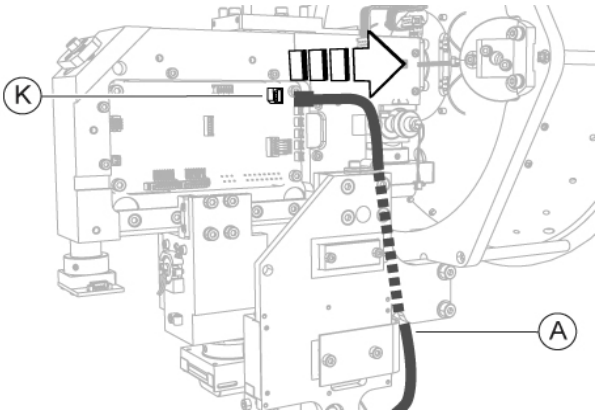


Fig 107 – Disconnect the cable (A) from the J17 pin

10 Unscrew the screw (L).
11 Remove the structural unit.
12 Remove the electrical cables from the holes on the structural unit.

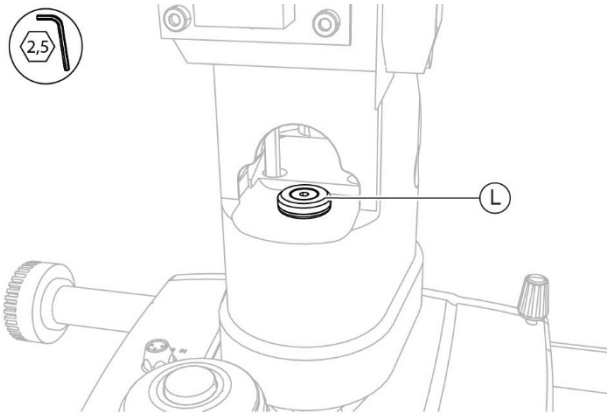


Fig 108 – Removing the structural unit

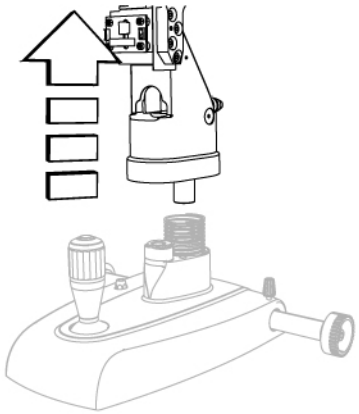


Fig 109 – Removing the structural unit

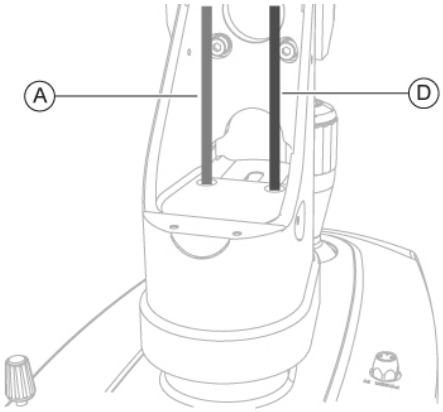


Fig 110 – Remove the electric cables coming from the base

Assembling procedure for the structural unit:

1 Insert the electrical cables in the holes on the structural unit.
2 Place the structural unit on the base

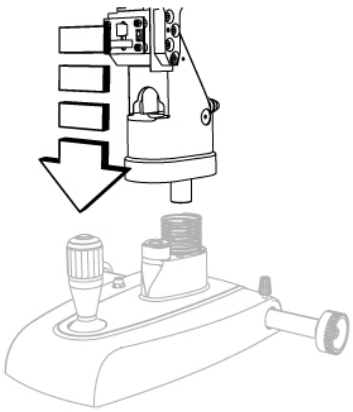


Fig 111 – Removing the structural unit

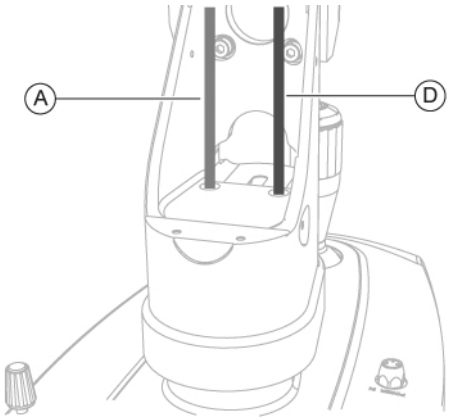


Fig 112 – Insert the electric cables coming from the base

3 Fasten the support screw (L) to the base.
4 Connect the power supply cable (A) to the J17 pin (K) of the control board.

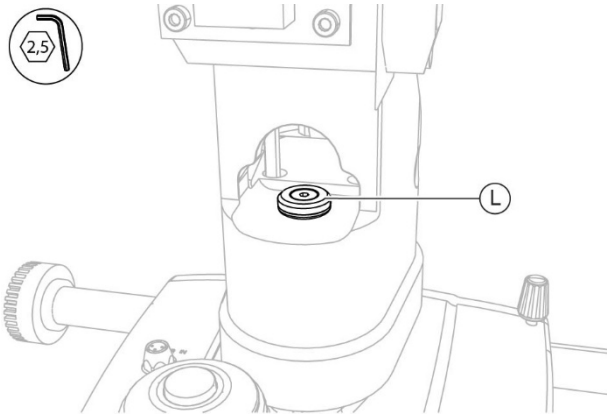


Fig 113 - Fastening the base

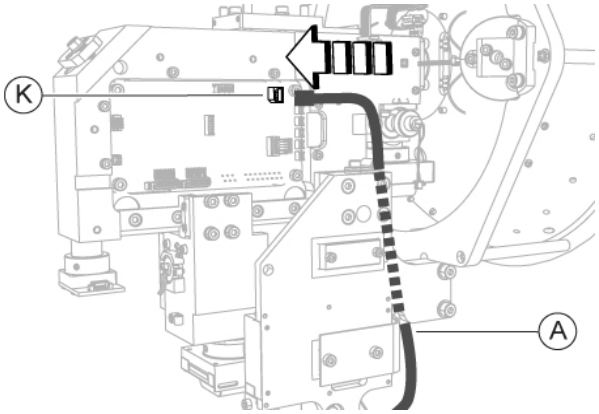


Fig 114 – Connect the cable (A) from the J17 pin

5 Reinstall the control board protective shell (I).
6 Fasten the screws (J).
7 Place the duct tape (H) to fix the cable (A) on the structural unit.
8 Fix the cable (A) to the structural unit by means of the cable tie (G).
9 Connect the connecting cable (D) to the J2 pin (F) of the opto-coupler board.

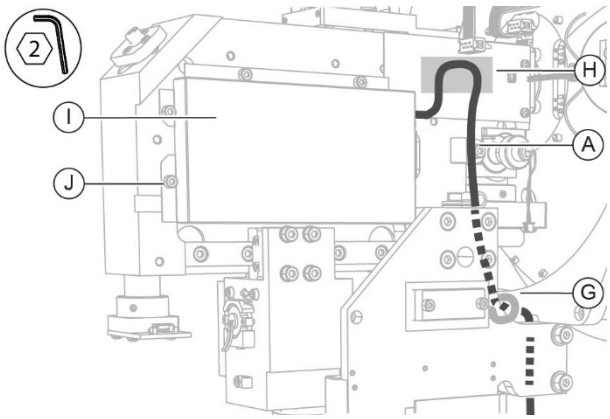


Fig 115 – Reinstall the board protective shell

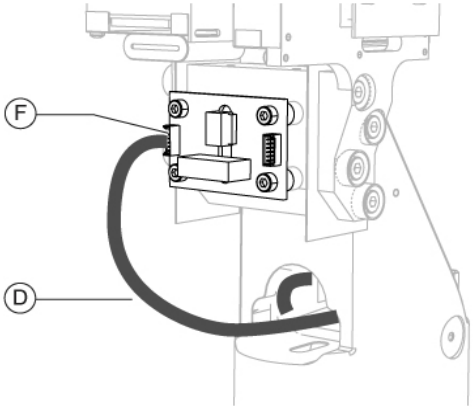


Fig 116 – Connect the cable (D) from the J2 pin

10 Secure the power supply cable (A) by means of the cable clamp (B).
11 Secure the connecting cable (D) by means of the cable clamp (E).
12 Fix by means of the cable tie (C) the power supply cable (A) and the connecting cable (D).

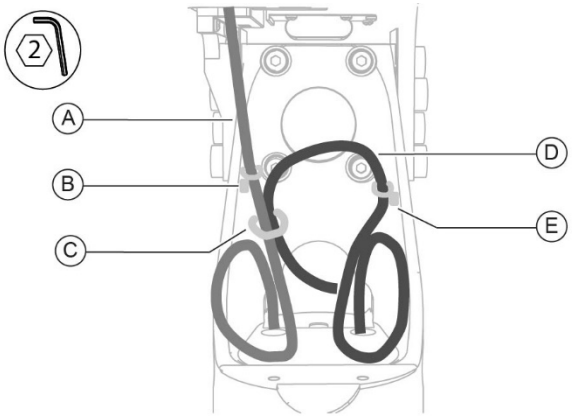


Fig 117 – Reinstall cables

13 Reinstall the USB 3.0 cable as described in paragraph **"Replacement of the 3.0 USB** cable**" on page 60.**
14 Reinstall the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75**.

6.4.7 REPLACEMENT OF THE PLATE WITH LEFT/RIGHT SENSOR

Material and warnings:

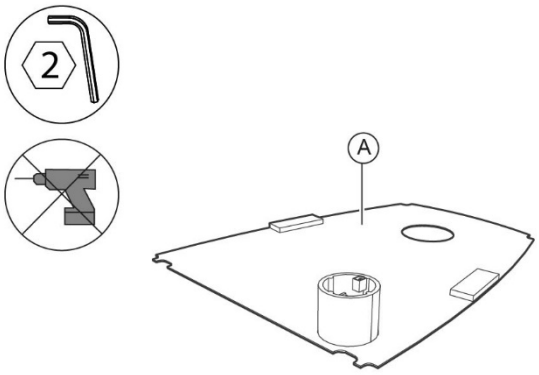


Fig 118 – Plate with left/right sensor

Pos	Description
A	**Plate with left/right sensor** - code 100250420

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Plate replacement procedure:

1 Place the device so that the optical head is directed downwards. It shall be placed on a stable surface and on a soft cloth in order to avoid damaging the device.
2 Remove the four screws (A) M3x10 from the plate sides.

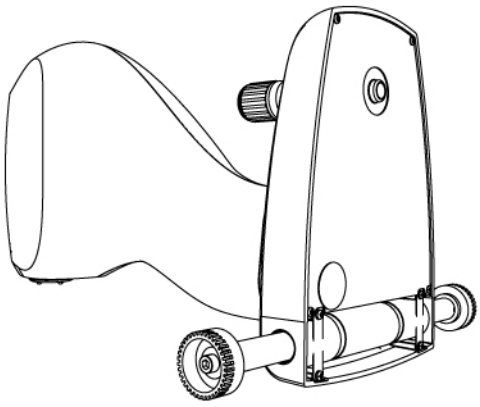


Fig. 119 - Placement of the device

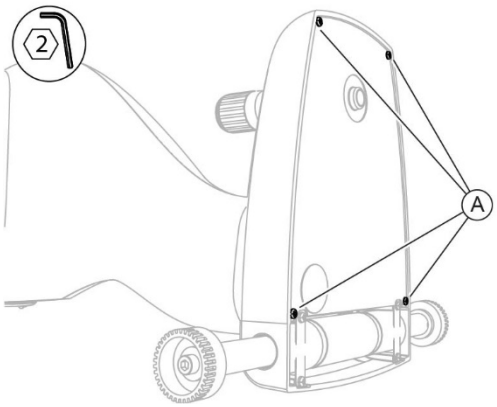


Fig 120 - Plate removal

3 Lift up the plate and disconnect the cable (B) that connects the joystick unit and the left/right sensor (D)
4 Disconnect the cable (C) that connects the opto-coupler board and the left/right sensor (D).
5 Remove the plate.

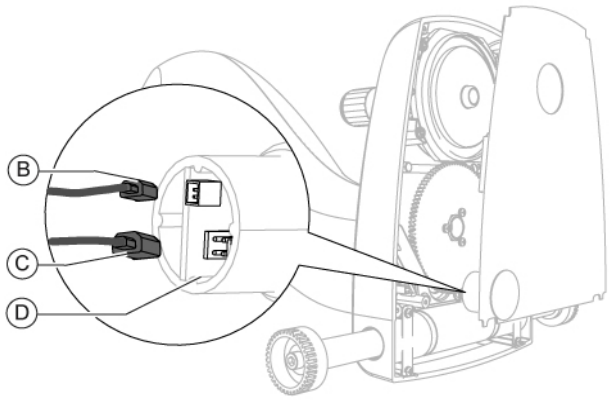


Fig 121 – Cable connection

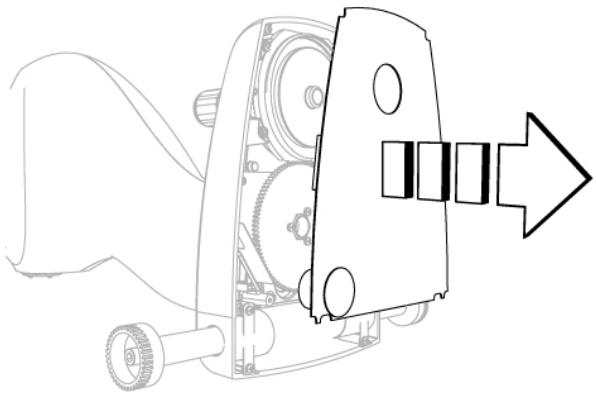


Fig 122 - Plate removal

6 Reconnect the cable (B) that connects the joystick unit and the left/right sensor (D).
7 Reconnect the cable (C) that connects the opto-coupler board and the left/right sensor (D).

8 Place the plate under the device base.
9 Fasten the four fixing screws M3x10 (A) to the plate.

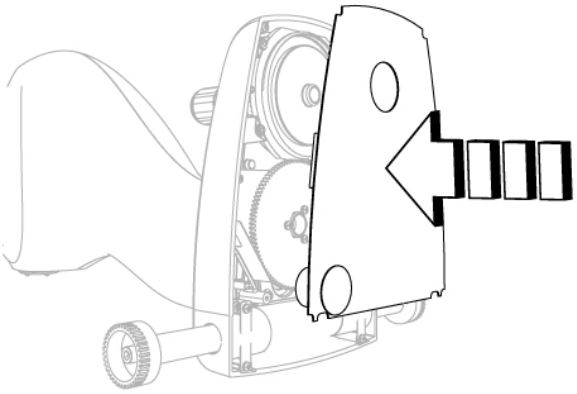


Fig 123 – Placement of the plate

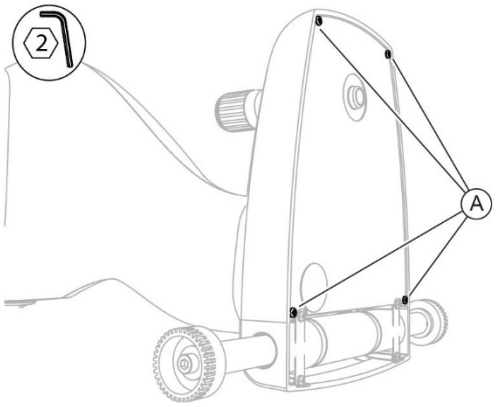


Fig 124 - Fastening the plate

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety** test**" on page 75**.

6.4.8 REPLACEMENT OF THE JOYSTICK UNIT WITH BUTTON

Material and warnings:

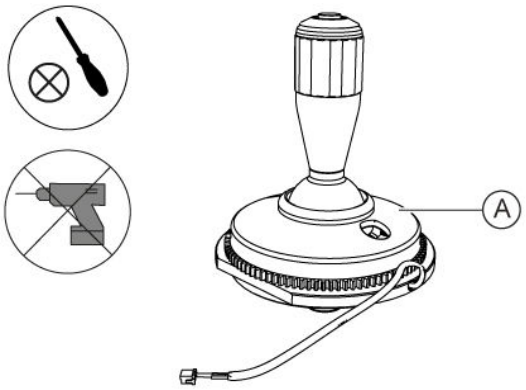


Fig 125 – Joystick unit with button

Pos	Description
A	Joystick unit with K12 button- code **960270403**

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Procedure:

1 Remove the plate as described within the procedure **"Replacement of the plate with left/right sensor" on page 74.**
2 Remove the screws M3x8 (A).
3 Remove the joystick unit from the base. Be careful when removing the joystick cable.

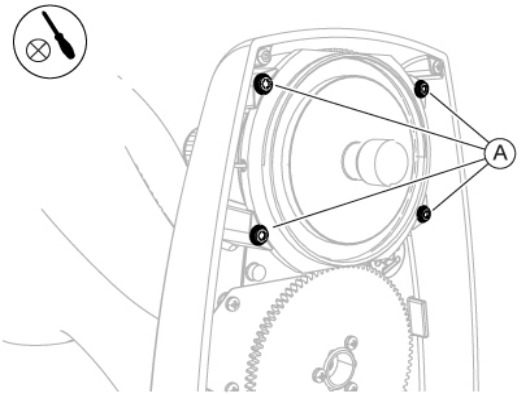


Fig 126 - Fixing the joystick unit

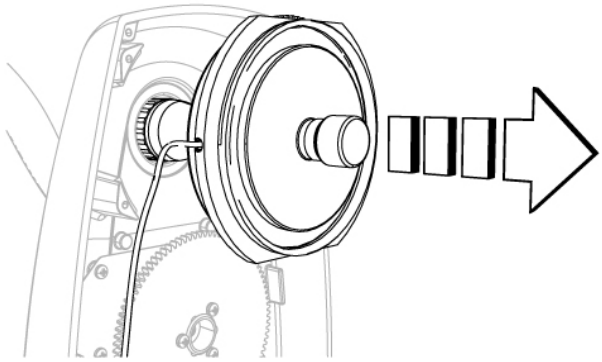


Fig 127 - Removing the joystick unit

4 Place a new joystick unit under the base.
5 Fasten the four fixing screws (A). Make sure it is properly assembled. The unit shall not move.
6 Reinstall the plate as described within the procedure **"Replacement of the plate with left/right sensor" on page 74.**

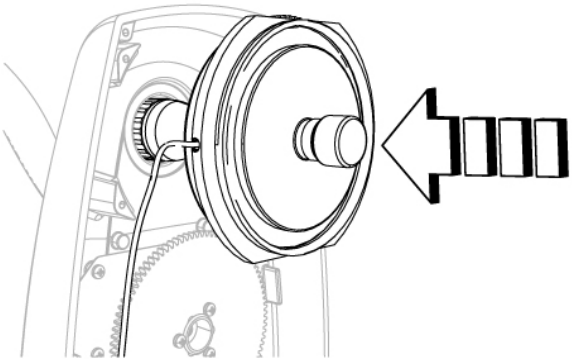


Fig 128 – Joystick unit

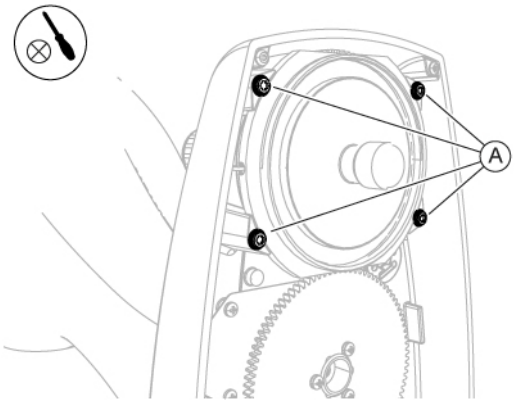


Fig 129 - Fixing the joystick unit

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.1 REPLACEMENT OF THE JOYSTICK BUTTON

Material and warnings:

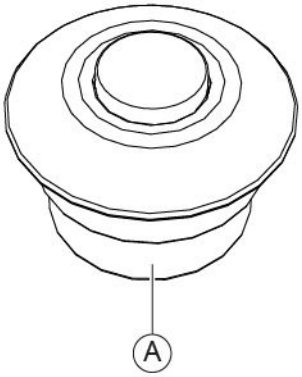


Fig. 130 - Joystick button

Pos	Description
A	Joystick button - code **100258402**

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Disassembling procedure for the joystick button:

1 Remove the joystick button.
2 Disconnect the connection cable (A) from the joystick button (B).

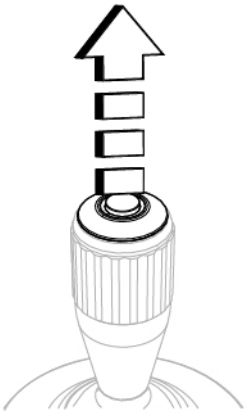


Fig. 131 - Remove the joystick button

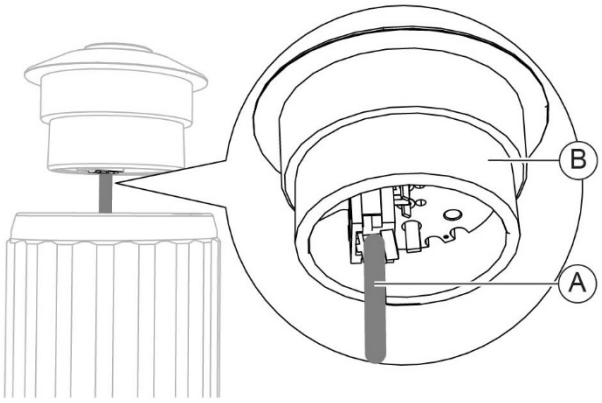


Fig. 132 - Disconnect the cable

Assembling procedure for the joystick button:

1 Connect connection cable (A) to the joystick button (B).
2 Insert the joystick button in its seat.

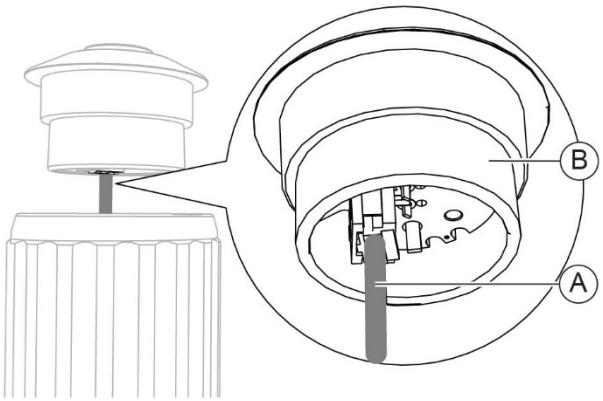


Fig. 133 - Connect the cable

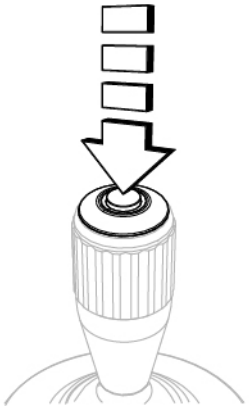


Fig. 134 - Insert the joystick button

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.4.2 REPLACEMENT OF THE COMPLETE BASE

Material and warnings:

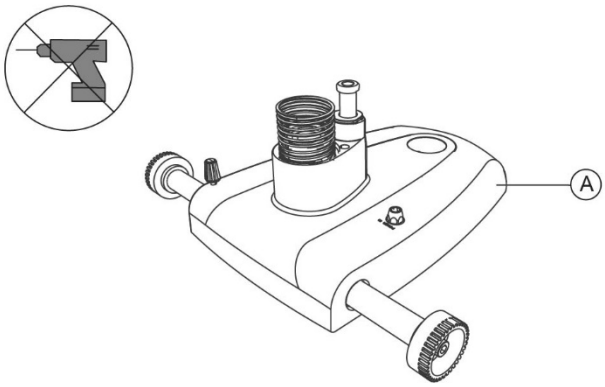


Fig 135 – Complete base

Pos	Description
A	Complete base - code 963103402 (Osiris)
A	Complete base– code 963102402 (Osiris-T)

CAUTION
Take appropriate precautions when handling components sensitive to electrostatic discharges (ESD).

Before replacing, make sure all tools and materials required for the installation are available.

It is prohibited to use a powered screwdriver during fixing or adjusting operations on the components.

Base disassembling procedure:

1. Remove the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**
2. Remove the USB 3.0 cable as described in paragraph **"Replacement of the 3.0 USB cable" on page 60.**
3. Remove the structural unit as described in paragraph **"Replacement of the structural unit with optical-electronic head" on page 65.**
4. Remove the plate with left/right sensor as described in paragraph **"Replacement of the plate with left/right sensor" on page 68.**
5. Remove the joystick unit as described in paragraph **"Replacement of the joystick unit" on page 71.**

Assembling procedure for the base:

1. Reinstall the joystick unit as described in paragraph **"Replacement of the joystick unit" on page 71.**
2. Reinstall the plate with left/right sensor as described in paragraph **"Replacement of the plate with left/right sensor" on page 68.**
3. Reinstall the structural unit as described in paragraph **"Replacement of the structural unit with optical-electronic head" on page 65.**
4. Reinstall the USB 3.0 cable as described in paragraph **"Replacement of the 3.0 USB cable" on page 60.**

5 Reinstall the right protective shell and the left protective shell as described in paragraphs **"Replacement of protective shells (Osiris)" on page 53 and "Replacement of protective shells (Osiris-T)" on page 56.**

When the operation is complete, carry out the safety test as described in paragraph **"How to carry out the electrical safety test" on page 75.**

6.5 HOW TO CARRY OUT THE ELECTRICAL SAFETY TEST

The electrical safety test shall always be carried out after a technical intervention on the device, in compliance with EN 60601-1 standard.

For proper cable connection and test procedure read the instructions for tester use.

Do not touch the device during the test.

Medical device	Osiris	Osiris-T	PSP2402
Description	Aberrometer	Topo-Aberrometer	Power supply unit
Class	I	I	I
Type	B	B	B
Number of applied parts	1	1	1
IEC 60601-4th edition	Inspection - Enclosure Leakage Patient Leakage Isolation 500Vac	Inspection - Enclosure Leakage Patient Leakage Isolation 500Vac	Inspection Ground Leakage Enclosure Leakage Patient Leakage Isolation 500Vac

Procedure:

1 Before carrying out the test, check that all safety devices have been assembled correctly.
2 To properly connect the tester, check if the PC is placed inside or outside the patient area.

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.

3 If the PC is placed inside the patient area, connect the tester as indicated in the following figure.
4 If the PC is placed outside the patient area, connect the tester as indicated in the following figure.

6.5.1 TESTER CONNECTION INSIDE THE OSIRIS PATIENT AREA

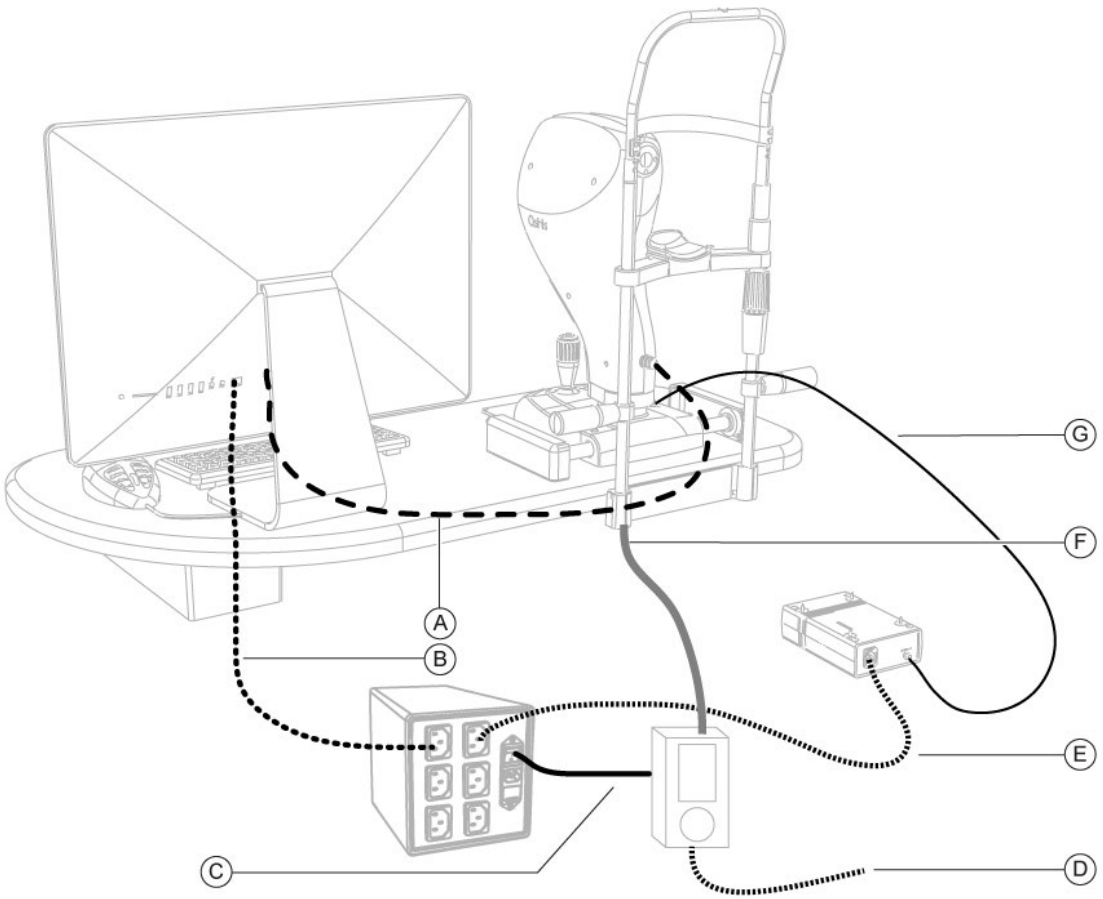


Fig 136 - Tester connection inside the Osiris patient area

Pos	Name
A	Connection between device and PC
B	Connection between PC and isolation transformer
C	Connection between isolation transformer and tester
D	Connection between tester and mains power socket
E	Connection between isolation transformer and device power supply unit
F	Connection between applied part and tester
G	Connection between the power supply unit and the device

6.5.2 TESTER CONNECTION OUTSIDE THE OSIRIS PATIENT AREA

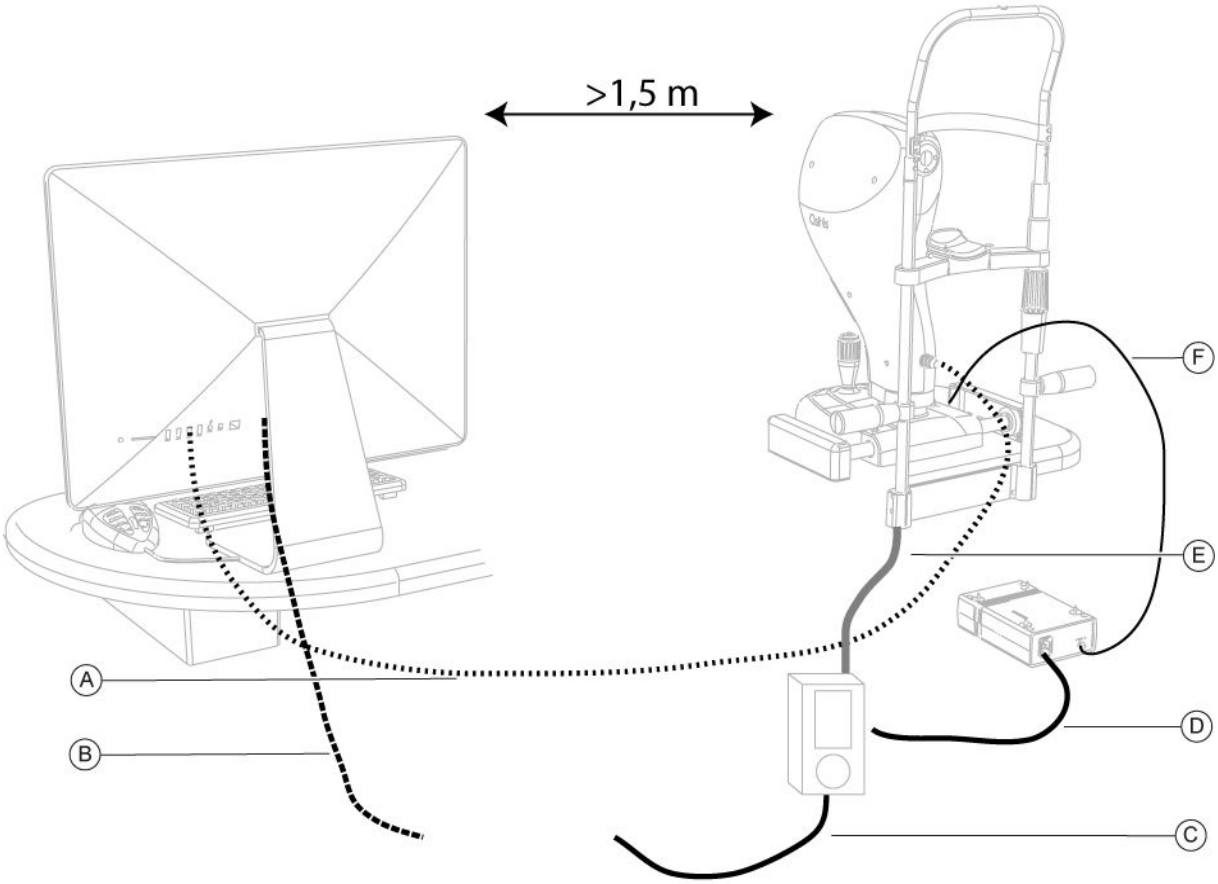


Fig 137 - Tester connection outside the Osiris patient area

Pos	Name
A	Connection between device and PC
B	Connection between PC and mains power socket
C	Connection between tester and mains power socket
D	Connection between tester and power supply
E	Connection between applied part and tester
F	Connection between the power supply unit and the device

1 Carry out the test. Follow the tester instructions for use.
2 Print the test.
3 Check test results are correct.
4 Include the test printing in the activity report.

6.5.3 TESTER CONNECTION INSIDE THE OSIRIS-T PATIENT AREA

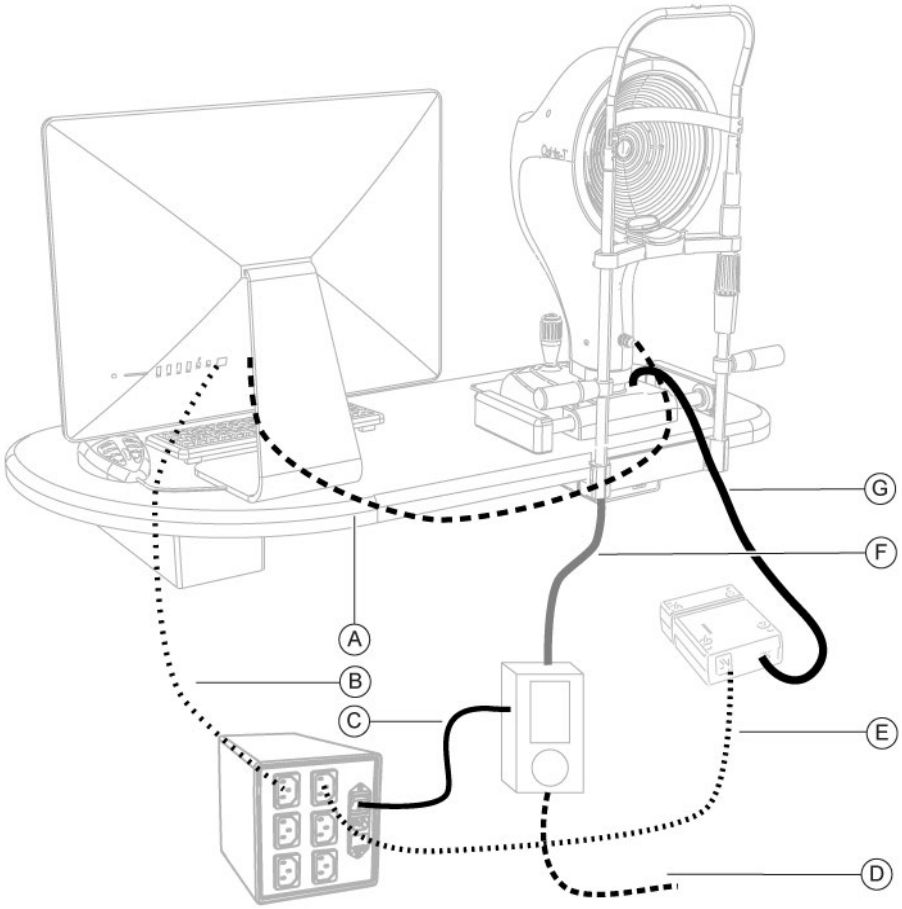


Fig 138 - Tester connection inside the Osiris-T patient area

Pos	Name
A	Connection between device and PC
B	Connection between PC and isolation transformer
C	Connection between isolation transformer and tester
D	Connection between tester and mains power socket
E	Connection between isolation transformer and device power supply unit
F	Connection between applied part and tester
G	Connection between the power supply unit and the device

6.5.4 TESTER CONNECTION OUTSIDE THE OSIRIS-T PATIENT AREA

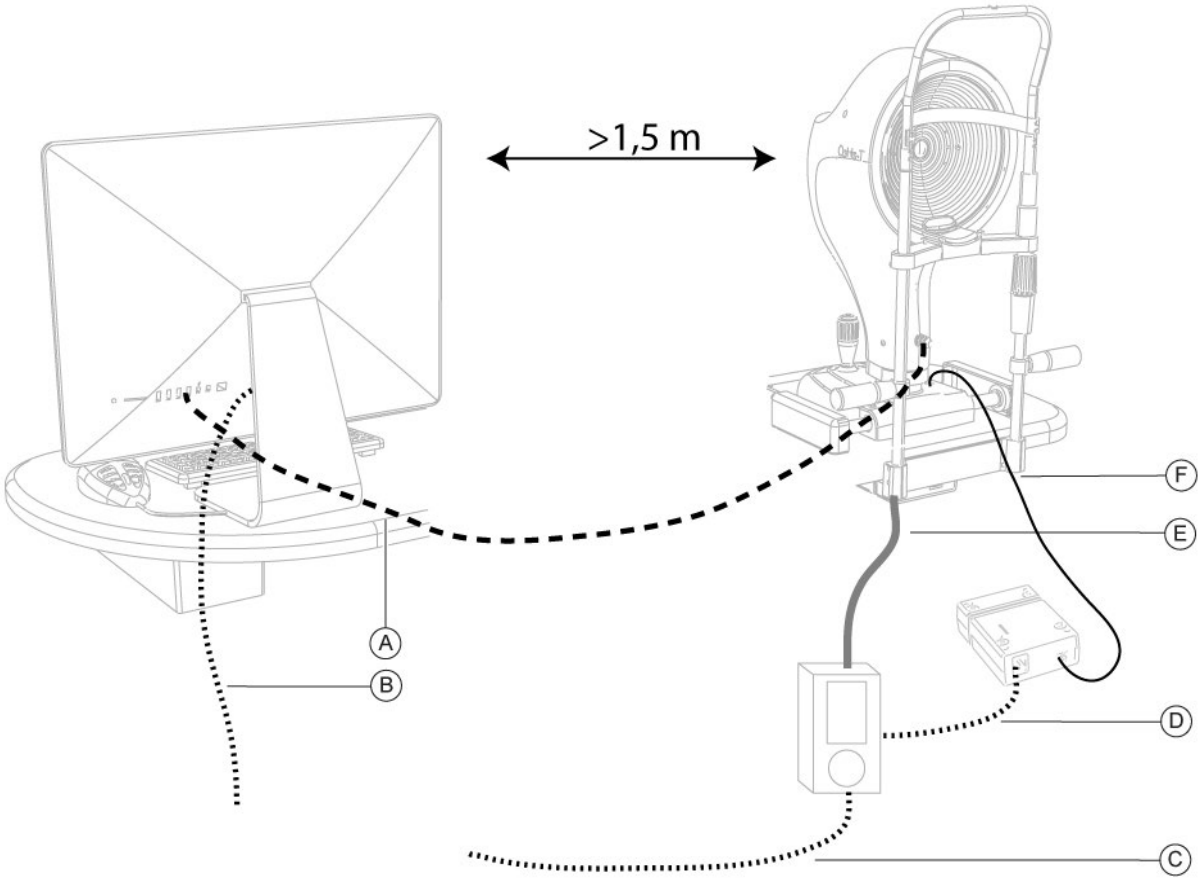


Fig 139 - Tester connection outside the Osiris-T patient area

Pos	Name
A	Connection between device and PC
B	Connection between PC and mains power socket
C	Connection between tester and mains power socket
D	Connection between tester and power supply
E	Connection between applied part and tester
F	Connection between the power supply unit and the device

1 Carry out the test. Follow the tester instructions for use.
2 Print the test.
3 Check test results are correct.
4 Include the test printing in the activity report.

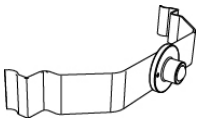
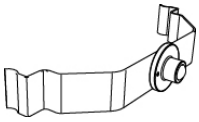
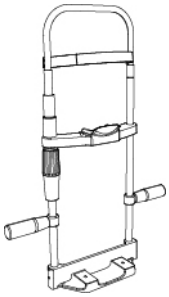
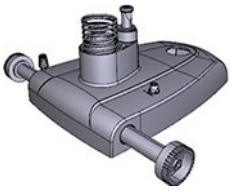
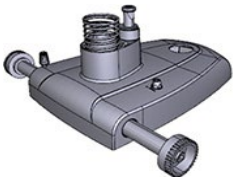
6.6 TESTING DEVICE OPERATION AFTER MAINTENANCE ACTIVITIES

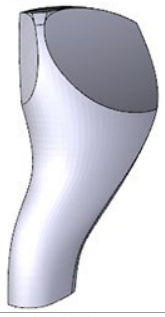
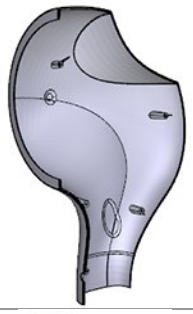
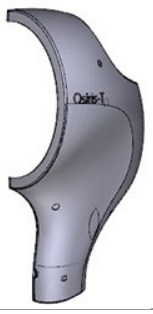
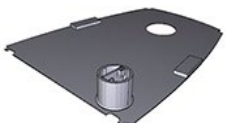
A device operation test shall always be carried out after any maintenance activity, following the table hereafter.

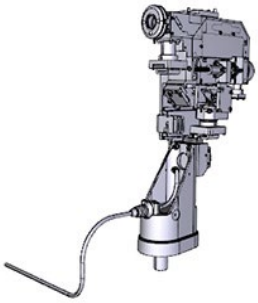
ID	Test type	Procedure	Acceptability criteria
1	**Check the joystick unit button**	Perform an acquisition by pressing the button on the joystick unit	Check an image has been saved.
2	**Right and left acquisition check**	Perform two acquisitions, one in the right position and one in the left position	Check that the two saved images are respectively OD, OS
3	**Checking semicircles alignment**	Perform an acquisition. Align the device with the calibration tool so that semicircles are aligned and overlapped	Check the image is in focus
4	**Axis control**	Place the device in front of the plumb line, look on the monitor and place the vertical rod of the large cross on the plumb line	Verify that there is perfect coincidence
5	**Fixation point centring check**	Place the reflection of the fixation point in the centre of the cross on the calibration tool (sphere r = 8 mm)	Make sure it is centred
6	**Check that Placido disk is turned on (Osiris-T)**	Start a topography acquisition	Check that Placido's disk lights up and that the lighting is uniform
7	**Check that the pupillography LED is switched on (Osiris-T)**	Start a pupillography acquisition	Check through the camera that the pupillography LEDs are on
8	**Check calibration for the topographer section (Osiris-T)**	Following the program instructions, capture the calibration tool provided with the device (sphere r = 8 mm)	Verify that the message "calibration successful" is displayed
9	**Check accuracy for the topographer section (Osiris-T)**	Capture the calibration tool provided with the device (sphere r = 8 mm) at least twice. Read the measurements on the sagittal map	Verify that each measurement is within a tolerance of ±0.03 mm
10	**Check calibration for the aberrometer section**	Perform an acquisition using the calibration tool provided with the device. Check that the measured value for a diameter of 4mm@12.5mm corresponds to the value indicated on the calibration testing tool	Verify that each measurement is within a tolerance of ±0.125 D
11	**Screen printing control**	Carefully inspect the screen printed parts	Verify that there are no imperfections

ID	Test type	Procedure	Acceptability criteria
12	**Paint Control**	Carefully inspect the painted parts	Verify that there are no imperfections
13	**Final check**	Check the operation of the Phoenix software for a further check of the previous points	Check the compliance
14	**Electrical safety test**	Carry out the electrical safety test following the instructions IV07-05A1 on page 75.	Check compliance of the measured parameters. Include the report of the electrical safety tests and the calibration certificate of the device used.

7 SPARE PARTS AND ACCESSORIES LIST

Code		Description
300409135		Power supply cable 1.5 m, connectors MD/MA
103103201		Calibration testing tool for the Aberrometer section for Osiris and Osiris-T
100130201		Calibration tool for the Topographer section for device Osiris-T (sphere radius 8 mm)
100130700		Chin rest with adjustable chin cup
103103900		Power supply unit PSP2402 input 100-240 V AC 50/60 Hz max 0,9 A output 24 VDC 2 A **(*)**
963103402		Full base Osiris
963102402		Full base Osiris-T
3020804		USB 3.0 Cable 2 m length
963103504		Opto-coupler board

960270403		Joystick unit with button
100258402		Joystick button
103103560S		Left protective shell for device Osiris
103103561S		Right protective shell for device Osiris
103102596S		Left protective shell for device Osiris-T
103102595S		Right protective shell for device Osiris-T
100250420		Plate with left/right sensor

963103527		Structural unit Osiris-T
963103526		Structural unit Osiris

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

The standards for medical devices quality management prescribe the obligation of traceability of each device placed on the market.
(*) The same rule applies to critical components and replaced spare parts, which therefore requires the obligation to notify the Manufacturer.

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